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Original Paper

A Text Messaging Intervention (Txt4HappyKids) to Promote Fruit and Vegetable Intake Among Families With Young Children: Pilot Study

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Abstract

Background: Increasing fruit and vegetable intake among low-income populations, especially children, is a priority for United States federal food assistance programs. With over 49 million federal food assistance program recipients, cost-effective and efficient methods are needed to effectively deliver nutrition education to such a large population.

Objective: The objective of our study was to examine the preliminary efficacy and acceptability of a text messaging intervention, Txt4HappyKids, to promote fruit and vegetable intake among families with young children.

Methods: The intervention was evaluated using a pre-post study design. Parents (N=72) in Alaska were recruited from venues that serve a predominantly low-income population to participate in an 11-week intervention based on social cognitive theory. Parents received two texts per week promoting child fruit and vegetable intake. Behaviors, self-efficacy, and attitudes related to fruit and vegetable intake were measured at baseline and postintervention. Perceived changes in behaviors and open-ended feedback were also collected postintervention.

Results: Of all participants, 67.3% (72/107) completed the intervention. We found no changes in behavior ($P=.26$), self-efficacy ($P=.43$), or attitudes ($P=.35$) related to fruit and vegetable intake from pre- to postintervention. Completers reported that since their participation in Txt4HappyKids, 92% (66/72) served more fruits and vegetables to their child because they thought fruits and vegetables were beneficial, 86% (62/72) tried to follow a healthier diet, 85% (61/72) tried different ways of preparing fruits and vegetables, and 81% (58/72) were more aware of the foods their child consumes. Additionally, 79% (57/72) of completers thought that Txt4HappyKids was credible, 71% (51/72) found texts useful, and 82% (59/72) would recommend it to a friend.

Conclusions: A text messaging intervention was not sufficient to increase fruit and vegetable intake among families with young children. However, parents felt positively impacted by Txt4HappyKids and were receptive to nutrition information, despite the absence of face-to-face contact. High satisfaction among completers indicates that text messaging may be an acceptable complement to budget-constrained nutrition programs. These findings are an important first step in developing larger multi-level interventions utilizing mobile technology; however, a more rigorous evaluation of the Txt4HappyKids intervention is warranted.

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KEYWORDS

fruits and vegetables; nutrition education; nutrition intervention; young children; text messaging

Introduction

In the United States 39.8% of adults and 18.5% of youth are obese, increasing the likelihood that they will develop cardiovascular risk factors that can lead to chronic diseases [1]. Fruit and vegetable (FV) consumption can protect against obesity; however, less than 18% of adults and 10% of youth meet the recommendations for FV intake [2-4]. Low-income populations are at an even greater risk for poor dietary patterns and are disproportionately impacted by obesity [4,5]. Understanding effective strategies to increase FV consumption among low-income people, low-income children in particular, could help to reduce diet- and obesity-related health disparities in this population.

Increasing FV consumption among low-income populations, especially children, is a priority for US federal food assistance programs such as the Supplemental Nutrition Assistance Program (SNAP) and the Women, Infants, and Children Program (WIC). Most interventions to increase FV intake among children involve nutrition education that is delivered in person through primary care, home visits, or school-based programs [6,7]. Although this strategy has resulted in small, significant increases in FV consumption at the individual level, face-to-face approaches are generally resource intensive and cannot be implemented at the population level. More cost-effective and efficient methods are needed to effectively deliver nutrition education to over 42 million SNAP [8] and 7 million WIC [9] participants in the United States.

Texting is an ideal tool to promote healthy behaviors among hard-to-reach populations, such as participants in US federal food assistance programs, for a number of reasons. First, the technology is ubiquitous. More than 90% of adults in the United States own a cell phone and more than 80% of cell phone owners report sending or receiving text messages via their phone [10,11]. Cell phone ownership is prevalent across income groups, and approximately 85% of adults with an annual income below \$30K own a cell phone [11]. Second, text messaging is personal, and texts are important to recipients. Approximately 90% of text messages are read within 3 minutes [12]. Finally, text messaging is a cost-effective way to distribute health information on a large scale, thus reducing health service costs and participant burden [13] and improving reach to traditionally underserved populations [14].

Federal food assistance programs in the United States, such as SNAP and WIC, are shifting toward public health approaches for obesity prevention [15] and a growing number are incorporating text messaging into their programming [16,17]. Although results from these programs have not yet been published, studies demonstrate that text messaging can effectively promote diabetes and weight management, medication compliance, smoking cessation, and other health behaviors [18-25]. Although most of these studies have examined the use of text messaging to enhance treatment outcomes in clinical settings, less information is available on how text messaging can be used for preventive behaviors such as FV consumption [26-28].

A text messaging intervention to promote FV intake may be a convenient and cost-effective way for low-income parents to receive health-related information about their children. This paper reports on the preliminary efficacy and acceptability of a text messaging intervention to promote FV consumption among parents of young children from low-income families in Fairbanks, Alaska. Alaska was an ideal place to pilot test this program because insufficient FV intake is a common dietary shortcoming resulting from unique environmental factors. Additionally, low population density across the state and lack of affordable travel between communities significantly limits traditional, face-to-face nutrition education [29].

Methods

Study Design

Txt4HappyKids is an 11-week, theory-based intervention that sends parents twice weekly text messages encouraging them to serve more FV to their child. The intervention was evaluated using a pre-post study design. Parents completed a self-administered questionnaire to assess behaviors, self-efficacy, and attitudes related to FV intake at baseline and postintervention.

Participants were recruited using convenience sampling at the following venues that serve a predominantly low-income population: Head Start (n=18); WIC (n=18); the public library (n=12); and a free family health fair (n=59) in Fairbanks, Alaska. Fairbanks is the second largest city in Alaska with a population of approximately 30,000 people. Inclusion criteria were being the parent or guardian of a young child (no age specified) and having an unlimited texting plan on a mobile phone. The unlimited texting plan was a necessary inclusion criterion to ensure that participants would not incur charges from intervention-related text messages, which this pilot study could not reimburse.

Researchers set up an information table at each location to recruit parents in person to participate in the study. Researchers collected informed consent and administered the baseline questionnaire to interested parents. Parents then provided their email and cell phone number to complete study enrollment. Participation was incentivized so that parents received a small prize, such as a water bottle, upon enrollment. Owing to logistical constraints, the postintervention questionnaire was administered online via an email link. Follow-up was incentivized by offering participants a \$25 gift card to a local grocery store upon completion of the follow-up assessment. All procedures were approved by the University of Alaska Fairbanks Institutional Review Board for human subjects.

Intervention

Text message development was guided by the social cognitive theory (SCT) and messages were designed to address the personal, behavioral, and environmental factors related to FV intake [30] (Table 1). Messages were limited to 160 characters and content was adapted from the TXT4Tots library of evidence-based messages created by the US Department of Health and Human Services and the American Academy of Pediatrics [31].

Table 1. Development of Txt4HappyKids using the social cognitive theory. Social cognitive theory factors appear in bold and predictive factors are nested.

Factors	Explanation of predictive factors	Example text
Personal		
Knowledge	Provide information about the health benefits of consuming fruits and vegetables	Eating fruits & veggies helps your child build strong muscles and bones. Give your child the gift of health by serving fruits & veggies with every meal.
Preference	Portray fruits and vegetables as tasting good and something children enjoy eating	Apples are on sale for 1.49/lb @ Fred Meyer! Peel, core & chop. Add water & ground cinnamon. Cook for 30 min until soft, then mash. Kids love warm applesauce!
Time	Portray shopping and cooking with children as a great way to spend quality time together	Kids love to be helpful! Let them help with dinner by washing the fruits & veggies, stirring, or measuring. This is a great way to spend quality time together!
Behavioral		
Self-efficacy	Improve skills related to preparing fruits and vegetables by providing recipes and other tips	Frozen broccoli has as much fiber as fresh broccoli! Microwave until tender & toss with some olive oil, lemon juice, garlic powder, salt & pepper!
Environmental		
Cost	Announce sales at grocery stores so more fruits and vegetables are available at home	Satsuma Mandarins are on sale @ Fred Meyer for \$5.99/5 lb box! Keep your kids on the fast track to health with this sweet snack that is quick & easy to eat.
Role models	Motivate parents to be positive role models for their children by consuming fruits and vegetables	Your kids look up to you! Set another good example for your kids by eating fruits & veggies with your meals & as snacks.

The research team developed 61 text messages that were pilot tested with 15 low-income women through individual or group interviews. Individual interviews (n=3) took place in the waiting room at the Fairbanks WIC clinic. The group interview (n=12) took place during a class at a local organization. During these interviews, women were provided with a list of text messages and participated in an informal discussion about message preferences, such as which messages they liked, disliked, and why. Notes from these interviews were compiled into a spreadsheet and messages were ranked based on women's preferences. Messages were then revised accordingly and selected for use in the Txt4HappyKids intervention. Text messages were delivered using an online text marketing service.

Instrument

The baseline questionnaire was administered in person and the postintervention questionnaire was administered electronically via SurveyMonkey. Scale items were adapted from the Food Stamp Program Fruit and Vegetable Checklist [32] and the Fruit and Vegetable Inventory [33], which were developed at the University of California Davis and validated for use in a low-income population [34-36].

Variables Measured

Behaviors were measured using a single scale comprising the following four items related to serving FV to children: how often (1) participants serve meals with FV, (2) their child eats FV as a snack, (3) their child eats more than one kind of vegetable a day, and (4) their child eats more than one kind of fruit a day. Response options ranged from 1 (rarely) to 5 (always); therefore, higher scores represented more frequent behaviors that involved serving FV to children ($\alpha=.84$, $r=.56$).

Self-efficacy was measured using a single scale consisting of six items related to shopping for and serving FV to children.

Participants were asked how strongly they agreed with the following statements: I feel that I can (1) serve more FV as a snack, (2) buy more vegetables next time I shop, (3) serve meals or snacks with more fruit during the next week, (4) serve two or more servings of vegetables at dinner, (5) serve meals with more vegetables during the next week, and (6) add extra vegetables to casseroles and stews. The response options ranged from 1 (strongly disagree) to 5 (strongly agree); therefore, higher scores represented greater self-efficacy related to buying and serving children more FV ($\alpha=.88$, $r=.54$).

Attitudes were measured using a single scale consisting of five items related to perceived benefits of serving FV to children and role modeling FV intake. Participants rated their agreement with the following statement: I feel that (1) I am helping my child's body by serving them more FV, (2) my child may develop health problems if they do not eat FV, (3) eating FV will help my child succeed in school, (4) I might be able to influence my child to be healthier by eating FV more often, and (5) I would set a good example for my child if I ate more FV. Response options ranged from 1 (strongly disagree) to 5 (strongly agree); therefore, higher scores represented more favorable attitudes toward serving FV and being a positive role model for FV intake ($\alpha=.88$, $r=.58$). In addition to these measures, at postintervention, participants answered questions related to perceived changes in behaviors related to FV intake. These questions used the stem "Because of the information that you learned from Txt4HappyKids..." and included items such as "Have you tried different ways of preparing fruits and vegetables?" and "Have you tried to follow a healthier diet?" with response options of "No," "Yes," and "Don't Know." Participants also answered questions related to intervention satisfaction, such as "Would you recommend Txt4HappyKids to a friend?" Finally, participants answered open-ended questions, including "What did you like most about

Txt4HappyKids?” and “What changes would make Txt4HappyKids better?”

Analysis

Frequencies were calculated using the IBM SPSS Statistics 19 Software [37] to examine participant demographics and general response patterns. Fisher’s exact tests were used to examine the differences in the demographic characteristics between completers and noncompleters. A paired samples *t* test was used to compare paired pre- and postintervention responses to each scale. Open-ended questions were coded for concepts and themes by two separate coders using the constant comparative method of analysis in Microsoft Excel [38]. Coders discussed the disagreements in coding until a consensus was reached. Only participants who completed both the baseline and postintervention assessments were included in the final analysis.

Results

Participant Characteristics

Of all participants, 67.3% (72/107) completed the intervention. The demographic characteristics of completers (N=72) are presented in Table 2. The majority of completers were white

females between 25 and 34 years of age with some college education and a child under 5 years old. Almost half of them reported receiving food assistance during the last 12 months. There were no differences between completers and noncompleters in terms of race ($P=.07$) or whether food assistance was received in the last 12 months ($P=.53$); however, males were significantly more likely to be noncompleters than completers ($P=.01$).

Preliminary Efficacy

Estimates of behavior, self-efficacy, and attitudes related to FV intake were close to optimal at baseline. A paired samples *t* test showed that there were no significant changes in the participant responses to these measures postintervention (Table 3). However, 92% (66/72) of completers reported that since their participation in the Txt4HappyKids intervention, they served their child more FV because they thought FV were beneficial, 86% (62/72) tried to follow a healthier diet, 85% (61/72) tried different ways of preparing FV, and 81% (58/72) were more aware of the food their child consumes. Additionally, 83% (60/72) and 78% (56/72) of completers agreed or strongly agreed that more fruits and vegetables, respectively, were available in their home since their participation in the Txt4HappyKids intervention.

Table 2. Demographic characteristics of completers (N=72) in the Txt4HappyKids intervention.

Variable	n (%)
Sex	
Female	70 (99)
Race	
White	50 (69)
Alaska Native	9 (12.5)
Other	13 (18)
Age	
Under 25 years	12 (17)
25-34 years	37 (51)
35-44 years	16 (22)
45-54 years	7 (10)
Education	
No college	14 (20)
Some college	57 (80)
Age of children^a	
Under 5 years	52 (72)
5-8 years	40 (56)
9-17 years	24 (33)
Income proxy	
Food assistance ^b	35 (49)

^aParticipants could report the age of more than one child in their household; therefore, response options were not mutually exclusive.

^bReceived food assistance in the last 12 months from SNAP or WIC; emergency food banks, food pantry, soup kitchen; or meals served at a food kitchen or community site.

Table 3. Changes in behavior, self-efficacy, and attitudes related to fruit and vegetable intake using a paired samples *t* test (N=72).

Measure	Preintervention, mean (SD)	Postintervention, mean (SD)	Mean difference, (SD)	<i>P</i> value
Behavior ^a	3.51 (0.92)	3.61 (0.80)	0.10 (0.73)	.26
Self-efficacy ^b	3.97 (0.62)	4.04 (0.59)	0.06 (0.69)	.43
Attitudes ^b	4.47 (0.55)	4.54 (0.52)	0.06 (0.57)	.35

^aResponse options ranged from 1 (rarely) to 5 (always).

^bResponse options ranged from 1 (strongly disagree) to 5 (strongly agree).

Program Acceptability

Overall, parents liked the intervention; 79% (57/72) of completers thought Txt4HappyKids was very credible and 71% (51/72) found the text messages very useful. In addition, 67% (48/72) of completers reported wanting to receive more texts about consuming FV and 82% (59/72) stated that they would recommend the program to a friend; 76% (55/72) of completers felt that they received the right number of messages, and no one reported that they received too many messages.

Responses to Open-Ended Questions

Parents were highly positive regarding their experience with the intervention; 89% (64/72) of completers responded to the question “What did you like most about Txt4HappyKids?” The most frequently mentioned components were the sales announcements (22/64 respondents) and the recipes (11/64 respondents). Respondents noted that sales announcements “helped me plan what to buy” and that recipes “helped me help my son explore new foods.” Of 64 respondents, 19 stated that the intervention gave them new ideas: “it wasn’t just ‘you should do this or that.’ It was actually ideas” and “I wouldn’t have thought about it (the ideas) without the text.” Of 64 respondents, 6 talked about the simplicity of the program, stating that it was “convenient, consistent and free” and “easy, short and to the point.” Of 64 respondents, 6 noted that the texts served as useful reminders, stating “I think one of the most helpful things is that it puts the idea in your mind and you think about it through the day” and “I also liked the reminder that if I eat better, my kids will see that as an example. It’s easy to forget that at times.” Another respondent said the program was “great encouragement for those who are trying to feed their kids healthier foods and a great reminder for those parents already feeding their kids healthy.”

Furthermore, 67% (48/72) of completers responded to the following question: “What changes would make Txt4HappyKids better?” Eighteen out of 48 respondents did not think that there should be any changes. Of 48 respondents, 8 (17%) wanted to receive texts more frequently, such as every other day, every time there was a sale on produce, or for more than 11 weeks; furthermore, 2 respondents (4%) wanted an interactive element and 2 respondents (4%) expressed interest in receiving emails or being able to access a website. Regarding message content, 7/48 respondents (14.5%) wanted more recipes, 3/48 respondents (6%) wanted more sales information, and 2/48 respondents (4%) suggested providing links to additional information. Furthermore, 3/48 respondents (6%) suggested including more tailored message content, such as “different levels of

information,” “more ideas of how to get my kids to eat fruits and vegetables,” and “more infant friendly ideas.”

Discussion

This pilot study examined the preliminary efficacy and acceptability of a text messaging intervention to promote FV intake among families with young children. We found no changes in behavior, self-efficacy, or attitudes related to FV intake from pre- to postintervention. However, the majority of parents felt positively impacted by the intervention and reported high satisfaction. This is important because parents were engaged and receptive to the nutrition information received, despite the absence of face-to-face interaction, which can be costly and resource intensive. A recent study by Pedersen et al showed greater increases in FV intake among adolescents with a higher engagement in a text message-based feedback intervention [27]. High levels of engagement demonstrate the acceptability of this low-cost intervention.

Parents expressed particular satisfaction with texts about sales and recipes and the reassurance of receiving reminders and encouragement to serve more FV. The most frequently used word to describe what parents liked most about the program was “ideas.” Parents felt that the program provided ideas for new ways to prepare and serve FV, which may indicate feelings of ownership of the information provided. These findings suggest improvements in the self-efficacy of parents. Self-efficacy is the most important construct in SCT because individuals with a greater sense of self-efficacy feel more capable of changing their behavior, despite barriers [39].

There was no change in pre-post measures, which may be explained in part by the high percentage of completers (92%) who reported at baseline that the foods their child consumed were somewhat or very healthy. Additionally, 51 out of 72 completers (71%) reported that they served meals with FV very often or always. In other words, given the favorable responses at baseline, there was little room for improvement. However, only 32 out of 72 (44%) and 23 out of 72 (32%) completers reported that they were already serving the recommended amounts of fruits and vegetables per day, indicating that there was still room to improve behaviors related to FV intake in this population. Parents may recognize that FV are an important part of a healthy diet but may not be aware of the daily recommended amount for children, which could negatively influence parental encouragement of child FV consumption [40]. Another explanation is that our instrument did not accurately measure child FV intake, which may have resulted in a ceiling effect and limited our ability to detect changes.

Although scale items were adapted from measures that have been validated for a low-income population, items were rewritten to assess child, as opposed to parent, FV intake. High Cronbach alphas and moderate interitem correlations indicated an acceptable scale reliability. However, additional validity testing is needed. Using different modes to administer the questionnaire at pre- and postintervention may have introduced additional variance in the participant responses, which may also have contributed to the null findings.

It is also possible that the number of text messages sent or the intervention duration, or both, may have been insufficient to observe an improvement from pre- to postintervention. Although the use of text message-based interventions for changing health behaviors has increased in recent years [25], it is possible that text messaging is not sufficient as a stand-alone intervention to increase FV intake. Many other interventions utilizing text messaging have provided supplementary materials, including interactive websites [18], consultations or education sessions before or during the intervention [19], printed materials [20], and self-monitoring components [21]. Additionally, many text message-based interventions have been implemented in clinical settings so that participants received the standard of care plus text messaging [22-24]. Promising effects of such interventions are likely the synergistic effects of multiple components because these studies did not isolate the effects of text messaging on outcomes. Electronically delivered health interventions, however, have shown promise for effecting change in dietary behaviors, such as FV intake [28,41,42]. Future research is needed to explore whether such materials would strengthen program effects.

A more rigorous evaluation of the Txt4HappyKids intervention is needed. However, given our interest in understanding participant satisfaction, an important first step in developing larger multi-level interventions utilizing mobile technology, the pre-post study design was appropriate for this pilot study. One limitation of this study design was that these findings can only

be interpreted in the context of our convenience sample, which may not represent the general population. Parents were recruited primarily from a family health fair; therefore, they may have been more interested in health and nutrition compared with the general population. Additionally, only results from completers are presented in this study, which may have yielded higher reported satisfaction with the intervention. Another limitation of this study was that the participants were relatively homogenous, and only half of them were considered as low income according to the proxy measure of whether food assistance was received during the last 12 months. However, it is possible that we underestimated the numbers of low-income participants because some participants likely met the eligibility requirements for food assistance but may not have applied for or received it. Other factors, such as child age (in the case of WIC), could have played a larger role in determining whether food assistance was received. Future research should target more diverse populations, which would provide important insights into cultural and community differences regarding how the program is perceived, thereby expanding the generalizability of the intervention.

The findings from the current research demonstrate that a text messaging intervention to promote FV intake did not change behaviors related to FV intake; however, text messages did create positive perceptions of behavior change among parents of young children. High levels of satisfaction with the intervention among completers indicates that text messaging may be an acceptable complement to federal food assistance programs, such as SNAP or WIC, which have limited funding to deliver nutrition education to millions of people. Using text messaging, time-constrained staff can more effectively reach a large number of clients. Additionally, incorporating text messaging into SNAP or WIC programming would support the federal priority to move toward public health approaches and may increase satisfaction with the existing nutrition education by providing information in a format that clients prefer [43,44].

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Conflicts of Interest

None declared.

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Abbreviations

- FV:** fruit and vegetable
SCT: Social Cognitive Theory
SNAP: Supplemental Nutrition Assistance Program
WIC: Women, Infants, and Children Program
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Original Paper

Electronic Swallowing Intervention Package to Support Swallowing Function in Patients With Head and Neck Cancer: Development and Feasibility Study

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Abstract

Background: Many patients undergoing treatment for head and neck cancer (HNC) experience significant swallowing difficulties, and there is some evidence that swallowing exercises may improve outcomes, including quality of life. This feasibility study developed an evidence-based, practical Swallowing Intervention Package (SiP) for patients undergoing chemoradiotherapy (CRT) for HNC. As part of the study, an electronic version of SiP (e-SiP) was concurrently developed to support patients to self-manage during treatment. This paper reports on the e-SiP component of this work.

Objective: The objective of our study was to develop and conduct a preliminary evaluation of an electronic support system (e-SiP) for patients undergoing CRT for HNC.

Methods: The study was conducted using a recognized mHealth development and evaluation framework and involved health professionals and patients who were undergoing CRT for HNC. The scoping stage of e-SiP development investigated the potential usefulness of the app, exploring how e-SiP would look and feel and what content would be appropriate to provide. Patient and carer focus groups and a health professionals' consensus day were used as means of data gathering around potential e-SiP content. A repeat focus group looked at an outline version of e-SiP and informed the next stage of its development with regard to refining the requirements for the tool. This was followed by further development and a testing stage of e-SiP that involved the coding of a prototype, which was then evaluated using a series of steering group meetings, semistructured interviews with both patients and health care professionals, and analysis of e-SiP log data.

Results: Feedback from focus groups and health professional interviews was very positive, and it was felt e-SiP use would support and encourage patients in conducting their swallowing exercises. However, of the 10 patients who were offered e-SiP, only 2 opted to use it. For these patients, the aspects of the e-SiP app were considered useful, in particular, the ease of keeping a diary of exercises performed. Interviews with users and nonusers suggested significant barriers to its use. Most significantly, the lack of flexibility of the platform on which e-SiP could be accessed appeared a dominant factor in deterring e-SiP use.

Conclusions: The results suggest that further research needs to be conducted around the implementation of e-SiP. This involves evaluating how e-SiP can be better integrated into usual care and through patient training and staff engagement, can be perceived as a beneficial tool to help support patients in conducting swallowing exercises.

KEYWORDS

head and neck cancer; eHealth; self-management; mHealth; chemoradiotherapy; mobile phones

Introduction

There are an estimated 400,000-600,000 new cases of head and neck cancer (HNC) globally each year [1]. In the United Kingdom (UK), approximately 11,000 people are diagnosed with HNC annually, making it the eighth most common cancer. In Scotland, the rates of HNC are almost 40% higher than those in England [2]. There is a link between HNC and the presence of the human papillomavirus (HPV), and HPV-positive cases now account for around 30%-65% of HNCs [3]. The demographics of HNC are therefore changing because patients who are positive for HPV tend to be younger at diagnosis generally have a higher socioeconomic status and better education and a better prognosis (despite often presenting at a more advanced stage of cancer) than patients with HPV-negative HNCs [3-5]. Younger age at diagnosis and improved treatment effectiveness mean that more people are now living with the consequences of HNC and its treatment.

Treatment for HNC can include a combination of surgery, radiotherapy, and chemotherapy [6], leading to both acute and chronic adverse effects. The site of the tumor and the side effects of treatment can impact eating and drinking, physical appearance, and communication [7,8]. Improved treatments have lowered mortality rates but at the expense of greater morbidity with many patients experiencing long-term or permanent swallowing problems (dysphagia) [9] and younger survivors reporting the most severe problems [10]. Preparing patients for potential swallowing problems is clinically advised, but it is unclear when and how this should be done [11].

There is emerging evidence that giving patients prophylactic swallowing exercises may improve long-term swallowing outcomes for HNC patients [12]. These exercises target the swallowing muscles to strengthen and maintain the normal range and speed of swallowing movements and increase blood flow to muscles, which may reduce or prevent fibrosis [13,14]. Trial results are mixed [15], however, and questions remain about the most effective type of exercises, the dose, the most optimal time of introduction, and how best to support patients in adhering to the exercises [14]. Only 13%-14% of participants practice swallowing exercises as recommended [16,17], although how to effectively measure adherence to swallowing exercises is unclear, especially because the optimal dose of exercise is often unknown [18]. There is evidence that those able to maintain their exercise schedule achieve improved swallowing outcomes [19] and are less likely to need a feeding tube [20].

A number of commercial mobile apps have now been developed to support people with dysphagia, and there is anecdotal

evidence that these are used and valued by speech and language therapists (SLTs) in clinical practice. It has been suggested that mHealth technology should be developed in partnership with stakeholders and tailored to the unique needs and experiences of the specific population it seeks to support [21,22]. Many of the apps currently in use are generic, rather than being developed for use with a specific population. To date, little empirical research has been carried out to evaluate the effectiveness or the extent of their use with the HNC population. Starmer et al [23] conducted a feasibility study to explore the use of an app for patients undergoing radiation-based treatment for HNC. Our research complements and extends this work by involving patients, carers, and clinicians in the design and development of a suitable tool to support swallowing function.

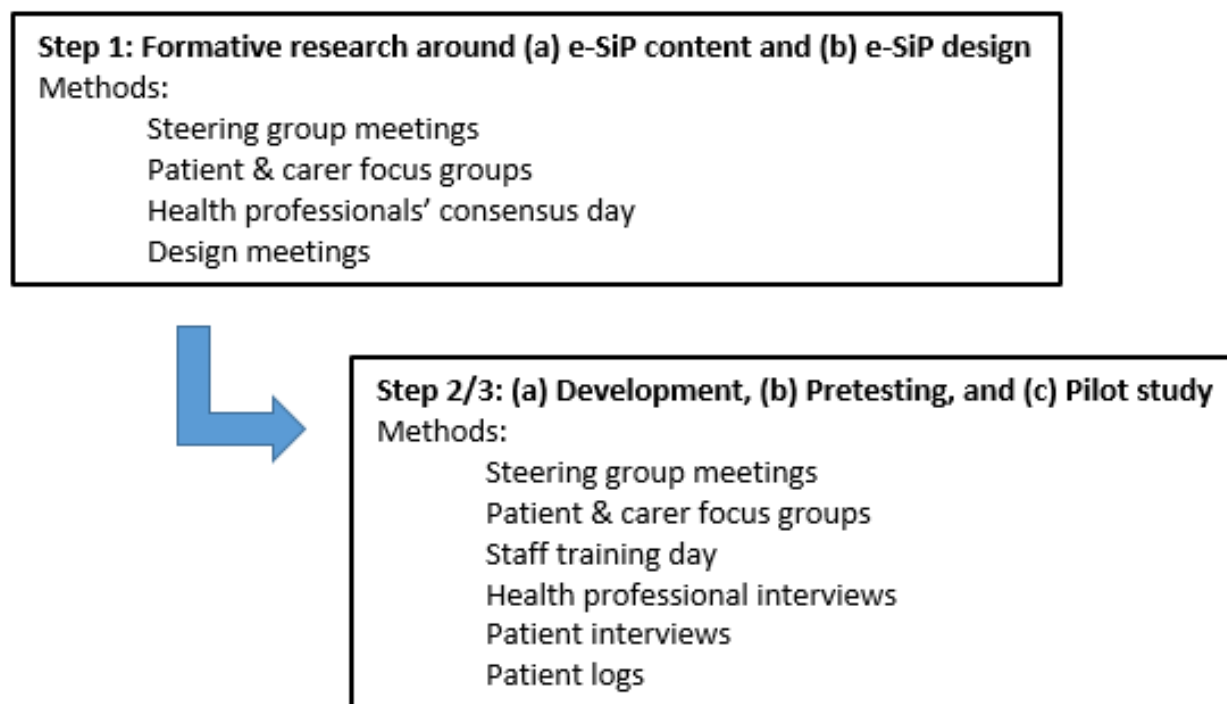
This paper reports on research that was undertaken to develop and evaluate an electronic Swallowing Intervention Package (e-SiP) for patients undergoing chemoradiotherapy (CRT) for HNC. The tool aims to support patients to conduct swallowing exercises to improve long-term swallowing function and quality of life. The work was performed as part of a larger feasibility study to develop and test a paper-based SiP for the above patient group [24]. In the remainder of this paper, we describe the work undertaken in the development and testing of e-SiP, which involved an initial scoping exercise, development of the tool, and a preliminary evaluation. Findings are presented followed by reflections and concluding comments on how this research might be used to inform future studies.

Methods

Overview

The development and feasibility testing of e-SiP were conducted following the development and evaluation framework proposed by Whittaker et al [25]. This framework highlights the importance of a staged approach to mHealth apps to ensure that the development and evaluation process is rigorously conducted. Our paper focuses on the early steps of the process: the conceptualization of e-SiP, conducting formative research using a number of group meetings with relevant stakeholders, and pretesting and piloting the prototype system. [Figure 1](#) depicts the data collection methods used at each stage.

Recognizing the importance of user-centered design in the development of any mHealth app, our work has also drawn on social cognitive theory [26] to explore how individuals acquire information and use this to influence behavior. In addition, the work of Cooper et al [27] around patients' beliefs and its impact on adherence has underpinned discussions about the design of the e-SiP app.

Figure 1. Electronic Swallowing Intervention Package (e-SiP) development and evaluation process.

Step 1: Electronic Swallowing Intervention Package Formative Research

Questions about the key components of a feasible and evidence-based e-SiP for HNC patients undergoing CRT were incorporated into a series of events and meetings held to gain views from clinicians, patients, and carers. This scoping exercise comprised patient and carer focus groups, a health professionals' consensus day, and steering group committee meetings. The purpose of these meetings was to elicit appropriate content to include in e-SiP and how the tool should look and feel. Feedback from these discussions were used in a series of design meetings held with software architects.

Steps 2 and 3: Electronic Swallowing Intervention Package Development, Pretesting, and Pilot Study

An initial version of e-SiP was developed, and this prototype was demonstrated and discussed at a further series of events (clinical staff training day, steering group, and a patient focus group) to clarify that the content and design was acceptable and usable for clinicians and patients. This participatory approach ensured that the views of a range of stakeholders were incorporated into the software design prior to the final version of e-SiP being trialed. In addition, an e-SiP user guide was developed and presented to staff along with the training to further support them in using the system and teaching patients wanting to use e-SiP. This iterative process of codesign was crucial in ensuring that the tool met user needs.

e-SiP was offered to study participants, and its use was evaluated through electronic logs and semistructured interviews with patients (both e-SiP and paper-based SiP users) and health

professionals. Eligible patients were approached by an SLT or clinical nurse specialist (CNS) in their local health board, and the SiP study was explained to them (Table 1). If a patient indicated that they might be interested, they were provided with information about the study and gave verbal consent for the research nurse team to contact them in a few days' time. If they opted to take part, consent and baseline data collection were undertaken by the local research nurse team. Participants in the health board that trialed e-SiP had the additional option of using an iPad loaned by the study to access e-SiP. Digital literacy was not examined, and all patients were offered the use of an iPad regardless of their previous experience. All patients were given the option of consenting to be contacted regarding a later qualitative interview and were given information sheets to pass to their carers, should they also wish to be interviewed.

Outcome Measures

Patient- and clinician-reported questionnaires were completed at baseline (before the intervention started), at the end of CRT, and 3 and 6 months after the end of CRT. These included the water swallow test (not performed at the end of CRT) and MD Anderson Dysphagia Inventory measures of swallowing, performance status scale for HNC patients, and the Functional Oral Intake Scale. Measures of quality of life were the EuroQol EQ-5D-3L, the EORTC Quality of Life Questionnaire-C30 with the additional Head and Neck Cancer Module HN37, and the Brief Illness Perception Questionnaire.

The questionnaires were completed during appointments with a research nurse or via post if the patient was too ill to attend. Both the patients using e-SiP and the paper-based SiP completed the questionnaires on paper.

Table 1. Main components of Swallowing Intervention Package.

Time of intervention	Type of support provided	Details of support provided
Pretreatment intervention: One-on-one consultation with SLT ^a (with carer present as desired and appropriate).	Discuss Swallowing Intervention Package folder (or electronic Swallowing Intervention Package if selected); demonstrate swallowing exercises. ^b	<ul style="list-style-type: none"> • Instruct patient about the importance of practicing swallowing daily. • Instruct the patient about how to do swallowing exercises including a demonstration. • Increase patient motivation to complete swallowing exercises. • Help patient plan swallowing exercises and overcome barriers. • Help patient to set long-term goals.
Weekly review during radiotherapy: Consultation with SLT or clinical nurse specialist as part of usual care.	Reinforce intervention; complete weekly assessment sheet; Monitor symptoms and pain management, and record behavior change techniques used.	<ul style="list-style-type: none"> • Check homework and review goals. • Motivate and encourage patient to complete swallowing exercises and diary record sheets. • Address any issues which have arisen. • Provide additional demonstration of exercises if requested.

^aSLT: speech and language therapist.

^bEffortful swallow, Masako maneuver, Mendelsohn maneuver, Shaker head-lifting maneuver, and jaw exercises.

Analysis

Log data detailing the patients' use of e-SiP were analyzed using SPSS (IBM Corp, Armonk, New York, USA). Transcripts of the interviews and focus groups conducted were analyzed using a thematic framework approach [28] and coded with the support of NVivo 10 software (QSR International, Melbourne, Victoria, Australia). The initial framework was devised both inductively and deductively. Field notes were used to capture discussions on the consensus day, training day, and steering group meetings. These were analyzed, and the data were structured around emerging themes.

Results

Step 1: Electronic Swallowing Intervention Package Formative Research

Step 1a: Electronic Swallowing Intervention Package Content

The content of e-SiP was developed through an analysis of the literature and discussions with patients and health professionals, as outlined below. The aim was to make it a tool that was regarded as patient-focused, practical, and evidence-based.

Patient and Carer Focus Groups

Four initial focus groups were carried out across two health boards (one of which was the health board in which the SiP was to be trialed). In total, 23 people participated (16 patients, 7 carers). The experiences discussed by focus group participants helped us to identify the most important information to include in the e-SiP package. Using the thematic framework approach, 3 researchers were involved in coding, cross coding, and sense checking of the data collected. The emerging themes from the data are discussed below.

Effects of Treatment

Participants spoke of the pain associated with the side effects of treatment, the long recovery time (for which many felt unprepared), and the effort and time required for eating and drinking as their swallowing deteriorated. Difficulties around eating included discomfort, dry mouth, changes in taste, the requirement for a softer diet, and fatigue, which made eating a

chore. Many of the patients had used a feeding tube during their treatment. Even months after the end of treatment, many patients still experienced swallowing difficulties with 2 patients being unable to swallow anything at all.

I was dehydrated because I had stopped eating, I'd stopped drinking and it was physically impossible for me to swallow, the pain was just unbearable. [Patient]
...well, basically to grind...I can't eat meat. Oh, to have a steak, would be brilliant. To have chips would be brilliant. Although, it has helped my weight. But no, I can't chew, so it's pasta, fish. I'm adapting, you know, to chewing. [Patient]

Need for Clearer Explanation of Possible Swallowing Difficulties

Participants reported that although clinical staff had discussed potential swallowing problems with them, they had found this difficult to grasp without any previous experience of what swallowing problems could be like. Participants stated that it would be useful to hear about experiences from other patients who had been through treatment because for many patients, this was the first time that they had met others who had undergone HNC treatment. Firsthand experiences and accounts from previous patients were, therefore, included in the e-SiP resource. Focus group participants also felt that information on preparing food and understanding more about how the swallowing muscles worked would be useful to include in the package.

Need for Clearer Description of Recommended Exercises

Some focus group patients had been given a sheet of exercises during their treatment but with little explanation, and others had not been given any exercises. The participants suggested that for e-SiP, access to both written instructions and videos of the exercises would be useful. They also liked the idea of having access to information and support to motivate them and manage the psychological challenges of going through treatment for HNC.

Yes, I must admit I didn't know if I was doing them [exercises] right and how long to have them for and things like that so [videos of exercises] would be useful. [Patient]

You could do them without thinking. Then you just have a wee bit, oh they're doing that and then you try it for a wee while and again, right oh they're doing that one, they're doing this one, and you're still watching the telly. I used to do mine watching the football and sit there and the wife's going, what are you doing? I've been doing my exercises. But, whether I was doing them right is another thing, or long enough is another one. [Patient]

Need for a Diary to Support Tracking of Progress Performing the Exercises

It was also decided that e-SiP should feature an electronic diary in which patients could mark down how many exercises they had managed to achieve in a day or even just record their eating habits over a period of time. Patients felt that this would help them track progress, keep motivated to continue conducting the exercises, and give back some control over their illness.

I think breaking it down is very, very, important and when you're probably at your bleakest and at your tireddest, you wouldn't want to fill things in or write things down. But,...[filling in a diary] it's giving you control again to your illness, it's giving you ownership of your condition. [Patient]

Health Professional Consensus Day

Nineteen clinical and academic staff attended a consensus day where the content of the paper-based package and e-SiP was agreed. All of the swallowing exercises proposed for inclusion in e-SiP are already in clinical use, but the delivery and instructions given vary between different health boards. The standard package of exercises for e-SiP was therefore decided upon using a consensus exercise with SLTs. Exercise instructions were gathered from health boards involved in the e-SiP study (or in which the advisors worked) and rewritten or redrawn to make a consistent package that could be used for e-SiP. Attendees also provided input into additional health information e-SiP would feature, such as keeping the mouth clean, managing mood and anxiety, and suggestions for eating a modified diet. A link to the Macmillan website discussing nutrition in cancer was also suggested.

There is a significant body of research on health communication and the importance of tailoring information to an individual's needs [29,30]. In many apps, tailored health information has been seen to increase the effectiveness of the message [31,32]. As such, discussion at the consensus day also focused on how e-SiP could be personalized to individual patients. It was decided that the videos of individuals performing the exercises would be a useful inclusion. Rather than using generic videos already available online, to personalize and customize the information to the individuals who would use e-SiP, new recordings of the videos by UK-based SLTs were produced. A further request regarding the swallowing exercises was that only exercises relevant to a particular patient be included for that particular patient. Again, this ensured that e-SiP was highly tailored to individuals in an attempt to encourage its relevance and subsequent use by participants.

Steering Group

Our steering group comprised 13 clinicians, 3 academics, and 3 patient advisors, who gave us invaluable information about their experiences of going through treatment for HNC. The patient advisors read through all the proposed e-SiP information to make sure that it was suitable and accessible to the patients in our study. Additional features were also proposed, including an assessment of barriers to performing the exercises (symptoms and time), an email facility, and the ability to record a video diary.

Final Electronic Swallowing Intervention Package Content

The content of the e-SiP can be categorized as follows: study information; exercise videos; exercise information; HNC and treatment information; audio and written information on managing anxiety and low mood; diary, calendar, and email facility; video diary; and patient stories. Many of these features overlapped with those provided with the paper-based SiP. However, there were perceived to be certain advantages over the paper copy: (1) e-SiP would include direct links to external sites with information about HNC, whereas we could only provide the website address for the paper-based SiP; (2) for the exercise diaries, e-SiP would include an automatic recording of when the diary was filled in and would also prevent patients filling in diaries for the previous days, an aspect that could not be fulfilled by the paper-based version. We hoped that this would give us a good comparison to assess if hoarding occurred with patients using the paper diaries, as has been reported elsewhere [33-35]; and (3) e-SiP would contain videos of exercises, recordings of coaching exercises for managing anxiety and low mood, and clips of former patients discussing eating and drinking. The provision of this information in the paper-based version of SiP was via a digital video disc.

Step 1b: Electronic Swallowing Intervention Package Look and Feel

A series of 6 design meetings were held with key researchers on the project and the e-SiP app design team. These meetings were held over a 6-month period and involved an iterative process of design, reflection, and development. Initial ideas for e-SiP were developed using a storyboard approach, mapping out how users might progress through the app. The storyboard constructed to represent interaction with e-SiP is shown in [Multimedia Appendix 1](#). Having finalized the storyboard, work began to translate this into a usable prototype app.

Steps 2 and 3: Electronic Swallowing Intervention Package Development, Pretesting and Pilot Study

Steps 2 and 3a: Electronic Swallowing Intervention Package Development

e-SiP was developed using Apple's XCode Integrated Development Environment and is written in Objective-C. It makes use of locally stored media, including web content and video, and enables users to save their video recordings and access remote content relevant to the SiP project (eg, the Macmillan Cancer Support website). The current version of e-SiP is compatible with Apple iPad 2s, and it is via this medium that the app was made available for user testing. Currently, the

app is not available for any other operating system, and it is not available on Apple's App store for download onto an individual's device.

In line with the storyboard developed as part of the Phase I exploration, e-SiP provides users with an easy-to-use, simple interface through which the variety of services it offers can be accessed. [Multimedia Appendix 1](#) depicts e-SiP's main screen through which all the functionality available can be accessed. The interface is very much in keeping with the current style of interface offered by Apple and is generally regarded as intuitive to use. However, testing of the prototype's usability, as well as the suitability of content and ease of navigation, was conducted at the pretesting phase of the project.

The main screen is divided into four main sections: study information, swallowing exercise videos, exercise instructions, and patient stories. These sections allow the patient to access information about each area described. These four information sections are accompanied by a menu bar at the bottom of the screen. This menu is designed such that the user can keep track of the exercises performed as well as record information about their symptoms, keep a diary relating to how they felt on a particular day and their experiences of the exercises, and use the calendar function to track hospital appointments and important dates. The settings component of the menu bar allows e-SiP to be tailored to an individual patient; for example, when giving e-SiP to a patient for the first time, SLT can specify what exercises should be provided for the specific patient, ensuring only exercises appropriate to the patient's needs are shown on e-SiP's main screen.

The recording of calendar entries whereby patients can detail exercises completed each day along with information relating to their experience of conducting these exercises is depicted in [Multimedia Appendix 1](#). In the example given, the patient has created 6 entries on the September 17 and 2 entries on the September 18.

Along the top of the calendar screen is a further option bar allowing users to "Add Event," "Record Exercise Reps," "Exercise Feedback," and "Send Email." The "Record Exercise Reps" option allows the user to record details of exercises completed. The "Exercise Repetitions" screen is shown in [Multimedia Appendix 1](#).

As explained in the instructions at the top of the screen, the user should select which session they are completing, after which they should use the slide bar to select how many of each exercise they completed. If the user was unable to complete any exercises in a given session, they could move the slide button to the right next to the option "I was not able to complete any of the exercises" to indicate that none were completed.

The "Exercise Feedback" option allows the user to record whether anything interfered with them in conducting their exercises. This should be completed daily. For each option listed, the user should indicate how much (from "not at all" to "very much") each option made it more difficult for them to complete their exercises. In the example shown in [Multimedia Appendix 1](#), this user had no pain or discomfort, was moderately tired, was feeling very low, and felt they didn't have much time.

Steps 2 and 3b: Electronic Swallowing Intervention Package Pretesting

Prior to evaluating e-SiP with patients, the tool was demonstrated in a number of settings to receive and act on feedback regarding its usability and potential for incorporation into care provision. e-SiP was trialed and evaluated by participants in a repeat focus group (2 patients, 1 carer), at a clinicians' training day (n=19), and steering group meetings (n=18). Feedback from these meetings was extremely positive and indicated that e-SiP had the potential to support patients in conducting swallowing exercises and monitoring their progress. Some of the key themes arising from the meeting were that e-SiP was felt to be something patients would benefit from (patient focus group) and that the exercise videos were an extremely useful component (patient focus group, staff consensus day).

See, when I tried the Mendelsohn maneuver, and actually, you can do it wrong as well as right. I mean, if you just lift...you can lift without swallowing. But if you don't swallow, there's no point doing it. And it's very easy done. And it was described to me, and it was described to me in about three and a half seconds, and that was it. And I was given a piece of paper, but the piece of paper, it's not bad. But a video, that's the answer. [Patient, focus group]

Furthermore, patients would engage with the tool as it felt "local" and relevant to those receiving treatment as part of the National Health Service (NHS) system (steering group, SLT). Lastly, patient experience stories are a useful inclusion because it was felt that patients are more likely to listen to other former patients than a clinician (steering group, patient advisor).

Steps 2 and 3c: Trialing Electronic Swallowing Intervention Package With Patients

Although the wider SiP study was conducted in 5 NHS boards across the UK, e-SiP was only trialed in 1 health board owing to complexities around gaining information technology (IT) governance within the timescales of the study. e-SiP was offered to 10 participants with 2 choosing to use it. As reported in more detail in the qualitative interviews below, most of those who declined e-SiP were simply happy with the paper copy. The very small numbers preclude any analysis of demographic or clinical factors that may have influenced the uptake of e-SiP. Both participants who opted to use e-SiP were men aged 54 and 62 reflecting the demographics of the SiP cohort as a whole. Both lived in postcode areas coded as level 4 on the Scottish Index of Multiple Deprivation (SIMD) [36], which was slightly higher (more affluent) than the median SIMD. The log of e-SiP use by the 2 users was analyzed (see below). Both patients using e-SiP took part in qualitative interviews along with 15 other study participants purposively sampled to represent people of different ages, diseases, and treatment characteristics. They were also asked their views about the potential use of e-SiP. Additional feedback from health professionals was gained through qualitative interviews.

Patients using both e-SiP and the paper-based version of SiP were asked to start exercises and diary record cards on their

first day of radiotherapy and continue logging their exercise achievements daily throughout their course of radiotherapy (approximately 6 weeks). Posttreatment, patients were advised to stop the exercises when SLT agreed that their swallowing levels had returned to an acceptable level. Patients on the paper version were provided with diary cards for around 1 month posttreatment. However, most had stopped logging their exercises by 2 weeks posttreatment. All questionnaires (eg, quality of life questions) carried out as part of the trial were given on paper, regardless of whether the patient was an e-SiP or a paper-based SiP user.

Summary Electronic Swallowing Intervention Package Log Data

From the log data recorded from patients' use of e-SiP, we were able to see what aspects of the system were used by patients and how often. Both patients used the diary facility each day. In addition, they recorded daily feedback relating to how they were feeling, how easy (or not) the exercises were to complete, and which exercises proved to be more challenging than others. One patient used e-SiP to record his symptoms each day. Both patients viewed the videos showing how to conduct the various recommended exercises at the beginning of their treatment. They also viewed the film clips of people talking about their experiences of eating and drinking after the HNC treatment, and they looked at the "Managing Worries" and "Useful Links" sections. All of this activity took place at the beginning of treatment. Once they had started carrying out the swallowing exercises regularly, they no longer looked at the other materials. Neither participant used the video diary facility.

Given that only 2 patients opted to use e-SiP, it is not possible to draw any conclusions from the data about which components were most useful, although the use did appear to mirror how people used the paper version (mostly for recording exercises and how they were feeling).

Feedback From Patient Interviews

The 2 participants who used e-SiP were interviewed and had the opportunity to talk about their experiences of using it. Ten participants (of the 15 interviewed) who had used paper-based SiP also talked about the potential use of e-SiP. The following themes arose from the interviews.

Ease of Use

Participants who used it found e-SiP easy to use and had no problems navigating the system:

Aye, great, aye, no problem at all, very self-explanatory, basically. [T004, e-SiP user]

However, both participants found it frustrating that they had to record which exercises they had done on the specific day rather than completing it retrospectively:

I remember, in actual fact, it was literally on, I think, I'm pretty sure it was on the stroke of midnight. Because, you know, if we were late or something, and then, I'd go at quarter past midnight, or something, and you would go, oh no, it wouldn't let you do it. It was just so blooming frustrating. [T010, e-SiP user]

Both participants completed the diary entries once a day rather than as they did the exercises.

Use of Own Technology

Participants who used e-SiP would have preferred to have been able to use it as an app on their own phone or tablet rather than having to use an extra piece of technology:

Some people would find that easier to carry, you've always got your phone on you. So, it would probably be something that you could take into the hospital, and you could sit while you were getting your chemo, and your different thing, rather than carrying a big iPad about with you. Yeah, that would probably be quite a good idea. [T004, e-SiP user]

But one less bit of technology to have about, probably, would have been helpful. Or even if the app could have been downloaded onto my iPad, do you know what I mean? [T010, e-SiP user]

Video Diaries

Neither participant who used e-SiP used the video diary function and did not appear to be very interested in this as a feature:

I'm not very good with that stuff, to be honest. [T004, e-SiP user]

Video Material

One participant found the film clips of people demonstrating the swallowing exercise helpful:

Well that's probably, I found that [watching videos] more helpful than reading the literature...because you actually, they were showing you exactly what to do, and you were getting into the way of it better. [T004, e-SiP user]

The same participant engaged in the Web-based materials and found them useful, particularly being able to hear about other people's experiences:

But again, if you read that, and then you have a look at the videos and you can see, okay, this is what I have, and that one is a lot bigger than mine, you know, the growth, and some people could hardly even swallow. Mine was quite small, it was like a little bit of popcorn, you know, that's what it looked like, or a nugget, kind of thing, one of these nugget things. [T004, e-SiP user]

A small number of patients who had not used e-SiP were ambivalent about the videos, 2 specifically saying that they thought that the written information was sufficient. However, others wanted to be able to see (through diagrams and video) whether they were doing the exercises correctly.

Reasons for Opting for Electronic Swallowing Intervention Package

One participant chose to use the iPad because he was accustomed to using it on a daily basis and felt that it helped him to remember to use it:

I suppose, I have an iPad, so I'm used to using the iPad. And it's more likely, if I'm using the iPad every

day, that I'll, at some point during the day, I'll be reminded that I need to update the information on that iPad. [T010, e-SiP user]

Two participants who had not used the e-SiP felt that they would have found it useful because one was accustomed to using their iPad regularly. Another felt that it would have reduced the amount of paper around the house. Most of the others interviewed appeared to be more comfortable with the paper-based SiP, saying things such as:

I've got a computer, I could've used it but I prefer this...I like being able to flip backwards and forwards. [L012]

Overall, participants were ambivalent about having a choice between the electronic and paper copy of SiP with some preferring the paper version and others saying that they may have opted for e-SiP if they had been able to download it onto their own device.

Feedback From Health Professional Interviews

Overall, 15 health professionals involved in the delivery of the SiP intervention were interviewed about their experiences with some questions asked about the e-SiP app. Key findings from these interviews are summarized below.

Why Participants Opted for Swallowing Intervention Package (Not Electronic Swallowing Intervention Package)

Staff were surprised that only 2 participants used e-SiP and discussed the possible reasons for this:

No, and in terms of the iPads I'm not really sure why people have been reluctant because...Okay, we missed the first couple because we didn't have them but they've been offered to the majority of people. [SLT1]

I cannot believe that nobody, well, not nobody, but hardly anybody took that up, it's just...and maybe we didn't sell it enough at this end, I don't know or maybe it's the population, maybe if we were...I know [place] is a city, but not many of the patients were actually from [place], quite rural communities that they came from, so whether that makes a difference, I was really surprised. [SLT2]

Some professionals felt that participants would have preferred to have used e-SiP on their own phones or iPads:

And I can see that if I was doing it and I had to have a separate iPad rather than it being on my iPad, not that I have an iPad, it gets taken over by everybody else, family iPad, so then maybe you have more ownership of it if it's on yours as an app, I don't know if that's impossible to do with the small scale that we were looking at, I don't know, I was surprised that nobody wanted it. [SLT2]

Others felt that people just preferred a paper-based system:

I did too but actually I think sometimes when people write things down on a bit, I think they feel that actually that's then...they like the folder because they all came with their folder and all the local cards in their folder, so everything was there for them without

having to scroll through an iPad. I think they liked that. [CNS3]

Logistics

Professionals felt that more participants may have engaged with the technology but because there was a delay in having the iPads ready, not everyone had the option to use e-SiP right from the beginning:

Yeah, because I'm sure [Patient T001] would have used an iPad, but it wasn't available when she went through.... And she's very computer literate. [SLT2]

Knowledge of Technology

Professionals felt that participants' knowledge of technology varied, and this may have affected their desire to use e-SiP:

I suppose it depends on how computer literate you are. But I did think that would have maybe been easy because you're not actually having to jot anything down, you're just hitting buttons if you like. [CNS1 and SLT4, joint interview]

I think it would very much depend on the patient and how, kind of, text-savvy they already are. [SLT5]

Own Technology

Most professionals agreed that more people would have opted for e-SiP if it could have been downloaded onto participants' own smartphones or tablets:

I think as they're moving up, I think the population is changing, I think they will all be onto smartphones. I mean, the gentleman that I would never have thought, but that's a smartphone that he's just shown me – how good he is at using it I'm not sure, but certainly it was a smartphone he had, and I think over the coming years anyway, the next couple of years, it's just going to be second nature. [CNS1]

And I definitely think our patients are such a diverse group that yeah, some will have them, some won't. [SLT4]

Monitoring and Review

In practice, professionals were unsure how to review diary entries on the iPads, and this was problematic for them both in terms of reviewing and monitoring:

No, because you could read in the comments, in the diary comments you could actually read the comments that patients have written so that if somebody for instance had said it was very painful or a struggle, I can go back and say right last week you said this and this, is it better this week? Whereas with the iPad I didn't have access to that. [CNS3]

Compliance exactly, compliance as well because somebody can just fill in an iPad to say yes I've done it but actually have you really done it? Whereas the diary cards and because they needed to write comments I think for me I think were better. [CNS3]

Overall, professionals were surprised by the low uptake and use of e-SiP but concluded that a variety of factors contributed to

this, including that they may not have promoted it sufficiently. One clinician, when interviewed, admitted that she had forgotten about e-SiP and, therefore, did not discuss it with any of her patients. This reflects the complexity of the study as a whole because clinicians had many aspects to remember with e-SiP being only one small part of the overall study.

Quality of Life Measures

EQ-5D-3L questionnaires asked patients about issues such as mobility, pain and discomfort, and anxiety and depression. Owing to the low numbers of patients using e-SiP and in the control population of the study, it was not possible to draw any definite conclusions about the quality of life changes of patients. However, it appeared that there were potential improvements in self-care and anxiety and depression in the SiP patients.

Discussion

Principle Findings

This paper describes the development and preliminary evaluation of an e-SiP designed to support patients with HNC to maintain swallowing function during treatment. Our findings illustrate the potential for involving different stakeholders in the development of a tailored electronic intervention and show that e-SiP offers a practical alternative to a paper-based diary and support system.

However, our experience shows that patients with HNC tend to prefer the paper-based system rather than an electronic app. Patient interviews suggest that having to access the app on a bespoke iPad rather than on a patient's own phone or tablet was largely responsible for the low uptake of e-SiP. Patient logs illustrate that although the diary feature and videos were well used, other aspects of e-SiP received limited attention. Videos tended to be used during the first few days of a patient's treatment and less so as the weeks went on (quite possibly reflecting their growing confidence in conducting the exercises correctly).

Staff interviews suggest that the complexity of the study overall [24] meant that clinicians already had a range of responsibilities for data collection and intervention delivery and that they paid relatively little attention to encouraging e-SiP use. Additionally, IT governance systems varied across different NHS sites and created barriers to offering e-SiP to all patients involved in the larger study. This may have also led to e-SiP being presented as an addition to the paper-based version rather than a straight choice between one or the other, which may have driven patients to stick with the status quo of the paper version.

The study highlights a number of issues that would need to be addressed in the future development and adoption of e-SiP. Firstly, it is clear that electronic apps are more likely to be attractive to patients if they can be used on patients' own devices and are offered on a variety of platforms. However, providing an iPad free of charge to participants in the SiP study eliminated a potential problem of reduced uptake by participants from lower socioeconomic areas who might not otherwise be able to afford the technology [37]. Secondly, mechanisms for sharing

e-SiP data between patients and clinicians must be developed so that information and progress can be discussed during consultations. Despite the email facility offered on e-SiP, health care practitioners did not show this feature to users. In addition, one user did make use of the facility, but their corresponding SLT did not check the emails received. Furthermore, if electronic apps are to be integrated into routine practice, IT governance systems need to be more flexible and encouraging of their use. Finally, patients and health care professionals need support and training to use all the features of e-SiP even when they are familiar with the technology. Despite the clinical training and user guide provided, it became apparent from staff interviews that some of the functionality of the app was not used to its full advantage by staff; for example, none of the staff talked about the use of the "back area" of the app to allow them to change goals or add and remove certain exercises for participants. The patients who used the app found it easy to navigate. However, they both were already familiar with the use of technology and iPads, and this is known to make the use of such apps more likely [37,38].

Study Limitations

This study was conducted to investigate the feasibility of an electronic tool to support swallowing exercises for those living with HNC. The study provided a means of exploring how, through coproduction with patients, carers, and health care professionals, a tailored health tool could be developed. A small pilot of the resulting tool has provided interesting results for the refinement and larger scale testing of such a tool in the future.

It is recognized that given the low numbers of patients that opted to use e-SiP, more extensive testing of the prototype needs to be conducted to draw conclusions about its potential usefulness in promoting swallowing exercises. Our intention is to build on this work and conduct a larger trial of e-SiP considering findings from this study. This work will incorporate more extensive analysis of system log data and recruitment of a larger population of e-SiP users such that further understanding of its potential usefulness can be gained. The study will also make e-SiP more widely available and enable users to freely download it onto their own mobile device.

Contribution to the Field

This paper provides valuable insight into the potential use of e-SiP technology to support patients to undertake swallowing exercises and manage their swallowing difficulties while they are receiving treatment for HNC. It also provides important lessons for the wider application of technology to support individuals to self-manage and take ownership of their care. In particular, the study highlights the importance of stakeholder involvement in the development of any intervention and the need to address issues of implementation and their potential to impact on the success or failure of an intervention. Initial findings suggest that further evaluation is needed to look specifically at acceptability and usability using "psychometrically robust measures," as recommended by Darlow and Wen [22].

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Authors' Contributions

JC was responsible for overseeing the development of the e-SiP app. She has also contributed to and managed the production of this paper. SB was responsible for analyzing the quantitative data arising from the study and supporting collation of this with the qualitative data. She has also contributed to the writing of this paper. EK was the research fellow employed on the project and conducted all interviews and meetings with patients, carers, and health professionals. She has also contributed to the writing of this paper. DC was responsible for the development of e-SiP and has reviewed this paper. MW was the principal investigator on the project and has reviewed and contributed to the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Electronic Swallowing Intervention Package (e-SiP) storyboard and selected screenshots.

[[PDF File \(Adobe PDF File\), 237KB - formative_v2i2e15_app1.pdf](#)]

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Abbreviations

CNS: clinical nurse specialist
CRT: chemoradiotherapy
e-SiP: electronic Swallowing Intervention Package
HNC: head and neck cancer
HPV: human papillomavirus
IT: information technology
NHS: National Health Service
SIMD: Scottish Index of Multiple Deprivation
SiP: Swallowing Intervention Package
SLT: speech and language therapist
UK: United Kingdom

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Original Paper

Web-Based Tailored Intervention to Support Optimal Medication Adherence Among Kidney Transplant Recipients: Pilot Parallel-Group Randomized Controlled Trial

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Abstract

Background: Optimal immunosuppressive medication adherence is essential to graft survival. *Transplant-TAVIE* is a Web-based tailored intervention developed to promote this adherence.

Objective: The objective of our study was to evaluate the *Transplant-TAVIE* intervention's acceptability, feasibility, and preliminary efficacy.

Methods: In a pilot, parallel-group, randomized controlled trial, we randomly assigned a convenience sample of 70 kidney transplant patients on immunosuppressive medication either to an experimental group (*Transplant-TAVIE*) or to a control group (existing websites). Kidney transplant recipients had to be older than 18 years, be taking immunosuppressant medication, and have access to the internet to participate in this study. *Transplant-TAVIE* was composed of three interactive Web-based sessions hosted by a virtual nurse. We documented user appreciation of and exposure to the intervention. Furthermore, we assessed medication adherence, medication self-efficacy, intake-related skills, and medication side effects at baseline and 3 and 6 months later. Analyses of variance were used to assess intergroup differences over time.

Results: After baseline questionnaire completion, participants were randomly assigned either to *Transplant-TAVIE* (n=35) or to the websites (n=35) group. All participants had received their kidney graft <1 year to 32 years earlier (mean 6.8 years). Of the experimental group, 54% (19/35) completed the sessions of *Transplant-TAVIE*. Users found the intervention to be acceptable—33% were extremely satisfied (6/18), 39% were very satisfied (7/18), and 28% were satisfied (5/18). At baseline and over time, both experimental and control groups reported high medication adherence, high medication self-efficacy, and frequent use of skills related to medication intake. No intergroup differences emerged over time.

Conclusions: The results of this study support the feasibility and acceptability of *Transplant-TAVIE*. It could constitute an accessible adjunct in support of existing specialized services.

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KEYWORDS

medication adherence; transplant recipient; self-management; nursing; Web-based tailored intervention; randomized controlled trial

Introduction

Background

Optimal immunosuppressive medication adherence is essential to graft survival [1,2]. However, lifelong daily intake of medication is a major challenge for kidney transplant patients. A meta-analysis revealed that across different types of transplantation, 19-25 per 100 patients per year were not adherent to immunosuppressant, and kidney recipients showed the highest rate of medication nonadherence of all (36 per 100 patients per year) [3].

In two separate systematic reviews of interventions aimed at enhancing medication adherence among kidney transplant patients, De Bleser et al (n=7) and Low et al (n=12) found interventions targeting multiple components—educational, behavioral, and affective—to be promising [4,5]. The evidence was only of a modest level, however, given the methodological limitations and small sample sizes of the studies reviewed. Similarly, in a scoping review, Oberlin et al concluded that no intervention was superior to another and proposed that transplant centers support medication adherence using multilevel strategies that include developing collaborative partnerships, stratifying the population, and employing multiple interventions [6]. In this regard, some researchers have suggested that technology could help improve and support medication adherence among kidney transplant recipients [4,7]. The use and added benefits of information and communication technologies (ICT) to support daily adherence in other patients with chronic conditions, such as cardiovascular diseases, asthma, or HIV, are well documented [8-10].

Against this background, we developed *Transplant-TAVIE*, a Web-based tailored nursing intervention, to empower kidney transplant recipients to manage their immunosuppressive drug treatment.

Objective

The objective of our study was to evaluate the acceptability, feasibility, and preliminary efficacy of *Transplant-TAVIE* intended to support medication adherence among kidney transplant recipients.

Methods

Trial Design

We conducted a pilot, parallel-group, randomized controlled trial (RCT; 1:1 allocation ratio) to assess the acceptability and feasibility of the intervention. Adherence was the primary outcome measured. In addition, self-efficacy, skills, medication side effects, and self-perceived general state of health were secondary outcomes taken into consideration. There were three measurement times: baseline (T0) and 3 months (T3) and 6 months (T6) later. The study was approved by the Research Ethics Board of the Centre Hospitalier de l'Université de Montréal (CHUM). The RCT was reported according to the Consolidated Standards of Reporting Trials (CONSORT)

statement guidelines for randomized pilot and feasibility trials [11]. We did not register the trial as recommended by the International Committee of Medical Journal Editors.

Participants and Setting

The target population was composed of kidney transplant recipients followed up at the CHUM transplantation unit (Canada). The CHUM treats one of the largest cohorts of kidney transplant recipients in the province of Quebec (Canada). To participate in this study, patients had to be at least 18 years old, be on immunosuppressive medication, and have internet access. Anyone with an uncontrolled psychiatric or cognitive condition was excluded from the study.

At regular follow-up visits, potential participants were informed about the ongoing study by the unit receptionists who handed them a promotional flyer. The interested patients were invited to meet face-to-face with the research team in a room adjacent to the clinic, at which time the team went over a consent form to explain what the participation entailed. Patients who agreed to participate in the research signed the form. The baseline questionnaire was completed at the hospital, and follow-up questionnaires were completed by email or telephone at participants' choice.

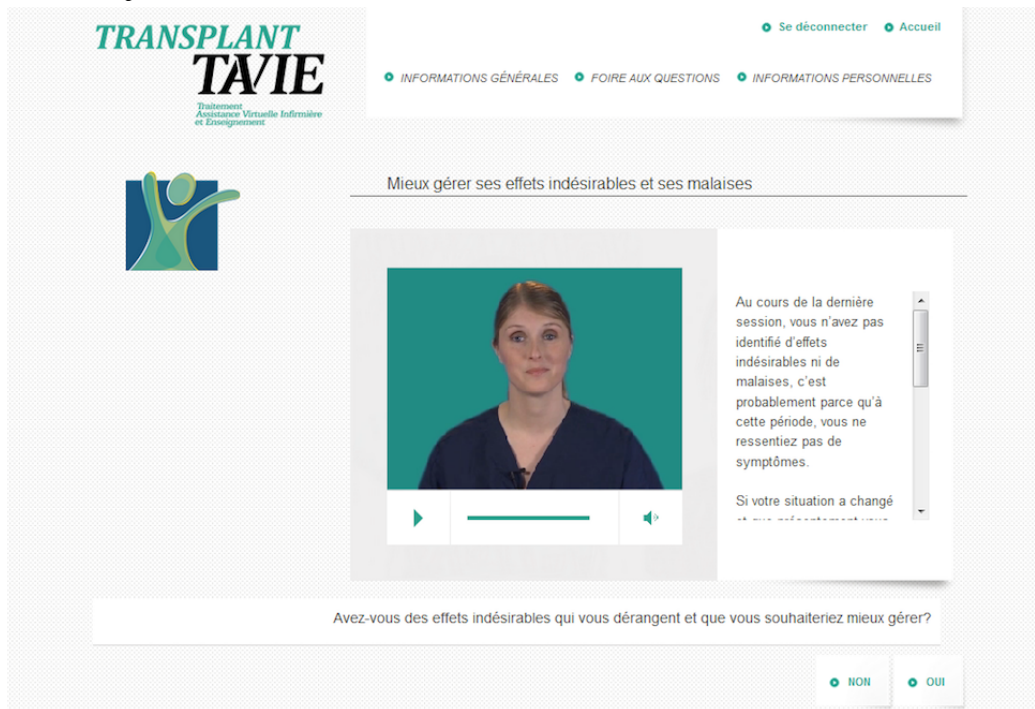
Interventions

Experimental Group

Transplant-TAVIE was composed of three interactive Web-based sessions hosted by a virtual nurse, each 20- to 30-minute long. Over the course of sessions, users strengthened their sense of self-efficacy by developing and reinforcing self-management skills required for medication intake. The sessions aimed to help users incorporate the therapeutic regimen in their daily routine, cope with medication side effects, handle situations or circumstances that could interfere with medication intake, interact with health care professionals, and mobilize social support. The learning objectives included strengthening various capacities such as self-motivation and self-monitoring (session 1), problem solving and emotional control (session 2), and social interaction (session 3).

Transplant-TAVIE is modeled on the TAVIE (French acronym for Treatment, Virtual Nursing Assistance, and Education) concept and platform previously developed by Côté et al [12]. This intervention is informed by social learning theory and behavior change techniques [13]. Aside from delivering teaching, feedback, and positive reinforcement (verbal persuasion), the virtual nurse also refers to the experiences of other patients and holds them up as role models. The three sessions of *Transplant-TAVIE* are consecutive and follow a predefined sequence to ensure the gradual acquisition of knowledge and abilities (skills mastery).

Transplant-TAVIE was available only in French and contained 93 pages, 89 short videos and animated clips, and 58 PDF files (see Figure 1). Access to the intervention was unlimited in terms of intensity, frequency, and length of use between baseline and 3-month follow-up.

Figure 1. Screenshot of Transplant-TAVIE intervention.

Control Group

Participants in the control group (CG) were invited to visit three predetermined conventional transplantation-related websites offering libraries of information. The websites belonged to three recognized organizations (ie, The Kidney Foundation of Canada, Canadian Transplant Association, and Transplant Companions) to ensure the reliability of content and quality of information. The choice of websites was validated by experts in the field of transplantation (MCF, NB, and IV).

The three main differences between CG and the experimental group (EG) lied in message tailoring, presence of a messenger (ie, the virtual nurse), and use of specific techniques or strategies based on theoretical methods. Accordingly, *Transplant-TAVIE* was a tailored intervention hosted by a virtual nurse that followed a decision tree, whereas the predetermined websites offered general information in written and graphic forms.

All participants had the interventions explained to them by a research assistant at the unit on the first study visit. A personalized reminder was sent to all participants by email or phone according to the participant preference 14 days after baseline to optimize participation in the interventions.

Outcomes

Acceptability and Feasibility of Intervention

Intervention acceptability was measured on the Web-Based Nursing Intervention Acceptability Scale [14]. The 18-item scale covers nine dimensions: ease of navigation (2 items), ease of understanding (2 items), appreciation of nurse interaction and credibility of messenger (2 items), tailoring of information (2 items), individual pertinence (3 items), applicability (1 item), appreciation of user interface design (2 items), dosage (2 items), and general appreciation (2 items). Participants in the EG were handed the scale at baseline along with a prestamped envelope.

They were asked to mail it to the research team after having completed the intervention. A personalized reminder was sent by the research assistant to participants who did not mail the questionnaire.

Intervention feasibility was assessed on the basis of intervention exposure. Participants in the EG were asked to sign up for the intervention by creating a user profile (ie, username and password). This one-time registration allowed data to be collected automatically on each user, including exposure to the intervention, pages most visited, time spent on pages, and PDF files most viewed.

We recorded the number of completed sessions for each participant. Intervention fidelity was determined by comparing the projected number of sessions (3) to the number of completed sessions. This was taken to reflect the feasibility.

Primary Outcome: Medication Adherence

We used two medication adherence measures. The *Immunosuppressant Therapy Adherence Instrument* is a 4-item scale with a potential score range of 0 (very poor adherence) to 12 (perfect adherence). The instrument has been found to be psychometrically sound: good validity (alpha, .81), strong intercorrelation between items (>0.84), and a single factor [15]. It is the first published scale to measure immunosuppressant therapy adherence.

We also assessed medication adherence using a visual analog scale from 0% to 100%.

Secondary Outcomes: Self-Efficacy, Skills, Medication Side Effects, and Self-Perceived General State of Health

The medication-taking self-efficacy was measured using 14 items rated on a 5-point scale ranging from 0% (“I cannot do it”) to 100% (“I am certain that I can”). The items were adapted from the *Long-Term Medication Behavior Self-Efficacy Scale*

[16] and the barriers to adherence targeted by Chisholm et al among 222 graft recipients [17]. We carried out content validation and obtained a Cronbach alpha of .88 for this study.

A 24-item questionnaire rated on a 4-point Likert scale was developed for this study to assess medication intake-related skills such as motivation, self-observation, problem solving, emotion regulation, and social skills. Medication side effects were assessed with one question on whether signs or symptoms were present (yes or no) and how much discomfort was experienced (4-point scale ranging from “not at all” to “a lot”). We rated self-perceived general state of health on a visual analog scale.

Furthermore, we gathered sociodemographic data and information on transplant (ie, dialysis, wait time for transplantation, type of organ donor).

The preliminary effects regarding the primary outcome (medication adherence) and secondary outcomes (self-efficacy, skills, medication side effects, and self-perceived general state of health) were measured three times—at baseline and 3 and 6 months later. To promote participant engagement in the study, personalized reminder emails were sent out and direct calls were made. Participants were compensated for time spent completing the follow-up questionnaires; they received a Can \$10 cheque after the second and third measurement time points.

Sample Size

We planned a sample size of 70 participants (35 per group). No power calculations were performed. This sample size was justified by the fact that this was a pilot study [18].

Randomization

As recommended in the CONSORT statement, participants were randomized after completion of the baseline assessment [19]. A permuted block randomization list (block size=10) was generated by computer. This method ensured a close balance between participants in each group at all times during the study. The allocation concealment mechanism consisted of copying the information about the randomization group (EG or CG) on a sheet and concealing it in consecutively numbered, opaque, and sealed envelopes. During data collection, one envelope was opened in front of each participant, thus, revealing the randomization group assigned to the participant.

Blinding

Given the differences between the two interventions described in the consent form, participants were aware of the intervention they were randomized to. However, participants did not know which was the EG and which the CG. During data entry, the research team was blinded to group assignment (one database contained participant information and another only the collected data). All analyses were performed by an external statistician.

Statistical Methods

Descriptive statistics such as frequency distribution and means with SDs were computed to describe the study population and intervention acceptability and feasibility. All patients were analyzed according to their randomized assignment. Analyses of variance (ANOVAs) were run to assess intergroup differences

over time. Because of the small sample size, no missing data imputation was performed. Statistical significance was set at $P=.05$. All statistical analyses were performed using R freeware version 3.3.1 [20].

Results

Participant Flow

The participant timeline, based on the CONSORT statement [11], is illustrated in Figure 2. Approximately 600 flyers were distributed by the transplantation unit staff to patients visiting the hospital for their usual follow-up. Overall, 98 patients responded and met face-to-face with a member of the research team. After being assessed for eligibility and being informed of what the research entailed, 70 patients consented to participate in the study for an acceptance rate of 71% (70/98). For the 28 patients who declined to participate, the principal reasons were lack of time, no access to a computer, and would think about it.

All 70 participants completed the baseline questionnaire and were randomized to either the EG ($n=35$) or the CG ($n=35$). The follow-up questionnaires were completed at 3 months postbaseline by 46 participants (EG: 27/35; CG: 19/35) and at 6 months postbaseline by 39 participants (EG: 23/35; CG: 16/35). More participants in the CG were considered lost to follow-up; there was a greater attrition in the CG than in the EG (19/35, 54% vs 12/35, 34%). In addition, participants lost to follow-up had a lower adherence mean score at baseline than those who completed both assessments (11.3 vs 11.7; $P=.02$). However, given that the maximum score on the adherence scale is 12, this difference was not clinically significant. In their study with 252 kidney transplant recipients, Weng et al defined nonadherent patients as those with a score of <9 on the Chisholm scale [21].

Baseline Demographics and Clinical Characteristics

The detailed sociodemographic and clinical characteristics are presented in Table 1. Nearly two-thirds of the participants were male (EG: 24/35, 69%; CG: 22/35, 63%). The mean age was 54.03 years in the EG and 51.37 years in the CG (EG: range 36-75 years; CG: range 25-73 years). Nearly three-quarters of the participants had more than a high school education (EG: 25/32, 78%; CG: 23/32, 72%) and a little more than one-half worked full- or part-time (EG: 18/35, 51%; CG: 19/35, 54%). In addition, more than half lived with a partner (common law or married; EG: 28/34, 82%; CG: 25/34, 74%). Regarding clinical characteristics, most of the participants had been on dialysis before their transplantation (EG: 30/34, 88%; CG: 30/35, 86%). They had received their kidney graft <1 year to 32 years earlier (EG: mean 7.6 years, SD 7.3; CG: mean 6.1 years, SD 5.4).

Intervention Acceptability

Of the participants randomized to receive *Transplant-TAVIE*, 51% (18/35) completed the acceptability questionnaire. All of them were generally satisfied with the virtual intervention (6/18, 33%, extremely satisfied; 7/18, 39%, very satisfied; and 5/18, 28%, satisfied).

All items regarding the ease of navigation, ease of understanding, appreciation of nurse interaction, and dosage were ranked positively. "Ease of navigation" referred to the ease with which the users surfed or moved about within the virtual intervention. Participants reported that the instructions were easy to follow: 12 of 17 said "totally easy" and 5 of 17 said "very easy" (1 case of missing data). They also reported that navigation within the virtual intervention was easy: 11 of 18 said "totally easy," 6 of 18 said "very easy," and 1 of 18 said "easy." "Ease of understanding" referred to the users' comprehension of the contents of the intervention. Participants reported that the language used by the virtual nurse was easy to understand (18/18, 100%) and that the content of the intervention was clear (17/18, 94%). Participants appreciated the interactions with the virtual nurse (18/18, 100%). Regarding the dosage, all (18/18, 100%) participants reported that the number of sessions was appropriate, and almost all (17/18, 94%)

participants reported that the time allocated to each session was appropriate.

Regarding the appreciation of the user interface design, almost all (17/18, 94%) participants reported that the videos were interesting, and most (14/17, 82%) of them reported that the visual aspects were attractive. Most of the participants perceived the intervention to be useful (individual relevance): the intervention seemed appropriate to 83% (15/18), intervention helped with self-management of care in 72% (13/18), and the nurse proposed skills and strategies that met the needs of 89% (16/18) participants. All (18/18, 100%) of the completers felt that they were able to apply the tips and tricks recommended in the virtual intervention (applicability criteria); 83% (15/18) of the participants felt that they had access to a personalized consultation and 67% (12/18) felt that the messages in the virtual intervention were personally addressed to them. All (100%, 18/18) completers indicated that they would recommend it to other transplant recipients.

Figure 2. Participant flow diagram. ANOVA: analysis of variance.

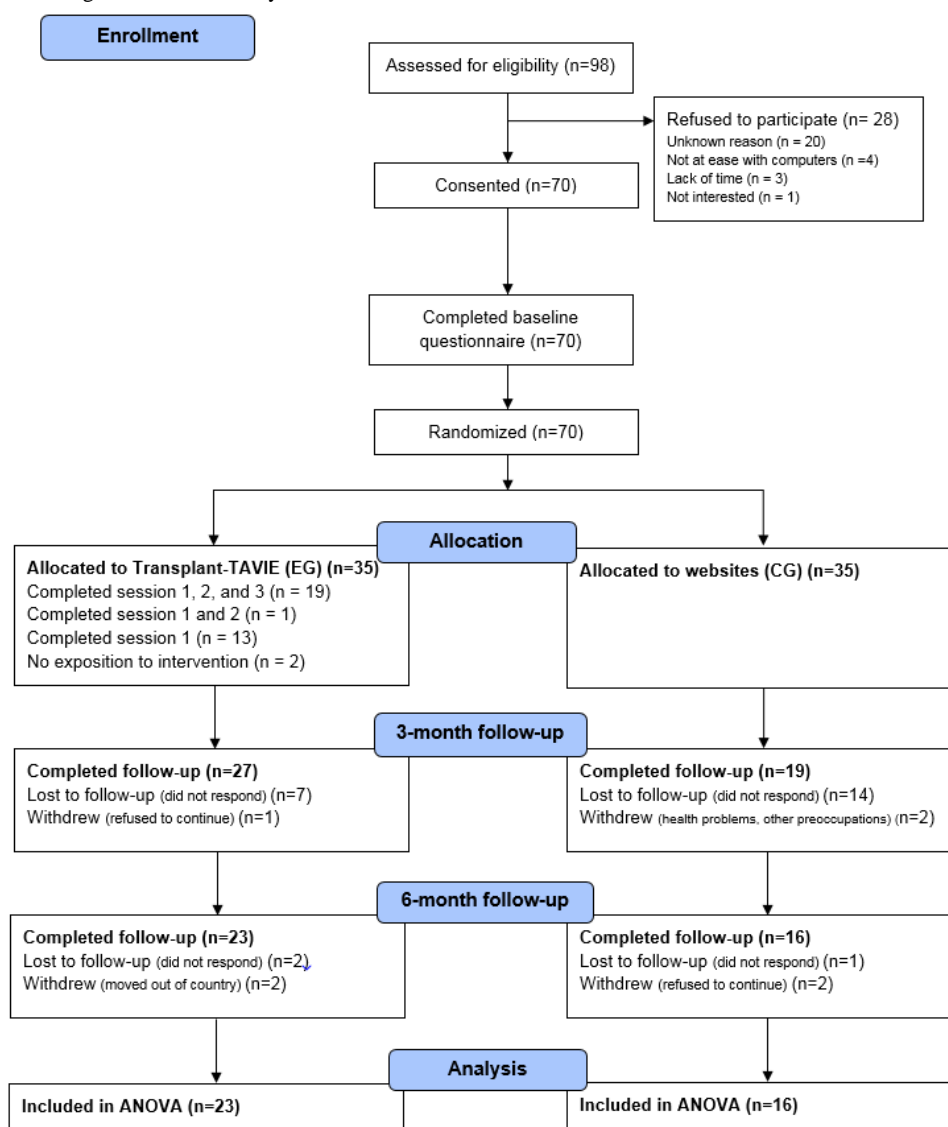


Table 1. Baseline sociodemographics and clinical characteristics.

Variable	<i>Transplant-TAVIE</i> (experimental group, n=35)	Websites (control group, n=35)
Sex, n (%)		
Male	24 (69)	22 (63)
Female	11(31)	13 (37)
Age (years), mean (SD)	54.03 (9.75)	51.37 (11.99)
Ethnic origin, n (%)		
Canadian	29 (83)	27 (77)
Other	6 (17)	8 (23)
Education (n=64), n (%)		
≤High school	7 (22)	9 (28)
>High school	25 (78)	23 (72)
Employment status, n (%)		
Employed	18 (51)	19 (54)
Retired	11 (31)	6 (17)
Unemployed	6 (17)	10 (29)
Income, n (%)		
<Can \$15,000	1 (3)	5 (14)
Can \$15,001-Can \$30,000	3 (9)	6 (17)
Can \$30,001-Can \$50,000	9 (26)	9 (26)
Can \$50,0001-Can \$100,000	11 (31)	7 (20.0)
Other	9 (26)	8 (23)
Living situation, n (%)		
Alone	5 (14)	6 (17)
With partner	18 (51)	22 (63)
With family, friend, roommate	10 (29)	5 (14)
Other	1 (3)	2 (6)
Marital status (n=68), n (%)		
Single	4 (12)	7 (21)
Married or living common law	28 (82)	25 (74)
Divorced or widowed	2 (6)	2 (66)
Kids (n=69), n (%)		
Yes	22 (65)	15 (43)
No	12 (35)	20 (57)
Dialysis before transplantation (n=69), n (%)		
Yes	30 (88)	30 (86)
No	4 (12)	5 (14)
Years since transplantation, mean (SD)	7.6 (7.3)	6.1 (5.4)
Wait time before transplantation (in months), mean (SD)	35 (23)	36 (28)
Type of kidney donor, n (%)		
Living	8 (23)	15 (43)
Deceased	26 (74)	20 (57)

Table 2. Change in the adherence and secondary outcomes by the groups and over time (analysis of variance).

Variable	<i>Transplant-TAVIE</i> (experimental group), mean (SD)			Websites (control group), mean (SD)			Group × Time interaction, <i>F</i> (<i>P</i>)
	Baseline (n=35)	3-month follow-up (n=27)	6-month follow-up (n=23)	Baseline (n=35)	3-month follow-up (n=19)	6-month follow-up (n=16)	
Adherence score ^a	11.4 (1.0)	11.5 (0.8)	11.7 (0.6)	11.6 (0.7)	11.7 (0.7)	11.3 (2.0)	1.65 (.20)
Adherence visual scale ^b	97.1 (4.7)	96.8 (6.4)	98.7 (2.6)	98.3 (3.9)	98.7 (2.9)	98.9 (2.0)	0.45 (.64)
Self-efficacy ^c	1380.7 (60.7)	1397.7 (17.0)	1381.5 (37.9)	1391.4 (21.0)	1390.8 (17.1)	1393.8 (14.4)	1.02 (.37)
Skills ^d	81.3 (14.8)	79.8 (13.5)	78.6 (14.3)	79.0 (11.7)	75.3 (15.3)	77.4 (12.2)	0.94 (.39)
Degree bothered by side effects ^{e,f}	1.1 (1.4)	0.7 (1.0)	0.9 (1.2)	0.9 (1.3)	1.3 (1.2)	1.4 (1.2)	0.85 (.44)
Self-perceived state of health ^g	8.3 (1.1)	8.2 (1.2)	8.2 (1.4)	8.1 (2.0)	8.3 (1.7)	7.9 (2.2)	0.98 (.38)

^aPossible score range: 0-12.

^bPossible score range: 0-100.

^cPossible score range: 0-1400.

^dPossible score range: 0-96.

^ePossible score range: 0-3.

^fAmong those who presented medication side effects.

^gPossible score range: 0-10.

Feasibility: Exposure to Intervention

In the EG, exposure to *Transplant-TAVIE* varied: 54% (19/35) completed all three sessions, 3% (1/35) completed only sessions 1 and 2, and 37% (13/35) completed only session 1. Furthermore, 6% (2/35) participants were not exposed to the intervention.

Preliminary Efficacy of Intervention: Evolution of Adherence and Secondary Outcomes

The adherence scores were high in both the groups and remained stable over time (Table 2). At all three measurement times, both groups reported high self-perceived medication self-efficacy. Data revealed high self-confidence in the ability to take medication in different situations and frequent use of medication-taking skills. However, some participants were experiencing medication side effects and were slightly bothered by them. Most of the participants evaluated their general state of health as good. ANOVAs revealed no statistically significant differences between the groups or over time (Table 2).

Discussion

Principal Findings

The results of the study support the acceptability of the *Transplant-TAVIE* intervention. The EG participants generally appreciated the intervention in terms of the suitability of approach, convenience, ease of understanding, ease of use, and applicability of skills. However, some participants felt that the message from the virtual nurse could be more personalized to their needs. Given that the messages were prerecorded and presented following a pre-established algorithm, this remains a limitation of such an asynchronous intervention.

Regarding the intervention's feasibility (ie, the extent of usage), 54% (19/35) participants completed all three sessions. This is congruent with the findings that emerged from the systematic review by Kelders et al to the effect that only an average of about 50% of participants adhered rigorously to the interventions of the sort [22]. The issue of engagement in Web-based and digital interventions is well documented in the literature [22-24]. In their systematic review of qualitative studies (n=19), O'Connor et al found that four factors affected patient engagement in digital health interventions: personal agency and motivation, priorities and values, contact with the intervention, and quality of the intervention [24]. The engagement in the health behavior is the starting point, and the technology remains a means to achieve this end.

In this study, the participants were already engaged in the behavior of taking medication and sought to achieve or maintain optimal adherence to their drug regimen. They had received their kidney graft many years earlier and had been taking medication since. The two adherence scores were high to begin with. Participants also reported high medication-taking self-efficacy and indicated frequently applying specific skills for the purpose of medication intake. In other words, our patients were already firmly engaged in the target behavior and they already used various strategies and skills in support of this behavior. Moreover, they were highly motivated and optimal medication intake was a priority for them.

The few ICT-based interventions offered in the field of nephrology have been proved highly acceptable to transplant recipients. For example, in a proof-of-concept trial, McGillicuddy et al found that a mobile phone-based remote health monitoring system developed to enhance medication adherence and blood pressure control enjoyed a high degree of acceptance among renal transplant recipients [25]. The added benefits of ICTs have also been documented for adolescents in

terms of acceptability and feasibility [26]. Finally, in a review of mobile health resources in the field of solid organ transplants, Fleming et al documented the use of ICTs across the continuum from the pretransplant phase to the posttransplant phase [27]. However, the evidence amassed to date has been scant.

In a recent RCT conducted among kidney transplant recipients, Reese et al demonstrated that customized reminders, such as telephone calls, texting, and emails, significantly improved medication adherence compared with the usual treatment [28]. The main outcome, adherence, was measured using wireless pill-bottle openings. The researchers concluded that providing notifications and customized reminders showed promise as a measure to help patients improve adherence. As part of this pilot RCT, we aimed to determine the preliminary efficacy of the intervention by comparing the change in adherence scores between the EG and the CG. The results yielded no statistically significant intergroup difference in this regard.

The intervention studies conducted to date have focused on more traditional interventions and have demonstrated that these have a modest effect on medication adherence. In fact, in a meta-analysis of 8 studies involving 546 patients who received intervention through a pharmacist, intervention groups, or continuing education, Zhu et al found that adherence rates and adherence scores were significantly higher for the EG than for the CG [29].

In their systematic review of the literature, Low et al recommended that interventions target new transplant recipients and patients with medication adherence problems [5]. The question we must ask ourselves is who should a Web-based intervention such as *Transplant-TAVIE* target given the lower intensity of this type of intervention relative to support provided face-to-face? Should the target be people already engaged in the desired health behavior who are ready to engage in tech-based support? What about highly motivated individuals beginning treatment? In this regard, *Transplant-TAVIE*, like other interventions of the sort, is seen as adjunctive to the usual face-to-face care.

In addition, it is worth asking whether the intervention can appeal to individuals for whom medication adherence is a real problem, that is, whose suboptimal intake is related to a lack of motivation, shortage of resources, or limited capacity, or for whom the desired health behavior is not a priority. Given that individuals need to be motivated to engage in the health behavior in order to then engage in an eHealth intervention, does this sort of intervention serve the needs of people with real

medication adherence problems? The fact that a Web-based intervention is accessible at all times in no way guarantees that it will be used.

According to Low et al, adherence enhancement efforts should focus on supportive, cost-effective, and multidimensional interventions [5]. Motivated people already under treatment or just beginning treatment are the ones most likely to benefit from ICT-based interventions adjunctive to usual or current care. People who have real difficulty taking medication, instead, would be better served by higher-intensity face-to-face interventions and more sophisticated intervention strategies better suited to reaching, attracting, and mobilizing this client group. Although a hybrid approach incorporating face-to-face and virtual interventions could be an interesting alternative, we recommend giving careful consideration to the opinions and needs of this patient group during the process of developing and implementing interventions [30].

Strengths and Limitations

This study has some limitations. First, the attrition rate was high and more participants were lost to follow-up in the CG than in the EG (19/35, 54% vs 12/35, 34%). Second, as all the data collected were self-reported, social desirability and memory biases might have played a role in people's responses. The results on the acceptability of the intervention reflect the point of view of half of the participants who returned their questionnaire. Finally, patients who accepted to participate in this study were not necessarily representative of the general transplant recipient population; they were highly educated and employed. Many of them were married or living common law; thus, most participants were not isolated. In future, researchers would do well to measure medication adherence more precisely and reliably by means of innovative tools and methods, such as remote wireless electronic monitoring of pill-bottle openings.

Conclusions

Notwithstanding the limitations mentioned, we believe that the *Transplant-TAVIE*, a Web-based tailored nursing intervention, is acceptable and could constitute an accessible adjunct in support of existing specialized services. Further research is needed to determine more clearly the utility of this Web-based intervention for kidney transplant recipients beginning drug treatment. However, given that this treatment is life long, it is important to deploy interventions adapted to the different phases of the medication management continuum in order to support these patients more effectively.

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Conflicts of Interest

Granting of licensing options for marketing VIH-TAVIE.

Editorial Notice

This pilot randomized study was not registered. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials because the risk of bias appears low and the study was considered formative. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness.

Multimedia Appendix 1

CONSORT-EHEALTH checklist (V 1.6.1).

[\[PDF File \(Adobe PDF File\), 110KB - formative_v2i2e14_app1.pdf\]](#)

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Abbreviations

ANOVA: analysis of variance

CG: control group

CHUM: Centre Hospitalier de l'Université de Montréal

CONSORT: Consolidated Standards of Reporting Trials

EG: experimental group

ICT: information and communication technologies

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Original Paper

Utilizing a Prototype Patient-Controlled Electronic Health Record in Germany: Qualitative Analysis of User-Reported Perceptions and Perspectives

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Abstract

Background: Personal electronic health records (PHR) are considered instrumental in improving health care quality and efficiency, enhancing communication between all parties involved and strengthening the patient's role. Technical architectures, data privacy, and applicability issues have been discussed for many years. Nevertheless, nationwide implementation of a PHR is still pending in Germany despite legal regulations provided by the eHealth Act passed in 2015. Within the information technology for patient-oriented care project funded by the Federal Ministry of Education and Research (2012-2017), a Web-based personal electronic health record prototype (PEPA) was developed enabling patient-controlled information exchange across different care settings. Gastrointestinal cancer patients and general practitioners utilized PEPA during a 3-month trial period. Both patients and physicians authorized by them could view PEPA content online and upload or download files.

Objective: This paper aims to outline findings of the posttrial qualitative study carried out to evaluate user-reported experiences, perceptions, and perspectives, focusing on their interpretation of PEPA beyond technical usability and views on a future nationwide implementation.

Methods: Data were collected through semistructured guide-based interviews with 11 patients and 3 physicians (N=14). Participants were asked to share experiences, views of perceived implications, and perspectives towards nationwide implementation. Further data were generated through free-text fields in a subsequent study-specific patient questionnaire and researcher's notes. Data were pseudonymized, audiotaped, and transcribed verbatim. Content analysis was performed through the Framework Analysis approach. All qualitative data were systemized by using MAXQDA Analytics PRO 12 (Rel.12.3.1). Additionally, participant characteristics were analyzed descriptively using IBM SPSS Statistics Version 24.

Results: Users interpreted PEPA as a central medium containing digital chronological health-related documentation that simplifies information sharing across care settings. While patients consider the implementation of PEPA in Germany in the near future, physicians are more hesitant. Both groups believe in PEPA's concept, but share awareness of concerns about data privacy and older or impaired people's abilities to manage online records. Patients perceive benefits for involvement in treatment processes and continuity of care but worry about financing and the implementation of functionally reduced versions. Physicians consider integration into primary systems critical for interoperability but anticipate technical challenges, as well as resistance from older patients and colleagues. They omit clear positioning regarding PEPA's potential incremental value for health care organizations or the provider-patient relationship.

Conclusions: Digitalization in German health care will continue to bring change, both organizational and in the physician-patient relationship. Patients endorse and expect a nationwide PEPA implementation, anticipating various benefits. Decision makers and providers need to contribute to closing modernization gaps by committing to new concepts and by invigorating transformed roles.

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KEYWORDS

personal patient-controlled electronic health record; eHealth; nationwide implementation; continuity of care

Introduction

Personal electronic health records (PHR) and patient access to them have been discussed for quite some time. Since Shenkin and Warner [1] proposed that patients should have complete access to their medical records in 1973, supporting arguments have been confirmed in multiple studies and stand unaltered. This has led to (1) improved doctor-patient communication, (2) patient empowerment and education, (3) increased understanding of treatment plans, and (4) therapy adherence [2-5].

German law entitles patients to review their medical records and request paper or electronic copies of documents detailing their care processes [6]. However, there is no structured exchange of information beyond the doctor's written reports [7] and the majority of health documentation is retained by the treating physician or hospital. While few primary care practices still use paper records, others have long since introduced electronic systems for documentation and administrative purposes. These primary systems contain patient records that are often inaccessible and lacking in health history documentation control. Information exchange between health care providers is often done by mail or fax, and sometimes even by the patients themselves or family members [7].

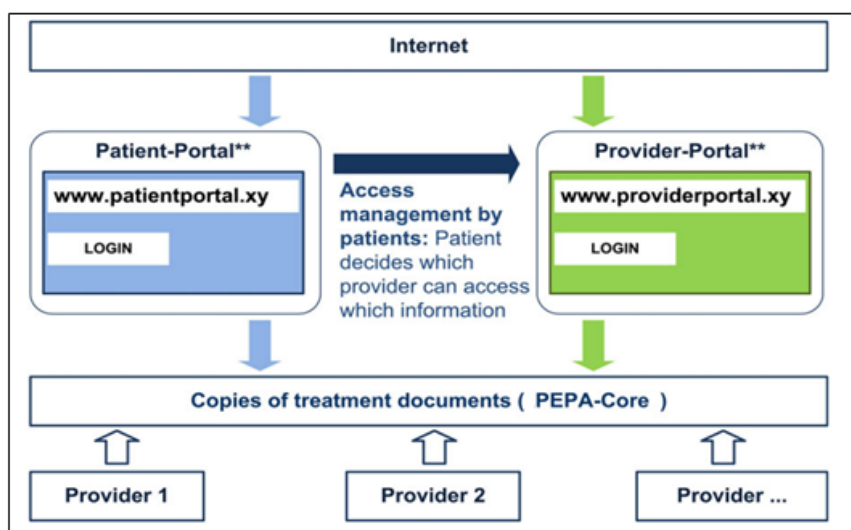
In December 2015, the passing of the Act for Secure Digital Communication and Applications in the Health Sector (eHealth Act) [8,9] laid the legal groundwork for an electronic exchange of health-related documentation for all patients in Germany. This law promotes the entry point for a PHR since prerequisites for a secure digital infrastructure now are due to be in place by

the end of 2018. From then on, digital patient-related data like physician reports, emergency, and medication information can be made available in a PHR, enabling patients to access their data and inform providers about their medical history [9]. However, the type of record has yet to be determined.

The Web-based personal electronic health record prototype (PEPA) developed within information technology for patient-oriented care (INFOPAT) differs from institution-related solutions moderated by health care personnel. Based on previously determined and integrated user requirements [10,11] and explored perceived benefits and concerns [12], its unique user-centered design facilitates a patient-controlled Web-based exchange of information across different care settings and providers (Figure 1 adapted from [13]). It understands patients as active participants in the care process [13] and enables them to manage which providers can access their medical documentation.

PEPA's concept comprises a patient portal as well as a professional portal. For a 3-month trial period, PEPA was implemented into a real-world regional care setting to be utilized by gastrointestinal cancer patients and general practitioners (GPs), with the outpatient clinic at the National Center for Tumor Diseases (NCT) being involved as a cancer treatment facility. Patients and their authorized physicians could view PEPA content online and perform uploads and downloads of files, including doctor's reports, laboratory, and imaging results. Sharing information and communication between all involved has been identified to be among the specific challenges of care delivery to this particular patient collective [14].

Figure 1. The PEPA concept [13].



Previous studies focused on recurring themes of data privacy, functionality, expectations or identifying barriers to adopting electronic solutions [12,15-17]. The purpose of this posttrial qualitative study was to look beyond the factors mentioned above to better understand user-reported experiences which are integral to efforts of refinement. To answer the question which insights could be gained from utilizing the prototype, the reported overall experiences were evaluated with a focus on users' interpretations of PEPA, perceived implications, and views on a potential future nationwide implementation.

Methods

Overview

Following the technical development of PEPA, the prototype was exclusively implemented into a real-world regional health care setting. After receiving tailored training, enrolled participants used the patient portal to upload and download personal health documentation, access linked certified educational information, and authorize others to add, and view content. Participating health care providers could use the professional portal to upload medical documentation related to the respective patient and read files if patients had granted access. All users could access and utilize the portals until the prototype was discontinued at the end of November 2016. The study was approved by the Ethics Committee of the University of Heidelberg (S-462-2015). Participants all gave written informed consent. Confidentiality and anonymity were ensured throughout the study.

Study Design

As defined by the study protocol [13], a posttrial qualitative study was conducted to evaluate user-reported experiences and perceptions, using semistructured guide-based interviews with 11 gastrointestinal cancer patients, and 3 physicians. To ensure a broad perspective, the interview guide was developed by an interprofessional team of researchers (social scientists, physician, health scientist). It was designed to explore participants' interpretations of PEPA, how and whether involvement in care was affected, behavioral and emotional experiences resulting from utilizing PEPA, assessment of training and support, and to gain insights into their perspectives regarding a future nationwide implementation. Also, participants were required to fill in a survey after the interview at the end of the trial period and return it by mail.

Sampling and Recruitment

No formal sample size was calculated. Between July 25 and August 25, 2016, a random sample of 17 gastrointestinal cancer patients was recruited through NCT and the INFOPAT study team (Department of General Practice and Health Services Research, University Hospital Heidelberg). Potential participants had to be in ongoing therapy at NCT with a diagnosis of colorectal cancer (ie, C18, C19, or C20), or other gastrointestinal tumor diseases (ie, C16, C23.9, C24.0, C24.1), be at least 18 years old, and legally fully competent. Other prerequisites were a fluent command of German, access to a computer with internet

connection, and participation in the study-specific training. Patients with severe acute psychiatric disorders, dementia, and behavioral or psychological disorders after consuming psychoactive substances were excluded. Since the sample consisted of gastrointestinal cancer patients—some with a limited diagnosis—recruitment followed a structured screening procedure conducted by an oncologist and included a thorough assessment of the patients' condition and status prior and during recruitment efforts as well as their confirmed interest in participating [13]. Only the 17 patients who met all defined criteria in the recruitment month were included in the study, received printed material, and were provided with additional information over the phone.

Following the individual training sessions, all 17 patients were asked if they thought their GP would like to join the study and could be approached by the study team. Pursuing a purposive sampling strategy, recruitment letters were mailed to 15 GP practices, supplemented by detailed background information. Follow-up calls outlined study goals and procedures, the 3-month-long trial phase and PEPA's concept (Figure 1). Five GPs expressed interest, but 2 had to be excluded due to technical challenges. Three GPs were recruited. Two were trained and used PEPA's professional portal during the trial phase. The third GP did not receive training as the patient no longer required treatment at NCT at the time of the scheduled session. Identified challenges that led to the small number of participating GPs will be reported separately.

A total of 13 patients filled in the posttrial survey which was designed as a composite of German versions of validated measurement instruments (see Table 1, adapted from [13]) and gave room for free text. Based on their condition or passing away during the trial period, 6 patients could not be interviewed and were lost to the sample. No substitute patients could be recruited. Eleven patients (5 male, 6 female) utilized PEPA and participated in the interview and the posttrial survey. They ranged in age from 27 to 64 years. The physician age ranged from 29 to 58 and all 3 were female. All participants gave written informed consent for the study and audio recording of the interview and received a small reimbursement for their participation.

Data Collection and Analysis

Table 2 summarizes the data collection sources. All interviews were conducted and audio recorded between November 2016 and January 2017 by researchers of the study team. Patient interview duration ranged from 37-82 minutes, with a mean of 50 minutes. Physician interviews lasted between 30-42 minutes, with a mean of 36 minutes. To accommodate a patient's request, a spouse was present during 1 interview. All patient interviews and the first physician interview were conducted face-to-face at the Department of General Practice and Health Services Research of the University Hospital Heidelberg. The second physician interview was performed over the telephone. The third took place at the GPs practice. Additional notes were taken during and after 5 interviews.

Table 1. Compilation of the posttrial survey.

Outcome parameter	Outcome measurement instrument	# of items
Patient self-efficacy	Cancer Behavior Inventory Brief German Version [18,19]	14
Involvement in care	Perceived Involvement in Care Scale [20,21]	13
Psychosocial distress	Distress Management Thermometer [22,23]	1
Control preferences	Control Preferences Scale [24]	5
Usability of PEPA prototype	System Usability Scale [25,26]	10
Utilization of medical services	Mannheimer Module Resource Consumption ^a	30

^aNot published.

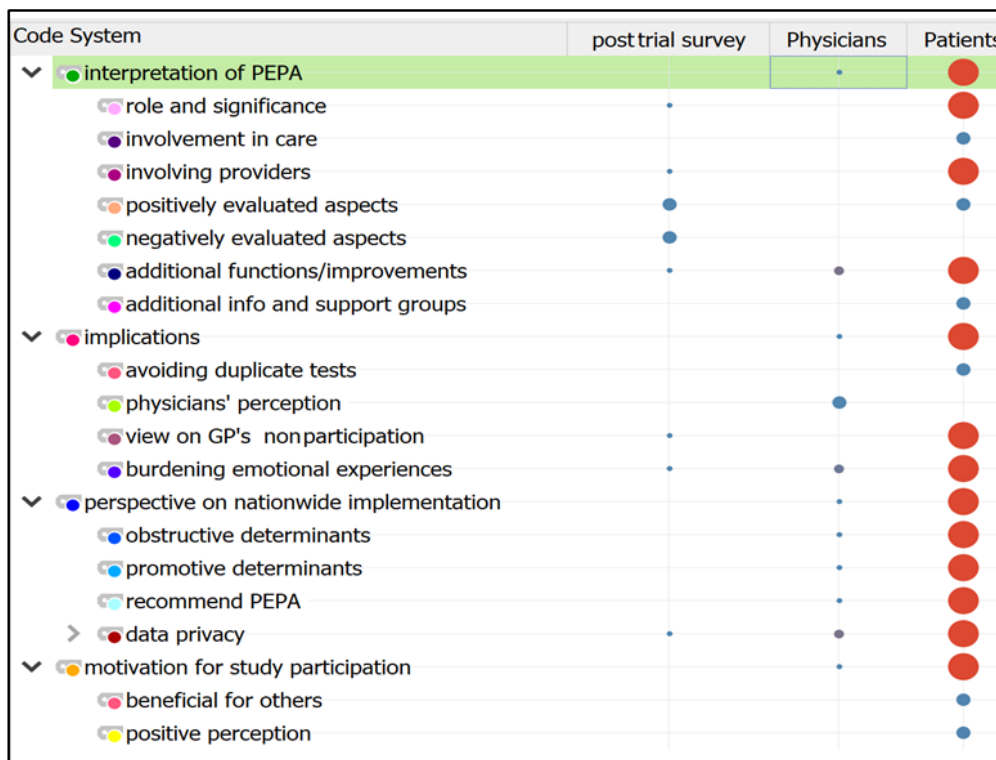
Table 2. Source of data collection for this study (N=14).

Source of data collection	Patients	Physicians	Description of data source
Number of interviews conducted, n (%)	11 (78)	3 (22)	Face-to face and telephone interviews
Interview duration (minutes), mean (range)	50 (37-82)	36 (30-42)	Audio files and transcripts
Surveys conducted, n (%)	11 (100)	—	Free text, after interview and participant characteristics
Researcher's notes, n (%)	1 (20)	4 (80)	Notes taken during and after interviews

Table 3. Translated interview guide used to conduct the qualitative interviews with patients and physicians.

Question or stimulus	Addressed to:	
	Patient	Physician
Relate your experience of utilizing PEPA to its significance for you regarding:		
Your medical condition	Yes	—
The provider-patient-relationship	—	Yes
Talk about how and how often you used PEPA	Yes	Yes
What has been positive or negative from your perspective?	Yes	Yes
Tell us about changes you registered during your use of PEPA with regards to:		
Disease-specific knowledge and health literacy	Yes	—
Provider-patient dialogue and general communication	Yes	Yes
Being involved in care processes	Yes	—
In hindsight, what can you tell about the training session and support?	Yes	Yes
Did you experience any distress or anxiousness related to using PEPA?	Yes	—
Did you experience any distress or difficulties using PEPA?	—	Yes
Thought experiment: Which aspects should a friend consider if given the chance to utilize PEPA? Which advice would you provide?	Yes	—
Which chances or obstacles do you see for intersectoral collaboration?	—	Yes
What is your perspective on a nationwide PEPA implementation regarding:		
Potential users, additional functionality, chances, and obstacles?	Yes	Yes
Integration into existing care process?	Yes	Yes
Appropriate support activities?	—	Yes
What would you like to tell us besides already discussed topics?	Yes	Yes
What was your motivation for participation in the study?	Yes	Yes

Figure 2. The thematic analysis framework reflected by the code system matrix. GP: general practitioner.



After data collection was completed, verbatim transcripts were coded using the matrix-based method of Framework Analysis [27-29] which is seen as an appropriate content analysis approach in a study with predetermined research questions [30]. Themes of interest were identified deductively a priori from the interview guide (Table 3) as well as inductively de novo from the data during the analysis. Transcripts, researchers' additional notes, and free texts and comments given in the survey were coded iteratively using MAXQDA Analytics PRO 12 (Release 12.3.1). To enable a broader view, participant characteristics and selected items of the post-trial survey data were analyzed descriptively by using IBM SPSS Statistics Version 24.

Adequate methodological strategies were followed to ensure the trustworthiness of the analysis and findings. These include seeking out similarities and differences across and within accounts to ensure different perspectives are represented, as well as engaging with other researchers to minimize research bias, thus reducing the risk of losing relevant content.

Charting participant views concerning identified themes enabled comparisons within and across interviews [30] thus enhancing the transparency of the analysis [29]. The code system matrix reflects the thematic framework for the analysis (Figure 2). Here the symbol size indicates the proportional distribution of themes in the 3 document groups.

Results

Overview

The primary results outlined broadly reflect the thematic spectrum of PEPA user experiences (Figure 3). Participant characteristics provide further indication referring to user

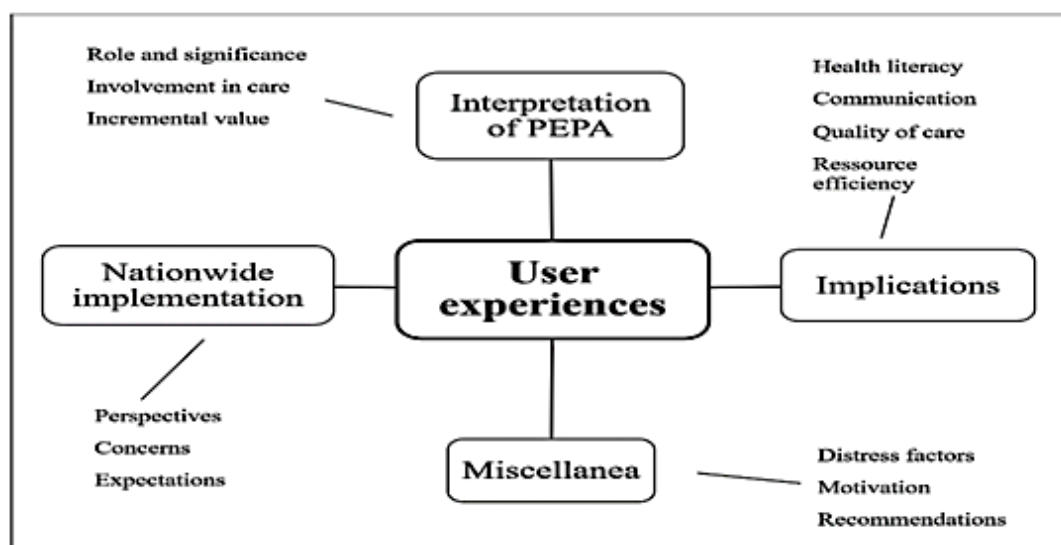
perceptions (Table 4). Findings are presented in categories, subcategories, and key aspects and are differentiated by user group where applicable (Table 5). Quotes extracted from the data and cited here were translated into English with due diligence.

User's Interpretation of the Web - Based Personal Electronic Health Record and its Role

Some thematic aspects were common to all 11 participating patients. PEPA was interpreted as a well-functioning administrative documentation system and regularly utilized to follow up on care processes. A frequently described benefit was keeping the chronological health-related digital documentation in a central, easily accessible medium that facilitates and simplifies data sharing across care settings. Emphasis was also put on the importance of the prompt availability of documentation which could make paper documentation obsolete.

The advantage is, I think, to have everything consolidated, I don't have to search for everything and ask for MRI images somewhere or a doctor's report, but I have a chronological history where I have instant access and, in this respect, I think it would be an asset for doctors as well. [Patient #21, male]

A few patients were skeptical of system maintenance reliability, and therefore 2/11 (18%) still asked for paper copies of documents to maintain their paper files. Focusing on future needs, 4 (36%) patients developed a problem-oriented strategy and produced electronic copies to keep on their electronic storage devices or even turned to a different cloud solution for file sharing during the trial phase.

Figure 3. Overview of identified principal results of user experiences.**Table 4.** Outline of the participant characteristics (N=14).

Characteristics	Patients (n=11)	Physicians (n=3)
Participant disease or physician specialty	Gastrointestinal cancer	General practitioner, oncologist
Gender, n (%)		
Female	6 (55)	3 (100)
Male	5 (45)	—
Age (years), range	27-64	29-58
Age (years), mean		
Female	47 (10.9)	42 (11.9)
Male	57 (5.0)	—
Frequent internet user, n (%)	9 (85)	—
Internet connection at home only, n (%)	4 (36)	—
Mobile and at home, n (%)	7 (64)	—
Researching health topics on internet, n (%)	8 (73)	—
Confident when using PEPA, n (%)	10 (91)	—
Classified PEPA as easy to use, n (%)	9 (82)	—
Need expert support to use PEPA, n (%)	1 (9)	—

All 3 participating physicians rated PEPA positively and reported having used the system mainly to upload and share lab results or to look for new reports. They interpreted PEPA as a structured well-functioning documentation medium with the potential of improving communication between health care providers and patients as well as across different care settings.

Resembling patients' views, both GPs attributed an incremental value to having fast access to structured information essential during the care process. Physicians also addressed the importance of provider-patient dialog.

What gets the patient ready for therapy preparation certainly is the dialog with the treating physician.
[Physician #15, female]

Involvement in Care

Utilizing PEPA, patients felt more involved in care processes and expressed their hope for a more wholesome view of the patient via an extensively functioning PEPA. However, 5 (45%) patients stated disappointment about their GP not participating in the study and saw this as a break in the continuity of care. They speculated about potential reasons, expressed understanding, or saw missed opportunities for change and felt deprived of a very important user of the system.

Table 5. Overview of findings regarding patient and physician experiences and perspectives.

Category and aspect of the experience	User group
Interpretation	
Role and significance	
PEPA facilitates central documentation	Patients, physicians
Easy access and sharing	Patients, physicians
Makes paper obsolete	Patients, physicians
Improving communication	Physicians
Involvement in care	
Patient takes control	Patients
More involved	Patients
Hope for wholesome view	Patients
Provider-patient dialog	Physicians
Incremental value	
Fast access to structured data	Patients, physicians
Implications	
Health literacy	
Engaging with documentation	Patients
Preparation and follow-up	Patients
Potential promoting factor	Patients
Communication	
Face-to-face important	Patients
Faster communication	Patients, physicians
Resource efficiency	
Reduction of expenditures	Patients
Economy of time	Physicians
Quality of care	
Transparency of documentation	Physicians
Patient safety	Physicians
Optimization of care processes	Patients, physicians
Implementation	
Perspectives	
Implementation realistic	Patients
Life-long usage	Patients
Concerns	
Presumed non-acceptance	Patients, physicians
Data privacy	Patients, physicians
Functionally reduced systems	Patients, physicians
Expectations	
Obligatory for general practitioners	Patients
Integration into primary system	Physicians
Misuse improbable	Patients, physicians
Miscellanea	
Distress factors	

Category and aspect of the experience	User group
Emotional distress excluded	Patients
Influence of individual factors	Patients, physicians
Provider-patient dialog important	Patients, physicians
Keep personal notes inaccessible	Physicians
Recommendations	
Careful access authorization	Patients
Advice to use PEPA	Patients, physicians
Motivation	
Intent to contribute to research	Patients, physicians
Help others through input	Patients, physicians
Learning opportunity	Physicians
Varying perceptions of own role	Patients, physicians

One (9%) patient reported the GP was not involved in the cancer care at all.

Let's say, as a patient one would take over a little more control. ...I think you tend to inform yourself more thoroughly, perhaps. [Patient #21, male]

My GP simply could have uploaded my lab results into the PEPA portal for NCT to look at them the day of my chemo. He didn't do it, so he had to send them by fax. [Patient #27, female]

Implications of Utilizing the Web - Based Personal Electronic Health Record

With regards to dealing with their illness, 6 (55%) patients generally did not attribute strong significance to PEPA or perceive a difference to receiving paper documentation. After being confronted with the illness for quite some time already, they felt empowered by disease-specific knowledge and confident to objectively classify the report content. However, they reported that utilizing PEPA made engaging with health documentation easier, considered it valuable for preparation and follow-up of appointments, and saw the potential for health literacy aspects.

I don't believe utilizing PEPA will lead to somehow increased literacy, just by using it, but it could be developed into this direction. [Patient #06, male]

Nearly half (5/11, 45%) of the patients addressed communication aspects and the provider-patient relationship by pointing out the importance of having a face-to-face conversation with their physician about their status or new findings before reports would be uploaded into PEPA. Also, they voiced the expectation for physicians to take the time and go over digitally provided information before a meeting to enhance its' quality. Other perceived implications were the potential of resource-efficient avoidance of duplicate tests thus reducing expenditures for 2 (18%) patients and connecting further providers including hospitals, rehabilitation clinics, and medical specialists to improve care processes overall for 3 (27%) patients.

Certainly, I expect that we can have a more efficient conversation after providing information ahead of the appointment, rather than handing over a paper document to the doctor who starts reading and I start explaining what I actually understood. [Patient #06, male]

Physicians saw positive implications for cross-sectoral care with regards to the possibility of faster communication between all parties involved, the economy of time in case of emergency or locum care, and second opinion cases. Besides the implied optimization potential for care processes and patient safety, utilizing PEPA was also considered to be an incentive to increase the transparency of documentation. With regards to aspects of health literacy, PEPA was not viewed as a promoting factor.

I don't think patients who don't have a medical background would have a better preparation for their treatment. My opinion. [Physician #15, female]

Nationwide Implementation

The majority (8/11, 73%) of the interviewed patients considered a PEPA implementation in Germany to be realistic in the near future. While some favored voluntary use, other patients (5/11, 45%) envisioned a lifelong use for the general population starting with the date of birth and covered by adequate legal regulation.

A more pessimistic view was shared when skepticism about the intent to implement was voiced by 3 (27%) patients or when obstacles for an implementation process within 5 to 10 years were anticipated by 2 of the 3 (67%) physicians. Concerns were general skepticism and presumed non-acceptance, data security, and privacy advocates, financing of the system, and missing IT infrastructure on the provider level.

Although both user groups anticipated data privacy concerns, they did not report having any themselves. They assumed data security comparable to online banking and misuse highly improbable. Expressing disbelief in the impact of their contribution, interviewees were concerned about a potential implementation of functionally reduced systems or multiple

diverse systems. Patients only contemplated possible ways of financing PEPA.

I don't see a pure on-top financing, but it would have to be through passing along incurred savings from physicians and health insurers. [Patient #06, male]

Patients and physicians shared perspectives on old or impaired people's abilities and willingness to manage online records. The lack of necessary skills or general interest and older age were assumed to be restricting factors among 6 (55%) of the patients and all 3 providers alike. Implementing a proxy regulation to remedy such circumstances was suggested by 2 (67%) of the physicians.

...very old people and people living in care facilities, or impaired people, certainly there would be someone else managing it for them, that's a totally different thing. [Patient #05, female]

Anticipating potential improvements for care processes for patients as well as for providers, the expectation was phrased that a nationwide implementation would make the use of a PEPA system obligatory for GPs. The physicians saw potential with regards to inter-provider communication or second opinion cases, but anticipated patients' concerns about transparency, resistance from older colleagues and technical challenges where digital documentation is not used yet. Both groups of users considered integration into primary systems critical for interoperability.

It was an extra step. I had to leave my primary system and enter the internet. The software is good, but it was an extra step for me. I would integrate it otherwise it is not reasonable. [Physician #03, female]

Miscellanea

Users did not report burdening, uncomfortable emotional experiences referring to utilizing PEPA. Patients excluded emotional distress caused by PEPA content as they deemed a difference to paper documentation unlikely. However, they had clear ideas for scenarios in which distress could occur. Three (27%) of the patients considered a high volume of documentation being uploaded within a short period as a potentially stressful situation. Patients also weighed in on the influence of individual factors like age, reluctance to system changes or being less computer-savvy in general. While both groups of users again stressed the importance of provider-patient dialog to minimize potential emotional distress, 1 (33%) physician also saw a need to keep doctors' notes inaccessible to patients in cases where those are essential for the treatment but meant to stay invisible to the patient. This view was shared by 1 (9%) patient.

In a thought experiment, interviewees were asked for their advice to a friend or family member who hypothetically would be offered a chance to use PEPA. All gave positive feedback and stated they could only recommend it. Five (45%) of the patients would advise careful consideration of provider access authorization and were aware of potential computer literacy and transparency concerns. Physicians would not advise against utilizing PEPA and see it as a solution to centrally available documentation. Again, they anticipated the citing of data privacy

and security concerns. A clear positioning regarding a potential incremental value for patients, care processes or institutions was not provided.

The predominant motive for study participation of all interviewees was the intent to contribute to research progress and help others by providing feedback. Patients also ascribed their decision to participate to personal attitude, belief in the system, professional background, and personal interest. Physicians saw an opportunity to learn about a new development and to participate for the patient's or the university's benefit and felt motivated by their patient. Participants had varying perceptions about PEPA's concept and their role during the trial period, broadly ranging from simple system tester to valuable study participant. However, all participants provided detailed insights into their experiences, interpretations, and perspectives referring to PEPA.

Discussion

Principal Results

This study evaluated reported experiences to understand which insights could be gained from utilizing PEPA. Supporting previous findings [3,31,32], results show that patients recognized benefits and felt enabled to participate more actively in their care. One of PEPA's values was seen in the prompt sharing of digitally available documentation. Since accessing and engaging with documentation was simplified, PEPA functioned as a starting point for preparation and follow-up of appointments and related research. Patients added and read the documentation at their convenience, allowing them to view, review and contemplate content and its' meaning before asking for additional explanations. This more active role implicated expectations for a transformed physician-patient interaction and care delivery. Naturally, patients felt that PEPA's value was diminished where GPs chose not to participate.

Although the benefits of a central chronological documentation system were apparent to physicians, they did not use it to follow-up on patient history and mainly contributed by collecting and sharing data. Given the situation of working closely with a cancer patient they knew well, history details possibly were of lesser importance than they might have been with a different patient collective and outside of the study context. Physicians acknowledged the system's potential to provide important information in emergency situations, locum care, and second opinion cases and to improve cross-sectoral communication. Nevertheless, they omitted a positioning regarding an incremental value for the physician-patient relationship or their health care organization. This reflects in postulating the integration into primary documentation systems as being crucial for interoperability and willingness to adopt PEPA.

All participating patients endorse implementing PEPA into standard care on a national level where availability of its various benefits is pending. They expect physicians to see the chances, not just obstacles and join modernization efforts thus fostering more effective, satisfying and genuinely collaborative care. Though they had diverse self-concepts or even doubts regarding

their role and impact as study participants, all of them provided valuable input and shared the desire to purposefully contribute to research progress for the future benefit of others. This conveys the significance of including patients' views and experiences in research projects.

Despite a thorough investigation and integration of user requirements [10,11], and exploration of challenges for cancer care coordination (14), utilizing PEPA was not an easy, self-explanatory concept for all participants. Depending on individual aptitudes and skills, deficits in understanding e-technology and PEPA's functional concept became apparent. Though a longer usage period may contribute to a better understanding, a nationwide implementation would likely encounter similar circumstances to be addressed, both at the outset and continuously.

Both user groups anticipated concerns about data privacy but did not cite any themselves. While the concerns presumably recede into the background when people are confronted with severe illness and focus on optimized continuity of their care, a nationwide implementation most likely would encounter them. For the benefit of future users and a successful PEPA adoption, it appears advisable to address concerns and skills deficits in explanatory, educational efforts.

While patients see transparency as significant for the continuity of cross-sectoral care, physicians presume a lack of readiness among their colleagues. This points to a potential obstacle for health service modernization efforts inherent in current role concepts. However, to unfold its' full potential and become a systemwide feature, PEPA's socially challenging concept requires all parties involved to see its' value and address a changing provider-patient relationship and transformed roles. A strategy of passively awaiting a change in traditional role concepts presumably will not suffice.

Comparison to Previous Work

The findings in this study are supported by prior research showing patient empowerment effects through full health record access [33], patient benefits deriving from using a patient-controlled PHR [34], reservations regarding data privacy and the significance of the provider-patient relationship [35]. It demonstrates that patients with severe illness can utilize PEPA and manage their health documentation without experiencing related distress, provided constructive physician-patient

communication is maintained. It can be assumed that further patient collectives would acknowledge the benefits and use of PEPA without distress as well. Nevertheless, concerns for older and impaired persons and corresponding support strategies are to be addressed by relevant politically responsible institutions.

Strengths and Limitations

After implementing the prototype into a real-world care setting, exploring user experiences and perspectives was essential to understand potentially influential connotations regarding a future nationwide implementation and adequate refinements and went beyond an outcome-focused evaluation. To minimize research bias and to reduce the risk of losing relevant content, the analysis was guided by adequate methodological strategies. To indicate the typicality of observations, simple counts have been included where their support of the analysis can be expected and to meet potential notions of anecdotalism and exoticism, thus contributing to transparency.

However, some limitations must be declared for participant recruitment. PEPA was implemented for gastrointestinal cancer patients and their physicians for 3 months. The sample resulted from clinical practice and potentially was subject to selection bias. There was no control group for comparisons. Since the sample size was solely based on matters of feasibility, this resulted in a number of patients meeting the inclusion criteria which was too small to form a control group. Participants lost to the sample could not be substituted. A higher number of participants could have provided more diverse results. Though structural variance was given through age and sex, the small number of participants and short implementation period require cautious interpretation of all findings.

Conclusions

Health care providers and patients alike can benefit substantially from ongoing digitalization efforts in the organization of German health care services. New skills will be needed on both sides to design and invigorate modern care processes and transformed roles. Decision makers and providers need to position themselves clearly and contribute towards closing modernization gaps. Committing to new concepts such as PEPA will be essential, and physicians need to sign on to them to make a nationwide implementation and utilization possible in the near future.

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Conflicts of Interest

None declared.

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Abbreviations

GP: general practitioner

INFOPAT: information technology for patient-oriented care

NCT: National Center for Tumor Diseases

PHR: personal electronic health record

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Original Paper

Game Plan: Development of a Web App Designed to Help Men Who Have Sex With Men Reduce Their HIV Risk and Alcohol Use

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Abstract

Background: Men who have sex with men (MSM) are at high risk for HIV, and alcohol use is a major risk factor for HIV infection. Internet-facilitated brief interventions have been shown to reduce alcohol use and HIV-risk behavior in other at-risk populations, but have so far incorporated limited content and have not been tested among MSM.

Objective: This manuscript describes Game Plan, an interactive, tablet-optimized web application designed to help heavy drinking, high-risk MSM consider reducing their alcohol use and sexual risk behavior. In this paper, we discuss the rationale, goals, and flow for each of Game Plan's components, which were modelled after common in-person and web-based brief motivational interventions for these behaviors.

Methods: The development of Game Plan was informed by a thorough user-focused design research process that included (1) audits of existing interventions, (2) focus groups with stakeholders and (3) intended users (high-risk, heavy drinking MSM), and (4) usability testing. The aesthetic, features, and content of the app were designed iteratively throughout this process

Results: The fully-functional Game Plan app provides (1) specific and personal feedback to users about their level of risk, (2) exercises to help prompt users to reflect on whether their current behavior aligns with other important life goals and values, and for those open to change, (3) exercises to help users understand factors that contribute to risk, and (4) a change planning module. In general, this flow was constructed to roughly align with the two phases described in early accounts of motivational interviewing (MI): (1) Content intended to elicit intrinsic motivation for change, and when/if sufficient motivation is present, (2) content intended to translate that motivation into specific goals and plans for change. This sequence first focuses on the user's HIV risk behavior, followed by their alcohol use and the connection between the two. The app's overall aesthetic (eg, branding, color palettes, icons/graphics) and its onboarding sequence was also designed to align with the "spirit" of MI by conveying respect for autonomy, open-mindedness (ie, avoiding judgment), and empathy.

Conclusions: Should future research support its efficacy in facilitating behavior change, Game Plan could represent a wide-reaching and scalable tool that is well-suited for use in settings where delivering evidence-based, in-person interventions would be difficult or cost-prohibitive.

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KEYWORDS

alcohol; HIV risk; internet; intervention

Introduction

Background

In the United States, new HIV infections have declined among most at-risk groups in recent years but remain stable among men who have sex with men (MSM) [1,2]. As a result, MSM account for an ever-increasing percentage of all new infections, at nearly 67% in 2015 [3]. Alcohol use is a major risk factor for HIV infection, both among MSM and in other risk groups [4,5], and evidence suggests that this may be due in part to alcohol's role in increasing the likelihood of engaging in sex that could transmit HIV. Specifically, event-level studies show that MSM are much more likely to engage in anal sex without protection after consuming 5 or more drinks on a given occasion [6,7]. This level of drinking is widespread among MSM. Nationally representative surveys suggest that 20.4% to 50.4% of young MSM drank at this level at least once in the last month [8,9]. Together, these studies suggest that exploring ways to reduce the spread of HIV among MSM is a critical and urgent public health priority [10,11] and that addressing alcohol use among these men may be a key target in this effort.

Brief Motivational Interventions Can Change Alcohol Use and HIV Risk Behavior

Meta-analyses have shown that brief (30- to 60-minute) face-to-face interventions for alcohol use can help recipients reduce their drinking and these brief interventions are often as effective as longer and more extensive ones [12-14]. In particular, brief interventions that are inspired by the principles of motivational interviewing (MI) and use similar techniques (or brief motivational interventions [BMIs]) have received some of the most robust empirical support [12,15,16]. These interventions typically involve a handful of essential elements including feedback about recipients' personal risk, emphasizing personal responsibility for change, providing a menu of change options, and enhancing self-efficacy for change, all of which should be conveyed with empathy [13]. BMIs have been shown to reduce heavy drinking and alcohol-related harms across a variety of key populations, including college students, treatment-seeking adults, and non-treatment-seeking adults [12,14,17]. Several recent studies have also shown greater reductions in alcohol use among heavy drinkers in HIV primary care settings who received a BMI compared with brief education and advice [18,19].

MI-inspired interventions (both brief and longer versions) focusing specifically on HIV risk behavior have also been shown to reduce these behaviors in a number of populations, including heterosexual HIV-negative and HIV-positive young adults [20,21], racial minority MSM [22], and people living with HIV in international settings [23]. Monti and colleagues [24] recently showed that a dual-behavior BMI reduced heavy drinking and condomless sex among heterosexual male and female emergency department patients compared with brief advice over 9 months of follow-up. Together, these results demonstrate that BMIs can help at-risk individuals change their alcohol use and sexual risk behavior and suggest that addressing both could provide additional benefit. However, to date, use of BMIs in many medical settings has been limited, perhaps because of high cost

and resources needed to implement them. Delivering a similar intervention over the internet could ultimately provide a more scalable solution that is more likely to reach those at high risk in these settings, and therefore, could ultimately have a greater impact on public health.

Brief Interventions Delivered Over the Internet Can Help Change Alcohol Use and HIV Risk Behavior

Given their brevity, BMIs have frequently been adapted for digital and Web-based delivery using a self-guided format [25]. Meta-analyses similarly support the efficacy of these Web-based BMIs for reducing alcohol use and related outcomes across a variety of settings and populations [26-28], with some evidence suggesting that they may be particularly successful among those who are especially high risk, like college students and heavy drinking medical clinic patients [26,29-31]. Few studies are available on similar interventions for HIV risk behavior, but at least 1 study has shown that an MI-inspired, internet-facilitated intervention increased condom use among heterosexual men and women [32].

One key limitation of existing Web-based BMIs, however, is that they have often incorporated only a small subset of the content that is typically included in face-to-face BMIs, and at least some of this content may be important in producing change. For example, most Web-based BMIs primarily involve developing discrepancy by providing basic feedback about behavior, but face-to-face MI interventions often incorporate a number of other approaches to building discrepancy, especially when clients are resistant to change [33]. These approaches frequently involve using activities or thought experiments to help develop discrepancy between clients' current behavior and important life goals and values, such as the "looking forward/looking back" and "personal values card sort" exercises [34,35]. Building further discrepancy among clients who are resistant to change with these activities may be an important step in facilitating change [36,37].

Past research also shows that the strength of patients' commitment to change is predictive of intervention outcomes in MI sessions [19,38,39]. Miller and Rose [40] argue that the explicit verbalization or acknowledgement of this commitment may not be a necessary precondition for change, but MI interventions involve tasks like change planning that are intended to help strengthen clients' commitment to change. This involves presenting clients with a menu of potential change goals and allowing them to select specific steps they might take toward the goals they choose. While several existing Web-based BMIs offer users a list of strategies for reducing harm, few have incorporated substantive change planning components [28]. Addressing these limitations by integrating additional reflective activities that may further amplify discrepancy and incorporating substantive change planning components that may strengthen users' commitment to change could help improve the efficacy of existing BMIs and lead to more durable changes in behavior [41].

HIV Testing May Be an Opportune Time to Intervene

Past research on BMIs has shown that delivering these interventions at the right time could also boost their effects on

health risk behaviors. That is, the impacts of BMIs may be most profound when delivered immediately after recipients have experienced negative consequences from a behavior because it may naturally prompt them to consider changing the behavior to avoid similar occurrences in the future [42,43]. With respect to alcohol use, meta-analyses have shown that college students who receive a BMI after an alcohol-related incident (an event that required medical, police, or administrative attention such as an injury, citation, or policy violation) showed greater reductions in drinking than wait-list controls [44] or those who received an abbreviated feedback intervention [45]. However, other studies have found few differences in alcohol outcomes across individuals who received BMIs after an incident or injury compared with heavy drinkers who did not experience these events [46-48].

With respect to HIV, in principle getting tested should constitute a part of routine health care for many high-risk MSM. However, in practice voluntary testing is often sought after a possible sexual exposure to HIV [49,50]. In 1 nationally representative sample, up to 60% of MSM listed a possible exposure as a reason for testing [51]. For those who test negative, having been potentially exposed to a life-threatening illness could naturally prompt MSM to consider the potential for change. As such, HIV testing could represent an optimal time to intervene because of this natural opportunity to initiate behavior change. Counseling is already routinely offered alongside voluntary HIV testing in many settings. There are standard recommendations about the content of this counseling [52], which involves providing basic education about HIV infection and identifying specific behaviors that may increase risk. However, in practice no specific approach to counseling is used consistently [53]. Moreover, in a recent study, Metsch et al [54] showed that a broad, person-centered counseling approach delivered alongside voluntary testing did not reduce sexually transmitted infection (STI) incidence or sexual risk behavior among MSM compared to information alone. While these findings have widely been interpreted as evidence that providing counseling alongside testing does not reduce risk, they could instead suggest that for posttest counseling to be effective, it must involve a more consistent, theoretically informed, and empirically supported approach to behavior change. Due to the urgent need to expand HIV testing and eliminate barriers [55], testing is also often provided by paraprofessionals who are given minimal training and guidance about counseling [56]. While this approach may indeed ensure that as many MSM who are at-risk have access to testing as possible, it may do little in terms of reducing future risk. Meanwhile, providing these paraprofessionals with thorough training in a specific counseling approach would be difficult and costly to implement, scale, and

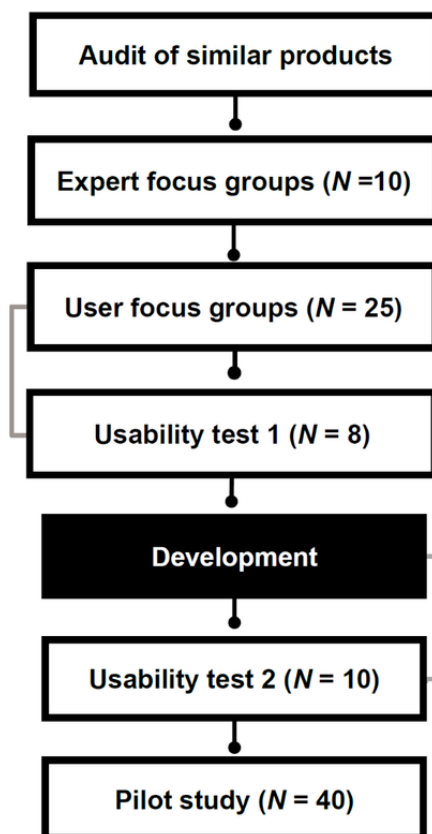
maintain [57]. Together, this evidence suggests that while voluntary HIV testing interactions may be a unique opportunity for individuals to reflect on their risk, consolidate motivation to reduce it, and plan for change, ensuring that those who currently provide testing are trained in empirically supported counseling techniques is likely prohibitive. Web-based approaches that provide many of these same components, however, may help capitalize on these opportunities without the need for extensive training and supervision.

Goals of the Research

Given this landscape, we developed Game Plan, an interactive Web app optimized for tablet computers that aims to help high-risk MSM consider reducing their HIV risk behavior and alcohol use after they test negative for HIV at a clinic. Game Plan was designed to help users understand and reduce these health risk behaviors by (1) providing specific and personal feedback about their level of risk, (2) prompting them to reflect on whether their current behaviors align with other important life goals and values, and for those open to change, (3) helping them understand factors that contribute to risk and (4) making a plan to reduce risk behaviors in the future. This manuscript describes the components and their rationale. In this paper, we will provide an abbreviated overview of our methods for designing and developing Game Plan as well as its components and plans for future research to examine its efficacy in changing behavior.

Methods

We began the development of Game Plan by conducting a thorough user-focused design research process [58,59]. The first step of this process involved conducting an audit of similar existing interventions and tools to compile lists of possible modules and their content. Next, we conducted a focus group with 10 subject matter experts and key informants (ie, HIV test clinicians and counselors) to better understand key content and the logistics of delivery in HIV testing clinics (eg, timing, duration). Then, we conducted participatory design focus groups with 25 high-risk, heavy drinking MSM who had recently tested for HIV. These groups directly engaged intended users in the process of design by enlisting their help in designing user personas, detailed, personal models that represent who the typical users of the app might be. These personas help the design team to develop empathy for the app's intended users and provide them with a guide that can inform their decisions about the app's design, flow, and aesthetic [58]. These steps can help designers create an app that is engaging and interesting to its intended users (see Figure 1).

Figure 1. Design research phases and steps.

Results

App Flow and Content

The following sections review the overall spirit we hoped to achieve in the fully developed Game Plan app as well as each of its components. Table 1 presents these components and a brief summary of their purpose, and a flow of these components is shown in Figure 2. In general, this flow was constructed to roughly align with the 2 phases described in early accounts of MI: content intended to elicit intrinsic motivation for change, and when/if sufficient motivation is present, content intended to translate that motivation into specific goals and plans for change. This sequence first focuses on the user's HIV risk behavior followed by their alcohol use and the connection between the two.

Overall Spirit, Aesthetic, and Onboarding

Past research on MI shows that the therapist's interpersonal style is one of the strongest predictors of change [60,61]. This style calls for therapists to respect the client's autonomy and freedom to choose, be collaborative, avoid judgment, and elicit the client's own motivation rather than trying to impart it. Empathy, or developing a thorough understanding of another's perspective and reflecting that understanding back, is at the heart of this style [60]. In Game Plan, we attempted to convey a similar style by including 3 screens in the onboarding process that explicitly informed them of this purpose. This mirrors what many MI therapists do at the beginning of their sessions [33] and is an approach adopted by many other digital behavior

change interventions [28]. We also attempted to convey this style by designing the app's aesthetic to reflect open-mindedness (ie, avoiding judgment) and respect for autonomy. To facilitate this, designers were briefed on the "MI spirit" and attended user focus groups in person, ultimately developing the app's aesthetic (eg, branding, color palettes, icons, and graphics) with this style in mind. To help convey a nonjudgmental and open tone, we believed it was important to adopt a sex-positive, relatable, and at times, playful, aesthetic. Yet, given Game Plan's purpose of providing honest information about risks, it was important that these concepts be reflected in a classy and refined way. For these reasons, the direction we chose incorporated playful, handwritten icons to convey sex-positivity, relatability, and respect for users' choices and a color palette intended to reflect a classy tone while ensuring readability. This aesthetic is represented in Figure 3.

Affirming HIV Testing

Since Game Plan was developed specifically for use in HIV testing situations, we believed that first acknowledging users' feelings and thoughts about testing could be an important way to communicate empathy and transition them to the task of reflecting on their sexual choices. Thus, after users complete the onboarding sequence, 2 screens ask users to indicate how they are feeling and what they are thinking about testing for HIV. Users drag various feelings and thoughts into an area represented by a heart or thought bubble. A modal dialog window then appears providing an empathetic message tailored to their responses.

Table 1. Brief summary of Game Plan components.

Section	Goals
Testing affirmation	<ul style="list-style-type: none"> • Help users express feelings and thoughts about testing • Express empathy
Demographic assessment	<ul style="list-style-type: none"> • Assess fit for the users (eg, high-risk men who have sex with men [MSM]) • Assess tailoring variables (eg, age)
HIV risk	
Assessment	<ul style="list-style-type: none"> • Assess number of partners and their HIV statuses in the past year • Assess number of insertive/receptive anal sex acts with and without condoms or preexposure prophylaxis with status unknown partners
Profile and norms	<ul style="list-style-type: none"> • Present potential risk for HIV in the past year, compare to overall risk in men, MSM • Compare number of partners, condomless anal sex events in the past year with other MSM
Reflective activities	<ul style="list-style-type: none"> • Weigh the pros and cons of changing choices about sex • Reflect on how sexual choices affect future goals • Reflect on how well sexual decisions align with important personal values
Change planning	<ul style="list-style-type: none"> • Explore menu of options for reducing risk • Identify important reasons for making that change • Identify the specific steps involved in making change • Identify a specific start date for each change
Alcohol use	
Assessment	<ul style="list-style-type: none"> • Assess number of drinking days in the past 30 days • Assess quantity of drinking on each day
Profile and norms	<ul style="list-style-type: none"> • Present feedback for alcohol risk, binge drinking, and typical quantity • Compare drinking with other MSM
Alcohol and HIV risk	<ul style="list-style-type: none"> • Review risks involved in sex under the influence • Assess reasons for drinking prior to or during sex • Reframing beliefs about alcohol's effects on sex
Change planning	<ul style="list-style-type: none"> • Explore menu of options for changing alcohol use or alcohol-related harm • Identify specific steps to make changes in drinking • Identify a specific start date for this change and/or others who can help
Referrals	<ul style="list-style-type: none"> • Present contact information and hours for various medical and mental health services • Allow users to print or email their change plan anonymously

Demographic Assessment

For program purposes, the next section assesses users' basic demographic characteristics including age, sex assigned at birth, current biological sex, current gender, current sexual orientation, preexposure prophylaxis (PrEP) use, and region of residence in the United States. To ensure anonymity of users, no other personal or identifiable information is collected.

HIV Risk Assessment, Profile, and Norms

This section provides personal, easy-to-understand estimates of users' potential risk for HIV in the past year given their current sexual behavior during that time and their projected 5-year risk using data from past research [62-65]. It also

compares users' total number of sex partners and number of times they engaged in anal sex without a condom in the past year with other gay and bisexual men in their age group using available national survey data [66]. The purpose of this feedback is to help develop discrepancy between users' recent behavior and what they would like it to be in the future, a central theme of MI [37]. To inform this feedback, users first complete an assessment of their risk behaviors over the past year (ie, number of insertive/receptive anal sex acts with unknown status partners without using condoms or either partner using PrEP). Reminders about the app's anonymity and nonjudgmental approach are provided in this section to encourage honesty. An example of this screen is presented in [Figure 4](#).

Figure 2. Flow of Game Plan components.

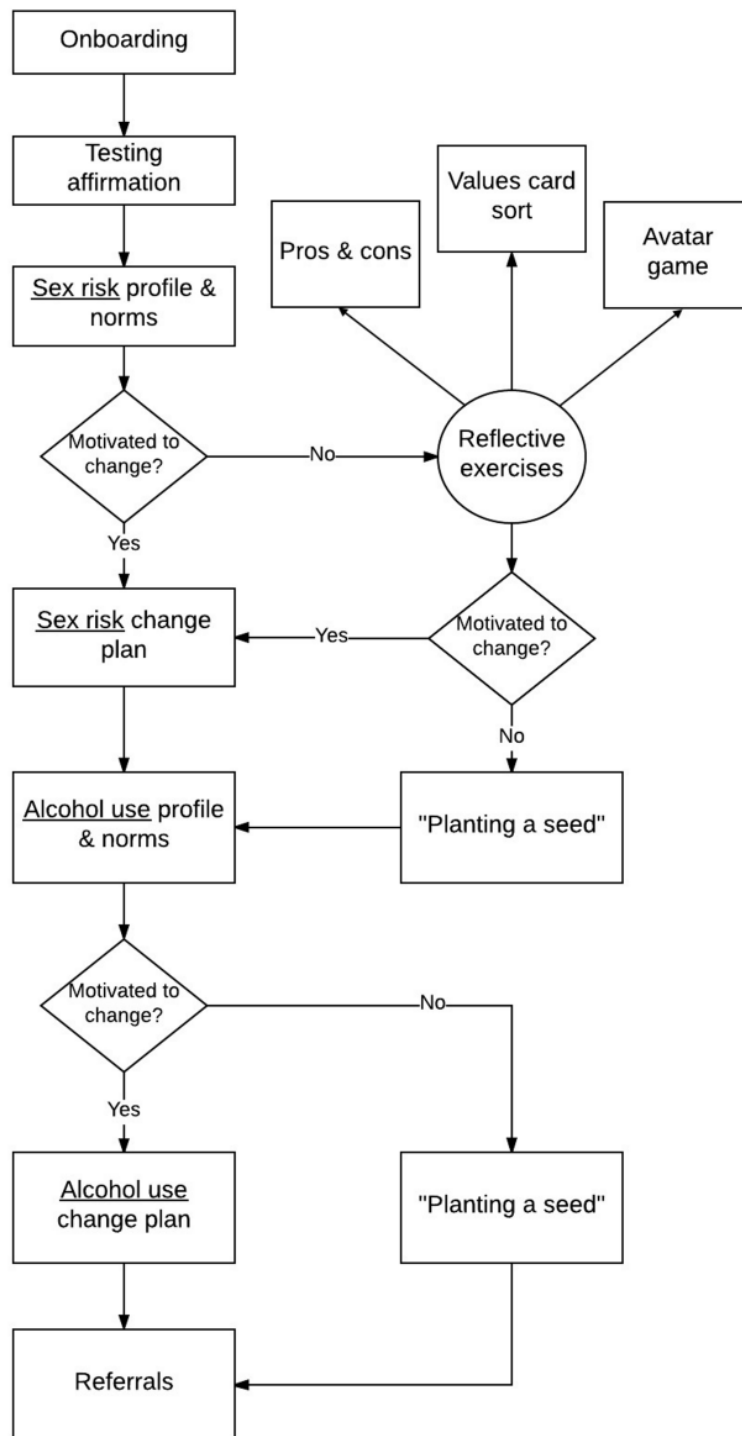
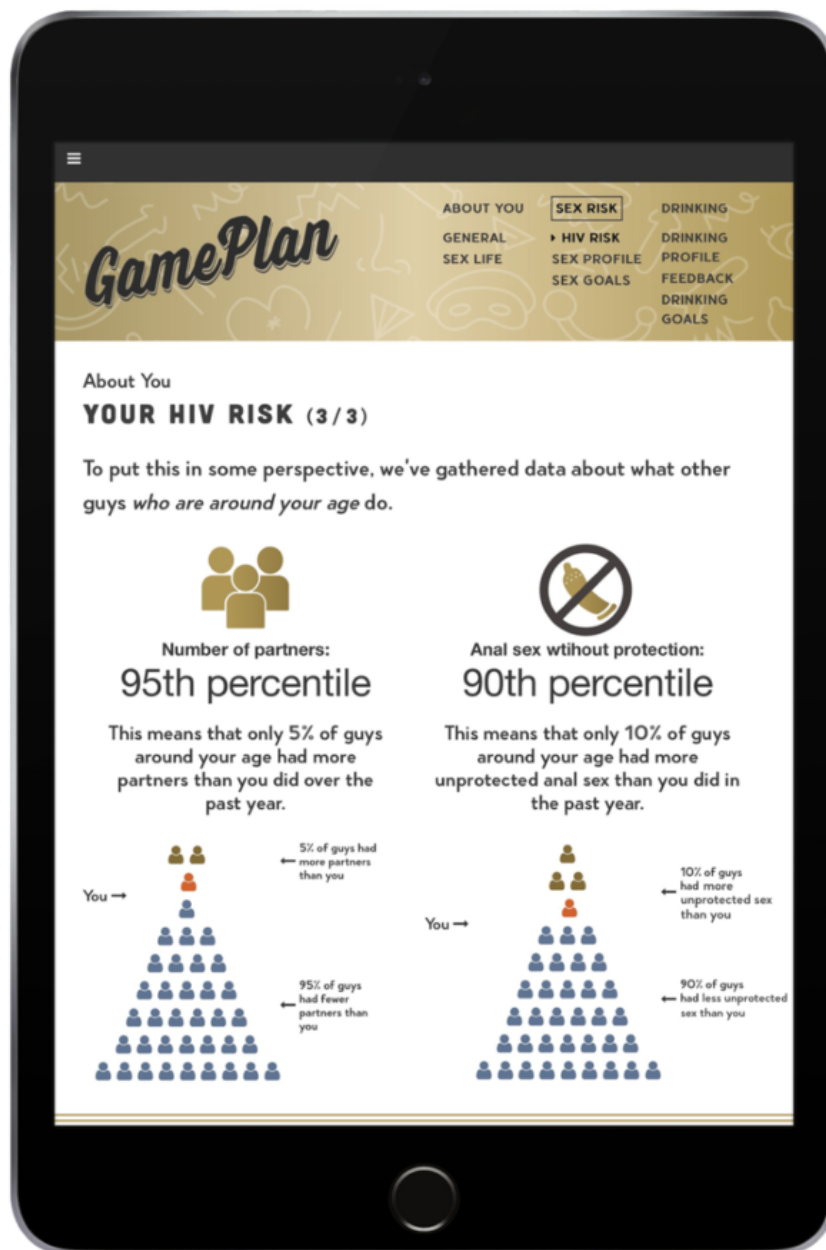


Figure 3. Game Plan branding.



Figure 4. Example screen providing feedback on HIV risk behavior.



Reflective Activities

After the final feedback screen, a modal dialog asks users about their current motivation to start making safer choices about sex. Users rate this scale from 1 (not at all) to 9 (a lot), and those who select a value less than 7 are directed to a landing page that presents 3 exercises designed to help encourage users to reflect further on their sex lives and whether their recent choices align with their broader goals and values. Each of these activities was modeled on similar thought exercises commonly used in MI intended to elicit change talk or client speech that provides arguments for change [35]. While Game Plan's reliance on a tablet-based drag-and-tap interface clearly does not permit users to verbalize these motivations through speech as they would in face-to-face MI sessions, we believe that prompting users to reflect through these activities may encourage a similar internal process that underlies change talk. The first of these is a pros and cons exercise and is similar to decisional balance exercises used in a number of in-person and internet-delivered personalized feedback interventions (PFIs) [67-69]. It is designed to help users identify both the positive aspects of their recent sexual decisions and the drawbacks of these choices and determine whether the drawbacks ultimately outweigh the positives. The second is a values card sort and is very similar to a card sort often used in face-to-face MI sessions [34]. Users are presented with a deck of cards on which several personal values appear and asked to select 3 cards that best represent values that are important to them. Users are then presented with feedback about their sexual risk behavior from earlier sections and asked to rate how consistent these recent sexual choices are with their selected values before being provided with a tailored dialog message reflecting this response. Finally, the avatar exercise is intended to encourage users to picture what they hope their lives will be like in 10 years and reflect on whether their recent sexual decisions will get them closer to or further away from those goals. Users construct an avatar reflecting their future selves and are asked to identify goals they hope to achieve in the next 10 years. Feedback about users' sexual risk behavior in the past year from earlier sections is then presented. Users are asked to imagine they made changes to be safer and rate whether that might get them closer to or further away from these hopes on the same scale. Once users complete at least 2 of these exercises, a dialog window appears asking them to again rate how much they would like to start making safer sexual choices on a 1 (not at all) to 9 (a lot) scale. Those responding with a 2 or above (not really) are directed to a change planning section that presents several options for reducing their sexual risk. Those who rate this item a 1 (not at all) are directed to a section intended to plant a seed for changing their sexual risk behavior in the future.

Change Planning to Reduce Sexual Risk

The sex risk change planning section presents users with a menu of possible goals that could help them reduce their risk and

assists them in identifying steps they can take toward those goals. Goal options are shown and color coded according to the extent to which they reduce risk for HIV, with those that reduce risk a lot presented in green, those that reduce risk a little bit presented in yellow, and those that reduce risk somewhat in orange and red (see Figure 5). Those that reduce risk a lot are presented on the first screen, but users who are not satisfied with these options can click a link to reveal those that reduce risk somewhat or a little bit. Once a goal is selected, users can identify important reasons for making this change, practical steps that could help them, and when they will start. Doing so adds this information to a change plan that appears below and can be later printed or emailed to themselves.

Those who rate that they are not at all interested in making a change are directed to an exercise about planting a seed commonly used in MI for those low in motivation to change [33]. This section was included given evidence from past research that pushing these users to begin planning for change may further increase their resistance and decrease the likelihood of change [38]. This section first provides a summary (eg, "it sounds like you're pretty happy with your sex life as it is now") before asking users to identify specific events that, if they occurred, might make them think about making a change to be a little safer.

Alcohol Use Assessment, Profile, and Norms

After these sections, a dialog box appears that transitions the focus to alcohol use. The alcohol use assessment and feedback screens are very similar to many other existing PFI tools [25,28]. After completing an assessment of drinking in the last 30 days using a graduated frequency approach [70,71], users' drinking is classified as moderate or hazardous according to National Institute on Alcohol Abuse and Alcoholism guidelines [72]. The total number of drinks consumed, total binge drinking days, and average number of drinks per drinking day are then shown before comparing users' drinking with that of other gay and bisexual men in the United States [73].

Other screens in this section focus on the connections between alcohol use and sexual risk, noting the role of drinking in HIV transmission [5,7] and asking users to identify specific reasons they might drink prior to or during sex [74]. Brief text content is then presented addressing the specific reasons users identified, suggesting an alternative interpretation of alcohol's effects on sexual behavior based on available research. Finally, users assess their motivation to change their drinking in a manner similar to earlier sections. Those indicating an interest in changing are directed to an alcohol-specific change planning section, while those decidedly resistant are directed to a section intended to plant a seed for changing their drinking in the future.

Figure 5. Example change planning screen for HIV risk behavior. PrEP: preexposure prophylaxis.

Plan

SELECT GOALS

Here are some goals that might help you reduce your risk. Think about the kind of situations you've been in before that put you at risk, and select some goals. Then, add more detail to the steps you will take below.

■ Reduces risk a lot
 ■ Reduces risk quite a bit
 ■ Reduces risk somewhat
 ■ Reduces risk a little bit

Select ones you are interested in working on:

- Use condoms with all partners Select
- Use condoms with any new or casual partners Select
- Take a daily medication that can prevent me from getting HIV Select
- Have sex with only one partner at a time, someone I know well Select

Aren't thrilled about these? [Show some others](#)

MY GOALS

Goal: Take a daily medication that can prevent me from getting HIV

- To make me healthier/keep me from getting a disease
- To feel safer

Steps I will take	I plan to take these steps on	People who can help me	I know this is working when
Talk to a doctor about getting on Truvada®/PrEP	Sep 6, 2017	<ul style="list-style-type: none"> Doctor: PC Edit 	I go to my doctors appointment to talk to him about PrEP. Edit

Change Planning for Alcohol Use

The alcohol change planning and planting a seed sections are similar to those used for sex risk. In these sections, users select from drinking goals (ie, stop drinking entirely, reduce how much I'm drinking or cut down, or change how I'm drinking to keep bad things from happening as often), which are similarly color coded. Users can indicate important reasons for making this change, specific steps they can take (including protective behavioral strategies [75,76]), and a date they will start. These goals and their details are then added to any other goals they had selected throughout their session. Afterward, all users are directed to a final page where they can elect to either print or email their plan and/or information on referrals to themselves. Referral information is provided for local lesbian, gay, bisexual, and transgender-friendly agencies and organizations that provide

HIV/STI testing, general medical care, mental health care, and alcohol and drug treatment. To ensure users' anonymity, no personal information is included in these materials and a portable printer is used for those who elect to print their materials.

Discussion

Principal Findings

To our knowledge, Game Plan is one of the first internet-facilitated, combined brief interventions that focuses on both HIV risk behavior and alcohol use. The features described in this paper also set it apart as among one of the most complete self-guided brief interventions inspired by the principles of MI. Meta-analyses exploring the effects of digital and internet-facilitated behavioral interventions provide strong evidence that highly tailored interventions may be more

successful in facilitating behavior change than those that present all users with similar content [25,77,78]. Game Plan provides content that is tailored to users' demographic characteristics (eg, age, sexual orientation), behavior (eg, sexual risk, alcohol use), readiness to change, preferred change goals, and other characteristics. The overall spirit, structure, and aesthetic elements of Game Plan were also designed specifically with the needs of intended users (high-risk, heavy drinking MSM) as a roadmap. To facilitate this, we used interaction design research methods, a process used in many industry software development projects [58,59]. This process enabled all members of our design and development team to thoroughly understand the motivations that intended users might have for engaging with this tool so that we could use these insights to help guide our design decisions.

Game Plan was specifically designed to be used alongside HIV testing, when intended users may already be naturally considering behavior change and when prevention services reach many intended users. Offering Game Plan to users after HIV test results have been provided may also be fitting because its content addresses many of the same topics that are often priorities of traditional posttest counseling including identifying and assessing risk behaviors and developing a plan to reduce risks [52]. However, Game Plan may approach these tasks in a manner that is more consistent with existing evidence-based interventions that have been shown to reduce HIV risk behavior and major precipitating factors (ie, alcohol use [24,27]). Given that guidelines on HIV testing and counseling recommend that prevention counseling not be a required component of HIV testing, it may be that Game Plan could best be used as an alternative for those who are uncomfortable with or are unwilling to engage in traditional counseling or as a complement to it.

Future Directions

Research on Game Plan is currently in its preliminary phases. As such, little is known about its effects on behavior change, including when and how it might be most effective or how it compares with other available internet-facilitated brief interventions and comparable evidence-based face-to-face interventions. While a pilot test of its effects on behavior and theoretical mediators of change (eg, readiness to change, self-efficacy, norms) is currently ongoing, a larger trial will be needed to explore whether it helps intended users change their behavior and whether these changes, in turn, impact key end points like HIV/STI incidence. If evidence supports its efficacy, future research could also be devoted to optimizing the efficacy of its components. Finally, if Game Plan's effects appear promising, further research will also be needed to inform implementation and dissemination strategies, including a plan for providing ongoing technical maintenance, support, and updates.

Limitations

While Game Plan has many strengths, several limitations are also important to note. First, Game Plan's components were developed based on existing models of brief interventions. As such, it was intended to provide users with only a single exposure to intervention content and provides no longer term support for behavior change over time. More frequent support will likely be needed in order to achieve durable changes in both HIV risk behaviors and alcohol use. This could involve expanding this program to allow users to check in on their goals over time or by using existing text message interventions for these behaviors [79,80]. Similarly, brief interventions that served as models for Game Plan were based on the principles of MI, which is a person-centered counseling technique. As such, these approaches emphasize that therapist characteristics like warmth, genuineness, and empathy [60] are key to successfully facilitating behavior change. Some of these characteristics are most intuitively conveyed through natural language and other, nonverbal behaviors (eg, by mimicking another's expressions of emotion [81]), and some concepts like empathy may only be conveyed by a human interventionist, since they often involve a person's ability to subjectively experience and understand another person's feelings [82]. As such, the point-and-drag interface used by Game Plan may be less natural or impactful than the interactions provided in traditional face-to-face MIs, since it lacks these important interpersonal elements and could also fail to incorporate critical facets of MI interventions that lead to change. However, our past research on brief computer-delivered interventions for alcohol use has shown that participants rate both natural language and point-and-click interfaces as consistent with an MI counseling style. Moreover, there were no differences between participants assigned to interact with the intervention via these 2 interfaces, either in terms of their willingness to set a goal or in their alcohol use a month after intervention [83]. A final limitation is that Game Plan was designed specifically to meet the needs of high-risk gay, bisexual, and other MSM. Given that content focuses on anal sex with other MSM, its use should be limited to this population.

Conclusion

Game Plan is a brief, tablet-optimized intervention that aims to help gay, bisexual, and other MSM reduce their alcohol use and risk for HIV by providing interactive, personal feedback about users' risks, facilitating reflection on the impact that these risks have on users' lives and goals and enabling them to select from a menu of possible change options to begin planning for that change. Developed to mirror common components of existing evidence-based brief interventions for these behaviors, Game Plan could represent a wide-reaching and scalable tool that can help facilitate risk-reducing behavioral changes in settings where delivering evidence-based in-person interventions would be difficult or cost prohibitive.

Conflicts of Interest

None declared.

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Abbreviations

- BMI:** brief motivational intervention
- MI:** motivational interviewing
- MSM:** men who have sex with men
- PFI:** personalized feedback intervention
- PrEP:** preexposure prophylaxis
- STI:** sexually transmitted infection

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Original Paper

Assessing the Feasibility and Pre-Post Impact Evaluation of the Beta (Test) Version of the BeUpstanding Champion Toolkit in Reducing Workplace Sitting: Pilot Study

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Abstract

Background: The Web-based, evidence-informed *BeUpstanding Champion Toolkit* was developed to provide employers (via a “train-the-champion approach”) with resources and support to help in reducing prolonged sitting in their own desk-based workplace. As part of a five-phase research-to-dissemination process, this study reports on the evaluation of the beta (test) version of this toolkit (Phase 2).

Objective: The objective of our study was to evaluate (1) the implementation of the toolkit by workplace champions and (2) the impact of the toolkit on sitting (primary outcome), standing, and moving; use of activity-promoting strategies; knowledge and attitudes; and indicators of health and work performance.

Methods: An implementation study using a pre-post design was conducted in 7 desk-based workplaces in Australia (September 2015 to May 2016), with work teams (one per workplace) purposively recruited to ensure representation across a range of sectors (white- or blue-collar), organizational sizes (small or medium or large), and locations (metropolitan or regional). All staff within participating teams were invited to participate in the relevant toolkit activities. Implementation outcomes (time commitment required by champions and toolkit activities completed) were collected from each champion via telephone interviews. Changes in impact outcomes, measured via a Web-based questionnaire completed by employees at baseline and 3 months postimplementation, were assessed using mixed models, correcting for clustering.

Results: Champions reported a 30-60 minutes per week time commitment to the toolkit activities. All teams formed a wellbeing committee and sent the staff surveys at both time points; most champions held a staff consultation workshop (6/7), identified team-level strategies within that workshop (5/7), used the communication resources provided within the toolkit (emails, posters; 6/7), and completed the action plan (5/7). In total, 52% (315 of ≈600) employees participated in at least one survey and 97 (16%) participated in both. At follow-up, there was a significant ($P<.05$) reduction in self-reported workplace sitting time compared to baseline (−6.3%, 95% CI −10.1 to −2.5; $n=85$) equating to ≈30 minutes per workday. Significant benefits were also observed for

the use of activity-promoting strategies, with small, nonsignificant changes observed for knowledge and attitudes and indicators of health and work performance.

Conclusions: The beta version of the *BeUpstanding Champion Toolkit* was feasible to implement and effective in reducing self-reported workplace sitting across a broad range of desk-based workplaces. The next phase (Phase 3) will build on these findings to optimize the toolkit for wider-scale implementation and longer term evaluation.

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KEYWORDS

BeUpstanding Champion Toolkit; implementation; physical activity; sedentary; workplace sitting

Introduction

Regular participation in moderate-to-vigorous physical activity (MVPA) has long been the cornerstone of chronic disease prevention efforts. However, in Australia, population participation levels of leisure time MVPA are low and have been relatively unchanged for 22 years, despite associated public health efforts [1]. More recently, the relevance of time spent in nonexercise activities, such as sitting and light intensity activities, for indicators of health and wellbeing has been increasingly recognized. Excessive sitting is now acknowledged as a probable contributor to the risk of major chronic diseases (type 2 diabetes and cardiovascular disease in particular [2]). Notably, a meta-analysis using data from over one million adults reported that only very high volumes of MVPA (≥ 60 minutes per day) seemed to eliminate the risk of death associated with high sitting time [3]. As such, public health guidelines now recommend a dual message of moving more and sitting less [4].

One of the key settings to address excessive sitting time is the desk-based workplace [5]. On average, desk-based workers spend 75% of their work day sitting, with much of this time accrued in prolonged, unbroken bouts of ≥ 30 minutes [6,7]—a pattern that may be particularly harmful to indicators of cardiometabolic health [8]. As such, desk-based workers have been identified as a large and growing at-risk population subgroup [9,10]. The relevance of addressing workplace sitting time for workplace health and safety [10,11] and for public health [12] has been acknowledged, and there have been several recent interventions, incorporating a range of activity-promoting strategies, which have demonstrated that reducing prolonged sitting is feasible and acceptable to both employers and employees within the desk-based workplace [6,7,13-15]. Many, but not all, interventions are also effective [16,17].

To provide employers with the resources and support to translate this research evidence into practice, we developed the *BeUpstanding Champion Toolkit*. This free, Web-based toolkit provides an evidence-informed, step-by-step guide with accompanying resources to help work teams create a dynamic work environment where standing up, sitting less, and moving more is the norm. The *BeUpstanding* program delivered through the toolkit is primarily based on the interventions developed, and evidence generated, from the *Stand Up Australia* program of research [6,7,13-15,18-22]—a program that targeted multiple levels of influence (organizational, environmental, individual, or combinations of these) to address reductions in prolonged workplace sitting time [7]. The flagship of this program was the *Stand Up Australia* intervention [18], which was shown to

be strongly efficacious for reducing workplace sitting time within the context of a cluster randomized controlled trial [7]. The key adaptation from *Stand Up Australia* for *BeUpstanding* was the transfer of intervention implementation and evaluation from the research team to a workplace champion. This “train-the-champion” approach recognizes that workplace champions, as the role models and drivers, are critical for successful and sustainable workplace change [23-25].

The translation of the *Stand Up Australia* intervention program into a scalable and sustainable workplace health and safety program involves multiple phases [26]. Phase 1, which has been completed, involved the initial development of the toolkit and formation of research-government partnerships. A detailed description of this development has been described elsewhere [26]. The current paper concerns Phase 2, in which the beta (ie, test) version of the toolkit was piloted among a small, diverse set of workplaces. This pilot enabled us to evaluate whether the Web-delivered “train-the-champion” approach, as a potentially scalable way to deliver *Stand Up Australia*, was feasible to implement by workplace champions. As noted above, the interventions that informed *BeUpstanding* have undergone rigorous evaluation and have demonstrated strong efficacy for workplace sitting reduction [6,7,13-15]. The impact evaluation within this pilot study was intended to provide some corroborative evidence about the likely effectiveness of the intervention following the adaptations made for scalable delivery, as well as explore relevant measurement issues (responsiveness to change and likely effect sizes). The specific aims were to evaluate (1) the implementation of the toolkit by the workplace champions and (2) the impact of the toolkit on sitting (primary outcome), standing, and moving; use of activity-promoting strategies; knowledge and attitudes; and indicators of health and work performance. The findings from this phase of research will inform the optimization (Phase 3) of the *BeUpstanding Champion Toolkit* prior to any wide-scale implementation and evaluation.

Methods

Study Design and Recruitment

The evaluation used a pre-post design. A key limitation of the previous trials evaluating the *Stand Up Australia* intervention is the limited diversity of workplaces (typically, white-collar employees of reasonably large metropolitan organizations have been represented) [7,14,15]. Accordingly, the evaluation used purposive sampling to ensure coverage of desk-based workers from a range of industries (including white- or blue-collar),

organizational sizes (small or medium or large, ie, <20/20-500/>500), and locations (metropolitan or regional). The sample size of 7 work teams was selected to cover the range of desired workplace attributes; it was not selected *a priori* based on the requirements of the impact evaluation. Over a two-month period, workplace representatives were made aware of the study by project staff (who extended personal invitations to existing contacts and delivered seminars to workplace wellness networks) and by the project’s government partners (who used a variety of promotional endeavors), with workplaces selected from those who expressed interest. While the workplaces were selected purposively, the project staff had no input concerning the selection of teams within workplaces (one per workplace), nor champions for teams. A senior project manager guided workplace champions through the consent stage and provided access to the beta version of the toolkit via a password-restricted login page. This manager was also available throughout the study to answer questions as required. All employees within the participating work team were provided information on the program, were exposed to program messaging (via the champion), and were invited to take part in the staff consultation workshop and Web-based surveys (see below). The study was approved by the Behavioral and Social Sciences Ethical Review Committee of the University of Queensland, with champions providing written informed consent and staff providing informed consent prior to participating in any data collection.

The BeUpstanding Champion Toolkit: Beta (Test) Version

The Web-based *BeUpstanding Champion Toolkit* provides a step-by-step guide to support workplace champions to adopt, deliver, and evaluate the program within their own work teams. The structure of the toolkit and the associated resources are detailed in [Figure 1](#), with the 5 steps following the “Plan, Do, Review” phases of the Work Health and Wellbeing Framework [27]. The Plan phase involves obtaining support from management (step 1), conducting a needs assessment (step 2), and preparing for the program (step 3). The Do phase involves putting the program into practice (step 4), while the Review phase involves evaluation of the impact of the program on both

policy and practice (step 5). Each step includes an instructional component explaining the purpose of the step (ie, to “train” the champion). The activities within the toolkit are intended to be implemented over a three-month period at the level of the work team (broadly defined as a colocated group, employed by the same organization, and having the same workplace policies). Resources within the toolkit are mixed media, including editable word and email templates, PDF posters and tips sheets, and videos. These supporting materials were designed to help initiate change through increasing awareness (eg, email templates, posters), as well as create longer term organizational level change through building a supportive work culture and environment (eg, sample policy statements, workplace audits).

Core tasks supported by the toolkit include forming a wellbeing committee and holding a wellbeing committee workshop to plan the initiative; holding a staff consultation session to educate staff and collectively, through a participative approach, identify 3 top strategies to stand up, sit less, and move more; and implementing and promoting these strategies across the work team ([Figure 1](#), Steps 3 and 4). The accompanying resources for the workshops included in the toolkit emphasize selecting strategies to increase standing or moving (predominantly light intensity activities) that target work practices within a team (eg, standing meetings) or the work environment (eg, centralizing printers) to encourage sustainable organizational level change. Suggestions were provided within the toolkit for the wellbeing committee concerning strategies that may be able to be implemented immediately (including low-cost or no-cost strategies) as well as those that may require longer term planning or resourcing, with teams also encouraged to brainstorm their own strategies that best suited their team.

Data Collection and Measures

Characteristics of Workplaces, Champions, and Staff

Data on the workplaces (size, location, sector), as well as reasons for taking part in the program, were collected via the initial expression of interest and confirmed with champions. Information on the job role of the champion was collected as part of the initial contact by the senior project manager.

Figure 1. BeUpstanding Champion Toolkit steps, tasks, supporting resources, and timeline.

	Plan			Do	Review
Steps	Step 1: Getting support from management	Step 2: Needs assessment	Step 3: Preparing for the program	Step 4: Putting it into practice	Step 5: Evaluation
Champion Tasks	<ul style="list-style-type: none"> • Make a case for BeUpstanding • Formalize management’s commitment in writing 	<ul style="list-style-type: none"> • Conduct a workplace audit • Conduct a staff survey 	<ul style="list-style-type: none"> • Create & maintain a support network • Hold a wellbeing committee workshop • Hold a staff consultation workshop 	<ul style="list-style-type: none"> • Set an action plan & launch • Promote with posters, health information, & emails to staff • Encourage change champions • Celebrate success 	<ul style="list-style-type: none"> • Do follow-up workplace audit • Do follow-up staff survey
Supporting Resources	<ul style="list-style-type: none"> • Business case template • Sample policy 	<ul style="list-style-type: none"> • Staff email templates • Links to workplace audit & staff survey • Staff email templates 	<ul style="list-style-type: none"> • Wellbeing committee member invitation template/video/planning tool • BeUpstanding staff video & summary email template 	<ul style="list-style-type: none"> • Action plan example & template • BeUpstanding posters • Tips & tools • Email guide/templates • Change champion guide 	<ul style="list-style-type: none"> • Links to follow-up surveys
	1-2 months			2-3 months	Ongoing

Anonymous Web-based surveys were used at baseline and 3 months postimplementation to collect self-reported data regarding the primary and secondary impact outcomes as well as age, gender, work hours, job role (management, general staff, other), and education (some high school, completed high school, post high school). Participants were also asked the number of days in the last week where they had done a total of ≥ 30 minutes of physical activity that was enough to raise their breathing rate [28]. The responses were used to identify the participants who met minimal physical activity guidelines (ie, ≥ 30 minutes moderate activity for ≥ 5 days per week) [4]. Satisfaction with the program was assessed in the postimplementation survey only (single-item, 10-point scale; 10 = “very satisfied”). The participant responses to 3 questions generated an identity code that was used to match pre- and postintervention survey data to the same (anonymous) participant. A cross-check of the gender and date of birth of “new” respondents at the postintervention survey against possible partial matches from the baseline survey was used to identify failures in the matching process (n=3 participants) and rectify the data accordingly.

Implementation Measures

Implementation data were collected via telephone interviews with the champions following the completion of Step 5 of the program described in Figure 1 (after approximately 3 months of implementation). A checklist was used to collect data on the completion of the steps in the program and the use of the accompanying resources, as well as the estimated time commitment by the champion for program implementation. This information was used to inform the feasibility of implementation.

Impact Outcomes

Sitting, Standing, and Moving

The primary impact outcome was self-reported workplace sitting time. The secondary activity-related outcomes were as follows: workplace time spent standing, walking, in heavy labor, and moving (walking + heavy labor); workplace sitting accumulation; and time before and after work and on nonwork days spent sitting, standing, and moving.

Behaviors at work were measured by the Occupational Sitting and Physical Activity Questionnaire [29], which asks about the percentage of time on a typical day in the last 7 days spent sitting, standing, walking, or in heavy labor or physically demanding tasks. This questionnaire has acceptable validity and reliability compared with posture-based activity monitors [30] and is responsive to change [30]. In addition to asking about work hours, the questionnaire was further adapted to measure these activities outside of worktime on work days (ie, “How would you describe the time you were awake before and after work on a typical work day in the last 7 days?”) and nonwork days. All questions referred only to times the participants were awake.

Participants were also asked how many breaks from sitting (0-5 or more) they typically took in an hour while at work [31]; the longest period they spent without getting up at work on a typical work day in the last 7 days; and the percentage of their workplace sitting time that involved sitting for long periods at

a time (≥ 30 minutes continuously) and conversely sitting in an “interrupted” manner (< 30 minutes), with the sum total of their 2 responses being 100% of workplace sitting time. The last 2 questions were new questions developed for this study.

Knowledge and Attitudes Toward Sitting, Standing, and Moving

Baseline awareness of the health impacts of “too much sitting” was assessed by an open-ended question in the staff survey. Participants were asked to list all the health impacts of sitting of which they were aware. These response options were then coded into mutually exclusive categories concerning plausible benefits (5 categories: musculoskeletal; weight gain or obesity; cardiovascular health or diabetes or metabolism; other vascular (eg, circulation); and fatigue or concentration), “other”, “not sure”, and “none”. Change in knowledge was assessed via a knowledge score. Participants were asked “How often do you think you should get up from sitting?” with response options of “Every? hours” or “Every? minutes”. One point was assigned for every 5 minutes that their response deviated from the message provided in the *BeUpstanding* program (at least every 30 minutes). Responses of 25-35 minutes were treated as correct (0 points), with the lowest scores indicating the best knowledge.

The impact on attitudes was assessed in terms of the following: desired activity at work; the difference between desired and performed behavior; control over sitting and standing at work; and workplace support for sitting and standing. Through the question “If you were given a choice at work, what percentage of the time would you spend...,” participants were asked about their desired sitting, standing, and moving at work (scores were required to add up to 100% of the time). Gap scores were then calculated as the absolute value of the difference between self-reported desired and performed activity at work. In theory, gap scores range from 0 (desired and performed are exactly the same) to 100 (desiring 100% and doing 0%, or vice versa). Control over sitting and standing at work, and workplace support for sitting and standing, were assessed by participant responses concerning the extent to which the participants agreed with the two statements: “I have control over whether I sit or stand at work” and “My workplace is committed to supporting staff choices to sit or stand at work” [32]. Both questions used a five-point Likert scale (strongly disagree, disagree, not sure, agree, or strongly agree).

Activity-Promoting Strategies

Participants were provided with a menu of 13 common strategies that have been used to promote standing up, sitting less, and moving more in the desk-based environment [6,33,34] and were then asked to indicate the extent to which they used these strategies (never or rarely, sometimes, often or very often, not applicable). Strategy use was measured as the percentage of the 13 strategies participants reported using at least “sometimes”.

Work Performance Indicators and Perceived Health Status

Work performance was measured by a 9-item, 10-point scale [35] with findings reported as the mean of the 9 items. Job satisfaction in the past week was measured by a single-item, 10-point scale (1 = very dissatisfied; 10 = very satisfied) [36].

Current energy and stress levels were measured on a single four-point scale (1 = “I always have lots of energy”; 4 = “I feel exhausted most of the time” and 1 = “I don’t feel unduly stressed most of the time”; 4 = “I feel under incredible stress most of the time”), with energy and stress scores reversed such that a higher score indicated more energy or less stress. Self-rated health in the past week was measured on a single, five-point scale (1 = poor; 5 = excellent) that has shown strong correlation with the World Health Organization self-rated health measure [37].

Analyses

Data were analyzed in SPSS (version 24, IBM Corp., Armonk, NY, USA) and STATA version 14 (StataCorp, College Station Texas, TX, USA). Descriptive data are reported as mean (SD), median (25th, 75th percentile), or n (%). Findings are reported in terms of the effect size and statistical significance, with significance set at two-tailed $P < .05$. Minimum differences of interest (MDI) for the activity measures were set at 30 minutes of sitting and standing or 10 minutes of walking, heavy labor, or moving per workday or per day (ie, 6.25% of work hours, 3.125% of waking hours based on a theoretical 8-hour workday and 16 hours awake). The 30-minute MDI for sitting and standing is consistent with a single bout of prolonged sitting time (30 minutes) and is in between the MDIs used in Stand Up Victoria of 45 minutes [32] and average sedentary reductions in intervention studies (approximately 20 minutes) [16]. Ten minutes is the smallest period of activity that self-report questionnaires, such as the Active Australia, typically require participants to recall [38]. For other outcomes, MDI was set at changes consistent with a “small” effect (0.2 SDs), with changes less than the MDI considered very small.

Changes over time in the primary and secondary impact outcomes (all continuous) were tested using STATA’s mixed procedure, using random terms for the repeated measures and site-level clustering. To yield insight concerning which workplaces may benefit most or least (in terms of workplace sitting time) from the intervention when upscaling the intervention, mixed models were used to explore workplace variation in change. The main analyses for the primary and secondary outcomes were evaluable case analyses. To assess the sensitivity of conclusions to missing data, the primary outcome (workplace sitting) was re-evaluated using multiple imputations by chained equations, with a mean of 80 imputations used in view of the fraction of missing information. Other analyses corrected for clustering via linearized variance estimation (survey commands). Not all questions were compulsory; hence, the number of respondents varies depending on the question. Sociodemographic predictors of survey completion or noncompletion were tested using linear or logistic regression. To inform future evaluations of *BeUpstanding* and similar interventions, we report on the extent of clustering encountered and the responsiveness to change of each of the outcome measurements, that is, standardized effect size (SES) and standardized response mean (SRM). SES was calculated as mean change divided by SD at baseline, while SRM was

calculated as change divided by SD of change with mean and SD of change scores calculated using linearized variance estimation. Larger absolute values of SES or SRM indicate better responsiveness to change.

Results

Characteristics of Participating Workplaces, Champions, and Staff

Workplace Characteristics

The 7 teams of desk-based workers were recruited across organizations that were small (Team A), medium (Teams B, D, F, and G), or large (Teams C and E; Table 1). Industries with primarily blue-collar work were represented by Teams B and G. In total, 4 of the work teams were from governmental organizations (Teams C, D, E, and F) and the remaining were from the private sector. Of the workplaces, 2 (Workplaces C and F) already had sit-stand workstations installed. The reasons champions provided for taking part in the intervention were consistent across work teams, with all indicating that they anticipated the program would help create a healthier workplace. Furthermore, 6 workplaces mentioned that they expected the program would change awareness, culture, or practices around excessive sitting.

Champion Characteristics

A total of 7 workplace champions (4 women, 3 men) delivered the *BeUpstanding* program, with 6 of the champions employed in a managerial or senior leadership role (Table 1).

Staff Characteristics

In total, approximately 600 staff were exposed to the program with 315 workers participating in at least 1 survey, 237 workers responding to the baseline survey, 170 responding to the follow-up survey, and 97 workers responding (at least partially) to both surveys. Participation rates, that is, the total number of respondents to either survey divided by the work team size as reported by the champion, ranged from 37% to 100% across the work teams, with approximately 52% participation overall (Table 1). Table 2 shows the participants’ sociodemographic and work-related characteristics. They had an average age of approximately 40 years and work hours consistent with full-time work. Most of the sample were women (65%), had a university education (72%), and described their job role as management (78%).

Approximately a third of participants reported meeting the physical activity guidelines. Although nonparticipants were not assessed, a comparison of those who completed only one survey, as opposed to both, suggested that participation biases were minimal. Compared with their counterparts, those who completed 1 survey were significantly younger ($P = .04$; mean difference = -3.7 years; 95% CI: -7.1 to -0.4) but were otherwise similar in terms of gender, education, job role, work hours, and meeting minimal physical activity guidelines (all differences were nonsignificant and $< 10\%$).

Table 1. Baseline characteristics of work teams and champions participating in the pilot study.

Work place	Industry	Location	Reasons for taking part	Approximate work team size, n	Survey participation rate ^a , n (%)	Champion job role	Wellbeing committee, n
A	Engineering	Regional	Hoping to get everyone in the office moving a little more and being mindful about their health and how much time they're spending in a chair.	12	9 (75.0)	Receptionist	4
B	Plumbing	Outer region of CBD ^b	Explore options for us to lead the way in creating a healthier workplace.	16	16 (100.0)	Corporate Services Manager	3
C	Public administration	CBD	Improved employee health, work culture, and practices.	300	117 (39.0)	Rehabilitation and Employee Relations Case Manager	8
D	Public administration	Outer region of CBD	Assistance to make my workplace healthier in order to help staff and the organization.	40	27 (67.5)	Assistant Principal Officer	6
E	Public administration	CBD	We hope to improve the way we promote and sustain better health for our staff making use of the research outcomes (learning and aids) of the program developers and the research outcomes of the pilot to provide a healthy workplace that staff are interested in being part of. This should then lead to people wanting to work here (our division), and for those already here, to their achievement of improved outcomes.	100	74 (74.0)	Principal Governance and Improvement Officer	7
F	Workplace policy regulation	CBD	To raise awareness, educate staff, change current sedentary work practices, and contribute positively to the long-term health of our staff.	100	54 (54.0)	Acting Government Solicitor and Senior Procurement and Contracting Officer	5
G	Transportation and logistics	Outer region of CBD	A change in the consistent sitting in the office. A change in thinking around being tied to the desk other than break times. Regular standing breaks and use of the stairs. An overall improvement in the sense of wellbeing of all desk-based staff.	35	18 (51.4)	Customer Support Manager	4

^aNumber of respondents to one or both surveys and approximate workplace size; an indicator of the "reach" of the intervention.

^bCBD: central business district. Outer region of CBD: >15 km from CBD.

Table 2. Characteristics of participants who completed the Web-based surveys.

Characteristics	Either survey	Both surveys ^a	Baseline survey only	Follow-up survey only
Number of participants, n	315	97	237	172
Age in years, mean (SD)	39.7 (11.5)	42.3 (11.1)	40.0 (11.3)	42.3 (11.1)
Work (h/wk), mean (SD)	38.2 (6.3)	38.1 (5.3)	38.2 (6.5)	38.5 (6.1)
Women, n (%)	202/311 ^b (65.0)	64/96 (66.7)	154/236 (65.3)	112/171 (65.5)
University education, n (%)	223/311 (71.7)	66/96 (68.8)	173/236 (73.3)	120/170 (70.6)
Management job role, n (%)	241/311 (77.5)	73/96 (76.0)	179/236 (75.9)	135/170 (79.4)
Met minimum physical activity guidelines of ≥30 min moderate activity for ≥5 d/wk, n (%)	83/294 (28.2)	31/96 (32.3)	64/215 (29.8)	46/161 (28.6)

^aAs reported in the baseline survey.

^bNumber of participants vary as not all participants provided information pertaining to the characteristics listed.

Aim 1: Evaluation of the Implementation of the *BeUpstanding* Program

Table 3 provides details on the implementation checklist according to work team. All champions made the program available to all staff within their work team, all teams formed a wellbeing committee to identify potential strategies, and all champions sent the surveys (baseline and follow-up) to all staff within their team. Most champions held a staff consultation workshop (6/7), identified strategies within that workshop (5/7), used the communication resources provided within the toolkit (emails, posters; 6/7), and completed the action plan (5/7). When asked how much time on average they spent working on the program, the majority of champions indicated between 30 minutes and 1 hour per week, with more time spent initially (ie, the first month). This initial commitment varied from 1 to 2 hours for most work teams to 1 day per week for the first month for the largest workplace (Team C), where multiple staff consultation sessions were conducted by the champion.

Work Team Strategies to Stand Up, Sit Less, and Move More

A broad range of standing and movement strategies were chosen by the work teams as part of the staff consultation workshop (**Table 4**). Notably, 2 of the work teams did not choose any strategies (A and E); 2 (C and D) made further divisions within their team, with strategies identified for each of these “subteams” (Teams C and D had 6 and 3 subteams, respectively); and 1 (G) chose approximately 30 strategies, with a different staff member responsible for leading one of the strategies each day. Common strategies chosen by work teams included standing phone calls, taking the longer route to a destination, walking meetings, centralizing printers or bins, and the use of prompts and reminders. Unique strategies included dance-offs and stepathon competitions (ie, the accumulation of steps over a time period).

Table 3. How many and which teams implemented each implementation checklist item.

Implementation checklist item	Work team							Frequency (N=7), n (%)
	A	B	C	D	E	F	G	
Was the program made available to all staff?	✓	✓	✓	✓	✓	✓	✓	7 (100)
Did you form a wellbeing committee?	✓	✓	✓	✓	✓	✓	✓	7 (100)
Did the wellbeing committee attend the committee information workshop?	✓	✓	✓	✓	✓	✓	✓	7 (100)
Did the wellbeing committee watch the committee information video?		✓	✓	✓		✓		4 (57)
Was the wellbeing committee involved in the identification of strategies?	✓	✓	✓	✓	✓	✓	✓	7 (100)
Was a staff consultation workshop held?	✓	✓	✓	✓		✓	✓	6 (86)
Was the staff information video played?			✓	✓		✓		3 (43)
Did staff identify top strategies at the workshop to do as a team?		✓	✓	✓		✓	✓	5 (71)
Was an action plan template completed?	✓	✓	✓			✓	✓	5 (71)
Were posters placed around the office?	✓		✓	✓	✓	✓	✓	6 (86)
Were program information emails/newsletters sent to staff?	✓	✓	✓		✓	✓	✓	6 (86)
Were all staff sent the link to the online staff survey at baseline?	✓	✓	✓	✓	✓	✓	✓	7 (100)
Were all staff sent the link to the online staff survey at follow-up?	✓	✓	✓	✓	✓	✓	✓	7 (100)

Aim 2: Evaluation of the Impact of the *BeUpstanding* Program

Prior to *BeUpstanding*

At baseline, participants showed some awareness of the potential health effects of excessive sitting, with 170 (n=216) listing at least one impact, while 43 indicated that they were “not sure” of any health impacts and 3 stated there were no health impacts. Of the 170 participants who listed at least one impact (376 impacts in total), musculoskeletal effects were the most commonly identified (128/376, 34.0% of responses), followed by cardiometabolic (which included cardiovascular health, diabetes, and metabolism; 70/376, 18.6%), weight gain or obesity (60/376, 16.0%), other vascular issues (50/376, 13.3%), and fatigue or concentration (24/376, 6.4%). The diverse range of responses grouped as “other” (44/376, 11.7%) included impacts relating to cancer, stress, fatty liver, and digestion. All responses given were broadly plausible given the evidence, though some were nonspecific (eg, negative impact on health and wellbeing) or indirect (eg, loss of fitness).

Table 5 shows the average levels of each primary and secondary outcome among those participating in the baseline survey (n=212-218; baseline data from evaluable participants who participated in both surveys is presented in **Multimedia Appendix 1**). Prior to the intervention, on average, most workplace time was spent sitting (mean 78.6% [SD 15.7%]), while less time was spent standing (mean 11.6% [SD 12.5%]) or moving (ie, walking or engaging in heavy labor; mean 9.8% [SD 7.6%]). Furthermore, the reported accumulation of workplace sitting was consistent with sitting for long periods at a time, with an average of 71.1% (SD 20.2%) of sitting time reportedly accrued in a prolonged unbroken manner and with the longest period of continuous sitting over the last week averaging 138.1 (SD 62.2) minutes.

Table 4. Strategies chosen at the staff consultation workshops to Stand Up, Sit Less, and Move More.

Work team ^a and subteam	Strategies
Work team B	<ul style="list-style-type: none"> • Standing meetings • Walking teams • Removed extra chairs from champion's office • Stretching sessions • Encourage face-to-face meetings internally rather than just picking up the phone • Group activities for staff outside of work hours that encourage movement like bowling and mini golf
Work team C	
Subteam 1	<ul style="list-style-type: none"> • Centralized recycling bins • Outlook calendar reminder to stand every 30 min • Take the longer route
Subteam 2	<ul style="list-style-type: none"> • Outlook calendar reminder to stand every 30 min • Walk and talk • Use alternative printer that is further away
Subteam 3	<ul style="list-style-type: none"> • Standing phone calls and greetings • Drink more water • Active breaks away from desk
Subteam 4	<ul style="list-style-type: none"> • Outlook calendar reminder to stand every 30 min • Walk and talk • Drink more water
Subteam 5	<ul style="list-style-type: none"> • Standing phone calls • Centralized printer • Deliver and collect mail
Subteam 6	<ul style="list-style-type: none"> • Fill your own water bottle – take the long route • Walk and talk • Centralized printer
Work team D	
Subteam 1	<ul style="list-style-type: none"> • 11 am and 2:30 pm team stretch • Stand up when you hang up • Drink more water
Subteam 2	<ul style="list-style-type: none"> • Stand and stretch to welcome the last person in • Walk to talk to colleagues • Take breaks outside
Subteam 3	<ul style="list-style-type: none"> • Collect and deliver mail • Remove the mail trays • Rhythm and Blues Friday dance-offs
Work team F	<ul style="list-style-type: none"> • 10 at 10 – email every day to stand up and stretch at 10 am • Standing meetings • Stepathon
Work team G ^b	<ul style="list-style-type: none"> • Break up sitting every hour by doing squats, funny dances • Having a “wear your sneakers to work” day • At lunch, doing a 20-minute walk and 10 minutes of eating

^aThere were no specific staff-level strategies chosen by Workplace A or Workplace E.

^b30 strategies put forward: participants took part in the “strategy of the day” (listed on calendar). Strategies listed for this workteam showcases examples of “strategy of the day.”

Table 5. Baseline levels and changes in primary and secondary impact outcomes following *BeUpstanding*. Mean and SD corrected for clustering (linearized variance estimation) at baseline in baseline survey respondents and mean change (95% CI) and *P* values reported for difference from mixed models in, within those reporting outcome data and follow-up survey respondents (n=80-85 depending on the outcome).

Impact outcomes	Baseline (n=218)		Evaluable cases (n=85)		
	n ^a	Mean (SD)	n ^b	Change (95% CI)	<i>P</i> value
Work activity, % of work time					
Sitting	218	78.6 (15.7)	85	-6.27 (-10.08 to -2.46) ^c	.001 ^d
Standing	218	11.6 (12.5)	85	2.33 (-0.55 to 5.21)	.11
Moving ^e	218	9.8 (7.6)	85	3.94 (1.97 to 5.91) ^c	<.001 ^d
Walking	218	9.0 (6.6)	85	3.46 (1.54 to 5.38) ^c	<.001 ^d
Heavy labor	218	0.8 (3.0)	85	0.48 (-0.13 to 1.10)	.12
Work sitting accumulation					
Longest continuous sitting bout, min	218	138.1 (62.2)	85	-12.65 (-24.92 to -0.38) ^c	.04 ^d
Prolonged sitting, % of sitting	218	71.1 (20.2)	85	-8.74 (-14.14 to -3.34) ^c	.002 ^d
Before and after work activity, % of nonwork time (on work days)					
Sitting	218	47.2 (21.7)	85	-5.42 (-9.78 to -1.07) ^c	.02 ^d
Standing	218	18.1 (12.0)	85	0.46 (-2.33 to 3.25)	.75
Moving ^e	218	34.7 (18.4)	85	4.96 (1.08 to 8.85) ^c	.01 ^d
Nonworkday activity, % of nonwork time (on nonwork days)					
Sitting	218	39.9 (20.5)	85	-4.68 (-8.80 to -0.57) ^c	.03 ^d
Standing	218	17.7 (11.6)	85	1.14 (-1.26 to 3.55)	.35
Moving ^e	218	42.5 (18.9)	85	3.54 (-0.17 to 7.25) ^c	.06
Desired activity, % of work time					
Sitting	216	41.2 (19.0)	82	-0.06 (-3.20 to 3.08)	.97
Standing	216	28.2 (15.2)	82	2.17 (-1.60 to 5.94)	.26
Moving ^e	216	30.6 (17.0)	82	-2.11 (-5.80 to 1.58)	.26
Desired versus performed, absolute difference in % of time					
Sitting	216	37.7 (19.8)	82	-6.04 (-9.92 to -2.15) ^c	.002 ^d
Standing	216	18.2 (14.4)	82	0.70 (-3.15 to 4.54)	.72
Moving ^e	216	21.7 (16.8)	82	-5.66 (-9.32 to -2.00) ^c	.002 ^d
Other outcomes					
Strategy usage (% strategies used ≥ “sometimes”)	215	41.3 (13.7)	82	7.32 (3.74 to 10.89) ^c	<.001 ^d
Knowledge score, 1 point=5 min incorrect	216	5.53 (8.19)	81	-0.33 (-2.63 to 1.96)	.78
Control over sitting and standing (1-5)	216	2.94 (1.38)	82	0.06 (-0.21 to 0.33)	.66
Support (1-5)	216	3.40 (1.20)	82	0.16 (-0.09 to 0.40)	.21
Job performance (1-10)	212	7.74 (1.17)	80	-0.08 (-0.31 to 0.14)	.45
Job satisfaction (1-10)	212	7.10 (2.17)	80	-0.05 (-0.45 to 0.35)	.81
Self-rated health (1-5)	212	2.97 (1.02)	80	0.06 (-0.17 to 0.30)	.60
Energy (1-4)	212	2.40 (0.68)	80	0.13 (-0.03 to 0.28)	.11
Stress (1-4)	212	3.03 (0.78)	80	0.01 (-0.16 to 0.18)	.89

^aNumber of participants that completed the item on the baseline survey.

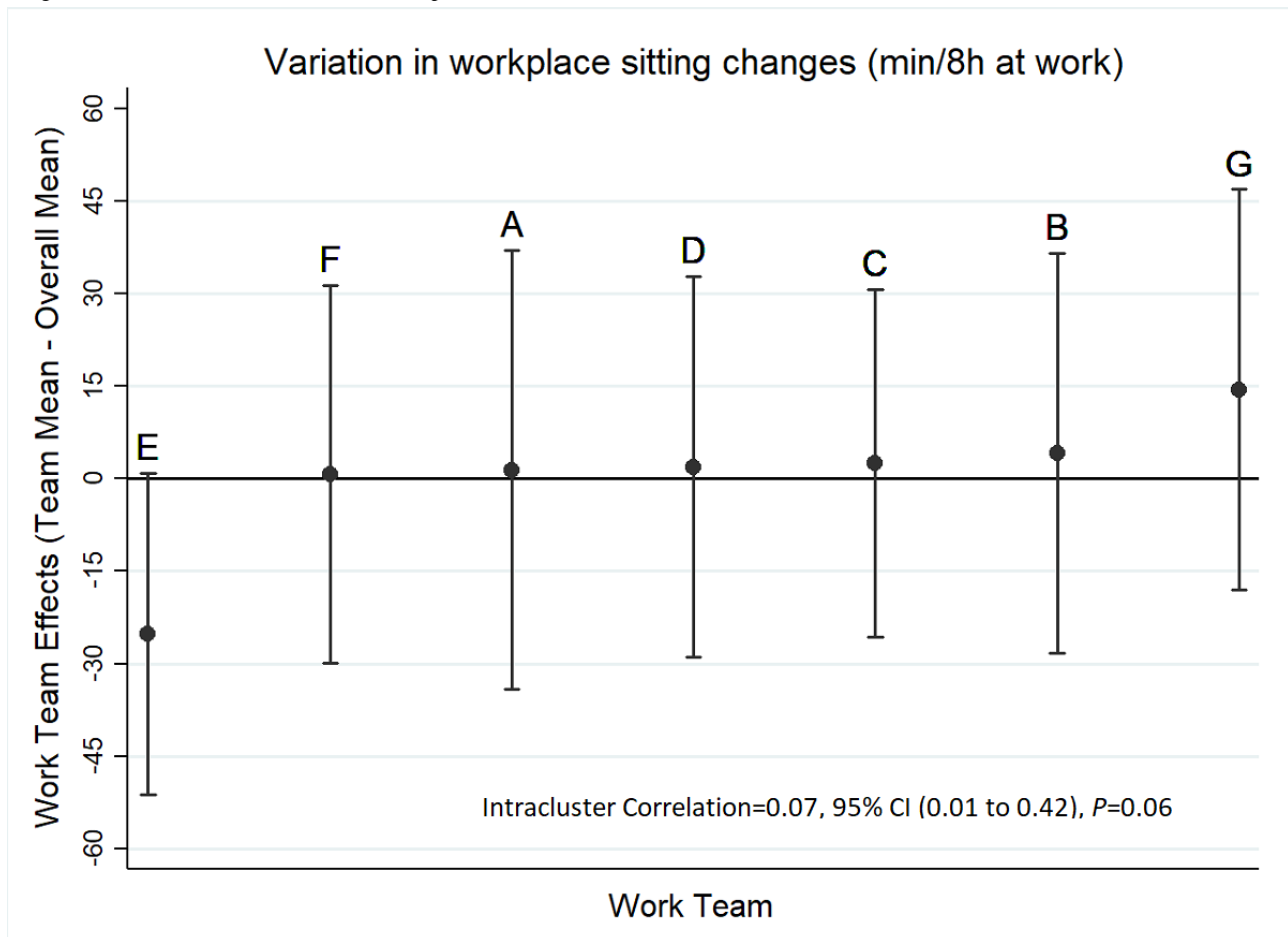
^bNumber of participants that completed the item on both surveys.

^cOutcomes had a notable change (\geq the minimum difference of interest).

^dMoving = walking + heavy labor.

^eOutcomes are statistically significant at $P < .05$.

Figure 2. Best unbiased linear predictions of work team effects on workplace sitting changes (n=85 workers; n=7 teams) estimated from mixed models adjusting for baseline values with a random intercept for team.



Time outside of work was also most commonly spent sitting (mean 47.2% [SD 21.7%] of time before and after work and mean 39.9% [SD 20.5%] of time on nonwork days). However, by contrast with workplace time, moving reportedly occupied more time than standing outside of work hours. There was a notable difference between reported workplace behavior and desired levels of activity, with desired behavior (on average) involving less sitting and more standing and moving. This is illustrated, separately for each workplace, in [Multimedia Appendix 2](#). When the difference between reported and desired sitting levels was considered at an individual level, 95% (205/216) of the staff wanted to sit less at work than they currently did.

The baseline survey results indicated that some of the potential impact outcome measures were more amenable to change compared with others, for which ceiling effects were a strong concern. On average, participants were using mean 41.1% (SD 13.7%) of the 13 activity-promoting strategies at least “sometimes” at baseline, leaving many strategies for participants to potentially adopt. In contrast, the mean levels of work performance and health indicators at baseline were typically well above midway on the scale on which they were measured, especially for stress and workplace support for reducing sitting.

Respectively, 30% (63/212) and 17% (37/216) of participants had reported optimal levels of these outcomes at baseline.

After BeUpstanding

Workplace Sitting (Primary Outcome)

Over the course of the *BeUpstanding* intervention, mean workplace sitting time reduced significantly ($P=.001$) and substantially (-6.3% , 95% CI -10.1 to 2.5) among workers reporting activity at both surveys (n=85). This reduction amounts to -30.1 minutes (95% CI -48.4 to -11.8) over an 8-hour workday. Even when accounting for all 315 participants of both surveys by multiple imputation, workplace sitting still reduced significantly over the intervention ($P=.02$), but by a smaller extent (-3.9% , 95% CI -7.3 to -0.5 or -18.8 minutes per 8-hour workday, 95% CI -35.1 to -2.6). There was some evidence that the average change in workplace sitting varied from workplace to workplace with the random intercept for workplace being borderline significant ($P=.06$) and a moderate to strong degree of clustering observed (intracluster correlation=0.07, 95% CI 0.01 to 0.42) (Figure 2). The best-performing work team (E) had a workplace sitting reduction that was better on average by approximately 30 minutes per 8 hours at work. The remaining workplace-specific mean changes were very similar to the

overall mean, with the largest deviation amounting to <15 minutes per 8 hours at work (Team G). Similar results were obtained even when accounting for the composition of each workplace in terms of worker age, sex, education, full-time equivalent, and job type (intracluster correlation=0.09, 95% CI 0.01 to 0.49, $P=.05$).

Secondary Outcomes

Changes in secondary outcomes are shown in [Table 5](#). Statistically significant changes (all improvements) were observed in workplace moving, workplace walking, both of the sitting accumulation measures, moving outside of work, sitting on nonwork days, the deviation between desired and performed sitting and moving at work, and usage of the activity-promoting strategies. All of these changes were of a notable magnitude (\geq MDI), or very nearly so in the case of sitting on nonwork days. Moving on nonwork days showed a notable improvement that did not reach statistical significance ($P=.06$). For the remaining nonsignificant activity-related outcomes, the 95% CIs indicated that substantial improvements were unlikely. The changes in activity outcomes indicated workplace sitting was primarily replaced with additional moving, specifically walking rather than heavy labor. This change resulted in there being a smaller gap between the behaviors participants reported performing and desiring, especially for sitting and moving. For those who completed both questionnaires, overall satisfaction with the program was high (80/86, 93% rated it $\geq 5/10$).

Use (at baseline and follow-up) and changes in the use of individual behavioral strategies are shown in [Multimedia Appendix 3](#). The strategies for which usage increased by >10% were as follows: “used an activity tracker/wearable device to track activity and/or sitting time” (+25.3%); “used prompts at my desk/around the office to remind me to stand up, sit less, move more” (+24.1%); “used the stairs instead of the lift” (+11.4%); and “stood up during a meeting” (+10.1%). The strategies most commonly used at least sometimes postintervention (partly due to high initial usage) were “walked to colleague rather than emailing/phoning” (97%); “ate my lunch away from my desk” (79%); and “went for a walk / did activity during the lunch break” (75%).

The average changes in the attitude, health, and work performance outcomes were both nonsignificant and very small. The observed change in self-reported energy levels (0.13, 95% CI -0.03 to 0.28) came the closest to a significant effect ($P=.11$), and at 0.18 SD fell just short of a “small” effect.

Intracluster correlations and responsiveness measures are reported in [Multimedia Appendix 4](#). Workplace clustering effects were often negligible (<0.001) but were very strong (≥ 0.1) for some of the outcomes, including gap scores for sitting and standing, and workplace support for sitting and standing. Responsiveness varied widely between the different outcomes. Both SESs and SRMs indicated that the most responsive of the activity outcomes were workplace activity (especially sitting, moving, and walking), while the percentage of sitting accrued in prolonged bouts was the most responsive sitting accumulation outcome. Strategy usage had a similar responsiveness as per the activity changes. Of the attitudinal measures, gap scores for sitting and moving were the most responsive, while support for

sitting and standing was the most responsive measure of job-related outcomes. Energy levels were the most responsive measure of health changes.

Discussion

Principal Findings

This study provides the first evidence of the feasibility of a sitting reduction intervention implemented by the workplace using a “train-the-champion” approach. The findings demonstrate that the beta (test) version of the *BeUpstanding Champion Toolkit* was feasible to implement by workplace champions. The impact findings from this pilot study also suggest that the adaptation of the *Stand Up Australia* intervention into its current, Web-based form (ie, *BeUpstanding*) was successful, as we saw significant, meaningful reductions in self-reported workplace sitting in staff who participated in the program evaluation.

A critical component for facilitating scale-up was the transfer of program delivery from the research team to a workplace champion, with support provided to the champion through a Web-based toolkit. The findings from this study suggest that this approach was successful, with the champions able to implement most or all of the intervention elements. Importantly, for scale-up, the time commitment required by the champions was relatively small, averaging 30-60 minutes per week across the study. The champions tended to be employed in job roles that facilitated conversations both up (to senior management) and down (to general staff). This ability to talk across levels has been previously identified as an important quality for workplace champions [39]. Additional research to identify and understand the key attributes of workplace champions will assist in providing guidance to organizations to inform their decisions on suitable candidates for the champion role.

All champions formed a wellbeing committee and involved members and work colleagues in the discussions of the strategies to promote increases in standing and moving more. Such support for the champion has been previously highlighted as key for helping maintain motivation for an initiative [39,40]. Notably, although the staff consultation workshop (and the associated collective decision on which strategies to implement as a team) is considered a core element of the program, one of the workplaces did not hold the workshop, 4 did not play the information video, and 2 did not choose any strategies as a team. These components (whose messages are then reinforced through the modifiable posters and email templates) are considered by the project team to be critical for raising awareness, building culture, and creating change (the 3 pillars of the *BeUpstanding* program). As such, an essential modification to the toolkit as part of the optimization process (Phase 3) will indicate the increased emphasis of the importance of the staff consultation session. Keeping track of implementation during the intervention and sending reminders to champions to complete critical steps will also be important.

Importantly, the toolkit enabled and empowered workers to choose and self-administer the changes that best suited their unique work team and environment, with a total of >30 different

strategies selected by the work teams as part of their staff consultation workshop. The strategies chosen ranged across the hierarchy of control [10] and included environmental adaptation (eg, centralizing bins), substitution of work task activities (eg, standing instead of sitting during phone calls), and administrative changes (eg, no lunch at desk). Notably, many of the strategies chosen were low-cost or no-cost to the organization or individual. However, although we know the strategies chosen by the work team, we do not know their uptake and utilization as the strategy usage measured in the staff survey did not capture the wide range of strategies chosen by work teams. Larger and longer term studies with associated data collection of usage will facilitate the examination of which strategies are the most effective and sustainable, noting that some of the more novelty-based strategies (such as “dance-offs”) may still have a key role in raising awareness and creating momentum for culture change.

At baseline, participants reported sitting for nearly 80% of their workday on average, and nearly all participants (95%) had a desire to sit less. This finding is in line with studies that have used objective measures of activity in similar populations [7] and highlights the importance of targeting the desk-based workplace to address high levels of sitting time. Following the intervention, average self-reported workplace sitting decreased by 6.3% in those who completed both surveys. Assuming an 8-hour workday, this equates to an approximately 30-minute reduction per day in workplace sitting time. Although the response rate and the fact that the data were self-reported should be taken into consideration when interpreting the data, the findings are consistent with those achieved when interventions have been led by external research teams [34,41,42]. Results from the multiple imputation analyses were attenuated (3.9%) but were still statistically significant.

Despite the variety of workplaces included, there was minimal evidence that any workplace “underperformed.” The workplace with the greatest change (workplace E; ≈ 30 minutes per 8-hour workday greater change than the average across all teams) had recently installed sit-stand desks for their staff, a factor that is likely to have contributed to their relatively larger sitting time reduction [17,42]. Interestingly, despite it being a workplace-delivered program, significant beneficial and meaningful impacts were also seen for out of work sitting and moving time. Although these findings are preliminary, they reinforce the potential of the workplace as a key setting for addressing sedentary behavior more broadly.

Importantly, there were significant reductions in the indicators of prolonged sitting time. Prolonged, unbroken sitting time detrimentally impacts both cardiometabolic [43] and musculoskeletal health [44]; consequently, much of the messaging within the *BeUpstanding* program emphasizes the importance of regular postural shifts (alternating between sitting, standing, and moving). Findings from this feasibility trial suggest that the *BeUpstanding* program is effective in achieving relatively frequent changes in posture. However, it should be noted that most participants did not achieve their preferred levels of workplace sitting, with the gap between desired and reported sitting time at $\approx 31\%$ on average at follow-up (compared with $\approx 37\%$ at baseline). Additionally, approximately half of the

participants did not agree that they had control over their sitting or standing. Such substantial changes, both in actual behavior and in perceived control, are unlikely to be achieved without associated system-level (eg, changes to work tasks and associated policies) and environmental-level (eg, incorporation of sit-stand workstations) supports, many of which are unlikely to be feasibly implemented within the short 3-month program timeframe. As part of the optimization process (Phase 3), the *BeUpstanding Champion Toolkit* will be revised to include more planning resources around longer term changes, and champions will be encouraged to repeat the program on an approximately annual basis, building on previous learning and successes. The revision will also include a sign-up page to recruit workplaces into the toolkit (access to the beta version was via a researcher-supplied login). Detailed evaluation of this process in the planned implementation trial (Phase 4) will be critical for informing the long-term success and large-scale dissemination of the program.

The health- and job-related outcomes did not change significantly following the *BeUpstanding* program. However, it is important to interpret these results cautiously in view of the study design and the survey response rates. The indices of responsiveness to change (SEs and SRMs) indicated limited responsiveness in all of the measures, due to both limited mean changes and high variability. The limited responsiveness could either be due to a genuine limited impact on these outcomes, measurement issues, or both. Notably, the phenomenon of ceiling effects was likely relevant to the limited change and may be an issue in any future implementation, with many outcomes having very favorable initial mean values with limited room to move. For example, 30% of participants had already reported the lowest possible stress level at baseline. While it is a common timeframe to assess behavior change, 3 months may not be a sufficient time to elicit measurable changes in health outcomes in this general worker population [45]; longer evaluations are needed. Concerning workplace performance, the lack of a sizable change beneficially or detrimentally was consistent with findings from systematic reviews [17,46]. Measurement may still be an issue, with the general measures used within the survey not tailored to workplace-specific tasks. Among the job- and health- related outcomes, the most promising indications of change concerned perceived support for sitting and standing, and self-reported energy levels; future evaluation with higher-quality measures is warranted. The use of performance and health indicator data routinely collected by the organization (eg, absenteeism rates, compensation claims, and employee engagement) may allow for a more robust evaluation of the impact of the *BeUpstanding* program, in both short and long term. Collaborating with workplaces to access such information and including business-relevant key performance indicators within the evaluation, will be important in helping to assess the business case for sitting reduction interventions such as *BeUpstanding*.

Strengths and Limitations

A key strength of this study was the generation of practice-based evidence that will be used to inform the future optimization of the toolkit for wide-scale implementation. The work teams were purposively sampled, which provided input from a range of

sectors, organizational sizes, and team locations. The sample was diverse in many regards but not necessarily representative, so generalizability is still a concern. For example, the sample was highly educated, had high baseline knowledge of the detrimental health impacts of excessive sitting, and predominantly had management responsibilities. Data were all self-reported, and response rates at follow-up were low, particularly for some work teams. This limits the quality of evidence gathered in the impact evaluation to corroborate the initial rigorous evaluation of the intervention prior to its adaptation into the Web-based *BeUpstanding* toolkit. Although this response rate is not untypical for this stage of research [47], future adaptations need to consider means of further engaging workers in the intervention. Technological advances mean that there are exciting opportunities for more regular and objective data capture options, such as through mobile phone platforms (eg, ResearchKit.org), or wearable activity tracker platforms (eg, Fitabase.com). These might help with both data collection and engagement. Further, data on any adverse impacts of the program were not collected as part of the staff survey, and detrimental impacts may have been missed.

Conclusions

In summary, our findings indicate that this beta version of the *BeUpstanding Champion Toolkit* was feasible to implement using a “train-the-champion” approach and that the *BeUpstanding* program was effective in reducing prolonged workplace sitting and changing workplace practices without significantly or substantially detrimentally impacting the indicators of work performance. Besides significantly advancing the evidence base and providing proof of concept to inform larger implementation trials, this study has also begun to capture the practice-based evidence needed to inform ongoing, sustainable success. In addition to understanding how the program was implemented along with its impact, it is also important to know the acceptability of the program and champion and staff perceptions of the program, including facilitators and barriers to implementation. This, along with feedback regarding how the toolkit could be improved, will be used to inform the optimization of the toolkit to facilitate wide-scale uptake and implementation.

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Conflicts of Interest

None.

Multimedia Appendix 1

Baseline levels of the primary and secondary outcomes of the evaluable cases (n=85).

[\[PDF File \(Adobe PDF File\), 27KB - formative_v2i2e17_app1.pdf \]](#)

Multimedia Appendix 2

Mean of actual activity (a) and desired activity (b) at baseline within each workplace (n=216).

[\[PDF File \(Adobe PDF File\), 28KB - formative_v2i2e17_app2.pdf \]](#)

Multimedia Appendix 3

Strategies to sit less and move more at work that were used at least “sometimes.”

[\[PDF File \(Adobe PDF File\), 29KB - formative_v2i2e17_app3.pdf \]](#)

Multimedia Appendix 4

Intracluster correlation for change in primary and secondary outcomes and responsiveness measures.

[\[PDF File \(Adobe PDF File\), 29KB - formative_v2i2e17_app4.pdf \]](#)

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Abbreviations

- MDI:** minimum differences of interest
MVPA: moderate-to-vigorous physical activity
SES: standardized effect size
SRM: standardized response mean

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Original Paper

Conversation Within a Facebook Smoking Cessation Intervention Trial For Young Adults (Tobacco Status Project): Qualitative Analysis

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Abstract

Background: Smoking cessation interventions delivered through social media have the potential to engage young people in behavior change.

Objective: The aim of this study was to describe participant-posted messages in a Facebook smoking cessation intervention for young adults to discern support for behavior change.

Methods: We qualitatively analyzed data from the treatment arm of a randomized trial testing the efficacy of the Tobacco Status Project Facebook intervention. Young adults (N=138) aged 18-25 years (female: 81/138, 58.7%; white: 101/138, 73.2%; mean age 21 years) were recruited using Facebook and placed into one of the 15 secret Facebook groups based on readiness-to-quit smoking. Messages posted to groups for 90 consecutive days were tailored to readiness-to-quit: Not Ready (46/138, 33.3%), Thinking (66/138, 47.8%), and Getting Ready (26/138, 18.8%). Groups were randomized to receive up to US \$90 for posting or no incentive. Two independent coders conducted open coding of user posts. We considered content by readiness-to-quit group and incentive condition.

Results: There were 4 dominant themes across all groups: coping skills, friends and family, motivation to quit, and benefits of quitting. The dominant themes in Not Ready groups were friends and family (incentive) and motivation to quit (no incentive), whereas coping skills was the dominant theme in Thinking and Getting Ready groups. The expression of themes varied by readiness-to-quit group but not by incentive condition.

Conclusions: Intervention messages tailored to readiness-to-quit appear useful in eliciting the desired responses from young adult smokers, with limited influence by monetary incentive.

Trial Registration: ClinicalTrials.gov NCT02207036; <https://clinicaltrials.gov/ct2/show/NCT02207036> (Archived by WebCite at <http://www.webcitation.org/722XAEAAz>)

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KEYWORDS

Facebook; intervention; qualitative analysis; smoking cessation; social media; young adults

Introduction

Nearly all smokers (98%) begin smoking in adolescence and young adulthood (before the age of 26 years) [1]. Despite being just as motivated to quit as other adults and the wide availability of evidence-based smoking cessation interventions including quit lines, counseling, and medication, young adults are less likely to use these strategies to quit smoking than adults of other ages [1-4]. While emerging evidence shows that Web-based smoking cessation interventions have high user satisfaction and are effective for adults [5-7], among younger adults' adherence to and engagement in online smoking cessation interventions remains low [8-11]. Still, with extremely wide use among young adults (88% of Americans aged 18-29 years in 2016) [12], Facebook may serve as an engaging tool, with broad reach, to deliver evidence-based smoking cessation interventions to this population.

Most research analyzing the content of digital interventions for smoking cessation has focused on quantitative analyses of data from online cessation communities (eg, volume or timing of posting). Across cross-sectional and longitudinal studies, participant engagement with digital interventions is associated with and predictive of smoking cessation [7,13-18]. Online smoking cessation communities have also been evaluated using social network analysis, a tool that helps describe the patterns of social relationships that form between groups and individuals [19]. Social network analysis revealed that the online smoking cessation community QuitNet has the characteristics necessary to sustain the support and promotion of cessation and that Facebook interactions were centralized, with a small number of users ("superusers") leading the communications [20] and that demographic characteristics and posting behavior were similar across free public and private Web-assisted smoking cessation communities [20,21].

There is a smaller literature using qualitative methods to analyze the content of online and social media-based smoking cessation interventions. Computer-driven techniques (eg, latent Dirichlet allocation, correlated topic modeling) have been used to analyze social media data and offer advantages over human coding in analyzing large datasets [22,23]. One report identified concepts and themes in peer-to-peer messages on QuitNet to discern which themes were associated with abstinence. Investigators identified 12 themes comprising 43 concepts and found that abstinence was associated with interpersonal themes such as social support and cessation progress [24]. Another study described the content of "first-posts" by members of StopSmokingCenter.net to determine what content garnered a response-post and found that *problems with quit attempts* received a response the most often [25]. A study using framework analysis to characterize the content of posts to the Facebook page of Crush the Crave, an intervention aimed at young adults, found that the main purpose of participant posts was cessation support and identified 7 subthemes: management of cravings, promoting social support, denormalizing smoking, providing health information, encouraging cessation, exposing tobacco industry tactics, and group stimulation [26].

By facilitating change talk and conversations about change and abstinence, social media-based cessation interventions have the potential to support the change process; however, it is not yet understood if this is so. Nevertheless, the text-based nature of social media interventions offers a unique opportunity to characterize the representations of smoking and the change process across the stages of change. Our group developed the *Tobacco Status Project* (TSP) smoking cessation intervention delivered entirely through Facebook. Results from the randomized controlled trial (RCT) evaluating TSP showed significantly greater biochemically verified abstinence from smoking at treatment end in those who received the intervention (8.3%) than in those who received referral to the National Cancer Institute Smokefree.gov website: 3.2%, odds ratio 2.52 (95% CI 1.56-4.04), $P<.001$ [27]. There were no 12-month treatment effects for reported abstinence ($P=.74$), reduction in smoking by $\geq 50\%$ ($P=.53$), likelihood of having made a quit attempt ($P=.39$), or stage of change over time ($P=.97$); retention was 71%. Participants in TSP engaged more and rated the intervention more favorably than those in the control condition.

Until now, there have been no qualitative reports on the content of participant posts in smoking cessation interventions embedded entirely within social media (ie, Facebook) and findings could be used to maximize the effectiveness of intervention messages within the context of social media smoking cessation interventions. In this study, we examined the overall content of participant-generated posts from the RCT testing the effectiveness of TSP and identified recurrent themes within the 3 readiness-to-quit groups and across the incentive condition. We have used specific quotes to illustrate the nature of frequent themes in each group.

Methods

Participants and Procedures

Data derived from the treatment arm of an RCT testing the efficacy of TSP is described elsewhere [27,28]. Young adults aged 18-25 years, residing in the United States, who had smoked ≥ 100 lifetime cigarettes, and who smoked ≥ 3 cigarettes per week were eligible and were recruited using Facebook ads [27]. Informed consent to participate was obtained online through the study website. Three multiple choice questions confirmed the understanding of study risks; identity was verified by email or social media; and then the online baseline assessment link was emailed [27,28]. Participants were randomized to either the treatment condition (TSP) or the control condition (referral to the National Cancer Institute Smokefree.gov website). Within the TSP condition, participants were assigned to a private Facebook group based on and tailored to their readiness-to-quit smoking at enrollment (precontemplation: "Not Ready"; contemplation: "Thinking"; preparation: "Getting Ready"); participants were assessed using the *Stages of Change Questionnaire* [28]. Groups began on a rolling basis starting when the first participant had been waiting no longer than 2 weeks; thus, group size varied. Groups were open for the duration of the trial (12 months), although content was only generated by the study team for the first 3 months.

Table 1. Study sample characteristics (N=138) from Tobacco Status Project, a smoking cessation intervention delivered entirely through Facebook.

Characteristic	Value
Male, n (%)	57 (41.3)
Age (years), mean (SD)	20.8 (1.9)
Hispanic, n (%)	8 (5.8)
Race, n (%)	
White	101 (73.2)
More than one race	20 (14.5)
Black	5 (3.6)
Native American	1 (0.7)
Asian	1 (0.7)
Other	10 (7.2)
Region, n (%)	
West	38 (27.7)
South	52 (38.0)
Midwest	32 (23.4)
Northeast	15 (10.9)
Annual household income, n (%)	
≤\$40,000	94 (68.1)
\$41,000 - \$80,000	28 (20.3)
\$81,000 - \$200,000	15 (10.8)
Currently in school (full time or part time)	42 (30.5)
Currently employed (full time or part time)	89 (53.5)
Smoking characteristics	
Are you a social smoker? (yes), n (%)	101 (73.2)
Daily smoker, n (%)	121 (87.7)
Fägerstrom Test For Nicotine Dependence, mean (SD)	2.9 (2.1)
Number of years smoked, mean (SD)	2.8 (0.6)
Cigarettes smoked per day, mean (SD)	10.4 (6.3)
Readiness-to-quit group, n (%)	
Not ready to quit	46 (33.3)
Thinking about quitting	66 (47.8)
Getting ready to quit	26 (18.8)
Past month marijuana use (yes)	59 (42.8)
Past month hookah use	33 (23.9)
Past month vape or e-cigarette or e-hookah use	69 (50.0)

At the group level, participants were randomized to receive a monetary incentive (daily, weekly, or monthly) for commenting on intervention Facebook posts (up to \$90) or no incentive. The participant pool for this study included all participants assigned to receive no incentive and those assigned to receive a monthly incentive (N=138), and the majority were white (102/138, 74.0%) and female (84/138, 60.0%; see [Table 1](#) for detailed demographics and smoking characteristics).

Participants received 90 consecutive daily intervention posts (see [Multimedia Appendix 1](#) for sample intervention posts) and “live” weekly one-hour counseling sessions during which a counselor, using Facebook commenting features, could answer participant questions in real time; and for those in the preparation stage of change at baseline, 7 state-of-the-art group cognitive-behavioral sessions were delivered through private Facebook groups. Intervention posts, including textual content, were designed and agreed upon before the study launch; dispatch of these posts was automated throughout the intervention

according to the schedule. Trained intervention staff monitored the groups daily for any inappropriate content in responses to intervention posts. Additionally, doctoral-level trained smoking cessation counselors facilitated live weekly counseling sessions. Participants remained in the same group throughout the 3-month intervention. Daily posts employed the aspects of motivational interviewing, cognitive behavioral therapy coping skills, and the transtheoretical model (TTM) [29-31]. Posts to Not Ready groups were designed to enhance motivation and the importance of quitting, as well as to identify problems related to smoking. Posts to Thinking groups emphasized challenging the cons to change, the benefits of quitting, and TTM processes of change including consciousness-raising (learning new facts, ideas, and tips that support the behavior change), and making a small commitment to change. Posts to Getting Ready groups provided strategies for long-term smoking cessation together with making a commitment to quit, including setting a quit date and making a detailed plan for quitting, removing smoking paraphernalia from the home, and engaging in alternative behaviors. All posts included an image with text designed to elicit a response from participants (Multimedia Appendix 1).

Analysis

First, data were downloaded from the Facebook app program interface, which was accomplished using “tools” from Facebook’s API Explorer. Data extraction included use of Facebook “access tokens,” which allowed study personnel to extract textual data from selected fields (all fields containing textual data were selected) within each group. Next, these data were provided to coders in a spreadsheet form with columns representing chosen fields. Next, two coders independently identified themes in transcripts using inductive or “open” coding. Open coding is data driven, that is, codes are based in the data (a “bottom-up” approach) rather than a theory-driven (“top-down”) one [32]. Investigators met after each transcript was coded to compare themes, resolve any discrepancies, and refine codes or themes. When it was agreed that thematic saturation had been reached (no emergent codes), a codebook containing identified codes was agreed upon.

Thematic analysis [33] was conducted first among all data then by readiness-to-quit group and incentive condition. Thematic “prevalence” (defined as the number of posts containing a particular theme) was calculated to account for differences in group size (number of participants) to identify and interpret dominant themes. Themes were described and patterns of themes within the data were examined and summarized to interpret their broader meanings and associated implications. All analyses were performed using Dedoose version 7.5.14 (SocioCultural Research Consultants, Los Angeles, CA, US) or Excel 2013 (Microsoft Corporation, Redmond, WA, US) [34].

Results

Findings

The 35 themes common to all groups are represented in [Textbox 1](#). Four themes were most prevalent (“dominant themes”) across

all readiness-to-quit groups and incentive conditions: (1) coping; (2) friends and family; (3) motivation; and (4) benefits of quitting. Within each readiness-to-quit group, differences in the frequency of themes varied negligibly by the incentive condition ([Figure 1](#)). The dominant themes in the Not Ready groups were friends and family in the incentive condition and motivation in the no incentive condition. The dominant theme for Thinking and Getting Ready groups was coping across incentive conditions. An examination of theme content across incentive conditions in all groups showed little variation by incentive, and thus, expression of codes was interpreted by theme and readiness-to-quit, rather than by incentive.

In response to any intervention content, 2517 posts ($\mu=503$) were made in the Not Ready groups, 1687 in the Thinking groups ($\mu=281$), and 1943 in the Getting Ready groups ($\mu=486$), totaling 6147 comments with a mean of 423 comments per group. The average number of comments did not differ between the Not Ready and Getting Ready groups (independent sample $t_7=0.15$, $P=.89$), Not Ready and Thinking groups ($t_9=1.56$, $P=.15$), and Getting Ready and Thinking groups ($t_8=1.37$, $P=.21$). Likewise, the average number of comments did not differ by incentive condition within Not Ready groups ($t_3=1.06$, $P=.37$), Thinking groups ($t_4=0.09$, $P=.93$), and Getting Ready groups ($t_2=0.88$, $P=.47$).

Coping

Not Ready

Posts coded as coping were ambivalent:

I enjoy walking, and watching movies or episodes of my favorite TV shows. But unfortunately as much as I enjoy those things, I don't see them holding my interest... [Male, 20 years]

They were often pessimistic:

I can't think of something that would help me, except eating. [Female, 22 years]

Posts containing outlandish suggestions were not uncommon:

Go climb a mountain! [Female, 22 years]

Still, participants were able to name activities that could help them cope with smoking triggers and support quitting, as well as ways in which they currently cope with the drawbacks of smoking:

I like the extending time [between cigarettes] idea a lot... [Male, 20 years]

I wear a separate shirt to smoke in... [Male, 20 years]

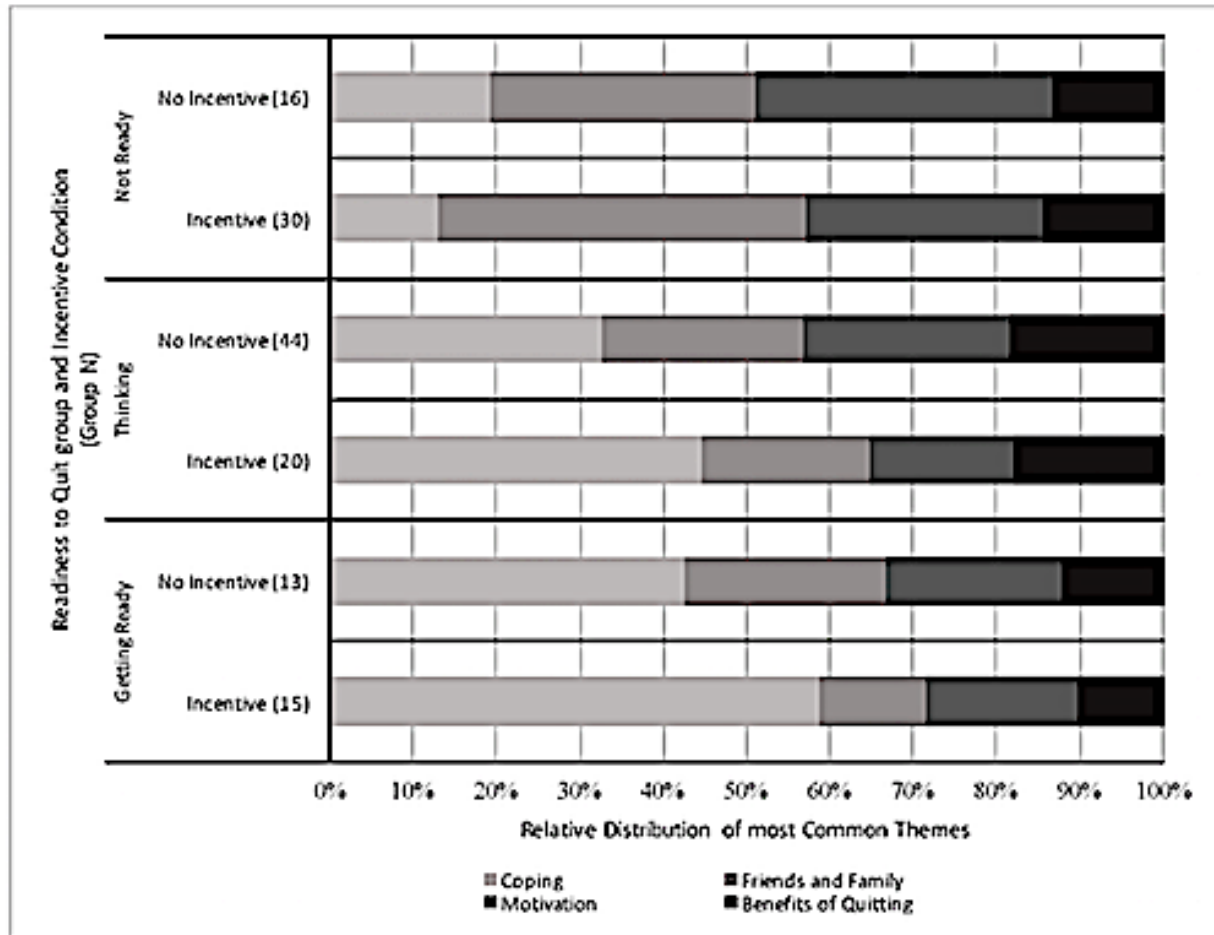
At the same time, participants of the Not Ready groups directly negated the potential of coping strategies to be effective and the necessity of current strategies:

I've tried breathing exercises but none seem to be as instant as smoking... [Male, 20 years]

Sometimes I spray perfume, but I usually don't care... [Female, 18 years]

Textbox 1. The top 35 themes identified in the Tobacco Status Project.

1. Alcohol
2. Big tobacco
3. Co-use
4. Cold turkey
5. Coping
6. Dependence
7. Dissonance
8. Drawbacks
9. Feedback
10. Flavors
11. Friends and family
12. History
13. Identification
14. Initiation
15. Media
16. Medication
17. Money
18. Motivation
19. Movies
20. Nicotine replacement therapy
21. Obstacles
22. Progress
23. Quit Benefits
24. Quit history
25. Secondhand smoke
26. Self-efficacy
27. Smoke-free policy
28. Smoker persona
29. Smoking benefits
30. Smoking legislation
31. Smoking norms
32. Social support
33. Teachable moments
34. Triggers
35. Vape

Figure 1. Dominant themes by readiness-to-quit group and incentive conditions from the Tobacco Status Project.

Thinking

Posts among participants in the Thinking groups mostly shared coping strategies that they had experience with and that worked for them:

Keeping hands busy, or keeping a tooth pick in my mouth helps. Also keeping something in my hand, like a cup of coffee or tea also helps... [Male, 22 years]

Most the time when I was stressed I was just over thinking things so I just took a step bak [sic] n [sic] took a deep breath... [female, 23 years]

Participant posts also revealed willingness to try strategies in the future:

I would choose to be more active and start jogging/running daily... [Male, 19 years]

Posts generally had a supportive tone when making suggestions (on how to cope when quitting) to the group:

Get up and do something active and because it takes my mind to a different place then [sic] smoking... [Female, 24 years]

Fill your free time with activities such as learning a new skill. Its [sic] hard to think about smoking when you're immersed in concentration. [Male, 19 years]

Getting Ready

Coping-coded posts for this group were rooted in the present insofar as participants posted predominantly about what they are doing:

Keeping them [cigarettes] all the way in my car really helps because I am really lazy lol... [Female, 22 years]

I workout [sic] for half an hour and run two miles every day :)... [Male, 19 years]

Posts were generally upbeat and often humorous:

Walk with two drinks in my hand. Can't hold a cigarette if your [sic] holding two drinks right?! [Male, 21 years]

Go to my other addiction, the internet lol... [Male, 24 years]

Friends and Family

Not Ready

Friends and family coded posts indicated friends and family were seen as either supportive of participants' quitting or indifferent to participants' smoking:

My sister tells me she doesn't want me to die... [Female, 19 years]

They don't really say anything about it... [Female, 21 years]

At the same time, participants indicated the potential of friends and family members as motivation to quit, and posts coded “friends and family” were more often than not coded also with “motivation”:

I can quit I just really dont want to unless my girlfriend gets pregnant... [Male, 20 years]

Thinking

Posts coded as friends and family in the Thinking groups typically referred to friends and family members as people harmed by participants’ smoking or who may suffer as they quit smoking:

I think of my housemates and friends, whom I constantly smoke around. I always feel guilty when someone talks about secondhand smoke... [Male, 19 years]

I'm worried about being mean to those I love. [Male, 19 years]

A less-common yet consistent concern posted about was how to deal with the smokers in their lives:

I think it will be hard to hang out with a lot of my friends who smoke after I quit. A majority of my friends smoke so it might be difficult to get away from other people smoking... [Male, 21 years]

Posts generally reflected ambivalence, consistent with “contemplating” quitting.

Getting Ready

For this group, most posts reflected the doubt participants perceived among their friends and family:

My support system was excited, skeptical but happy that I'll be quitting. [Female, 25 years]

A few said I won't quit and it won't last. [Male, 21 years]

They don't believe me lol... [Female, 18 years]

The remaining posts within this theme were mainly pragmatic—both when alluding to support and hindrance:

Luckily, im [sic] very close to family, so I will very likely go to my sisters [sic] or brothers [sic] for...support... [Male, 20 years]

My girlfriend hasn't helped much considering she asks me if I wanna [sic] smoke one when she gets home everyday [sic]. [Male, 21 years]

In addition to being pragmatic, posts reflected “when” participants would quit, not “if.”

Motivation

Not Ready

Posts that coded motivation in the Not Ready groups were generally dual-coded with “friends and family.” Posts reiterated participants’ unwillingness to quit while citing friends and family or other things outside themselves that could be motivating in the future:

It's not really important to me right now, but it's a 10 [on a scale of 1 to 10] to quit before I have children... [Female, 21 years]

Although some posts were solely about participants’ (lack of) motivation:

Well we all die in the end. Smokers and non smokers [sic]. Morbid, I know but. [sic] #sorryboutit... [Male, 22 years]

Thinking

Most posts that coded motivation in the Thinking groups referred to future or external motivations to quit. Saving money and health were common motivations to quit smoking:

I'd only like to quit for the financial benefits really... [Male, 21 years]

It's a horrible habit and I want to quit. For health reasons alone! [Female, 23 years]

Secondarily, benefit to family (including pets) and friends was cited as motivation to quit:

My dogs honestly! Lol everyone in this house smokes except them, and they can't exactly crack the window now can they? [Female, 23 years]

I think about my friends that don't smoke and my little cousins. [Female, 23 years]

Posts often included ≥ 2 of these ideas:

More money, better health... [Male, 21 years]

I would definitely have more money to buy other things that are needed like planning [sic] my little girls [sic] first birthday and helping my husband see the importance of quitting for her and our health reasons... [Female, 21 years]

Getting Ready

Motivation-coded posts for Getting Ready groups were emphatic and predominantly self-focused:

I want to be able to run faster for longer. I want to be dependent on nothing. I want to make my Dad proud. [Male, 20 years]

My lung capacity. Not coughing up stuff. [Male, 21 years]

...then I coughed up blood. Nope. [Male, 19 years]

I've been going to the gym 3 times a week! [Male, 24 years]

Participants’ health was the unifying thread here:

My health. My health. My health. [Female, 22 years]

Benefits of Quitting

Not Ready

Most posts specified health or monetary benefits associated with quitting and were future-focused, yet some had a skeptical tone:

I could swim again. Without DYING... [Male, 22 years]

Probably be healthier. Feel better throughout my day.

[Male, 18 years]

Many of these posts referenced participants' image, particularly with regard to smelling like smoke:

I won't smell "icky"... [Male, 20 years]

Other than the occasional use of "would", posts were devoid of language indicating participants thought for certain that their health (or sport or recreational activity performance, voice, sensory perceptions) would improve with quitting smoking:

My teeth would look better and I would have more money... [Female, 21 years]

And chances are you'd be able to smell smoke a lot easier... [Female, 21 years]

Thinking

Benefits of quitting posts revealed that participants in this group were looking most forward to being free from (nicotine) dependency or withdrawals, breathing easier, and having more money. All posts coded with benefits of quitting for the Thinking groups listed >1 benefit:

I would be able to breath [sic] better, do more activities because I can breath better and I would save a lot of money every year... [Female, 23 years]

Best case senario [sic], better health, no taking time away from work or hanging out to go smoke, more money, less debt, freedom... [Female, 23 years]

I would lose dependency on an item when I'm stressed or hurt and could actually face what was causing those feelings right away. And I would save so much money. [Female, 18 years]

Generally, these posts were optimistic and enthusiastic:

Everything will be better! My teeth, my breathing, my health in general, my wallet, and just feeling great about myself knowing that nicotine doesn't control me anymore!!! [Female, 19 years]

Getting Ready

Benefits-coded posts in the Getting Ready groups had a sense of impending liberation and referred to improved health and demeanor:

I will definitely feel my stamina come back when i [sic] quit. I love to run and play soccer. [Male, 20 years]

No smoke smell on my clothes. [Female, 22 years]

Saving money and my health having better self-discipline and not giving into an unhealthy coping mechanism [sic] ...Working out and not dying... [Female, 20 years]

Participants had a tendency to incorporate comparisons of their current self-image with images after quitting:

Freedom, I won't smell, more energy, won't be SOB... [Female, 25 years]

...being able to breathe better! i [sic] get winded so easily... [Female, 22 years]

Discussion

Principal Findings

To begin to understand how social media-based interventions may support behavior change (ie, quitting smoking), we examined the content and volume of participant posts from TSP, a smoking cessation intervention for young adults delivered entirely through Facebook. We identified dominant themes throughout by readiness-to-quit group and by monetary incentive for engagement. There were slight variations in the content expressed in groups across readiness-to-quit and incentive conditions, and young adult smokers were most likely to post content related to motivation to quit, coping strategies, exploring relationships with friends and family members in the context of quitting, and exploring the benefits of cessation in all groups. These topics are consistent with the overall intention of the TSP intervention to enhance motivation, support change talk, and promote the use of coping strategies for cessation.

While all 3 readiness-to-quit groups across incentive conditions had the same 4 dominant themes, how these themes manifested in each group was quite different. Consistent with stage-matched intervention theory and the tailored content within intervention posts, participant posts in the Not Ready groups were related to raising doubt about continuing to smoke and enhancing motivation through values evaluation. In more motivated groups, participant posts were more focused on strategies for coping with quitting (eg, changing behaviors to ameliorate effects of withdrawal) and less on motivation. Findings show that participant behavior in the context of private social media groups is consistent with the intent of in-person smoking cessation interventions tailored to readiness-to-quit smoking and support online delivery of such tailored interventions.

Across incentive conditions and themes, those in Not Ready groups reiterated their unwillingness to quit smoking now. Posts in the Not Ready groups consistently contained qualifier words such as "if," "but," "might," "maybe," and "sometimes" when responding to intervention posts suggesting possible ways to change their smoking behavior. This is consistent with a hesitant stance favoring no change and speaks about the importance of using motivational interviewing techniques such as expressing empathy and rolling with resistance, even in the context of social media posts [35]. The posts with content coded "family and friends" also typically contained content coded "motivation" in the Not Ready groups, which contextually suggested that focusing on family and friends may function as a barrier to change for participants not ready to quit. Content emphasizing the availability of social support through a social media smoking cessation intervention may be particularly effective for this group [36].

While participants in the Thinking groups shared their experiences of past quit attempts and indicated in their posts that they would be willing to try new behaviors, posts for this group had an ambivalent tone overall. Indeed, it is this ambivalence that can keep individuals stuck in this stage for long periods of time [37]. Furthermore, just as these participants posted about how they felt smoking had affected the people in their lives, they tended to focus on how quitting could benefit

these people (versus themselves). This external focus could also be an indication that smokers in contemplation have yet to internalize the benefits of quitting for themselves [38]. Still, many Thinking posts referred to participants' wish to be free from nicotine dependence; targeting this group with messaging focused on freedom from addiction could aid in moving them toward action (quitting).

Posts in the Getting Ready groups were emphatic and permeated by levity. For example, posts evidenced doubt among participants' social groups that they would be successful in quitting. These misgivings were addressed pragmatically and with humor by participants and seemed to have motivated rather than discouraged participants in their efforts to quit. Furthermore, posts indicated that participants were internally focused: they described actions they were already taking and posted about how better they felt and how they would feel upon successfully quitting, indicating perceived self-efficacy, which is a necessary component of successful behavior change [37-39]. The usefulness of tailored TSP posts to this group is exemplified by participants' drive to stay the course of abstinence to achieve freedom from dependence. Employing the same or similar messaging in future social media interventions for young adults is warranted.

There were only negligible differences in dominant themes between incentive conditions, suggesting that the content was not altered by the presence of a monetary incentive tied to engagement. This finding supports the literature suggesting that incentives do not undermine participants' intrinsic motivation to change health behaviors; unlike other behaviors, which have shown an undermining effect of incentives [40]. In the TSP-evaluating RCT, incentives were found to be related to

comment volume in contemplation ($\chi^2=14.59$, $df=2$, $P=.002$) and preparation ($\chi^2=9.95$, $df=2$, $P=.02$) but not precontemplation ($\chi^2=6.80$, $df=2$, $P=.08$), suggesting that there is some promise for using monetary incentive to increase the number of participant posts in social media-based smoking cessation trials without an associated impact on quality [27]. Limited differences in the expression of common themes in Not Ready and Thinking groups suggest that content could potentially be merged in future interventions.

Limitations

The themes identified in participant comments were guided in part by the content of the posts themselves. However, given the nascent literature on behavior in social media intervention, it was not clear whether the content would be germane to the intervention. Participant posts from The Doctor Is In sessions were not investigated independently of daily intervention posts. The results of our analysis of data from a Facebook intervention for young adult smokers may not generalize to other social media platforms (eg, Instagram), user profiles (eg, older adults), or health risk behaviors.

Conclusions

Overall, tailored messaging delivered through a social media smoking cessation intervention appears to support content reflective of the theories driving the intervention across all stages. As social media continues to be a resource for engaging young adults in healthy behavior change, qualitative analyses can inform treatment targets and show that tailoring interventions to readiness to change is likely an ideal strategy for enhancing motivation and supporting behavior change.

Conflicts of Interest

DR has consulted with Carrot Sense, which makes a tobacco cessation device. KM has no conflicts of interest.

Multimedia Appendix 1

Sample intervention and participant posts from each of the four most common themes across readiness-to-quit groups in the Tobacco Status Project.

[PDF File (Adobe PDF File), 4MB - [formative_v2i2e11138_app1.pdf](#)]

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Abbreviations

- TSP:** Tobacco Status Project
TTM: transtheoretical Model
RCT: randomized controlled trial

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Original Paper

A Stress Management App Intervention for Cancer Survivors: Design, Development, and Usability Testing

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Abstract

Background: Distress is prevalent in cancer survivors. Stress management interventions can reduce distress and improve quality of life for cancer patients, but many people with cancer are unfortunately not offered or able to attend such in-person stress management interventions.

Objective: The objective of this study was to develop an evidence-based stress management intervention for patients living with cancer that can be delivered electronically with wide reach and dissemination. This paper describes the design and development process of a technology-based stress management intervention for cancer survivors, including the exploration phase, intervention content development, iterative software development (including design, development, and formative evaluation of low- and high-level prototypes), and security and privacy considerations.

Methods: Design and development processes were iterative and performed in close collaboration with key stakeholders (N=48). In the exploration phase, identifying needs and requirements for the intervention, 28 participants gave input, including male and female cancer survivors (n=11) representing a wide age range (31-81 years) and cancer diagnoses, healthcare providers (n=8) including psychosocial oncology experts, and eHealth experts (n=9) including information technology design and developers. To ensure user involvement in each phase various user-centered design and service design methods were included, such as interviews, usability testing, and think aloud processes. Overall, participants were involved usability testing in the software development and formative evaluation phase, including cancer survivors (n=6), healthy volunteers (n=7), health care providers (n=2), and eHealth experts (n=5). Intervention content was developed by stress management experts based on well-known cognitive behavioral stress management strategies and adjusted to electronic format through multiple iterations with stakeholders. Privacy and security issues were considered throughout.

Results: The design and development process identified a variety of stakeholder requirements. Cancer survivors preferred stress management through a mobile app rather than through a personal computer (PC) and identified usefulness, easy access, user friendliness, use of easily understandable language, and many brief sections rather than longer ones as important components of the intervention. These requirements were also supported by recommendations from health care providers and eHealth experts. The final intervention was named *StressProffen* and the hospital Privacy and Security Protection Committee was part of the final intervention approval to also ensure anchoring in the hospital organization.

Conclusions: Interventions, even evidence-based, have little impact if not actively used. This study illustrates how user-centered design and service design can be applied to identify and incorporate essential stakeholder aspects in the entire design and development process. In combination with evidence-based concepts, this process facilitated development of a stress management intervention truly designed for the end users, in this case, cancer survivors.

Trial Registration: ClinicalTrials.gov NCT02939612; <https://clinicaltrials.gov/ct2/show/NCT02939612> (Archived at WebCite at <http://www.webcitation.org/7119HfcB>)

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KEYWORDS

stress management; mindfulness; cancer; eHealth; mHealth; mobile apps; development; usability; user-centered design; mobile phones

Introduction

Cancer diagnoses and subsequent treatments can be disruptive and traumatic, often accompanied by a multitude of stressors for the cancer patients and their support network [1-3]. Uncertainty of outcome and medical procedures with adverse side effects are not uncommon, and although people differ widely in how they experience and cope with such challenges, cancer-related distress, including worry, anxiety, depression, and reduced quality of life (QoL), are prevalent [2,4,5]. Fortunately, cancer survival rates are improving, but survivorship is accompanied by long-term health challenges, and many survivors struggle to cope and maintain a positive QoL [6,7].

Psychosocial cognitive behavioral stress management interventions are usually delivered face-to-face, either as individual or group interventions. They are widely recognized as effective, well documented, structured, and multidisciplinary, focusing on specific strategies to improve physical, social, emotional, functional, and overall well-being [4,8-13]. The interventions are based on the cognitive behavioral therapeutic models and address factors related to cognitive, emotional, and behavioral aspects that might enhance coping, including but not limited to educational information, problem-solving skills, self-care strategies, thought awareness and mood management, health behavior change, communication strategies, social support, and relaxation and mindfulness training. Such psychosocial cognitive behavioral stress management interventions have been shown to facilitate psychological adaptation to cancer, including reducing distress, anxiety, negative affects, and depression, as well as improving QoL in cancer patients and survivors [4,8-10,12,13]. These positive findings are also supported by reviews and meta-analyses [14-20]. Some of the psychosocial cognitive behavioral stress management interventions for cancer patients and survivors have even been shown to have beneficial effects on immune markers [8,21,22], and there are indications that cancer recurrence and survival rates may also be positively affected [20,23].

Unfortunately, face-to-face psychosocial interventions are not always offered or easily available to the cancer survivor. In addition, patients with cancer face many demands and stressors, often feel overwhelmed, and may be reluctant to take on the additional commitment of attending and engaging in psychosocial intervention programs [13]. If psychosocial

interventions are unavailable or attending in-person services appears too challenging despite unmet needs, innovative thinking is needed about how psychosocial challenges can be addressed and coping skills supported in a format that is appealing and available to cancer survivors.

With the rapid advance of technology, the evolving concept of eHealth encompasses a range of systems or services in a novel cross-section between medicine, health care, and information technology. eHealth solutions have the potential to provide support anytime and anywhere, which again can facilitate ways to reach, service, and intervene when most needed or convenient for the cancer trajectory [24]. Development and testing of psychosocial eHealth interventions programs for cancer survivors are still at an early stage, and evidence of the effects of eHealth interventions so far are mixed. A meta-review identified eHealth interventions to have positive links to perceived support, knowledge, and information competence among cancer patients but found inconsistent or lacking results for areas such as psychological well-being and QoL [25]. Another systematic review examining the use of Web-based resources for adult cancer survivors also found efficacy to vary with some positive effects on QoL and related psychosocial factors but overall mixed efficacy and limited duration of benefit [26]. Examples of promising findings include improved self-efficacy for coping with cancer through the use of a Web-based stress management workbook for breast cancer patients [27], improved QoL and physical activity for breast cancer survivors through use of a Web-based portal [28], and improved QoL and reduced distress for newly diagnosed patients with cancer through use of a Web-based structured Web-based stress management program guided by psychologists [29]. There are indications that the therapist-guided eHealth interventions may be more effective than self-guided interventions [30]. With promising yet mixed results, some investigators and clinicians have called for more use of evidence-based interventions and rigorous monitoring of program impact for future eHealth intervention research in cancer [26]. Even though several studies report on results from psychosocial interventions delivered via the internet, Web, or Web-based sources, few, if any, have explored building and testing app-based psychosocial interventions for cancer survivors. A recent review of available breast cancer apps concluded that most such apps appear to be lacking evidence and an evidence base and that health care providers, not just start-up companies and entrepreneurs, should be included in such developments [31].

This study reports on the design and development of a technology- and app-based stress management intervention for cancer survivors. The study combined well-established cognitive behavioral stress management concepts shown to be effective for patients with cancer in face-to-face interventions [4,8-10,12,13,32,33] with a user-centered design approach to ensure that the intervention was designed in line with users' needs and context of use. The main philosophy behind the user-centered design approach is to include users in the design and development process and allow system end users to influence how the product takes shape [34,35]. To support this process, the user-centered design provides a variety of methods enabling user involvement in different phases of development with different levels of user engagement. Service design is another approach to system design, focusing on service development. This approach focuses on the entire ecosystem and experiences around it (eg, how it is used, by whom, when, and where) rather than the end product alone [36]. This study combined the user-centered and service design approaches to enable stakeholder involvement throughout the entire design and development process. This was done to ensure intervention alignment with the needs and requirements of cancer survivors and health care professionals alike. The ultimate goal was to have an end product that is both user friendly and useful and also engaging and motivating and that fits into the bigger context of the everyday life and challenges of people living with cancer. Cancer survivors, health care providers, including psychosocial oncology specialists, and eHealth experts were actively involved in the entire process.

Methods

Overview

The design and development process encompassed a multidisciplinary approach and continuous systematic evaluation throughout, as recommended in the Center for eHealth Research and Disease Management comprehensive roadmap approach to improve the uptake and impact of eHealth technologies [37]. The intervention development work was led by the study principal investigator, who is a clinical psychologist with health psychology specialization and longstanding experience in psychosocial oncology, stress management, and cognitive behavioral treatment approaches for medical patients. The multidisciplinary project team had weekly meetings during the design and development phase and consisted of experts in stress

management, psychosocial oncology, eHealth research, and information technology (IT) developers as well as a designer and content specialists. User-centered and service design methodologies were applied to ensure user involvement throughout the entire design and development process. Patient representatives, health care providers, including psychologists and cancer nurses, and security experts were consulted throughout.

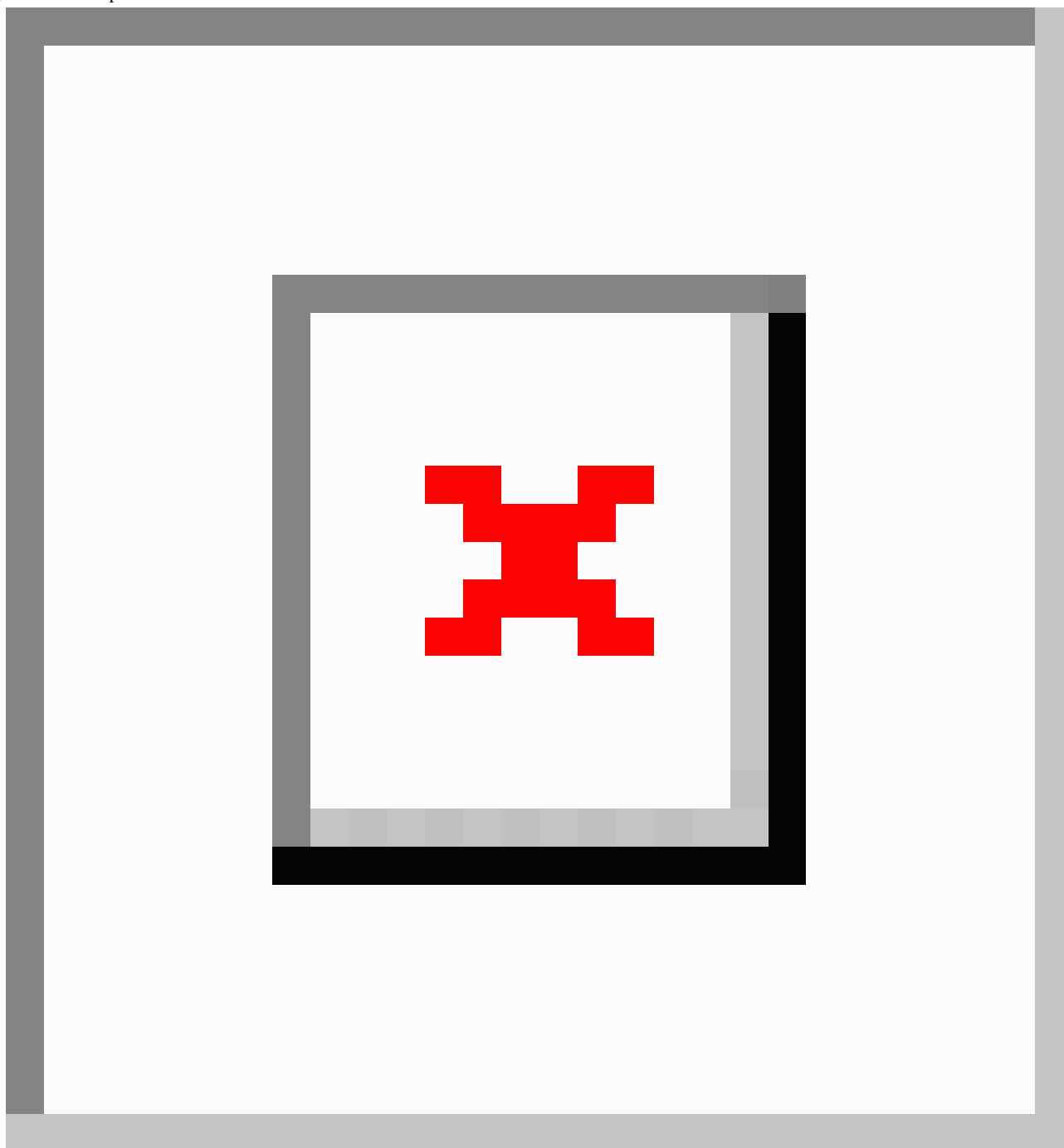
The stress management intervention program was developed in iterative processes, as shown in Figure 1, through a combination of exploration phase: input from user representatives (ie, cancer survivors), health care providers, and eHealth experts including designers and developers; intervention content development: identified and adjusted from the evidence-based cognitive behavioral stress management concept; iterative software development and formative evaluation; and (4) privacy, security, and organization anchoring considerations.

Exploration

Input from User Representatives (Cancer Survivors)

To identify user needs and requirements of the technology-based stress management intervention, people with any type of cancer diagnosis were invited to participate in individual interviews. They were recruited through the Oslo University Hospital, Oslo, Norway, and collaborating networks, social media such as Facebook, and through the Norwegian Cancer Society. Inclusion criteria for participation in interviews were as follows: diagnosed with cancer or cancer survivors, 18 years or older, and fluent in the Norwegian language. Potential participants were given oral and written information about the study and if interested in participation, they were provided written informed consent prior to study enrollment.

Participants in this phase could choose if they wanted to be interviewed face-to-face or by telephone. They were asked about challenges in their health situation, their use of technology (eg, smart phones; tablets; or personal computers [PCs]) and health technology (eg, websites and apps), their requirements for the use of eHealth interventions, and any suggestions they might have for the design and development of an electronic stress management intervention. Interviews were conducted by 2 representatives from the research team and audiotaped, then transcribed focusing on essential parts, and analyzed using content analysis [38].

Figure 1. Development timeline.

Input from Health Care Providers and eHealth Experts

Supplementing patient user input, health care providers (ie, registered nurses and clinical psychologists) with longstanding experience working with cancer patients were invited to act as consultants and give input on intervention development, including design, intervention content, and ideas on how and when a stress management intervention could be offered to cancer survivors. eHealth experts collaborating with the project team with extensive experience in development of self-management apps for chronically ill people were also invited to give input on how the intervention could best be designed and delivered to optimize presentation, engagement, adherence, and potential effect.

Intervention Content Development

Evidence-Based Content Development

A major goal of this study was to identify evidence-based factors and areas from well-known cognitive behavioral stress management strategies and then synthesize and adapt these into a new technology-based stress management intervention for cancer survivors. When identifying concepts and factors to develop content for this intervention, potential underlying mechanisms, including likely mediators such as psychosocial resources, were considered to best integrate theory, research, and practice in support of cancer survivors [8,10,15,39-41]. Such integrations have the potential to address a wide array of issues and challenges faced by many patients with cancer.

Adjustment to Electronic Format

Intervention content was adjusted to an electronic format to facilitate intuitive use for the cancer survivors. Adjustments were made in 6 iterations to ensure easy language, short sentences, and focus on clear content for small screens.

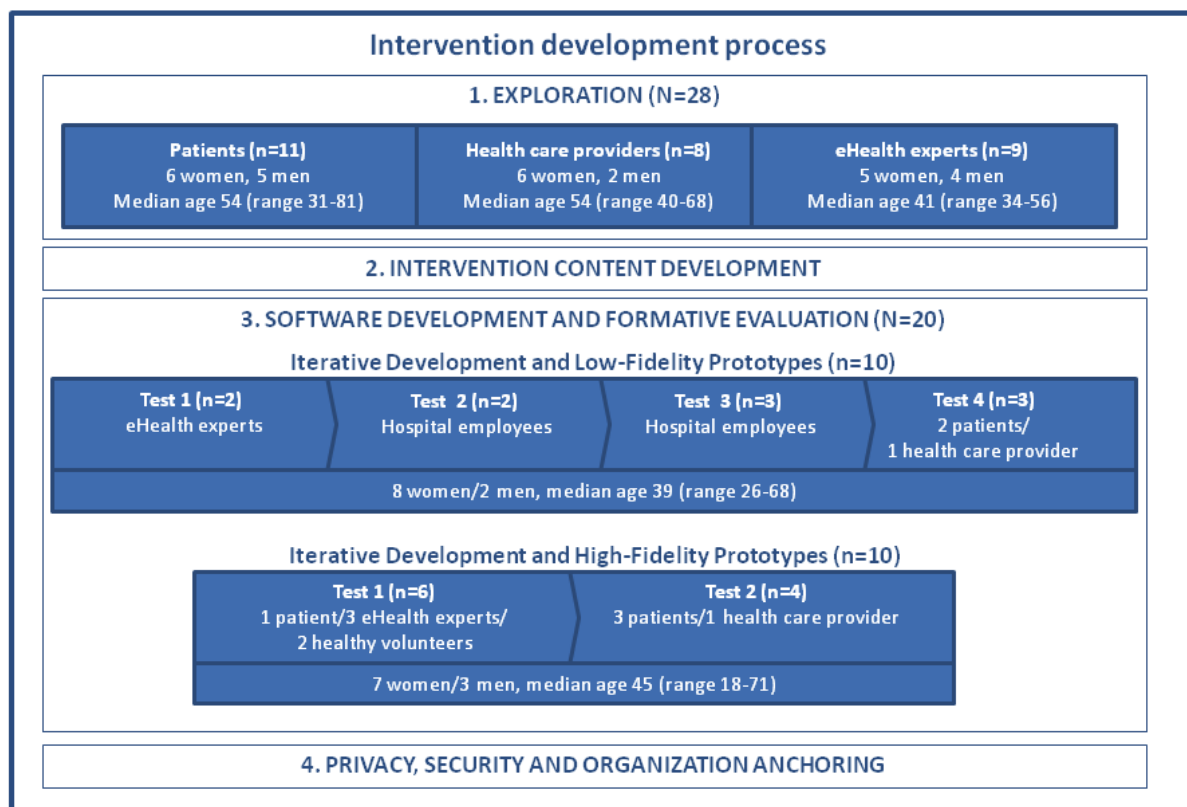
Software Development and Formative Evaluation

Iterative Development and Low-Fidelity Prototypes

Based on needed content adjustments and stakeholder input identified in the exploration phase, the first low-fidelity prototype version of the software was developed. This initial paper prototype consisted of the start page, the menu page, and screens presenting the first intervention module design and content. Next, the prototype was evaluated via 4 consecutive iterations and refined and adjusted based on user feedback, as seen in [Figure 2](#).

In the first iteration, eHealth experts tested and gave feedback on the prototype to ensure that the intervention program was logically built and would meet the stakeholder requirements. After minor adjustments, the paper prototype was implemented into an electronic tool for testing of paper prototypes by simulating the app idea (Prototyping on Paper app by Marvel) [42]. Hospital-employed healthy volunteers then tested the prototype in the second iteration and provided feedback. A third iteration, including hospital-employed healthy volunteers, resulted in minor adjustments, and the prototype was deemed ready for usability testing with cancer survivors. In the final iteration, 2 female cancer survivors and one health care provider (psychologist) tested the final version of the low-fidelity prototype. Healthy volunteers and cancer survivors were given oral and written information about the study and provided written informed consent prior to user testing.

Figure 2. Intervention development process and participants.



During testing, the participants were asked by a facilitator to navigate through the prototype and describe their actions. All movements from elbow to fingertips were filmed; using the think aloud method, a research assistant asked follow-up questions as the module testing progressed [43]. An observer made notes and summarized the input from notes and the video into a report that subsequently provided recommendations for prototype adjustments. Following the development of a final low-fidelity prototype, the high-fidelity prototype development started.

Iterative Development and High-Fidelity Prototypes

Usability refers to the ability of an app to be understood, learned, used, and also be attractive to intended users under specific

conditions of use [44]. During the high-fidelity prototype development, the actual software start page, menu page, and first intervention module were built. To ensure the usability and user need fit of the high-fidelity prototype, a new round of iterative testing and evaluation was performed. To incorporate the gender and age perspective, testing encompassed male and female participants aged 18-70 years old. Six participants were involved in this iteration, as elaborated in [Figure 2](#).

Following adjustments, the new high-fidelity prototype version was then tested by 3 cancer survivors and a health care provider (a psychologist). During this high-fidelity prototype testing, participants were asked to go through the entire first intervention module and comment on their movements. Testing was again

performed through the filming of movements (elbow to fingertip), follow-up questions (eg, Can you tell me why you are doing this? Can you find the exercise overview/my page/settings?), note taking, and a summarizing report. Resulting stakeholder feedback data were again used to evaluate, refine, iteratively adjust, and upgrade the prototype. All functionalities, content descriptions, and modules were tested, and user feedback was obtained. Because this is a self-help program with extensive and, at times, repetitive cognitive behavioral content, all functionalities, but not all content paragraphs, were user tested.

Privacy, Security, and Organization Anchoring

One major stakeholder in this project is the hospital (ie, organization) where the intervention is developed. To plan for postproject implementation, the initial project idea and plan were registered at the hospital innovation unit. This unit provides advice for potential commercialization and anchoring in the organization and welcomes all innovative ideas. It is a requirement to register all innovations at the hospital innovation unit. To ensure that all privacy and security requirements were considered and attended to for the project, the hospital Privacy and Security Protection Committee was consulted at a very early stage. Topics discussed were options to store personal and health-related data in the solution, local versus server data storage, user authentication requirements, and other related issues. All procedures, including the informed consent process, were conducted in accordance with existing ethical standards [45]. The study was approved by the hospital Privacy and Security Protection Committee. It describes development of the intervention that will be tested in a Randomized Controlled Trial as registered at ClinicalTrials.gov (NCT02939612).

Results

Exploration

Participants

Cancer survivors (n=11) with a variety of cancer diagnoses participated in individual interviews giving input on daily challenges and support during cancer treatment, their use of technology and health information, and needs and requirements for a stress management intervention program. Participants were women (6/11, 55%) and men (5/11, 45%) aged 31-81 years old (median 54 years). Time since cancer diagnosis was 0-14 years (median 4.7 years). Most participants (8/11, 73) chose telephone interviews. The participants represented a variety of demographic factors, including gender, age, and diagnosis. Few new topics emerged after the first 2/3 of interviews, and recruitment was therefore completed at n=11 (saturation).

Health care providers (n=8), 3 cancer nurses and 5 psychologists working within psychosocial oncology, eHealth experts (n=9), 3 research scientists, 2 content experts, a designer, and 3 developers also gave input on when a stress management intervention could or should be offered to cancer survivors and how the intervention content could best be presented and delivered.

Input from User Representatives (Cancer Survivors)

Participants reported a broad spectrum of everyday challenges during cancer treatment including stress, loss of memory, confusion about the situation, sleep disturbance, depression, worries, new self-image, fatigue, pain, stiffness, and being isolated from work and society or social settings. Their main sources of social support during treatment were reported to be family and friends, but they also reported support from health care providers, including nurses, psychologists, and general practitioners, as well as peer support through the internet.

All participants had access to a smartphone and a PC and rated their user experience as medium to high. The majority (7/11, 64%) had access to a tablet. They all used apps, installed either by themselves or by their children, and they used the internet at least once a day. Mostly, they reported using the smartphone for practical issues, communication, or distraction. Those who used health apps preferred relaxation programs. Others had installed health apps but had limited engagement, stating that they forgot to use them or lost interest after a while.

User-reported needs and requirements for the use of an eHealth intervention can be summarized in 3 key areas. The app had to fulfill their needs as cancer survivors, be easily accessible, and be intuitive and easy to use. When asked about the potential use of a PC for stress management, a majority of participants reported associating use of PC with work. When relaxing, they preferred to use either their tablet or their smartphone. Some of the oldest participants (n=4; age range 51-81 years) anticipated that they would not use a stress management program on a smartphone owing to difficulties with a small screen. Two participants preferred to use their smartphone, however, because it was “always around” 4 participants preferred to use an app compared with a static website because they expected an app to be more easily accessible. Preferred presentation of the intervention content was a combination of sound files, text, and a video. Some participants expected that they would like to have a possibility to read more about the topics.

Input from Health Care Providers and eHealth Experts

It was advised that patients should wait to utilize the intervention until minimum 1 month after receiving a cancer diagnosis and at least a few weeks after the initial cancer treatment had started. This is often a very challenging time with patients mainly focusing on processing the new situation and getting started with cancer treatment as soon as possible. The intervention could be offered at out-patient clinics, radiation treatment clinics, and the learning and mastery units or psycho-oncology units. Male patients were described as those who seldom attend group interventions for stress management, and the design team was advised to focus on a design that could appeal to male as well as female users.

Because cancer diagnosis and subsequent treatment are often accompanied by lack of energy, problems with concentration, stress, and distress, it was suggested that the content is made easy to access and understand as possible, written in a common nonacademic language, and made available in smaller sections to avoid overwhelming patients. To increase engagement and adherence, it was considered essential to ensure that all

participants could easily download the intervention. Having an actual person, a “human contact,” connected to the technology was also described as a potentially important factor for success. [Table 1](#) summarizes participant comments in the exploration phase of the research.

Personas and Journey Map

Insights from the interviews were used to create Personas. The use of Personas is a method from user-centered and service design utilized to create and visualize fictional representations of the target group [46]. Use of Personas is an effective method for all project team members, particularly for the IT designers and developers, to get an enhanced understanding of the target group that the app is built for. Personas in this study contained information about the cancer survivors’ background and challenges, their use of technology, and their needs and requirements for an electronic stress management intervention, as seen in [Figure 2](#). The Personas were used in the design and development process as a tool to ensure that user voices were taken into account during the design and development phase; See [Figure 3](#) for illustrated examples of study personas.

In addition, a Journey Map (a roadmap visualizing the user interaction with the service) [36] was created based on the

interviews and input from the multidisciplinary team with health care providers, eHealth experts, the designer, and IT developers (see [Multimedia Appendix 1](#)). The Journey Map was created to visualize a common project understanding, displaying touch points between the user and the intervention (from the user or patient perspective), including all potential contact points with the project team and health care providers during the information stage, inclusion process, app use, and follow-up.

Needs and Requirements: Decisions and Deliverables

Based on input from cancer survivors, health care providers, and eHealth experts, the research team decided that the stress management intervention program would be developed as an app made available for tablets and smartphones. This would also facilitate offering a combination of text, sound files, pictures, and a video. Suggestions were solicited to identify an appropriate intervention app name; with many inputs containing the words “stress,” “management,” and “boss” or “professional,” the final name of *StressProffen* was chosen. Given the described cancer survivor difficulties, such as concentration problems and fatigue, it was also decided that the content should be presented in smaller parts, be intuitive, and easy to navigate.

Table 1. Exploration phase: user needs and requirements.

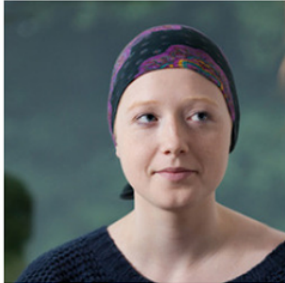
Topics of importance to users	Cancer survivors (n=11)	Health care providers (n=8) and eHealth experts (n=9)
Content	<ul style="list-style-type: none"> • Fulfill their needs • Accessible • Easy to use • Intuitive and user friendly • Combination of sound files, text, and a video 	<ul style="list-style-type: none"> • Small content sections • Easy to access and understand • Use of common or lay language
Design	<ul style="list-style-type: none"> • Smartphones or tablets preferred 	<ul style="list-style-type: none"> • Gender neutral or appeal to male and female cancer survivors alike
Timing and place for intervention delivery	<ul style="list-style-type: none"> • N/A^a 	<ul style="list-style-type: none"> • A while after diagnosis • Out-patient clinics • Radiation treatment clinics • Learning and mastery units • Psycho-oncology service units
Engagement and adherence	<ul style="list-style-type: none"> • N/A 	<ul style="list-style-type: none"> • Easy to download • Offer log-on support • Human contact point

^aN/A: not applicable.

Figure 3. Illustrated examples of personas. PC: personal computer.

PERSONAS

Mona 25 years



«My cell phone is my lifeline now when I'm ill»

BACKGROUND

Mona lives alone and has moved back to her parents. She has just finished chemo for

TECHNOLOGY

Uses smart phone, tablets and pc. She uses the cell phone for "everything". Active on

PERSONAS

Edvard, 60 years old



«I am very lucky, but I often feel reduced, tired and dizzy. I am not in good condition »

BACKGROUND

He is divorced, lives alone, and is on sick leave from his work as a lawyer. He has

TECHNOLOGY

Uses smart phone, tablets and pc. He prefers to use tablets or pc, as his fingers are "too big"

To facilitate individual contact and increase the potential for engagement and adherence, it was also decided that the stress management intervention would include one face-to-face introductory session where participants would also receive help installing the app. It was also decided that participants would receive a follow-up call during the course of the intervention.

Intervention Content Development

At the base of the *StressProffen* intervention are concepts from well-known cognitive behavioral stress management interventions for cancer patients [8-12], including the Mayo Clinic QoL and Stress Less Interventions [4,13,33], all guided by theoretical models where cognitive, behavioral, social,

personal, and environmental factors interact in guiding motivation and behavior.

The actual initial intervention content for this study was first developed by the primary investigator, then adapted and tailored to Norwegian conditions by the entire research team through iterative processes (average 6 iterations per module) to fit a 10-module-based intervention in electronic format through text, sound, video (explaining the fight-or-flight concept), and pictures. Each version was user tested to meet user requirements described above, make the content easily accessible, confirm adaptation to an app format, and ensure that the scientific foundation for the intervention was intact. The iterative content development processes were parallel to app programming, and adjustments were made based on usability testing. The final

intervention contained a face-to-face introductory session where *StressProffen* could be downloaded and installed on study participant smartphones or tablets. Figure 4 lists and briefly describes the 10 modules and the topics covered in each module.

Software Development and Formative Evaluation

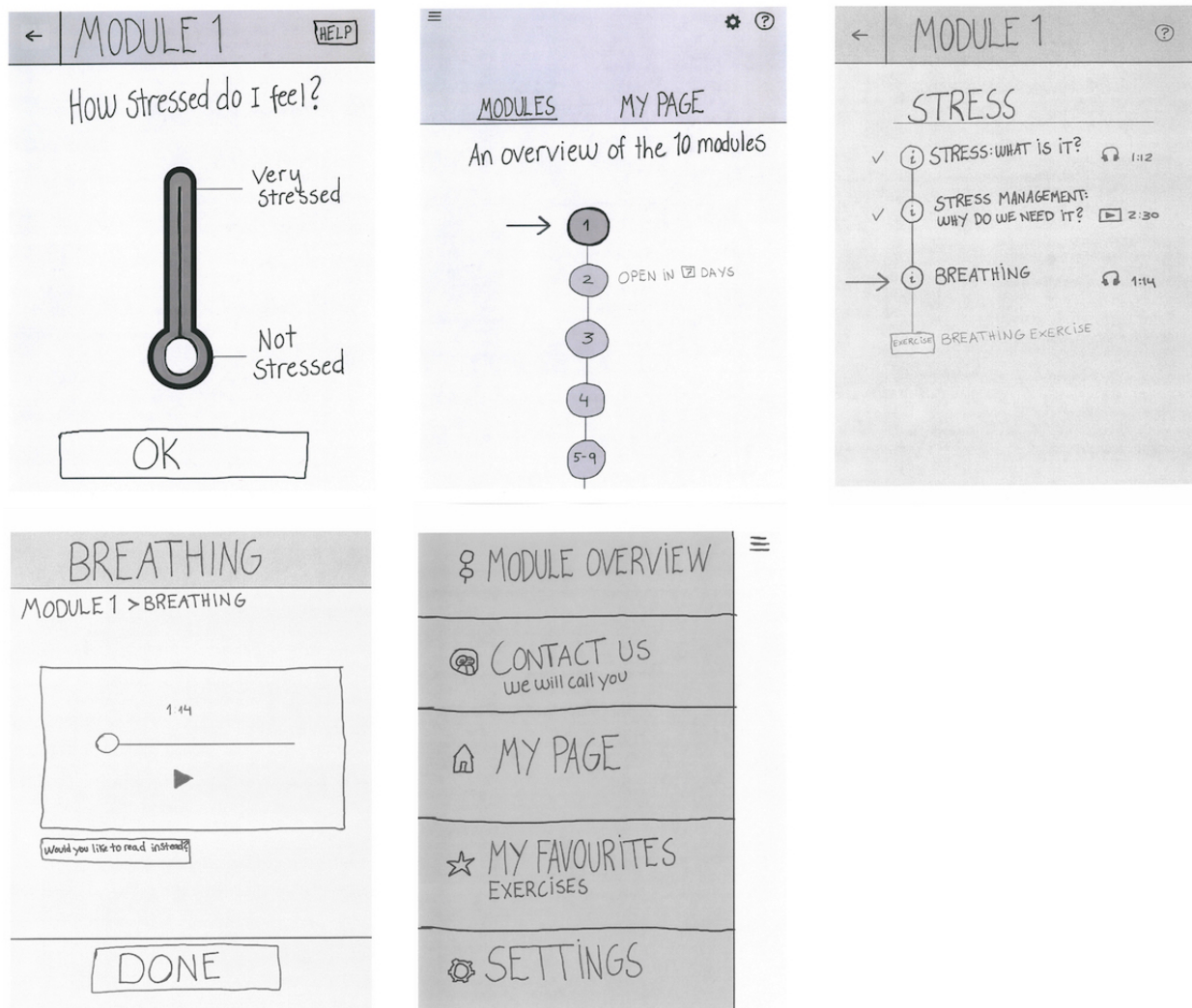
Usability testing of the paper prototype app resulted in adjustments to ensure easier navigation, new icons, and implementation of engaging design to stimulate adherence,

adding optional quotes and a more visible option of listening versus reading. In addition, to allow for individual user preferences, it was decided that the app-based program would allow users to mark favorite exercises, which would show up as “My favorites-Exercises.” Individual progress would be available as a part of “My Page,” where participants could find their tracking and progress information, as seen in seen in Figure 5.

Figure 4. The StressProffen overview of modules and their content. QoL: quality of life.



Figure 5. Paper Prototypes from development.



Following app programming and complete content implementation, a new set of usability testing and iterations was conducted, as described in the Methods section. Based on user feedback in this phase, the following design recommendations were made and used to adjust the prototype: information should be stepwise, brief, and short (eg, presented as maximum 3 screens of text); provide information about how much time would be required; all modules should require approximately the same amount of time to complete; type of content (eg, informative, a recommended practice exercise) should be easy to determine by the user; favorite exercises should be easy to locate and access; it should be easy to choose whether one would like to read or listen; the content should be easy to understand and presented in common language with no academic or medical terminology; use of animations and illustrations to create visual aids and substantiate the information in clear and engaging manners; and recorded stress levels should be easy to track in a “My page” option.

The final version showed the duration of information or exercises (ranging from 1 to 14 minutes), and users could easily see how long each module and section would last, as seen in the screenshot examples in Figure 6.

Privacy, Security, and Organization Anchoring

Security and Privacy Considerations

The *StressProffen* intervention program focuses on stress management for cancer survivors. It was developed at and would be distributed from a major hospital with cancer centers. Therefore, sensitive health-type information had to be carefully considered and protected. When asked about data protection and security, most participants had no concerns. One participant expressed “My life is not that exciting,” and another said “I have nothing to hide.” Protecting patients and patient information is, nevertheless, the responsibility of the hospital and health care professionals, and some of the participants did acknowledge safety concerns and reported being careful about what they posted about their personal information on social media.

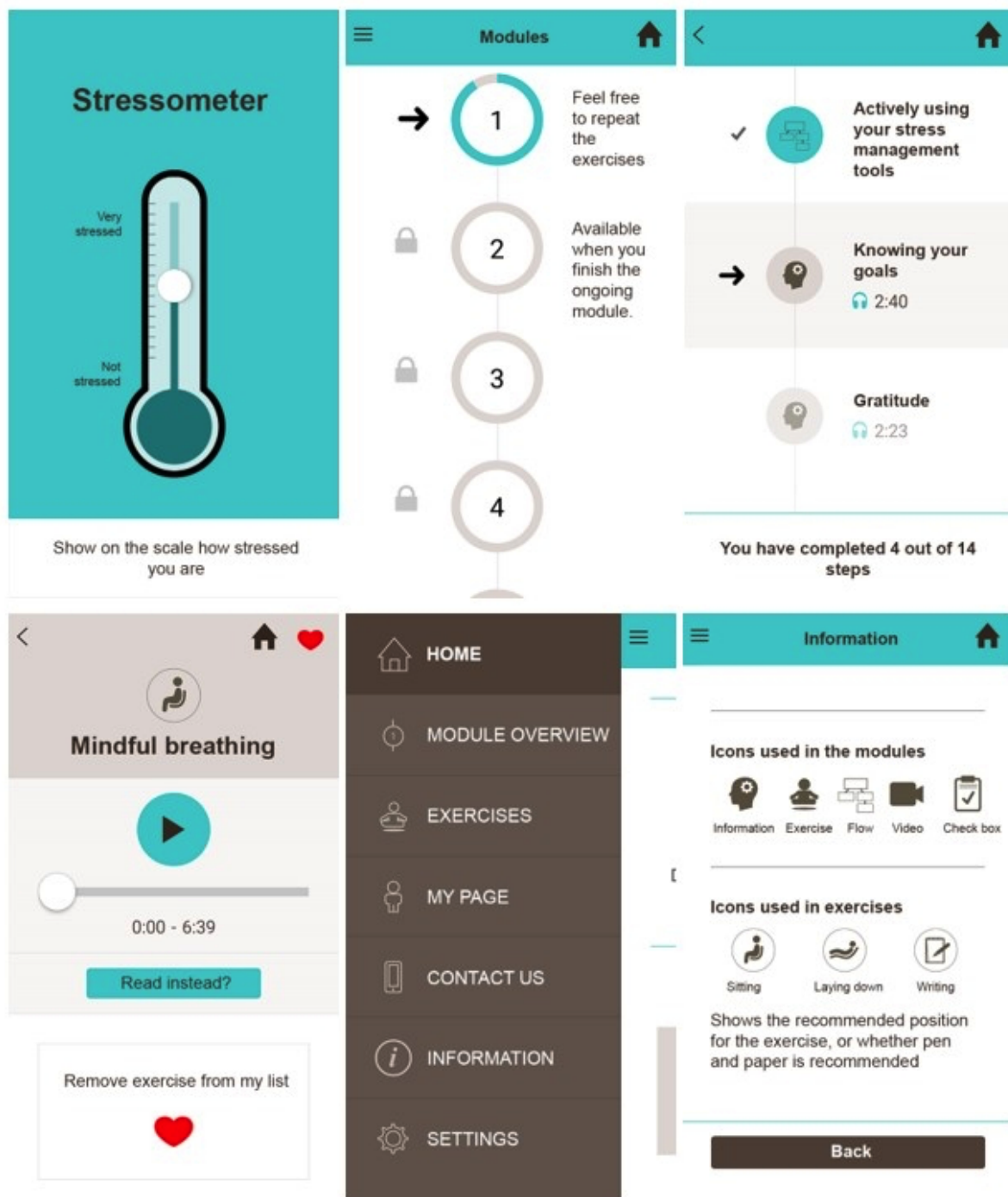
To address all security and privacy issues, a risk assessment of the *StressProffen* intervention was evaluated and approved by the hospital Privacy and Security Protection Committee. For example, one security concern was that if the intervention mentioned diagnoses (eg, cancer), this could compromise user privacy. To ensure that patient diagnoses is not revealed if anyone was watching or the phone or tablet lost, one alternative

was to ask users for a pin code or password each time they were accessing the app. Even though this measure would protect privacy for the users, such protection could potentially reduce ease of use, which was one of the most important user requirements, and thereby also reduce engagement, adherence, and the potential effect of the intervention. Another option was to completely avoid the word cancer and any cancer-specific information in the app. Based on user input and security recommendations, it was decided to choose the second option and not include diagnosis-specific information.

Anchoring the Intervention Within the Organization

To anchor the intervention within the organization, receiving approval from the hospital Privacy and Security Protection Committee was essential. The project was then registered with the hospital innovation unit (ie, *Idépoliklinikken*). The following topics were addressed in the registration: the potential usefulness of the innovation for patients and providers, potential economic impact, a prospective plan for upgrading, and responsibility for running the intervention program after study completion to test intervention effects. After registration, the *StressProffen* app was approved as an official Oslo University Hospital app.

Figure 6. StressProffen app screenshots.



Discussion

Principal Findings

This study process identified a variety of stakeholder needs, requirements, and challenges in designing and developing a user-centered evidence- and technology-based stress management intervention program for cancer survivors. Cancer is a major threat to life, health, and well-being [2,4-7], and interviews with cancer survivors in this study underlined this, describing a multitude of stressful daily challenges including fatigue, pain, social isolation, worries, and depression. Targeting these issues through interventions has great potential, but the process of involving stakeholders in intervention design and development is fundamental [37].

Interviews with cancer survivors and feedback from health care providers and eHealth experts in the study gave vital direction for intervention design and development. Cancer survivors preferred stress management through an easy-access user friendly mobile app and identified usefulness, easily understandable language, and brief and to the point sections as other important intervention components. These requirements were also supported by recommendations from health care providers and eHealth experts. Intervention content was rooted in evidence-based cognitive behavioral stress management strategies, synthesized, and adapted to the new *StressProffen* intervention. As an easy-to-access app with evidence-based content in 10 main modules, the intervention was divided into briefer subsections in a variety of readable, auditory, or visual presentations.

User Requirements

All users stressed the importance of easy access and intuitive programming for them to use a stress management intervention program on an ongoing basis. They also described the importance of using an easily understandable language rather than an academic language or difficult-to-understand medical terminology and stressed the importance of not receiving too much information at once but rather dividing the intervention into smaller, more manageable parts.

A majority of participants preferred using either a tablet or smartphone for stress management because they associated the use of PCs with work. Age appeared to play a role in the preferred choice of device because younger cancer survivor users anticipated preferring smartphones due to easy access, whereas some of the older patient users (>50 years) anticipated preferring to use tablets due to the smaller smartphone screens. Older age has been reported to be a barrier to the uptake of a Web-based intervention for cancer-related distress [47]. However, once enrolled, older individuals have demonstrated better intervention adherence. Adjusting the intervention to fit preferences among different age groups might, therefore, increase uptake and adherence [47].

Several cancer survivors in the study described not having any interest in health apps, with the exception of relaxation apps already used by some of them. Some cancer survivors described searching the internet for health information at times, whereas others stated that they did not want to be scared by all the

available information without knowing whether the information “out there” could be trusted. This again pointed to the need for evidence-based information.

Intervention Content

Rooted in the concept of cognitive behavioral stress management, the final *StressProffen* intervention app contains educational material related to topics such as stress, QoL, planning, thoughts and feelings, coping, social support, anger management, assertiveness and communication, health behaviors, and setting goals. The intervention also contains a variety of exercises, including thought challenges, positive self-talk, diaphragmatic breathing, progressive muscle relaxation, guided imagery, mindfulness, and meditation. Finally, the app also contains a video visualizing and explaining the fight-or-flight concept.

Cancer-specific education material was not included because this would have required a higher privacy and security level (eg, pin code or password log-on), subsequently impacting the user-required aspect of easy access. Such cancer-specific material would also need continuous field-related updates, which would have been labor intensive and potentially complicate implementation. Writing exercises were encouraged, separately from the intervention program, because typing information into the actual app would again require higher privacy and security levels.

Importance of User Involvement and Evidence

StressProffen as a stress management intervention program is rooted in evidence-based methods, a necessity for bringing about change and stress reduction in cancer survivors. Nevertheless, intervention success also depends on whether the intended users consider the app helpful and easy to use [35]. An intervention that is poorly designed, focuses on providing too much or too little information, or complicated to use will not have the intended effect due to low engagement, no matter how evidence-based the stress management content is. The opposite is also true. Although a perfectly designed and pleasurable app may be used a lot, if it is not rooted in evidence, the chance of bringing about positive change is unlikely. Evidence-based strategies, user input, and user-friendly technology need to work in harmony for an app to be widely used and effective.

In this study, using service design and user-centered design methods, involving stakeholders, including cancer survivors, health care providers, and essential organizational units such as the hospital Privacy and Security Protection Committee and the Innovation unit, facilitated the identification of a range of necessary needs and requirements for a potentially effective stress management app for cancer survivors. This process is in line with the Center for eHealth Research and Disease Management comprehensive roadmap approach to improve the uptake and impact of eHealth technologies [37]. The approach recommends multidisciplinary project management in combination with contextual user and environmental inquiry along with iterative design processes with end-user prototype testing to enhance chances of future implementation success.

Privacy and Security Aspects

An important factor contributing to use is the fact that an app is easy to use and access [35]. The *StressProffen* intervention is developed by and anchored in a large hospital with health-related privacy and security regulations at the forefront. Any information considered sensitive requires a secure user log-in procedure for user access. Therefore, *StressProffen* contains no cancer-specific information and does not allow users to write or store their own notes in the app. As such, the user requirement of easy access was given priority over providing cancer-specific information or advice. It remains to be determined if this decision will be viewed as a weakness or strength by future users. The lack of cancer-specific content might limit the user's sense of having an individually tailored app, which again might reduce engagement, adherence, and effect.

In contrast, neutralizing content to allow for easy app access through reduced demands for privacy and security can be particularly beneficial for cancer survivors who face challenges such as fatigue and difficulties with memory and concentration. Additionally, in the long run, a more generic stress management program might have a potential benefit for other groups of patients, caregivers, or family members [48].

Strengths, Limitations, and Future Directions

The study has some limitations that need to be considered. Cancer survivors participating in the user interviews responded to hospital or social media-related invitations and represented a sample of convenience, which can introduce selection bias. However, the cancer survivors were both male and female and represented a wide range of age and cancer diagnoses. As such, the survivors participating in the study were representative of future potential app users. The usability testing methods in this study may also present with limitations. First, usability testing involved all functionalities but not all content sentences. Second, the usability testing included a limited number of participants, which is, however, not uncommon for iterative design processes [49]. Based on the above, it is possible that the usability testing of *StressProffen* so far captured only some of the potential

barriers to continuous use over time. This will need to be further addressed in ongoing user research. Accordingly, to refine the *StressProffen* intervention, a feasibility pilot is planned where a larger number of participants will test the entire 10-module intervention in their own environment, complete outcome measures to gauge preliminary effects, and participate in qualitative interviews to elaborate on user experiences. User log data will also be extracted to observe actual use.

This design and development study also has a number of strengths. First, the study employed key stakeholder involvement from the very beginning, including cancer survivors, health care providers working with survivors in various hospital units, eHealth experts including a designer and IT developers, the hospital Privacy and Security Protection Committee, and the Innovation unit. Having user involvement from the start and combining input obtained from the patient user with that obtained from health care providers along with evidence-based concepts and content likely increases the potential for the intervention to be effective. Also, early stakeholder involvement, including ensuring privacy and security requirements and anchoring the intervention in the organization, may increase the potential for poststudy implementation.

Conclusions

Intervention programs, even evidence-based, have at best limited impact if not actively used over time. The ultimate goal of the *StressProffen* intervention is to have an end product that is both user friendly and useful, engaging and motivating, and fits into the bigger context of the everyday life and challenges of people living with cancer. Even though the user-centered design process can be labor intensive, time consuming, and as such also costly, it is likely a waste of resources not to invest enough time and effort in the essential design and development phase. This study illustrates how user-centered design and service design approaches can identify and incorporate vital user and stakeholder aspects in the early design phase and then in combination with evidence-based concepts facilitate the development of a stress management intervention truly designed for the end users, in this case, people living with cancer.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Journey map.

[[PNG File, 2MB - formative_v2i2e19_app1.PNG](#)]

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Abbreviations

IT: information technology
PC: personal computer
QoL: quality of life

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Original Paper

Adapting a Behavioral Weight Loss Intervention for Delivery via Facebook: A Pilot Series Among Low-Income Postpartum Women

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Abstract

Background: Efforts to translate evidence-based weight loss interventions, such as the Diabetes Prevention Program (DPP), to low-income postpartum women have resulted in poor intervention attendance and high attrition. Strategies that improve engagement and retention in this population are needed to maximize the reach of evidence-based weight loss interventions.

Objective: The objective of this study was to adapt a DPP-based weight loss intervention (Fresh Start) for Facebook delivery and to evaluate its feasibility among low-income postpartum women.

Methods: This study comprised 3 single-group pilot studies where feasibility outcomes iteratively informed changes from one pilot to the next. We paralleled the in-person program for Facebook delivery by translating the protocol to a content library of Facebook posts with additional posts from lifestyle coaches. Low-income postpartum women were recruited from Women, Infants, and Children (WIC) clinics in Worcester, Massachusetts. Participants were enrolled into a 16-week weight loss intervention delivered via Facebook. During the first 8 weeks, Facebook intervention posts were delivered 2 times per day, with additional posts from coaches aiming to stimulate interaction among participants or respond to participants' questions and challenges. For the following 8 weeks, posts were delivered once per day without additional coaching. Feasibility outcomes were engagement (defined by number of likes, comments, and posts measured throughout intervention delivery), acceptability, and retention (survey at follow-up and assessment completion rate, respectively). Changes in weight were also assessed at baseline and follow-up.

Results: Pilot 1 had a retention rate of 89% (24/27), and on average, 62% (17/27) of women actively engaged with the group each week during the 8-week coached phase. Mean weight loss was 2.6 (SD 8.64) pounds, and 79% (19/27) would recommend the program to a friend. Pilot 2 had a retention rate of 83% (20/24), and on average, 55% (13/24) of women actively engaged with the group weekly during the 8-week coached phase. Mean weight loss was 2.5 (SD 9.23) pounds, and 80% (16/24) would recommend the program to a friend. Pilot 3 had a retention rate of 88% (14/16), and on average, 67% (11/16) of women actively engaged with the group weekly during the 8-week coached phase. Mean weight loss was 7.0 (SD 11.6) pounds, and 100% (16/16) would recommend the program to a friend.

Conclusions: Our findings demonstrated that a Facebook-delivered intervention was acceptable and could be feasibly delivered to low-income postpartum women. Future research is needed to evaluate the efficacy of a Facebook-delivered weight loss intervention.

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KEYWORDS

Facebook; health disparities; postpartum women; social media; weight loss

Introduction

Obesity rates are disproportionately high among racial and ethnic minority and low-income groups [1-3]. These disparities are even greater among women as 42% of those living below the poverty level are obese compared with 29% of women living above the poverty level [4]. Similarly, the prevalence of obesity is 54.8% in non-Hispanic black women and 50.6% in Hispanic women compared with 38% in non-Hispanic white women [5]. Pregnancy and postpartum weight retention places socioeconomically disadvantaged women at a higher risk for overweight and obesity as racial or ethnic minority and low-income women are more likely to exceed the Institute of Medicine guidelines for pregnancy weight gain and to retain weight after pregnancy [6-10]. As a result, excessive gestational weight gain and postpartum weight retention are risk factors for obesity over the life course [8], and thus, interventions to facilitate weight loss among low-income and racially or ethnically diverse postpartum women are needed.

A small body of literature has translated evidence-based interventions, such as the Look AHEAD (Action for Health in Diabetes) [11] and Diabetes Prevention Program (DPP) [12], to socioeconomically disadvantaged groups [13]. However, with a few exceptions [14], translating evidence-based protocols to real world settings has proven difficult. Previous behavioral weight loss trials designed for postpartum women have had limited impact and cited several challenges, including poor intervention attendance and high attrition rates due to difficulties finding transportation, securing childcare, and coordinating schedules [6,15-18]. Thus, innovative strategies that improve intervention engagement and overcome challenges of attendance and attrition among low-income postpartum women are needed.

Social media (eg, Facebook, Twitter, and Instagram) holds great promise as a potential means to deliver behavioral weight loss interventions, while overcoming previously identified challenges to participation and engagement among low-income postpartum women [19,20]. Social media usage is high among US adults, and Facebook is currently the most widely used social media platform, with 68% of adults currently using Facebook [21]. Facebook usage rates are also high among women and low-income groups. For example, 74% of female adults use Facebook, compared to only 62% of male adults. Social media use has penetrated even the very poor such that 66% of adults earning < US \$30,000 per year use Facebook [21]. Individuals use social media to seek information on a variety of topics, including health and weight loss [19]. Users can also access social media at their convenience and overcome attendance barriers and burdens commonly experienced during in-person interventions (ie, transportation, childcare responsibilities, and scheduling) [14,19].

In multiple studies, social media has been one of the several components of behavioral interventions focusing on diet, physical activity, weight management, smoking cessation, and sun protection [20,22-26]. Recent literature reviews have concluded that weight loss interventions utilizing social media produce modest but statistically significant weight loss among overweight and obese individuals [20,27,28]. However, social

media was mostly used in combination with other delivery modalities (eg, in-person groups, short message service (SMS) text messages) [6,29,30], and a few studies have evaluated the feasibility and effectiveness of delivering a weight loss intervention primarily via a publicly available social media network (eg, Twitter, Facebook) [20,22]. Furthermore, the existing evidence on social media-delivered interventions is based largely on white and high socioeconomic status samples, and additional research on the feasibility of interventions delivered via social media among socioeconomically disadvantaged populations is needed [6,28,31]. To examine the feasibility of social media as a delivery mode for behavioral weight loss interventions among low-income and minority postpartum women, this study translated a previously adapted, DPP-based weight loss intervention (The Fresh Start Trial) for low-income postpartum women to be delivered via Facebook. We describe a series of 3 pilot studies in which we evaluated the feasibility and acceptability of using Facebook as the primary intervention delivery modality. The iterative format of the pilot studies allowed us to test the Facebook-adapted intervention and refine the intervention materials and study methods based on feedback received after each pilot study. Methods, results, and lessons learned from each of the 3 pilot studies are described.

Methods

Design

All 3 pilot studies followed similar methodology unless otherwise noted. Each pilot study utilized a single-group pretest-posttest design. Study procedures were approved by the Institutional Review Board at the University of Massachusetts.

Recruitment

Study participants were low-income postpartum women in Worcester, Massachusetts recruited from the Worcester Women, Infant, and Children (WIC) program over the course of 8 months [32]. Potentially eligible women were identified at their first postpartum appointment or via electronic records that identified likely eligible women based on their baby's birthdate, body mass index, and language (ie, able to communicate in English). WIC providers prescreened women by completing a checklist of study pre-eligibility criteria based on chart information. Women who met these criteria were informed about the program during their next WIC visit. Pre-eligible women received a study fact sheet from the providers, who also asked the women about their interest in learning more about the study. Interested women provided their contact information. The study recruiter then contacted these women to explain the study further, ask additional eligibility questions, and determine interest in participating in the study. Eligibility criteria included the following: (1) childbirth in the previous 6 weeks to 6 months; (2) age ≥ 18 years; (3) body mass index ≥ 27 kg/m²; (4) English-speaking; (5) approved by their health care provider to participate in a weight loss program; (6) daily access to the internet; and (7) regular Facebook use, defined as at least once per week. Exclusion criteria were as follows: (1) unable or unwilling to give informed consent; (2) pregnant or planning to become pregnant during the study period; (3) psychiatric

illness that limits their ability to participate; (4) medications that cause weight change; (5) no access to a telephone; and (6) planning to move out of the area within the study period. Eligible women provided verbal consent for the study staff to contact their health care provider to seek approval for their participation in the study. Formal written informed consent for study participation was obtained during the baseline visit, prior to the completion of study assessments.

Intervention Description

Adaptation Process

Intervention content was adapted from the original Fresh Start intervention, a weight loss treatment protocol based on content from the DPP [11], adapted for mothers with young children [14,33]. Briefly, the original Fresh Start protocol involved an 8-week group-based curriculum delivered by a WIC nutritionist. The intervention format included a narrative component, group discussions, print materials, and access to fitness facilities, followed by 9 monthly follow-up telephone calls.

This intervention was adapted for delivery via Facebook. First, the research team held regular meetings to review the protocol for the in-person Fresh Start Trial [33], which was adapted from the DPP curriculum [34]. The team identified key constructs and topics from the sessions and created a draft library of Facebook posts that were originally copied verbatim from the in-person protocol. In accordance with the Fresh Start protocol [33], posts emphasized one new topic each week (eg, tracking food and beverage intake, reading nutrition labels) and the use of behavioral strategies including self-monitoring and goal setting. The language was then simplified, and messages were shortened into simple terms and short sentences. The adaptation process for the Facebook intervention using goal setting as an example as well as a collage of posts can be found in [Multimedia Appendix 1](#) and [Multimedia Appendix 2](#). As research has shown that Facebook engagement is higher when a post has a photo or video [19,35], videos and pictures from the in-person protocol were included in posts where applicable and supplemented by additional photos, infographics, and videos extracted from Web-based sources with special attention to maintaining the original message. These were created using Microsoft Publisher and Windows Media Player. To promote interaction among participants in the Facebook group, all posts ended with an open-ended question regarding the topic of the post [19]. Facebook posts were then systematically ordered into a “feed” based on the order and progression of the original protocol and previous social media marketing research reporting an ideal frequency of 1-2 Facebook posts per day [19,35].

Finally, 8 research staff members with experience in weight loss intervention and social media approaches participated in a mock Facebook group where posts were delivered and pilot-tested. These individuals were asked to provide feedback on the wording of the posts, including the language, pictures, and videos, and whether the posts emphasized behavioral weight loss strategies and principles of motivational interviewing. Posts were revised and finalized for the first pilot based on feedback from the mock group.

Intervention Procedures

The intervention consisted of an 8-week intervention phase followed by an 8-week maintenance phase delivered via a secret, private Facebook group, preceded by a 90-minute in-person orientation session. Each of the 3 pilots held 2 orientation sessions (one in the morning and one in the evening) that women attended based on their needs, and sessions were required for participation in the study. The orientation allowed women to meet other women in their Facebook group, provided instruction on how to join the Facebook group, and informed women about the rules of the Facebook group.

Women were also introduced to the concepts of goal setting and taught how to track their diet, physical activity, and weight loss using a commercial mobile app (MyFitnessPal) or paper records. They were also provided a scale, pedometer, workbook, measuring cups, and a 1-year gym membership to YWCA Central Massachusetts at no cost to them.

Following the orientation, participation in the Facebook intervention commenced. During the first 8 weeks, Facebook intervention posts were delivered 2 times per day (8 am and 4 pm), 7 days per week, from study-created Facebook accounts (one from the intervention coach and one from the assistant coach) via the social media management platform Buffer [22]. The intervention coach was a postdoctoral fellow with experience and training in behavioral weight loss intervention delivery, and the assistant coach was a doctoral student. The coaching tasks included liking and commenting on the women’s posts or comments, encouraging discussion and sharing of strategies to deal with challenges to goal attainment or weight loss among the women, answering questions, and providing support. Coaches also provided group-based feedback based on women’s answers to intervention prompts. For the second 8-week period of the intervention (weeks 9-16), Facebook posts were delivered once per day without additional input from coaches.

Outcome Measures

Measures Assessment

Outcome measures for each pilot study focused on feasibility outcomes including retention, engagement, and satisfaction. [36]. Weight change also was assessed. Participants completed the survey and anthropometric measures at baseline (preintervention assessment) and 16-week follow-up (postintervention assessment). Additional engagement data were obtained from Facebook, as described below. Participants who completed the postintervention assessment received a \$50 gift card incentive.

Height and Weight

Height and weight were measured at baseline and after 16 weeks by trained research staff using a stadiometer and digital scale, respectively, with participants removing their shoes.

Engagement

As in previous studies [19,22,23], engagement was operationalized as participants’ behavior and interactions with the Facebook group, including all likes, comments, and posts in each week. Facebook data were downloaded weekly using

Facebook Downloader V5.0.1, and it included the number of comments, likes, and original posts from each participant over the course of the intervention. Additional survey questions asked women to self-report their level of engagement with a series of items that inquired how often they read the entire intervention posts and how often they read part of the intervention posts. Response options were on a 6-point scale ranging from “never (0% of the time)” to “almost always or always (90%-100% of the time).” Indiscernible Facebook engagement, or “lurking,” was also defined via the extent to which women read the intervention posts without commenting on it or liking it [37]. Specifically, women reported how often they read the entire post and did not respond by liking it or commenting on it on a 5-point scale ranging from “never” to “always.”

Acceptability

Survey items at the follow-up assessment asked about satisfaction with the intervention overall and satisfaction with the amount of weight lost during the program. Responses were rated on a 5-point scale ranging from “very dissatisfied” to “very satisfied.” Women also rated how helpful they found the program in helping them lose weight on a 5-point scale from “very unhelpful” to “very helpful.” We asked the participants how likely they were to participate in a similar weight loss program and how likely they were to recommend the program to a friend on a 5-point scale from “very unlikely” to “very likely.” Women also rated how often they felt supported by other participants in the group on a 5-point scale ranging from “never” to “always.” Finally, women rated the extent to which

they felt the other participants were motivating and the extent to which they felt the coaches were helpful and motivating based on a 5-point scale from “strongly disagree” to “strongly agree.”

Qualitative Group Discussion

Upon completion of the postintervention assessment, participants were invited to participate in a 60-minute group discussion, during which they provided feedback on their experience in the intervention. These discussions were led by an experienced facilitator, and a note taker was present. The discussions were recorded, and 2 members of the study team independently listened to the recordings, looking for concrete suggestions from the women to improve the Facebook intervention. The interventionists and facilitator then met and used an expert consensus approach to reach an agreement on what changes and modifications would be made to the intervention from pilot to pilot.

Results

Pilot 1 Results

Overview

A total of 29 women were initially enrolled in Pilot 1. However, 2 participants became ineligible during the intervention, one due to medical reasons and the other due to intake of a weight-altering medication (study exclusion criterion). Thus, the final sample for Pilot 1 was 27 women (Table 1). The retention rate for this pilot was 89% (24/27).

Table 1. Baseline characteristics of women participating in the three pilot studies.

Characteristics	Pilot 1 (n=27)	Pilot 2 (n=24)	Pilot 3 (n=16)
Age, mean (SD)	32.1 (5.6)	29.4 (6)	29.4 (4)
Body mass index, mean (SD)	35.1 (5.5)	38.2 (6)	34.9 (7)
Race or ethnicity, n (%)			
Hispanic or Latina	11 (41)	5 (21)	7 (44)
Non-Hispanic black	5 (19)	7 (29)	2 (13)
Non-Hispanic white	8 (30)	9 (38)	6 (38)
Asian	2 (7)	1 (4)	0 (0)
Other	1 (4)	2 (8)	1 (6)
Education, n (%)			
High school degree or less	13 (48)	7 (29)	4 (25)
Some college or 2-year degree	8 (30)	10 (41)	9 (56)
College degree or more	6 (22)	7 (29)	3 (19)
Marital status, n (%)			
Single	10 (37)	8 (33)	7 (44)
Married or living with partner	16 (59)	14 (53)	8 (50)
Divorced or separated	1 (4)	1 (4)	1 (6)
Facebook activity prior to enrollment, n (%)			
Posted a Facebook status once per week or more	17 (63)	18 (75)	11 (69)
Posted a video or photo to Facebook once per week or more	16 (59)	16 (67)	10 (63)
Commented on a friend's Facebook post once per week or more	22 (82)	22 (92)	13 (81)

Engagement

Table 2 displays the engagement for all 3 pilots during the coached (weeks 1-8) and noncoached (weeks 9-16) phases of the intervention. On average, about 63% (17/27) women engaged in the group each week. Of the 24 women who completed the 16-week assessment, 71% (17/24) reported reading the entire intervention posts either most of the time or always and 42% (10/24) said that they read only part of the posts either most of the time or always. When asked about lurking, 1 woman reported never reading a post without commenting on it or liking it; 38% (9/24) women reported occasionally reading a post without commenting on it or liking it; 17% (4/24) women reported lurking half the time, 21% (5/24) women much of the time, and 21% (5/24) women always.

Weight Loss

Weight loss outcomes at the 16-week follow-up are presented in Table 3. Women lost an average of 2.6 (SD 8.64; range -23.4 to 14.4) pounds or 1.4% of their baseline weight (SD 4.4; range -12.4 to 5.8). At the 16-week follow-up, 63% (15/24) women lost weight and 38% (9/24) women gained weight.

Acceptability

A majority (75%, 18/24) of the participants reported being satisfied or very satisfied with the intervention, and 19 out of 24 women (79.2%) felt the program was somewhat or very helpful in facilitating their weight loss (Table 3). Furthermore, 63% (15/24) women felt supported by other participants in the group at least half of the time, and 67% (16/24) felt that the other women in the group were motivating. Finally, all 24 women (100%) felt that the coaches were helpful and motivating.

Lessons Learned and Intervention Adaptations

We learned several key lessons from Pilot 1 based on the group discussions and Facebook group engagement data. First, we explored intervention posts with lower engagement, as defined by <5 comments on the post or <3 women who commented on the post, to identify key themes or similarities between posts with poor engagement. From our review of engagement data,

we discerned that goal setting posts, posts with lengthy videos, and posts asking multiple questions were associated with lower engagement among the participants. As a result, we edited goal posts to include sample goals, exchanged long videos for infographics, and reduced the word count of lengthier posts to simplify the posts further. Of note, when iterations were made to the approach to behavioral strategies, the core evidence-based behavioral strategies were maintained across groups. During the group discussions, we learned that women were more likely to read and comment on a post that included helpful pictures and visuals. For example, a few of the women shared that they took "screenshots" of the intervention pictures and saved them to the photo library on their mobile phones to be able to access them later. We therefore carefully reviewed intervention posts that included photos (eg, a picture of a mom walking) versus infographics (eg, a diagram of healthy snacks with calorie amounts), and where applicable, we enhanced posts to include infographics.

Second, during the first few weeks of the intervention, women reported via Facebook posts to the group and private messages to the coaches that they were having difficulties tracking their diet or activity using the recommended app (ie, MyFitnessPal). We thus modified intervention posts during the first 2 weeks to include posts that provided support in learning to use the app. Specifically, we created 4 new Facebook posts for Pilot 2 that included both videos and infographics and directed women on key features of tracking their food using the app.

Finally, during the group discussions, women reported that they wished there were more opportunities for the participants to meet in person and suggested that this be accomplished via increased utilization of the free YWCA membership. Based upon this suggestion that in-person interactions be in the form of workout groups or other exercise participation, during the coached phase of Pilot 2, participants received Facebook posts with invitations to join and participate in an exercise class at the YWCA with other women in the group and one of the coaches. Class type (eg, Zumba, yoga) and day and time varied each week to facilitate the attendance of women with different scheduling needs.

Table 2. Measures of intervention engagement for the three pilot studies.

Measures	Pilot 1 (n=27)		Pilot 2 (n=24)		Pilot 3 (n=16)	
	Coached phase	Noncoached phase	Coached phase	Noncoached phase	Coached phase	Noncoached phase
Engagement measures per participant, mean/week (SD)^a						
Original posts	2 (2.5)	0 (0.62)	3 (3.8)	0 (0.3)	3 (2.6)	0 (0.3)
Comments	18 (25.2)	2 (4.4)	24 (31.2)	4 (6.6)	16 (15.5)	3 (4.9)
Likes	33 (57.7)	5 (8.8)	19 (27.1)	3 (4.5)	19 (21.8)	2 (2.8)
Women engaged, n (%)						
Women who engaged in all 8 weeks	8 (33)	1(4)	4 (20)	2 (83)	4 (29)	1(19)
Women who engaged in ≥3 out of 8 weeks	21 (88)	11 (41)	17 (85)	11 (46)	12 (87)	6 (38)
Women who did not engage	1 (4)	10 (37)	3 (13)	9 (38)	0 (0)	6 (38)

^aEngagement indicators are averages rounded to the nearest whole number.

Table 3. Weight change and participant satisfaction outcomes in the three pilot studies.

Outcomes	Pilot 1 (n=24)	Pilot 2 (n=20)	Pilot 3 (n=14)
Participant weight loss outcomes			
16-week weight change (lbs), mean (SD)	-2.6 (8.64)	-2.5 (9.23)	-7.0 (11.6)
16-week weight change (%), mean (SD)	-1.4 (4.38)	-1.2 (3.97)	-3.6 (5.6)
16-week body mass index change, mean (SD)	-0.5 (1.5)	-0.5 (1.6)	-1.3 (2.2)
Lost any weight at 16 weeks, n (%)	15 (63)	10 (50)	10 (71)
Gained any weight at 16 weeks, n (%)	9 (38)	9 (45)	2 (14)
Participant satisfaction outcomes			
Satisfied with the program, n (%)	18 (75)	16 (80)	9 (64)
Program helpful in facilitating weight loss, n (%)	19 (79)	12 (60)	11 (79)
Would recommend program to a friend, n (%)	19 (79)	16 (80)	14 (100)
Would continue program after study ends, n (%)	15 (63)	18 (90)	13 (93)

Pilot 2 Results

Overview

Pilot 2 had initially enrolled 25 participants. However, 1 woman became ineligible due to pregnancy, leading to a sample of 24 women (Table 1). The retention rate for this pilot was 83% (20/24).

Engagement

An average of 13 (55.2%) women engaged in the group each week. Of the 20 women who completed the 16-week assessment, 70% (14/20) reported reading the entire intervention post either most of the time or always, and 65% (13/20) women said that they read only part of the post most of the time or always. When asked about lurking behavior, 35% (7/20) women reported occasionally reading a post without commenting on it or liking it; 25% (5/20) women reported lurking half the time, 25% (5/20) women much of the time, and 5% (1/20) woman always.

Weight Loss

Women lost an average of 2.5 (SD 9.23; range -26.2 to 8.8) pounds or 1.2% of their baseline weight (SD 3.97; range -9.8 to 3.8; Table 3). Half (10/20, 50%) of the women lost weight, 5% (1/20) woman maintained her baseline weight, and 45% (9/20) women gained weight.

Acceptability

A majority (16/20, 80%) of the women reported being satisfied or very satisfied with the intervention, and 60% (12/20) women felt the program was somewhat or very helpful in their weight loss effort. Furthermore, 65% (13/20) women felt supported by other women in the group at least half of the time, and 60% (12/20) women felt the other women in the group were motivating. Finally, 90% (18/20) women felt that the coaches were helpful, and 95% (19/20) women felt that the coaches were motivating.

Lessons Learned and Intervention Adaptations

Observations and findings from Pilot 2 provided additional insight on how to enhance the intervention. First, women endorsed opportunities to attend group exercise classes with

one of the intervention coaches at the YWCA. However, only 3 of the women ever attended these classes. Challenges to attendance included lack of time, class timings not working well with their schedules, and childcare responsibilities (babysitting). Second, women expressed that they wished more women would have engaged actively in the Facebook group. Factors that got in the way of active engagement included feeling uncomfortable posting about themselves and not wanting to post if they were not experiencing successful weight loss. In terms of intervention content, women expressed that they were less likely to read posts that were too long and endorsed posts that elicited responses via questions and included visuals. Examples of helpful visuals included pictures of appropriate portion sizes, recipe substitution ideas, and number of calories of specific commonly consumed foods.

From the lessons learned in Pilot 2, we made several modifications for Pilot 3. First, we again carefully reviewed the posts based on the women's feedback, as well as posts that elicited low engagement (<5 comments or <3 women commenting). We adjusted the language to make them more concise and engaging, and where applicable, we replaced some of the text with a picture or video. In response to feedback regarding the use of gym, we extended the orientation by 5 minutes to include more information about the YWCA and provide women with a map to the facility and the group exercise schedule. We were also able to secure babysitting at the YWCA for 2 hours, 3 days per week: 1 day in the morning, 1 day in early afternoon, and 1 day in the late afternoon or early evening. To encourage women to post more in the group, we added 2 posts in the first week of the intervention; one asked women to introduce themselves to the group and one encouraged women to post in the group regardless of their motivation throughout the program (eg, when they lost weight vs when they did not lose weight; when they had a good week vs when they had a bad week).

Pilot 3 Results

Overview

Pilot 3 had 17 enrolled participants. However, 1 woman became ineligible during the study due to a new pregnancy, leading to

a final sample of 16 women (Table 1). The retention rate in Pilot 3 was 88% (14/16).

Engagement

On average, 67% (11/16) women engaged in the group each week. Out of the 14 women who completed the 16-week assessment, 43% (6/14) women reported reading the entire intervention post most of the time or always ($\geq 75\%$ of the time), and 43% (6/14) said that they read part of the post most of the time or always. When asked about lurking behavior, 36% (5/14) women reported occasionally reading a post without commenting on it or liking it; 21% (3/14) women reported lurking half the time, 36% (5/14) women much of the time, and 7% (1/14) woman always.

Weight Loss

During Pilot 3, women lost an average of 7.0 (SD 11.6; range -31.8 to 13.8) pounds or 3.6% of their baseline weight (SD 5.62, range -11.9 to 6.1; Table 3). Out of 14 women, 71% (10/14) women lost weight, 14% (2/14) women maintained their baseline weight, and 14% (2/14) women gained weight.

Acceptability

A majority (9/14, 64.3%) of the women reported being satisfied or very satisfied with the intervention, and 79% (11/14) women felt the program was somewhat or very helpful for their weight loss effort. Furthermore, 64% (9/14) women felt supported by other women in the group at least half of the time, and 57% (8/14) women felt the other women in the group were motivating. Finally, all 14 (100%) women felt that the coaches were helpful and 93% (13/14) women felt that the coaches were motivating.

Lessons Learned

We learned several key lessons from the women in Pilot 3. Women reported that they would have liked there to be more interaction among the women in the group, and a few suggested more opportunities for in-person meetings or get-togethers (eg, Pilates in the park, walking around the neighborhood). However, like Pilot 2, a discrepancy existed between these suggestions and attendance in in-person group opportunities, as none of the women in Pilot 3 utilized the babysitting or attended the classes at the YWCA with one of the coaches. Women also reported several factors that contributed to their engagement with the Facebook group, including the time of day of the post, how much time had passed since the post, and how many other women had commented on the post. Women also offered several suggestions for improving communication between each other within the Facebook group, such as exchanging phone numbers during the orientation session, having nonweight loss related ice breakers on the Facebook group (eg, asking about work schedules or how many kids women have), and having weekly step or weight loss competitions. Finally, women provided feedback on intervention content and reported that they found practical tips related to meal planning, proper food storage, food preparation, and recipes to be particularly helpful.

Based on the findings and feedback from Pilot 3, as well as Pilots 1 and 2, important lessons that could inform further intervention refinement were the intervention posts that included

concise language; open-ended questions that elicited responses; infographics and content related to weight loss progress, calorie goals and budgeting; and practical tips for meal planning and cooking. Furthermore, while women in all 3 pilots liked receiving the intervention content via Facebook, they desired more social support from one another and suggested solutions, such as a longer orientation session, more ice breakers and discussions on Facebook, and face-to-face interactions to facilitate this support. It is important to note, however, that when women in these pilots were offered more opportunities for in-person interaction, they did not utilize them.

Discussion

Principal Findings

This series of 3 pilot studies demonstrated that an adapted behavioral weight loss intervention delivered primarily via Facebook is feasible and acceptable among low-income postpartum women. On average, more than half of the women in each of the 3 pilots actively engaged (measured by likes, comments, and posts) in the group each week during the coached phase of the intervention (weeks 1-8). Furthermore, women were highly receptive as shown by the fact that most of them found that the intervention was helpful for losing weight, the coaches were supportive, and they would be likely to recommend the program to a friend. Given this high level of receptivity, the finding that satisfaction decreased slightly from pilot 1 to pilot 3 is difficult to interpret. Finally, women in Pilot 3 lost an average of 7 pounds compared with those in Pilots 1 and 2 who lost 2.6 pounds and 2.5 pounds, respectively.

Several previous studies among postpartum women enrolled in WIC programs have observed no significant changes in body weight following a variety of intervention delivery modalities including digital virtual discs (DVDs) and support group teleconferences [16], peer-led support groups [15], and mobile apps [38]. Our pilot series suggests that intervening via Facebook as a primary delivery modality is feasible and may be acceptable in this population. Additionally, although our findings are preliminary, they suggest that the intervention may have potential to surpass weight loss outcomes observed with other intervention modalities targeting WIC clients. However, these 3 pilots were conducted without a control group, and confounding factors (eg, time of year, weather) may have contributed to the improved weight loss across pilots. For example, the first study took place during the holiday season (October-January), the second study right after the new year and the third study during the summer. Thus, a larger randomized controlled trial to evaluate the effect of a Facebook-delivered weight loss intervention on short- and long-term weight loss among low-income postpartum women is warranted.

While direct comparisons with in-person interventions are not possible due to different delivery modalities, our results suggest slightly higher engagement levels. For example, in the original Fresh Start pilot intervention, 26% (7/27) of the women attended the first 3 weekly sessions, while 54% (36/67) of women across our 3 pilots participated in the Facebook group at least once in each of the first 3 weeks [14]. Another study among WIC

women in West Virginia (N=151) reported that 47.4% (72/151) of the women attended at least 1 session, and 57% (86/151) never attended a group session [15]. Comparatively, 94% (62/67) of women across all 3 pilots actively engaged at least once during the 8-week coached intervention. Finally, the mean number of sessions attended in the aforementioned study was 3.6 out of 10 [15], which was similar to the mean 3.8 (out of 8) in in-person group sessions attended by women in the Active Mother Postpartum trial (N=450) [17]. Women across all 3 pilot studies engaged, on average, in 5 out of 8 weeks during the coached phase.

Despite a higher participation in the Facebook-delivered intervention, active engagement decreased throughout the intervention, particularly after the removal of the coach, in all 3 pilots. Instead, we observed an increase in passive engagement given that with fewer women liking, posting, and commenting, more women reported lurking. Previous research with low-income postpartum women has also consistently demonstrated poor engagement in weight loss intervention sessions [15,16,39]. These findings also are consistent with previous social media-delivered interventions where engagement declined over the course of the intervention [28].

To improve active engagement across the 3 pilots, we included additional opportunities for in-person exercise classes at the YWCA based on the women's suggestions. However, when provided the opportunities to meet in person, women did not participate. This is an important factor for researchers to consider when evaluating available resources for interventions, and additional research is required to better understand this discrepancy. Future research may consider utilizing user experience design, which observes individuals in their daily lives, to better inform intervention design [Yardley, 2015 #1414]. This methodology may serve to close the gap between participant suggestions or desires and actual behaviors.

One approach to sustain engagement could be to enhance the coaching component of the intervention. As stated above, women across the 3 pilot studies were very receptive to the coaching aspect of the intervention, and active engagement declined considerably from the coached to noncoached phase of the study. Furthermore, while previous studies adapting the DPP have provided personalized feedback regarding weight, diet, and physical activity changes, feedback in this study was limited as it was based on women's responses to posts rather than a thorough review of individual self-monitoring logs. Future studies may enhance the coaching component by providing more personalized feedback in addition to group-based feedback. Another approach could be to intervene with dyads or cohorts of individuals who already know each other [29,40,41]. For example, a pilot study evaluating the Mums Step it Up Facebook app used a snowballing recruitment method in which women enrolled in phase one recruited 3-7 of their friends to join their team in phase 2 in order to enhance the social nature of the intervention [40]. A third approach has been to incentivize participants based on the number of posts they contribute to the Facebook group [42]. Finally, some recent studies have investigated the type of intervention content that stimulates the highest level of engagement [24,43-46]. One study found that polls (ie, posts asking participants to suggest a tip for others)

and weight-related posts, compared with recipe-related posts, nutrition information, and news, were the most engaging among participants in a 4-month weight loss study [43]. Another study found that polls and photos were the most engaging posts in a weight loss study among college students [45]. Together, these strategies, among others, may be critical to exploring how we can optimize the short- and long-term engagement of postpartum women in a Facebook-delivered intervention.

Limitations

This study has several limitations. First, the sample sizes of the 3 pilots were relatively small and decreased over the 3 pilots due to declining WIC enrollment during our study period (October 2016-August 2017) and study time constraints. A limitation in our measures was that we were not able to obtain objective measures of lurking behavior or directly relate changes in the types and content of posts to engagement. This suggests that women may have had greater exposure to the intervention that was not reflected in our measures of engagement, and future studies that utilize social media to deliver behavioral weight loss interventions should investigate strategies or intervention iterations specifically related to engagement (eg, types of posts, post content) to sustain participation over time. Additionally, we were unable to conduct mediation analysis to determine the influence of engagement as a mediator of weight loss given that the sample size of our pilot studies was small. This study recruited women who were regular Facebook users, which may limit the generalizability of our findings. However, we found that access to social media was not a major barrier to women participating in this study, and only 2 women were ineligible due to limited Facebook use. This is consistent with recent research suggesting that low-income and minority populations have similar technology access to other population subgroups. As of 2017, internet usage, smartphone ownership, and social media usage were similar among Hispanic (88%, 75%, and 74%), and black (85%, 72%, and 63%) adults compared with white adults (88%, 77%, and 69%) [47,48]. While all 3 pilot studies sought qualitative feedback from participants, we did not conduct a formal in-depth qualitative analysis of the group discussions. Future studies may consider a mixed-methods approach to further understand the opportunities and challenges of this intervention modality. Lastly, an important challenge of delivering interventions via publicly available social networks is the ever-changing settings, interfaces, and features. For example, between Pilot 1 and Pilot 3 of this study, Facebook added reactions, an extension of likes where users could click "love," "haha," "wow," "sad," or "angry." Because the existence of this feature was not consistent across pilots, we were not able to investigate engagement based on reaction types. While changes in the features of social media platforms are often difficult to predict, future investigators should consider the potential for network updates and the extent to which unforeseen changes may impact the intervention delivery and potentially its outcomes.

Conclusions

Social media-delivered behavioral weight loss interventions show great promise due to their high potential of reaching low-income diverse individuals, reducing intervention burden,

and decreasing the cost of weight loss intervention delivery. The findings from this series of 3 pilot studies demonstrated that a Facebook-delivered intervention was acceptable and could be feasibly delivered to reach low-income postpartum women. Future research is needed to evaluate the efficacy and sustainability of delivering a weight loss intervention via Facebook.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Step-by-step depiction of the adaptation process for Facebook posts.

[[PNG File, 167KB - formative_v2i2e18_app1.png](#)]

Multimedia Appendix 2

Collage of Facebook posts.

[[PNG File, 484KB - formative_v2i2e18_app2.png](#)]

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Abbreviations

DPP: Diabetes Prevention Program

WIC: Women, Infants, and Children

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Original Paper

Improving Transitions of Care for Young Adults With Congenital Heart Disease: Mobile App Development Using Formative Research

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Abstract

Background: Congenital heart diseases (CHDs) are the most common type of birth defects. Improvements in CHD care have led to approximately 1.4 million survivors reaching adulthood. Successful transition and transfer from pediatric to adult care is crucial. Unfortunately, less than 30% of adolescents with CHD successfully transition to adult care; this number is lower for minority and lower socioeconomic status populations. Few CHD programs exist to facilitate successful transition.

Objective: The goal of our study was to describe the formative research used to develop a prototype mobile app to facilitate transition to adult care for adolescents with CHD.

Methods: A literature search about best practices in transition medicine for CHD was conducted to inform app development. Formative research with a diverse group of CHD adolescents and their parents was conducted to determine gaps and needs for CHD transition to adult care. As part of the interview, surveys assessing transition readiness and CHD knowledge were completed. Two adolescent CHD expert panels were convened to inform educational content and app design.

Results: The literature review revealed 113 articles, of which 38 were studies on transition programs and attitudes and 3 identified best practices in transition specific to CHD. A total of 402 adolescents aged 15 to 22 years (median 16 years) participated in semistructured interviews. The group was racially and ethnically diverse (12.6% [51/402] African American and 37.8% [152/402] Latino) and 42.0% (169/402) female; 36.3% (146/402) received public insurance. Most adolescents (313/402, 76.7%) had moderate or severe CHD complexity and reported minimal CHD understanding (79.0% [275/348] of those aged 15 to 17 years and 61.1% [33/54] of those aged 18 to 22 years). Average initial transition readiness score was 50.9/100, meaning that transition readiness training was recommended. When participants with moderate to severe CHD (313/402, 77.9%) were asked about technology use, 94.2% (295/313) reported having access to a mobile phone. Interviews with parents revealed limited interactions with the pediatric cardiologist about transition-related topics: 79.4% (331/417) reported no discussions regarding future family planning, and 55.2% (230/417) reported the adolescent had not been screened for mental health concerns (depression, anxiety). Further, 66.4% (277/417) reported not understanding how health care changes as adolescents become adults. Adolescents in the expert panels (2 groups of 3 adolescents each) expressed interest in a CHD-specific tailored app consisting of quick access to specific educational questions (eg, "Can I exercise?"), a CHD story-blog forum, a mentorship platform, a question and answer space, and

a checklist to facilitate transition. They expressed interest in using the app to schedule CHD clinic appointments and receive medication reminders. Based on this data, a prototype mobile app was created to assist in adolescent CHD transition.

Conclusions: Formative research revealed that most adolescents with CHD had access to mobile phones, were not prepared for transition to adult care, and were interested in an app to facilitate transition to adult CHD care. Understanding adolescent and parent needs, interests, and concerns helped in the development of a mobile app with a broader, tailored approach for adolescents with CHD.

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KEYWORDS

adolescent health; chronic disease; transitions of care; health disparities; mobile health; mHealth; patient empowerment; patient involvement; self-efficacy; user-centered design

Introduction

Congenital heart diseases (CHDs) are the most common type of birth defects, observed in 40,000 babies born in the United States each year [1,2]. Improvements in the care of those with severe CHD have led to a decline in childhood CHD mortality over the last 20 years [3], with roughly 1 million survivors now reaching adulthood [4-8]. This emerging survivor population requires lifelong surveillance and disease management, as patients are often palliated but not cured [9], putting them at risk for substantial morbidity and mortality and placing a large burden on health care resources [10].

While it is critical that CHD patients suffer no lapses in cardiac care, this is often not the case. A further concern is that lapses in CHD care appear to be a predictor for morbidity [11]. Disparities in the medical care provided to the growing CHD adolescent survivor population involve poor care transition (an age and developmentally appropriate process addressing the medical, psychosocial, and educational and vocational aspects of care) from child-centered to adult-centered health care [8,12] and lack of appropriate transfer of care (the point at which an adult cardiac provider assumes the medical care of a CHD patient) [1,2,12-14]. Lack of assessment of transition readiness (capacity of the adolescent and medical team to initiate and successfully complete the transition process) [15,16] compounds disparities in quality care [17]. Disparities become further magnified in ethnic minorities [4-8,13,18]. Beyond health care access, disease knowledge, and transition readiness, studies show a mentoring relationship [19-21] for adolescents with chronic disease is crucial for successful transition to adult care [22].

The transition period is a vulnerable time for adolescents with CHD, and many drop out of active health care at this time. This leads to poor health outcomes and impedes transfer to adult care [23,24]. Improving transition and transfer are critical to successful long-term disease management and survival. In the clinical setting, providers often do not have the time or resources to address the educational and preparatory needs of transitioning adolescents. One study surveying CHD providers reported that 31% of them feel that adolescents are adequately prepared for transition. When asked about barriers to their involvement in the transition process, 69% of providers stated lack of a structured transition program and 56% stated lack of time in clinic [25]. In the clinical setting, if a general resource for transition is provided, it is often a nontailored educational

handout about CHD and does not address transition readiness or social support needs during this high-risk period. To address these important gaps in care, the needs and concerns of all transitioning adolescents with CHDs should be identified and addressed beyond what is available in clinic.

Patient-centered self-management programs (clinical and online) have shown improvements in adults with chronic disease across health status measures, healthy behaviors, and self-efficacy as compared to usual care [26,27]. Of the chronic disease patient-centered mobile apps that currently exist, most target daily management of medications and symptoms for conditions like diabetes and asthma [28]. While there is little evidence regarding patient self-management e-based programs for care transition in adolescents, there is evidence that young adults have an interest in internet- and mobile-based programs for chronic disease management [29-31]. Many adolescents have ready access to mobile technology; 1 in 4 adolescents are cell-mostly internet users, 78% of adolescents have a mobile phone, and nearly half (47%) of those own smartphones [32]. Mobile phone access is particularly high for minorities. In Latinos aged 18 to 29 years, more (66%) own a smartphone than a computer (34%) [33]. Additionally, 72% of all African Americans and 98% of 18- to 29-year-olds in the group have either a broadband connection or a mobile phone [34]. A 2017 study found that African American adolescents are more active on social media and messaging apps than their white peers [35]. Historically, black adolescents report greater mobile phone use than white adolescents and are now more likely to use social media platforms optimized for mobile phones.

Prior research was conducted with adolescents and adults with CHD before and after their transition to identify their preferred methods for learning about CHD care transition. Findings revealed that while patients preferred to learn about their condition and long-term implications of their CHD directly from their physicians, they were also receptive to Web-based modalities to obtain similar information important to the success of adolescent transition [36]. Nine out of 10 adolescents used their mobile phone to access the internet, and 100% of those sent text messages daily. They were uniformly interested in a mentorship program with adults who have CHD and were interested in interacting with other CHD adolescents [36]. This research proposed that there were other ways, beyond face-to-face with a physician, that adolescents were willing to learn about their CHD and gain transition skills. It also demonstrated that the majority of CHD adolescents had ready

access to mobile phones regardless of socioeconomic status. This suggests that adolescents with CHD would be receptive to a mobile app for the purpose of CHD knowledge and transition.

Methods

Project Overview

Our research was conducted to collect formative data to inform the content and structure of a mobile app that facilitates transition and transfer of adolescents with CHD to adult care. It was conducted as part of (1) a quality improvement project for adolescents with mild-to-severe CHD to improve their experience when transitioning from a pediatric cardiologist to an adult cardiologist and (2) a research study to inform the creation of a mobile app (principal investigator Julie Miller, U24HL13569 and principal investigator KNL, K23HL127164). The project was based on the Got Transition website [37], the American Heart Association's best practices for transitioning adolescents with CHD [13], and an ongoing randomized controlled trial for transitioning adolescents with CHD [10]. The formative research included a literature review, parent and adolescent interviews, and discussions with 2 expert panels.

Setting

The formative research was conducted in a hospital-based pediatric cardiology clinic serving patients with CHD in the southwestern United States. The clinic services over 2000 adolescents with CHD per year. The clinic also has an adult congenital component that services young adults with congenital heart disease. The quality improvement project was initiated to improve transition readiness and transfer of care from the pediatric to adult congenital cardiologists. Prior to the project, there was no formal transition process, which put patients at risk for being lost to follow-up and having gaps in care upon being discharged from the pediatric cardiology clinic.

This quality improvement project began in April 2016 and had several iterative cycles to determine clinic flow, create a standardized transition-based CHD educational curriculum, and determine adolescent CHD patient needs and preferences and identify gaps regarding transition-related education. The research project began to build the mobile app in September 2015, and it was revised based on patient data surrounding knowledge and transition readiness deficits. This research was approved by the Human Subjects Review Committee at Baylor College of Medicine (H-39154).

Literature Review

A literature review was conducted to determine best practices and guidelines in transition medicine for CHD adolescents. For our search methods, we searched PubMed for papers published from January 2001 through November 2017. Our search terms included transition, congenital heart disease, and adolescents. We considered articles that described best practices, guidelines, expert opinion, literature reviews, transition programs, and surveys exploring attitudes surrounding transition for adolescents with CHD.

Interviews

Selection Criteria

Inclusion criteria were adolescent patients aged 15 to 21 years with congenital heart disease or electrophysiologic abnormalities who were being seen for a scheduled appointment in our pediatric cardiology clinic. Exclusion criteria included adolescent patients who had a known genetic or chromosomal disorder or a significant developmental delay.

Recruitment

Based on a quality improvement initiative conducted at our institution to improve transition in the pediatric cardiology clinic, we approached parents and patients prior to their cardiology clinic visit to determine if they wanted to participate in our study. Beginning April 2016, patients were identified by searching weekly clinic schedules for patients meeting the inclusion criteria. Prior to the clinic visit, pediatric cardiology providers were contacted by a transition nurse and social worker to determine if there was any hesitation to initiating transition in patients meeting inclusion criteria. Parents and adolescents were then approached in the waiting room by a transition nurse or social worker to determine interest in participating in the quality improvement project. Parents and adolescents were then given an introduction and explanation regarding the program; if they were interested in participating, they were offered an information packet about our transition program and scheduled to formally see the transition team on their the next clinic visit with the pediatric cardiologist. If they were not interested in the program, they could opt out of the program at the time of introduction.

Procedure

A standardized script guided discussions with both adolescents and their parents. Sample questions included "Can you name your congenital heart disease?" and "Do you know your medications and why you are on them?" Semistructured private interviews were conducted by members of the transition team (transition nurse, social worker) trained in qualitative methods. Adolescents and parents were interviewed separately during the clinic visit between medical procedures (echocardiogram, electrocardiogram, cardiologist visit).

Adolescents

Parents of adolescents with CHD were asked to leave the clinic room while adolescent interviews took place. Adolescent demographics, CHD type, access to mobile technology, and transition-specific topics were asked by the interviewer using a standardized script developed during the quality improvement process. Responses were manually recorded by the interviewer. CHD knowledge and motivation were also assessed by asking the adolescent to complete a paper version of a draft knowledge questionnaire that we developed as a part of the quality improvement initiative. Adolescents completed a paper version of the Transition Q survey [38] to assess transition readiness.

Parents

Parents left the clinic room where adolescents were being interviewed and were taken to a separate room in the clinic where they were interviewed. The interviewer asked parents

about their interest in having their child begin the transition process, communication with pediatric cardiologists regarding transition topics, familiarity with the transition process, and systemic changes that occur as their children become adults (insurance, advanced directives, etc). Sample questions included “Does your child have a plan to keep their health insurance after age 18 years?” and “Has your pediatric cardiologist ever discussed the topic of advanced directives with you?”

Data from all interviews and self-report questionnaires were manually entered into a Research Electronic Data Capture (RedCAP) database by the transition team for the iterative process.

Expert Panel

Adolescents with CHD who expressed an interest in mobile app development during their interview were contacted by phone to determine interest in being a part of an expert panel. Adolescents agreeing to participate in the expert panel were asked to assist more specifically in the development of the mobile app. Qualitative data were obtained in an unstructured group interview conducted by the transition team director and nurse. Panel members were asked their feelings and thoughts about what should be included on a CHD mobile app about transition. Manual notes were taken by the transition social worker who was not participating in the interview, and these were subsequently coded into themes. Adolescents were shown several images of the prototype mobile app on a tablet device to determine their general impression of the design and appearance of the app. Data from these interviews were subsequently manually entered into RedCAP.

Prototype

The mobile app structure was created based on best practice guidelines, our formative research, and CHD expert panel suggestions. An iterative, user-centered design process was used to ensure that the design and functionality of the app and content were compatible with the target population’s needs and preferences. The app was structured with a client-server architecture, with all user data retained on the server to facilitate secure data storage and transfer.

Results

Literature Review

A total of 113 journal articles from the United States and Europe addressing transition were identified. Of these, 38 were studies on transition programs and attitudes surrounding transition. Three articles gave best practices and guidelines in transition specific to CHD [13,38,39]. Transition best practices included timing of transition, establishing a medical home, long-term medical and surgical follow-up, anticipatory guidance, exercise restrictions, family planning, and insurance preparation. Information on transition-related topics, best practices in transition goals, and attitudes about existing transition programs were then considered for incorporation into our mobile app.

Interviews

Adolescents

Demographics

We completed 402 individual interviews with adolescents who had CHD (Table 1). Adolescents were aged 15 to 22 years (median age 16 years; interquartile range [25% to 75%] 14 to 17 years). Interviews lasted an average of 18 to 22 minutes.

Mobile Phones

Of the patients asked, 94.2% (295/313) of the adolescents had their own mobile phone, with 67.8% (200/295) of those being iPhones and 32.2% (95/295) having Android operating systems. A total of 23 adolescents were interested in mentoring other adolescents with CHD.

Congenital Heart Disease Knowledge

Most adolescents with all levels of CHD complexity reported minimal to no understanding of their CHD (79.0% [275/348] of those aged 15 to 17 years and 61.1% [33/54] of those aged 18 to 22 years).

Transition Readiness

Average initial transition readiness for all adolescents was 50.9 out of 100. Thus, roughly half of the transition readiness metrics were being met by adolescents during the transition period.

Parents

We conducted independent interviews with parents of adolescents with CHD; 89.7% (374/417) of parents felt that their child was ready to start learning about and participating in the transition process, and 89.0% (371/417) reported understanding the need for eventual transition and transfer to an adult CHD provider. One in 5 (86/417, 20.6%) parents required an interpreter. Only 5.0% (21/417) of parents reported that the pediatric cardiologist saw their child independent of them. More than three-quarters (331/417, 79.4%) of parents reported that the pediatric cardiologist had not addressed family planning or birth control, 55.2% (230/417) reported never having received a question about the mental health of their adolescent (ie, no questions about depression or anxiety), and 81.5% (340/417) of parents reporting that the pediatric cardiologist had not addressed the topic of advanced directives.

Finally, 63.8% (266/417) of parents had not discussed anticipating independent decision making by their child after age 18 years, 66.4% (277/417) of parents reported not understanding how health care may change after age 18 years, and 40.8% (170/417) reported not understanding what happens to their child’s insurance after age 18 years.

Expert Panel

On initial interview, 10 adolescents expressed an interest in mobile app development. These adolescents were contacted, and 6 expressed an interest in being a part of an advisory council to assist in the development of a CHD mobile app. In 2 expert panels of 3 adolescents each, 4 themes arose around main areas desired in the mobile app, along with specific recommendations for topics to include (Textbox 1). Quotations addressing distinct

design components of the mobile app for each theme can be seen in [Textbox 2](#).

Mobile Prototype

A summary from concept to creation of mobile app is shown in [Figure 1](#). The server component was built in an environment compliant with the Health Insurance Portability and Accountability Act and the Federal Information Security Management Act within Amazon Web Services that included administrative and reporting features in addition to a JavaScript Object Notation–based Representational State Transfer application programming interface used by the client application. Patient data (including portable health summary documents and other structured protected health information) was stored in encrypted storage and decrypted only when required for delivery

to an authenticated and authorized client, at which time it was delivered via a secure, encrypted channel.

The client application was a native iOS application built using the React Native framework. This technology was chosen for its efficient development cycle and support for cross-platform deployment capability (the potential for deployment to both Android and iOS devices with minimal platform-specific development). Users could authenticate to the server by providing a username and password in the app. Future new users of the app could use a 1-time activation code to establish authentication credentials during their first time using the app. Mobile app prototype included user profile, transition checklist component, CHD-specific educational modules, portable medical summary and CHD diagram, a space for medical questions, and a blog space ([Figures 2-5](#)).

Table 1. Characteristics of patients with congenital heart disease on the expert panel making recommendations for mobile app.

Characteristics	Total, n (%)
Sex (female)	169 (42.0)
Age (15-17 years)	348 (86.5)
Race (African American)	51 (12.6)
Ethnicity (Latino)	152 (37.8)
Public insurance	146 (36.3)
Moderate/severe complexity congenital heart diseases	313 (76.7)

Textbox 1. Themes and recommendations for the mobile app.

<p>Tailored application:</p> <ul style="list-style-type: none"> • Create a congenital heart disease (CHD) diagram specific to CHD patient • Enable a transition checklist • Create way to monitor transition progress • Create portable medical summary • Create medication and appointment notifications <p>CHD-specific education:</p> <ul style="list-style-type: none"> • Focus on CHD education that is disease specific • Make learning topics searchable • Create short CHD videos • Focus on how to recognize an emergency • Do not make people take a full quiz <p>Mentorship:</p> <ul style="list-style-type: none"> • Design a way to connect with others who have CHD • Connect with peer mentors • Adult CHD mentor access • Enable chat features with mentors <p>Social media:</p> <ul style="list-style-type: none"> • Create a CHD story blog for adolescents to share their experiences • Create forum to ask medical questions • Create way to comment on other CHD posts
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Textbox 2. Themes and quotations addressing distinct design components for the mobile app. CHD: congenital heart disease.

Tailored application:

- “I like assessment tailored to me...it shouldn’t be too long or I’ll just click anything.” [female]
- “I would like a personalized medical summary.” [male]
- “I prefer one-on-one education versus learning in a group.” [multiple similar quotes]
- “I would like an app aspect of being able to ask a question anonymously.” [anonymous]

CHD-specific education:

- “I knew I had surgery but did not know specifics of my CHD, and life has been worrisome.” [female]
- “I don’t want a lecture, an hour is too long. Fifteen to thirty minutes max.” [male]
- “A checklist would be helpful in knowing where I am as far as my knowledge about my CHD; seeing it helps me remember.” [multiple similar quotes]
- “Between age 13 or 14 is when I really became curious about what I had.” [anonymous]

Mentorship:

- “Pairing someone who is comfortable with their CHD to someone who isn’t comfortable with their CHD is important.” [female]
- “I would like a learning night; a good way to be social with others and learn.” [male]
- “I don’t know what questions to ask my doctor about my future, but I want to learn.” [multiple similar quotes]
- “I feel like I need knowledge and a CHD community.” [anonymous]

Social media:

- “I think it’s important to connect with others with CHD and without CHD.” [female]
- “I’d like to connect with people with similar CHD stories.” [multiple similar quotes]

Figure 1. Flow diagram from concept to mobile app creation. CHD: congenital heart disease; QI: quality improvement.

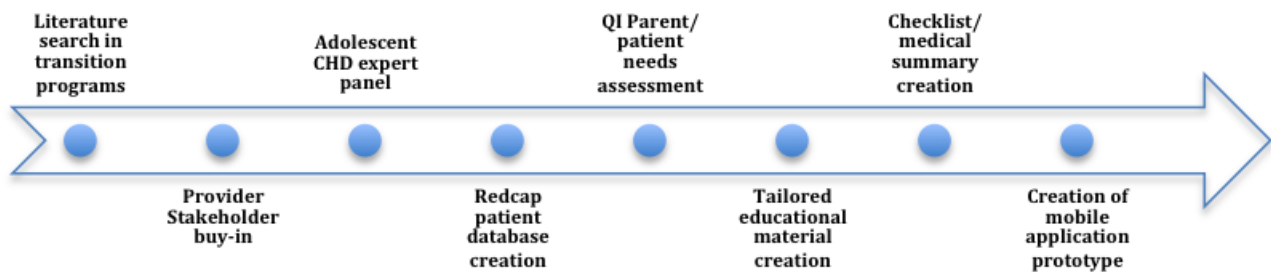


Figure 2. Screenshots of the mobile app: (a) profile page with congenital heart disease diagram and medical summary and (b) congenital heart disease transition checklist.

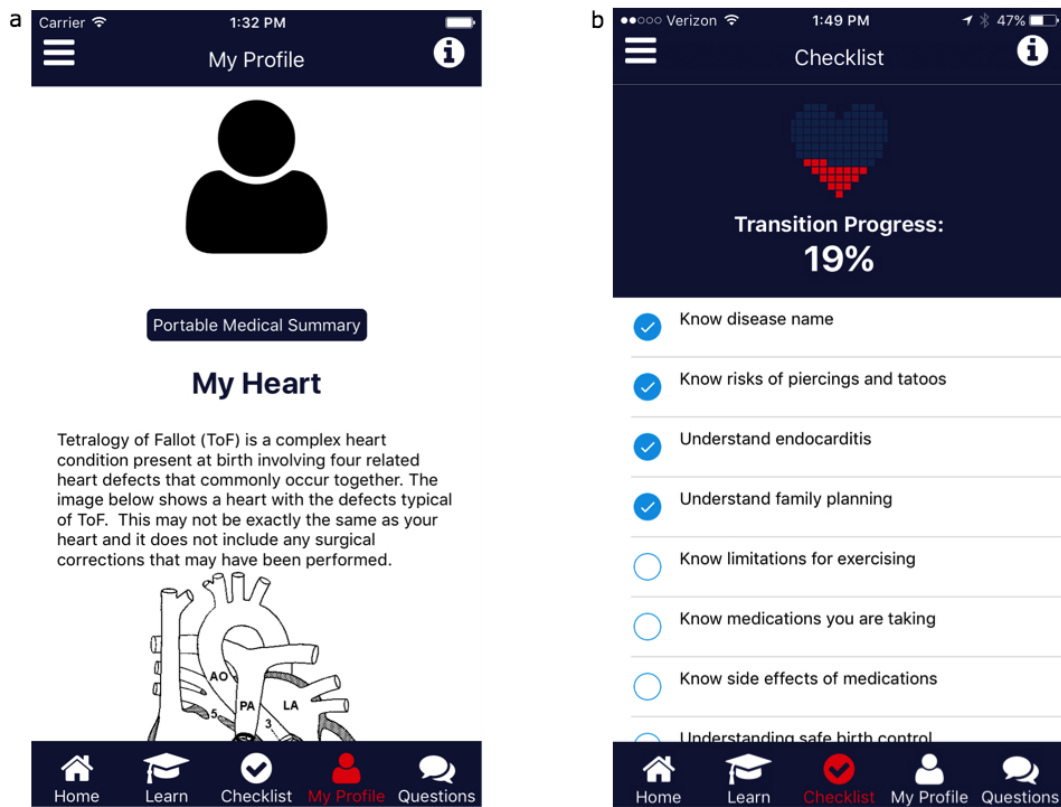


Figure 3. Transition education on congenital heart disease medical emergencies and blog entry on life with congenital heart disease for mobile app. CHD: congenital heart disease; ToF: Tetralogy of Fallot.

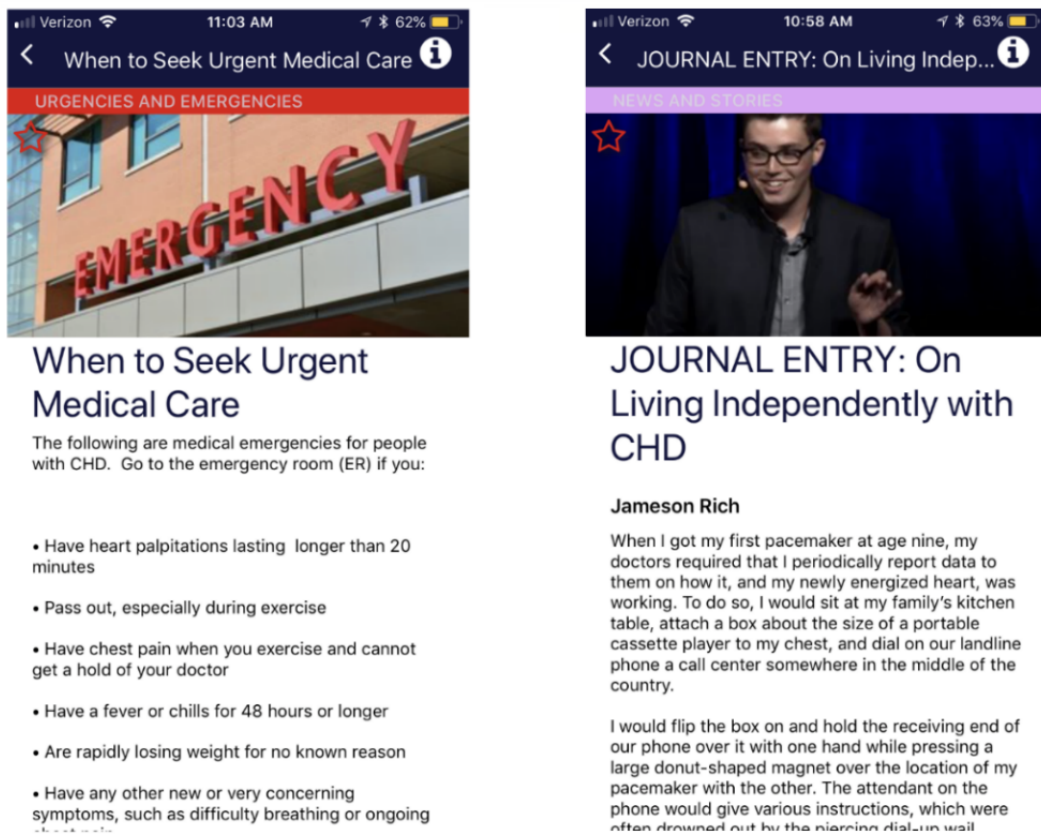


Figure 4. Congenital heart disease (CHD) in-clinic transition skills, out-of-clinic transition skills, and adult resources for mobile app. ToF: Tetralogy of Fallot.

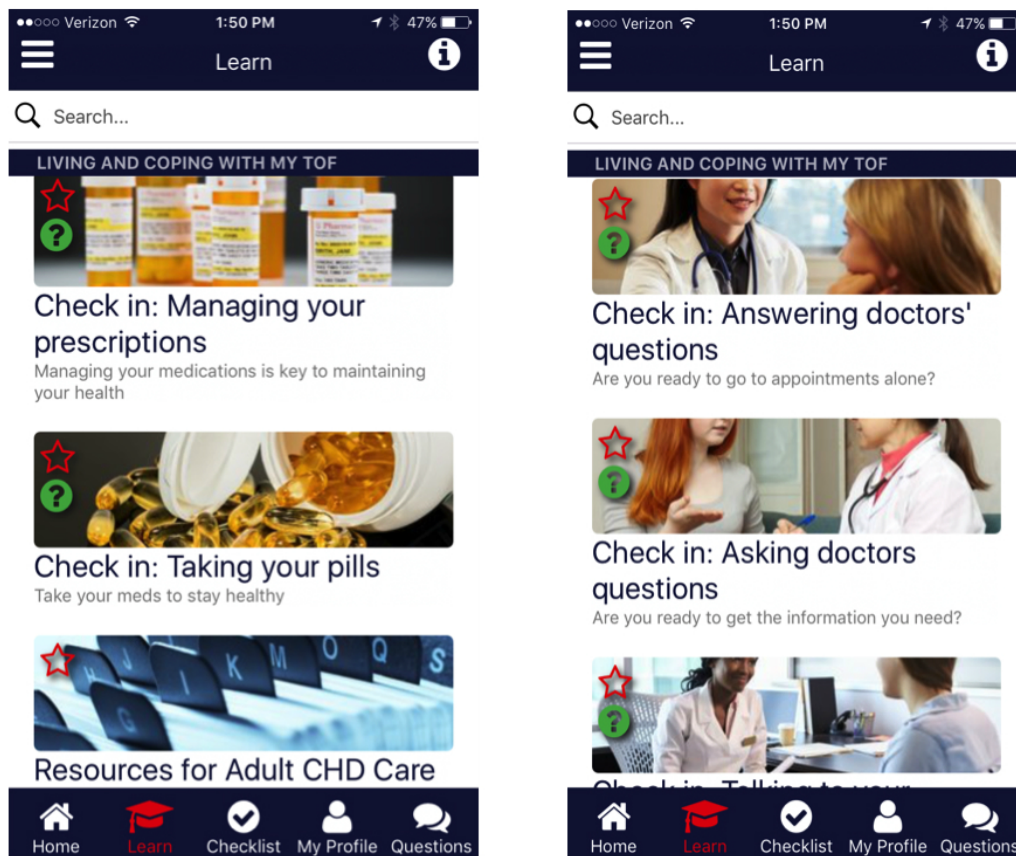
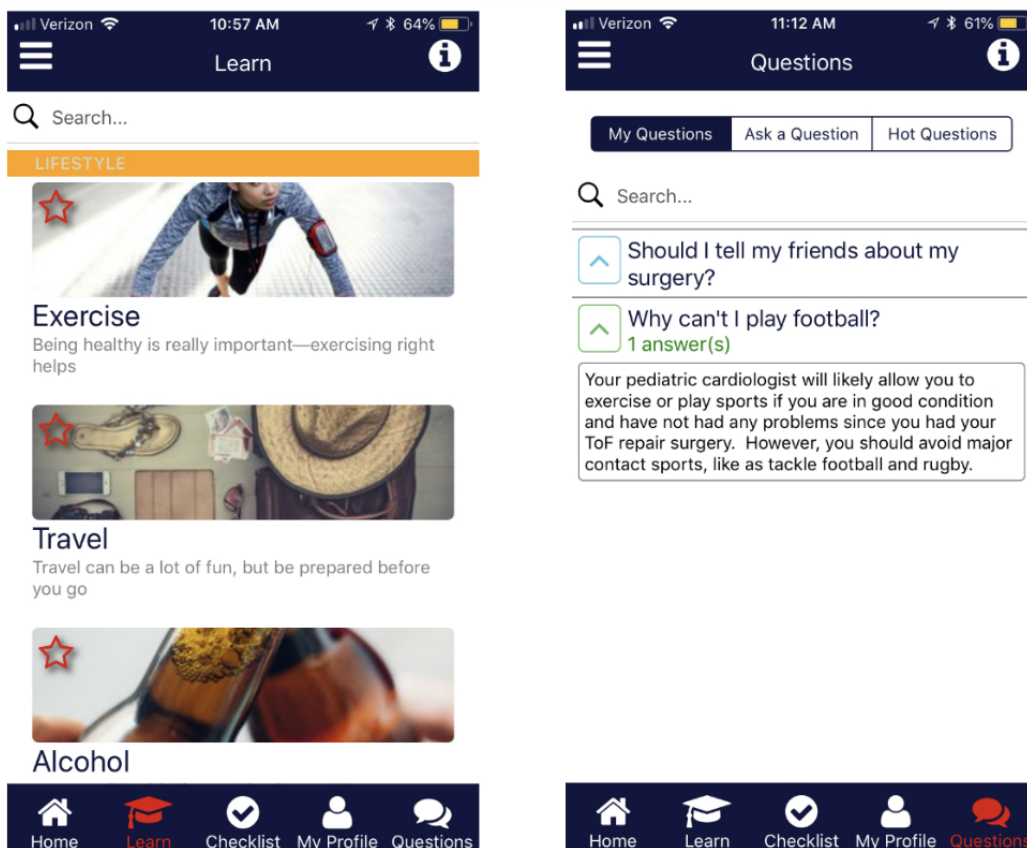


Figure 5. Transition education on congenital heart disease (CHD) aspects of lifestyle and message board for CHD related questions.



Discussion

Principal Findings

There are increasing numbers of adolescents with chronic conditions surviving to adulthood and needing adult-centered care, and significant declines in treatment adherence are observed during the transition period [40]. Given that CHD is the most common birth defect and there are now more adults surviving than children, empowering adolescents to appropriately transition care is of utmost importance. Personal management of chronic physical conditions requires 5 main skills: problem solving, decision making, resource utilization, patient-doctor relationships, and taking action [41]. This prototype mobile app can assist in aiding problem solving and decision making by providing disease-specific and lifestyle information and creating portable tools, including a portable medical summary and a CHD diagram of their disease, that adolescents can use to convey important disease information.

The formative research with adolescents and their parents provided insight into the transition domains that adolescents with CHD seem to be lacking in terms of education during routine clinic visits with their pediatric cardiologist. These domains include more precise CHD knowledge, medication knowledge, lifestyle choices, long-term care, and family planning, and we have directly integrated these into a mobile app created to assist in the transition of care for adolescents with CHD.

Several health-related mobile apps exist for adults with a variety of chronic diseases. A 2015 systematic review of studies of adolescent use of mobile apps supporting management of chronic disease revealed only 4 studies that contained pre-post or randomized controlled data [42]. Of the 4 apps studied, 2 were focused on type 1 diabetes and the other 2 focused on asthma and cancer. Three out of the 4 studies reported some level of patient involvement in the design, development, or evaluation of the app. This review noted that the dearth of studies and overall small sample size emphasized the need for future studies on the development, use, and effectiveness of mobile apps to support adolescent personal management of chronic disease [42]. There is no mobile app currently available, to our knowledge, for assisting patients with CHD in the transition process or in managing their disease. Thus, our mobile app fills a gap for a high-risk, heterogeneous population that requires lifelong management and care of their disease.

Two other systematic reviews were conducted in 2017 looking at using mobile phone apps and text messaging to improve medication adherence in adolescents with chronic diseases [43] and improve preventative behavior in adolescents [44]. The first review found that 7 out of 15 studies meeting inclusion criteria demonstrated significant improvement in adherence with moderate to large standardized mean differences. The second review found 19 studies meeting the inclusion criteria for promoting preventative behaviors, with 4 of those studies involving mobile apps and 15 involving only text messages. About half of the included studies (8/19) demonstrated

significant improvement in preventative behaviors with moderate standardized mean differences.

Given that some of our domains are adherence-related and others are preventative, this is encouraging news for the potential impact our mobile app can make. That being said, the evidence to support the cost effectiveness of text messaging and mobile phone-based interventions in improving medication adherence in adolescents with chronic health conditions is insufficient. More research needs to be done in this area to better understand their role in cost savings while improving medication adherence and health outcomes [45].

Next steps include surveying pediatric and adult cardiologists on the content in the mobile app and conducting focus groups on the existing prototype of the app to obtain feedback on the design, interface, and information included in the mobile app.

Limitations and Strengths

Our formative research was performed in the context of a quality improvement project, and as the project changed our practice to address clinical needs, our parent and patient intake changed (so not all questions were asked to all parents and patients). The evolution of the quality improvement project along with the expert panel then helped inform our mobile app.

For our quality improvement project, we excluded patients with chromosomal abnormalities, genetic syndromes, or developmental delays. Therefore, parental attitudes and concerns for those populations were not reflected in parental interviews. This may limit the generalizability of a CHD transition mobile app for these populations.

One strength of our formative research reported here is that it was conducted with adolescents from different socioeconomic levels and races/ethnicities. These adolescents also had differing levels of disease severity, making our formative research informative for all patients with CHD. We are hoping this assists in the acceptance, usability, and adoption of the mobile app.

Conclusions

Given the limitations most providers face in terms of resources and time to address and teach about transition topics, the purpose of this paper was to report formative research conducted to inform the development of a mobile app to facilitate the transition and transfer care of adolescents with CHD to adult care.

This research revealed knowledge gaps and lack of transition readiness for CHD adolescents and their parents surrounding the transition process. Parents were largely interested in initiating the transition process with their adolescent and noted several areas specific to transition that were not addressed during pediatric cardiology visits. This research also revealed that in a racially, ethnically, and socioeconomically diverse population of CHD patients, the majority had access to mobile phones. Adolescents expressed interest in a mobile app to facilitate transition to adult care and had specific content areas that they wanted included in the mobile app. Future directions include a further query of pediatric cardiology providers and usability and feasibility testing with the prototype CHD mobile app.

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Conflicts of Interest

None declared.

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Abbreviations

CHD: congenital heart disease

RedCAP: Research Electronic Data Capture

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Original Paper

Adolescent Preferences and Design Recommendations for an Asthma Self-Management App: Mixed-Methods Study

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Abstract

Background: Approximately 10% of adolescents in the United States have asthma. Adolescents widely use apps on mobile phones and tablet technology for social networking and gaming purposes. Given the increase in recreational app use among adolescents, leveraging apps to support adolescent asthma disease management seems warranted. However, little empirical research has influenced asthma app development; adolescent users are seldom involved in the app design process.

Objective: The aim of this mixed-methods study was to assess adolescent preferences and design recommendations for an asthma self-management app.

Methods: A total of 20 adolescents with persistent asthma (aged 12-16 years) provided feedback on two asthma self-management apps during in-person semistructured interviews following their regularly scheduled asthma clinic visit and via telephone 1 week later. Interviews were audiorecorded, transcribed verbatim, analyzed using SPSS v24, and coded thematically using MAXQDA 11.

Results: Regarding esthetics, app layout and perceived visual simplicity were important to facilitate initial app use. Adolescents were more likely to continually engage with apps that were deemed useful and met their informational needs. Adolescents also desired app features that fit within their existing paradigm or schema and included familiar components (eg, medication alerts that appear and sound like FaceTime notifications and games modeled after Quiz Up and Minecraft), as well as the ability to customize app components. They also suggested that apps include other features, such as an air quality tracker and voice command.

Conclusions: Adolescents desire specific app characteristics including customization and tailoring to meet their asthma informational needs. Involving adolescents in early stages of app development is likely to result in an asthma app that meets their self-management needs and design preferences and ultimately the adoption and maintenance of positive asthma self-management behaviors.

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KEYWORDS

asthma; mHealth; mobile app; patient engagement; self-management; usability

Introduction

In the United States, 1 in 10 adolescents have asthma [1], and poorly controlled asthma among children and adolescents (aged 6-17 years) can lead to greater health resource utilization and health care expenditures estimated at US \$5.35 billion per year [2]. However, negative health outcomes can be drastically reduced and prevented through proper disease self-management [3], and leveraging technology to support adolescent asthma management seems warranted. A little over half (58%) of adolescents aged 13-17 years have access to a tablet, approximately 75% have access to a smartphone, and 92% of teens report going online daily [4].

Although adolescents are early adopters of technology and mobile app use is increasing among the adolescent population, only 8 out of 147 asthma apps are targeted toward children or young adults [5]. Given that declines in treatment adherence have been observed during adolescence and adolescents with asthma are at higher risk for poor health outcomes than other age groups with asthma [6-8], apps targeting this age group are crucial. However, a challenge for health apps compared with popular mainstream apps is their lack of use over time considering that many health-related apps are cumbersome and uninteresting to the app user [9]. Research has found that although 21% of teens have downloaded a health-related app, only 8% of these teens often used the app and 47% hardly ever or never used them [10]. Qualitative research on adolescent preferences for health apps, including how they perceive and would use apps to support their asthma self-management, has been lacking [11,12].

The objective of our study was to assess adolescent preferences and design recommendations for an asthma self-management app. We obtained feedback from adolescents with asthma on 2 existing asthma self-management apps and examined preferences for aesthetics, features, and app content that would encourage continued engagement with the app. In addition, we assessed adolescents' overall opinions of the apps, focusing on aspects of app usability. Understanding adolescent preferences and reasons for suggested changes and design recommendations could lead to the development of an app with better usability, user engagement, and improved clinical outcomes.

Methods

Study Population and Recruitment

A total of 20 adolescents were recruited from 2 pediatric medical practices in urban North Carolina. Eligible adolescents were (1) 12-16 years of age; (2) able to read and understand English; (3) owned a cell phone, smartphone, or tablet; (4) present at the medical visit with an adult caregiver; and (5) had persistent asthma (defined as asthma-related daytime symptoms >2 times a week and nighttime symptoms >2 times a month or receiving ≥ 1 long-term asthma control therapies) [13,14]. A clinic liaison used the electronic health record to identify potentially eligible adolescents with asthma at both pediatric practices and informed their caregivers about the study over the phone prior to the adolescent's regularly scheduled clinic appointment. When they arrived for their appointment, interested adolescents and their

caregivers were introduced to the study research assistant and were screened for eligibility. Participating adolescents provided written informed assent, and caregivers provided parental permission for their child to participate.

Study Procedures

Adolescents completed a brief demographic questionnaire prior to their clinic visit. After their visit, the research assistant gave adolescents an iPod with 2 preloaded asthma self-management apps. The two apps were purposively selected by a behavioral researcher, an mHealth expert, and a respiratory therapist from those available on the iOS platform due to their user-friendly interface and inclusion of features for asthma self-management. Since no apps at the time of the study (pre-2017) were targeted specifically for adolescents, we selected one app geared toward children and one for adults. The research assistant reviewed the features of the apps with the adolescents and their caregiver, and then let them explore the apps on their own for approximately 10 minutes. After adolescents were familiar with the apps, adolescents and caregivers provided their feedback during a semistructured 30-minute interview. Adolescents were asked to use the apps over the next 7 days, after which they completed a 30-minute telephone interview that further assessed their app preferences and design recommendations. In-person and telephone interviews were both audiorecorded. iPod touches were given to the adolescents as study incentives. The study was reviewed and approved by the Institutional Review Board at the University of North Carolina and was conducted in accordance with the tenets of the Declaration of Helsinki.

Measures

Sample Demographic and Clinical Characteristics

Adolescents reported the following demographic characteristics: (1) gender (male or female); (2) age (in years); (3) ethnicity (Hispanic, Latino or Spanish origin); and (4) race (white, black or African American, American Indian or Alaskan Native, Asian, Native Hawaiian or Other Pacific Islander, or other), which was recoded into 3 variables (white, black or African American, or other) for descriptive purposes. Adolescents also reported their grade in school, how long they have had asthma (in years), and how serious they think their asthma is (1=very serious, 2=fairly serious, 3=somewhat serious, and 4=not at all serious).

Technology Use

Adolescents were asked the following yes or no questions:

1. Have you downloaded an app to a cell phone, tablet, or other handheld device?
2. Have you ever downloaded a health-related app to a cellphone, tablet, or other handheld device?
3. Have you ever used an asthma app before today?
4. Do you enjoy spending time on social internet sites such as Twitter, Instagram, Facebook, or Pinterest?

Participants were also asked, "Which site(s) do you use most of the time?", and were able to select ≥ 1 of the sites above or select "other" and list the other site used most of the time.

Interview Content

Adolescent app preferences and design recommendations were assessed using a process of qualitative inquiry [15]. Researchers employed an evaluation methodology to ascertain adolescents' feedback on the apps during both in-person visit and 1-week follow-up telephone interview [16]. During the initial in-person interview, adolescents were asked questions focusing on the visual appeal of the apps, suggestions for improvement (eg, additions and changes), and overall feedback on the apps. They were also asked about their opinions on the apps after exploring them for a week, including ease of use, barriers and facilitators to use, and additional suggestions for improvement.

Interview questions that assessed adolescent interest in additional components like asthma quizzes, avatars, and videos for inhaler technique, as well as questions pertaining to preferred app and app self-management potential, were quantified (yes or no). Table 1 lists the relevant interview questions that were used to assess adolescent preferences and design recommendations.

Table 1. Adolescent preferences and design recommendations guide.

Coding category	Interview questions
Qualitatively analyzed questions	
Ease of use	<ul style="list-style-type: none"> • Can you please describe what it was like learning how to use these apps?^a • How much time would you say that it took you to learn how to use (preferred app)?^{a,b}
App engagement/barriers and facilitators to use	<ul style="list-style-type: none"> • Do you think you will continue to use (preferred app)? Why or why not?^a • Can you tell us the reason or reasons that you did not use the applications?^a • Can you think of anything that would have helped you use the applications?^a
Overall feedback	<ul style="list-style-type: none"> • Is there anything else that we haven't covered about the apps that you would like to share?^c
Suggestions for improvement	<ul style="list-style-type: none"> • How could (child app) be changed to make it better?^c • How could (adult app) be changed to make it better?^c • What would you add that you didn't see as a feature—in either app—and why?^c • How could any of these features be improved?^a • Is there a feature that you think was missing in this app that you would like to use?^a • What would you change about (preferred app)?^a
Visual appeal	<ul style="list-style-type: none"> • Which app do you think looks better and why?^{b,c}
Quantitatively analyzed questions	
Asthma quizzes	<ul style="list-style-type: none"> • Would you take asthma quizzes if they were part of the app?^a
Avatar	<ul style="list-style-type: none"> • Would you be more likely to use an asthma app if you could create an avatar?^a
Inhaler technique	<ul style="list-style-type: none"> • Would you use the app to watch videos of correct inhaler technique?^a
Preferred app	<ul style="list-style-type: none"> • Using a scale of 1-5, 1 being not at all satisfied and 5 being extremely satisfied, please rate your overall satisfaction with (app name). (App with higher score=preferred app)
Self-management potential	<ul style="list-style-type: none"> • Which app helped you most with managing your asthma?^a

^aTelephone interview.

^bQuantified for analysis.

^cIn-person interview.

All audiorecorded transcripts were coded independently by one research team member, and a secondary coder coded 10% of all transcripts. Interrater reliability was $\kappa=.85$.

Results

Adolescent Demographic Characteristics

The demographic characteristics of adolescents who participated in our study are shown in Table 2. Among them, 20 completed the in-person interview and 16 completed the 1-week follow-up phone interviews. The demographic characteristics of the 4 adolescents who did not complete the phone interviews did not differ from those who completed the study (2 white, 2 black, and 3 females with a mean age of 14.5 years).

Adolescent Technology Usage

Although all 20 adolescents had previously downloaded an app, only 15% (3/20) had downloaded a health-related app and none had used an asthma app before the study. Moreover, 75% (15/20) adolescents said that they enjoyed spending time on social media, and the site(s) that adolescents reported using most of the time were Facebook (11/20, 55%), Instagram (8/20, 40%), Twitter (5/20, 25%), and Pinterest (3/20, 15%).

App Ease of Use

The minimum time an adolescent spent learning how to use the apps was 30 seconds, with one adolescent stating it took them “a couple of minutes” and another one describing the time as “not long.” About a third of the adolescents from the follow-up interviews (5/16, 31%) spent approximately 5-10 minutes learning how to use the apps, and others reported it took them longer—1-3 days (the maximum time reported) (6/16, 38%).

App ease of use was an important facilitator of adolescent engagement with the app and continual use over the 7-day period. When asked, “Do you think you will continue to use [preferred app], and why?”, one adolescent responded that she would continue to use the app.

It's very simple and easy to use...you just go in and put in a couple of things [in the app] instead of a really long process because I think once you have too many features on it, you know, you don't want to use it every single day. [Female, 14]

While some adolescents stated that learning how to use the apps was “pretty easy for the most part” because “there wasn't much to them, they're kind of self-explanatory,” others expressed some difficulty.

It was easy and it was a little confus-, well, it wasn't confusing, it was just—I had to learn how to use it, because I'm not—you know, I'm not used to using the app—well, I am now, but I wasn't at the time, so I had to learn how to use it and I had put information in it. [Female, 15]

Like I mean like to understand it real well and to know how to use it, like I had to get used to it cause I never seen another application like this one. [Male, 14]

One adolescent stated that, “it doesn't explain how to use it well.” Adolescents reported unfamiliarity with the apps and a lack of understanding on how to use the apps as barriers to initial app use. However, adolescents suggested improvements to the apps that would aid in their app understanding, including video tutorials and picture explanations, and increase their app ease of use.

Maybe it could give you like a list of it, like a tutorial before you like actually started using it...to like show you through the app and what the stuff is. [Male, 12]

[Add] Videos of people actually like using it, you know, like a tutorial walk through. And also, like the things like also showing like how some people are using it, like some videos of people using it and getting used to it. [Male, 12]

Add pictures to [app name]. Because I think if you were to add that, I think more teenagers my age could understand the app better because they don't understand what it is. [Male, 14]

Table 2. Adolescent sample characteristics (N=20).

Adolescents	Value
Age in years (range: 12-17), mean (SD)	14.7 (1.6)
Female, n (%)	9 (45)
Race, n (%)	
White	9 (45)
Black	8 (40)
Other	3 (15)
Ethnicity, n (%)	
Hispanic, Latino, or Spanish origin	4 (20)
Non-Hispanic	16 (80)
Grade in school (range: 6-11), mean (SD)	8.3 (1.6)
Years with asthma (range: 1-16), mean (SD)	9.9 (4.8)
Perceived asthma severity (range: 1-4), mean (SD)	2.4 (0.9)

App Visual Appeal

Figures 1 and 2 depict screen shots taken from the apps. Adolescents expressed mixed opinions regarding the visual appeal of the two apps. Referencing the child app, adolescents commented the following:

I like how like it's all like colorful and like playful and like looks like it's real—like it looks interesting, you know. [Male, 12]

[Child app] made me smile when I used it, I don't know. It's kind of funny, like every time you click, and you know how it made that noise? Yeah it was pretty cool...that makes me want to interact with it more. [Male, 16]

They stated that the app was “interactive for kids,” and they liked that it was simplistic—citing the fact that it does not have too many features as a plus. They also liked that all the main features were visible on one main page, so it “has everything like right there so like you can just click on it” [Male, 12]. However, others stated:

It's kind of kid-is to me, it's more for younger kids, not really for teens...it seemed like it was more for kids that were like 12 and under. [Male, 15]

The monsters and stuff that it has, I personally don't like it. [Female, 16]

Some also negatively commented on the design layout, mentioning that things were “all clumped on one page,” and “cluttered...and need to be split up.”

Figure 1. Screenshots from the child app. Source: iAsthma.



Regarding the adult app, some participants stated that “It’s more organized [than the child app]” [Female, 16], and they liked that the app labels everything. However, others stated:

[The adult app] has so much stuff in it, and I don't really know how to use all that stuff just quite yet [Male, 13]

[It looks] really complex...[developers need to] make it a little more appealing to kids [Male, 13]

Despite mixed reviews regarding which app was more visually appealing and organized, app layout and perceived visual simplicity were important to adolescents. When asked, “How could [preferred app] be changed to make it better?”, one adolescent stated that they would like to see the app organized differently, with the main features in an alphabetical order. Adolescents also enjoyed visual aids, such as pictures, graphs, and charts, stating:

They just work that you might see or want to learn with maybe, like the charts, stuff like that. [Male, 14]

That [chart] was what really...helped me because you could really visualize how your asthma is doing. [Female, 14]

Qualitative Themes

Three qualitative themes emerged from the interviews.

Customization to Fit Within the Schema

Adolescents suggested feature-specific customizations, such as adding more preselected symptoms, triggers, and medications to the medication list, as well as the option to input your own.

Figure 2. Screenshots from the adult app. Source: AsthmaMD.



They also proposed improvements to the interface, including the option to have bigger icons, as well as changes to text, background, graphics, and pictures. One adolescent stated that their preferred app “would keep someone’s interest, because with all the colors and the characters and stuff” [Female, 16]. However, many agreed that:

It might be cool if you could choose like your colors and stuff on it...if you wanted to choose like a theme color. [Female, 14]

Several adolescents criticized the apps stating the following:

The graphics weren't like good enough, like for a teen to like want to use it...it would just like make them feel like they've downloaded it so like they...have to use it because they have like a, um, certain situation, it won't make them like want to use it, it'll just like, you know, make them feel like they have to use it. [Male, 12]

The main menu looks...kind of hard to read because of the shadow, um it looks kind of like PowerPoint, a strange PowerPoint slide. I feel like the shadow in the background does not need to be there...it looks like someone took a lot of the word art things that you can do and then put them all there. It looks like I could probably go and make something very similar. [Female, 14]

The words are kind of a little blurry, but like I know they try their best, I give them props and stuff for that cause I can't do that, and they did good, but the graphics [are] just like a little off and like it's kind of blurry. [Male, 13]

One adolescent pointed out that the app might not look the same on the new version of the iPhone, stating the new iPhone “has a different kind of interface, so it might look a little outdated on those.”

It seems to look like the iOS, it doesn't look like the new operating system. So, it might be nice if it could look different for the different type of like devices because I know the, the iPhones, my friend has one, it's got a whole new like look to it. Catch up with that one. [Female, 14]

Adolescents specifically stated app customizations that seemed to fit within their current schema or apps and technology with which they were already familiar. For example, one adolescent suggested the addition of a medication reminder that would...

...pop up on your screen with an—with, uh, your like ringtone for maybe FaceTime or something... You would have to set a ringtone through the app, though, but it would like—your phone would either buzz—your iPod or phone or whatever you have would buzz and

it would just like remind you to take the medicine.
[Male, 12]

One adolescent stated they would be attracted to an app if it could incorporate “something that teens are interested in...like there’s a game that like most of us play, called Minecraft” [Male, 12]. He suggested modeling an asthma game after Minecraft, and another one similarly suggested modeling a game after QuizUp to facilitate app engagement.

I know like that app, the QuizUp is like really fun, even though it’s like quiz stuff, it’s fun to do because you’re like competing against other people. And yeah, I know a lot of people who like that game, so, if you could like do basically something like that, except with asthma stuff, I think it’d be fun. [Female, 16]

When asked, “How could any of these features be improved?”, one adolescent responded by mentioning adding puzzle games because she plays those on other apps, and many adolescents suggested the addition of asthma games or turning existing features into gaming components since “kids love games” [Female, 13]. For example, one adolescent stated, “if there was a cool game on it that interpreted what the asthma stuff [means], then I guess I’d use it,” and another one stated “Like if there was like a game on the app, I think kids would enjoy it better” [Female, 13]. An adolescent suggested a game idea below:

Let’s say like a normal patient has asthma and they had to take their inhaler, sort of a few puffs day and night, so like you could set a notification for like 12 hours for them to take their medication. And like if, like if you want to make it like a little more good to the kid population, like you could say, you know, you took your medication, 50 points or something. [Male, 13]

One adolescent stated that he would like to see more...

...pictures of stuff that like inspire you. Like for me, I like sports, so I would like to see like sports people or, uh, game characters and stuff like that. [Male, 14]

Similarly, one adolescent stated that he would add Cam Newton or his favorite sports character and incorporate him into the app, possibly as an avatar, or include an image of him on a page of the app. When asked, “would you be more likely to use an asthma app if you could create an avatar?”, 63% (10/16) said yes, 6% (1/16) said most likely, 12% (2/16) said probably, and 19% (3/16) said no.

Utility or Functionality of Apps Over Visual Appeal for Continual Engagement

Although adolescents stressed that an app should be visually appealing in order to facilitate app use, many adolescents appeared to place equal to higher importance on app functionality and self-management potential over app appearance for continual engagement. Of the 16 adolescents who completed the follow-up interview, 63% (10/16) said the child app looked better, while 31% (5/16) said the adult app looked better (1 adolescent did not respond). However, despite majority preference for the visual appeal of the child app, only 31% (5/16) of these adolescents said the child app was their preferred app compared with 69% (11/16) adolescents citing

the adult app as their preferred app. Furthermore, 63% (10/16) adolescents said the adult app was best for managing their asthma compared with 25% (4/16) adolescents for the child app (2 did not respond).

One adolescent stated the child app was “too basic” with its one primary page layout. She stated that “the [adult app] has more pages to choose from and you can find out more things, like going on the website and asking questions” [Female, 16]. When it came to meeting asthma self-management needs, the child app was deemed “less comprehensive” with adolescents stating:

I like the graphics, they’re cute, but, um, it doesn’t—it doesn’t seem like it would be as useful. [Female, 14]

I don’t understand the point of it, personally. Um, so do you—when you take your meds do you just drag it into the mouth?...I didn’t under—like I didn’t get the point of it, but, I mean, it’s cute, but I didn’t get the point. [Female, 16]

Similarly, some adolescents stated that they liked the adult app because “it covers more stuff” [Female, 14] and “it was very useful... It looks like it helps more, and it takes it [asthma] more serious and stuff” [Male, 14]. They noted the wide range of self-management features available in the adult app, citing:

It [adult app] has more things that are like useful to like track the stuff that you are entering than the [child app]. [Male, 12]

One adolescent stated she would...

...just use the monster one [child app] to look at the monsters, but... I would use the other one to like keep track of like how my asthma was that—like that day, like if it got real bad. [Female, 13]

Similarly, another adolescent stated:

The [child app] is more attractive and the [adult app] is more like functional. [Female, 14]

Tailoring the App to Meet Asthma Informational Needs

Adolescents really wanted app features that met their asthma self-management and informational needs. For example, one adolescent suggested that if the app had more information where...

...if something bad happened, like if something triggered my asthma, and then I wanted to like find out more about it and how I could get better and like why my asthma flared up or whatever, so if it had that, then I’d use it [the app]. [Female, 16]

Adolescents suggested improvements to the apps that would aid in their self-management, including features for tracking their asthma over a 12-month period rather than the 3-month period in the app, medication reminders every 24 hours at the same preselected time every day, and a calendar in the app where each day you could input...

...like what appointments you have, when, with what doctor, where, and at what time...and then have the app remind you [all within the app]. [Female, 16]

They also suggested a geo-mapping feature where you can plot the location at which you had an asthma attack, as well as a feature that projects the air quality for the day. Regarding the air quality checker, one adolescent stated:

If you could put some kind of air quality checker that would be really good...Just maybe put in your zip code and it could tell you like maybe just what the air quality is projected for that day, since so many people have problems with pollen and dust, and I don't know. I just thought that I would use that a lot if that was an option. [Female, 14]

Many adolescents suggested adding informative asthma videos to the app. One adolescent stated:

I like the idea of having videos in the apps for people who don't really know much about asthma and they want to learn more. [Female, 16]

These informative videos would cover adolescent-recommended topics, such as peak flow, understanding asthma symptoms, and general asthma information. A video showing a medical provider was also suggested.

It has to have links to tutorials like on how to do the medication, how to work a peak flow right because that really can skew your results if you're doing it the wrong way. [Female, 14]

Like, I mean, you can look up information like reading stuff, but also like somehow put YouTube stuff, like you can like...look for videos and stuff on like how doctors and what their insight is and actually like see someone talking about it [asthma]...that'd be cool. [Female, 16]

One adolescent also suggested an educational “kiddie show” for little kids with asthma, stating:

Not saying like a Sponge Bob show but...sometimes little kids don't really pay attention to just plain old stuff, so you could put a video in there like a little kid, a kiddie show for like for asthma. [Male, 13]

Furthermore, when asked, “Would you use the app to watch videos of correct inhaler technique?”, 88% (14/16) adolescents said yes. In addition, 94% (15/16) adolescents said they would take asthma quizzes if they were part of the app.

Suggestions for Improvement and Overall Thoughts on The Apps

Adolescents also suggested other innovative features to be added to the app. These include the option to operate the app via voice command, a feature that read information in the app out to participants, a bilingual mode so individuals could engage with the app in Spanish, and an emergency button that would automatically call a contact if they were having an asthma attack. Some suggested a feature to video chat and communicate with other adolescents who have asthma as a learning opportunity to hear about how they manage their asthma, although adolescent preferences for involving friends and interacting with other adolescents who have asthma are reported elsewhere [19].

In general, adolescents responded positively to using an app for their asthma self-management needs. One adolescent stated:

I think an app can help me by like reminding me of appointments and, um, what medications to take...and organizing myself. [Female, 16]

They cited that the app could help them “keep myself in check” [Male, 12], and they liked that apps allowed them to...

...really just like being able to see where you are with your asthma and you can see all of these dates at one time, and you can, you know, watch how your asthma is doing, sort of just looking at numbers and flipping through different dates. It has it all there and you can really see if it's gone up or down or anything like that. [Female, 14]

Adolescents stated that they frequently use their mobile technology for fun, and thus using apps for educational and asthma self-management purposes would easily incorporate within their daily activities.

Discussion

Principal Findings

Our study examined adolescent preferences and design recommendations for an asthma self-management app. Publications prior to this study have (1) elicited parent and clinician app feedback [20]; (2) documented adolescent use of apps for social support [19]; and (3) shown how existing app features positively influenced adolescent self-management via self-regulation theory constructs [21]. Adolescents additionally provided feedback on app user experience, including ease of use and new features or modifications that would encourage continued engagement. Although almost 200 asthma self-management apps exist, few comprehensive asthma self-management apps that accommodate the interests and needs of adolescents are currently available [11,22]. Our study is an important step in developing an app that optimizes the user experience by involving users in app design.

In order for a health app to be successfully adopted and regularly used, it has to be feasible or usable by an individual as part of their daily routine or in relation to a particular behavior or activity that they wish to change [23]. Adolescents in our study frequently use their mobile technology for recreational purposes and mentioned that using their devices to self-manage their asthma could be easily incorporated within their usual daily routines. Additionally, research shows that linking medication-taking with established routines may enhance health outcomes, and thus, an app that supports medication-taking and other self-management features that can be easily incorporated into their daily routine has the potential to improve health outcomes and lead to better overall asthma self-management [24].

Nearly 75% of teens play video games online or on their phone, and 47% of teens talk with others over video connections, such as Skype, Oovoo, FaceTime, and Omegle [4,10]. Therefore, our findings that adolescents are comfortable with and desire app features—including visual and auditory components—that

fit within their schema, or existing frameworks of how apps should look and operate, fit well given current statistics on adolescent technology use. Our study found that although all 20 adolescents had downloaded an app, only 3 had downloaded a health-related app. Adolescents expressed that they were not accustomed to using apps like the ones in our study, and therefore, there was a slight learning curve with some adolescents expressing difficulty learning how to use the apps. To overcome this barrier, adolescents suggested video tutorials and picture tutorials that may increase their self-efficacy in using the apps.

In the context of technology adoption, research shows that self-efficacy, or the “confidence consumers have in their own abilities to understand and effectively use a new piece of technology” [25], plays a substantive role in shaping an individual’s perceived usefulness and ease of use of technology [25]. Therefore, incorporating comprehensive picture or video tutorials to show how to use the apps seems warranted to increase their perceived usefulness and ease of use of the apps, as well as subsequent asthma management. Similarly, organization and perceived visual simplicity (encompassing the use of visual aids such as pictures, graphs, and charts) were important components of the visual appeal of the apps. This is indicative of their desire for features that increase their confidence in their ability to understand and effectively use the apps, as well as engage in adequate asthma self-management. Picture and video tutorials or aids may also be beneficial for younger adolescents and those with low health literacy.

Adolescents also suggested informative asthma videos covering topics such as peak flow, understanding asthma symptoms, and general information to meet their asthma self-management needs, and 88% (14/16) adolescents said they would watch videos demonstrating correct inhaler technique. Research shows that using videos to teach inhaler technique to children with asthma can improve their inhaler technique [26,27], and thus, the incorporation of these and other informative asthma videos may increase adolescent self-efficacy in managing their asthma and lead to better health outcomes. Furthermore, adolescents in our study suggested videos showing a medical professional or age-appropriate material, as mentioned by the addition of “kiddie show” for adolescents with asthma. Research shows that adolescents and caregivers of adolescents with asthma obtain health information from health care professionals and have a high level of trust in the health care information obtained from health care professionals [28,29]. Therefore, allowing such individuals to provide clinically sound asthma information in an asthma app and directing adolescents to evidence-based asthma resources may prove beneficial. Furthermore, having peers present asthma information or appear in asthma informational shows can increase adolescent self-management efficacy through peer modeling [30,31].

Among the adolescents included in our study, 75% (15/20) said that they enjoy spending time on social networking sites, including Facebook (11/20, 55%). Some adolescents in our study suggested a feature to video chat and communicate with other adolescents who have asthma as a learning opportunity to hear about how they manage their asthma. Accordingly, 65% of the top mHealth apps connect to social media, underscoring the importance of communication features for consumer engagement [32].

In addition to including components that meet adolescent informational needs, adolescents also expressed a desire to tailor app components to meet their personal design preferences. Although perceived visual simplicity and organization were important for adolescents, mixed reviews existed on whether the adult app or child app possessed these features. Adolescents suggested modifications to the color scheme and layout (including the ability to personalize it), the inclusion of games, and other features such as the ability to incorporate Cam Newton or another person deemed inspiring by the adolescent, perhaps in an avatar format.

Limitations

Our study has several limitations. We used a convenience sample to recruit adolescents from 2 urban pediatric clinics. Although our sample was racially diverse, we are unable to generalize our results, especially to adolescents in rural areas who may have less access to a cell phone [33]. Moreover, those who agreed to participate may have had stronger positive preferences for using technology given the iPod incentive and may have been more receptive to using an asthma app for self-management. Although 4 adolescents were lost to follow-up, they did not differ demographically from those who completed the study. Nonetheless, selection bias could have affected our results. Although participants had experience using the apps for a 1-week period, giving adolescents a longer time to explore the apps may have probably yielded additional insights.

Conclusions

Our study found that adolescents have specific preferences for features that meet their self-management needs. App developers should consider including customizable features, such as color schemes, avatars, fonts, graphics, and sounds that fit within adolescents’ existing schema. Future research should explore whether adolescent preferences vary by gender, age, race, ethnicity, or other demographic characteristics. It is important that app developers take into consideration both adolescent feedback and evidence- and theory-based app components to ensure the development of apps that meet end-user needs and lead to improved clinical outcomes [23].

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Conflicts of Interest

None declared.

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Abbreviations

P: in-person interview

T: telephone interview

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Original Paper

A Locally Developed Electronic Health Platform in Uganda: Development and Implementation of Stre@mline

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Abstract

Background: Electronic health records (EHRs) are especially important in low-resource settings due to their potential to address unique challenges such as a high number of patients requiring long-term treatments who are lost to follow-up, the frequent shortages of essential drugs, poor maintenance and storage of records, and inefficient clinical triaging. However, there is a lack of affordable and practical EHR solutions. Stre@mline is an EHR platform that has been locally developed by Ugandan clinicians and engineers in Southwestern Uganda. It is tailored to the specific context and needs of low-resource hospitals. It operates without internet access, incorporates locally relevant standards and key patient safety features, has a medication inventory management component, has local technical support available, and is economically sustainable without funding from international donors. Stre@mline is currently used by over 60,000 patients at 2 hospitals, with plans to expand across Uganda.

Objective: The purpose of this article is to describe the key opportunities and challenges in EHR development in sub-Saharan Africa and to summarize the development and implementation of a “Made-for-Africa” EHR, Stre@mline, and how it has led to improved care for over 60,000 vulnerable patients in a rural region of Southwestern Uganda.

Methods: A quantitative user survey consisting of a set of 33 questions on usability and performance was conducted at Kisiizi Hospital. Users responded to each question through a Likert scale with the values of strongly disagree, disagree, agree, and strongly agree. Through purposive sampling, 30 users were identified and 28 users completed the survey.

Results: We found that users were generally very satisfied with the ease of use of Stre@mline, with 96% (27/28) finding it easy to learn and 100% (28/28) finding it easy to use. Users found that Stre@mline was helpful in improving both clinical efficiency and enhancing patient care.

Conclusions: The partnership of local clinicians and developers is crucial to the design and adoption of user-centered technologies tailored to the specific needs of low-resource settings. The EHR described here could serve as a model for the development of future technologies suitable for developing countries.

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KEYWORDS

electronic health record; locally developed technology; appropriate technology; eHealth in low-resource settings

Introduction

Background

Although often viewed as a resource only available to well-funded health facilities in developed countries, electronic health records (EHRs) are especially important for low-resource settings such as those in sub-Saharan Africa due to the unique challenges they can address. A well-developed EHR system can fill critical gaps common to such environments, such as assisting busy frontline workers to treat diseases, especially those requiring long-term treatment and monitoring (such as HIV and diabetes), and to anticipate and prevent frequently reported shortages of essential drugs. Furthermore, limited human resource capacity often leads to poorly developed and maintained medical records as well as poor triaging of patients presenting to hospitals. An optimized EHR can efficiently help address these ubiquitous issues. While EHRs can, and should, be instrumental in helping resource-poor countries meet the UN Sustainable Goals, many unique challenges have prevented the development and scaling of EHR systems in many resource-poor environments, including Uganda. The purpose of this article is to describe the key opportunities and challenges in EHR development in sub-Saharan Africa and to summarize the development and implementation of a “Made-for-Africa” EHR and how it has led to improved care for over 60,000 vulnerable patients in a rural region of Southwestern Uganda.

Opportunities and Challenges With Electronic Health Records

One of the biggest public health challenges to the success of managing diseases like HIV/AIDS and tuberculosis is the high rates of patients who are “lost to follow-up” [1]. EHRs have been proposed as one of the top solutions [2,3], with preliminary evidence suggesting EHRs can significantly reduce the estimated 24% of all HIV patients lost to follow-up [4]. In addition, EHRs are useful for the long-term follow-up of chronic illnesses like cancer, high blood pressure, and diabetes and to ensure that patients are treated following the correct guidelines. Moreover, accurate and thorough data collection using EHRs can also inform targeted allocation of limited resources by recognizing trends and helping define priorities.

Inventory management and triaging challenges are also especially important for low-resource settings. Severe shortage of essential drugs as well as the dispensing of expired drugs are the major problems faced by patients in developing countries [5,6]. Poor patient record storage as a result of staffing shortages is another key challenge in low-resource hospitals. Thus, EHRs can play a significant role in allowing hospitals to better track and plan resources to ensure that essential medications are in stock and not expired and in ensuring that medical records are available and organized. Both of these are expected to result in improved patient care. Another intriguing advantage offered by EHRs is that supportive tools and guidelines for triaging, which are especially important given severe staffing shortages in low-resource settings [6], can be embedded within EHRs to focus resources on the most vulnerable patients. Improved triaging has been demonstrated to improve outcomes, including mortality, without the need for additional staffing [7].

Despite the many potential advantages of EHR systems, several important implementation challenges specific to developing countries have been identified. High initial costs associated with computer purchase and infrastructure setup is a critical barrier [8]. However, this can, at least, be partially mitigated by potential cost saving from reductions in record-keeping costs [9] and significantly improved staff efficiency [10]. Arguably, the most critical challenge to the success of existing EHR systems is the lack of involvement of local staff in the design and testing of systems to ensure that they are designed according to local needs and workflows. Other significant challenges include the purchase cost of the EHR software, the lack of local and inexpensive technical support to maintain EHR systems, frequent power and internet outages, the lack of computer literacy, and the fact that most EHRs are not sustainable without funding from international partnerships [8,11,12]. Overcoming these challenges will be crucial to ensure successful implementation and scaling of any EHR in a low-resource setting.

Stre@mline: A “Made-for-Africa” Electronic Health Record

Local Setting

In Uganda, there are currently 1.5 million people living with HIV/AIDS and 79,000 new cases of active tuberculosis are reported every year. In addition, as many as 50% of essential drugs are not available at public hospitals [13]. Moreover, there is a significant shortage of qualified health workers, with only 0.12 physicians and 1.3 nurses per 1000 people [14]. Uganda is one of the poorest countries in the world, with about one-third of Ugandans living on less than US \$1.90 purchasing power parity per day. The region in which the described EHR was implemented (Kisiizi, a rural region in Southwestern Uganda) is among the poorest regions in Uganda, thus, providing an ideal context for the development of a system ideal for rural and remote health facilities in sub-Saharan Africa. The EHR system, Stre@mline, was codeveloped by Ugandan software developers at a technology startup named istreams (acronym for Innovation Streams) and a team of physicians from the Kisiizi Hospital, a private not-for-profit hospital in Southwestern Uganda.

Partnerships

The partnership between istreams and the Kisiizi Hospital was initiated in 2013 when physicians from the hospital approached istreams to assist in developing a very simple EHR to overcome several specific challenges faced by the hospital that could not be adequately addressed by commercially available software applications. Over the following 2 years, the team met regularly to develop and pilot a platform tailored to the specific constraints and criteria of a busy Ugandan hospital. The resulting product is a sustainable and scalable EHR system that can address many of the shortcomings in the existing EHR platforms described earlier. The development cost for Stre@mline was funded by a National Science & Technology Improvement Grant (NSTIP) from Uganda National Council for Science & Technology (UNCST) as well as from the Kisiizi Hospital.

Unique Features of Stre@mline

In addition to the standard features such as interfaces for clinicians from different departments to communicate with one another, Stre@mline has a pharmacy interface that can be seen by prescribers, and it continuously updates stock, expiry date, and price of all drugs in real time. Stre@mline enrolls the patients' journey through a system of unique identifiers. If a patient's folder name is not present in the system, a unique identifier specific to the hospital is generated for the patient (eg, KH-60570 for one patient and KH-60571 for the subsequent patient). In addition, identifier information including the patient's first and last name, village name, phone number, sex, and age is also recorded in the database because oftentimes, there are multiple patients with the same name in the hospital's database. For returning patients, at triage, a patient's folder will be searched based on the abovementioned identifiers. When the patient's folder is found, a new file will be created for the current visit; this file will be time stamped and appended to the patient's previous files in the folder.

The Stre@mline platform is also unique as it does not require internet access to operate. This is very important as internet access is very unreliable and expensive in Uganda. Instead, the program operates through a local area network consisting of 30 computers connected with each other and a local central server run through Ethernet cables. All data are backed up on the central server that is backed up through a battery-powered

inverter system designed to prevent data loss during power outages.

Another key sustainability feature of the platform is that istreams offers local technical support to promptly solve technical issues and make improvements according to user needs. Through continuous and consistent user input, Stre@mline incorporates many locally relevant standards and guidelines, such as the locally developed Kissizii Early Warning System and the World Health Organization Emergency Triage Assessment and Treatment guidelines, local drug guidelines, and built-in linkage to the Uganda National Drug Authority adverse drug reactions reporting system. These systems are described in more detail in [Table 1](#). Codesigning with local clinicians ensures simplicity of training and general use. Clinicians who have basic knowledge of using a computer can learn the key features of Stre@mline in less than 30 minutes. Furthermore, Stre@mline can be customized to integrate with local insurance plans, such as the Kisiizi Hospital Health Insurance Scheme used by 40,000 users, to monitor health-seeking behaviors. Finally, Stre@mline is affordable, with funding for development of this program coming entirely from within Uganda.

Currently, Stre@mline has been implemented in 2 hospitals in Southwestern Uganda and has been used for over 60,000 patients. Furthermore, the system is being set up in 3 additional hospitals in the region. istreams hopes to expand the system to 50 hospitals in Uganda over the next 2 years.

Table 1. Key local health care challenges addressed by Stre@mline.

Issue and problem	Stre@mline response
Follow-up for long-term treatments	
High number of patients lost to follow-up	Monitoring of follow-up attendance, facilitation of contacting patients to ensure good on-going care in place
Medicines	
Severe shortages of drugs	Live monitoring of stock levels of medicines and triggering ordering in good time to avoid stock-outs
Drugs often expire in storage, wasting valuable resources	Warns pharmacists of drugs due to expire in 2 months, facilitating better resource planning by pharmacists and prescribers
Auditing of drug prescribing errors is often poor or erratic	Facilitates 100% capture of prescribing errors through built-in linkage to the Uganda National Drug Authority drug reactions reporting system
Triage	
Triage often poorly done, especially in children	Incorporates the World Health Organization Emergency Triage, Assessment, and Treatment (ETAT) tool and the locally developed Kisiizi Early Warning System
Paper-based triage systems were often omitted or only partially done	Ensures that 100% children are properly triaged using ETAT tool as it uses mandatory fields. Users rapidly learn the new routine and comply happily as they see the benefits.
Medical records	
Often incomplete, poor quality records were kept	Captures key data relating to a patient's symptoms, investigations, treatment, and follow-up
Patients often forget to bring previous notes, images, etc, and may end up undergoing unnecessary duplicate tests	Allows files to be stored (eg, x-rays, clinical letters, and photographs, for immediate access in future)
Customization	
Commercial systems are often difficult and expensive to customize to local requirements	Stre@mline is designed to allow free, easy, and comprehensive customization by local institutions to ensure that the system is optimal for the local environment

Methods

A quantitative user survey was conducted at the Kisiizi Hospital by a Masters student at the Mbarara University of Science and Technology, who is not affiliated with istreams, between January and June 2017. It was a paper-based survey consisting of a set of 33 questions on system usability and performance. Users responded to each question through a Likert scale with the values of strongly disagree, disagree, agree, and strongly agree. Through purposive sampling, 30 users were identified to complete the survey. In total, 28 users (6 doctors, 3 clinical officers, 6 nurses, 4 other health professionals, 6 administrative staff, and 3 support staff) consented and completed the survey. The analysis of survey data was performed primarily through descriptive statistics using Microsoft Excel (Redmond, USA). The key findings are described below.

Results

The results of this survey showed that users were generally very satisfied with the ease of use of Stre@mline, with 96% (27/28) finding Stre@mline easy to learn and 100% (28/28) finding it easy to use. The Stre@mline platform has addressed several problems at the hospital. First, Stre@mline has allowed physicians at the Kisiizi Hospital to reliably access patients' past medical records and investigations, which was generally not possible with the prior paper-based system. This feature has also increased workflow efficiency, with 80% (8/20) of users agreeing that it has allowed them to "see more patients in a day" as well as increased apparent trust in physicians by patients (as identified by clinicians). The embedded guidelines and triage assistance within Stre@mline has also substantially improved patient care, with 100% (20/20) of respondents agreeing that it has improved their "decision making."

Furthermore, clinicians interviewed at the Kisiizi Hospital generally agreed that Stre@mline has allowed clinicians to prescribe alternatives if one drug is not in stock, and this has, in turn, "improved patient care and compliance rates." Stre@mline has also improved resource planning by allowing pharmacists to track their drug stocks in real time, thus, improving consistent stocking and availability of essential medications at the hospital, with 96% of clinicians agreeing that it has "provided better mechanism for drug availability" and 100% agreeing that *system has led to "safer and more reliable prescriptions."*

Discussion

Principal Findings

Designing the EHR according to the specific needs of Ugandan hospitals has been critical to the successful implementation of Stre@mline. Having senior clinical input throughout the process

has ensured the achievement of maximum benefits for patient care. In contrast, many health information technology programs fail when the software use is difficult for the intended users, thus, reducing the efficiency of the provider. Thus, it is critical to understand the clinical workflows, the patient journey, and key clinical data points needed.

Partnerships between local technology entrepreneurs and clinicians have the potential to not only create well-designed, but more importantly, sustainable and scalable technological solutions for these settings. Such technologies are more likely to have access to effective local support for maintenance and further development through an intimate understanding of local needs. Furthermore, these solutions tend to be more economically sustainable, with less external donor funding needed. In addition, leveraging local pride can be an important contributor to the adoption of any technology and has certainly been well leveraged in the development and application of Stre@mline. Supporting local developers of health care technologies financially and technologically is, therefore, a model that may be far more sustainable and impactful than developing such technologies in Western countries. Finally, another key to the success of Stre@mline in Kisiizi has been strong leadership from clinician-administrators who ensured and mandated computer workshops for all hospital employees and organized piloting the EHR sequentially, one department at a time, until it was scaled across each department. The approach described could thereby serve as a model for the development of future appropriate technologies for research-limited settings.

Limitations

Limitations of the current system include a lack of data portability between different hospitals because data are currently stored on local area networks. In addition, although the system is low cost, it may still be cost prohibitive for small public hospitals and clinics within Uganda and other African countries. Finally, quantitative data on cost savings and patient safety are yet to be collected and analyzed, limiting the ability to generate any cost metrics. These data are, however, currently being collected and will be incorporated into a cost-benefit analysis in the future.

Conclusions

Stre@mline is a locally developed EHR system tailored to the specific needs of resource-constrained settings. It is unique in being entirely locally developed through a partnership between a local hospital and a local technology company; it has been developed and is sustainable without funding from outside Uganda. The EHR system is currently being used by over 60,000 patients at 2 hospitals across Uganda with plans for further scaling. The process described here could serve as a model for the development of future appropriate technologies in developing countries.

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Conflicts of Interest

None declared.

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Abbreviations

EHR: electronic health record
ETAT: Emergency Triage, Assessment, and Treatment
NSTIP: National Science & Technology Improvement Grant
UNCST: Uganda National Council for Science & Technology

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Original Paper

Effects of Cold Stimulation on Cardiac-Vagal Activation in Healthy Participants: Randomized Controlled Trial

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Abstract

Background: The experience of psychological stress has not yet been adequately tackled with digital technology by catering to healthy individuals who wish to reduce their acute stress levels. For the design of digitally mediated solutions, physiological mechanisms need to be investigated that have the potential to induce relaxation with the help of technology. Research has shown that physiological mechanisms embodied in the face and neck regions are effective for diminishing stress-related symptoms. Our study expands on these areas with the design for a wearable in mind. As this study charts new territory in research, it also is a first evaluation of the viability for a wearables concept to reduce stress.

Objective: The objectives of this study were to assess whether (1) heart rate variability would increase and (2) heart rate would decrease during cold stimulation using a thermode device compared with a (nonstimulated) control condition. We expected effects in particular in the neck and cheek regions and less in the forearm area.

Methods: The study was a fully randomized, within-participant design. Volunteer participants were seated in a laboratory chair and tested with cold stimulation on the right side of the body. A thermode was placed on the neck, cheek, and forearm. We recorded and subsequently analyzed participants' electrocardiogram. The cold stimulation was applied in 16-second intervals over 4 trials per testing location. The control condition proceeded exactly like the cold condition, except we manipulated the temperature variable to remain at the baseline temperature. We measured heart rate as interbeat intervals in milliseconds and analyzed root mean square of successive differences to index heart rate variability. We analyzed data using a repeated-measures ANOVA (analysis of variance) approach with 2 repeated-measures factors: body location (neck, cheek, forearm) and condition (cold, control).

Results: Data analysis of 61 participants (after exclusion of outliers) showed a main effect and an interaction effect for body location and for condition, for both heart rate and heart rate variability. The results demonstrate a pattern of cardiovascular reactivity to cold stimulation, suggesting an increase in cardiac-vagal activation. The effect was significant for cold stimulation in the lateral neck area.

Conclusions: The results confirmed our main hypothesis that cold stimulation at the lateral neck region would result in higher heart rate variability and lower heart rate than in the control condition. This sets the stage for further investigations of stress reduction potential in the neck region by developing a wearable prototype that can be used for cold application. Future studies should include a stress condition, test for a range of temperatures and durations, and collect self-report data on perceived stress levels to advance findings.

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KEYWORDS

cold stimulation; heart rate reduction; lateral neck region; diving reflex; stress reduction; wearable electronic devices; thermode-based stimulation; acute stress; technology for stress relief; vagus nerve stimulation; psychological stress

Introduction

Background

Never before in human history have people been exposed to such fast-paced lifestyles as today, where stress penetrates all areas of everyday life. Stress is a central issue in modern life that affects a broad range of people at various ages and in different professions, beyond levels that are believed to be healthy (eg, [1-3]). Some groups are, however, found to be more vulnerable to stress than others. According to the American Psychological Association [1], groups that are consistently struggling with stress are women and parents, but also younger generations (18-35 years old). In particular, younger people report higher stress levels than any other generation and seem to have difficulties coping with stress [4]. Similarly, a pan-European poll conducted with the general European population showed that 51% of all workers reported that work-related stress was common in their workplace, while 66% attributed stress to hours worked or workload [2]. Additionally, 77% of the European population (36 countries) believed that their job-related stress would increase over the next 5 years [3]. The European Commission has noted the severity of the problem and has made stress and stress management a priority area in Europe's health strategy for 2014-2020 under the framework of psychosocial risks [5].

This snapshot of psychological stress shows that higher stress levels are quite common in highly industrialized nations. Although the situational context that causes stress for the individual may differ between people, depending on personality characteristics, personal history, etc, physiological responses to perceived stress (eg, elevated heart rate and increased respiration) are consistent indicators across individual stress experiences. Acute stress stimulates the sympathetic nervous system, resulting in the ergotropic activation of the cardiovascular, endocrine, and immune systems [6-8]. Physiological stress responses are highly adaptive in the short term, but with regular elicitation they may become maladaptive and the individual's activation level turns chronic. Prolonged exposure to stress has been shown to be associated with long-term health consequences that can lead to disease [6-9].

An ever-growing number of individuals are pursuing well-being in their lives by seeking to deploy smart watches and other digital devices in the hope of reaching a better state of health [10]. Wearable devices have been a popular support in social movements that are spearheading physical self-improvement (eg, the quantified self movement [11]). But digitally mediated solutions for stress reduction are rather sparsely forthcoming. Most devices that aim to reduce daily stress experiences track body metrics (eg, heart rate and respiration) and make offline suggestions, such as exercise and meditation, to disengage from stress [12]. As a result, these solutions are limited in their effectiveness because they do not intervene directly at the time of the acute stress experience. They require behavioral changes

that, when applied, will lead to stress reduction. Yet behavioral change necessitates a dedicated time investment, which presents a dilemma for individuals who are already struggling with insufficient time in their day [13,14]. Not only a time commitment is needed; some of the suggested solutions also require an undisturbed personal space. This is an additional factor that may make these solutions impractical in everyday settings, where most people are involved with ongoing interactions with other individuals, such as at the office or when taking care of children. Hence, there is a market demand for technologies that provide an approach that not only measures stress but also presents an integral, noninvasive, digitally mediated solution to stress reduction. The solution should provide effective results but also fade into the background of the fast-paced lifestyles that most people experience.

We present an initial study investigating a wearable concept for well-being with the prospect of reducing stress as indexed by increased cardiac-vagal activation. The concept presents an integral solution. It measures an individual's stress levels using heart rate and computing heart rate variability, and it comprises the strategic placement of a cold stimulus to counteract physiological stress by increasing cardiac-vagal activation.

This study is a first exploration of the effects of cold stimulation in the neck region on heart rate and heart rate variability under resting conditions. Stimulation of the neck region as location on the body and cold temperature as a stimulus have been investigated in previous research on stress reduction, but in separate contexts and on different grounds, for example, vagus nerve stimulation (VNS) and cold water face immersion (CWFI). To the best of our knowledge, cold stimulation in the neck region has not yet been combined into a single study. As this is the first study to investigate the effects of cold stimulation in the neck area on heart rate variability and heart rate, we focused on parasympathetic nervous system activation to clearly assess any potential for heart rate reduction. We accordingly selected a study design that de-emphasized complexity and favored a conservative approach by testing participants under resting conditions.

The Relationship Between Heart Rate, Heart Rate Variability, and Stress

Heart rate variability is associated with functions of the regulatory and homeostatic autonomic nervous system, which is a key structure in physiological arousal with its sympathetic and parasympathetic nervous system branches. Heart rate and heart rate variability constitute measures of autonomic function, whereas heart rate variability provides more information on the dynamic modulation between the sympathetic and parasympathetic branches of the autonomic nervous system [15].

Research has also suggested that the brain and the heart are connected bidirectionally due to the efferent outflow from the brain affecting the heart and the afferent outflow from the heart

affecting the brain [16,17]. The vagus nerve is an integral part of this heart-brain system [18], and heart rate-related measures (eg, heart rate variability) can provide valuable information about the functioning of the heart-brain system. Heart rate variability is the fluctuation of the length of heartbeat intervals [19] and has been suggested to represent the ability of the heart to respond to a variety of physiological and environmental stimuli [20,21].

In recent years, perceived stress levels have been known to be closely associated with measures of cardiac autonomic function, such as heart rate and heart rate variability. For example, Uusitalo et al [22] found that chronic, work-related stress was associated with cardiac autonomic function in hospital nurses at work who were tested over the course of 2 days. Collins et al [23] observed similar findings over a period of 48 hours, studying 30 men who experienced job strain in various job settings. Many other studies (eg, [24-26]) recording short-term or long-term electrocardiograms (ECGs) found comparable results, confirming the association between subjective stress and heart rate variability in larger populations. A recent meta-analysis by Kim et al [27] indicated that heart rate variability can serve as a physiological indicator of stress, which substantiates the findings of an earlier meta-analysis by Thayer et al [28].

Heart rate and heart rate variability are reliable, easily recorded and computed measures. They are assumed to be objective measures of psychological health and stress [27,28] and have often been assessed in cardiovascular and stress research [29-33]. It has also been shown that individuals engaging in biofeedback training are able to control heart rate variability and therefore influence their perception of stress and anxiety [34-36].

In the research reported here, low physiological arousal, or relaxation, was associated with low heart rate and high heart rate variability, indicated by predominately parasympathetic nervous system activation. High physiological arousal, such as that caused by the experience of stressors, indicates high heart rate and low heart rate variability with prevailing sympathetic nervous system activation [37-39]. From the perspective of a wearable concept for stress reduction, heart rate measurements and heart rate variability calculations are already implemented in commercial wearable devices such as chest-worn ambulatory heart rate monitors (eg, heart rate chest belts by Polar [40]). The technology of these heart rate monitors is mature; it has been tested for accuracy and robustness (eg, [41-47]) and can be engineered as part of the design of a stress reduction device.

Vagus Nerve Stimulation and the Diving Reflex

Cardiovascular research has identified physiological mechanisms that promote relaxation in patients with different physiological and psychological disorders. Methods for heart rate reduction are equally of interest to athletes, who need to speed up their return to homeostasis after physical exertion (eg, [48,49]). Various scientific disciplines, such as sports science and the neurosciences, have studied these physiological mechanisms that initiate relaxation, but their relationship and functional purpose in the body have yet to be fully explicated (eg, [50,51]).

The physiological mechanisms involved are predicated on cranial nerves that are responsible for cardiac-vagal activation and are typically located in the facial area and the head and neck regions. The ascending pathways of the cranial nerves, for example the vagus nerve, transmit various interoceptive signals to the brain (eg, temperature, pain, and pressure), and the descending pathways regulate the functioning of inner organs.

VNS and the diving reflex are the most relevant and accessible physiological mechanisms in relation to our wearable concept. VNS has been used for decades as a therapeutic option in refractory epilepsy. As a method, it has been continuously refined so that applications have broadened to wider patient populations addressing, for example, migraine headaches, Alzheimer disease, depression, and treatment-resistant anxiety disorder [51,52]. VNS is applied to counteract sympathetic nervous system activation by increasing activation of the parasympathetic nervous system, which then induces relaxation in the patient. Direct VNS necessitates the surgical implantation of electrodes in the patient's chest region with extensions threaded under the skin that attach to the cervical vagus nerve in the neck region. Through the implant, electrical impulses are delivered to the vagus nerve that lead to activation. Newer medical VNS applications cause fewer side effects than their invasive VNS counterpart because they deliver electrical impulses through the skin. There are two approaches, termed transcutaneous VNS and noninvasive VNS.

These newer applications either stimulate the auricular branch of the vagus nerve on the external ear through an intra-auricular electrode, or they use metal disks to make contact with the skin on the neck for stimulation of the cervical vagus (commercial examples are Nemos [53] and GammaCore [54]). Transcutaneous VNS and noninvasive VNS are officially classified as noninvasive applications; however, all types of VNS devices use low-voltage electrical signals that aim to produce neurological stimulation.

The efficacy of transcutaneous VNS and noninvasive VNS has been analyzed in studies with patients and healthy individuals to better understand the mechanisms involved [55-58]. Still, there are differences between the cervical vagus and its auricular branch, which need to be taken into account when assessing the vagus nerve's overall potential for stress reduction. Nonis et al [59] conducted an experiment with 12 healthy volunteers, comparing noninvasive VNS with transcutaneous VNS applications. In the control condition for each approach, the stimulation was applied to the long muscle of the neck (sternocleidomastoid muscle). Measuring the electrical activity of the brain (somatosensory evoked potential) during stimulations, the researchers found that cervical noninvasive VNS elicited a reproducible response of vagal afferent activation in 11 of the 12 healthy volunteers, whereas stimulation of the auricular branch evoked a comparable response in only 9 of the 12 healthy volunteers. Morphological studies may explain the predominant response of the cervical vagus nerve. Verlinden et al [60] analyzed 11 pairs of cervical vagus nerves and 4 pairs of intracranial vagus nerves with computer software. They found that the right cervical vagus nerve on average had a 1.5 times larger effective surface area than the left vagus nerve. They also showed that the right cervical vagus nerve contained on average

2 times more tyrosine hydroxylase-positive nerve fibers than the left nerve, which can positively influence stimulation.

These results informed our study design. We justified the placement of the cold stimulus during experimentation on the cervical vagus nerve, choosing the right lateral neck area to maximize the potential for a parasympathetic nervous system response.

The diving reflex in humans has been characterized by a pattern of respiratory, cardiac, and vascular responses. Some researchers believe that the diving reflex's primary role is to ensure survival when diving into water by conserving oxygen, although there is no consensus on this explanation. A potent stimulus to induce the diving reflex is water contact on the forehead, cheek, eyes, and nose. Trigeminal-brainstem-vagal pathways supply these areas, and stimulation inhibits respiration and provokes vasomotor centers and cardiac-vagal motoneurons [61-65].

In particular, the (cold) temperature aspect of water causes superficial cold receptors to be innervated by the ophthalmic branch of the trigeminal nerve, which promotes the cardiac-vagal activity of the diving reflex [66,67]. De Oliveira Ottone et al [48] studied 8 active men who exercised at submaximal levels and subsequently underwent a 15-minute recovery period in a water tank with cold water at 15°C, and hot water at 28°C and 38°C. The results indicated that CWFI accelerates while hot water immersion blunts postexercise parasympathetic activation.

Cold water immersion may also be effective at short time intervals. Buchheit et al [68] reported that cold water immersion for 5 minutes at 14°C after 10 male cyclists performed submaximal aerobic fitness exercise produced faster parasympathetic reactivation than the control condition. Heindl et al [69] studied the effects of ice cubes on heart rate and blood pressure in 9 healthy volunteers who self-administered the stimulus on forehead, hand, and nasal cavities at 2.5-minute intervals alternated with a 10-minute rest. The bronchial system was also cooled down via cold air at -25°C. Heart rate was significantly reduced only during cooling of the nasal cavities and forehead. In sum, cold stimulation applied in short intervals is a promising candidate for parasympathetic activation, and we incorporated it into our study design.

The diving reflex was previously assumed to be strongly linked to breath holding, but recent research suggested otherwise. Kinoshita et al [70] conducted an experiment with 8 healthy volunteers to observe the effects of CWFI and warm water face immersion with and without breathing on heart rate and heart rate variability. The results showed that CWFI diminished cardiac output and increased vagal activity independent of change in body position caused by bending over a basin and unrelated to breath holding. The findings on breath holding confirmed earlier research by Hayashi et al [71], who tested 15 healthy volunteers in 12 trials over 2 days on CWFI with and without breathing. The researchers found that the diving reflex without breath holding increased heart rate variability significantly, indicating that CWFI alone increases vagal activity.

Based on the reviewed research outcomes, we investigated the effects of cold stimulation of the right lateral neck region using

a thermode instrument. Control body locations selected for the study were the cheek and forearm. We chose the cheek region because it is central to the diving reflex, and we expected our results to reflect activation of the diving reflex. As the forearm has no known sympathetic or parasympathetic innervation, we did not expect any changes to heart rate or heart rate variability from baseline.

Potential mechanisms underlying any effects of cold stimulation in the neck region are difficult to predict because, in both cranial nerves (vagus and trigeminal nerves), signal relay involves the brainstem regions that indirectly or directly influence the neurochemistry of large areas in the central nervous system [72].

Objective

Noninvasive VNS is a medical procedure that reduces stress symptoms by lowering heart rate and increasing heart rate variability in patients with serious illnesses. This is achieved through low-voltage electrical impulses sent to the cervical vagus nerve. However, when addressing the general public, the use of electrical impulses as a preventive measure for acute stress is not a viable option without medical supervision.

A safer alternative is cold stimulation, which has been used elsewhere to trigger relaxation (eg, [48,49,67,68,70,71]). The overall aim of this project was to design a technique that is effective as a relief strategy for acute stress and can be deployed by otherwise healthy individuals. The technique combines the placement of the stimulus along the cervical vagus (informed by noninvasive VNS) with cold stimulation (referenced from research on the diving reflex).

The objective of this study was to address the following hypotheses: (1) that cold stimulation of the neck and cheek (but not the forearm) should result in higher heart rate variability than in the (nonstimulation) control condition, and (2) that cold stimulation of the neck and cheek (but not the forearm) should result in decreased heart rate compared with the (nonstimulation) control condition.

Methods

Recruitment

Participants were 71 healthy volunteers (43 female), with a mean age of 26.8 years (SD 8.57). Volunteers were university students and staff from Luxembourg University. Exclusion criteria were self-reported chronic physical and mental health conditions (eg, bronchial asthma, cardiovascular disorders, depression) or current acute illnesses (eg, flu) and medication intake with known effects on autonomic nervous system function. We further excluded participants with addictions (eg, alcohol, nicotine), as well as pregnant women. We assessed participants' health status via a telephone interview prior to the study. All participants gave informed consent at the start of the study, which was approved by the university's Ethics Review Panel. On completion of the study, participants were compensated for their time and effort in the form of gift vouchers (€10).

Study Design

The design was a fully randomized, within-participant study. Participants were presented consecutively with cold and neutral stimuli through a thermode device (PATHWAY Model ATS Pathway System, Medoc Ltd, Ramat Yishai, Israel) on 3 body locations (neck, cheek, and forearm). The order of presentation was counterbalanced over participants (see Figure 1), resulting in 6 configurations (see Table 1). Each participant followed the same configuration order throughout the experimental blocks. An experimental block is defined as 3 sessions, 1 for each body location (neck, cheek, and forearm). Each participant engaged in 2 experimental blocks (cold stimulus and control condition), whereby the order of the blocks was counterbalanced from one participant to the next. A total of 35 participants received the cold stimulus condition first followed by the control condition, and 36 participants completed the study in inverse order. Participants individually attended a single experimental session at the university’s psychophysiology laboratory. Prior to the main study, we conducted a pilot study with 18 participants.

Calibration Phase

During the calibration phase, we assessed cold sensitivity by determining whether the preselected temperatures were appropriate for the individual participants (see Figure 1 and Figure 2). Final temperatures were scaled by age and gender and adjusted after a pilot study with 18 participants. During the pilot sessions, we used the temperatures indicated in Table 2. Cold temperatures were determined by corroborating indexes from pain studies (eg, [73]) and studies on postexercise recovery experiments using CWFI (eg, [49,68]). After collecting all the data from the pilot sample, we adapted the temperatures on the basis of participants’ input (see Table 3). Among the participants in the pilot sample, 7 considered the temperatures too cold. We then made adjustments to accommodate a larger number of participants and to ensure that temperatures were perceived as not unpleasant. During the calibration period, we marked thermode positions on the participant’s skin to ensure that the placements remained identical when repeating trials.

Figure 1. Schematic breakdown of the experiment: each session consisted of four 16-second trials at one body location and 16 seconds at baseline temperature after each trial. The duration of baseline and recovery periods was 3 minutes, and the rest period (pause) between experimental blocks was 5 minutes.

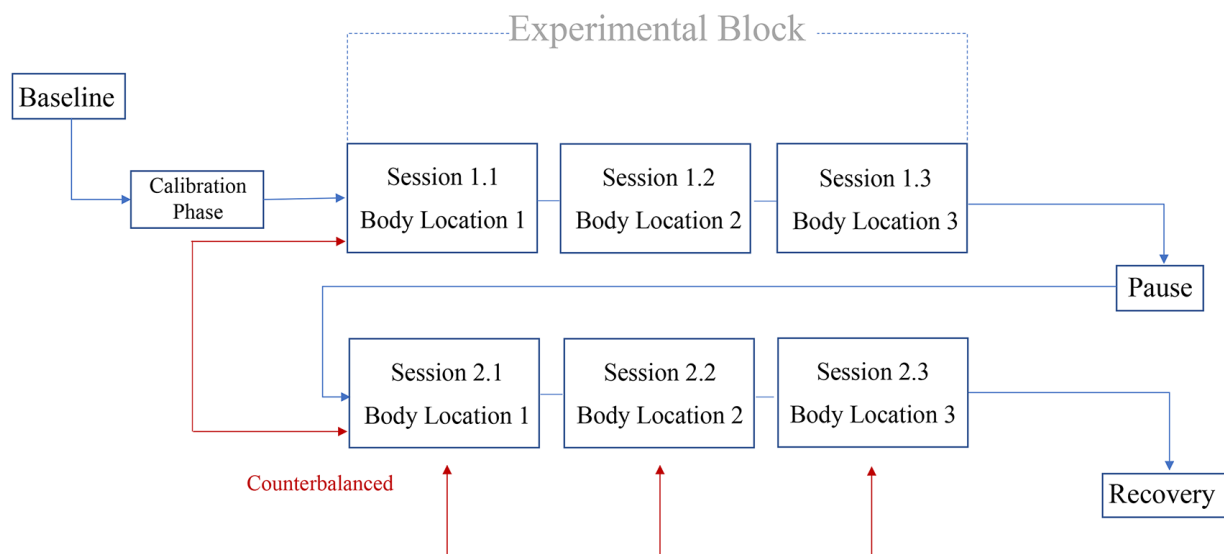


Table 1. Order configurations for cold stimulus and the control condition on neck, cheek, and forearm. Assignment of orders was randomized.

Applied configurations	Sequence of stimulus on body locations
1	Cheek, neck, forearm
2	Cheek, forearm, neck
3	Neck, forearm, cheek
4	Neck, cheek, forearm
5	Forearm, neck, cheek
6	Forearm, cheek, neck

Figure 2. Thermode head used for stimulus application during the sessions. Cold is transmitted only via the 3×3-cm surface (dark red) of the head.**Table 2.** Initial temperature ranges used for participants (N=18) in the pilot sessions.

Group by age and body location	Temperature by gender (°C)	
	Female (n=14)	Male (n=4)
Adults <40 years old		
Cheek	16	13
Neck	16	13
Forearm	14	10
Adults >40 years old		
Cheek	10	9
Neck	10	9
Forearm	8	5

Table 3. Adjusted temperature ranges used for participants (N=71) of the main sample during the experimental sessions.

Group by age and body location	Temperature by gender (°C)	
	Female (n=43)	Male (n=28)
Adults <40 years old		
Cheek	18	17
Neck	19	18
Forearm	18	17
Adults >40 years old		
Cheek	18	16
Neck	19	17
Forearm	18	16

Stimulus Application

The experimental block consisted of 3 sessions with 4 trials at 1 body location, adding up to 24 trials for the entire course of the study. Each set of 12 trials comprised either the cold stimulus or control conditions for the neck, cheek, and forearm. Trials carried out in the control condition used the baseline temperature of 31°C during the thermode application. The control condition proceeded in identical manner to the cold stimulation. Any differences in responses were therefore due to temperature stimulation and not, for example, tactile stimulation due to the thermode being placed onto the skin.

Stimulus duration was 16 seconds in total and consisted of a 3-second ramp-up period from baseline (31°C), a 10-second leveling-off period, and a 3-second ramp-down period back to baseline (Figure 3). The 16-second stimulus was succeeded by 16 seconds at the baseline temperature of 31°C. Participants were instructed to focus their gaze on a cross displayed on a computer screen that changed from white to green when the stimulus was active. The sequence of body locations was communicated to the participant via the monitor screen.

Procedure

On arrival, participants gave informed consent and were generally informed about the upcoming procedure but were not made aware of the research hypothesis. Participants were then led into a separate chamber inside the laboratory room, where they were seated in an armchair, facing a computer monitor with a computer mouse within their reach. Transducers were attached in an Einthoven lead-II position for ECG monitoring. A baseline of a 3-minute continuous ECG was recorded under resting conditions. During this time, participants were unattended and instructed to fixate their eyes on a white cross displayed on a computer monitor located in front of them.

After the baseline was recorded, participants started with the first experimental block. To induce cold stimuli, we used a thermode with a 3×3-cm head. All stimulus and control applications were placed only on the right side of the body. Throughout the experimental blocks, 2 research assistants trained in the experimental procedure handled and held the thermode stationary onto the designated places of the

participant's body. The research assistants were oblivious to the research hypotheses and to any temperature ranges or shifts in the thermode while holding the device (see Figure 2).

The cold stimulus for the cheek was positioned in the middle of the participant's right cheek. For the cold stimulus on the right lateral neck, we selected a place inside the posterior triangle near the clavicle head. The cold stimulus applied to the forearm was placed on the right outer forearm, halfway between the right hand and elbow.

Between experimental blocks, the participant was moved from the chamber to the main laboratory room where he or she sat down unattended for 5 minutes. Heart rate recording was paused during this time, but electrodes remained attached to the chest region. After the pause, the participant returned to be seated in the chamber, and the study advanced with the second experimental block.

Once the trials of both experimental blocks were completed, a 3-minute recovery period was recorded. As with the recording of the baseline at the beginning of the study, during the recovery recording, the participant was also left unattended. When the recovery period was completed, the research assistants removed the electrodes and the markings from the participant's body. After being compensated, the participant left the laboratory. Figure 4 depicts the overall timeline of the study procedure.

Data Collection

Equipment and Materials

We recorded the participants' ECG at a sampling rate of 256 Hz using a Biopac MP150 amplifier and data acquisition system with AcqKnowledge software version 5.0 (Biopac Systems, Inc, Goleta, CA, USA). ECG was continuously recorded throughout the experimental blocks, as well as at baseline and during recovery periods. We programmed the experiment in E-prime (Psychology Software Tools, Inc, Sharpsburg, PA, USA), which triggered the Medoc thermode (Figure 2) and presented instructions on a computer screen. The ECG signal was stored on a hard disk. Beat detection and artifact control was performed offline with WinCPRS software (Absolute Aliens Oy, Turku, Finland).

Figure 3. Schematic depiction of the thermode's temperature change during stimulus application.

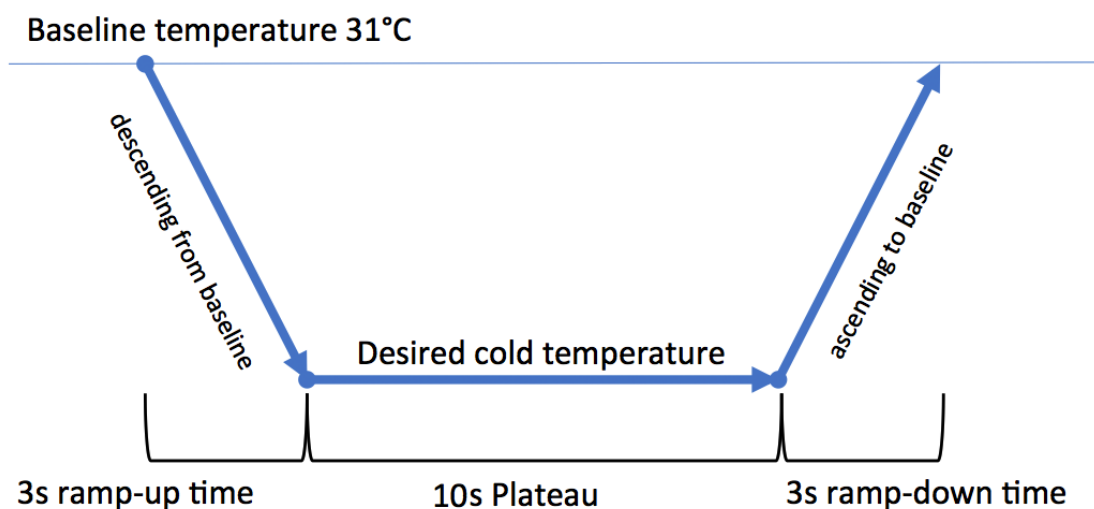
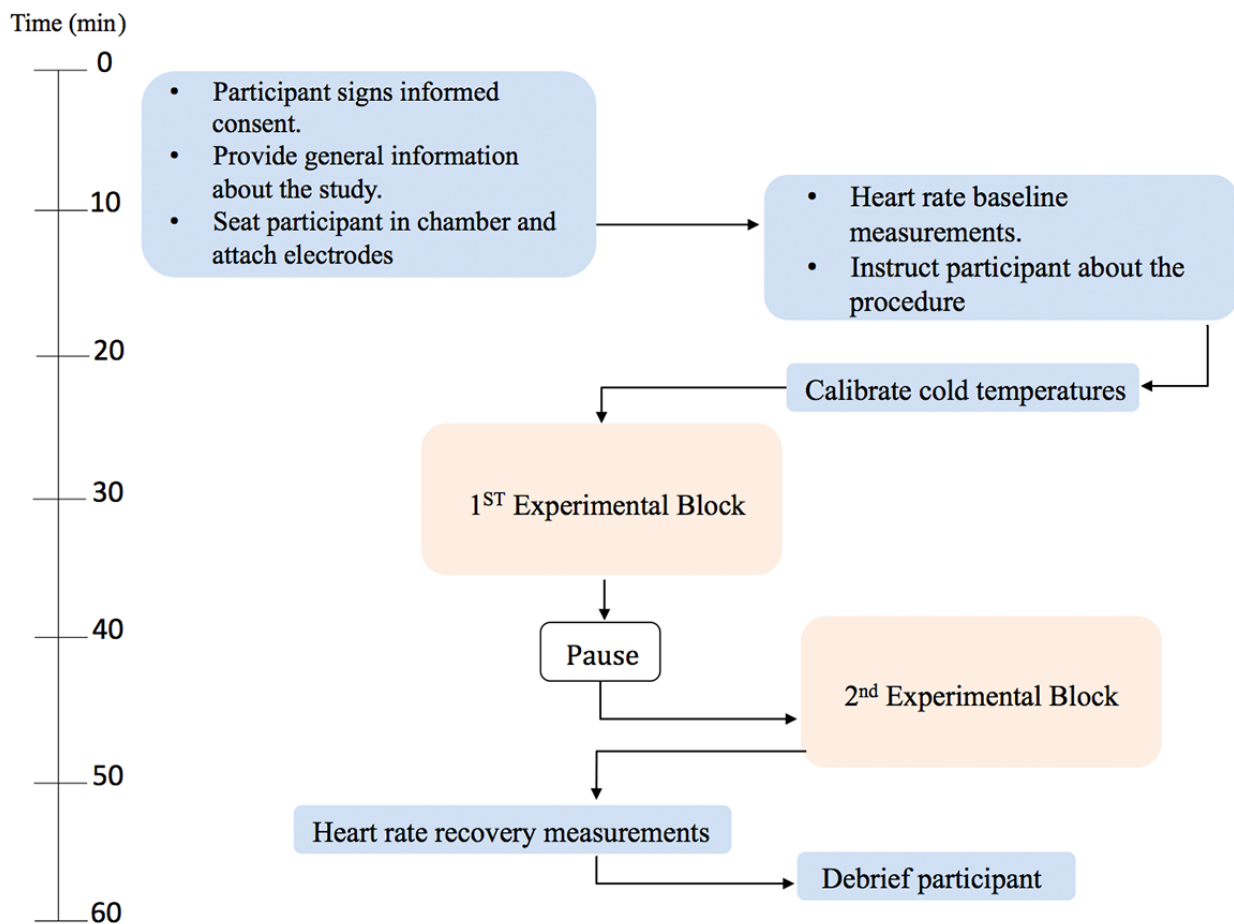


Figure 4. Timeline for the randomized controlled trial. The duration of the experimental blocks and the pause was calculated at 20-25 minutes to compensate for the time of thermode placement on the different body areas and for restabilization of the electrocardiographic signal.



The R-wave peak was detected automatically and was followed by a manual correction step where QRS complexes in some cases were not detected by the automatic algorithm and we had to set it manually. We based the automatic R-wave peak detection on application of a distribution-related threshold criterion that we adjusted individually for each participant. As the data showed no ectopic beats or arrhythmia, no other artifact control was necessary. Time domain measures were directly calculated from R-R interval series.

Data Reduction and Statistical Analysis

We expressed heart rate as interbeat intervals (IBIs) measured in milliseconds. We separately averaged IBIs from baseline, cold stimulus, and control condition trials, as well as recovery values. We analyzed heart rate variability from the IBI in ultrashort-term heart rate variability analysis. The time intervals had a duration of 64 seconds, each comprising 4×16 seconds per body region (neck, cheek, and forearm). We analyzed heart rate variability using WinCPRS.

As the heart rate variability index, we used the root mean square of successive differences (rMSSD), which is the standard time domain measure for detecting autonomic nervous system activation, in particular parasympathetic activity in short-term measurements.

rMSSD is correlated with the vagus-mediated components of heart rate variability [74] and has better statistical properties than other metrics, such as the proportion of the number of successive N-N intervals that differ by more than 50 milliseconds divided by the total number of N-N intervals [75]. rMSSD has been found to be the most reliable metric for ultrashort-term heart rate variability analysis, especially for 10-second intervals under resting conditions [76-80]. We excluded as outliers rMSSD and IBI data with more than 3 SD above the mean for each possible combination of location and condition, reducing the sample included in the analysis to n=61.

We analyzed data using a repeated-measures ANOVA (analysis of variance) approach with 2 within-participant factors: body location (neck, cheek, forearm) and condition (cold, control). We conducted follow-up pairwise comparisons using paired *t* tests, with the Sidak method used to correct for multiple comparisons. All statistical analyses were carried out with IBM SPSS 24 Statistics (IBM Corporation).

Results

Sample

The participants' ages ranged from 19 to 51 (mean 26.8, SD 8.57) years. Age was nonnormally distributed with a skewness

of 1.16 (SE 0.28) and kurtosis of 0.40 (SE 0.56). Women accounted for 60% of the sample.

Heart Rate Variability

A first exploration of the rMSSD data showed skewness and kurtosis in the ranges of 1.71 (SE 0.28) to 2.63 (SE 0.28) and 2.01 (SE 0.56) to 8.26 (SE 0.56), respectively, indicating deviations from the normal distribution. To normalize data, we transformed the data using log transformation (log base 10).

A 2×3 ANOVA on rMSSD with condition-by-body-location trials (cold and control condition at neck, cheek, and forearm) as within-participant factors revealed a main effect for condition ($F_{1,60}=14.68$, $P<.001$, $\eta_p^2=.20$), demonstrating that heart rate variability across body locations differed significantly between conditions. Throughout the stimulation sites, heart rate variability was significantly higher during cold stimulation (mean 1.04, SD 0.25 ms) than in the control stimulation (mean 1.01, SD 0.24 ms). Furthermore, the main effect for body location was marginally significant ($F_{2,120}=2.52$, $P=.08$, $\eta_p^2=.04$). Pairwise comparisons indicated that heart rate variability at the neck (mean 1.03, SD 0.25 ms) was marginally higher than at the forearm (mean 1.01, SD 0.25 ms) stimulation site ($P=.07$). No other comparison was significant.

The interaction effect for condition and body location was also significant ($F_{2,120}=21.37$, $P<.001$, $\eta_p^2=.26$). Follow-up t tests

showed that the experimental and control conditions differed only for neck and cheek, but not for forearm. Cold stimulation on the neck led to higher heart rate variability (mean 1.07, SD 0.26 ms) than in the control condition (mean 1.00, SD 0.25 ms; $t_{60}=6.24$, $P<.001$). On the cheek, cold stimulation induced higher heart rate variability (mean 1.04, SD 0.25 ms) than in the control condition (mean 1.01, SD 0.24 ms; $t_{60}=2.88$, $P=.006$). There was no appreciable difference between cold (mean 1.01, SD 0.26 ms) and control (mean 1.02, SD 0.25 ms) stimulations for the forearm ($t_{60}=-1.15$, $P=.26$). Figure 5 shows the interaction effect [81].

Heart Rate

We computed a 2×3 repeated measures ANOVA on IBI with condition (cold and control) and body location (cheek, neck, and forearm) as within-participant factors. This analysis revealed significant main effects for condition ($F_{1,60}=9.84$, $P<.01$, $\eta_p^2=.14$) and for body location ($F_{2,120}=7.79$, $P<.001$, $\eta_p^2=.14$). Pairwise comparisons showed significantly longer IBIs in response to stimulation in the neck (mean 912.84, SD 146.69 ms) than in the cheek (mean 905.46, SD 145.06 ms; $P=.04$) region. Similarly, stimulation in the neck area also resulted in longer IBIs than in the forearm (mean 898.87, SD 145.81; $P=.002$). There was no discernable difference in IBIs between cheek and forearm stimulation sites ($P=.24$). The findings, illustrated in Figure 6, show that stimulation in the lateral neck region engendered the lowest heart rate.

Figure 5. Normalized root mean square of successive differences (rMSSD) of all body locations for cold stimulus and control conditions (n=61). The error bars depict within-participant standard error following Cousineau-Morey corrections [81].

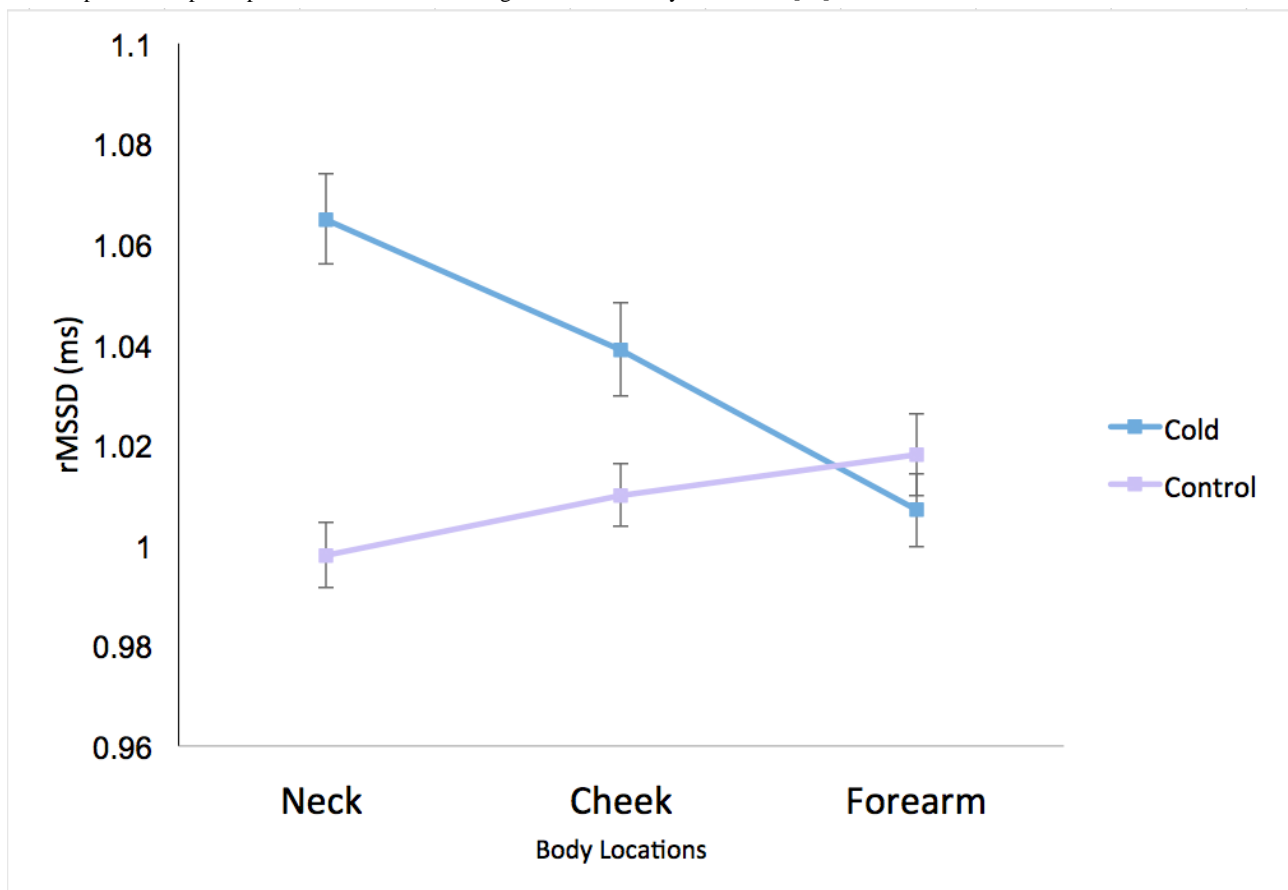
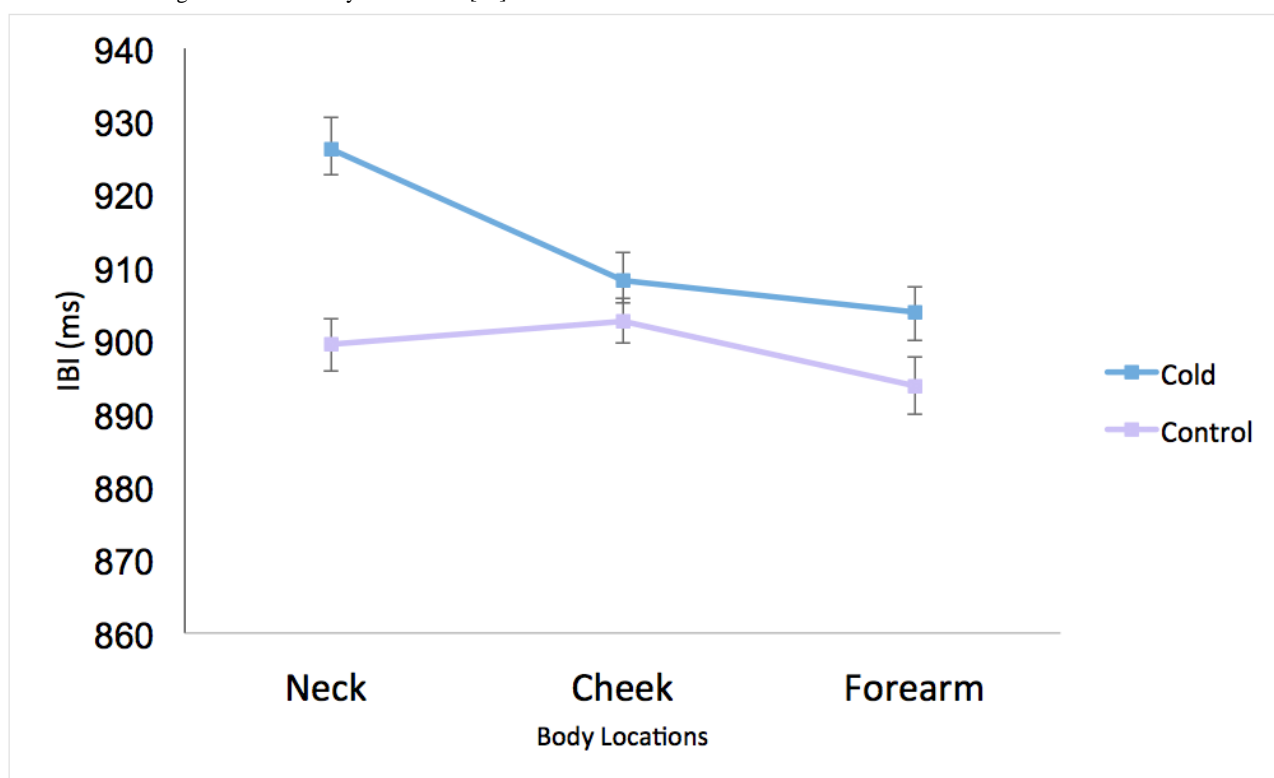


Figure 6. Mean interbeat intervals (IBIs) of all body locations for cold stimulus and control conditions (n=61). The error bars depict within-participant standard error following Cousineau-Morey corrections [81].



There was also a significant condition-by-body-location interaction effect ($F_{2,120}=9.76$, $P<.001$, $\eta_p^2=.14$). As Figure 6 shows, IBIs were longest—that is, heart rate was lowest—during cold stimulation in the neck region (mean 926.25, SD 153.29 ms), as opposed to the control condition (mean 899.43, SD 143.74 ms; $t_{60}=4.42$, $P<.001$).

For the forearm stimulation site, IBIs were slightly longer in the cold (mean 903.97, SD 149.14 ms) than in the control condition (mean 893.83, SD 144.82 ms; $t_{60}=2.12$, $P=.04$). There were no distinguishable differences in IBIs between the cold (mean 908.23, SD 149.38 ms) and the control (mean 902.7, SD 143.54 ms) conditions for the cheek region ($t_{60}=1.06$, $P=.29$).

The overall findings of the study confirmed our main hypothesis that cold stimulation at the lateral neck region would result in higher heart rate variability and lower heart rate than in the control condition.

Discussion

Principal Results

This study was motivated by the need for technological support that is effective in reducing acute stress levels in otherwise healthy individuals. With this study, we carried out a first empirical evaluation of the effects of cold stimulation in the lateral neck region on heart rate variability and heart rate. This is an initial step toward assessing the viability of a wearable concept for stress reduction and contributes to the body of basic experimental research conducted toward understanding the effects of temperature stimuli on heart rate and heart rate variability at various body regions. The study design was

conservative in that we investigated heart rate reduction and cardiac-vagal activation under resting conditions. To chart this new research territory, which was informed by the combined knowledge from studies in VNS and CWFI, we selected a within-participant approach to collect physiological data in an experimental laboratory setting.

We hypothesized that cold stimulation in the lateral neck and cheek regions would induce higher heart rate variability than in the (nonstimulation) control condition, except for the forearm. Our results confirmed that cold stimulation in the right lateral neck and the cheek areas increases heart rate variability, denoted by higher rMSSD values. These outcomes are in line with previous cold stimulation paradigms, such as CWFI research (eg, [48,49,67,70,71]), which have been shown to modulate parasympathetic activation similar to that observed in the diving reflex. As there have been no previous studies testing for the effects of cold administered to the neck, our findings suggest that the area sensitive to cold potentially extends from the cheek to the neck. Alternatively, cold stimulation in the neck area may have triggered physiological mechanisms known to have an impact in noninvasive VNS. Future studies are needed to investigate the exact physiology underpinning the effects of cold stimulation in the right lateral neck region.

Our hypothesis on heart rate outcomes was only partially supported. Overall, the results showed a pattern of cardiovascular reactivity to cold stimulation as expected; however, we observed this effect only for the neck, but not for the cheek. The heart rate findings regarding the right lateral neck area replicated those observed with heart rate variability. This suggests that cold stimulation in the right lateral neck

region has the potential as an effective alternative to electrical impulsing used in VNS interventions.

Unexpectedly, we did not observe any differences in heart rate between the cold and control conditions in the cheek region. Previous research investigating the effects of cold stimulation on heart rate predominately focused on using heart rate variability and the time constant heart rate recovery as postexercise outcome measures (eg, [49,68]). It is consequently difficult to infer from related research the reason behind this contrast in findings.

Limitations

While the results of our study are promising, there are also limitations. First, the skewed age distribution limits the generalizability of the study's results. Future studies should strive for an even spread of age when recruiting participants. From the perspective of the wearable, it will be important to confirm the effects of cold stimulation across the whole age range, including the elderly population, because this will determine which market should be targeted for commercialization.

Second, we appropriated a medical device (the thermode) for cold application during the study. It had to be handheld by 2 research assistants at the prespecified location of the participant's body. Prolonged holding of the thermode may have caused shifts in pressure across body locations and experimental blocks. However, we aimed to minimize any effects by using the counterbalanced study design. Outcomes may have also been influenced by the close physical proximity of the 2 researchers to the participant. However, the distance between research assistants and participants was consistent across experimental blocks.

Third, although a sampling rate of 256 Hz for ECG data collection is a well-established standard in the field (cf [75,82]), future studies may consider using a higher sampling rate to increase the temporal accuracy of heartbeat detection.

Future Consideration

For this study design, we purposefully omitted a stress condition to perform a first evaluation of the effects of cold stimulation

in the lateral neck region on heart rate variability and heart rate. To continue the evaluation, subsequent studies should include a stressor in the study design. A stressor, such as the Trier Social Stress Test, which requires the participant to give a speech in front of a disapproving panel and perform an arithmetic task, would be an effective choice and the next logical step in the evaluation procedure. A follow-up study should also investigate the relationship between heart rate and rMSSD with regard to age and gender by recruiting participants within a wider age bracket.

It would also be advantageous for the continued evaluation to gain insight into the participant's experience of the cold stimulation. However, we based our choice to exclude self-report ratings in this study on the fact that requesting participants to fill out ratings on the experience of stress repeatedly during the experimental session would have affected our physiological measurement. A follow-up study should collect self-report data on several dimensions, such as perceived stress, relaxation, and pleasantness levels of the cold stimulation placed on the neck.

Since a wearable solution for stress reduction must stand up to the demands of daily living, a field study that assesses the effects of cold stimulation on heart rate variability and heart rate in the neck region in real-life stress situations also suggests itself as a future investigation. A range of cold temperatures and durations should also be included in future research. However, as a thermode would not be suitable for a field study because it is not mobile and cannot be easily fastened to the neck, the development of a basic prototype is required that can be used for cold application under real-life circumstances.

Conclusion

Our results demonstrated that cold stimulation in the lateral neck region activates the parasympathetic nervous system in ways that resemble significant research findings in VNS and CWFI. For research, it may be of interest to continue this line of investigation, to broaden the scope of VNS and CWFI, which may expand our understanding of the biological mechanisms that underpin parasympathetic activation. For the development of a wearable for stress reduction, this study's outcomes confirm our hypotheses and substantiate the first step in the evaluation procedure toward the development of a commercial product.

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Authors' Contributions

MJ and CV designed the experiment. MJ carried out the experiment. SV assisted during the laboratory experiment. CV, MJ, and SV conducted the statistical analysis. DVR gave input to the statistical analysis. MJ drafted the manuscript. CV revised and commented on the manuscript. SV and DVR contributed to manuscript preparation. All authors approved the final version to be published.

Conflicts of Interest

None declared.

Editorial Notice: This randomized study was not registered, in possible violation of ICMJE rules for prospective registration of randomized trials. The editor granted an exception because the risk of bias appears low (also due to the within-subject comparisons) and the study was considered formative. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness.

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Abbreviations

- ANOVA:** analysis of variance
CWFI: cold water face immersion
ECG: electrocardiogram
IBI: interbeat interval
rMSSD: root mean square of successive differences
VNS: vagus nerve stimulation

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Original Paper

Linking Podcasts With Social Media to Promote Community Health and Medical Research: Feasibility Study

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Abstract

Background: Linking podcasts with social media is a strategy to promote and disseminate health and health research information to the community without constraints of time, weather, and geography.

Objective: To describe the process of creating a podcast library and promoting it on social media as a strategy for disseminating health and biomedical research topics to the community.

Methods: We used a community and patient engagement in research approach for developing a process to use podcasts for dissemination of health and health research information. We have reported the aspects of audience reach, impressions, and engagement on social media through the number of downloads, shares, and reactions posted on SoundCloud, Twitter, and Facebook, among others.

Results: In collaboration with our local community partner, we produced 45 podcasts focused on topics selected from a community health needs assessment with input from health researchers. Episodes lasted about 22 minutes and presented health-related projects, community events, and community resources, with most featured guests from Olmsted County (24/45, 53%). Health research was the most frequently discussed topic. Between February 2016 and June 2017, episodes were played 1843 times on SoundCloud and reached 1702 users on our Facebook page.

Conclusions: This study demonstrated the process and feasibility of creating a content library of podcasts for disseminating health- and research-related information. Further examination is needed to determine the best methods to develop a sustainable social media plan that will further enhance dissemination (audience reach), knowledge acquisition, and communication of health topics.

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KEYWORDS

biomedical research; community health; community and patient engagement in research; podcast; social media

Introduction

Social media presents a powerful tool for reaching, engaging, and connecting individuals for public health and health promotion [1]. Social network platforms have a large reach at

relatively low cost, representing a distinct advantage over face-to-face approaches [2]. Social media is used for promoting health literacy through education and dissemination of information to the lay public [3] to encourage behavior changes [4] (eg, smoking cessation, diabetes prevention, exercise) and

promote research participation [5], among others. In addition, social media has been utilized among health professionals for continuing education [6] and dissemination of clinical practice changes [7]. Social media (ie, Web 2.0 technologies) can increase the depth of engagement and connection with extensive reach to underserved, diverse populations [8,9] and with evidence-based content.

Integrating technology, such as podcasts into traditional health care communication or dissemination models, is an effective and practical strategy for not only delivering quality health-related information to the public, such as clinical practice changes, education, and health research [10,11], but also for creating opportunities for engagement with the content [12,13]. Podcasts are downloadable, digital, episodic audio recordings streamed through a Web-based platform that can be easily accessed using portable media players and then shared on multiple social media platforms such as Facebook, Twitter, or blogs. Over time, the number of people listening to podcasts has increased, especially among those interested in health care, research, and education [11-14]. Between 2013 and 2016, 21% of Americans aged ≥ 12 years have reported listening to a podcast in the previous month, a steady 36% increase from 2008 to the present that coincides with use and access to smartphones, tablets, and other mobile devices [14,15]. This strategy fits well into the principles of community and patient engagement in research (CPER) [16] that aim to establish sustainable ways to build trust, respect culture, and create clear expectations of outcomes to increase wellness. Traditional CPER approaches have involved intensive face-to-face communication formats to promote communication between researchers, community members, and other stakeholders [17-19]; yet these approaches limit audience reach and can restrict participation due to constraints of time, geography, and weather. Podcasts, on the other hand, can accomplish similar aims, but are subject to none of these limitations; their content can be created based upon the interests and listening patterns of their audience. The process of creating a community topic driven podcast afforded us the opportunity to design a dissemination tool to raise awareness about health and biomedical research. After creating our podcasts, we realized that our experiences might benefit others with community-academic partnerships with similar challenges. Moreover, we realized that our approach was a novel way to share health- and community-related information using social media platforms to stimulate communication and maximize audience reach.

Methods

Developing Podcasts

The idea for developing podcasts arose from a discussion during a community advisory board meeting about the need to transfer the content of a Science Café to the Web-based realm. Science Cafés are in-person, casual events that encourage two-way conversations about health- or science-related topics between scientists, health practitioners, and the lay public to enhance health literacy, trust, and colearning. A series of these events had been recently conducted in the community, and they were termed as “garden cafés,” as many had taken place in community

gardens. While successful in stimulating conversation and idea exchange, the reach of these cafés was limited due to the barriers of geography, weather, and time. Therefore, the decision was made to create a series of health-related podcasts based upon a recent community health needs assessment that would provide an extensive library of topics to share via social media. Therefore, our team decided to incorporate another social media platform to disseminate community health and medical research information. The Mayo Clinic Center for Clinical and Translational Science’s Community Engagement Program (CEP) had a strong social media presence. The program had a WordPress blog, Twitter page, and Facebook page [8]. One area that we decided to explore was the creation of a community-academic podcast. Like the cafés, we planned to use a similar process to determine topics and considered this part of what we called our Social Media Community Garden Café approach.

The development of meaningful podcast content was supported by CEP and Smartride Network. Our partner, Smartride Network, is a collaborative, community-based organization that hosts a variety of cultural, art, health, and biomedical research programs. To select topics for podcasts, we referred the Olmsted County Community Health Needs Assessment (CHNA) [20]. The CHNA not only recommended health topics, but also stated that new social media approaches should be developed for disseminating information within the growing Olmsted County community. This article reports the process that stakeholders used to develop podcast topics and promote the podcasts themselves on social media, as well as the basic analytics of audience reach, impressions, and engagement as reported through the number of downloads, shares, and reactions posted on SoundCloud, Twitter, and Facebook.

The podcast team decided to focus the first few episodes on community-identified health and wellness needs. The systematic community-engaged approach involved Olmsted County Public Health Services, Olmsted Medical Center, Mayo Clinic, and several community service organizations jointly collecting data from residents on their health needs [20]. The organizers of the CHNA held a number of community events as well as other activities with local community members and community organizations to prioritize the most pressing health topics locally. The top 5 topics included: injury prevention, immunizations, overweight or obesity, mental health, and financial stress. After the initial episodes, the podcast team expanded the content list to topics related to cultural events, health and wellness, and international health. The change in content selection also expanded the pool of guest speakers for the podcast. Local media and internal communications for events like academic seminars provided other sources of inspiration for the podcast.

Guests were invited in-person by the host or other team members to share their stories. We determined the credibility of guest speakers by exploring local content expertise. For national and international speakers, we connected with the organizers of a number of speaker series at our academic medical center (eg, Grand Rounds and other medical seminars) to ask visiting faculty to create a podcast during their visit. Guests shared their stories related to community priorities and biomedical research.

The episode format consisted of the following:

- Welcome and introduction by the host and guest
- Guest describes the personal journey that led to current work
- Guest shares current projects, findings, resources, and engagement opportunities for listeners
- Guest creates the titles of the episodes with the host to enhance promotion in their networks
- Host concludes each episode with a call-to-action to follow our social media platforms and for listeners to share the podcasts with their networks

We used a CPER research approach to determine sponsorship for podcast recording equipment and to prioritize episode creation. This approach involved working directly with the CEP, local community partners, and health care providers. The podcast design process focused on audience and delivery. We recognized that the podcast alone does not foster communication and information dissemination like other forms of social media. Therefore, it was linked to other interactive social media tools such as Twitter and Facebook, where listeners could comment and post reactions.

Audience

Our primary target audience for the podcasts was residents of Olmsted County, MN, with an interest in learning about (1) health and wellness; (2) community events; (3) opportunities for civic engagement; and (4) biomedical research. The podcast featured guests from local agencies, nonprofits, the health department, community members, and academic researchers (local, national, and international) [9].

Podcast Hosting

SoundCloud was selected as the main hosting platform for the podcast [21]). This platform allows members to share digital audio content in the form of a podcast. It also allows broadcasters to create albums and playlists for their recorded and posted content. Our podcast was shared on iTunes through a plug-in of the Rich Site Summary feed. Podcast episodes are sharable over other forms of social media.

Episode Design

Podcast Promotion

An open, searchable Facebook page, called Community Board, was created for consistency in branding the community podcast initiative. The episodes were listed on the CEP WordPress blog and Twitter account. A Rich Site Summary feed was used to ensure that the podcast was accessible on mobile devices and computers [11,22]. We shared information about new episodes via email and asked community members, guests, and others interested in the topics to share the podcast link with colleagues and stakeholders. The podcast stakeholders were also members of the Olmsted County Community Needs Assessment Team.

Assessing Podcast Reach

We assessed podcast reach using available social media analytics from SoundCloud and our CEP Facebook and Twitter pages.

The SoundCloud analytics allowed us to capture information on social media engagement (ie, likes, reposts, and comments). Other analytics provided information on (1) episode length in minutes and seconds, (2) number of times the podcast was played, and (3) geographic location of listeners [23]. Episodes were grouped by three focus areas (ie, biomedical research, art and cultural events, and local resources) and by guest speakers' geographic location. SPSS (IBM SPSS Statistics for Windows, Armonk, NY, USA) was used to calculate descriptive information including frequencies and measures of central tendency.

Results

The Community Board Podcast produced 45 episodes with 1843 cumulative plays, 728 of which occurred between February 2016 and June 2017 (Table 1). Our Facebook page has 72 subscribed followers and has reached 1702 listeners. Just over half of the episodes featured local speaker(s) from Olmsted County, MN (24/45, 53%), with the other half of speakers from organizations in the state of Minnesota (3/45, 7%), the United States (14/45, 3%), and outside the United States (4/45, 9%). Biomedical research topics garnered the greatest number of listeners (1058/1843, 57.40%), followed by community resource awareness (417/1843, 22.63%) and information on art and cultural events (368/1843, 19.97%).

In the first 6 months of the podcast, 21 episodes were produced (Table 2), most of which aired in April (7/21, 33%). However, the greatest number of total downloads occurred during the month of March (163/728, 22.4%). During the first 6 months of each airing, the episode that was played the most was The Great Lakes Inter-Tribal Council (87/725, 12.0%). This topic was selected in collaboration with a community partner and research team focused on Native American health. Overall, there were 42 "likes" (indicating a positive reaction to the podcast), with most of the "likes" occurring in May (17/42, 40%). Nearly two-thirds of the listeners listened to the podcast via SoundCloud platforms (498/722, 68.98%).

From February 2016 to June 2017, the top 5 episodes played were (1) Women's Health-Uterine Fibroids (n=119), (2) The Great Lakes Inter-Tribal Council, Incorporated (n=104), (3) Wellconnect SE MN (n=80), (4) Black History Month Meet the Researcher-Camara Phyllis Jones, MD (n=72), and (5) Music is Medicine to the People (n=66). The average episode length was 22 minutes and 19 seconds (SD 12 minutes and 25 seconds). The podcast received 1846 cumulative plays between February 2016 and June 2017. There were 1653 listeners in the United States, with 590 in Olmsted County, MN, and 193 were from other countries. The top played episodes featured guests with a strong social media presence. After publishing the episodes, we linked them directly to our WordPress blog, Facebook, and Twitter accounts, allowing the guests to share the posts with their stakeholders.

Table 1. Podcast episodes since February 2016.

Episode titles	Geographic focus	Episode theme	Publication date	Length in minutes	Total plays
Introduction to Community Board	Local	Resource	February 2016	8:07	44
KnuFunk Band	Local	Art & Culture	February 2016	14:47	43
Three Rivers Community Action	Local	Resources	February 2016	11:50	22
Black History Month Meet the Researcher – Camara Phyllis Jones, MD	National	Research	February 2016	14:22	72
Artist Bobby Marines’ New Work	Local	Art & Culture	March 2016	18:00	52
Wellconnect SE MN	State	Research	March 2016	16:29	80
Women’s History Month	Local	Art & Culture	March 2016	8:47	36
stART-up Fund Program	Local	Art & Culture	April 2016	10:24	21
Women’s Health-Uterine Fibroids	National	Research	April 2016	22:10	119
RNeighbors #RochMN	Local	Resource	April 2016	16:53	32
Dr. Paul Spaicer Learning with Natives Communities	National	Research	April 2016	22:53	68
Black Hair Politics of Beauty	Local	Art & Culture	April 2016	12:14	52
Airbnb and Research	International	Research	April 2016	18:33	26
Art on the Ave	Local	Art & Culture	April 2016	16:19	25
Learn about Uterine Fibroids and Underwater Hockey	National	Research	May 2016	21:01	66
The Commission #RochMN	Local	Resource	May 2016	28:12	31
#Prince, Blues, and BBQ	Local	Resource	May 2016	22:04	47
Mission 21 Sex Trafficking	Local	Resource	May 2016	53:18	35
The Great Lakes Inter-Tribal Council, Inc.	National	Research	June 2016	32:30	104
Affordable Housing-Volunteer Opportunities	Local	Resource	June 2016	26:45	41
Juneteenth Commemorating the Ending of Slavery in US	Local	Art & Culture	June 2016	10:39	31
Community Prioritization Session #CHNA	Local	Research	July 2016	11:35	32
NAMI Mental Health Resources	Local	Resource	September 2016	30:02	30
Day of the Dead Poet Slam	Local	Art & Culture	October 2016	20:50	30
Your Local Farmers Market	Local	Research	October 2016	24:09	40
BMG Basement Music Group	Local	Art & Culture	November 2016	18:06	43
MondayCampaigns.org	National	Research	November 2016	8:59	34
Clinical-Scholars.org	National	Research	November 2016	19:35	34
Community-Campus Partnerships for Health (CCPH)	International	Research	November 2016	13:28	48
Men’s Health Caucus 1	National	Research	November 2016	8:12	43
Men’s Health Caucus 2	National	Research	Novembers 2016	9:50	24
Men’s Health Caucus 3	National	Research	December 2016	18:30	30
Improving Health Globally by Studying Health Locally	National	Research	December	33:27	51
Youth and Men’s Health Caucus 4	National	Research	December 2016	7:05	29
Working Together to Strengthen Our Future	Local	Resource	December 2016	22:38	44
Music is Medicine to the People	National	Research	January 2017	52:10	66
The Power of Movement Dr. James Levine	National	Research	January 2017	56:59	41
Community Interfaith Dialogue on #islam	Local	Art & Culture	February 2017	44:44	35
Girls on the Run #RochMN	Local	Resource	March 2017	16:44	22
Diversity Council	Local	Resource	April 2017	24:12	32
South Side Community Health Services	State	Research	April 2017	22:28	27

Episode titles	Geographic focus	Episode theme	Publication date	Length in minutes	Total plays
Main Street Project	State	Resource	May 2017	46:02	30
Indigenous Smoking An Australian Perspective	International	Research	May 2017	28:20	19
Health Disparities Study in South Africa	International	Research	May 2017	29:43	5
Bee Keeping Year 1	Local	Resource	June 2017	30:23	7

Table 2. Analytics for the first 6 months of community board podcasts.

Analytics	Values n (%)
Episodes produced during first 6 months (n=21)	
February	6 (28.6)
March	3 (14.3)
April	7 (33.3)
May	2 (9.5)
June	2 (9.5)
July	1 (4.8)
Total listeners by month (n=728)	
February	103 (14.1)
March	163 (22.4)
April	189 (26.0)
May	116 (15.9)
June	146 (20.1)
July	11 (1.5)
Total likes (n=42)	
February	6 (14.3)
March	5 (11.9)
April	6 (14.3)
May	17 (40.5)
June	8 (19.0)
July	0 (0)
Reposts (n=2)	
February	0 (0)
March	0 (0)
April	0 (0)
May	1 (50.0)
June	1 (50.0)
July	0 (0)
Platforms for playing podcasts (n=722)	
SoundCloud Apps, Embedded, and Mobile	498 (69.0)
Apple Core Media and iTunes	80 (11.1)
Rich Site Summary Feed	144 (19.9)

In addition to determining the number of plays, we wanted to see additional social media engagement of the podcast. During the reporting period, we had 70 likes for the podcasts, suggesting that these listeners “liked” or enjoyed that episode. We also had

a total of 4 reposts from listeners to other social media sites. The analytics did not allow us to see beyond one repost from our originating site, so it is possible that there were further

shares or reposts, but they cannot be tracked. We had 3 listeners comment on episodes and 3 listeners download episodes.

Discussion

Principal Findings

The Community Board Podcast produced 45 episodes with most featuring local speakers. Most of the listeners for the podcast were from the United States, with a small portion from other countries. We used existing social media platforms to promote the podcasts and asked community stakeholders to promote the episodes to their stakeholders. The episodes that garnered the greatest number of listeners were those related to biomedical research topics, with women's health having the most total plays.

Podcasts are an emerging strategy for dissemination of pertinent issues in the community with the potential to raise awareness and increase knowledge of health and wellness as well as biomedical research. We purposefully selected podcasts as a social media platform because they allowed us to create quality content that was sharable within the community without limitations of time, audience reach, geography, or weather with our stakeholders. This platform has proven to be effective with diverse communities. Olmsted County, MN, is the 8th largest county in the state, with Hennepin County being the largest with continued growth in the community due to a new public-private economic initiative called Destination Medical Center [24,25]. The growing changes in our community have influenced the need to identify the most effective methods to share information related to health and wellness with community stakeholders. The increased use of mobile devices by patients, patient advocates, and community members allows new ways for academic medical centers to connect with stakeholders and increase knowledge about wellness and biomedical research. This use of a podcast in our local community facilitated a new approach for promoting communication and awareness of biomedical research and cultural events and information about local community resources (14). Additionally, the Community Board Podcast's reach extended beyond the local community, with downloads recorded throughout the United States and beyond. This unexpected reach in a global community is notable because the topics reflected not only the interests of the local community but also the interests of a larger global audience.

Strengths and Limitations

Using health priorities identified by community members through the CHNA as the basis for the initial podcasts proved to be a strength. These topics led to more direct conversations with stakeholders (ie, community members, patients, service providers, and biomedical researchers) on potential topics of interest. Another strength was the ease in linking podcasts to other social media platforms, which allowed a larger audience to experience, interact with, and discuss the podcasts in their own social networks. Unfortunately, we were unable to fully track the depth of reach of our podcasts with the available analytics or to capture an increase in knowledge since we did not include an evaluation measure for knowledge gain. Future studies should use more in-depth analytic programs for tracking

audience reach and interaction. Future studies could employ experimental designs to assess knowledge gain, audience reach, and longer-term consequences on health and wellness, clinical practice, and biomedical research.

One significant strength and key feature of the podcast is that it relates directly to recommendations from Dr Christopher Austin, Director of National Center for Advancing Translational Sciences at the National Institutes of Health (NIH), who advised us in an interview that researchers, "must talk in language the public can understand" [26]. Podcasts are an emerging platform that biomedical research programs can use to directly connect with the community in places where they will hear it and in language they will understand. Moreover, actively engaging community members and researchers in continued bidirectional dialogues helps reduce the time needed to raise the general population's awareness and understanding of research findings and how they address community-related needs [27].

While our results show that developing and promoting health- and research-related podcasts is feasible, more research is needed to determine the best ways to develop and promote these educational sessions to maximize audience reach (ie, number of downloads, shares, reactions, and reposts). An understanding of audience reach will stimulate colearning, thus increasing the knowledge of both community members and health care practitioners or researchers. For instance, podcasts are a platform often used in Free Open Access Medical education (FOAM). The FOAM movement has altered the way health care practitioners interact with each other and serves as a supplement to traditional pedagogical methods to increase the knowledge of medical learners [28,29]. Moreover, the use of social media platforms like podcasts promotes the translation of evidence-based medicine to the medical community to increase knowledge [30]. Lessons learned from the use of podcasts in the FOAM movement are translational to increase research literacy and overall knowledge of health in the community.

Future Work

Future directions for the podcast include developing and evaluating novel ways to better track active engagement and knowledge increase of listeners. The evaluation process should include the application of Kirkpatrick's model level 1 and 2 to determine listeners' reactions and knowledge gain from listening to the podcast [31]. We may also consider including moderated postings to our existing social media pages that will encourage direct communication about health topics and health research to aid in the evaluation process. This process may also include the use of Facebook Live or other video blogging tools to facilitate real-time communication with listeners. This process could increase bidirectional communication, engagement, and knowledge with health care experts and the community. Moreover, the addition of another theoretical framework, such as Reach, Effectiveness, Adoption, Implementation, and Maintenance, may provide more consistency and foster a process to determine individual and institutional impact [32,33]. Finally, we found that episodes that focused on community-identified topics and promoted by stakeholders were the most popular. Therefore, more effort is needed to devise a standardized community promotion plan to further extend our audience reach

to address other health and health research topics. For example, for future work, we plan to develop a toolkit to guide community organizations on the best methods and ways to promote podcasts developed in partnership.

Conclusion

In conclusion, our study suggests that podcasts linked with other social media platforms are a feasible strategy for sharing and

stimulating communication about health and biomedical information to a wide audience without barriers of time, geography, and weather. These preliminary results will inform the development of a large-scale trial of Social Media Garden Cafés (podcasts linked with social media) to educate and empower communities, health providers, and biomedical researchers for improving health care research and delivery.

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Conflicts of Interest

None declared.

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Abbreviations

- CEP:** Community Engagement Program
- CHNA:** Community Health Needs Assessment
- CPER:** community and patient engagement in research
- FOAM:** Free Open Access Medical
- NIH:** National Institutes of Health

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Original Paper

A Web-Based Interactive Tool to Reduce Childhood Obesity Risk in Urban Minority Youth: Usability Testing Study

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Abstract

Background: Childhood obesity is a serious public health issue among minority youth in the United States. Technology-enhanced approaches can be effective for promoting healthy behavior change.

Objective: The purpose of this study was to test the usability of prototypes of a Web-based interactive tool promoting healthy dietary behaviors to reduce childhood obesity risk in urban minority youth. The Web-based tool comprised a manga-style comic with interactive features (eg, sound effects, clickable pop-ups), tailored messaging, and goal setting, and was optimized for use on tablet devices.

Methods: Latino and black/African American children ages 9 to 13 years were recruited to participate in two rounds of usability testing. A modified think-aloud method was utilized. Self-reported surveys and field notes were collected. Audio recordings and field notes from usability testing sessions were systematically reviewed by extracting and coding user feedback as either positive comments or usability or negative issues. The quantitative data from self-reported questionnaires were analyzed using descriptive statistics.

Results: Twelve children (four female; eight black/African American) with a mean age of 10.92 (SD 1.16) years participated. Testing highlighted overall positive experiences with the Web-based interactive tool, especially related to storyline, sound effects, and color schemes. Specific usability issues were classified into six themes: appearance, content, special effects, storyline, terminology, and navigation. Changes to the Web-based tool after round 1 included adding a navigation guide, making clickable icons more visible, improving graphic designs, and fixing programming errors. In round 2 of testing (after modifications to the Web-based tool were incorporated), many of the usability issues that were identified in round 1 did not emerge.

Conclusions: Results of testing will inform further development and finalization of the tool, which will be tested using a two-group pilot randomized study, with the goal of reducing childhood obesity risk in minority, low-income youth.

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KEYWORDS

usability testing; interactive technology; mHealth, childhood obesity; minority; health nutrition; health education

Introduction

Background

Childhood obesity continues to be a serious public health challenge [1]. In the United States, the prevalence of obesity among youth is 18.5% [2]. The challenge remains pronounced particularly in low-income, minority populations. Latino and black/African American children have the highest rates at 25.8% and 22.0%, respectively [2]. Furthermore, adolescents (12-19 years) have the highest prevalence (20.6%) compared to school-aged (6-11 years; 18.4%) and preschool-aged children (2-5 years; 13.9%) [2]. Childhood obesity leads to negative health outcomes, such as type 2 diabetes, cardiovascular disease, and hypertension, which can continue through to adulthood [3-5]. This complex epidemic has been attributed to, among other behaviors, the increased consumption of energy-dense and low-fiber foods [6,7] as well as the reduced consumption of nutrient-dense fruits and vegetables [8,9].

Effective, yet innovative interventions are needed to capture the attention of children living in a multimedia environment. The pervasiveness of technology and new media use in youth, particularly within the Latino and black/African American population [10-12], highlights opportunities and potential new avenues to engage with this priority population [13]. A systematic review indicated that Web-based programs, as part of a multicomponent intervention, could reduce obesity and overweight in school-aged children [14]. Web-based and technology-assisted interventions, particularly if developed using human-centered approaches and informed by theory [15], have the potential to increase access, improve convenience, decrease cost, and increase participant engagement with dietary behavior change strategies, especially among culturally diverse and hard-to-reach communities [16-19]. At the same time, these types of interventions that allow for flexible engagement with health-related material may require more intrinsic motivation to initiate and maintain engagement over time. Thus, innovative dietary-focused interventions targeting youth should not only incorporate technology, but also integrate engaging features and components to sustain interest and use.

Theoretical Basis and Content of Intervention INC

Intervention INC is a theory-informed, Web-based interactive tool promoting healthy dietary behaviors, specifically increased fruit and vegetable or water intake, with the goal to reduce childhood obesity risk in Latino and black/African American youth. The main component of the Web-based tool is a novel interactive manga comic, optimized for use on tablet devices. Although research is limited, Japanese comic art, commonly known as manga, has previously been used as part of cognitive behavioral therapy to improve depressive symptoms in Japanese adults [20], as a mental health campaign for youth in England [21], and as an obesity prevention tool for minority children in the United States [22,23]. Unlike Western-style comic books, manga are a unique form of multimodal narrative media that stimulate a reader's attention by combining detailed visual images and text to create more of a subjective viewpoint of a story [24]. Another distinct feature of manga comics is their wider range of genres. Manga comics are an increasingly

popular form of entertainment in many countries, including the United States, irrespective of gender, nationality, or age [25-28]. Although such popularity increases the opportunity for reach of manga comics, components such as story plot and character details (eg, physical features, language use, personal preferences) can be developed to tailor these comics for specific minority populations.

The comic component of the Web-based tool was guided by the narrative transportation theory. The narrative transportation theory explains how narrative communication, such as manga comics, could contribute to changes in health-related beliefs and behaviors by transporting the reader into the narrative world [29]. According to the narrative transportation theory, transportation into a narrative world is believed to lead to acceptance of persuasive messages within a story through multiple mechanisms, which include positive relationships with story characters, lowered resistance to story messages, and similarities to real-world experiences [30-34]. If a reader likes or identifies with a specific character, the events experienced by the character or statements made by the character may have a greater effect in shifting the reader's beliefs [33,34]. As a result, narrative messages may be more effective than fact-based evidence, particularly when the messages are not similar to one's own beliefs [29]. Additionally, readers tend to be more engaged with stories that are similar to their personal experiences and cultural values [29]. Thus, embedding health messages into storylines with realistic and relatable scenarios could further engage readers, and thus potentially impact health-related attitudes and beliefs. The narrative transportation theory also suggests that images are most impactful when they are embedded in a story rather than provided in isolation as it could enhance the narrative influence [35]. Therefore, visual images relevant to the story's message, such as those incorporated in manga comics, may further impact attitudes and beliefs.

Social cognitive theory is a frequently used framework in effective dietary behavior change interventions [36,37], and it also lends explanation to ways in which a manga comic may influence health behavior in youth [22,23]. Exposure to characters in the storylines may facilitate observational learning and influence health behaviors, particularly when readers relate to the comic characters and consider them role models [38]. With input from members of the priority population throughout development, character personalities, interests, and appearances can be designed to increase the likelihood that readers may see them as relatable, and thus role models. The development of similar entertainment-education narratives draws greatly on social cognitive theory by using role models to perform new behaviors [39-41]. Further, the use of relatable characters to illustrate the positive effects of healthy eating and the negative effects of unhealthy eating operationalizes the construct of outcome expectations for comic readers. Thus, an engaging manga comic informed by the narrative transportation theory, which includes health messages and content guided by social cognitive theory, may be an effective vehicle to promote healthy eating behaviors.

Another key component of the Web-based tool is goal setting. Goal setting is discussed in several behavior change theories,

including social cognitive theory and goal-setting theory, and involves a commitment to change through small steps [42-44]. These theories similarly relate goals to outcome expectancy and self-efficacy, both of which are needed for goal commitment and attainment. Further, goal setting and self-monitoring are approaches through which self-regulation is operationalized. In the Web-based tool, goal setting, weekly assessment of goals, and tailored messages and feedback (based on initial screening questions and goal assessments) are integrated as theory-guided approaches to support healthy behavior change.

The Concept of Usability Testing

According to the US Department of Health and Human Services, usability testing refers to evaluating a product or service by testing it with representative users [45]. Usability testing is a crucial step in the development of online health tools and mobile health (mHealth) apps and technologies to ensure that they are accessible, understandable, and useful to end users, and are delivered in an efficient, effective, satisfying, and culturally competent manner [46,47]. Although several studies have emphasized how usability testing can improve technology-based tools [43-45], there is limited research detailing usability testing methods for mHealth tools with youth users, especially younger than 13 years of age [48-53]. A challenge often cited is that traditional usability testing approaches, whether via survey or qualitative methods, are designed for adults and may require different practical, methodological, and ethical considerations with children. The literature also highlights the importance of taking into account individual characteristics that may make it easier or more difficult to participate in these verbal reporting methods, such as level of “extraversion” and “friendliness” [51,53-55]. For example, usability testing done with very young children (younger than 7 years) have highlighted issues related to impatience during testing, unpredictable reactions (especially if the child is uncertain about what to do), and minimal remarks made by users while using a typical think-aloud protocol [55,56]. At the same time, authors have emphasized how behavioral observation (especially during “free play”) often provides the most useful information and insight into usability [55,56]. Although simplifying usability survey questions or think-aloud verbal probes may address issues of literacy and understandability in children, this may also diminish the depth of relevant feedback provided by youth users. Thus, more research is needed to demonstrate successful approaches to usability testing among youth, and particularly among the understudied preadolescent population (9 to 12 years). The lack of published studies in this area suggests that Web-based health promotion tools are being developed without formal involvement or evaluation by potential users, which can impact their potential usefulness, relevance, and effectiveness.

The purpose of this study was to conduct usability testing with Latino and black/African American preadolescents to evaluate prototypes of Intervention INC. Study results will be used to finalize the tool, which will be evaluated in a pilot randomized

controlled trial (RCT). This study also aims to add to the limited literature related to usability testing of Web-based tools with youth by describing usability testing methods used to evaluate a Web-based tool with urban minority preadolescents.

Methods

Study Overview

This study is part of a larger study that aims to design, develop, and evaluate the Intervention INC tool. [Textbox 1](#) outlines the multiple phases and research activities of the overall study; research activities specific to this study are marked. The methods described focus on the two rounds of usability testing conducted during the development phase with children using prototypes of the Intervention INC tool.

Sample Participants

English-speaking Latino and black/African American children ages 9 to 13 years were recruited to participate in two rounds of usability testing to provide feedback and identify problems to help inform final development of the Web-based tool. Participants were recruited from a contact list of 36 children, who had participated in previous formative phase focus groups or interviews (manuscript under review) and early development phase study sessions (manuscript in preparation). These youth were originally recruited via a community-based organization primarily serving children in high-need New York City neighborhoods and local outreach near businesses within the East Harlem, New York, neighborhood.

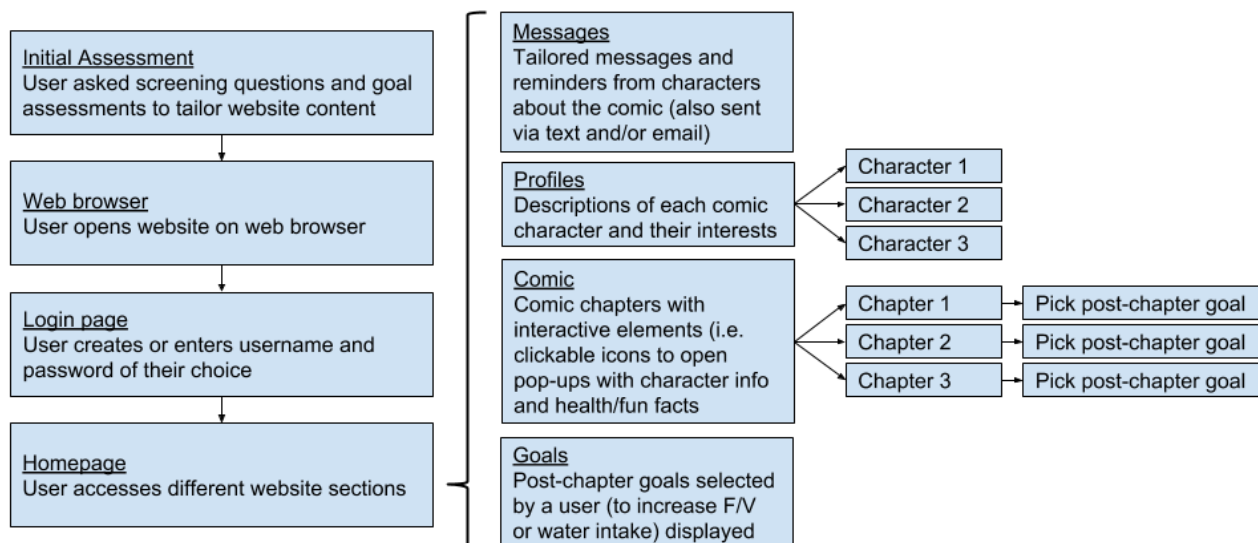
Eligibility criteria for this prior study sample consisted of the child being between the ages of 9 and 12 years; the child self-identifying as Latino and/or black/African American; the child being English-speaking; the child having internet access, as well as access to a mobile phone or tablet; and the child having an interest in talking about food and technology. We did not screen for reading or digital literacy level as content in the Web-based tool was delivered via multiple mediums, including text, audio, and images. Literature suggests that pictures and audio-assisted reading improves reading comprehension and lowers literacy level of the text [57,58].

Children meeting eligibility criteria were scheduled for a one-on-one usability testing session with a study staff member. Round 1 sessions were conducted in June 2017 and round 2 sessions in July 2017 after certain modifications were made to the Web-based tool. The goal was to recruit five to eight children in each round of usability testing as it has been reported that usability testing with five users will reveal 85% of usability issues [59,60]. Child assent was obtained prior to study participation, in addition to parental permission and a photo release form. Participants received a US \$10 gift card and a round trip Metrocard on completion of the session. All study activities were approved by the Institutional Review Board at Hunter College in New York, NY.

Textbox 1. Phases and activities of Intervention INC tool design and evaluation. *Research activity specific to this study.

Formative phase
Focus groups or interviews with children and parents
Development phase
<ul style="list-style-type: none"> • Internal development of initial Web-based tool concepts • Codesigning of Web-based tool content and design with children and parents • Usability testing of Web-based tool prototypes with children* and parents
Evaluation phase
Two-group pilot randomized controlled trial to evaluate feasibility and acceptability of Web-based tool with parent-child dyads

Figure 1. Flowchart of Web-based tool components. F/V: fruit/vegetable.



Web-Based Tool Description

The Web-based tool tested in round 1 and round 2 consisted of a three-chapter interactive nutrition comic with a character profiles section and embedded interactive features (eg, sound effects, character voice-overs, clickable pop-up windows) to engage users. At the end of each chapter, a tailored message from a character was provided to the user promoting either fruit and vegetable or water intake, as well as a prompt to select a goal related to either increasing fruit and vegetable or water intake (tailored content based on initial screening questions and goal assessments). [Figure 1](#) shows a flowchart of the Web-based tool components that were tested within the current study.

The Web-based tool was optimized for use on tablet devices as formative research with a similar population highlighted that most parents reported owning mobile phones and tablet devices, and a majority of children reported preferring tablets over laptops (manuscript in preparation). For the purposes of comic development, tablets were preferred over mobile phones because of the larger display size and also to maintain the touchscreen capabilities. Throughout development, the tool was tested on devices with iOS, Android, or Windows operating systems and across Safari, Chrome, Firefox, and Internet Explorer Web browsers.

The final version of the Web-based tool will include an additional three chapters (six chapters in total), post-chapter trivia questions, and rewards for correct answers, as well as expanded health information and fun-fact pop-ups throughout each chapter to reinforce health messages. Screening questions will also be incorporated and asked first to determine whether the child receives messages, goals, and comic content focused on either fruit and vegetable or water intake.

Data Collection

Testing sessions for round 1 and round 2 followed similar procedures. They were conducted in private rooms in a college campus building with two trained researchers (a moderator and a note taker). Demographic information (eg, age, gender, race or ethnicity) and technology use and preferences (eg, “What devices do you use to access the internet or download apps?”) of scheduled child participants were previously assessed during formative phase study sessions via a questionnaire. However, these data were collected from any unscheduled child participants, who attended usability sessions (additional details in Participant Characteristics section). During the usability testing sessions, a combination of qualitative and quantitative methods were implemented. Both methods are essential in the iterative design cycle [61]. Each session consisted of brief think-aloud training, usability testing of the Web-based tool with a modified think-aloud protocol and moderator guide (with

examples of prompts to encourage verbalized feedback from participants throughout testing), and a questionnaire to assess usability and acceptability. Each participant accessed the Web-based tool using a touchscreen laptop (Microsoft Surface Pro) as it provided flexibility for the participant to use the device as a computer or tablet. Usability testing sessions were audio-recorded and field notes were taken to document participant's comments, performance, behaviors, and nonverbal body language.

Think-Aloud Training

When using think-aloud with adults, examples from the literature suggest starting with a practice session where a moderator or evaluator asks the participant to do an example task similar to the target tasks to orient participants to the practice of talking out loud (as opposed to explaining) before actually engaging with the developed tool or system [62,63]. Once the participant starts interacting with the tool or system, evaluators should only intervene when a participant stops verbalizing their thoughts, and only use simple, short, and nondirective prompts such as "keep on talking" to minimize biasing the user to change their behavior. Prior to the usability testing with our Web-based tool, the moderator explained to participants the purpose of the session (eg, to test an early version of a website using a tablet to get feedback and suggestions on how to make it better) and provided instructions on how to "think aloud" while testing different sections of the website. Our protocol included the moderator explaining the concept (eg, "I want you to say out loud what you are thinking as you use the tablet to go to the website") and providing an example to practice (eg, "I want you to raise the volume of this tablet while thinking out loud"). This example was practiced until the child demonstrated an understanding of how to "think aloud" (eg, explained out loud that he or she is looking for the volume button on the side of the tablet and pressing the "up" button to raise the volume). In addition, as there is limited literature on using the think-aloud method with youth, moderators were prepared to use more directed prompts and questions in the case that child participants forgot to verbalize their thoughts while using the tool.

Usability Testing of Web-Based Tool

Participants were first asked if they would prefer to receive a message with a link to the website by text or email. They were then provided with a printed sample text or email message that included the website URL. The moderator asked the participant if he or she knew what to do next (ie, click on website URL or open a browser to type in the URL). Once the website URL was entered into a browser on the tablet, a log-in page was displayed with a form to enter a username and password. The moderator provided the username and password for participants, and observed if the participant was able to enter in the information to log in. Once logged in, participants were allowed to navigate freely through the different sections of the Web-based tool, but were guided to cover all the sections, which included comic chapters, goals, the message board, and character profiles (see Figure 1).

Throughout usability testing of the Web-based tool, participants were encouraged to think aloud to explain what they were thinking as they were navigating through the sections. While

reading the comic, the participants were specifically encouraged to read aloud, verbalize reactions, and share initial thoughts with the moderator. Examples of think-aloud prompts included, "What is the first thing you notice on this page?" "Can you tell me what you're doing?" and "Is there anything you would change?" Prompts were also provided to encourage specific feedback once a child experienced any special effects in the comic or interacted with clickable icons (eg, "What did you think about that animation?" "Why did you click that?" "What do you think of that pop-up message?").

A note-taking guide was also developed for use by the note taker to record observations of participant's responses (especially nonverbal) during usability testing of the comic section. The note-taking guide included screenshots of each panel of the comic, along with multiple checkboxes (eg, to check which automatic animations displayed automatically), yes or no options (eg, to indicate if user selected a goal), and reminders for the note taker to record start and end times and note general comments. Using this guide, data related to time taken to complete each comic chapter, number of usability issues, frequency of interaction with clickable features within the comic, and specific comments made in each panel of the comic could be collected.

Perceived Usability and Acceptability

The perceived usability and acceptability of the Web-based tool was assessed using a questionnaire provided to each participant after the usability testing session. The questionnaire was administered via pen and paper, and the moderator was available to answer any questions about the survey or clarify words that the participant did not understand. The moderator additionally highlighted that this questionnaire was not meant to test the child but was a way for the child to express how easy or hard it was to use the Web-based tool so that the developers could improve it for future users.

The questionnaire combined and modified items from the System Usability Scale (SUS) [64], the Usefulness, Satisfaction, and Ease of use (USE) questionnaire [65], and an acceptability/usability measure questionnaire [66] in order to assess five usability domains: usability, usefulness, ease of use, ease of learning, and satisfaction. The combined questionnaire consisted of 37 items scored on a five-point Likert scale from strongly disagree to strongly agree. The usability domain comprised the 10 items from the SUS questionnaire. Two items comprised the usefulness domain (one from the USE and the other from the acceptability/usability measure). Ease of use domain was assessed using 13 items (10 from the USE and three from the acceptability/usability measure). Ease of learning was assessed by the same four items found in the USE questionnaire. The satisfaction domain comprised eight items (all from the USE, except for one that was added from the acceptability/usability measure).

The combined questionnaire was pilot tested in earlier development phase study sessions with a similar population of children ages 9 to 12 years (manuscript in preparation). Based on this previous testing, some modifications were made to tailor the questionnaire according to children's literacy levels for this study. For example, the item "I found the system very

cumbersome to use” was replaced with “I found the website very awkward to use,” and “I would imagine most people would learn to use this system very quickly” was changed to “I think most people my age would learn to use this website very quickly.” Additionally, changes were made to make the questions more appropriate for our Web-based tool. For example, the word “system” or “tool” was replaced with the term “website.”

Data Analysis

Analysis of think-aloud data, including coding categories and themes were guided by approaches used in previous literature [46,67,68]. Audio recordings from usability testing sessions were not transcribed verbatim as the context of user interactions with the tool (eg, audio of character dialog prompted by touching interactive icons) would be more evident from listening to and directly analyzing audio recordings [69,70]. Microsoft Excel version 15.33 was used to assist with data organization and analysis. For both round 1 and round 2, the audio recordings and field notes were systematically reviewed. First, child utterances during usability testing were extracted and coded as either positive comments or usability issues (which also included negative comments verbalized by participants). Similar or related comments were then grouped into themes and subthemes. Each code was counted in coding units. Coding units consisted of sentences or reactions from the participants and programming glitches counted during usability testing. The major coding rules were as follows: (1) multiple sentences or reactions that referred to the same matter were coded as one unit (eg, if a participant made multiple comments about a picture being too small, they were all counted as one unit); (2) agreements between participants on the same matter in dyad sessions were counted as two units (eg, if a participant made a comment and his or her pair agreed, the two comments were counted separately); and (3) programming glitches that occurred during dyad sessions were counted as one unit.

To ensure the reliability of the content analysis, the coding and themes were continually validated by two other researchers throughout the analysis process. Specifically, the primary analyst coded the data and then presented the analysis to two other researchers, who reviewed code application to comments or verbalizations. If any inquiries or disagreements arose regarding codes and themes, the three researchers discussed and resolved any discrepancies. Coding revision and theme refinement continued until data analysis was complete. Field notes were reviewed to help inform analysis.

The quantitative data from self-reported questionnaires about participant’s usability and acceptability of the Web-based tool across the five domains were analyzed using SPSS version 22 and Microsoft Excel version 15.33 to calculate the means, standard deviation, and ranges (minimum-maximum) for the overall score as well as subscales. For usability domain questions (10 items), separate means, standard deviation, and ranges were also calculated based on the SUS scoring protocol [64].

Results

Participant Characteristics

A total of 12 children (n=6 per round) were recruited. Round 1 consisted of two dyad sessions and two individual sessions and round 2 consisted of six individual sessions. Although dyad sessions were not a part of the initial study design, they were conducted in round 1 as two scheduled children brought their relatives. The overall age of participants was mean 10.92 (SD 1.16) years (range 9 to 13 years). The mean age of participants in round 1 was slightly higher than in round 2 (mean 11.17, SD 1.33 years and mean 10.67, SD 1.03 years, respectively). The majority of participants were male (n=8) and black/African American (n=8). Among the 12 participants, eight (three in round 1; five in round 2) were involved in the codesigning process of the Web-based tool and participated in a previous usability session of the first prototype.

Technology Use

Prior to accessing the Web-based tool, participants were asked whether they would prefer to receive messages about the Web-based tool through text message or email. Participants’ preference was text message (7/12, 58%) over email (5/12, 42%). The most common devices used to access the internet or download apps were tablets (11/12, 92%) and mobile phones (10/12, 83%), followed by desktop computer or laptop (8/12, 67%) and xBox (5/12, 42%). Other devices participants reported to use to access the internet or download apps were iPod, Wii, and Kindle. Mobile phones and tablets were the top two devices used most often. However, mobile phones were the preferred devices among participants (8/12, 67%). Although the majority of participants used mobile phones, two of 12 indicated they did not use mobile phones. Among the participants who used mobile phones, four of 10 shared their mobile phones with someone else in the family, normally with their mom and siblings. [Table 1](#) summarizes the participants’ demographic and technology characteristics.

Usability Testing Themes

Overall mean testing time was 65 (SD 12) minutes with mean time in round 1 slightly higher than in round 2 (mean 67, SD 8 minutes vs mean 63, SD 15 minutes, respectively). Testing revealed a total of 586 comments or reactions. A greater number of comments and reactions were collected in round 1, especially during dyad usability sessions (329 collected in round 1, 257 collected in round 2). [Multimedia Appendix 1](#) provides a summary of participants’ comments and reactions identified from the content analysis, which have been classified under six themes: appearance, content, special effects, storyline, terminology, and navigation. Additional comments were labeled under general feedback. Participants’ comments and reactions were further categorized as either positive comments or usability issues. Overall, there were more positive comments (70.8%, 233/329 in round 1; 65.8%, 169/257 in round 2) compared to usability issues (29.2%, 96/329 in round 1; 34.2%, 88/257 in round 2) in both rounds.

Table 1. Demographic characteristics and technology use of participants.

Characteristics	Round 1 (n=6)	Round 2 (n=6)	Total (N=12)
Age (years), mean (SD)	11.17 (1.33)	10.67 (1.03)	10.92 (1.16)
Gender, n			
Male	4	4	8
Female	2	2	4
Race, n			
Black/African American	4	4	8
Latino	2	2	4
Preferred notification platform, n			
Text message	4	3	7
Email	2	3	5
Devices used to access internet or download apps, n			
Tablet	6	5	11
Mobile phone	5	5	10
Desktop computer or laptop	3	5	8
Xbox	3	2	5
Other (eg, iPod, Wii, Kindle)	2	1	3
Type of smartphone, n			
Android (eg, Samsung)	4	2	6
iPhone	1	3	4
Do not use a phone	1	1	2
Participants who share mobile phone with other family members, n	3	1	4
Participants who have been involved in the codesigning process of the Web-based tool, n	2	3	5
Participants who have been involved in a previous usability session, n	1	2	3

Appearance referred to the impressions of how the Web-based tool looked and included the design, layout, illustrations, font, and colors. Participants approved of the comic illustrations and the overall design of the Web-based tool. One participant mentioned this referring to the illustrations of the comic: "I like it's [the comic] anime." However, they had complaints on the colors as the comic was in black and white with only some instances of color. One participant expressed "I would like it [the comic illustrations] better in color, we are in 2017!"

Content included information that was delivered through the Web-based tool. Participants found the information provided in the character profiles section most interesting. Participants expressed particular interest in the character's favorite recipes, hobbies, and favorite links (ie, external online games and apps). One participant mentioned wanting to know the character's favorite color. Participants also reported liking the fun facts. For example, one participant said "Interesting, I didn't know that [basketball fun fact]." However, three round 2 participants felt that some of the pop-ups and post-chapter messages were "off topic" or not relevant to the story. Participants in round 1 suggested that a guide could be added to learn how to use the interactive features within the comic. However, after the guide was included, some round 2 participants commented that

although they thought the guide was useful, it was not necessary to include it at the start of each chapter.

Special effects were comic features, including sound effects, voice-overs of some selected character dialog, clickable pop-up windows with additional information, and animation, meant to increase immersion into and engagement with the comic. Participants commented positively on them and asked for more special effects. Suggestions were even provided as to specific scenes in the comic where additional special effects could be incorporated. Some of the quotes were: "It is funny that he's [the chameleon] blinking his eyes" and "It would be cool if they [the characters] were moving. Kind of funny too."

Storyline comprised any comment related to the plot of the nutrition comic. Overall, the storyline was positively received, especially the flashbacks (ie, of character memories) and the "love triangle" between characters. Participants were generally very engaged while reading the comic, often using vocal inflections to express reactions or, at times, reading character dialog out loud and mimicking the character voice. In general, participants thought the comic was humorous and chapters had interesting endings, which made them eager to read subsequent chapters. Participants also mentioned liking the characters and relating to at least one of them. However, there were parts of the storyline where the older participants had other expectations.

One participant mentioned, “That’s it? The worm thing...Oh, I thought it would be something different.”

Terminology referred to the words, abbreviations, and onomatopoeia used in the Web-based tool. There were a few words that participants had trouble reading, such as “high-fructose corn syrup” and “hypertonic solution.” Participants stated they did not know the meaning of some words and abbreviations (“What does NPS mean?” “What is an athlete?”). No problems were encountered with the onomatopoeia as children correctly identified the intended sounds.

Navigation reflected the way a user navigated the Web-based tool to complete tasks. For one participant, the steps that should have been followed to access the Web-based tool (ie, open a browser and typing in URL) were unclear. Three participants also pointed out that they did not know what to do after completing a section or a task. Their suggestions included adding some guidance texts such as “type this link into your browser” and “check back next week for a new chapter.” On the other hand, participants also provided positive comments related to navigation. Turning pages was often an issue for participants as the touch area to “swipe” was narrow and not as obvious to users. Four participants were confused on how to go back to the main page, commenting that “you should make Home link bigger and more obvious.” One participant said, “I love being able to swipe and zoom in.”

General feedback included any other broad comments related to the Web-based tool. Overall, participants’ general feedback was very positive. For example, two participants said, “I liked

it [the Web-based tool], I want it on my phone!” and “I would give it [the Web-based tool] a 9.9!!!”

Modifications to the Web-Based Tool Between Rounds 1 and 2

Although round 1 participants provided multiple suggestions and different usability issues were detected, modifications to the Web-based tool between round 1 and round 2 had to be prioritized. Prioritization adjustments were based on what the researchers believed would have the largest positive effect on usability. Additionally, adjustments were chosen based on the time, resources, and skills available on the development team.

The issues and problems highlighted by round 1 users that we sought to address with modifications between round 1 and round 2 included the following: (1) clickable icons for information pop-ups, sound effects, or character dialog were not obvious; (2) the touch feature to “swipe” pages was not intuitive; (3) the siblings in the comic story did not look related; and (4) multiple programming errors were identified (eg, tips not displaying after goals being selected, sound effect of “swiping” page not playing). Modifications to the Web-based tool to address these issues after round 1 included (1) making clickable icons more obvious and visible (changing shape, color, and pop-out effect), and improving graphic design, such as a making a more unified and vibrant color scheme, forms; (2) adding background and pop-up images; (3) adding a navigation guide to highlight how to identify and use touch features, including clickable icons and “swiping” the comic pages; (4) altering or improving comic illustrations; and (5) fixing programming errors. [Figures 2-4](#) are screenshots of some of the additions and modifications to the Web-based tool.

Figure 2. Screenshot of the navigation guide added as a modification to the Web-based tool after round 1 of usability testing.

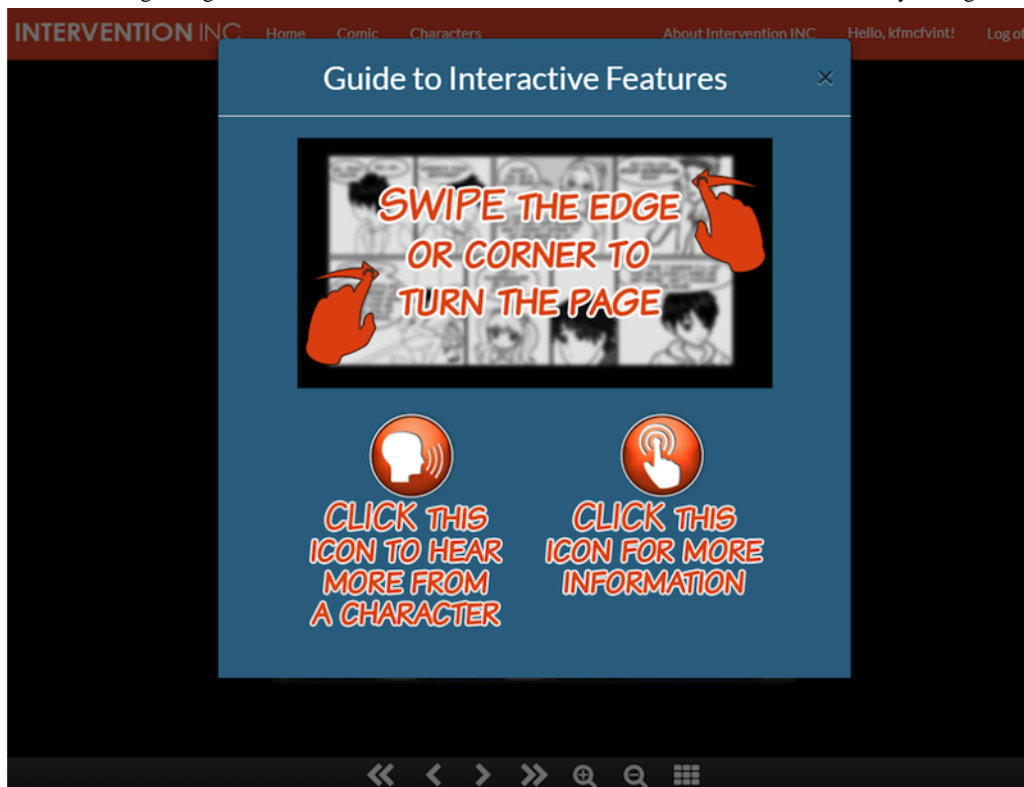
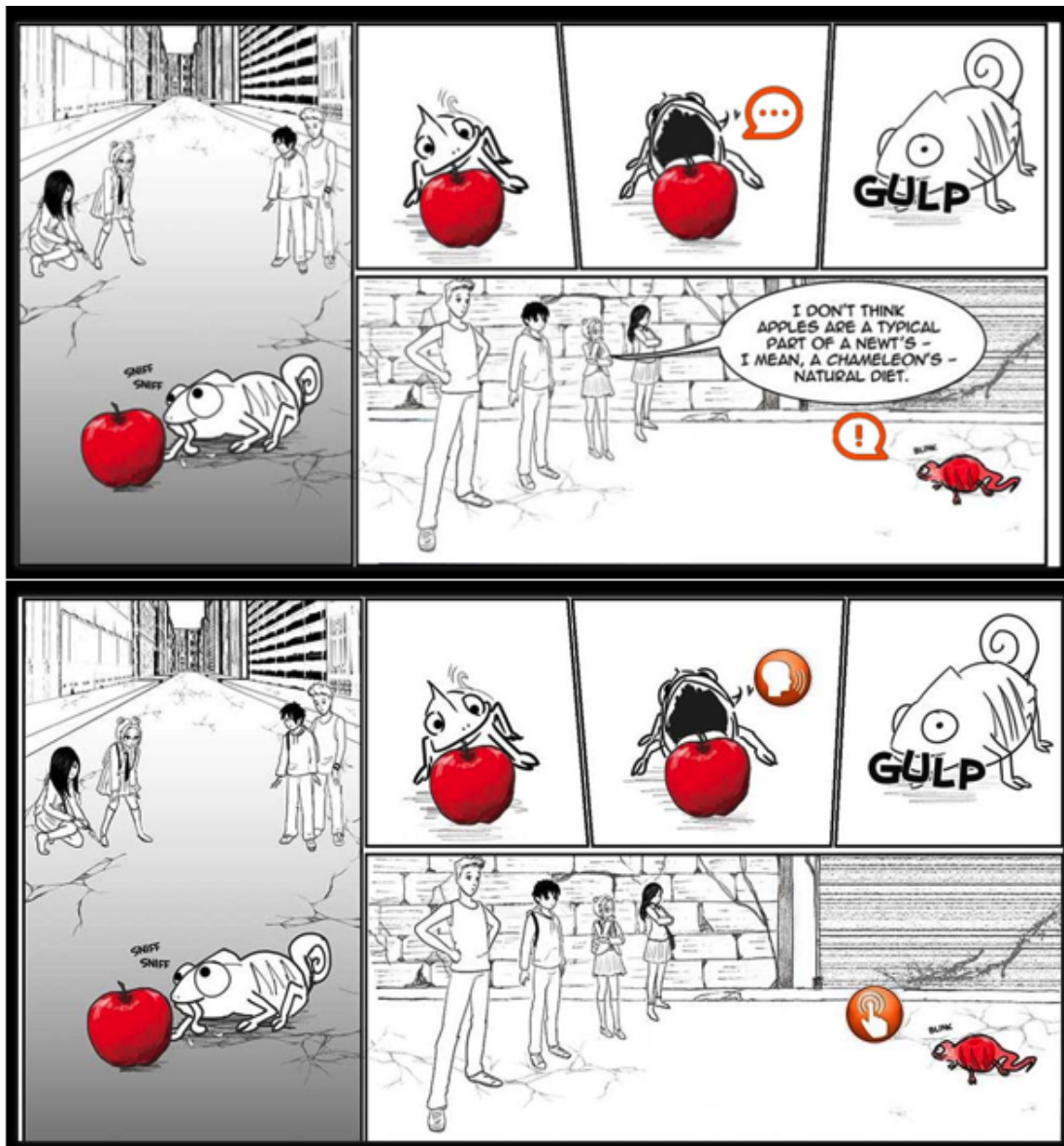


Figure 3. Screenshots of the clickable icon modification added to the Web-based tool after round 1 of usability testing premodification (top) and postmodification (bottom).



The modifications may have impacted users' usability in round 2. Although none of the six round 1 participants clicked the special effects icons initially without being prompted by the moderator, all six round 2 participants selected these clickable icons without any prompts. Also, the proportion of participants who navigated the comic pages by swiping was higher in round 1 (from 1/6 in round 1 to 3/6 in round 2). Additionally, it may have been clearer to round 2 users that they needed to select a

goal at the end of each comic chapter (see Figure 4). In round 1, only 2 of 6 participants understood that they had to select a goal after viewing the goal-setting page for the first time at the end of the chapter. However, all six round 2 participants selected a goal without prompting by the moderator. Lastly, there was an 80% reduction in unique programming glitches and errors in round 2 after modifications to the Web-based tool were made after round 1 (20 reported in round 1, 4 reported in round 2).

Figure 4. Screenshots of the goal setting modification added to the Web-based tool after round 1 of usability testing premodification (top) and postmodification (bottom).

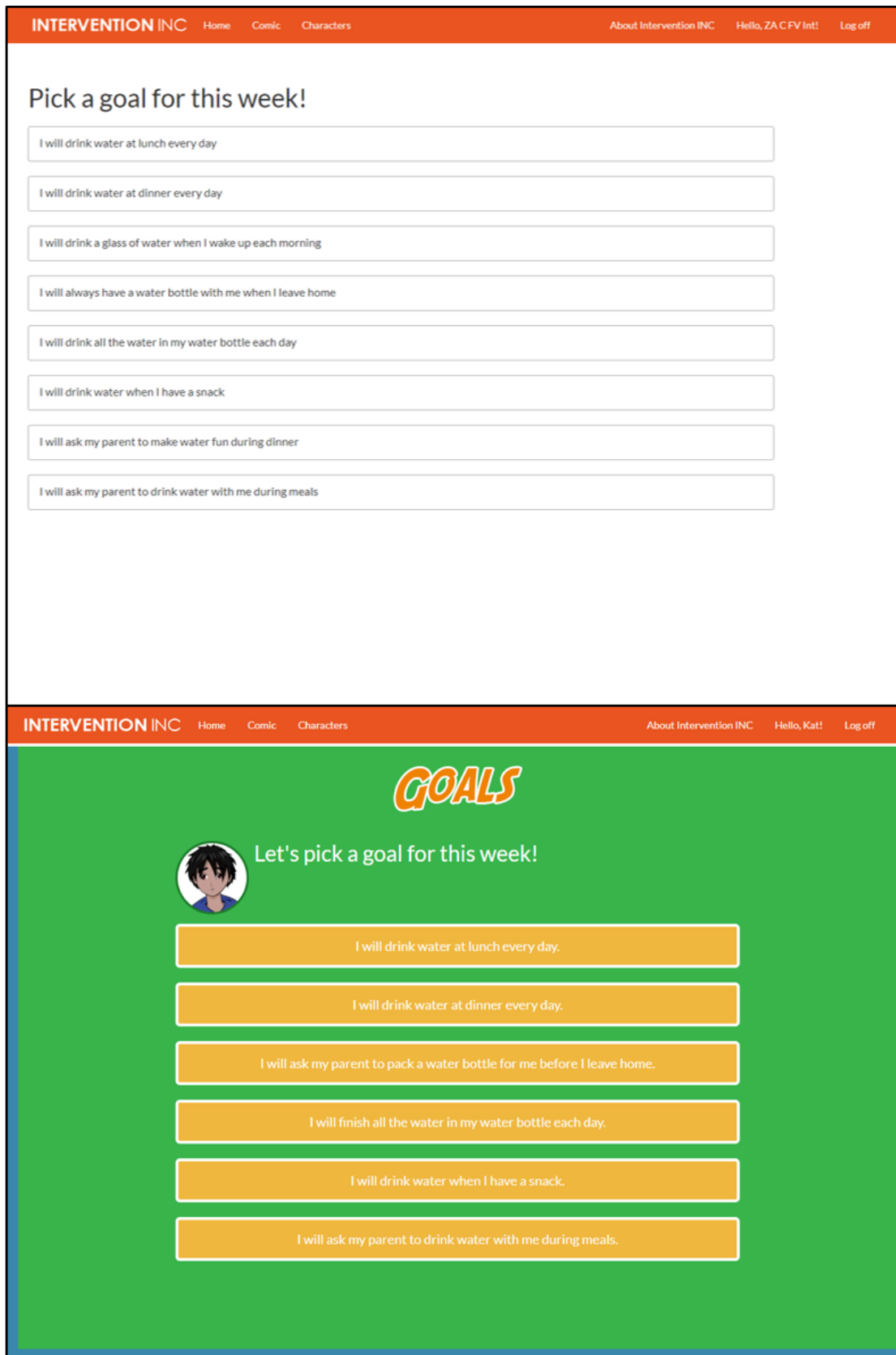


Table 2. Participant's perceived usability and acceptability of the Web-based tool.^a

Domain (37 items)	Round 1 (n=6)		Round 2 (n=6)		Combined (n=12)	
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
Usability (10 items)	4.40 (1.04)	3.80-4.80	3.80 (1.16)	3.10-4.60	4.10 (1.14)	3.10-4.80
Usefulness (2 items)	4.67 (0.65)	3.50-5.00	3.67 (1.23)	3.00-5.00	4.17 (1.09)	3.00-5.00
Ease of use (13 items)	4.50 (0.85)	4.31-4.69	4.00 (1.04)	2.85-4.92	4.25 (0.98)	2.85-4.92
Ease of learning (4 items)	4.96 (0.20)	4.75-5.00	4.25 (0.85)	3.25-5.00	4.60 (0.71)	3.25-5.00
Satisfaction (8 items)	4.73 (0.49)	4.38-5.00	4.23 (1.02)	2.88-5.00	4.48 (0.83)	2.88-5.00
Total	4.58 (0.81)	4.41-4.76	4.00 (1.07)	3.19-4.81	4.29 (0.99)	3.19-4.81

^aAssessment questionnaire was developed by using a combination of items from the System Usability Scale [64], Usefulness, Satisfaction, and Ease of use questionnaire [65], and acceptability/usability measure [66]. Response options ranged from 1 (strongly disagree) to 5 (strongly agree).

Participant's Usability and Acceptability Questionnaire

Table 2 highlights the mean scores of the five usability domains (usability, usefulness, ease of use, ease of learning, and satisfaction) for round 1, round 2, and combined (rounds 1 and 2). The combined total score of perceived usability and acceptability of the Web-based tool was high (total mean 4.29, SD 0.99, range 3.19-4.81). Additionally, all five usability domains had combined scores of over 4.00. Specifically, the ease of learning and satisfaction domains had the highest combined scores (mean 4.60, SD 0.71, range 3.25-5.00 and mean 4.48, SD 0.83, range 2.88-5.00, respectively). In round 1 specifically, all domains had a mean score higher than 4.00, ranging from mean 4.40 (SD 1.04, range 3.80-4.80) for usability to mean 4.96 (SD 0.20, range 4.75-5.00) for ease of learning. In round 2, three out of five domains had a mean score of 4.00 or greater. The usefulness and usability domains scored lowest with scores of mean 3.67 (SD 1.23, range 3.00-5.00) to mean 3.80 (SD 1.16, range 3.10-4.60), respectively. Only two individual questionnaire items of the 37 had a mean score lower than 3.00. In round 1, the item "I can use it without written instructions" (item under ease of use domain) had a mean score of 2.67 (SD 1.03, range 1.00-4.00). However, the same item in round 2 had a mean score of 4.00 (SD 1.10, range 2.00-5.00). In round 2, the item "I felt very confident using the website" (item under usability domain) had a mean of 2.33 (SD 1.51, range 1.00-5.00). This same item in round 1 had a mean score of 4.67 (SD 0.52, range 4.00-5.00). In separate scoring of the usability domain questions (10 items) according to the SUS protocol [64], the overall usability was relatively high (total mean 77.08, SD 13.97), with round 1 participants rating the usability of the Web-based tool higher than round 2 participants (mean 85.00, SD 8.94 and mean 69.17, SD 14.11, respectively).

Discussion

Principal Findings

This study describes the methods and results of usability testing of Intervention INC, a Web-based tool to promote healthy dietary behaviors in Latino and black/African American youth. Overall evaluation of the prototypes tested over two rounds revealed positive experiences with the Web-based interactive tool and opportunities to incorporate additions to increase engagement and improve usability.

We observed that round 1 participants did not engage with interactive clickable icons. Further probing revealed that, in most cases, users overlooked these icons despite moderators noting that there were interactive features in the comic. Adding a "Guide to Interactive Features" at the beginning of each chapter may have addressed this usability issue, evident by the fact that all round 2 participants clicked on the icons without prompting by the moderator. Except for incorporating a guide, no other content was added to the Web-based tool. However, three round 2 participants mentioned that certain pop-ups and post-chapter messages were "off topic" or not relevant. As each comment made by these participants was counted as a usability issue, this may have contributed to a higher number of content issues noted in round 2. Also, some participants were not familiar with browsers and one participant experienced difficulties when asked to type in URL links. Usability testing revealed the importance of providing training or including user guides for technology-based tools. This is consistent with a previous study in which youth participants needed a short training session prior to engaging with a Web-based program which was focused on increasing physical activity [71]. Although youth are familiar with technology and tablet-optimized tools such as apps, they may need some training at the beginning of Web-based interventions to learn how to access online tools.

Usability testing also reaffirmed the feasibility and acceptability of embedding health information into narratives, as well as the importance of using interactive features to enhance engagement and assist with accessibility. For example, interactive features such as pop-ups with specific health information and accompanying images may increase engagement with the content. In addition, the use of embedded (clickable) audio recordings for long character dialog can help with the literacy of the comic [72]. Overall, the use of a comic-style narrative to communicate health information is an approach to delivering content to low-literate readers [73,74]. In our study, all participants demonstrated great interest in the comic storyline and interactive features (ie, special effects, interactive pop-up, and swiping pages), and in some cases even provided suggestions on how to increase interactivity with the tool. This finding supports other usability studies conducted by the Nielsen Norman Group (leading user interface and user experience consulting firm), which concluded youth younger than age 12

years prefer animation and sound effects and enjoy “hunting for things to click” [75].

From the usability issues identified during round 1, modifications were made, such as incorporating an interactive feature guide and improving the comic’s graphic designs (eg, improved clickable icons and character features). These modifications appeared to enhance round 2 usability based on observation and qualitative feedback. In addition, the improved score for the questionnaire item “I can use it without written instructions” from round 1 to round 2 may be a positive indicator of the impact of an incorporated user guide. However, in general, scores from the usability and acceptability questionnaire (both from the overall questionnaire and just the SUS usability questionnaire items) were slightly higher in round 1 than in round 2. Although the sample was not large enough to make powered comparisons, the scores may have dropped because round 2 had a higher number of participants who were involved in the codesigning process or a previous usability session. Those who participated in previous Web-based tool development activities may have had higher expectations of the Web-based tool than the participants who did not have prior exposure. Age could be another explanation as children become substantially more Web-savvy as they get older [76,77]. Round 1 participants were, on average, half a year older than round 2 participants. Half a year may be a significant amount of time in relation to cognitive or literacy development, particularly with school-aged youth [78]. This age difference (and possible differences in reading or computer and digital literacy associated with age) could also explain why round 1 participants scored the item “I felt very confident using the website” with a much higher mark than round 2 participants. In addition, since some round 1 participants interacted with the tool as a dyad, they may have perceived the tool as having higher usability because they were able to navigate through the tool with a partner. Even if a child may have encountered a usability issue, these may not have been captured or explicitly experienced if the other child was not experiencing the same issue or helped the other child either consciously or unconsciously.

Modified Think-Aloud Approach Used With Our Participants

Previous studies recommend conducting usability testing with potential users prior to outcome assessment in studies involving larger samples [48,79,80]. The think-aloud method is commonly used as a usability testing approach among adults [81-83]. However, there are limited references in the literature describing the think-aloud approach in youth usability testing, and most have been conducted with older youth [46,84]. For this study, we modified this method by helping youth to express what they were thinking with directed questions and probes. We found that using a modified think-aloud approach was successful in eliciting important feedback to improve user experience. Usability guidelines recommend limiting testing sessions with youth to less than 25 minutes or using multiple stations to break up and vary the modes of engagement [85]. However, we were able to successfully keep youth engaged in usability testing for more than 60 minutes. Our approach provided structured and continuous opportunities for participants to verbalize their thoughts and encourage feedback. In addition, although

participants were not asked to read aloud, most of the kids preferred to. This allowed us to successfully identify reading and comprehension issues, which were addressed in the final Web-based tool.

It should be noted that our protocol aimed to conduct individual sessions. However, two dyad sessions were conducted in round 1, and we observed a greater number of comments in round 1 compared to round 2. One explanation for this is that having two participants in round 1 sessions provided many more comments than the individual sessions. Future usability testing of Web-based tools with youth using a modified think-aloud approach should consider dyad assessments (rather than individual) to facilitate more meaningful feedback in a peer-to-peer environment. Indeed, some of the limited evidence of usability testing with youth have discussed the benefits of a similar approach, referred to as “constructive interaction,” and the impact of different factors (eg, nonacquainted vs acquainted dyads, same gender dyads) on the identification of usability problems [86-89].

Implications for Future Research

Our study highlights the need for further research to be conducted to refine the approaches utilized and to further elaborate on our initial findings related to usability testing with youth, particularly with minority, urban preadolescents. However, multiple insights were gained during this study. First, the modified think-aloud approach used with preadolescents, especially in dyad sessions, were successful in collecting meaningful feedback. In future usability studies, we would continue to engage dyads, in combination with individuals, to evaluate Web-based tools with youth. Secondly, although we encouraged the participants to read the comic aloud, this was not mandatory. During future testing, we would request that all participants read aloud as this would allow for the proper assessment of literacy levels and identification of any reading and comprehension issues across all participants. From an evaluation perspective, we were unable to make direct comparisons between round 1 and round 2 as the participants differed between these two rounds of testing. Thus, future research may consider using the same participants across usability testing rounds, such that direct assessments and comparisons could be conducted. This approach may also have the added benefit of the ability to assess the impact of added or changed components (such as a navigation guide) on usability. Lastly, including a third round of usability testing to study how participants interact with the final product in a real-world setting (without guidance of a moderator) would have been informative. During this third round of usability testing, uninterrupted observational approaches such as screen recordings to capture interactions, along with participants’ voice (audio) as they are completing key tasks, would provide insight into any usability issues that may be encountered outside of a testing setting.

Limitations

It is acknowledged that this study is not without its limitations. First, the data analysis was performed by one researcher. However, the coding process was continually validated by two other researchers. Secondly, some participants had previously participated in the initial development process of the Web-based

tool or a previous usability testing session. This may have contributed to biases regarding certain preconceived ideas for how the Web-based tool would look like or how the storyline was actualized in the comic. However, engaging the same participants throughout tool and intervention development builds on prior knowledge and exposure to the tool, which may contribute to more relevant and informed feedback regarding needed improvements and criticisms [90].

In addition, although the usability questionnaire used in this study was informed by several usability questionnaires commonly used in the literature [64-66], the final combined version is not a validated tool and was only pilot tested in previous development phase study sessions. The general high usability ratings among users and the lack of difference between round 1 and round 2 scores on the self-reported questionnaires for participant's usability and acceptability of the Web-based tool are also suggestive of response bias, which has been observed in other studies using usability questionnaires with youth [91]. Furthermore, although there is always a risk of social acceptability bias while administering surveys with a moderator present, which may be higher with youth [91,92], it was important to ensure that a study staff member was available to clarify terminology or address questions, especially as children have varying levels of literacy. Lastly, one of the usability sessions in round 2 was not recorded due to technical issues. Although field notes were taken during this session, some comments and reactions may not have been documented.

Conclusions

Usability testing is critical during the developmental process of Web-based tools because it can enhance a tool's usefulness, engagement, and potential effectiveness for end users. This study adds to the limited literature related to usability testing of Web-based tools with youth by describing modified usability testing methods used to evaluate the Intervention INC tool with urban minority preadolescents. The authors engaged youth during usability testing sessions using a combination of a modified think-aloud approach with directed questions and prompts, behavioral observation of users interacting with the tool, and a usability questionnaire. Usability findings suggest that this Web-based tool was acceptable to youth and could be an engaging approach to communicate and promote healthy dietary behaviors among urban minority youth.

Results from this study will inform further development and finalization of the Web-based tool, which will be tested using a two-group pilot RCT targeting fruit and vegetable or water intake to reduce childhood obesity risk in black/African American and Latino youth. The final tool will be a six-chapter comic with one chapter being released each week. If such a tool is found to be effective in larger scale studies, it could be disseminated as a publicly available online health promotion tool that could be implemented in various settings, such as health care clinics, after school-based programs, and public schools, which highlights its potential for high reach.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Themes identified from a content analysis of usability testing data.

[[DOCX File, 19KB - formative_v2i2e21_app1.docx](#)]

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Abbreviations

RCT: randomized controlled trial

SUS: System Usability Scale

USE: Usefulness, Satisfaction, and Ease of use questionnaire

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Original Paper

Using Cocreation in the Process of Designing a Smartphone App for Adolescents and Young Adults With Cancer: Prototype Development Study

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Abstract

Background: Adolescent and young adult (AYA) oncology and hematology is a developing field of medicine, focusing on a population that faces many challenges throughout medical treatment and beyond. Mobile health (mHealth) interventions provide exciting new opportunities for improvement of health-related quality of life (HRQoL) in AYAs with cancer. Many smartphone apps are currently available for AYAs with cancer; however, for AYAs with cancer, very few apps have been designed with direct input from AYAs themselves or have demonstrated their effectiveness and benefit.

Objective: The objective of this project was to develop the prototype of a smartphone app for AYAs with cancer through the process of cocreation, with the active input of AYAs who have received treatment for cancer directly impacting content and design.

Methods: Patients were recruited from a population of Danish AYAs who had received treatment for cancer between the ages of 15 and 29 years. The cocreation process was completed over the course of 3 workshops and intermittent ad hoc meetings, where the recruited AYAs worked in coordination with 1 nurse, 1 doctor, and 2 representatives from a digital agency and app developer. During each workshop, participants prioritized their goals for the app. After new app content was developed, feedback was requested from the participants, and changes were made accordingly. This iterative process continued until consensus on final product features and design were achieved. Health care professionals provided minimal input and primarily performed observational roles in the workshops, with direct interaction limited to introducing the project and explaining measurement features of the app in development.

Results: Three key features to be included in the prototype app were identified from the cocreation workshops: (1) a community forum; (2) an information library; and (3) a symptom and side-effect tracking tool. Bright, warm colors were selected for the app by the participating AYAs. The final prototype will be launched for pilot testing and implementation testing in February of 2018.

Conclusions: The process of cocreation is a user-involved process that can create an end product that is useful and customized for the target population. This process, as such, is a beneficial process to utilize when addressing the specific needs of AYAs

with cancer. The results of the here described app prototype will be evaluated in more detail in the near future. However, this description of the cocreation process in app development can be utilized for the creation of other mHealth interventions.

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KEYWORDS

adolescent and young adult; cancer; cocreation; mHealth; oncology

Introduction

Adolescent and young adult (AYA) oncology and hematology is a developing field of medicine, focusing on a population that faces many distinct hardships throughout medical treatment and beyond. AYAs with cancer face many challenges, including those under physical, psychological, and social domains. A cancer diagnosis at any point is devastating, but as an adolescent or young adult, serious disease interrupts a critical period of physical and personal development where relationships, academic, and professional careers, and planning for the future have a significant level of importance [1,2]. As consequence, AYAs with cancer and cancer survivors report lowered health-related quality of life (HRQoL) in comparison to the general population [3-7]. Prior studies have found that AYA transplant patients have equivalent or better HRQoL in comparison to older transplant patients [3], yet both populations experience a drop in HRQoL.

AYA patients are a technologically savvy cohort that feels comfortable communicating and managing their problems and information needs in the digital world [8]. Current advances in technology provide exciting new methods of improving the lives of AYAs with cancer through webpages, smartphone apps, and electronic devices. These resources are designed to provide assistance in symptom tracking, health promotion, and social networking with other patients [9,10]. One of the more ubiquitous technology interventions used in the AYA cohort is that of the smartphone app, under the umbrella of mobile health [11]. Apps are a useful platform for AYAs due to portable access and the rise of smartphone utilization in the AYA age group [12-15]. Many apps are currently available for AYAs with cancer [16]; however, the effect of this health intervention approach is understudied. Few out of the hundreds of available smartphone apps for AYAs with cancer have demonstrated their effectiveness and benefit in the currently available literature, and few have been designed with direct input from AYAs themselves in a complete and thorough fashion [15-19]. Even with existing resources, there is still room and availability to expand patient technology options [11].

In order to create a smartphone app that would be useful and engaging, the input and involvement of end users in the app's development is imperative [20,21]. Kræftværket, named after the Danish words for "power plant" (Kræftværk) and "cancer" (Kræft), is a youth-friendly sanctuary for AYAs with cancer aged 15-29 years at Rigshospitalet in Copenhagen, Denmark. It was designed from a cocreation-based "hackathon" event where designers and AYAs with cancer or prior cancer experience worked together to design youth-oriented facilities.

This process allowed AYAs to play an active role in the creation of their own environment, thus empowering them throughout the time of disease [22,23]. It is this mindset—providing young patients with cancer with the tools to create their own preferred intervention—that inspired the research team to develop an mobile health intervention via the process of cocreation. Cocreation gives key decision-making capacity on app design and content to the target audience of the end product. This allows the young people who intend to utilize the app to become active contributors in their own desired outcome, bringing forward unique ideas and experiences that the health care team may not have [24].

The aim of this project was to develop a prototype of a smartphone app for AYAs with cancer through the process of cocreation; we here describe the cocreation process and how this procedure was used to develop specific youth-oriented features and directly involve AYAs. The resulting app prototype is entitled "Kræftværket," after its namesake youth sanctuary.

Methods

Recruitment

At all phases of the cocreation process, we continuously recruited patients from a population of Kræftværket users, consisting of Danish AYAs with cancer and cancer survivors aged 15-29 at the time of diagnosis who have received treatment at Rigshospitalet. Patients aged >29 years were eligible if they were diagnosed with cancer between the ages of 15 and 29 years. Patients currently receiving treatment and those no longer receiving treatment were eligible. An open invitation to participate in the cocreation workshops was posted by a hospital youth coordinator via the closed Kræftværket Facebook group before each event for recruitment. This method resulted in a combination of prior participants and new participants during the cocreation workshops. Patients were excluded from participation if they were unable to read or communicate in Danish.

The Cocreation Process

The app was developed via a cocreation process, in which young people defined the goals of a technology intervention and then had direct involvement on design and key features. Cocreation is a design principle in which the target consumer of a product or resource plays a principle role in an end product's formation [25]. This process expands on the ideology introduced in principles of user-centered design; however, in user-centered design, the target users typically play a passive role while being interviewed or observed by area experts [26]. Cocreation instead places the driving force with the target user.

Figure 1. Flow chart of cocreation meetings. AYA: adolescent and young adult; QoL: quality of life.

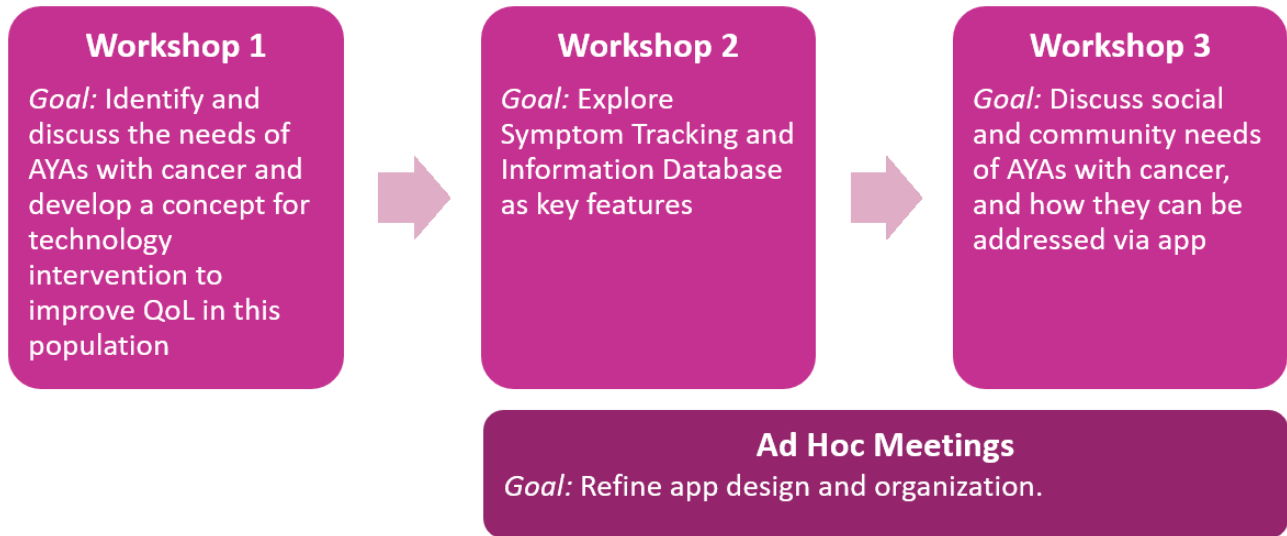
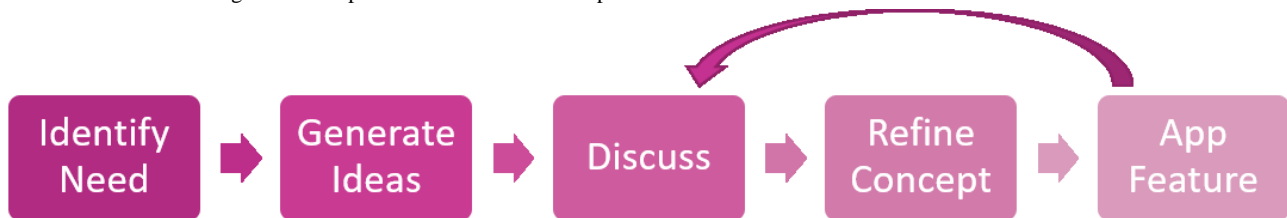


Figure 2. Flowchart detailing cocreation process utilized in workshop series.



The cocreation process was completed over the course of 3 workshops and intermittent ad hoc meetings, where the recruited youth panel worked together with a nurse, a doctor, and 2 representatives from the digital agency and app developer Daman. Workshops were selected as the primary cocreation method due to prior experience from the app developer and research team. The health care professionals did not actively participate in the workshops and only observed the events. Observers took notes on their observations of key issues discussed and relevant to AYAs with cancer. Representatives from the digital agency played a facilitative role, offering questions and guiding discussion based on the goals for the current workshop. Goals of the 3 workshops are outlined in [Figure 1](#). Workshops were held in nonhospital environments (eg, cafés and restaurants), while ad hoc meetings were held at the Kræftværket day room facilities at Rigshospitalet.

Before each workshop, participants were informed of the end goals of this project and specific goals of individual workshops. Specific content of each workshop was dynamic throughout this process and determined based upon the status of the app in development, as well as goals prioritized by youth during the current workshop or at workshops prior. No materials were needed for preparation of workshops excluding food and beverages for participants. Further detail on the content of each workshop is described in the results.

The cocreation process involved AYA participants at all levels of the project. During each workshop, participants described the needs of AYAs with cancer. The group was then asked to

present ideas involving how these needs can be addressed using an app intervention. The group then discussed these ideas, refining the concepts and prioritizing ideas deemed most beneficial by the group. The culmination of these discussions would then be integrated into an app feature or design aspect. This ensured a functional tool that is both usable and meaningful for the target users. When a design or functional change of any feature was made, the results were presented to participants to reassess, discuss, and then approve or disapprove of the current feature or design choice. [Figure 2](#) outlines the general structure of the cocreation process.

After each workshop and ad hoc meeting, collaborative efforts were made between the digital agency and the research team to create a finished app prototype reflecting the ideas and discussions of participating AYAs. The final app is expected after an evaluation phase or pilot test, as feedback throughout the next steps of the development process will be used to modify the current app prototype.

Ethical Considerations

All participants have completed informed consent forms prior to participation in any study procedure. If a participant was aged <18 years, caregiver informed consent was additionally obtained. This research was exempt from review by an institutional review_{board} or ethical authority under Danish law. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki

declaration and its later amendments or comparable ethical standards.

Results

Demographic Characteristics

Over the course of 3 workshops, 17 individual AYAs participated. The participants had an average age of 23.9 (range 17-32) years. Among the participants, 10 identified as male and 7 identified as female. Moreover, 9 participants had a hematologic diagnosis, while 8 had an oncologic diagnosis. Diagnoses varied and included leukemia, lymphoma, breast cancer, testicular cancer, primary brain cancer, adrenocortical cancer, and neuroendocrine cancer. Each workshop was composed of participants who were on and off treatment. Due to the continuous recruitment process, 10 participants attended 1 workshop, 4 attended 2 workshops, and 3 attended 3 workshops. Complete demographics per event are listed in [Table 1](#). Ad hoc meetings were open and held briefly at the hospital; 2-3 AYAs participated in each of the 3 ad hoc meetings.

Workshop I

Workshop I was performed over the course of a weekend retreat, with approximately 10 hours dedicated to cocreation. During the initial workshop, the AYA panel members were asked to describe an ideal technology resource that could be used to improve quality of life for AYAs with cancer and what resources would be most beneficial outside of the Kræftværket social room and closed Facebook group. During the workshop, participants identified needs that an electronic health intervention could address by answering questions such as the following: What is at stake when diagnosed with cancer as a young person? What is everyday life like with cancer? What is it like to undergo a course of treatment? Lastly, what digital tool could address the needs of a young person with cancer? A mobile app was confirmed as the most beneficial technology platform.

Workshop II

Workshop II was held during an afternoon meeting, with approximately 5 hours dedicated to cocreation. In this workshop,

AYAs defined their primary information needs during cancer treatment and what validated knowledge they believed should be accessible via the app. In addition, they were asked to identify what logging features, such as “Pain” or “Mood,” should be available in the symptom tracking feature of the app. Participants were divided into 2 discussion groups to brainstorm ideas, and the generated ideas were then narrowed and ranked in terms of importance. For both the symptom tracking parameters and the information resources, participants were asked to select the top 10 most important brainstormed ideas and then rank them in the order of most to least important. The 10 information resources and tracking parameters deemed most important overall were then integrated into the pilot app product.

Ad Hoc Meetings

During the time period between the second and third meeting, ad hoc meetings were arranged at Kræftværket over lunch to discuss the app’s design. During these meetings, Kræftværket users were approached to clarify, test, and evaluate different graphic designs available. They were also asked to assess development wireframes, which are blueprints of an app’s visual content and navigation elements ([Figure 3](#)). Feedback gathered from ad hoc meetings allowed the app development team to quickly adjust the design and functionality and gain direct feedback from anticipated app users.

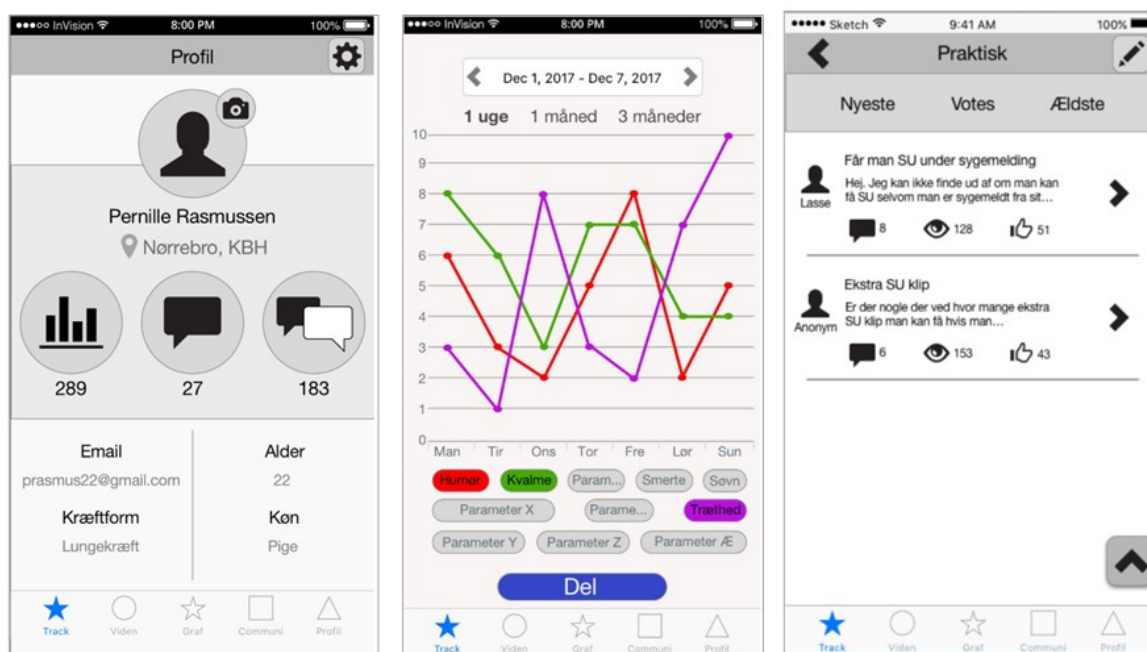
Workshop III

Lastly, Workshop III was held at an afternoon meeting, with approximately 5 hours dedicated to cocreation. At the final cocreation workshop, the aim was to identify how AYAs with cancer communicate with one another and how this can be utilized on a digital platform to share experiences and provide advice. Smaller discussion groups were formed to perform specific activities designed to highlight desirable features for a community-based app. Activities included “Brainwriting,” in which patients were asked to write down as many thoughts as they could on communication between AYAs with cancer in a 10-minute span, as well as “Dotting,” where patients narrowed the generated ideas by selecting those that they deemed most personally significant. The social and community features were refined for the app after the workshop’s completion.

Table 1. Participant demographics throughout cocreation workshops.

Characteristics	Workshop 1 (n=12)	Workshop 2 (n=9)	Workshop 3 (n=6)
Age (years), mean (SD)	24.44 (4.6)	23.11 (4.5)	23.17 (3.2)
Gender, n (%)			
Female	5 (42)	3 (33)	1 (17)
Male	7 (58)	6 (67)	5 (83)
Diagnosis, n (%)			
Hematologic	7 (58)	5 (56)	3 (50)
Oncologic	5 (42)	4 (44)	3 (50)
Treatment status, n (%)			
On treatment	9 (75)	4 (44)	2 (33)
Off treatment	3 (25)	5 (56)	4 (67)

Figure 3. Wireframe of the initial design for the app prototype used during cocreation ad hoc meetings.



Textbox 1. Information library items identified by participants from cocreation workshop and integrated into the app prototype.

- What is cancer?
- Medication and treatment
- How to disclose and discuss cancer diagnoses with family and friends?
- Hospitalization
- Navigating economic, municipal, and educational systems
- Alternative medicine
- Health and nutrition
- Hobbies and activities
- Cosmetics and personal grooming

In the final pilot prototype, 3 key app features were identified from the cocreation workshops: (1) a community forum; (2) an information library; and (3) a symptom and side-effect tracking tool. Design-wise, the participants selected a bright, warm color scheme reminiscent of the physical Kræftværket facilities that were initially chosen during Kræftværket's hackathon creation event [22].

The community forum is intended to serve as an open community network where AYAs with cancer can connect with peers. Participants stated that they would prefer a private area to speak with others who understand their situation, while also providing the freedom allotted in the form of an open forum. Private messaging features will also be included. Cocreation participants at the third workshop discussed the creation of a mentoring feature in which new users can be matched with someone of similar diagnosis to privately connect with. However, this feature was not included in the final app prototype due to financial, technical, and ethical limitations.

App users identified 10 items deemed important to include in an information library, as outlined in Textbox 1. Links to outside

resources were also suggested. Participants asked for informative links to hospital and governmental websites, as well as the ability for the app to suggest nearby activities, restaurants, and locations to visit when hospitalized.

Symptom and side-effect tracking were seen as important ways to monitor personal well-being as well as to provide a tool to explain side effects and symptoms in visits at the hospital with health professionals. Participants identified 5 initial trackable features, including sleep, pain, fatigue, nausea, and mood. Participants suggested customization of what symptoms and side effects could be tracked for a more personal experience to each individual that can be followed over time. As a consequence, the symptom tracking can have different metrics added and removed to the desire of the app user.

By this process, the Kræftværket app was completed for utilization both during and after cancer treatment on both iOS and Android platforms. The final prototype has been moved to pilot testing and evaluation, with results expected in future publications [27].

Discussion

Principal Findings

Based on the described cocreation process, a prototype for the Kræftværket smartphone app was developed. It is intended to serve as a tool for AYAs with cancer to improve quality of life during and after cancer treatment, as well as form a supportive community with other AYAs.

As designated by Bandura's theory of self-efficacy, perceived self-efficacy is defined as people's beliefs about their capability to influence change in their lives [28]. Cocreation addresses this by giving patients back the authority to address personal challenges via direct involvement in supportive resource creation, thus benefiting self-efficacy for both those involved in the process and the end users [29-32]. The utilization of cocreation, in addition, does more than simply provide an avenue for patient self-efficacy and agency. Increased participant input also allows for the creation of an end product that is useful, patient-centered, and engaging [15,19,21,33].

Currently the app prototype is under evaluation via ongoing pilot testing and an implementation test evaluating quality of life via the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (Figure 4) [27,34]. The hypothesis for the Kræftværket app is that in the long term, the app can serve as a patient support tool and assist in meeting many patient needs, including side-effect and late-effect management, handling existential and practical concerns, and confronting daily life with cancer in a supportive community of peers. This is proposed to benefit the global health status and functional scale domains of the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 while also improving the

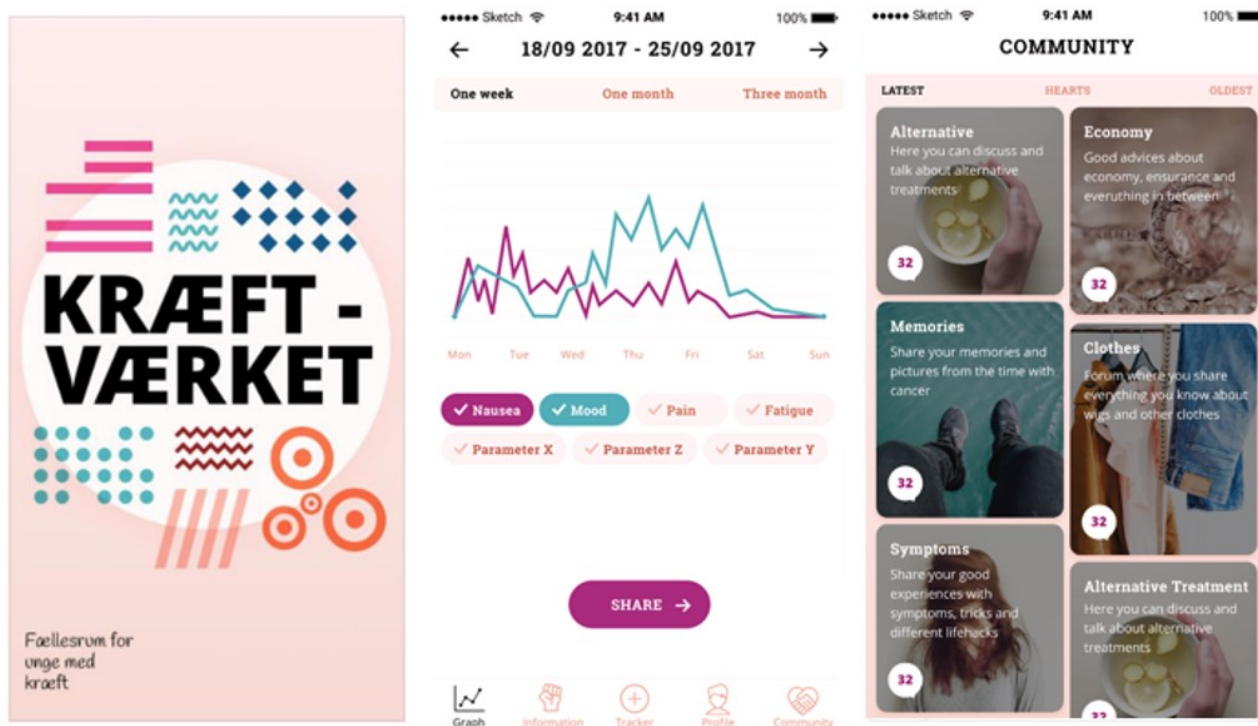
management of symptoms through tracking to a lesser extent under the symptom scales domain [34]. These social, psychological, and functional concerns have been identified as areas of concern for AYA patients that may be addressed by intervention [35,36]. However, this has yet to be investigated from the Kræftværket app. We hope that participants utilizing the Kræftværket app will report higher HRQoL using a standardized measurement in comparison to control groups and will qualitatively report that the Kræftværket app has benefited them in psychosocial and practical domains.

The cocreation approach is an approach to create user-friendly interventions, providing strength in development of a product that is both functional and desirable to its target audiences. For smartphone app interventions, a functional product does not necessarily guarantee success or frequent app usage [17]. Based on feedback from AYAs during the cocreation workshops, decisions may change, and the youth may orient the project in ways that the health care professionals and representatives from the digital agency may not have chosen on their own. As such, the project may be seen as more desirable and functional, addressing the needs from a user-focused perspective.

Strengths and Limitations

The cocreation process is one of the greatest strengths of this project; however, cocreation may also serve as a limitation. By giving significant decision-making to the youth, the ability to follow a rigid protocol of development is somewhat hindered; throughout this project, AYAs played an equally significant role in creating the prototype as any professional or area expert. However, we believe that the benefits of cocreation outweigh the limitations. In further studies, by adding quantitative surveys examining HRQoL, there will be a tangible method to analyze the impact of the project's end results and therefore the utility of the cocreation process.

Figure 4. Screenshots of current development model for the Kræftværket smartphone app.



The continuous recruitment process was an additional limitation, as the population was constantly fluctuating. A decrease in participant number was noted with each subsequent cocreation workshop, which may be attributable to the decreased time for recruitment with each subsequent workshop, and participant availability, as the initial workshop was held over a weekend while each subsequent workshop was on a weekday afternoon into the evening. Additionally, a different composition of AYAs was noted in each workshop, which may also be a limitation due to the inability for one group to comment on refinements to the app concept. Lastly, small sample sizes were provided for cocreation workshops, which may not be adequately heterogeneous to represent all AYAs with cancer. However, the quantitative and qualitative analyses that will be added in the prototype's evaluation will provide an opportunity to extend this project to a larger population of AYAs, who will be targeted during recruitment to achieve a more representative population of all AYAs with cancer.

It is the aim of the authors of this article to describe the development of an app for AYAs with cancer or cancer experience; however, the described cocreation process will be applicable for the development of applications and other interventions for AYAs with other chronic diseases. Previous studies have showed improved target outcomes via app utilization for disease management, such as blood glucose levels

in diabetes and improved asthma control [37]. The exact role that smartphone apps may have on AYAs' HRQoL is not quite clear. In addition, not all health applications are created in an equal process; many applications are not validated through evidence-based testing, and those that have been evaluated do not always report improvement of target health outcomes [37,38]. However, the potential remains for smartphone apps to serve as a new strategy for improving HRQoL and other health outcomes for broader populations of AYAs beyond those with cancer. While it is true that there are many applications currently available for AYAs with chronic diseases, there are few that have utilized AYA input in their development [18]. By applying the described process to a wider range of diagnoses and chronic illnesses, there is potential to develop a cocreated application with significant benefit to young people regardless of diagnosis.

Conclusions

In conclusion, using the process of cocreation, the prototype smartphone app Kræftværket was designed as an integrated tool for AYAs with cancer and cancer survivors. Further research and analysis are ongoing to evaluate the effect of this application on HRQoL. The application and design process have potential to serve as inspiration for the development of other interventions with a user-involved method; however, more evaluation is needed.

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Conflicts of Interest

None.

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Abbreviations

AYA: adolescent and young adult

HRQoL: health-related quality of life

mHealth: mobile health

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Original Paper

Time Series Visualizations of Mobile Phone-Based Daily Diary Reports of Stress, Physical Activity, and Diet Quality in Mostly Ethnic Minority Mothers: Feasibility Study

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Abstract

Background: Health behavior patterns reported through daily diary data are important to understand and intervene upon at the individual level in N-of-1 trials and related study designs. There is often interest in relationships between multiple outcomes, such as stress and health behavior. However, analyses often utilize regressions that evaluate aggregate effects across individuals, and standard analyses target single outcomes.

Objective: This paper aims to illustrate how individuals' daily reports of stress and health behavior (time series) can be explored using visualization tools.

Methods: Secondary analysis was conducted on 6 months of daily diary reports of stress and health behavior (physical activity and diet quality) from mostly ethnic minority mothers who pilot-tested a self-monitoring mobile health app. Time series with minimal missing data from 14 of the 44 mothers were analyzed. Correlations between stress and health behavior within each time series were reported as a preliminary step. Stress and health behavior time series patterns were visualized by plotting moving averages and time points where mean shifts in the data occurred (change points).

Results: Median correlation was small and negative for associations of stress with physical activity ($r=-.14$) and diet quality ($r=-.08$). Moving averages and change points for stress and health behavior were aligned for some participants but not for others. A third subset of participants exhibited little variation in stress and health behavior reports.

Conclusions: Median correlations in this study corroborate prior findings. In addition, time series visualizations highlighted variations in stress and health behavior across individuals and time points, which are difficult to capture through correlations and regression-based summary measures.

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KEYWORDS

change point; diet quality; mobile phone; moving average; physical activity; stress; time series

Introduction

Ecological momentary assessment (EMA) [1-3], daily diary, and weekly assessment, hereafter referred to as *intensive longitudinal assessment* (ILA), is a data collection framework that prompts individuals to self-report behaviors and events *in*

situ and often as they occur using paper diaries or electronic data collection devices. ILA offers several benefits over traditional in-person assessment that is often conducted in clinic settings, conducted less frequently, and requires recall over longer periods of time, including reductions in social desirability [4,5] and recall biases [1,6,7]. ILA has been used to examine relationships between psychosocial factors, such as stress,

cognition, and positive and negative effects, and health behaviors (HBs) over time, such as physical activity (PA) and diet [8-18]. Stress and HB relationships are of special interest as stress increases the susceptibility to cancer, heart disease, stroke, and other diseases [19-23]. HB confers protective effects against these same diseases [20,24-30]. An understanding of the interplay between stress and HB informs the design of healthy lifestyle interventions. ILA is favored over traditional assessment methods because changes in stress levels and HB occur over shorter periods of time (often over days or weeks) than time periods that are queried through retrospective recall [31]. ILA has gained popularity with the proliferation of mobile phones and advances in mobile phone technology as short message service text messaging and mobile survey apps replace paper diaries and other assessment tools of yesteryears, streamlining data collection and reducing participant burden. A proliferation of mobile phone-based studies across disparate fields of research has resulted, including studies on PA and diet [32-35], drug use [36-38], and HIV [39-41].

Amid advances in ILA data collection methods, analytical strategies to evaluate patterns in resulting data streams have yet to catch up. Random effects (RE) regression models (ie, multilevel and mixed-effects models [42,43]) are recommended [14] and commonly used to analyze data from ILA, or *intensive longitudinal data* (ILD), as in the analysis of EMA data to evaluate stress and PA relationships [31]. Similar to standard regression models, RE models include fixed effects or covariates. For ILA data, covariates are included for time in order to model outcome-level changes over time in the overall sample. In addition to fixed effects, RE models for ILD include RE for time that varies across individuals, and in doing so, allow for individual-level time trends to be estimated. By capturing variations at the individual level, RE models also adjust SE estimates for proper statistical inference. Walls and Schafer [44] adapted RE models for ILD analysis. ILD models provide the ability to analyze within-person effects over time with greater granularity than traditional RE models. Yet, the strength of both traditional RE and ILD models lies in their ability to evaluate between- (eg, sociodemographic) and within-person fixed effects (eg, time trends) that are averaged across individuals, while adjusting for between-person variation through RE.

RE model summaries typically present fixed effect estimates for effects that are averaged across individuals or another level of clustering. For example, studies that treat neighborhoods as clusters use RE models to adjust for neighborhood variation but present neighborhood-averaged effects [45]. When there is interest in health outcome patterns over time at the cluster level (ie, individual level), different analytic approaches are needed; this is especially true for individualized treatment plans that are increasingly utilized for chronic illnesses such as diabetes [46]. N-of-1 trials evaluate individual treatment plans by modifying treatment regimens over the study period based on responses or progress over the same period [47]. Similarly, microrandomized trials randomize treatments and record outcome responses at the individual level over time such as the evaluation of randomly assigned mobile phone health-promoting short message service text messages on PA [48]. Regardless of the individual-level study design, evaluation calls for an analysis

of an individual's data stream over time (hereafter referred to as a *time series*). Moreover, evaluations of both overall and individual-level effects are important for a better understanding of HBs at the population level. For example, PA levels have been shown to be impacted both by Alzheimer's disease status, as estimated through average effects in older adults [49], and seasonal variations that influence activity at the individual level [50], respectively.

This study fills gaps in the literature and illustrates how time series analyses can be applied to ILD or time series data in the health sciences. Time series analyses have largely been lacking in health sciences and have focused on analyses for single measures when they do occur such as PA accelerometer data from mobile devices [51,52]. We show how time series analyses can be used as an exploratory tool to visualize patterns in single and multiple time series at the individual level. Analyses are illustrated on daily diary data from a pilot study that collected information on stress, PA, and diet quality in mostly ethnic minority mothers [32,53]. Prior studies have explored mental and physical health relationships by applying regression models to ILD [8-18] and data from cross-sectional and longitudinal study designs that collected data over several time points [31,54]. To the best of our knowledge, stress and HB relationships have not been evaluated through time series analyses. In doing so, we highlight insights that time series analyses can provide as a complementary procedure to regression models.

Methods

Study Participants

From January 2012 through September 2012, 44 mothers with at least 1 child under the age of 18 years and living at home were recruited to pilot test a mobile app for self-monitoring stress, PA, and diet quality over a 6-month period in Los Angeles, California. Participants were recruited in public venues, such as grocery stores, and through local Web-based parenting groups in the Los Angeles area. The mobile app was designed to help them record stress, PA, and diet quality levels on a daily basis, and in doing so, to self-monitor stress and health-related behaviors. This study was approved by the Institutional Review Board at the University of California, Los Angeles.

Study Procedures

Once enrolled in the study, participants completed a Web-based baseline assessment to collect sociodemographic characteristics, measures on PA, dietary intake, and perceived stress. Anthropometric measures, including body mass index and blood pressure, and biomarker measures, including C-reactive protein levels and Epstein-Barr virus antibody levels, were also collected. Web-based assessments, anthropometric and biomarker data collection, were repeated at 3 and 6 months after the baseline. Further details on study measures may be found in Comulada et al [32] and Swendeman et al [53].

Following the baseline assessment, participants were assigned Samsung Vibrant smartphones running on the Android operating system version 2.2 or higher. For 6 months, participants received daily time-based prompts on their mobile phones to complete

EMA 3 times daily and an end-of-day assessment (daily diary) through a mobile app. Measures encompassed PA, diet quality, and stress in parallel to domains that were captured through Web-based assessment. Participants were also encouraged to use their mobile phone to take pictures of their meals as photographic food records.

Prior analyses examined correlates of adherence to EMA, daily diary reports, and photographic food records [32] and the validity and reliability of measures collected through the mobile app, Web-based assessment, anthropometric measurement, and biomarkers [53]. For this paper, time series analytical methods are illustrated on daily diary measures for stress, PA, and diet quality.

Sociodemographic and Baseline Characteristics

The average age of 44 study participants was 30.8 (SD 6.4; range 18-43) years. Most participants reported being an ethnic minority; 43% (19/44) reported being of Latina ethnicity and 39% (17/44) reported being nonLatina African American. A third of the participants (14/44, 32%) reported having a high school education or less. Nearly half of the participants (21/44, 48%) reported working part-time or less. On average, participants were obese with a body mass index of 32.1 (SD 7.0) kg/m². Mean systolic (121.6 [SD 14.6] mm Hg) and diastolic (79.3 [SD 9.9] mm Hg) pressures were in normal ranges.

Daily Diary Measures

Stress

Participants were asked, “How stressful was your day overall on a scale of 1-5 (with 5 being very stressful)?” Integer responses from 1-5 were permitted. Five was anchored as “very stressful” in the wording of the question, implying lower values for lower stress levels. Response categories were not explicitly labeled.

Physical Activity

Participants were asked, “How many minutes of activity did you do today” regarding the following 3 intensities of PA: light PA (eg, stretching), moderate PA (eg, fast walking), and vigorous PA (eg, running). Total minutes of PA were calculated as the sum of light, moderate, and vigorous PA minutes.

Diet Quality

Participants were asked, “How healthy would you rate your eating today, in terms of both quality and quantity, on a scale of 1-5 (with 5 being very healthy)?” Integer responses from 1-5 were permitted. Five was anchored as “very healthy” in the wording of the question, implying lower values for less healthy eating. Response categories were not explicitly labeled.

Statistical Methods

Data Preparation

In preparing data for time series analyses, it is important to acknowledge the assumed data structure. Equal spacing is assumed between adjacent observations over time. If an observation is missing for a specific time point, the time point with the missing observation is dropped from the analysis

dataset, and observations on either side of the missing observation are treated as adjacent observations. Therefore, missing data disrupt the assumed data structure. Our *ad hoc* approach to address missing data examines response rates for each participant’s time series and limits analyses to time series with minimal amounts of missing data so that the assumption of equally spaced time points is more tenable.

Time Series Analyses

We present 2 time series analyses that are useful for data visualization and exploration. Both analyses were implemented through R [55], a free and downloadable statistical software program. The first analytic method plots smoothed data points for the time series over time instead of the raw data to make it easier to visualize temporal patterns in the data. There are numerous smoothing techniques. See Cowpertwait and Metcalfe [56] for an overview of smoothing techniques implemented in R. We used unweighted and centered *moving averages* as a widely used general-purpose smoothing technique in the absence of *a priori* information on temporal patterns in the time series data. As the name implies, an average of *n* data points centered on time point *t* are plotted at *t* instead of the first data point in the subset of *n* data points. The interval *n* is chosen to strike a balance between a large *n* that smooths out too many variations in the data to provide useful visualizations and a small *n* that retains too much information from the original data so that patterns are difficult to visualize. We chose *n*=30, or approximately a month. Moving averages were plotted through the *tseries* package, version 0.10-42 [57].

Visual inspection of moving average plots provides a subjective guide as to points in time where mean levels, such as stress levels, tend to abruptly increase or decrease, that is, where *change points* occur. The second analytic method provides a formal statistical algorithm, referred to as *change point analysis*, to locate change points. Change point analysis formulates a maximum likelihood-based test statistic that rejects a null hypothesis that no change points are present in the time series data if the statistic is greater than a specified threshold. The maximum likelihood under the alternative hypothesis needs to accommodate the possibility of multiple time points where the change point occurs and the possibility of multiple change points. Finally, there is no clearly defined manner for choosing a threshold. Different change point algorithms have been developed to address these statistical testing complexities. We used the *change point* package, version 2.2.2, which contains 3 mainstream algorithms for detecting change points—binary segmentation, segment neighborhood, and Pruned Exact Linear Time (PELT) change point algorithms. Details are given in the *change point* documentation [58]. Briefly, binary segmentation is the oldest and, arguably, the most widely used change point algorithm of the 3. Binary segmentation works by first searching for a single change point. If a change point is found, the time series is bifurcated into 2 segments. The algorithm then checks for change points within each segment, and so forth, until no more change points are detected. In contrast, the segment neighborhood and PELT algorithms are more precise algorithms that do not condition the detection of additional change points on prior change points. PELT is the newest algorithm and the preferred algorithm that we used to detect change points when

possible. We defaulted to binary segmentation if segment neighborhood and PELT algorithms were overly sensitive at detecting changepoints and detected too many changepoints to provide useful visualizations. Changepoint analysis results are presented through plots from the *changepoint* package that superimpose mean levels and changepoints for the time series over the observed values.

Results

Analysis Dataset

Figure 1 shows patterns of compliance to filling out daily diaries for each of the 44 study participants, from the first (01) to the last participant enrolled in the study (44). We retained 32% (14/44) of the time series for analyses from participants who filled out a majority of the possible daily diaries over the follow-up study period based on the visual inspection of Figure 1. Gray and black dots represent time series that were retained and excluded from analyses, respectively. Exclusions included 3 time series for participants who became pregnant or moved out of state during the study period. Time series that were included and excluded in analyses did not significantly differ in terms of participants' sociodemographic characteristics, anthropometric, and biomarker baseline measures based on chi-square tests for categorical measures (eg, race or ethnicity) and *t* tests for continuous measures (eg, age).

Correlation Coefficients

As a preliminary analysis, Pearson product-moment correlation coefficients (*r*) were calculated for pairs of concurrent observations for stress and PA, and between stress and diet quality, for each participant. The median association between stress and PA was negative and small in absolute value ($r = -.14$, range: $-.39$ to $.15$; $n = 14$ time series). A similarly small and negative median relationship was found between stress and diet quality ($r = -.08$), but exhibited a wider range of correlation coefficient values from $-.62$ to $.65$.

Time Series Analyses

Figures 2-5 show plots for each of the 14 participants retained for analysis. Three pairs of plots are shown for each participant's time series of stress, PA, and diet quality measurements. For each pair, the plot on the left-hand side shows mean levels indicated by thick horizontal lines and changepoints indicated by line breaks superimposed over the raw time series data. The plot on the right-hand side shows a smoothed line based on

moving averages. Changepoint analyses for stress and diet quality were conducted using the PELT algorithm. The PELT algorithm produced too many PA changepoints to be useful for comparison with stress and diet quality changepoints. We resorted to binary segmentation for PA time series and set the maximum number of allowable changepoints to 2; the maximum number of changepoints that were detected for stress in most instances.

Almost all participants exhibited variation in their responses over time, but did not necessarily exhibit abrupt shifts in mean response levels such as reported diet quality for participant 32 in Figure 3; this highlights the utility of different time series visualizations. Moving averages provide for visual evaluation of long-term mean shifts versus abrupt mean level shifts that are detected through the changepoint analysis. To highlight the utility of the changepoint analysis, as well as moving averages, we divided participants between Figures 2 and 3 and Figures 4 and 5 such that Figures 2 and 3 represent participants who exhibited changepoints in both stress and HB (PA or diet quality) levels over the study period ($n = 6$ participants). Participants who did not exhibit changepoints for stress and HB are represented in Figures 4 and 5 ($n = 8$ participants). The division of participants between Figures 2 and 3 and Figures 4 and 5 is another reminder of the potential difficulty for evaluating stress and HB relationships in aggregate when there is heterogeneity in stress and HB relationships across the sample. The remaining discussion focuses on Figures 2 and 3.

Figures 2 and 3 show fairly consistent visual patterns in terms of moving averages for stress and PA levels. Stress and PA levels tend to be inversely related over time. For example, moving average plots for participant 08 show steady declines in stress levels over the study period, matched by a steady increase in PA. Stress and diet quality mean levels are less consistently related, exhibiting inverse relationships, for example, for participant 08, and positive relationships, for example, for participant 16. Changepoint analysis results show that stress and PA changepoints tended to occur at similar points in time; some of the diet quality changepoints did as well. Referring to participant 08 again, we see 3 mean segments for stress, indicating decreasing levels of stress. The first stress changepoint aligns with changepoints for PA and diet quality, indicating increasing levels for both HBs in line with accompanying moving averages. PA also exhibits a third changepoint that indicates a decreasing mean level of PA toward the end of the study.

Figure 1. Adherence to filling out mobile phone-based daily diary reports.

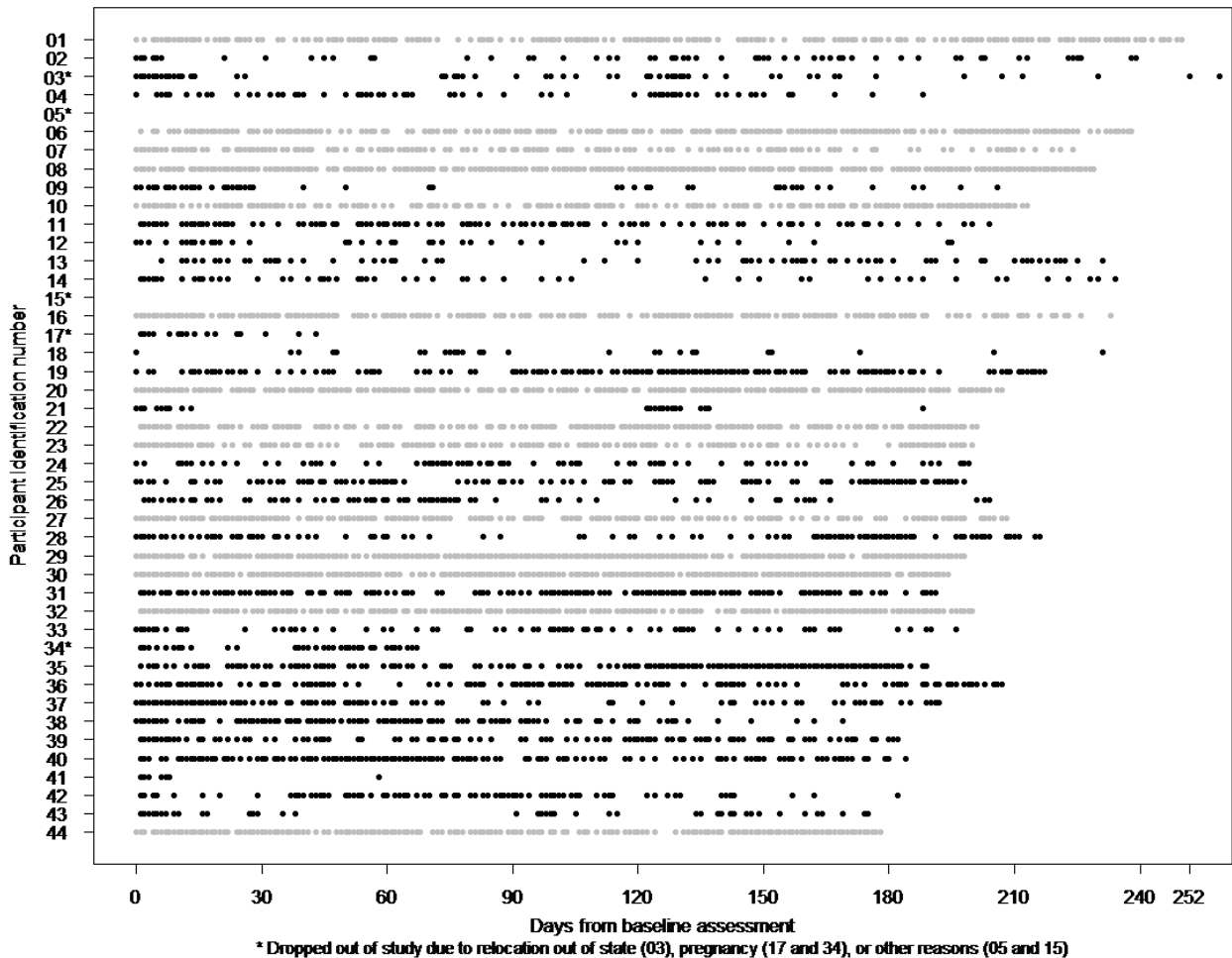


Figure 2. Time series plots for 3 participants exhibiting mean shifts in levels of self-reported daily stress and health behaviors. PID: participant identifier.

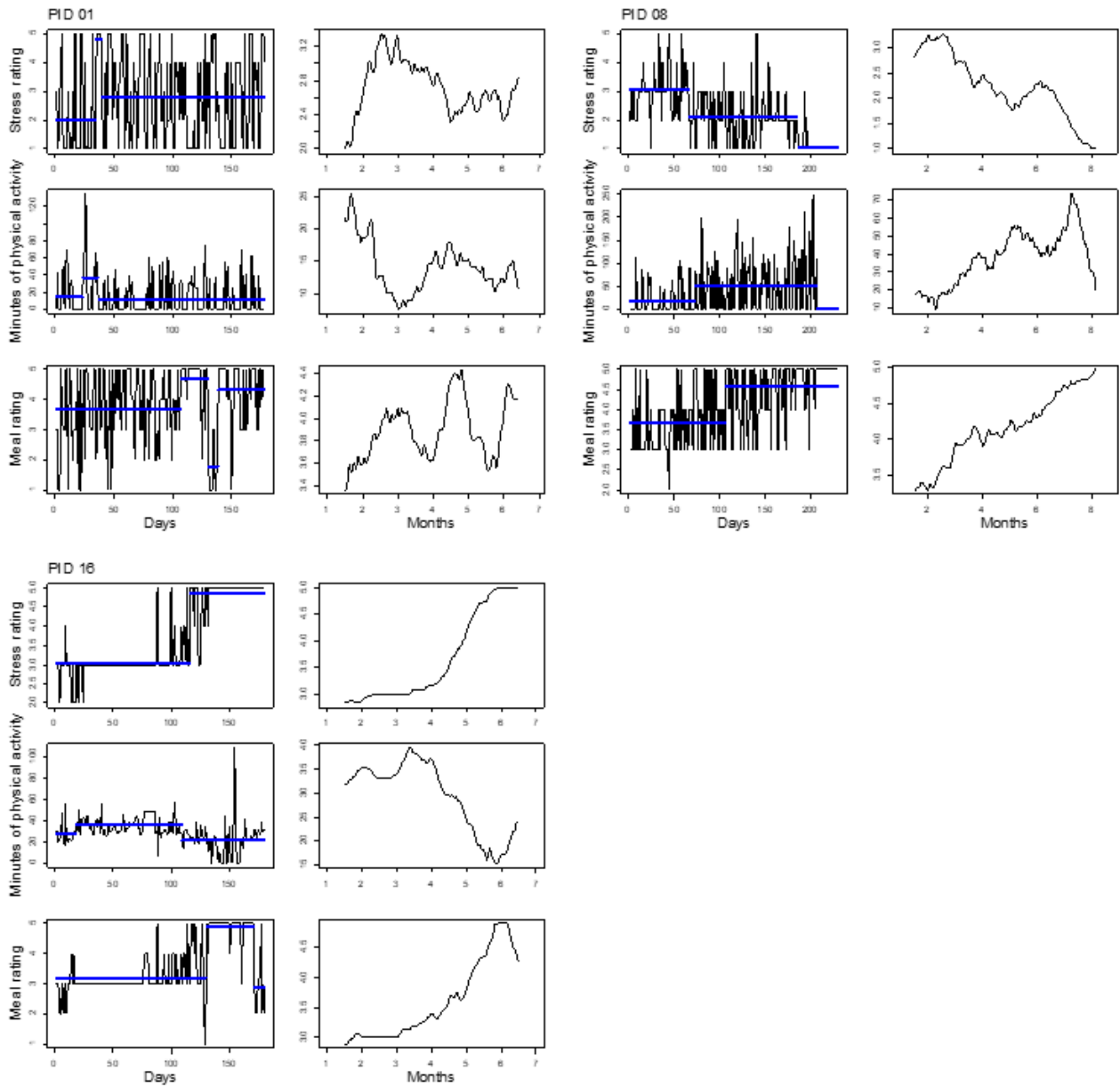


Figure 3. Time series plots for 3 participants exhibiting mean shifts in levels of self-reported daily stress and health behaviors. PID: participant identifier.

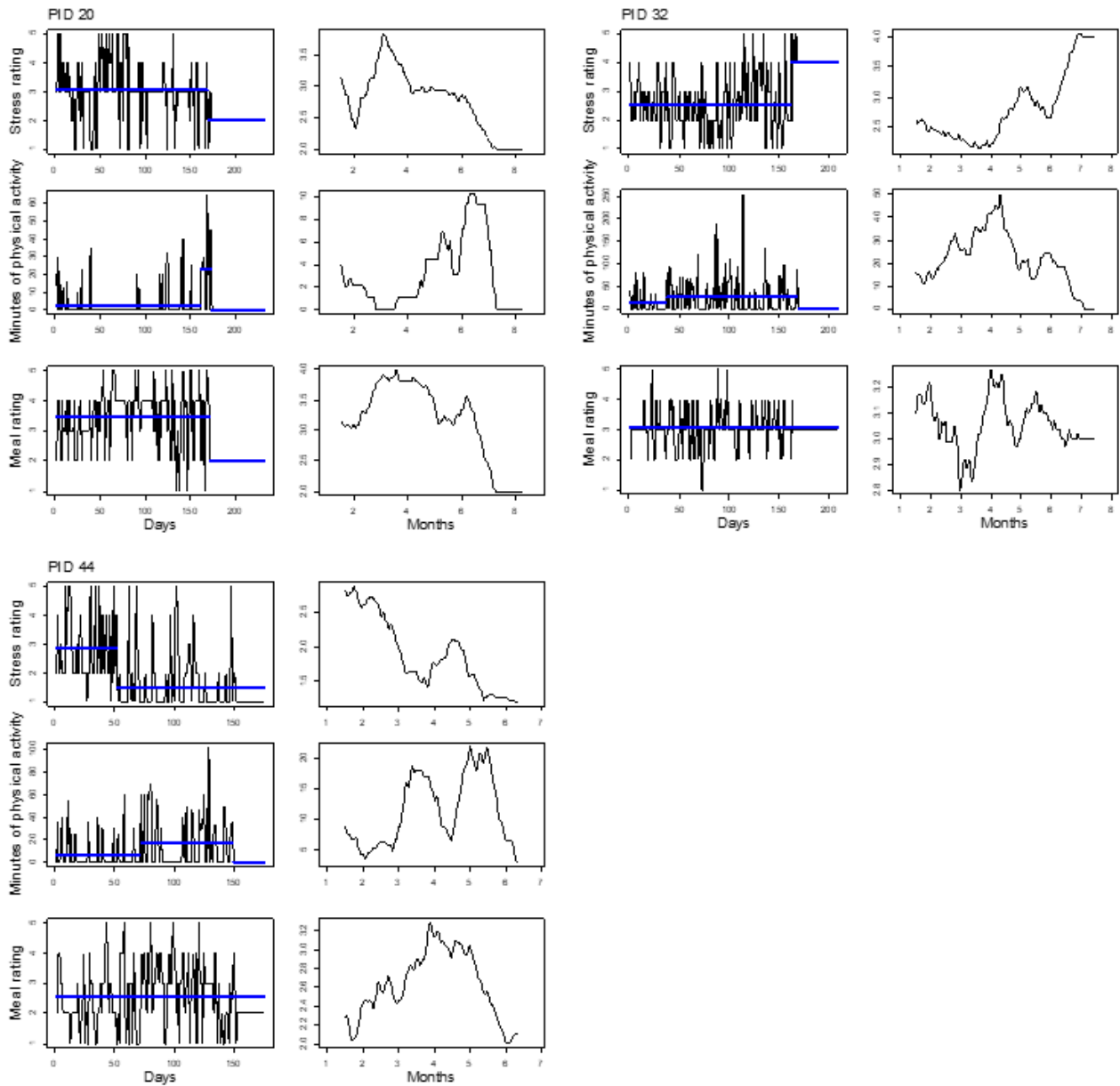


Figure 4. Time series plots for 4 participants not exhibiting mean shifts in levels of self-reported daily stress and health behaviors. PID: participant identifier.

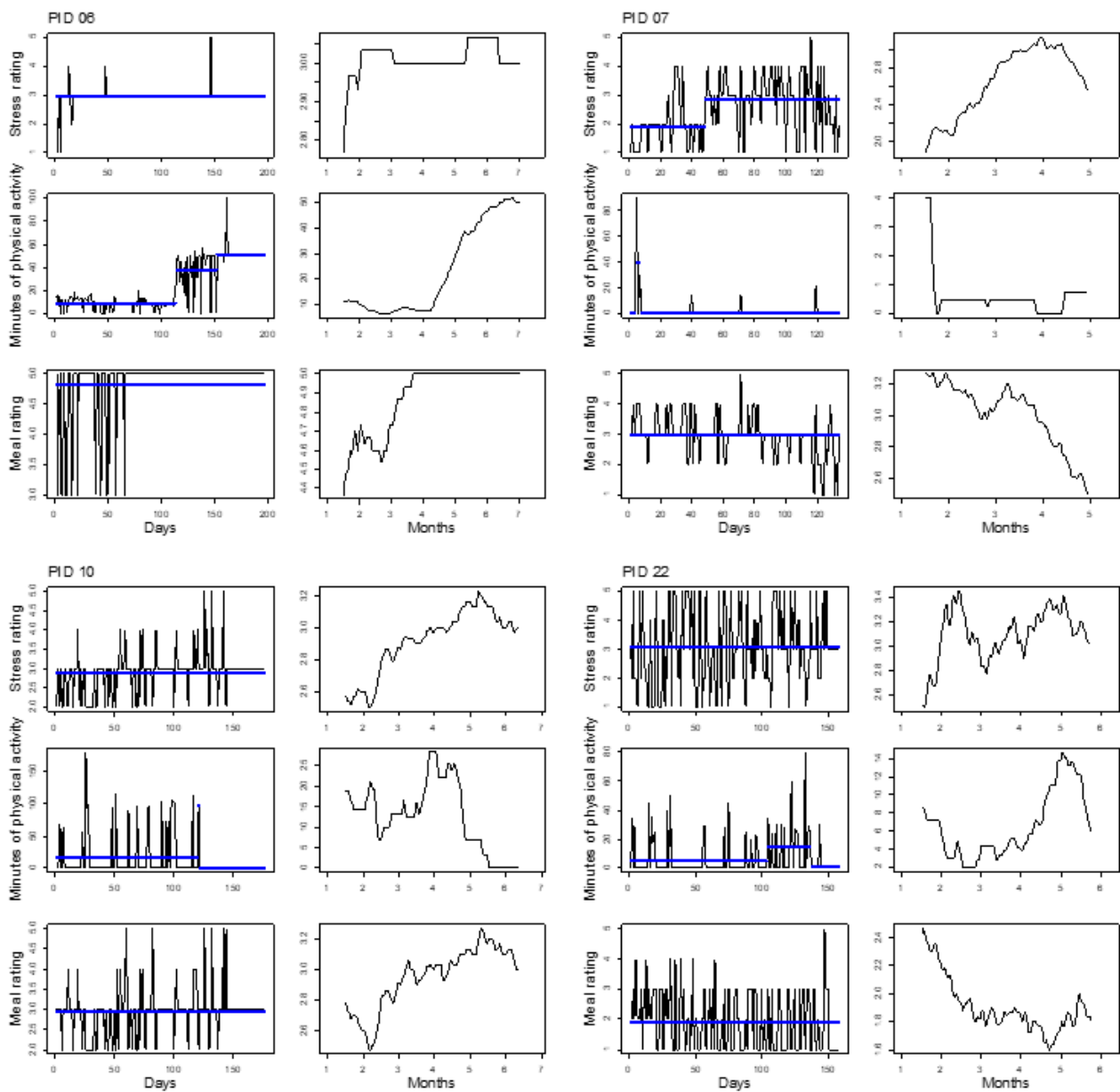
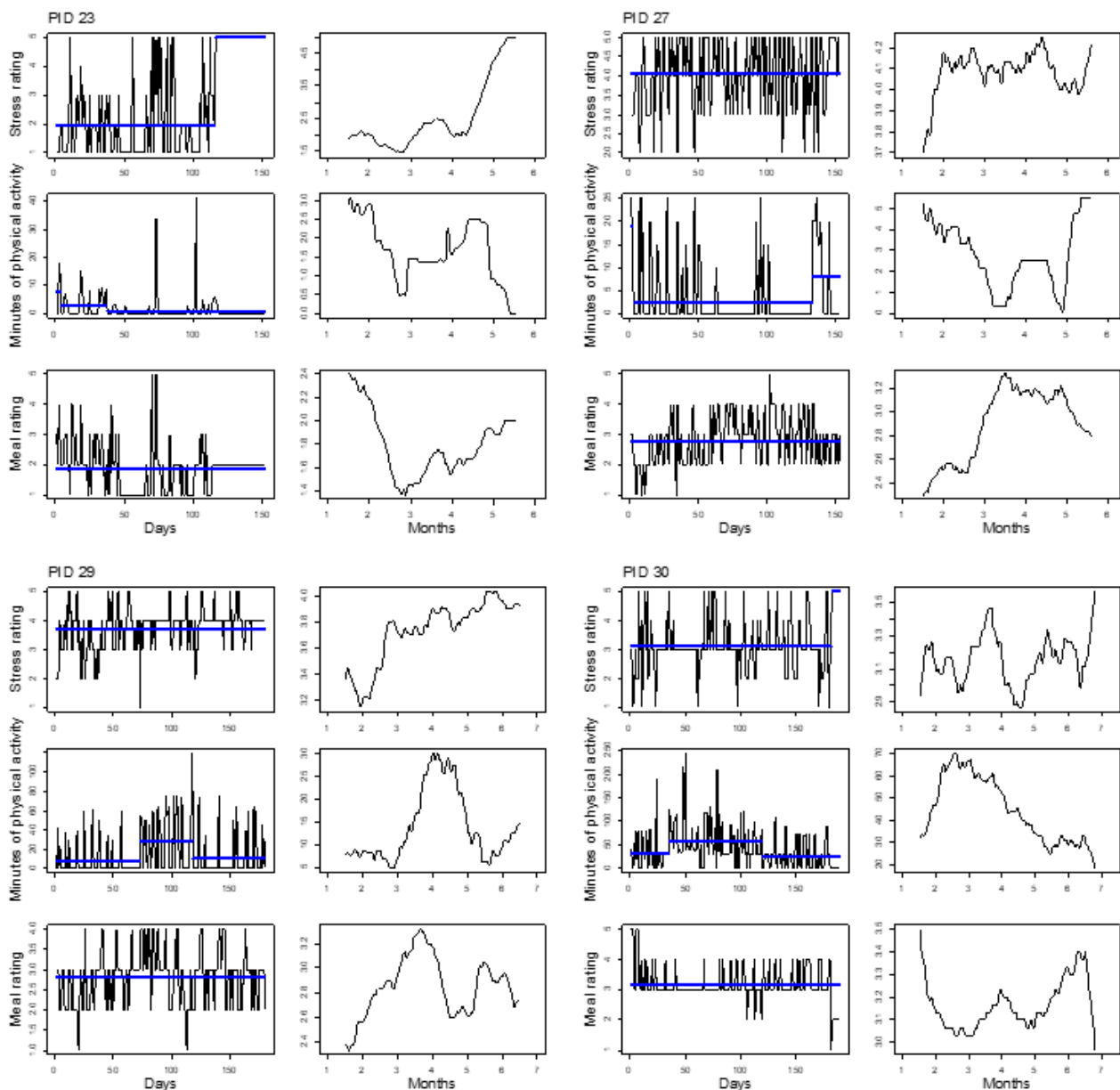


Figure 5. Time series plots for 4 participants not exhibiting mean shifts in levels of self-reported daily stress and health behaviors. PID: participant identifier.



Discussion

This paper gave an overview of time series analyses that can be used to better understand individual-level and frequently assessed longitudinal patterns of stress, PA, and diet quality. We highlighted an exploratory approach through visualizations and qualitative descriptions of time series patterns. Analyses began with the calculation of correlation coefficients for each time series as a commonly used statistic to summarize associations. Correlations between stress and PA time series indicated a negative association for 11 of 14 participants in line with negative associations reported in prior studies [31]. Magnitudes of the correlation coefficients were also in line with those reported in prior studies that found negative associations no higher than $-.28$ to $-.42$ [31]. The smallest correlation between stress and PA in our study was $-.39$. It is harder to compare correlations we found between stress and diet quality to prior studies as dietary intake, and not diet quality, is typically

assessed. However, a commonality existed in the wide range of correlation coefficients that were found for individual-level associations between stress and PA ($-.39$ to $.15$), and between stress and diet quality ($-.62$ to $.65$), which underscore the importance of examining stress and HB relationships at the individual level. Stress and HB relational differences across individuals may mask stress and HB relationships that are estimated as average effects across individuals.

Time series visualizations further emphasized variations in stress and HB relationships over time. On a more macro level, time series data yielded 2 groups of individuals based on abrupt shifts in mean levels of stress and HB or a lack thereof in Figures 2 and 5, respectively. Even among participants in Figures 2 and 3 who exhibited changepoints for stress and HB, variations occurred in stress and HB relationships. Stress and PA levels tended to be inversely related over time. Stress and diet quality relationships were more varied, as indicated by moving averages

for both measures that sometimes tracked together, in opposite directions, or not at all; diet quality time series did not yield any changepoints for some participants.

It is important to emphasize the exploratory nature of the study; study findings on stress and HB relationships are not confirmatory. A major point of the study findings is that variations in stress and HB relationships indicate the importance of understanding relationships at the individual level. It is also interesting to note that changepoint analyses in Figures 2 and 3 consistently produced 2-3 changepoints for both stress and PA time series that occurred at similar time points. Diet quality changepoints also occurred at similar time points for 3 participants. Commonly occurring changepoints for stress, PA, and diet quality suggest the same underlying causes for longer-term shifts in stress, PA, and diet quality levels; this has implications for interventions that target stress and HBs. A mixed-methods approach may help in understanding the underlying causes of stress and HB shifts or a lack thereof. Through qualitative interviews, participants can be shown visualizations and asked to recall events that precipitated changes. Not surprisingly, moving average patterns and locations as to where changepoints occurred differed across individuals. No shared event existed across individuals that would cause changepoints to align; this highlights a difficulty in RE models that estimate average time trends across individuals. For example, an interrupted time series analysis [59] is an RE modeling equivalent to changepoint analysis but requires an *a priori* specification of where changepoints occur. An *a priori* specification makes sense for interventions, public health policy changes, or other events where changepoints naturally line up across individuals.

In light of the advantages that time series analyses have over RE models for examining variation at the individual level, it is important not to discount the role of RE models in understanding HBs. Population-level inferences are still important. Time series visualizations are useful explorations in line with the notion of preliminary hypothesis-generating studies that inform the development of confirmatory studies with hypothesis-driven statistical tests [60,61]. For example, this study delineated 2 groups of participants based on the presence of changepoints (and a lack of changepoints) in stress, PA, and diet quality levels over time. Our sample size was small, but in a larger sample, subgroup characteristics that relate to variations in stress and HB may emerge and inform the design of large-scale studies that evaluate subgroup effects on stress and HB relationships at the population level.

The potential benefits of time series analyses are tempered by limitations in the assumed time series data structure and need to be contrasted with RE modeling limitations when designing analysis plans. Numerous data points are needed to visualize and evaluate time series in contrast to traditional longitudinal studies that collect data over several time points. Time series studies require careful consideration of both the number of data points to be collected and the length of time over which data points are collected, such as days versus weeks, depending on the measure of interest. For example, Bergman [62] concluded that several days suffice to measure habitual sedentary behavior, whereas close to 6 months are needed to measure habitual

vigorous PA with a reasonable degree of accuracy. More studies are needed to determine sufficient numbers of data points and time intervals for accurate inference across different health measures.

In contrast to sensor data, where observations are naturally collected over equally spaced intervals, as in the collection of PA accelerometer data [51,62], ILA tends to be unequally spaced because of missing data. Time series analyses should be applied to ILA data with caution. Methods to address missing time series data, including imputation and model-based approaches [63-65], are not readily available for standard time series routines in software. For example, the *imputeTS* package for R [66] imputes missing observations in time series data but is not integrated with other time series packages in R. Time series analyses should not be automatically ruled out in the presence of missing data, as fruitful inferences can still be made as was the case in this study. Our *ad hoc* approach for dealing with missing data was to only analyze time series analyses with a small amount of missing data so that missing observations would not impact the estimation of moving averages and changepoints to a large degree. Our *ad hoc* approach hinged on 2 main assumptions. Missing data in the time series we retained were minimal and spread out throughout the time series so that adjacent observations in the analysis data were all fairly close in proximity to each other, if not adjacent. Of course, missing data may not be evenly spread throughout the time series; nonresponse may increase over time [32,34,67,68]. Moreover, missing data patterns may differ between time series if participants tend to self-report one HB more than others on a daily basis, for example. This is problematic for commonly used models for multivariate time series (eg, see Tsay [69]), many of which assume equally spaced observations within and between time series.

As the second assumption for our *ad hoc* approach, we assumed missing data to be a random subset of observations from the same distribution as the observed data so that moving average estimates and other time series calculations were not biased by the exclusion of missing data. Missing data were assumed to be *missing completely at random* [70,71]; this is a strong assumption and best addressed by minimizing missing data. When considering study designs that incorporate ILA, it is important to consider buy-in in filling out ILA from the target population so that missing data are minimized. For example, higher rates of filling out ILA have been found in patient [36,38,72] versus nonpatient populations [40,73]. In addition to study design considerations, further statistical development is needed to address missing data in time series analyses and determine the sensitivity to be missing completely at random and other missing data assumptions.

Notwithstanding the limitations, time series analyses provide a starting point where prior studies have left off. In their review paper, Stults-Kolehmainen and Sinha [31] noted different findings for stress and PA relationships across studies, including findings of positive and negative associations, and no association. The same paper provided a reasonable rationale for differences with a focus on study design issues, such as differing levels of rigor and sample sizes. Arguably, different study findings are also attributed, in part, to individual-level

differences, some of which were accounted for by regression analyses and some which were not. Time series analyses can help fill in gaps in understanding what traditional regression modeling alone cannot do.

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Conflicts of Interest

None declared.

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Abbreviations

EMA: ecological momentary assessment

HB: health behavior

ILA: intensive longitudinal assessment

ILD: intensive longitudinal data

PA: physical activity

PELT: Pruned Exact Linear Time

RE: random effects

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Short Paper

Barriers and Opportunities for Using Wearable Devices to Increase Physical Activity Among Veterans: Pilot Study

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Abstract

Background: Few studies have examined the use of wearable devices among the veteran population.

Objective: The objective of this study was to evaluate veterans' perceptions of and experiences with wearable devices and identify the potential barriers and opportunities to using such devices to increase physical activity levels in this population.

Methods: Veterans able to ambulate with or without assistance completed surveys about their mobile technology use and physical activity levels. They were then given the option of using a wearable device to monitor their activity levels. Follow-up telephone interviews were conducted after 2 months.

Results: A total of 16 veterans were enrolled in this study, and all of them agreed to take home and use the wearable device to monitor their activity levels. At follow-up, 91% (10/11) veterans were still using the device daily. Veterans identified both opportunities and barriers for incorporating these devices into interventions to increase physical activity.

Conclusions: Veterans engaged in using wearable devices at high rates.

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KEYWORDS

veterans; wearable devices; connected health device; physical activity; mobile phone

Introduction

Regular physical activity is associated with numerous health benefits, including reduced risk of cardiovascular disease. Simply increasing step count is thought to lower the 10-year risk of death [1]. However, fewer than half of all veterans achieve the recommended physical activity levels to improve their health [2]. Many stakeholders, including the Veterans Health Administration (VHA), are interested in the potential of using mobile technologies such as smartphones and wearable devices to change health behaviors [3]. In particular, there is growing interest in the potential of wearable activity tracking devices to facilitate increased physical activity. These wearable devices provide feedback about physical activity levels in the

form of step counts and may encourage people to monitor and change their daily activities. They also offer a reward for positive behavior changes by indicating that the day's step goals have been achieved. Both techniques can be motivating for people attempting to make behavioral changes [4,5]. Wearable devices often differ from traditional pedometers in both their technology and ability to wirelessly transmit activity data. In 2015, the VHA commissioned a systematic review of the published literature on the use of wearable devices in veteran populations [6]. The review found that 12 of 14 trials focused on using wearables for physical activity but that more evidence was needed on how these technologies impact veterans. The objective of this exploratory study was to evaluate veterans' perceptions of and experiences with wearable activity trackers

to identify barriers and opportunities for their use in a future clinical trial using social interventions to increase physical activity among veterans.

Methods

Recruitment

In 2017, we recruited a convenience sample of adult veterans at the Corporal Michael J Crescenz Veterans Affairs Medical Center (CMC VAMC) in Philadelphia using flyers outside of clinic sites. Inclusion criteria were as follows: (1) patients of a CMC VAMC clinic and (2) able to ambulate with or without assistance. Interested veterans were offered US \$10 in compensation for their participation.

Study Design

All participants were asked to complete surveys on sociodemographic characteristics, experiences with and attitudes toward mobile technology (adapted from McInnes et al) [7], and physical activity levels using the short-form of the International Physical Activity Questionnaire [8]. After survey completion, we tested whether veterans would be willing to take home and use a wearable device to monitor their activity levels for 2 months. The Nokia Go wearable device was offered to interested participants because it can be worn on the wrist continuously without need for battery charging. Veterans were given the option of using this device and offered US \$15 to complete a 2-month follow-up telephone interview. The interview script focused on device use (prior to the study, currently, and future intentions) and interest in using the device in a future intervention (interest in participation and being paired with a family member, friend, or veteran). The interviewer (RHK) coded responses by question and identified representative quotes of common themes from the interview. Responses and themes were reviewed and adjudicated by a second reviewer (MSP). This study was approved by the CMC VAMC Institutional Review Board.

Results

The sample comprised 16 veterans with a mean age of 60.6 (SD 12.5) years; 88% (14/16) veterans were males (Table 1). All participants reported having regular access to the internet and a smartphone. In the past week, 12 participants had access to a tablet, but only 3 had access to a connected health device (1 had a smartwatch, 1 had a Bluetooth-connected hearing aid, and 1 had a smart pill bottle). The mean physical activity level was

59.1 (SD 57.6) MET-minutes per week. All 16 veterans agreed to take home and use a wearable device to track their activity. At follow-up, 91% (10/11) veterans were still using it daily, but 1 participant had misplaced it after 6 weeks of daily use.

Overall, participants felt positively about wearable activity tracking devices. Several participants mentioned feeling confident that most veterans they know would benefit greatly from owning a wearable device and cited financial restraints as the primary reason why they had not previously owned one themselves. When asked about potential barriers to using these devices in larger interventions for veterans, one participant stated: “people might not be comfortable with the idea of someone else tracking their behavior” (Table 2).

Many participants reported that the device motivated them to make incremental adjustments to their behavior by providing feedback on their daily activity. One veteran explained, “When I’m out, I tend to look and see if I got a star. If it doesn’t hit the star, I know I didn’t get out much that day [...] I might take some more steps if I don’t hit the star.” This activity change was not limited to physical activity. Several participants commented on the utility of the sleep tracking ability. For example, one veteran noted, “it made me set my alarm so I don’t sleep too long. I was sleeping too long.”

When asked about how this feedback translated to behavioral change, however, participants had variable experiences and identified both opportunities and barriers to incorporating wearable activity monitors into interventions to increase physical activity (Table 2). One veteran stated, “this increased my activity 100 percent,” and he credited the device with helping him lose 9 pounds and improve control of his diabetes. However, most of the participants noted that rather than motivating them to meet a minimum level of daily physical activity, the device kept them moving on days spent out of the house. For example, one veteran said, “sometimes I set goals, sometimes I just go with it,” indicating that the device helped him more so when he was already motivated.

Lastly, veterans also expressed contrasting opinions about the potential utility of combining this device with a social incentive to increase physical activity. Several felt that it would be beneficial, and one stated that it “would be motivating and could build on the MOVE! program.” However, 2 veterans noted that a disability might prevent them from participating in such a program. For these participants, the device allowed them to set their own physical activity goals based on their physical abilities.

Table 1. Baseline participant characteristics (N=16).

Characteristic	Value
Gender, n (%)	
Female	2 (13)
Age (years), mean (SD)	61.5 (11.6)
Race or ethnicity, n (%)	
Non-Hispanic black	7 (44)
Non-Hispanic white	7 (44)
Other	2 (13)
Marital status, n (%)	
Married	6 (38)
Separated	4 (25)
Never married	6 (38)
Education, n (%)	
Completed high school or obtained General Education Diploma	8 (50)
Some college	3 (19)
Completed college	5 (31)
Annual household income, n (%)	
<US \$50,000	9 (56)
US \$50,000-100,000	7 (44)
Employment status, n (%)	
Employed full-time	4 (25)
Employed part-time	2 (13)
Not employed or retired	10 (63)
Living situation, n (%)	
Own house or apartment	8 (50)
Rent house or apartment	6 (38)
Living with friend or relative	1 (6)
Living in a shelter	1 (6)
Military service, n^a	
Between WWII and the Korean Conflict	1
The Korean Conflict (1950-1955)	1
Vietnam (1961-1975)	5
Post-Vietnam	8
1991-2001	1
After 2001	3

^aSome people served during multiple periods.

Table 2. Veteran perspectives on opportunities and barriers to using wearable activity monitors to increase physical activity.

Perspective	Opportunity	Barrier
Providing wearable activity monitors to veterans	<ul style="list-style-type: none"> “Veterans would like it because devices like that are very expensive.” 	<ul style="list-style-type: none"> “People might not be comfortable with the idea of someone else tracking their behavior.”
Efficacy of wearable activity monitors in creating a behavioral change	<ul style="list-style-type: none"> “This increased my activity 100%. I lost 9 lbs. I went from taking three meds [for diabetes] to one, and I didn't have to go on insulin.” “When I'm out I might take some more steps if I don't hit the star” “I can check when walking, sleeping. It allowed me to adjust my behavior. It made me set my alarm so I don't sleep too long. I was sleeping too long.” 	<ul style="list-style-type: none"> “When I'm out and about, I set the goals differently. Sometimes I set goals, sometimes I just go with it.”
Potential interventions combining the device with a social incentive	<ul style="list-style-type: none"> “Sometimes you need another person.” “I think [it would help]. I didn't think I'd get into the watch, but I did, so yes.” “[Being paired with another person] would be motivating and could build on the MOVE! program [which is a national weight management program designed by the Veterans Affairs National Center].” 	<ul style="list-style-type: none"> “Hypothetically I would [be willing to be paired with a partner], but my disability prevents me from doing certain things, so it would be challenging.” “I do better alone.”

Discussion

Principal Findings

In this pilot study, there were several findings that could help inform future research on using wearables to help veterans increase physical activity. First, veterans engaged in using wearable activity trackers at high rates. This was the case even though most veterans in our sample had limited prior experience with these devices. Second, population-based studies suggest that wearable activity tracking devices are more likely to be used by individuals who are females, younger, and already very physically active [9]. However, our findings suggest that if barriers to access of wearable activity tracking devices are reduced, these technologies may play a meaningful role in increasing physical activity levels among the older veteran population. Of note, several veterans mentioned that they felt other veterans in their social network would benefit from activity tracking devices.

Third, veterans felt that the wearable devices were useful for monitoring their physical activity levels, but similar to prior work [3,10], more could be done to help motivate them. For example, many veterans were interested in how these devices could be paired with use among their social networks in ways

that incentivized them to increase their activity. Future research is needed to identify the social support that would most effectively supplement the use of these devices to increase physical activity in veterans. Fourth, several participants also commented on the utility of the sleep tracking function, suggesting that this functionality could be useful to incorporate in the design of future interventions [11].

Limitations

Our findings are limited by a small sample size from a single Veterans Affairs facility. However, this is one of the first evaluations of its kind among veterans and suggests that if programs are well designed, these devices could play a meaningful role in helping veterans change their physical activity behavior.

Comparison With Prior Work

Despite the growing body of literature on the potential of wearable activity tracking devices, few studies have explored their potential use among veterans.

Conclusions

Wearable activity tracking devices have the potential to be used in interventions targeting increased physical activity levels in veterans.

Acknowledgments

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Conflicts of Interest

MSP is supported by career development awards from the Department of Veterans Affairs HSR&D and the Doris Duke Charitable Foundation. MSP is the founder of Catalyst Health, a technology and behavior change consulting firm. He also has received research funding from Deloitte, which is not related to the work described in this manuscript.

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Abbreviations

CMC VAMC: Corporal Michael J Crescenz Veterans Affairs Medical Center

VHA: Veterans Health Administration

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Original Paper

The iPrevent Online Breast Cancer Risk Assessment and Risk Management Tool: Usability and Acceptability Testing

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Abstract

Background: iPrevent estimates breast cancer (BC) risk and provides tailored risk management information.

Objective: The objective of this study was to assess the usability and acceptability of the iPrevent prototype.

Methods: Clinicians were eligible for participation in the study if they worked in primary care, breast surgery, or genetics clinics. Female patients aged 18-70 years with no personal cancer history were eligible. Clinicians were first familiarized with iPrevent using hypothetical paper-based cases and then actor scenarios; subsequently, they used iPrevent with their patients. Clinicians and patients completed the System Usability Scale (SUS) and an Acceptability questionnaire 2 weeks after using iPrevent; patients also completed measures of BC worry, anxiety, risk perception, and knowledge pre- and 2 weeks post-iPrevent. Data were summarized using descriptive statistics.

Results: The SUS and Acceptability questionnaires were completed by 19 of 20 clinicians and 37 of 43 patients. Usability was above average (SUS score >68) for 68% (13/19) clinicians and 76% (28/37) patients. The amount of information provided by iPrevent was reported as "about right" by 89% (17/19) clinicians and 89% (33/37) patients and 95% (18/19) and 97% (36/37), respectively, would recommend iPrevent to others, although 53% (10/19) clinicians and 27% (10/37) patients found it too long. Exploratory analyses suggested that iPrevent could improve risk perception, decrease frequency of BC worry, and enhance BC prevention knowledge without changing state anxiety.

Conclusions: The iPrevent prototype demonstrated good usability and acceptability. Because concerns about length could be an implementation barrier, data entry has been abbreviated in the publicly available version of iPrevent.

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KEYWORDS

clinical decision support; breast cancer; BRCA1 gene; BRCA2 gene; risk; preventive health; screening

Introduction

Breast cancer (BC) is a major public health problem, accounting for over 2 million cases worldwide each year [1]. In addition to population-based educational and public health policy interventions to minimize exposure to modifiable BC risk factors and optimize cancer screening, identifying women at increased risk and implementing risk-stratified, evidence-based prevention and intensified screening strategies for them is a priority [2]. Health care providers often have difficulty assessing and communicating BC risk as well as the absolute benefits and disadvantages of risk management interventions such as risk-reducing medication, surgery, and cancer screening [3,4].

Several tools exist to estimate BC risk based on personal risk factors, but none provides risk-adapted, individually-tailored, risk management information [5,6]. iPrevent was designed to help women and their health care providers, including primary care physicians (PCP), breast surgeons (BS), and genetics clinicians (GC), to assess and manage BC risk collaboratively [7]. It integrates BC risk estimation, using either the International Breast Cancer Intervention Study model or the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm model (as appropriate for the woman's risk factors), with tailored risk management information [8-10].

iPrevent users are first given a qualitative risk estimate according to Cancer Australia definitions: average or slightly above average risk (<1.5 times population risk at that age), moderately increased risk (1.5-3 times population risk), or high risk (>3 times population risk) [11]. Women can then choose to see their risk information displayed as a percentage, a pictogram, and a graph. Women are also provided with a menu of risk management strategies appropriate to their risk category, based on Australian National Guidelines [11], with more detailed optional information about each strategy, including estimates of the absolute (rather than relative) risk reductions for each medical and surgical intervention and tailored lifestyle advice.

The aims of this pilot study of patients and their clinicians were to assess the iPrevent prototype with regard to its clinical usability and the acceptability of its content and layout and to identify potential barriers to its implementation. Exploratory aims included assessing its potential impact on patient risk perception, anxiety, BC worry, and BC prevention knowledge.

Methods

Study Setting

Stage 1 piloting was undertaken by the researchers with women who had previously received risk assessment and risk management advice at the Peter MacCallum Cancer Centre

(PMCC) Breast and Ovarian Cancer Risk Management Clinic [12]. Stage 2 piloting involved PCP, BS, and GC in public hospitals and private primary care and breast and genetics clinics as well as their patients. Patients and clinicians were not selected according to their level of BC risk or prior experience with BC risk assessment.

Eligibility Criteria

Eligible patients were women aged 18-70 years with no personal history of cancer who provided written informed consent. Patients with previous risk-reducing bilateral mastectomy or major medical comorbidities were excluded. Eligible clinicians were PCP, BS, or GC with a workplace computer with Web access. English proficiency was required for all participants. This study was approved by the Human Research and Ethics Committees of the University of Melbourne and the PMCC. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Stage 1: Piloting on Patients With Prior Risk Assessment

We enrolled 10 patients from the PMCC Breast and Ovarian Cancer Risk Management Clinic. Baseline information on age, education, computer literacy [13], and both the perceived BC risk category (average, somewhat increased, or substantially increased) [11] and perceived percentage lifetime BC risk were collected. Patients then used iPrevent under the supervision of a research assistant (PW or ES). The time for data input was recorded. Patients were emailed the report in a PDF format. Two weeks after using iPrevent, they completed a questionnaire assessing usability and acceptability of iPrevent, knowledge, and psychosocial outcomes. They could review the emailed iPrevent output while answering these questions.

System Usability Scale

This 10-item instrument [14] uses a 5-point Likert rating scale from "strongly agree" to "strongly disagree" to measure product usability. It is applicable to small samples [15] and correlates well with other subjective measures of usability [16,17]. Final scores range from 0-100, and a System Usability Scale (SUS) score >68 is considered above average.

iPrevent Acceptability Questionnaire

This 9-item measure, adapted from a previous evaluation of a decision aid [18], uses Likert scales to elicit perceptions of the length, clarity, balance, and usefulness of iPrevent.

Breast Cancer Risk Perception

This single item, adapted from a study measuring the impact of genetic counseling, asks patients about their BC risk category: “average,” “somewhat increased,” or “substantially increased” [19]. Women were classified as underestimators, accurate estimators, or overestimators based on comparison with the risk estimated by iPrevent.

Breast Cancer Worry Scale

The Lerman BC worry scale is a 3-item scale. Higher scores indicate increased frequency and impact of worry [20].

Spielberger State-Trait Anxiety Inventory

The short form State-Trait Anxiety Inventory (STAI; 6 items) measures state anxiety; higher scores indicate higher anxiety [21].

Breast Cancer Prevention Knowledge

We used 16 items assessing knowledge regarding BC (11 items), risk-reducing medication (3 items), and risk-reducing mastectomy (2 items), which were adapted from published knowledge measures (see [Multimedia Appendix 1](#)) [22,23]. Although every woman was asked to answer all questions, the number of responses scored for each participant was dependent on the iPrevent-determined risk category. All average-risk women and moderate-risk women who were aged <35 years were assessed only on BC knowledge questions. Older, moderate-risk women were also assessed on risk-reducing medication questions. High-risk women were assessed on all 16 questions. The proportion of correct responses was calculated.

Stage 2: Piloting With Clinicians and Their Patients

We recruited 20 clinicians from previous focus groups [3-4] (5 BS and 3 PCP), via email invitation from KAP (1 BS and 6 GC), and through the PMCC PCP liaison officer (5 PCP). Clinicians first underwent an iPrevent “familiarization” session. Supervised by a research assistant (PW or ES), clinicians first entered data into iPrevent on 3 hypothetical patients (high, moderate, and average risk) and reviewed the iPrevent output information. On the same day, clinicians then conducted 2 mock consultations with female actors: one at high risk and the other moderate risk. Patient (actor) information was pre-entered into iPrevent, and clinicians were asked to use the iPrevent output with the actors as they might in a clinical consultation.

Clinicians were then asked to invite 3 eligible patients from their practice (either during patient appointments or via telephone prior) during the following 3 months to participate by entering their information into iPrevent prior to a consultation and attending an appointment with the clinician to receive the “output.” Patients were provided a printout of their iPrevent output via email. Clinicians recorded the amount of time spent using iPrevent.

All patients were asked to complete the same pre- and post-iPrevent assessments as in Stage 1. Clinicians completed the SUS and Acceptability questionnaires 2 weeks after recruitment of 3 patients (or 3 months after familiarization, if full patient recruitment did not occur).

Statistical Analyses

All statistical analyses were performed in R 3.2.3 (R Core Team, 2015). The planned sample size of 20 clinicians and 60 patients was based on pragmatic estimates of the numbers it was considered possible to recruit over the available time period. The purpose of the study was to assess the acceptability and usability of iPrevent for clinicians and patients and not to test hypotheses. Therefore, descriptive statistics were used to summarize the data (mean, median, and range for continuous variables and counts and percentages for categorical variables). Patient and clinician data were analyzed separately. A pairwise *t* test was used to assess whether the STAI score changed from pre- to post-iPrevent assessment.

Results

Participants

We recruited 20 clinicians and 43 patients (10 for Stage 1 and 33 for Stage 2). Clinicians only recruited 33 of the planned 60 patients (planned 3 per clinician). BS (n=6) recruited 16 of a planned 18 patients, GC (n=6) recruited 14 of a planned 18 patients (1 GC moved overseas during the study and was, thus, unable to recruit her 3 planned patients), and PCP (n=8) recruited only 3 of a planned 28 patients.

Participant Characteristics

Patient characteristics are shown in [Table 1](#). Median age was 38 years (range 21-56 years), 74% (31/42) had a university education, and 51% (22/43) were at moderate risk for BC. Clinician characteristics are shown in [Table 2](#). Their median age was 47 years (range 28-66 years); of all clinicians, 40% (8/20) were PCP, 30% (6/20) were BS, and all but 15% (3/20) were females. The majority used computers often and rated themselves as having good computer skills.

iPrevent Data Entry and Consultation Times

Patients took a median of 15 (range 5-60) minutes to enter their risk factor data. The median time taken for clinician consultations in which iPrevent data were discussed was 20 (range 5-45) minutes.

System Usability Scale

SUS responses are summarized in [Figure 1](#). Data were missing for 6 patients and 1 clinician who did not return the questionnaire. Overall, 76% (28/37) patients and 68% (13/19) clinicians rated iPrevent usability as above average (SUS score >68).

Table 1. Patient characteristics (N=43).

Characteristic	Value
Age in years ^a , median (range)	38 (21-56)
Highest level of education, n (%)^a	
Secondary school	6 (14)
Vocational training	5 (12)
University	31 (74)
Use of computers at work or elsewhere, n (%)^a	
Often	33 (79)
Sometimes	8 (19)
Rarely	1 (2)
Computer skills (self-reported), n (%)^a	
Expert	9 (21)
Good	29 (69)
Poor	4 (10)
Sources of information on breast cancer (BC) risk in the past, n (%)^a	
Health professional	30 (71)
Family and friends	19 (45)
Internet	10 (24)
Health information booklets	6 (14)
Support organizations	4 (10)
BC risk category estimated by iPrevent, n (%)	
Average	14 (33)
Moderate	22 (51)
High	7 (16)
“Do you feel like you know what your own risk of breast cancer is?” n (%)^b	
Don't know my risk	12 (29)
I think I know my risk	25 (61)
Confident I know my risk	4 (10)

^aData missing for 1 patient.

^bData missing for 2 patients.

Table 2. Clinician characteristics (N=20).

Characteristic	Value
Age in years, median (range)	47 (28-66)
Gender, n (%)	
Female	17 (85)
Male	3 (15)
Year of graduation, n (%)	
1970-1979	1 (5)
1980-1989	7 (35)
1990-1999	4 (20)
2000-2009	7 (35)
2010-2015	1 (5)
Specialty, n (%)	
Breast surgeon	6 (30)
Genetic counselor	3 (15)
Geneticist	2 (10)
Primary care physician	8 (40)
Medical oncologist	1 (5)
Number of years working in specialty, median (range)	16 (1-34)
How many patients per year would you discuss breast cancer risk with? Median (range)	138 (4-960)
Use of computers at work or elsewhere, n (%)	
Often	20 (100)
Sometimes	0 (0)
Rarely	0 (0)
Computer skills (self-reported), n (%)	
Expert	0 (0)
Good	18 (90)
Poor	2 (10)

Figure 1. iPrevent System Usability Scale scores for clinicians and patients.

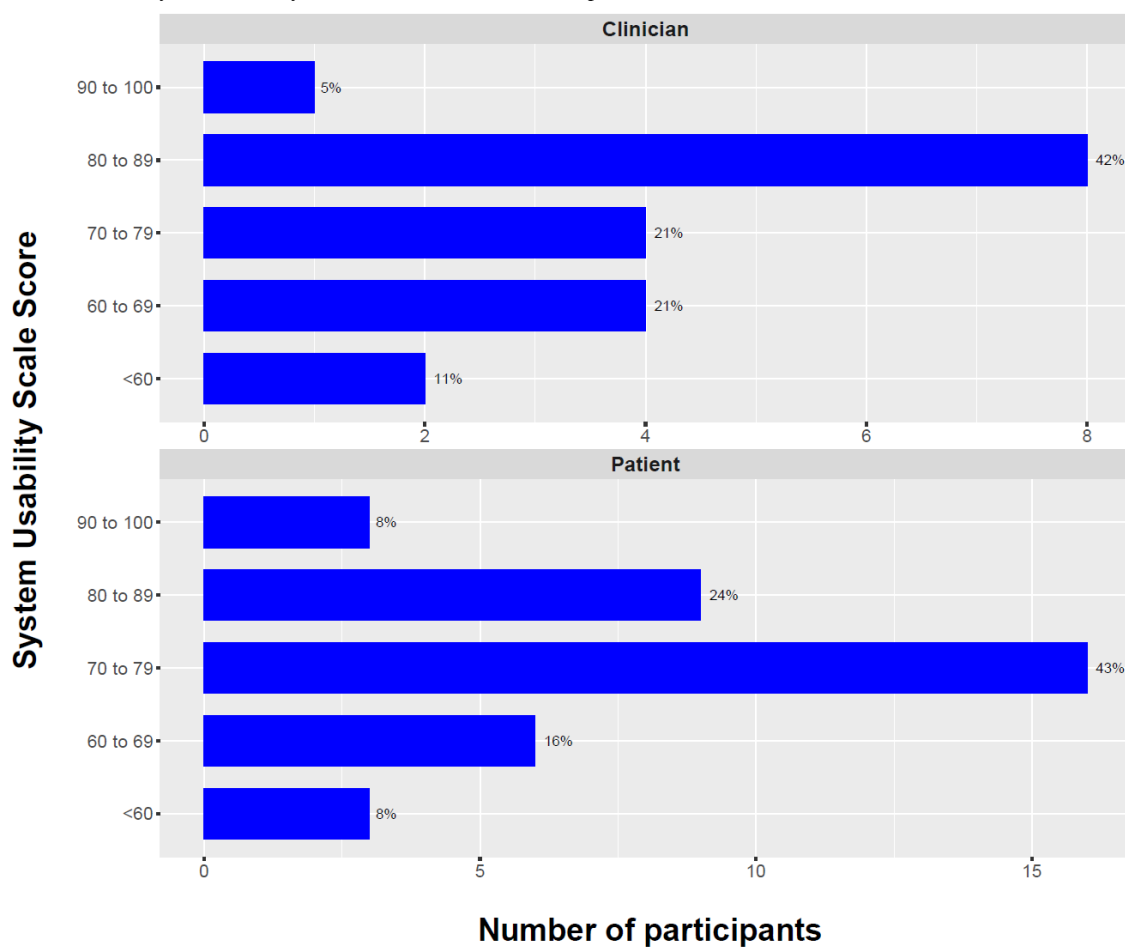


Table 3. iPrevent acceptability among clinicians and patients.

Acceptability assessment	Clinician, n (%)	Patient, n (%)
The amount of information provided is^{a,b}		
Too much	0 (0)	1 (3)
A little too much	2 (11)	3 (8)
About right	17 (89)	33 (89)
The length of the tool is^{a,b}		
Much too long	4 (21)	0 (0)
A little too long	6 (32)	10 (27)
About right	9 (47)	27 (73)
Clarity of information^{a,b}		
Very clear	8 (42)	7 (19)
Mostly clear	5 (26)	16 (43)
About right	5 (26)	13 (35)
Not clear	1 (5)	1 (3)
Regarding cancer prevention, how balanced did the information seem^{b,c}		
Biased toward prevention	3 (17)	9 (24)
Completely balanced	14 (78)	26 (70)
Biased against prevention	1 (6)	2 (5)
Any of the information new to you^{a,b}		
All	0 (0)	1 (3)
Most	0 (0)	11 (30)
Some	12 (63)	22 (59)
None	7 (37)	3 (8)
How helpful with regard to making a decision about BC risk management^{a,b}		
Very helpful	9 (47)	19 (51)
Somewhat helpful	7 (37)	13 (35)
A little helpful	3 (16)	5 (14)
Recommend this tool to others^{a,b}		
Definitely	12 (63)	18 (49)
Probably	6 (32)	18 (49)
Probably not	1 (5)	1 (3)
How simple to navigate through the tool^{a,b}		
Very easy	7 (37)	21 (57)
Somewhat easy	11 (58)	15 (41)
Not easy	1 (5)	1 (3)
Easy to read^{a,b}		
Very easy	8 (42)	22 (59)
Somewhat easy	11 (58)	15 (41)

^an=19 clinicians because of missing data for 1 clinician.

^bn=37 patients because of missing data for 6 patients.

^cn=18 clinicians because of missing data for 2 clinicians.

iPrevent Acceptability Questionnaire

Table 3 shows that iPrevent was generally acceptable to study participants. Of all, 89% (17/19) clinicians and 89% (33/37) patients reported that the amount of information provided by iPrevent was “about right.” Furthermore, 53% (10/19) clinicians and 27% (10/37) patients reported that iPrevent was too long. Only 1 patient and 1 clinician reported that the information was not clear and that they would “probably not” recommend iPrevent to others.

Exploratory Endpoints

Breast Cancer Risk Perception

Of patients who completed the relevant questions before iPrevent, 40% (14/35) correctly indicated their BC risk category, but 51% (18/35) overestimated and 9% (3/35) underestimated their BC risk category. Post-iPrevent, 86% (30/35) accurately estimated their risk category, although 11% (4/35) and 3% (1/35) continued to overestimate and underestimate their risk, respectively.

Breast Cancer Worry Scale

Pre-iPrevent, 26% (11/42) women reported worrying about BC “often” or “all the time,” while 19% (7/37) women reported this after iPrevent. Regarding the impact of BC worry on mood and daily activities, 69% (29/42) patients reported a low score (1-1.5 out of 4) pre-iPrevent. When this was compared before and after iPrevent, 25% (9/36) patients reported less impact, 47% (17/36) reported no change, and 28% (10/36) reported more impact.

Spielberger State-Trait Anxiety Inventory

The mean short form STAI score (maximum 24) pre-iPrevent was 11.3 (SD 3.8) with no significant change post-iPrevent (median increase of 1, 95% CI: 0.5-2; $P=$.14).

Breast Cancer Prevention Knowledge

Overall BC prevention knowledge improved for all risk groups. (Multimedia Appendices 1 and 2).

Discussion

This pilot study of the iPrevent prototype has found good usability and acceptability without evidence of an adverse impact on anxiety or BC worry. The observation that the 8 PCP recruited only 3 patients between them in the required 3-month period suggests that implementation of iPrevent into primary care might be substantially more challenging than implementation into the specialist setting, where recruitment of patients was much higher. Another interpretation is that the study requirements (eg, obtaining written informed consent) were onerous, especially for PCP in busy practices, and thus, the low recruitment by PCP in this study might not reflect the uptake of iPrevent in routine practice. However, as earlier focus groups had highlighted that PCP generally do not see BC risk

assessment and management as being in their domain, iPrevent might be able to contribute to overcoming provider unfamiliarity and lack of confidence for this group of clinicians [3].

The prototype was considered too long by a majority of clinicians and some patients, indicating another potential barrier to implementation. Patients took a median of 15 minutes and up to 60 minutes to enter their risk factor data, and the subsequent median time taken for the clinician consultation using the iPrevent output was 20 minutes. To address this issue, we have now incorporated changes to streamline the data entry for family history. This study also highlighted the need for patients to be able to enter their data into iPrevent at home prior to a consultation.

iPrevent may improve BC risk perception given an additional 46% (16/35) patients accurately estimated their BC risk category after using iPrevent. As a higher perceived risk of BC is associated with considering medical prevention and risk-reducing surgery among high-risk women [24-26], iPrevent could become a potential behavior-modifying tool. While this pilot study provides no information about the uptake of risk management strategies after using iPrevent, this issue will be an important endpoint for future larger studies. Other studies have found that women who have access to more thorough information from genetic counselors, combined with support to make decisions, have a higher uptake of risk reduction methods [27-29]; thus, we hypothesize that iPrevent might have a similar impact.

Use of iPrevent did not appear to increase patient worry or anxiety, consistent with the literature that has found that decreased anxiety and better psychological outcomes are associated with improved accuracy of perceived risk [24,30,31]. Use of iPrevent seemed to improve BC knowledge, a recognized critical first step in helping individuals understand screening options, weigh potential benefits and risks for risk-reducing measures, and make informed decisions [32-34]. In addition, 89% (33/37) patients indicated that some or most of the information contained in iPrevent was new to them (Table 3).

This pilot had several limitations. First, the sample was small and the study did not achieve its target patient recruitment. The majority of patients were young and highly educated, so the acceptability and usability of iPrevent might differ in the general community where computer literacy might be lower. Similarly, clinicians who chose to participate could have been more highly engaged with BC risk assessment and risk management than nonparticipant clinicians. Finally, only short-term outcomes were measured, and the impact on long-term satisfaction and uptake of BC risk-reducing measures could not be determined. As a result of this study, enhancements have been made to iPrevent with the aim of further increasing acceptability and usability.

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Conflicts of Interest

The International Breast Cancer Intervention Study model is offered for commercial use by Cancer Research UK, and JC receives a portion of the derived royalties. All other authors of this paper have declared no conflict of interest.

Multimedia Appendix 1

Breast Cancer Prevention Knowledge Questionnaire.

[[PDF File \(Adobe PDF File\), 40KB - formative_v2i2e24_app1.pdf](#)]

Multimedia Appendix 2

Results of Pre- and Post-iPrevent® Knowledge Questionnaire.

[[PDF File \(Adobe PDF File\), 118KB - formative_v2i2e24_app2.pdf](#)]

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Abbreviations

BC: breast cancer

BS: breast surgeon(s)
GC: genetics clinician(s)
PCP: primary care physician(s)
PMCC: Peter MacCallum Cancer Centre
STAI: State-Trait Anxiety Inventory
SUS: System Usability Score

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Original Paper

Assessing the Needs and Perspectives of Patients With Asthma and Chronic Obstructive Pulmonary Disease on Patient Web Portals: Focus Group Study

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Abstract

Background: As accessibility to the internet has increased in society, many health care organizations have developed patient Web portals (PWPs), which can provide a range of self-management options to improve patient access. However, the available evidence suggests that they are used inefficiently and do not benefit patients with low health literacy. Asthma and chronic obstructive pulmonary disease (COPD) are common chronic diseases that require ongoing self-management. Moreover, patients with COPD are typically older and have lower health literacy.

Objective: This study aimed to obtain and present an overview of patients' perspectives of PWPs to facilitate the development of a portal that better meets the needs of patients with asthma and COPD.

Methods: We performed a focus group study using semistructured interviews in 3 patient groups from the north of the Netherlands who were recruited through the Dutch Lung Foundation. Each group met 3 times for 2 hours each at a 1-week interval. Data were analyzed with coding software, and patient descriptors were analyzed with nonparametric tests. The consolidated criteria for reporting qualitative research were followed when conducting the study.

Results: We included 29 patients (16/29, 55% male; mean age 65 [SD 10] years) with COPD (n=14), asthma-COPD overlap (n=4), asthma (n=10), or other respiratory disease (n=1). There was a large variation in the internet experience; some patients hardly used the internet (4/29, 14%), whereas others used internet >3 times a week (23/29, 79%). In general, patients were positive about having access to a PWP, considering access to personal medical records as the most important option, though only after discussion with their physician. A medication overview was considered a useful option. We found that communication between health care professionals could be improved if patients could use the PWP to share information with their health care professionals. However, as participants were worried about the language and usability of portals, it was recommended that language should be adapted to the patient level. Another concern was that disease monitoring through Web-based questionnaire use would only be useful if the results were discussed with health care professionals.

Conclusions: Participants were positive about PWPs and considered them a logical step. Today, most patients tend to be better educated and have internet access, while also being more assertive and better informed about their disease. A PWP could support these patients. Our participants also provided practical suggestions for implementation in current and future PWP developments.

The next step will be to develop a portal based on these recommendations and assess whether it meets the needs of patients and health care providers.

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KEYWORDS

asthma; chronic obstructive pulmonary disease; health care; health literacy; internet; electronic medical record; self-management

Introduction

Self-Management

Annually, 38 million people worldwide die from noncommunicable diseases caused by unhealthy lifestyles. These diseases are chronic [1], and most are suitable for long-term self-management by self-monitoring, lifestyle changes, and symptom control. The aim of self-management is to improve physical, social, and mental well-being [2]. However, this requires the involvement of patients with their disease, which necessitates a greater understanding of their disease [3]. It has been shown that 60% of Europeans look for health information over the Web and almost 90% of these are satisfied with their findings [4]. Internet use has become increasingly important in health care, with the ever-increasing potential to improve outcomes [5,6]. Many Web-based tools have therefore been developed to support patient self-management, including smartphone apps, information websites, and patient Web portals (PWP).

Patient Web Portals

A PWP is a secure website provided by a health care provider, which serves as a gateway to services ranging from access to health records to the ability to contact a health care provider or make appointments over the Web [7]. Through apps, PWPs can provide these services that enhance patient involvement in care [8] and can provide tailored and timely information [9] by linking health information to medical records [10]. Many disease-specific portals exist (eg, mental illness and diabetes) [11], but portals have also been developed to present overviews of radiology reports [12] or reconcile medication regimens after hospital discharge [13].

Research into the benefits of PWPs is conflicting. Some research has shown the benefits of PWPs on disease status, patient satisfaction, or self-management, whereas others have shown no change in these parameters. Unfortunately, service accessibility varies significantly from easy to difficult [14]. One systematic review showed that self-management, communication [15], or medication adherence improved in some studies, but that there was no significant change in other studies [16,17]. Another problem is that studies have lacked clear outcome measures for the effect of the PWP [16]. Despite these shortcomings, PWPs have been associated with positive outcomes in the treatment of diabetes and hypertension [18-23] and have been shown to improve self-management and patient-physician communication [11,15]. Indeed, PWPs in psychiatric services can increase feelings of autonomy and improve appointment attendance [24,25], while in patients with osteoporosis, PWPs can improve self-management decisions

[26]. However, PWP is known to decline over time, with long-term adherence often being poor [27].

Digital Divide

The digital divide is the phenomenon where younger and more highly educated patients are more likely to use digital technology compared with their older and less-educated peers [15,27,28]. Health literacy, the ability to acquire, read, and understand health information to make appropriate health decisions [29], also needs to be taken into account when developing a PWP. Health numeracy, which can be unrelated to health literacy, is the ability to understand numeric results (eg, lab results). This is compounded because most people overestimate their numeric skills [30]. These issues have huge implications for the presentation of test results and medication advice [31] in a PWP.

The elderly are less likely to use digital technology because of security concerns and the increased effort needed to learn the technology. Motivation, negative attitudes, and satisfaction are other important predictors of PWP use in this context [32,33]. This is important to take into account because a typical population suffering from chronic obstructive pulmonary disease (COPD) has an average age of 67 years [34]. However, Dutch elderly are experienced internet users. In the Netherlands, 71% of citizens between 65 and 74 years are daily internet users; this is far above the average European internet usage of people between 65 and 74 years, which is 39% [35,36].

Patients from low socioeconomic groups are less likely to have internet experience because of health literacy or financial barriers [11,23,32]. This is important information for this paper because COPD and asthma are more prevalent in low socioeconomic populations [37,38]. Minorities and patients with low socioeconomic and educational status are difficult to reach through a PWP [11,18,32,37]. This is concerning because these groups are most prone to having chronic conditions and poor lifestyle behaviors [38].

When building a PWP, developers must take these difficulties into account [38-42]. A PWP should be accessible, understandable, and easy to use [39], especially for older adults [38] and patients with little or no internet experience [14]. Moreover, organizational commitment is needed to ensure successful implementation [9,43,44], focusing on training health care professionals in the proper use of the PWP [15]. Patients can be encouraged to use the PWP by improving immediacy and personalization of the content [45]. To achieve these aims, end users should advise developers [42].

Aims

Asthma and COPD are common chronic respiratory illnesses that require ongoing self-management. These patients might be supported by a PWP. In this study, we aimed to evaluate the

needs and perspectives of patients with asthma or COPD regarding PWPs to facilitate the development of future PWPs adapted to the needs of end users. Specifically, we evaluated their opinions regarding the daily effects of asthma and COPD, internet and health care use, access to medical records, suitable apps, and the relationship between patient and physician. We followed the consolidated criteria for reporting qualitative research [45].

Methods

Study Design

Participants

Participants were recruited through a patient organization (the Dutch Lung Foundation). Most of them lived in low socioeconomic areas in the north of the Netherlands. We chose to include these areas because patients with low socioeconomic status are often not included in scientific studies. To develop a PWP for this population, it is essential to also include patients with low social economic status. If the portal is understandable and usable for this group, it will be for all patients. We even picked up patients by car if they did not have transportation possibilities to attend the meetings. All participants signed informed consent. The Ethics Committee of the University Medical Center Groningen deemed that the study was not subject to the requirements of the Dutch legislation on “Medical Research Involving Human Subjects” (M13.139696).

Structure of the Focus Group Meetings

The focus groups were conducted by a psychologist or an epidemiologist trained for that purpose. Participants were placed in 3 groups according to where they lived, and attended 3 meetings at an average weekly interval. Each meeting lasted 2 hours with a 10-minute break half-way through. Meetings took place in 2013 and 2014 at easily accessible locations. All meetings were audiorecorded and videorecorded. Participant involvement was encouraged by providing regular newsletters about the status of the study. Figure 1 provides an overview of the meetings.

Focus Group Interview Structure

This is a qualitative study aiming at evaluating the needs and opinions of patients with asthma or COPD. Qualitative studies are exploratory. The aim was to get insight into the needs and opinions of participants. The results were provided by the focus groups, not by individual participants. It was, therefore, not possible to count the opinions of our participants. We can quantify patients’ opinions in future studies with the results of this study as the starting point.

We used semistructured interview schedules covering “Internet and health care,” “Access to personal medical records,” “Patient-physician relationship,” “Features,” and “Self-management.” Videos and PowerPoint slides were used to introduce and explain different topics. We alternated group discussions with individual assignments in which participants had to write their thoughts on post-it notes, which were then used as the starting points for further group discussion.

Figure 1. Overview of the focus group meetings and the discussed topics. COPD: chronic obstructive pulmonary disease.



Hypothetical Patient Web Portal Used for the Discussion About Features

Patients in this study had no access to a PWP. Their opinions were based on a hypothetical PWP. The findings will be used to build a PWP in an integrated primary care system for respiratory patients. We discussed commonly provided portal features and used a video with an example of a PWP from a Dutch hospital to enhance the discussion about “Features.” The features presented in this video [46] are shown in [Textbox 1](#).

Participant Characteristics Questionnaire

Before the group meetings, participants received a purpose-developed questionnaire that consisted of 12 multiple-choice questions and 3 open questions. This was used to collect information about demographics, internet use,

education, and medical history and could be answered on the Web or paper.

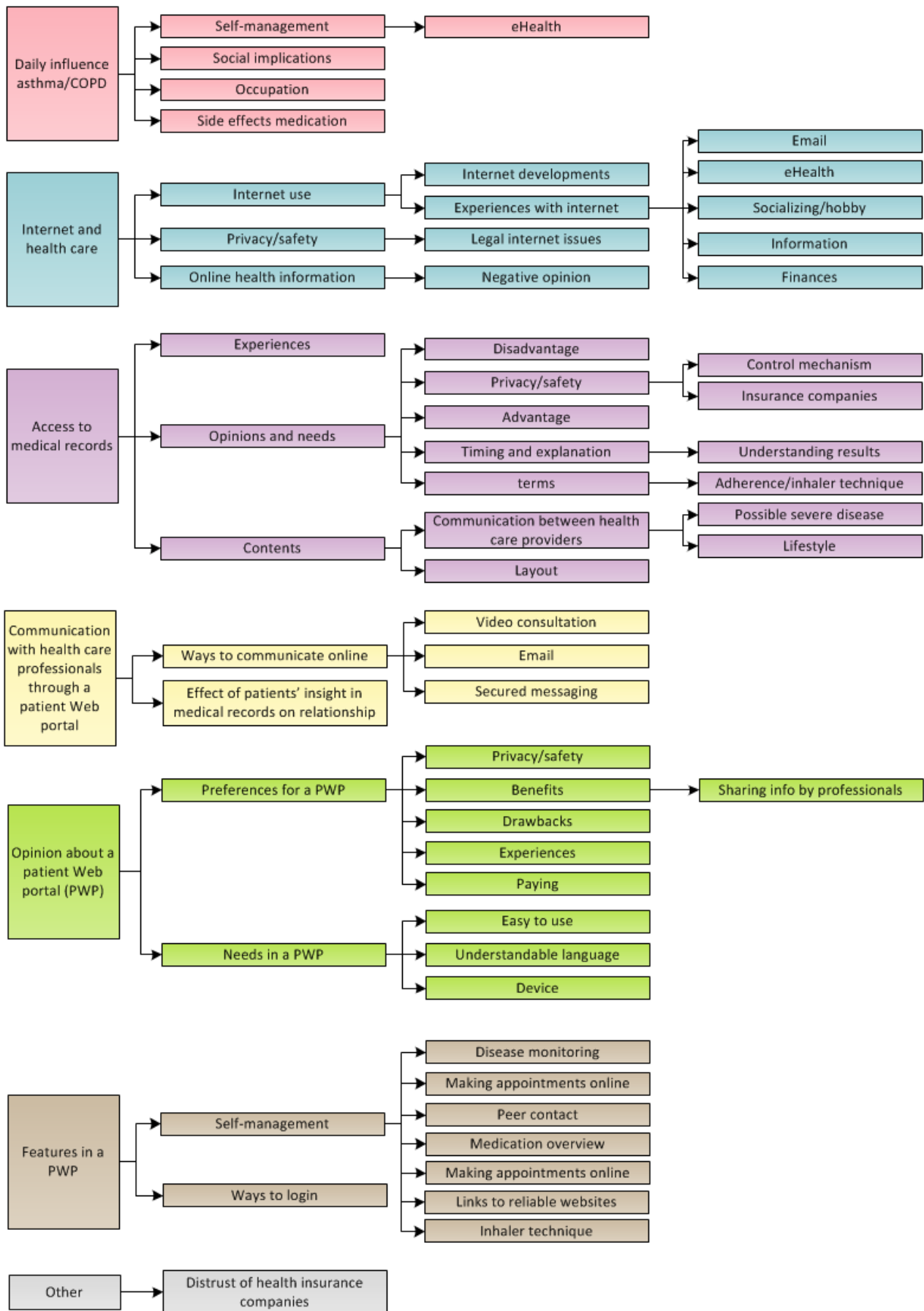
Data Analysis

All recordings were transcribed verbatim and thematically coded by 2 researchers independently using Kwalitan Version 7. After the decoding procedure, a consensus was reached between the researchers. We used the following 6 thematic codes ([Figure 2](#)): (1) daily influence of asthma and COPD; (2) internet and health care; (3) access to personal medical records; (4) communication with health care professionals; (5) opinion about a PWP; and (6) preferred self-management features. We used IBM SPSS Version 22 (IBM Corp, Armonk, NY, USA) for the descriptive analysis. Data are presented as mean and SDs. Differences in characteristics between frequent and infrequent internet users were compared by nonparametric tests.

Textbox 1. Features from the patient Web portal video that were used for the discussion.

- Logging in
- Web-based access to medical records
- Information about examinations and treatments
- Hospital appointments
- X-ray results
- Laboratory results
- Chatting with other patients
- Asking questions at a secured forum
- Contact with health care provider
- Medication monitoring
- Disease monitoring

Figure 2. Overview of the different codes. COPD: chronic obstructive pulmonary disease.



Results

Summary

The results section provides an overview of demographics and qualitative results. The qualitative results are divided into the main research topics. [Textbox 2](#) summarizes the content of the results section.

Focus Group Characteristics

We included 29 Dutch-speaking adults, and their characteristics are summarized in [Table 1](#); 23 participants who used the internet >3 times a week were on average younger (mean age 65.2 (SD 8.5) years) than the 6 who used the internet <4 times a week (mean age 74.3 (SD 10.9) years; Kruskal-Wallis test: $P=.02$). All but one participant regularly used email. Several older participants also reported taking computer courses.

Daily Influence of Asthma and Chronic Obstructive Pulmonary Disease

Occupational and Daily Life Restrictions

All participants experienced restrictions in daily life, especially in physical activities:

The list of things you can do gets shorter while the list of things you cannot do gets longer.

Several patients needed to quit working because of asthma or COPD. Differences were described between those with asthma and COPD:

We asthma patients have good times and troubled times. And you [COPD patients] always have bad times.

Self-Management Can Improve Symptoms of Asthma and Chronic Obstructive Pulmonary Disease

Planning was also made difficult because symptoms and fatigue can vary from day to day. Patients frequently mentioned the need to plan activities: "It [energy] is like money, you can only spend it once." Participants also commented on the need to adapt their lifestyles (eg, smoking cessation, regular exercise, or physiotherapy). Typical for patients with asthma and COPD is the need to avoid triggers or other symptom-provoking triggers (eg, fires and barbecues in winters and summers, respectively).

Textbox 2. Overview of the topics in the results section (Focus group characteristics). COPD: Chronic Obstructive Pulmonary Disease.

- Topic 1: Daily influence of asthma and COPD
- Topic 2: Internet and health care
- Topic 3: Access to personal medical records
- Topic 4: Communication with health care professionals
- Topic 5: Opinion about a patient Web portal
- Topic 6: Features in a patient Web portal
- Other

Side Effects of Inhaled Medication

Comorbidities were prevalent in our groups, and the medication use was considered important for good self-management. However, many participants reported side effects of the inhaled medication, including stridor, bruises, and cramps. Most patients discussed this with their physicians or pharmacists. Sometimes patients received other medication to reduce the side effects.

Social Implications of Asthma and Chronic Obstructive Pulmonary Disease

Asthma and COPD have social implications because they are invisible and the severity varies:

People do not see many signs of illness, but...I have to deal with my chronic condition [daily].

Specific for this patient population is the fact that environmental air can provoke symptoms. Participants explained that they experienced difficulties because others do not understand how allergens like smoke can exacerbate symptoms. They often feel not supported in their avoidance of triggers, which can lead to social isolation because others do not want to adapt their behavior (eg, quit smoking). Moreover, COPD is mostly caused by smoking and others might see the disease as self-inflicted, which leads to stigmatization.

Internet and Health Care

Internet Use and Experience of Patients

The internet was often used to search for information (eg, "If I want to know something, I will look it up"), watch movies, read newspapers, or play games. Others mentioned using Skype, internet banking, Web shops, or second-hand markets. Infrequent internet users were not willing to learn new uses:

The problem is that everything works different...each time you have to put effort in learning again, and I don't want that.

Some participants had used Web-based health apps, with one using a COPD app provided by their pharmacist; however, he was dissatisfied because he felt that the pharmacist collected his data. Another participant was satisfied with a nutritional app. Some participants valued YouTube movies about inhaler techniques.

Table 1. Patient characteristics of the focus groups participants (N=29) with COPD (n=14), asthma-COPD overlap (n=4), and asthma (n=10).

Characteristic	Total groups	Group I Groningen (n=8)	Group II Emmen (n=11)	Group III Assen (n=10)
Age in years, mean (SD)	67.1 (9.6)	63.8 (9.9)	67.8 (9.7)	68.9 (9.7)
Gender (male), n (%)	16 (55)	5 (63)	5 (46)	6 (60)
Diagnoses, n (%)				
Asthma	10 (35)	2 (25)	6 (55)	2 (20)
COPD ^a	14 (48)	5 (63)	2 (18)	7 (70)
ACO ^b	4 (14)	1 (13)	2 (18)	1 (10)
Other	1 (3)	N/A ^c	1 (9)	N/A
Internet use, n (%)				
<4 d/wk	6 (21)	1 (13)	3 (27)	2 (20)
≥4 d/wk	23 (79)	7 (88)	8 (73)	8 (80)
Education level, n (%)				
Low	9 (31)	2 (25)	3 (27)	4 (40)
Medium	13 (41)	4 (38)	3 (27)	6 (60)
High	12 (41)	3 (38)	6 (55)	3 (30)

^aCOPD: chronic obstructive pulmonary disease.

^bACO: asthma-COPD overlap.

^cN/A: not applicable.

Patients' Opinions About Privacy and Safety of the Internet

Several participants were worried about the internet safety and that governmental organizations increasingly rely on the internet (eg, "Sometimes you cannot oversee the overall consequences"). This is, in part, was related to the scandals in the winter of 2014 regarding the safety and usability of these websites in the Netherlands. The government uses a digital system to communicate with citizens, and it was feared that criminals could easily access valuable information like bank account numbers. Participants were also worried that some people could not use websites, especially older people. Others were happy with this development because it makes things easier.

Patients' Experiences and Needs Regarding Web-Based Health Information

One participant searched over the Web for alternative treatments when unsatisfied with her care (eg, "Every prescribed treatment made me sicker. Therefore, I decided to [look] for myself."), but most searched for health information and information regarding upcoming treatments or examinations. One participant searched for information about Alzheimer's disease when his father was diagnosed. However, several explained that they did not feel the need to surf the Web if their disease was well controlled. A disadvantage of Web-based information was that unnecessary anxiety and worry could result from the information not being adapted to individuals. It was notable that many had difficulties finding reliable and understandable websites (eg, too many medical terms), which led to some avoiding Web-based information. Others were satisfied with links to

reliable websites that were provided by their health care provider.

Access to Personal Medical Records

Most participants wanted access to their medical records and considered this the most important requirement of a PWP. One even wanted the opportunity to change things in his record. However, some wanted no access (eg, "I know how I feel").

Experiences of Patients Who Already Have Access to Personal Medical Records

Several participants had seen their medical records on paper because they changed general practitioner (GP), were curious, or wanted to compare current and past results:

It surprised me that... when I read it, it was like it was about someone else

Health care providers sometimes doubted whether participants had the right to access their records, and in some cases, refused to provide them; this angered one participant ("This is my data!").

Patients' Opinions and Needs Regarding Accessible Personal Medical Records

Patients wanted information about prescribed medication and a summary of medical visits, stating that they often had difficulties recalling information provided during consultations:

If I visit a physician I take my wife with me and often, when we get home, I have heard something [different to] my wife.

Web-based records could also be shown by the patient to other health care providers in emergencies. It was emphasized that Web-based information should provide a clear overview of examination results, helping patients become better informed about their disease. In turn, this could help them to prepare for a medical visit and communicate about their disease. Others thought that they might be taken more seriously if they were better informed (eg, “[physicians] need to take patients more serious”).

Preferred Content in the Personal Medical Records

Crude Assessment of Results

Most participants wanted lab results, reference values, and an explanation, stating “in that way you are well informed,” and emphasizing that results should be presented in lay terms. However, there was recognition of the need to have insight, having physicians first explain the results: “You will get sick and worried if you read [medical terms]!”. Some participants were not interested in this option, feeling sufficiently well informed by their physicians; others wanted psychiatric information to be excluded. One patient tried to commit suicide years ago and did not express any desire to share his experience with other health care professionals because he considered it too personal. There was also a desire to see x-rays, but with the caveat:

...if it takes a few hours to explain what it means, then I don't want to know.

The groups often mentioned that information takes a long time to be transferred to the GP after attending hospital, meaning that the GP is not always up to date. In these instances, patients could share information with their GP.

Consideration of Physician

We discussed whether there was a desire to see if physicians wanted further examinations to exclude severe disease. Most participants wanted this information in the PWP, but to avoid anxiety and worry, only after the examination results and options had been explained (one participant wanted to know immediately, stating “[the] sooner the better”). Several participants felt it would be safer to provide patients with a summary of the findings, not with the consideration of the physician:

I want to know what is wrong with me, not what can possibly be wrong.

It was notable that some wanted both details of any interpretations and the name of the physician, so that they could approach them if they disagree.

Lifestyle Advice From the Physician

Some participants considered lifestyle recommendations from their health care professional helpful, even suggesting making these firm requirements to stimulate change. However, others would feel judged or angry (eg, “This is how they think about me”), and one even said that such remarks might stop them from going to the physician again.

Communication Between Physicians (eg, Referral Letters)

There were comments that patient access could change the way physicians communicate:

He will think: ‘wait a minute, my patient can read this too. I need to make this understandable for my patient’

Some were worried PWP might make the patient too informed (eg, “What if we [patients] ask many irrelevant questions that have already been considered by the physician?”), whereas others wanted physicians to take patients more seriously. It was recognized that this may change the communication dynamic.

Communication With Health Care Professionals

Ways to Communicate Over the Web With Health Care Professionals Though a Patient Web Portal

Some already communicated with their health care provider through the internet (eg, “mostly after I have visited a specialist I send my GP an email”). One participant explained that it is nice to know that they have the email address, even if it is never used. Some participants have been satisfied when using Skype with health care providers, but most were not familiar with the service and were negative about the possibility of using it for contact. Several disadvantages of Web-based contact were mentioned, with one being that doctors could miss information when communicating through the internet (eg, in face-to-face assessments “you can see how someone is breathing...and what your color is.”). Despite this, most participants welcomed the possibility of Web-based contact to ask health care professionals general questions about asthma or COPD. However, it was felt that Skype meetings should be short and be reserved either to evaluate whether there is an emergency or to conduct routine visits, and only if the patient was comfortable with the method.

Effect of Patients' Access on the Relation With Their Health Care Provider

Participants explained that the internet helps inform patients, which can alter the level of communication with health care professionals:

It will be easier for physicians if you know what they are talking about.

A drawback of the PWP was that physicians might not be able to judge what information to give and what to withhold, the way they might be able to in face-to-face consultations. Physicians should, therefore, be trained on how to deal with assertive and better-informed patients.

Opinions About a Patient Web Portal

Preferences of a Patient Web Portal

Opinions About Privacy and Safety

Opinions on privacy and safety varied, with some being worried (eg, “My pulmonologist does not have to see why I have visited the gynaecologist” and “who is responsible if something goes wrong?”) and others being more pragmatic (eg, “Sometimes burglars break into houses, but that didn't stop us from building houses”). All participants agreed that commercial organizations must not be granted access to data on PWPs. Some participants

would like to be able to refuse access by certain health care providers.

Benefits of Patient Web Portals

Most participants were positive about PWPs (eg, “I can’t think of negative points”), especially in terms of their potential to be used as a reference site and improve transparency. The ability to access the portal from any location, as needed, was also seen as positive. Some participants mentioned that PWPs could reduce errors because medical costs, prescriptions, and test results will be checked by the patient (“Is it correct what was told [during consultation]?”).

Drawbacks of a Patient Web Portal

Some participants were afraid that the provided information would be too complicated, that they would receive too much information, or that it would cost the physician too much time. One participant did not want access to a PWP because she thought it would be too complicated for her, even though she wanted more insight into her medical information:

There is much talking about patients, but not always with patients...Most PWPs I have seen are not user-friendly.

Other participants were worried about practical problems, stating that all PWPs should be comparable and all health care providers should be able to work with them, specifically mentioning the potential difficulties in merging medical information from different health care providers. Several felt that merging the information in a PWP could enhance communication between health care professionals and allow GPs to receive information from the hospital faster (eg, “It would be nice [...] if I don’t have to tell my story every time”).

Experiences of Patients With a Patient Web Portal

Two participants had experienced medical errors and felt they could have been prevented if they had access to a PWP. One patient told that he could have prevented a wrong surgery (left vs right shoulder) and other patients experienced that their health care provider forgot to notify them about deviating lab results. If they had had access to a PWP, they could have prevented this. Patients can use the information from the patient portal to check whether they have correctly understood the information provided during the consultation.

Paying for a Patient Web Portal

Our participants did not want to pay for the PWP because they consider it part of routine care that should be covered by health insurance: “If you have to pay, less people will be interested.” They suggested examining whether a portal could save costs through improved disease control.

Patients’ Needs Regarding a Patient Web Portal

Preferred Device to Access the Patient Web Portal

It was agreed that the PWP should be assessable by a computer, and possibly by tablet, but that smartphone access may be unsuitable because the screen is too small.

Easy to Use and Understandable Language

The PWP should be clear, easy to use, and provide easily understood medical information. All participants agreed that there should be clear instructions about how to use the portal (eg, through an instruction video with access to an information and communications technology helpdesk):

The website must be clear, so that you know where to click and when.

Preferred Features in a Patient Web Portal

As PWPs were unfamiliar to most participants, they had difficulties thinking of useful features. To assist them, we screened videos with examples of common PWPs used by Dutch hospitals. The self-management apps that the participants preferred, together with their main comments, are summarized in [Multimedia Appendix 1](#) (summary of the preferred self-management features for patient portal).

Ways to Log In

Most participants have experienced DigID, which is a service provided by the Dutch government to provide secure log-in to government websites or medical insurance companies. As DigID was in the news because of fraud at the time of the focus groups sessions, most were worried about the safety of this system (eg, “It is like Big Brother”). They also wanted certainty that their medical records would be separate from those maintained by other governmental organizations or health care insurance companies. Furthermore, it was stated that DigID could be difficult to use, so other log-in options were discussed (eg, short message service; password; finger scans; face recognition; iris scan; or a specific card, like a bank card).

Insurance Companies

A major concern about medical privacy revolved around access by health insurance companies. Most expressed negative feelings regarding these companies and were fearful that their insurance options could be negatively affected if they were involved in the PWP (eg, “If they [insurance companies] receive information, they can exclude you from certain insurance packages”). Therefore, they did not want medical data to be accessible by insurance companies.

Discussion

Principal Findings

It was clear that an essential requirement of a PWP was Web-based access to medical records with an explanation of their meaning. Indeed, despite significant variations in internet experience, and despite the possibility of anxiety because of a lack of understanding, most participants still wanted Web-based access to their medical results. Most also wanted access to crude laboratory results, though they accepted the need for information to be presented at a level that they could understand. Overall, there was some consensus that a PWP should contain test results, a medication overview, information for others, links to reliable websites and a patient forum, and provide the ability to book and participate in Web-based appointments. Tools for disease monitoring and the provision of reliable lifestyle information would also be appreciated by some, but most would not use

these options. These findings can help professionals to facilitate the development of a PWP to the needs of patients with asthma and COPD.

Comparison With Current Literature

Although participants in our focus groups were positive about PWPs, health care providers do not always feel the same. Physicians in Sweden, for example, were afraid that patients would not understand the context of records and might become anxious, which would increase their workload [47]. Moreover, a PWP can be seen as a threat if physicians feel that patients are monitoring their work [43]. In contrast, other studies have shown that PWPs can be more convenient for physicians, not only by saving time on the telephone but also by introducing organizational efficiencies and reduced workflow through greater patient involvement [48].

Costs and Security

Participants thought that the costs for the PWP should be covered by their health care insurance, even though existing health care systems are not designed to cover Web-based programs [28]. PWPs might reduce unscheduled health care visits [43], although more research is needed to evaluate the cost-effectiveness of PWPs [17]. It was interesting that security was not a major concern, despite the recognition that issues concerning safety and privacy were potential barriers to PWP use [31]. The government-developed DigID log-in method used in the Netherlands was viewed negatively because it was in the news related to fraud. This will have influenced the opinions.

Patient Web Portal Users

Opinions about internet and PWP use varied among the focus groups, but were consistent with existing research; patients with least internet experience were least likely to want to use a PWP. Research shows that portal users are more experienced with the internet [7], are typically younger and female [22], and have better knowledge of their disease [41]. Developers can facilitate PWP use among the elderly and those with low socioeconomic status by providing explanations in plain language. This might include audio messages for laboratory results [31], videos [27] or Web-based tutorials [31] about how to use the PWP, or pictures for people who have difficulties reading [39]. PWPs should, therefore, be customized to these needs of users [48], with continued efforts to listen to users and make further adjustments over time [7].

Options That Should be Available in a Patient Web Portal

Participants generally agreed that PWPs should provide access to medical records, a medication overview, and reliable information, which is consistent with previous research, indicating that patients wanted to view laboratory results, refill medications, make appointments, and communicate with their doctor [7]. Several researchers have evaluated the effect of Web-based access of patients on disease control. At present, there are doubts as to whether providing patients direct access to crude numeric laboratory results is wise, not least because it can create confusion or anxiety if patients lack the expertise to interpret their results [49]. One solution might be to incorporate a delay before Web-based publishing to allow physicians time

to discuss results with patients. On balance, however, the existing literature is inadequate to allow us to conclude whether laboratory results should be provided immediately after a delay [15].

Links to external websites were considered an important feature because of difficulties finding reliable websites. It might also be useful to incorporate links to self-care information and exacerbation prevention [25]. A reliable website provided by Dutch GPs with Web-based health information for patients was related to a reduction in health care visits, with the average age of the participants being 40.2 (SD 22.9) years [50]. However, these websites can be difficult to understand [39], and developers must be critical when selecting external websites.

All participants were divided about the role of communication with their health care provider. Research has shown that Web-based consultations can be cost-effective for patients by reducing the need to attend in person, though this is often at the expense of insufficient information needed for assessment [51]. It is also unclear what effect secured messaging has on regular face-to-face contact, with some studies showing that it can reduce the numbers of outpatient visits, telephone calls, and emails [28], and others showing the opposite. However, it is generally agreed that patients and providers should use secured messaging specifically for questions that are not urgent [52]. On balance, it appears that Web-based visits do not change the frequency of face-to-face visits [51], with most recognizing that a PWP is no substitute for such contact [31]. If messaging is properly organized in a PWP and inboxes are monitored [9], this service can develop to include advice and encouragement messages and may help increase the usefulness of the system [31].

Finally, the participants in this study were less enthusiastic about lifestyle support options. This is consistent with other research that shows that patients consider laboratory results and treatment goals as most important, with lifestyle support less relevant [41].

Barriers and Facilitators to Patient Web Portal Use

During the focus group sessions, participants repeatedly said that information needs to be understandable and the portal should be “easy to use.” Research consistently indicates that, regardless of the educational level [10], patients prefer information that is presented in lay language [12]. Smart phrases and standardized text could facilitate this change to lay language. Moreover, PWPs should only contain essential information [12], and developers should consider that patients with low health literacy will have particular difficulty interpreting numbers and risk estimations [30]. The information should also be available in a printable format because patients perceive Web-based information as less trustworthy than printed information [53].

Although PWP use is influenced by personal factors, provider endorsement, and usability [54], the latter is the most important barrier. As patients with COPD often have low socioeconomic and educational status, it is essential that navigating through the different pages is easy and the interface is predictable. Language should be comprehensible and simple. Textual material can be supported by multimedia to enhance the

understanding. For example, pictures or videos can help to reach patients who have reading difficulties. Text-to-speech engines are promising and can support patient with reading difficulties [27]. Developers can be supported by automated algorithms that link medical jargon to lay language [55].

In addition, it may be relevant to address patient expectations and take their habits and intentions into account [56]. A pilot of a proposed PWP would be helpful, especially if a patient's own doctor stresses the potential benefits [11,32,41,56]. Healthcare providers will also need to establish specific training activities so that health care professionals can learn how to work with the portal [11]. Finally, for successful implementation, PWPs should be supported by technicians who can help with technical problems [14,44].

Effect of Patient Web Portals on Patient-Physician Communication

The patient-physician relationship could change if patients become better informed about their disease after introducing a PWP. Many of our patients felt that communication could become more equal if there were less of a knowledge differential. This is consistent with the results of a study in which patient-reported outcome measures were shown to produce better communication and decision-making between patients and health care professionals [9]. However, no study has specifically looked at the effect of PWPs on communication, and some researchers have argued that physicians can be worried that time spent on the PWP will reduce time available for face-to-face patient contact and that physicians can feel a loss of control if the patient is more engaged in their care [47]. For example, the implementation of a PWP for radiology results led to worries among radiologists [48]. It will be important to secure the involvement of clinicians and address their concerns if a PWP is to be successfully implemented [27].

Strengths and Limitations

In this paper, we presented an overview of 9 focus group sessions with patients who had asthma and COPD. The strength of this study is that these discussions were open, with 3 groups meeting 3 times at weekly intervals. Therefore, participants got to know each other and shared personal thoughts and emotions with the group. However, selection bias might have occurred because participants might have been more interested in PWPs compared with the general population. For example, participants were included through the Lung Foundation, which suggests

that they already had a degree of involvement in their illnesses. Internet experience also varied significantly, and although most were regular internet users, we tried to overcome this issue by stressing that we welcomed participants without internet experience and from areas where the average socioeconomic status was low. Thus, we improved the breadth of internet experience in our groups.

Another drawback of this study is that participants did not use real PWPs but were discussing hypothetical portals. This is important because the intention to use the PWP might differ from the actual use. To improve this issue, we presented videos and screenshots of a variety of example PWPs; for example, we showed examples of PWPs when our participants had difficulties thinking of useful apps. An unintended but inevitable consequence of this is that it was difficult to present suggestions without leading patients. We militated against this by presenting as broad a range of options as possible and allowing participants to choose their preferences. Nevertheless, further investigation with real access to a PWP is needed to understand how patients use portals.

Finally, this was a qualitative study with a small sample that was limited to patients with at least respiratory disorders, and possibly many of them had other morbidities as well [57]; the results cannot be generalized to all patients with asthma and COPD. However, this was not the aim of this qualitative study. Before this research, we did not have a real understanding of the opinions of patients with asthma and COPD regarding a PWP, so we started this study with an open mind and allowed patients to share their opinions freely. This would not have been possible in a quantitative study.

Conclusions

In general, the participants of this study were positive about PWPs and considered them a logical step in health care development, consistent with the facts that patients are better educated and that most households have access to the internet nowadays. Given that patients are also more assertive and better informed about their disease, PWPs can support them and their interaction with health care professionals. Our participants provided very practical suggestions for implementation in current and future PWPs. The next step should be to develop a PWP with these suggestions in mind and to test whether the portal meets the needs of both patients and health care providers. Future studies can evaluate options for users with asthma and COPD to optimize the PWP.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Opinions about the self-management features.

[PDF File (Adobe PDF File), 57KB - [formative_v2i2e22_app1.pdf](#)]

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Abbreviations

- ACO:** asthma-COPD overlap
COPD: chronic obstructive pulmonary disease
GP: general practitioner
PWP: patient Web portal

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Original Paper

Behavior Change for Youth Drivers: Design and Development of a Smartphone-Based App (BackPocketDriver)

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Abstract

Background: The over-representation of youth in road crash injury and fatality rates is a major public health issue globally. In New Zealand, youth drivers are most vulnerable in the restricted license period when they can drive without the requirement for supervision by an experienced adult. Behavioral change interventions delivered using mobile phone technology to young drivers could serve as a useful mechanism to develop safe driving skills, but this potential remains to be fully explored.

Objective: This study aimed to apply behavioral change principles to design and develop a smartphone-based intervention with the aim of helping youth drivers to develop and hone safe driving skills.

Methods: An iterative process was used to support development of the smartphone intervention. We reviewed behavioral change literature, identifying fundamental principles and exploring use of behavior change techniques (BCTs) in other areas of public health. We engaged with key stakeholders, including young drivers, government agencies, and relevant organizations. We also took into account technology adoption considerations when designing the app.

Results: We developed BackPocketDriver (BPD), an Android smartphone app that uses in-built sensors to monitor and infer driver behavior. The app implements features that were identified during the design process and are traceable to BCTs and theory. A key feature is messaging, which is used to instruct, motivate, educate, and relay feedback to participants. In addition, messaging addresses attitudes and beliefs. Other features include journey feedback summaries, goal setting, achievements, and leaderboards.

Conclusions: BPD's design rests on a sound foundation of theory and evidence. With explicit links between theory and features, the app aims to be an effective intervention to change and improve youth driver behavior. The next phase of this study is to run a small pilot study to assess BPD's effectiveness.

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KEYWORDS

smartphone; public health; telemedicine; telemetry

Introduction

Road safety is a significant public health issue worldwide, with approximately 1.3 million fatalities and 20 to 50 million injuries per year, many of which lead to lifelong disabilities. Internationally, road traffic injuries are the leading cause of death among people aged 15 to 29 years [1]. This pattern is also evident in New Zealand where young drivers aged 16 to 24 years are over-represented in crash statistics.

According to recently published data [2] by the New Zealand Ministry of Transport, in 2015, 4% of drivers were aged between 16 and 19 years; however, this age group accounted for 9% of all drivers in minor crashes, 9% of drivers in serious crashes, and 7% of those involved in fatal crashes. Drivers aged 16 to 24 years were involved in 90 fatal crashes, 579 serious injury crashes, and 2608 minor injury crashes. Of these, it was a young driver that was responsible for approximately 80% of the crashes. The social cost for which responsibility was attributed to young drivers was NZ \$951 million, 25% of the cost for all injury crashes over the 2015 period [2].

Over time, young drivers tend to become safer. Drivers aged 16 to 19 years are 6 to 8 times more likely to crash than those aged 55 to 59 years, whereas for 20- to 24-year-old drivers, this drops to 3 to 4 times [2]. Particularly, significant factors that cause crashes involving young drivers include speed and alcohol; 53% of young drivers in fatal crashes had alcohol or drugs and/or speed as a crash factor. Other significant factors are losing control of the vehicle and inexperience [2].

Recent and ongoing initiatives have made progress in tackling the youth driver problem. Such initiatives include legislation and graduated driver licensing (GDL), parental involvement to agree on protective limits on teen driving [3], education [4], and training [5]. According to the New Zealand Ministry of Transport's data, the period when young drivers are at greatest risk of being involved in crashes is when they are on their restricted license [2]. On a restricted license, drivers are subject to conditions, for example, they are not generally permitted to drive after 10 pm or carry passengers. Although legislation and GDL can serve as useful restraints on risky driving behaviors [3], and driver education and training can assist young people to gain the foundational knowledge to obtain their driving license, current initiatives fail to provide young drivers with support for continuous improvement, feedback, and development regarding their driving skills as they begin driving without adult supervision.

Smartphones offer a low-cost sensing platform that enables many facets of driver behavior to be monitored, including speed, acceleration, braking, and steering. These capabilities form a foundation for monitoring, analyzing, and providing feedback on driver behavior [6-9]. Applications of the technology include insurance telematics (Pay How You Drive) [10], detecting impaired driving [11,12], carpooling, and ride sharing—where driver reputation and safety are used to decide who to drive with, eco-driving [13] to reduce pollution, and use of crowdsourced data to identify potential crash-risk areas of the road network [14].

Used in the context of driving, the smartphone, nevertheless, is a double-edged sword. Using a mobile phone while driving is a key contributor to distracted driving, which claims the lives of 5000 Americans annually [15]. Hence, care needs to be taken with any attempt to use smartphones as the basis of a driving intervention. Although moral outrage has not been completely effective in eradicating drink and drive, combining moral arguments with technology shows promise to tackle distracted driving [15]. On one level, an app might block calls and messages while monitoring driver behavior; on another level, it could also augment the monitoring functionality with an array of other features that help to improve driving skills and attitudes.

Interventions in many areas of public health have been based on behavior change techniques (BCTs) [16-18]. A BCT is an observable, nonreducible component of an intervention that is designed to change behavior [19]. There is also strong evidence that particular techniques, for example, setting goals and providing feedback on behavior, have been successful in leading to positive behavioral change among participants [19]. However, the role of BCTs in youth driving interventions is largely unexplored. A notable exception is a review of 6 interventions [20] that found that only a small subset of techniques was employed. In addition, the review identified that the interventions ignored the evidence concerning effective techniques; the techniques actually employed had little overlap with those for which there is evidence that they have been used with success elsewhere.

This study aimed to apply behavioral principles to design and develop a smartphone-based intervention, BackPocketDriver (BPD), with an aim to help youth drivers to develop and hone safe driving skills. Rather than inventing a feature-set based on intuition, we have reviewed behavioral theory, BCTs, and evidence of their effectiveness to develop an informed smartphone app. BPD represents a step toward developing youth-driving interventions that are more theory-led and grounded in evidence. As a result, we expect BPD to be more effective in changing behavior than other apps that are currently available.

Methods

Scope

BPD's development was informed by engaging with key stakeholders, identifying appropriate techniques for behavior change, and relevant design principles for technology-assisted interventions.

This study does not report the outcomes for testing; however, these will be described in the paper on a pilot study of BPD.

Ethics Approval

The study was given ethics approval by the University of Auckland's Ethics Committee in February 2016. Informed consent was obtained by participants before participation in the study.

Stakeholder Engagement

Understanding and incorporating the priorities and preferences of the target audience as well as key stakeholders is important

to ensure the success of interventions. Therefore, it is vital to engage with the target population during the design and development process [21].

In the case of BPD, 3 groups were identified as key stakeholders for engagement: young drivers (aged 16 to 24 years), parents of teen drivers, and relevant organizations. The organizations included New Zealand Transport Authority (NZTA), a government entity with a mission to develop a safe land transport system for New Zealand. New Zealand Police were included because of their prevention-first strategy that aims to reduce fatalities and serious crashes. In addition, the Automobile Association (AA) is an independent organization that is actively involved in initiatives for youth driver safety, including license reforms and young driver education.

Engagement with each of the key stakeholder groups was undertaken either in the form of semistructured phone interviews with representatives from the relevant organizations or less formal discussion-based sessions with young drivers and parents. Topics covered with each group of key stakeholders included understanding the issue—causes and implications of crashes involving young people, the level of interest in a smartphone app for safe driving, barriers to engagement with a driving app, preferred functionality and features, and incentives. When interviews were undertaken, these were recorded and transcribed. During sessions with teens and parents, information was captured on flip charts. Teens and parents also completed questionnaires.

Behavioral Modeling

Several models have been developed to explain behavior. Many of the models share common concepts, and awareness of the fundamental ideas is important in developing BPD.

Drawing on the theory of planned behavior, the dual-process approach, and the prototype willingness model [22], the key concepts are as follows: *target behavior*, *emotions*, *barriers*, *facilitators*, and *willingness* to perform the target behavior. Target behavior is the behavior wanted of participants, contrary to unwanted behavior.

Emotions can influence performance of target behavior. There are 2 emotion types: *anticipated* feelings and *experienced* feelings. Anticipated feelings capture how a person thinks he or she will feel after performing a target behavior. Experienced feelings are the way a person feels at a particular point in time and can influence behavior independently to any intention to perform the target behavior.

Barriers are obstacles that can prevent a person from acting on his or her intentions to perform a target behavior. Intervention design involves helping people to anticipate and overcome particular barriers. Conversely, facilitators make it easier for people to perform target behaviors.

A person's willingness or intention to perform a target behavior is governed by the following:

- *Norms*. Norms are about what people believe is normal behavior. *Descriptive norms* address the question—"Do people like me perform the target behavior?" People are

more likely to perform the target behavior if they believe others like them do. *Injunctive norms* differ in that they are about whether others approve or disapprove of a particular behavior. People are more likely to perform a behavior if they believe others want or expect them to.

- *Control*. This concerns how much control a person believes he or she has over his or her behavior. Control poses the question—"How able am I to perform a target behavior?" Effective interventions build a person's confidence and capability, contributing to their belief that they can perform a target behavior.
- *Self-identity*. Self-identity addresses how a person's sense of self aligns with the target behavior. People who align themselves with the wanted behavior are more likely to perform the behavior than if they align with some other identity. Interventions often need to help people change their self-identity or find a solution that fits with their current identity.
- *Attitudes*. *Instrumental attitudes* focus on what a person thinks about a target behavior. For example, people might have the opinion that a target behavior makes them safe, excited, frightened, or bored. On the basis of their thinking, people make a judgment as to whether a behavior is good or bad; where the good outweighs the bad, people are more likely to perform the behavior. *Affective attitudes* are similar but concern how a person *feels* when performing the behavior.

Behavioral models are useful in developing interventions in which they identify a range of psychological elements to address. However, it is often unclear how a particular element can be operated to bring about behavioral change [20]. BCTs offer a solution and define the active ingredients of an intervention.

Behavior Change Techniques

A BCT is an observable, nonreducible component of an intervention that is designed to change behavior [19]. BCTs can be used in interventions to change one or more psychological determinants of a person's behavior, including the behavioral modeling elements discussed above [16].

To ensure that the proposed intervention is effective in changing behavior, a review of the literature was conducted to identify relevant BCTs for incorporation into the intervention. We focused on Michie et al's hierarchical taxonomy comprising 16 categories of 93 distinct techniques [23]. Table 1 introduces each category.

To illustrate a couple of BCTs, *goal setting*, from the *goals and planning* category is concerned with setting short-term goals. To meet a series of goals, a person's attitude and behavior might change in some desired way. Where a person takes ownership of goal setting, their intrinsic motivation also tends to increase [24]. *Social comparison*, from the *comparison of behavior* category, involves drawing attention to those who exhibit good behavior. In doing so, people are able to compare their own behavior with that of exemplars. This can motivate people to reach or exceed the exemplary behavior.

Table 1. Behavior change technique categories.

Category	Description
1. Goals and planning	Setting goals for the target behavior, making plans to achieve goals, and dealing with any barriers
2. Feedback and monitoring	Monitoring progress toward goals and providing feedback to users
3. Social support	Providing social support, from friends, family, colleagues, and professionals to help meet goals
4. Shaping knowledge	Assisting users to better understand their behavior and how to perform target behaviors
5. Natural consequences	Highlighting consequences of performing particular behaviors, enabling users to see that they would regret not changing behavior
6. Comparison of behavior	Comparing participants' behavior with that of others and leading users to consider whether others approve (norms in a psychological model)
7. Associations	Associating target behavior with positive things and reminding users to perform the behavior
8. Repetition and substitution	Enabling users to practice and develop skills so that target behavior becomes habitual
9. Comparison of outcomes	Allowing users to explore the outcomes of exhibiting or not exhibiting the behavior
10. Reward and threat	Rewarding the target behavior and punishing unwanted behavior
11. Regulation	Easing the task of performing the behavior, for example, by reducing negative emotions that result from the target behavior
12. Antecedents	Understanding what triggers unwanted behavior, taking steps to avoid the triggers, and changing the physical environment
13. Identity	Encouraging users to believe that the target behavior is right for them
14. Scheduled consequences	Arranging a schedule of punishments and rewards for users performing the target behavior and not the unwanted behavior
15. Self-belief	Building user confidence that a participant can perform the target behavior
16. Covert learning	Enabling users to imagine consequences arising from performing a behavior and observing the consequences to others as they perform behaviors

Table 2. Behavior change techniques that have generally featured in successful interventions.

Behavior change technique	Description
1.1 Goal setting (behavior)	Set or agree a goal defined in terms of the target behavior
2.2 Feedback on behavior	Monitor or observe behavior and provide feedback on performance of the target behavior
2.3 Self-monitoring of behavior	Establish a method for the person to monitor and record their behavior(s)
3.1 Social support	Advise on, arrange, or provide social support or encouragement for performing the target behavior
4.1 Instruction on how to perform the behavior	Agree or advise on how to perform the target behavior
5.1 Information about health consequences	Provide information about the consequences of performing the target behavior

BCTs have been widely used in many areas of public health. [Table 2](#) describes BCTs for which there is strong evidence that they have been effective in changing behavior for adolescents and adults regarding a broad range of behaviors: obesity, physical exercise, diet and nutrition, and drug use [19]. Each BCT is numbered in [Table 2](#) such that the first digit identifies its category (from [Table 1](#)), and the second digit uniquely identifies the BCT within the category.

Developing youth driving interventions that are informed by behavioral change theory has largely been ignored [22,19]. One study [1], however, conducted a review of 6 youth driving interventions to expose any BCTs being used. The interventions included conventional presentations, crash analysis activities, interactive discussions, and a theatrical show with road safety messages. The study found that all of the interventions gave information about consequences and risks (BCT 5.1). The

majority of the interventions also demonstrated how to perform target behaviors (a category 6 BCT) and provided feedback on performance of wanted behaviors (BCT 2.2). In 4 interventions, participants were supported in forming intentions (part of category 1 goals and planning) that would help them to perform a target behavior, such as not using a mobile phone while driving. In short, the study exposed that only a narrow set of BCTs were used in the interventions, and there is little overlap between those used and those with strong evidence of effectiveness ([Table 2](#)).

At the time of writing, we were not aware of any smartphone-based interventions for youth driving that have been designed with consideration of behavioral change theory. However, later in this paper, we report on popular apps for youth driving and identify features that can be traced back to particular BCTs.

Design for Technology-Assisted Intervention

Developing technology-assisted interventions is not without challenges. As discussed earlier, participants must be willing to engage in the intervention. With a smartphone-based intervention such as BPD, they must also be *willing* to use the mobile phone technology [25]. In this context, willingness requires that participants *accept* the technology and that they perceive *gains* and little *risk* from its use [25]. Gains can be extrinsic, for example, insurance discounts, or intrinsic, with participants genuinely willing to improve their driving skills. Risks represent potential barriers to use of the technology.

Technology acceptance can further be affected by 4 attributes [25]:

- *Delay discounting*. For youth driving interventions, the benefits—improved driving skills—are likely to come later. With no immediate benefit, youth drivers who discount delayed benefit tend to have a lower perception of the gains associated with engaging with the intervention. This suggests that the technology needs to include appealing features that offer value in the short term and which retain user interest until longer-term gains are evident.
- *Social influence* is concerned with how social groups and peer pressure influence norms, decision making, and behavior. For BPD, features that appeal to youths and youth groups are likely to lead to a more successful intervention. Similarly, features that are perceived by youth as *uncool* are likely to be detrimental to intervention success. Social influence is addressed in behavioral modeling using norms and self-identity.
- *Usability* covers a range of issues, including general user interface (UI) design, but more specifically, for BPD, it is the ease with which the app can be downloaded and used. If the mobile phone needs to be held in a fixed position while driving, necessitating the use of a dashboard mount and a calibration step before each journey, then the app's perceived usability would be reduced.
- *Attitude*, as discussed earlier in behavioral modeling, concerns an individual's disposition toward an intervention. Those who are intrinsically motivated or whose motivation can be developed, perhaps extrinsically, are more likely to engage with an intervention.

Results

Stakeholder's Feedback

A summary of the learnings from the stakeholders is presented in Table 3. All 3 groups recognized the youth driving problem and were concerned with the over-representation of road crashes involving young drivers. Limited experience and maturation were identified as key factors, with the Police noting that the majority of fatal crashes are caused by mistakes and inattention. The New Zealand transport agency (NZTA) was interested in the role an app could take as part of a more holistic program to

publicize safe driving and to make drivers aware of the effect of their actions on other road users. The Police were supportive of interventions such as BPD that could contribute toward addressing road safety issues. The stakeholder organizations were also more supportive where an app is evidence-based and grounded in (behavioral change) theory. Interest in the BPD concept from young drivers and parents was also positive, notwithstanding potential *risks* to adoption.

Young drivers raised a number of risks relating to privacy. Teens did not want their parents to be able to track their movements or to receive real-time alerts of poor driving behavior. Some teens also raised concerns about the data being made available to authorities and used, for example, to issue speeding infringement notices.

Quality of feedback was an important concern raised by young drivers. Youth drivers wanted reassurance that any feedback would be useful and effective. In addition, they felt that they would be stressed by negative or *nagging* feedback, for example, suggesting that they were a *bad* driver. Similar concerns were voiced about the app being able to consider real conditions, for example, the need to brake heavily to avoid an accident, and subsequently not rating the driving as poor.

Young drivers also expressed *usability* concerns about the effect of using the app on their smartphone's battery, storage, and mobile data. Liberal consumption of any of these resources would be unacceptable.

The Police identified that youth who are interested in using the app are unlikely to be those who engage in criminal behavior. There exists a correlation between criminality, antisocial behavior, and car crashes, with risk taking and poor decision making being contributory factors. Appealing to this demographic subset, given its *attitude*, therefore poses a challenge. Another attitude-related issue, raised by the NZTA, concerns the potential to subvert the intention, for example, youth using the app for bragging rights and sharing incidents of fast, dangerous, or reckless driving.

Constructive feedback was important to young drivers. Although negative feedback poses a risk, feedback that is encouraging and addresses both good and bad driving, allowing users to discover what they are doing wrong, was viewed as something that young drivers could *gain* from. Similarly, education was also important to youth, suggesting that tips for passing the practical driving test and practice questions for the theory test would be desirable.

Parents were interested in monitoring both routes driven and driving behavior of their teens. Similar to young drivers, parents saw value in the app providing their teens with driver education and instruction. Parents favored automatic deactivation of the phone while driving; however, teens wanted this tempered, for example, to be aware of when a short message service (SMS) text message had arrived but having to stop the vehicle before reading the message.

Table 3. Key findings from stakeholder engagement to inform app development.

Finding category	Young drivers	Parents of teen drivers	Relevant organizations
Risks to adoption	Threats to privacy; Negative or inaccurate feedback on driving; Battery and mobile data consumption; Excess use of push notification or audio alerts; Cost		App being used as a source of distraction; Appeal of app to most at-risk drivers; Potential to subvert intervention; Cost
Gain enablers	Constructive feedback; Safe driving education; Peer competition	Ability to monitor teens' driving and behavior; Automated deactivation of phone while driving; Suggestions to improve driving	Sticky intervention; Data analytics based on crowd-sourced data
Incentives	Recognition of achievements; Use of app data as proof of safe driving; Endorsement by relevant organizations, for example, NZTA ^a ; Aesthetics and ease of use	Integration with licensing process	Material rewards schemes, for example, fuel discounts; Automated starting or stopping of journey monitoring

^aNZTA: New Zealand Transport Agency.

Table 4. Mapping objectives to behavioral elements and behavior change technique categories.

Objective	Behavioral elements	Behavior change categories
1. Improve driving skills	Emotions; Control; Barriers	2. Feedback and monitoring; 4. Shaping knowledge; 7. Associations; 8. Repetition and substitution
2. Strengthen intentions to perform target behaviors	Facilitators	1. Goals and planning; 10. Reward and threat; 13. Identity
3. Increase positive attitudes toward performing target behaviors	Attitudes; Norms; Barriers; Facilitators	3. Social support; 5. Natural consequences; 6. Comparison of behavior
4. Manage self-identity	Self-identity	4. Natural consequences
5. Address the mismatch between perceived and actual driving skills	Facilitators	13. Identity

The AA reported that conventional driver training decays over time. Conversely, a driving app has the potential to remain supportive and of value to youth over time. To do so, it needs to be *sticky* by providing features that retain users' interest and engagement, for example, material rewards, peer competition, and social comparison. This also helps to combat delay discounting, where the benefit of improved driving skills is seen later and only after a period of participating with the intervention. In addition, to address *usability*, the AA suggested that BPD should automatically start and stop journey monitoring without the need for user involvement, thereby providing for seamless operation and preventing fatigue.

App Design

BPD has 3 target behaviors for young drivers:

1. To drive within speed limits.
2. To perform maneuvers safely and in a controlled manner.
3. To not use a mobile phone while driving.

These behaviors lend themselves to BPD's smartphone-based delivery platform because they can be automatically tracked by the smartphone. On the basis of the gathered data, the app can generate tailored responses to help participants develop the wanted behaviors.

We have identified 4 objectives from the target behaviors. For each objective, we have identified the relevant behavioral model

elements to operate on. In selecting particular BCTs for each objective, we have considered which BCTs have been proven to work in other interventions. In addition, we have considered which BCT categories are best placed to meet particular objectives. To increase skills, for example, category 8 (repetition and substitution) is appropriate, whereas category 5 (natural consequences) is well suited to changing attitudes [22]. [Table 4](#) presents the objectives, associated behavioral elements, and appropriate BCT categories.

Improving Driving Skills

For objective 1, to improve driving skills, BCT category 2 (feedback and monitoring) plays a key role by offering BCTs that can be used to monitor driving behavior and relay feedback to participants. On the basis of feedback, areas to focus on can be identified, enabling participants to practice and improve on these aspects. Category 4 (shaping knowledge) can be employed to assist with improving skills through BCTs that educate participants, for example, by providing instruction on how to perform maneuvers and antecedents to performing the target behaviors poorly. Category 7 (associations) includes BCTs for prompting wanted behavior at particular times. BCTs from category 8 (repetition and substitution) help with honing target behaviors through practice. They also facilitate formation of good habits.

A person's emotional state can affect his or her driving behavior. As discussed earlier, experienced feelings, such as being upset, can negatively impact performance of target behaviors even when a person has strong intentions and a positive attitude toward the target behaviors. Category 4 is of further value for objective 1 in which it has BCTs that can be used to educate participants in recognizing and managing emotions. Moreover, category 4 can be used to raise participants' awareness of barriers to performing wanted behaviors, for example, poor time management, drugs and alcohol, tiredness, and phone use. In shaping knowledge, the intervention can suggest how to deal with barriers.

A necessary element to improving driving skills is self-belief—participants must believe that they are capable of performing the target behaviors. BPD can strengthen participants' self-belief through applying BCTs in category 8. This category includes a BCT for graded tasks, where tasks become more difficult over time. As participants work through a grade or level, they become more proficient and prepared for the next. In terms of driving to speed limits, for example, successive levels might lower the speeding tolerance for achieving a speed-focused goal.

Strengthening Intentions to Perform Target Behaviors

Regarding the second objective, to strengthen intentions to perform target behaviors, we recognize that while many participants have a positive attitude toward the target behaviors, without goals they might lack the impetus to engage and develop the wanted behaviors. BCT category 1, goals and planning, is appropriate to draw on as it provides BCTs for participants to set and track progress with goals associated with target behaviors.

Category 10, rewards and threats, can also be used to incentivize participants. Social rewards recognize that participants have performed a target behavior well and provide a sense of achievement. Similarly, category 13, identity, includes a role-modeling BCT where a participant can be elevated to a role model after performing well in a target behavior. This can bring a sense of kudos to the participant, fostering their motivation and engagement.

Increasing Positive Attitudes Toward Performing Target Behaviors

Although attitudes of many young people align closely with safe driving, there are others who hold less positive attitudes toward BPD's target behaviors. Hence, for some participants, the intervention needs to change their thinking (instrumental attitude). This is the motivation for objective 3 to increase positive attitudes toward performing target behaviors. BCT category 5, natural consequences, includes BCTs that can be applied to help participants see the consequences of performing wanted or unwanted behaviors. Related to consequences is the notion of anticipated regret, which involves having a participant think about how they would feel if they did not change their behavior and continued to perform an unwanted behavior, for example, speeding. Thinking through an undesirable outcome may contribute to change in instrumental attitude.

Descriptive norms influence attitudes. To show that it is normal for other young people to perform the target behaviors, BCTs from category 6, comparison of behavior, can be used. Social comparison involves bringing to the attention of participants other participants who they consider to be part of the same social group and who are performing the target behaviors well. Category 6 also includes BCTs for addressing the approval of others (injunctive norms). In addition, where celebrity figures who are respected by young people endorse the target behaviors, this might also contribute to changing attitudes and meeting objective 3.

BCT category 3, social support, is also appropriate to consider for the third objective. The BPD app could include social networking functionality allowing participants to support one another in developing the target behaviors. Another supportive role for BPD would be to address barriers to performing the target behaviors. Barriers include peer pressure and triggers, for example, racing or using mobile phones while driving. The app could deliver advice on how to deal with such barriers.

Managing Self-Identity

Objective 4, to manage self-identity, recognizes that a person's attitude might be opposite to the target behaviors. For BPD, *boy racers* are an obvious group that is unlikely to view positively the target behaviors of driving within speed limits and conducting maneuvers safely. To address such groups, category 5 BCTs can be used to help change attitudes, similarly to their role in objective 3. Realistically, however, a more effective approach might be to complement use of natural consequences BCTs with a solution that allows boy racers to become aware that they can satisfy their need for speed and thrill seeking through other means.

Addressing the Mismatch Between Perceived and Actual Driving Skills

The final objective concerns the mismatch between perceived and actual driving skills. Young drivers tend to overestimate their safety margin, resulting in more risk taking [26] and a heightened optimism bias that leads them to underestimate the likelihood of negative outcomes from unwanted driving behaviors [22]. For example, young drivers might believe that using a mobile phone while driving is dangerous and choose to protect themselves by not doing so when driving on motorways; however, they may still be prepared to take the risk when driving around town [22]. Although BCT categories discussed earlier, notably 1 and 2 for setting goals and receiving feedback, can help to highlight to a driver that their skills are not as good as they think they are, BPD could also expose their incompatible beliefs, for example, thinking that it is not risky to use a mobile phone while driving in an urban environment. BCT category 13's incompatible belief serves this purpose.

Having identified the subset of BCT categories that are applicable to BPD, Table 5 introduces particular techniques from the categories as deemed relevant to this intervention. In each case, possible application of the technique in the context of BPD is described. The BCTs for which there is strong evidence that they have led to behavior change elsewhere, discussed earlier, and presented in Table 2, are shown in italics.

Table 5. Relevant behavior change techniques (BCTs). There is strong evidence that the BCTs shown in italics (outlined in Table 2) have generally featured in successful interventions.

Behavior change technique	Description
<i>1.1 Goal setting (behavior)</i>	Mutually agree on short-term goals to be achieved, such as “This week I will brake more gently.”
1.2 Problem solving	Prompt participants to analyze behaviorally influencing factors and develop strategies for overcoming barriers. For example, “So it seems you’ve been having trouble with your speed. How do you think you could try to change that next time you go out?”
1.3 Goal setting (outcome)	Facilitate longer-term goals, such as “Be a safe driver,” “Get my full license,” and “Avoid accidents.”
1.4 Action planning	Prompt participants to plan their driving, including factors such as context, frequency, and duration.
1.5 Review behavior (goals)	Review behavioral goals together with the participant and consider modifying them based on progress. For BPD ^a , goals can be reviewed and modified by the app.
2.1 Monitoring without feedback	Record behavior with the participant’s knowledge. Driving behavior data captured by the app could be made available to a participant’s parents. The knowledge that their driving behavior is being observed can influence their behavior.
<i>2.2 Feedback on behavior</i>	Monitor and provide informative feedback on performance. BPD could provide feedback in terms of poor driving behavior, suggestions on how to improve, and recognition of good behavior.
<i>2.3 Self-monitoring of behavior</i>	Establish a method for participants to monitor their own behavior. BPD could provide the ability to review earlier feedback and to identify behavioral trends.
2.7 Feedback on outcomes	After periods of prolonged safe driving, BPD might inform participants that they are now statistically less likely to be involved in an accident than when they started the intervention.
<i>3.1 Social support (unspecified)</i>	Arrange for participants to receive support from others. In BPD, this could take the form of a social network connecting participants and friends.
<i>4.1 Instruction on how to perform a behavior</i>	Provide advice on how to perform a behavior. BPD could present how-to messages, describing techniques, and practices that help participants to perform the target driving behaviors.
4.2 Information about antecedents	Provide information about situations, events, or emotions likely to cause poor performance of the target driving behaviors.
<i>5.1 Information about health consequences</i>	Provide information about the positive or negative health consequences of wanted or unwanted behavior. BPD could deliver messages concerning the benefits associated with target behaviors.
5.2 Salience of consequences	Use methods to emphasize consequences for <i>5.1</i> , for example, having BPD display images of car wrecks and devastated loved ones.
5.5 Anticipated regret	Have participants imagine how regretful they would feel if they perform unwanted behavior, for example, speeding and something negative happens.
6.2 Social comparison	Draw attention to performers of good behavior to allow comparison with a participant’s own performance. For example, BPD could maintain a <i>leaderboard</i> allowing participants to see how well others are driving.
6.3 Information about others’ approval	Provide information about what other people think about good and bad behavior. BPD could provide informational messages about the negative social perception of unsafe drivers (or vice versa).
7.1 Prompts or cues	Introduce stimuli to encourage good behavior. BPD might provide NFC ^b sticker tags that participants can place in their vehicles to remind them to use the app and put their phone away.
8.3 Habit formation	Prompt rehearsal and repetition of good behavior in the same context repeatedly, so the context elicits the behavior. Having finished using BPD, participants should continue to perform the target behaviors they have developed habitually.
8.7 Graded tasks	Set easy tasks and then gradually make them harder as participants improve. BPD could offer goals at varying difficulty levels and ensure that participants make progress through the more challenging goals.
10.1 Material incentive (behavior)	Inform participants that a material reward (eg, money or vouchers) will be given in exchange for demonstration of the target behavior. BPD might seek partnership with businesses and organizations to provide such rewards.
10.4 Social reward	Similar to 10.1, but rather than a material incentive, the incentive would enhance a participant’s standing in some way. Performing target behaviors in BPD could earn participants achievements.
10.11 Future punishment	Inform participants that punishment or loss of reward occurs if poor behavior continues. BPD might simply raise awareness of legal or social punishments in response to detecting prolonged poor driving behavior.

Behavior change technique	Description
13.1 Identification of self as role model	Inform participants that their good behavior is an example to others. BPD could promote demonstrably safe drivers to others, offering a level to aspire to.
13.3 Incompatible beliefs	Draw attention to discrepancies between current or past behavior and self-image to create discomfort. BPD could use messaging to highlight differences in actual versus perceived driving skills and incompatible beliefs over driving practices.

^aBPD: BackPocketDriver.

^bNFC: near field communication.

In addition to the BCTs for which there is strong evidence that they have led to behavioral change in other interventions, BCTs 4.2 information about antecedents, 5.5 anticipated regret, 7.1 prompts or cues, 8.3 habit formation, and 13.3 incompatible beliefs are seriously worth considering because they are founded in behavioral change theory [22]. Others, including 6.2 social comparison, 6.3 information about others' approval, 10.4 social reward, and 13.1 identification of self as role model, currently lack evidence but appear interesting and relevant to BPD. Although there is no evidence yet to support BCTs 6.2, 6.3, 10.4, and 13.1, it is nevertheless valid to apply them in our intervention to determine their success in the context of youth driving.

App Development

On the basis of the design considerations, as discussed above, we have identified several features for the BPD smartphone app. The features are informed based on the selection of BCTs that are appropriate for the intervention. Each feature is described below.

Achievements

BPD uses social rewards (*BCT 10.4*) to reward participants who exhibit the target behaviors. Essentially, participants accrue points over time. Recognizing achievement was also a feature wanted by the target demographic.

Goal Setting

Goals are fundamental to BPD (*BCT 1.1*). Goals are presented in the form of "I will..." statements to promote the user's sense of attachment to the task, for example, "This week I will try not to steer jerkily."

On the basis of a participant's prior driving performance, BPD suggests particular goals that users can modify in terms of difficulty. Users are encouraged to choose more difficult goals as their driving performance improves (*BCT 8.7*).

Journey Summaries

At the conclusion of each driving episode, users can review their performance (*BCT 1.5*). Information displayed includes a map with the participant's route, highlighting incidents of good driving behavior, and others where driving can be improved. Feedback is provided (*BCT 2.2*) to include advice on how to modify behavior to reach goals. Where goals are being achieved, suggestions on more challenging goals are offered (*BCT 8.7*).

In addition to postjourney feedback, users have the opportunity to view feedback on previous journeys (*BCT 2.3*) and are prompted to use this feature if they have not used it for a while. This encourages them to view their progress over time.

Messaging

BPD makes liberal use of messaging as a means to meet many of the intervention's objectives introduced earlier. Messages serve many purposes, including providing information relating to instruction, consequences, antecedents, anticipated regret, feedback, other's approval, and incompatible beliefs. [Table 6](#) lists a selection of messages to illustrate the type of content participants can expect to see and shows the mapping to objectives and BCTs.

Messages are generally framed in terms of gain as opposed to loss, which has been shown to be more effective in leading to behavioral change [20]. In addition, the app generates messages that are specific to participant behavior. Again, messages linked to actual behavior are more effective in facilitating behavior change than those that simply offer general encouragement to drive safely [20].

BPD displays messages to users at different times in response to different stimuli. *Prejourney messages* are shown whenever the user starts a new journey. Prejourney messages remind the user of their goals for the journey in an encouraging manner.

Postjourney messages offer feedback on how well a user has driven (*BCT 2.2*). Positive messages are shown if a user has done particularly well, for example, "You've kept to speed limits today! Well done!" In other cases, encouragement with constructive criticism and tailored advice is offered, for example, "Well done on your journey today, but we noticed it was a little rough at times. Try to allow more time to stop the vehicle in the future so you don't have to slam on the brakes" (*BCT 4.1*). Where prolonged periods of poor behavior are observed, message content discourages continued poor driving (*BCT 10.11*).

Daily messages are sent to educate participants, for example, the messages derived from BCTs 4.1 and 4.2 in [Table 6](#). They may also include content targeting attitudinal change, where appropriate, and based on behavior data gathered by the app, for example, the messages associated with objectives 3 and 4 in [Table 6](#). Daily messages additionally prompt self-monitoring (*BCT 2.3*) by reminding the user of BPD's functionality, for example, "Did you know you can review your past journeys by accessing the Journey History from the main menu?"

Friends

Users can connect with elected friends who are also using the app, facilitating social support (*BCT 3.1*). This provides users with the opportunity to share achievements, statistics, and commentary with others.

Leaderboards

The app operates a leaderboard with which users can compare their own progress with that of other participants. This facilitates social comparison (*BCT 6.2*) and promotion of good drivers with role models (*BCT 13.1*). Leaderboards are a popular gamification element and have been shown to be effective in incentivizing user engagement in other apps [27]. Leaderboards also offer a means to peer competition, which is attractive to the target demographic.

Detection of Driving Conditions

Smartphones are capable of detecting many aspects of the driving environment, for example, time of day, type of road, and prevailing weather. Detecting driving conditions is a feature that enables automated generation of a driving log, including hours spent driving on different road types. Such logs are a requirement for learner drivers in some jurisdictions. Automated logging protects against the possibility of fraudulently entered manual log entries. As part of the stakeholder engagement, the NZTA viewed logging positively.

Journey Detection

BPD implements near field communication (NFC)–initiated journey monitoring. Participants stick an NFC tag on their dashboard and swipe their phone over the tag to commence monitoring. The tag additionally serves as a cue (*BCT 7.1*), reminding users to put away their phone and drive safely. BPD automatically detects cessation of vehicle movement for a prolonged period of time, stopping monitoring, and recording that the driving episode has concluded. For mobile phones that

are not NFC-enabled, users begin monitoring by pressing a button within the BPD app.

An alternative approach would be to automatically detect, without any participant action, the start of a journey. This would promote usability and would also ensure that all journeys are monitored. However, automated detection requires the device's accelerometer to be activated at all times, which causes significant battery drain. As this sort of interference was seen as a risk to adoption by the target demographic, BPD does not implement the automated detection.

Additional Driving Behavior Detection

Detecting driver behaviors other than speed and smoothness, for example, following (stopping) distances, is possible by using additional mobile phone sensors. This is discussed further in the Discussion section.

Rewards Scheme

By offering material incentives (*BCT 10.1*) in exchange for demonstrating good driving behavior, some users will be more extrinsically motivated to achieve their goals. However, we focus on intrinsic motivation only in this study because, as noted earlier, intrinsic motivation tends to lead to better long-term behavior change [24].

Parental Interface

Parents showed interest in being able to monitor their children's driving behavior, although the target demographic viewed parental involvement as a risk to adoption and use of BPD. A parental interface has not been implemented.

Table 6. Sample messages derived from objectives and behavior change techniques (BCTs).

Message	Objective	BCT ^a
<i>Remember to take your foot off the accelerator prior to cornering so you don't need to brake so suddenly.</i>	1	4.1
<i>Distractions like eating, changing music, and passengers can make you unsafe when driving. Try to minimize distractions as much as possible.</i>	1	4.1
<i>Did you know that driving while tired is as risky as driving while intoxicated?</i>	1	4.2
<i>You're much less likely to be involved in an accident if you keep within the speed limit.</i>	1	4.2
<i>In a bad mood today? Don't take it out on the road. Take a few deep breaths before turning the car on.</i>	1	4.2
<i>Allow enough time for your journey so that you don't feel the need to speed.</i>	1	4.2
<i>You're just about to start driving. It's now time to put your phone away for today's journey.</i>	1	7.1
<i>Drive to the speed limits and you'll avoid demerit points. You'll keep your license and enjoy the freedom from driving.</i>	3, 4	5.1
<i>How would you feel if you crashed because you lost control of your car? How would it affect your friends?</i>	3, 4	5.5
<i>Kids want you to share the roads with them safely. Slow down around schools and watch out for kids playing.</i>	3, 4	6.3
<i>Does a mate want you to race with them? Weigh it up—is the thrill of a race that will be over before you know it worth the risks?</i>	4	5.5
<i>Feeling the need for speed? Arrange a go-karting track session with your mates. That's the way!</i>	4	4.2
<i>Using a mobile phone on the motorway would be crazy! Did you know it's just as risky using a mobile phone around town?</i>	5	13.3

^aBCT: behavior change technique.

Table 7. Feature wish list for BackPocketDriver (BPD).

Feature	Behavior change techniques applied
Must haves	
Location and speed detection ^a	— ^b
Acceleration, braking, and turning detection ^a	—
Phone usage detection ^a	—
Achievements	BCT 10.4 (<i>social reward</i>)
Goal setting	BCT 1.1 (<i>goal setting</i>); BCT 8.7 (<i>graded tasks</i>)
Journey summaries	BCT 1.5 (<i>review behavior goals</i>); BCT 2.2 (<i>feedback on behavior</i>); BCT 2.3 (<i>self-monitoring</i>)
Messaging	BCT 2.7 (<i>feedback on outcomes</i>); BCT 4.1 (<i>instruction</i>); BCT 4.2 (<i>info about antecedents</i>); BCT 5.1 (<i>info about health consequences</i>); BCT 5.5 (<i>anticipated regret</i>); BCT 6.3 (<i>info about others' approval</i>); BCT 13.3 (<i>incompatible beliefs</i>)
Should haves	
Journey detection	BCT 7.1 (<i>prompts or cues</i>)
Friends	BCT 3.1 (<i>social support</i>)
Leaderboards	BCT 6.2 (<i>social comparison</i>); BCT 10.4 (<i>social reward</i>); BCT 13.1 (<i>identification of self as role model</i>)
Detection of driving conditions	—
Could haves	
Additional driving behavior detection	—
Nice to haves	
Rewards scheme	BCT 10.1 (<i>material incentive</i>)
Parental interface	BCT 2.1 (<i>monitoring without feedback</i>)

^aNecessary for target behaviors: 1 (*drive within speed limits*); 2 (*perform maneuvers safely and in a controlled manner*); 3 (*not use a mobile phone while driving*).

^bNot applicable.

Table 7 summarizes the feature set for BPD showing the linkage between features and BCTs. Software development followed an agile development process. Target users contributed to the development of wireframe models of BPD's UI, and software development progressed iteratively taking into account user feedback. Feature development was prioritized using the Must have, Should have, Could have, Won't have (MoSCoW) [28] method. In implementing the app's UI, Android's material design guide [29] was applied to ensure conformance with established principles and patterns for implementing UIs on small mobile devices.

App Implementation

Figure 1 shows several aspects of the BPD app. To start a journey, users either press the car-shaped button on the app's home screen (a) or swipe an NFC tag.

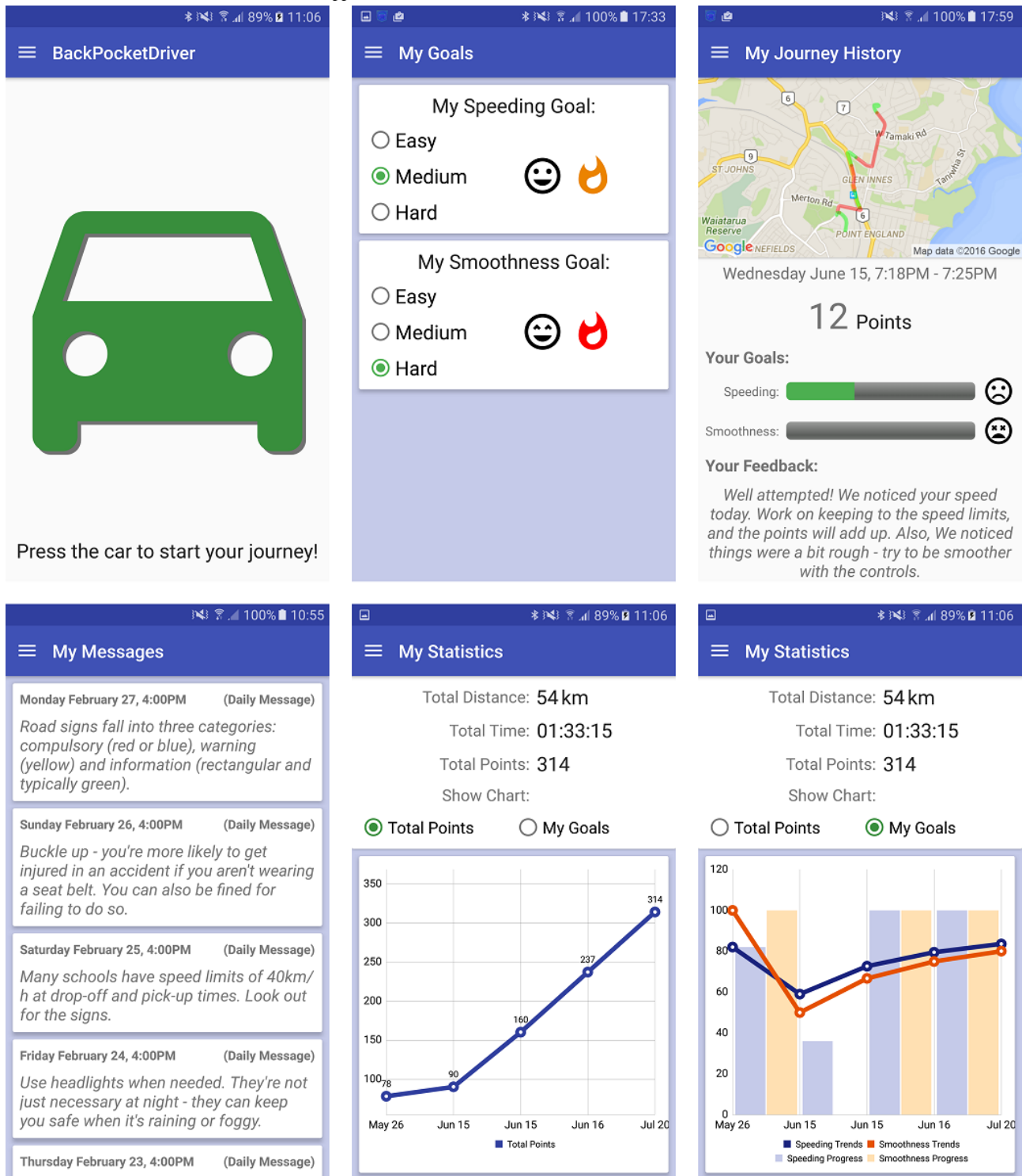
Before starting a journey, users choose goals to work toward, for example, Figure 1 (top center) where a user has chosen a moderate speeding goal and a more challenging smoothness goal. Once a journey has been completed, the smartphone app

sends the journey data to the BPD Web service, accessible via a Wi-Fi link, over the internet.

Having processed the data, the Web service sends feedback to the BPD app. Upon receipt, a notification appears in the device's notification tray. Users click the notification or navigate back into the app to view the journey summary (Figure 1, top right). The screen shows a map with their route, which is color-coded according to areas of good (green) or poor (red) driving behavior. Progress bars and icons detail how close a user was to achieving their goals for the journey, whereas a feedback message relays further information. Trends can be viewed such as those in Figure 1 (bottom center and bottom right), which allow users to view their progress over time.

All messages generated by BPD are viewable at any time on the screen shown in Figure 1 (bottom left). This includes journey-related messages in addition to daily messages that are sent via push notification to the device by a Web service. Messages are generated so as not to unnecessarily repeat content and to provide a fresh user experience.

Figure 1. Screenshots of the BackPocketDriver app.



The next step is to run a small study to assess BPD’s potential for effectiveness in developing safe driving skills among youth. A before-after study is currently underway involving 20 participants, aged 16 to 24 years, and on their restricted or full license. Participants are monitored using a minimal BPD app for 1 month to classify their driving behavior. They then switch to the full BPD app that includes the behavioral-change feature set for a second month. Following the study, any change in driving behavior will be identified based on app-generated data, and participants will have an opportunity to provide feedback on the intervention.

Discussion

Context

This study outlines the design of a smartphone-based intervention for developing safe driving skills among youth drivers. Although other researchers have investigated the use of smartphone technology in monitoring driver style and behavior, work that has sought to *improve* driving skills of youth is very limited. Moreover, we are not aware of other work that

has taken an approach rooted in behavior theory, evidence, and BCTs to inform design of a smartphone intervention.

Related Work: Existing Driving Apps

There is a plethora of driving-related apps available from app stores. Many apps target a particular aspect such as preparing for licensing theory tests (eg, Theory Test Kit and New Zealand Driving Theory Test), logging journeys (eg, DrivePad), and blocking messages, calls, and notifications during driving (eg, DriveMode, Shut Up and Drive, and Safe Ride). There are also apps that, similar to BPD, aim to assist young people to develop safe driving practices. We have selected 6 popular apps that appear to have overlapping objectives with BPD and which offer more than simple blocking or logging functionality.

For each app, we have examined its features and identified any BCTs to which features are attributable. Table 8 shows that BCTs are organized into 4 categories: the BCTs listed in Table 2 for which there is strong evidence that they have led to behavioral change, those that lack strong evidence to date but are rooted in behavioral theory, others that we identified earlier as interesting for a youth driving intervention, and others that we have not viewed as fundamental to BPD but are linked to the surveyed app(s).

LifeSaver is a blocking app that automatically silences a user's smartphone on detecting driving. Journey feedback (BCT 2.2) is limited to reporting on the unwanted behavior of using the phone, for example, to text while driving. At the end of a journey, the app displays a percentage score where 100 indicates that the user did not use their phone while driving. LifeSaver supports a family view, which is essentially a leaderboard that ranks the family members according to their scores. As the leaderboard shows each family member's score, teens are aware that their parents are monitoring them (BCT 2.1). Through location tracking of family members, the app facilitates social support (BCT 3.1) as users can see when their family members are driving and defer calling them until they have finished their journey.

TrueMotion Family is similar to LifeSaver in that it is also a family-oriented app with a leaderboard that publishes each family member's driving score. In addition to phone use, for example, texting and calling, TrueMotion Family also factors aggressive driving and speeding to generate a user's score. The app pinpoints unwanted behavior events on a map allowing the user to see where the events occurred; it also allows users to review their driving behavior over time (BCT 2.3).

Table 8. Behavior change technique feature matrix for popular youth driving apps.

Behavior change technique	LifeSaver	TrueMotion Family	Mojo	DriveSmart	EverDrive	Steer Clear
Behavior change techniques used in successful interventions						
1.1 Goal setting (behavior)						
1.3 Goal setting (outcome)						✓
2.2 Feedback on behavior	✓	✓	✓	✓	✓	
2.3 Self-monitoring of behavior		✓		✓	✓	
3.1 Social support	✓	✓				✓
4.1 Instruction on how to perform the behavior			✓			✓
5.1 Information about health consequences						
Behavior change techniques grounded in behavioral theory						
4.2 Information about antecedents						
5.5 Anticipated regret						
7.1 Prompts or cues						
8.3 Habit formation	✓	✓	✓	✓	✓	
13.3 Incompatible beliefs						
Behavior change techniques that appear relevant to a youth driving intervention						
6.2 Social comparison	✓	✓	✓		✓	
6.3 Information about others' approval						
10.4 Social reward	✓	✓	✓		✓	
13.1 Identification of self as role model	✓	✓	✓		✓	
Other Behavior change techniques						
1.8 Behavioral contract						✓
2.1 Monitoring of behavior by others without feedback	✓	✓	✓			
10.2 Material reward			✓	✓		✓
10.11 Future punishment				✓		

Mojo, similar to LifeSaver and True Motion Family, employs a leaderboard that ranks teens among their friends based on points earned while driving. As with LifeSaver, scoring is based on unwanted phone use alone. LifeSaver breaks down feedback, for example, providing a count of swipes and taps that a user makes on their phone while driving. Mojo differs by employing material rewards (BCT 10.2). Users who have amassed high scores are invited to spin a wheel for the chance to win a voucher. Mojo's feedback, rather than being limited to a score, also offers tips for improving behavior. For example, if the user has been making calls while driving, Mojo displays a message to tell the user that they will improve their safety and score by not making calls during future journeys.

DriveSmart monitors driver's behavior and generates a percentage score based on their braking, cornering, and speeding. Similar to TrueMotion Family, DriveSmart plots driving events on a map and allows users to review their behavior over time. Similar to Mojo, DriveSmart has rewards partners and can offer material rewards in exchange for good driving behavior. Unlike the above apps, DriveSmart does not offer any collaboration features such as a leaderboard; instead, it is intended to be used by an individual and not in a group context. As part of feedback, DriveSmart uses loss-framed messages, alerting users to future punishment (BCT 10.11), for example, for speeding.

EverDrive has a feature set similar to TrueMotion Family. It monitors a driver's acceleration, braking, cornering, speed, and phone use. Instead of providing feedback through percentage scores, it uses a 5-star scheme.

Unlike the above apps, Steer Clear does not monitor or provide feedback on driver behavior. It includes logging functionality that allows individuals to record their driving hours in different conditions. In addition, it has unique features: a behavioral contract (BCT 1.8), goal setting (BCT 1.3), and videos to share experiences of other users, a form of social support (BCT 3.1). When a user starts using the app, they make a pledge to drive safely; the pledge forms the basis of a behavioral contract. In using Steer Clear, users work toward the outcome goal of completing the set of Steer Clear modules. Once complete, users are eligible for insurance discount (BCT 10.2).

Table 8 reveals that the surveyed apps use quite a narrow band of BCTs. They generally provide feedback (BCT 2.2) and through monitoring and feedback, they help with forming good habits (BCT 8.3).

Many of the apps are group oriented involving family members and/or peers. They include a leaderboard feature, and the way that leaderboards are used is effective in exercising several BCTs. The leaderboards allow social rewards (BCT 10.4) in the form of stars and percentage scores to be publicized to the group, facilitating social comparison (BCT 6.2). They also enable higher scorers to identify themselves as role models (BCT 13.1). In addition, the leaderboards make users aware that they are being monitored by other group members in a way that does not involve feedback (BCT 2.1). Of these, BCTs 10.4 and 13.1 are particularly appropriate for strengthening intentions to perform wanted driving behaviors.

Of the apps that offer feedback on behavior, they do so in the form of a numeric score. Only Mojo and DriveSmart include textual feedback to supplement scores, and even here, the messages do not address health consequences, antecedents, anticipated regret, or incompatible beliefs—that either are proven or theoretically informed BCTs. Furthermore, none of the apps employ goal setting for behavior (BCT 1.1), which is a proven BCT. Similarly, instruction on performing wanted behaviors (BCT 1.4), another BCT for which there is strong evidence that it is effective, is employed very sparsely.

The apps have limited support for increasing positive attitudes toward wanted driving behaviors. The leaderboard feature, linked to BCT 6.2 (social comparison), can help address norms and demonstrates to a teen that others in their social group do exhibit the wanted behaviors. However, many of the other BCTs discussed earlier for addressing attitudes, managing self, and dealing with the actual or perceived skills mismatch are not associated with the surveyed apps' features. Hence, it seems unlikely that the surveyed apps can lead to long-term behavioral change.

Related Work: Monitoring Driver Behavior

In recent years, much work has been conducted to validate use of smartphones in providing a low-cost sensing platform and to supersede the older in-vehicle data recorder (IVDR) units that necessitate a fixed installation [8].

Today's smartphones include inertial sensors that enable smartphone driver support systems (SDSS) to detect driving events such as acceleration, braking, turning, and lane changing [7,9,30-32]. SDSS typically score a driver's behavior [7] or classify it in some way, for example, passive or aggressive and risky or safe [33]. Other apps have a narrower focus, for example, detecting events that suggest when a driver is driving under the influence of alcohol [11] that complement yet other apps concerned with drink and drive prevention [34]. SDSS offer high levels of accuracy, for example, with rates in excess of 90% for correctly classifying driver behavior [7,11,31,33].

Beyond a smartphone's inertial sensors, other in-built sensors include cameras and microphones that are being used to detect whether drivers are drowsy or distracted. CarSafe uses both the forward- and rear-facing cameras to monitor the driver's face and eyes along with the road ahead [12]. CarSafe detects and alerts drowsy drivers and warns them of events such as straddling the center line. DriveSafe [35] similarly warns drivers when they appear to be distracted or drowsy and, additionally, makes use of the smartphone's microphone, for example, to identify cases where the driver has turned without using the indicators (which are assumed to emit an audible signal when used).

Related Work: Youth Driving Interventions

In an early SDSS study [36], an app was developed to warn drivers in real time of speeding events and upcoming speed zone changes. Subsequently, and in the absence of any behavior change, the app sent text messages to participants to encourage them to reduce their speed. With 16 teen driver participants, the study found that use of the intervention resulted in a drop from 31% to 18% in speeding incidents. Other studies [37-39]

involving use of IVDR systems have similarly reported that monitoring and feedback does improve youth driving behavior. Moreover, an IVDR-based study involving 92 youth drivers found that teen coaching for 6 months is an insufficient period; when withdrawn, incidents of poor driving behavior, having previously declined, began to rise [40].

Parental involvement is a contentious issue for SDSS. Key findings for IVDR systems that involve parents, for example, [37,38,40], are that these interventions can provide useful and objective information to parents concerning teen driving behavior. Where teens believe that their parents might (but will not necessarily) review their driving, they tend to drive more safely. This is consistent with BCT 2.1, monitoring without feedback. Acceptance of parent-focused interventions is mixed because of issues of privacy and trust. In addition, systems that were evaluated by randomized controlled trials did not lead to a reduction in crash rates. Finally, parental involvement can be used to contribute to an intervention, but it is unlikely to be effective without other intervention elements [3]. We refer the readers to Curry et al's study [41] for more details on parent-focused interventions.

Gamification, the use of game elements in nongame contexts [42], is largely unexplored in SDSS for youth. Gamification uses extrinsic motivators to increase intrinsic motivation [27]. One app that employs gamification does so to encourage young drivers to undertake supervised driving in a range of conditions to improve their driving skills [43]. On the basis of a small study of 25 drivers, a gamified version of the app was found to be more enjoyable and motivating than a conventional nongamified version. Although the gamified app did not lead to behavioral change, it is likely to lead to greater adherence to an intervention.

With mobile phones known to be a source of distraction when driving, the role of SDSS in blocking incoming calls and text messages has been investigated. A study involving teen drivers [44] found that blocking did reduce the number of calls made and the number of text messages sent while driving. In particular, the intervention reduced impulsive calling and texting. However, the study also found subjective data showing that users tried to work around the blocking functionality, for example, by using a friend's phone while driving.

Principal Findings

BPD's feature set has been derived through the application of behavioral theory and BCTs and consideration of the evidence relating to BCT effectiveness elsewhere. Beyond monitoring and classifying driver behavior, which is where much of the existing work in SDSS stops, BPD's design includes a suite of features that have a clear mapping to distinct BCTs. A key feature is postjourney feedback. Messaging is also employed for many purposes: to instruct, motivate, educate, and relay feedback to participants and to address participants' attitudes and beliefs. BCTs and gamification are complementary; BPD's design combines elements of gamification with BCTs in offering goal setting and review and achievements and leaderboards. Leveraging the smartphone sensor platform, the design also allows for monitoring of additional facets of driving behavior and automated detection of driving conditions.

BPD's design has also taken into account technology acceptance considerations. The app enables youth to perceive gains through constructive feedback, education, and social comparison or competition. These features further contribute to addressing delay discounting and social influence in that they help to retain user engagement and interest over time, not only for individuals but also for peer or social groups.

Key risks have been mitigated. Unlike other SDSS and IVDR systems and apps, BPD does not present percentage scores or include raw or absolute figures for acceleration and speed when providing feedback. This ensures that BPD cannot be used to subvert the intervention, for example, by teens using the app to record and share race times and dangerous driving events. In addition, BPD allows users to control how they share their data in the interests of privacy. Moreover, the app conserves device resources—using no mobile data and minimizing power consumption—so as to have minimal perceived effect on users' smartphones for daily operation. Furthermore, BPD does not offer real-time feedback, contrary to many SDSS and IVDR systems. This is both to avoid distraction, which has been linked to real-time feedback in other studies [36,41] and to conserve mobile data.

Regarding usability, the app is easy to use. It requires no calibration before use, and during a journey the smartphone can be kept in the driver's pocket (the app functions accurately without requiring a fixed dashboard mount). The app does not provide a completely seamless experience in that it does not detect the start of a journey and begin monitoring automatically. Implementing this feature would increase the risk that youth would not use the app because the necessary power-draw would interfere with the normal operation of the smartphone. This represents a conflict between requirements; a key conflict among stakeholders is the issue of parent involvement versus youth privacy. In developing BPD, we have sought to minimize risks to intervention adoption.

BPD is complementary to fundamental research aimed at understanding the underlying issues that contribute to youths' over-representation in crashes. In Shope et al's study [45], a framework has been developed that identifies 7 categories of influence on teen driving behavior: driving ability, developmental factors, behavior factors, personality, demographic, and perceived and driving environments. Other research has targeted particular influences, for example, risk perception and sensation seeking [46]. As a technology-based intervention, BPD has much potential to address some influences, for example, driving behavior and ability. It could serve as part of a holistic approach to supporting youth driving; such comprehensive approaches necessarily require buy-in from many factions, including government, researchers, public health practitioners, parents, teens, and auto industries [3].

Conclusions

BPD is a smartphone-based intervention that aims to improve driving skills in youth. Critically, BPD's design has been informed by behavioral theory and behavioral change expertise. Stakeholder feedback and technology acceptance considerations have also been factored into the design. Having implemented the app on a sound theoretical foundation, the next step is to

evaluate its potential to be effective in changing youth driving behavior. A small study involving 20 youth participants is currently underway, and we expect to report on the results in the near future.

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Conflicts of Interest

None declared.

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Abbreviations

AA: Automobile Association
BCT: behavior change technique
BPD: BackPocketDriver
GDL: graduated driver licensing
IVDR: in-vehicle data recorder
NFC: near field communication
NZTA: New Zealand transport agency
SDSS: smartphone driver support system
SMS: short message service
UI: user interface

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Original Paper

Web-Delivered Multimedia Training Materials for the Self-Collection of Dried Blood Spots: A Formative Project

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Abstract

Background: The use of dried blood spots (DBS) in biomedical research has been increasing as an objective measure for variables that are typically plagued by self-report, such as smoking status and medication adherence. The development of training materials for the self-collection of DBS that can be delivered through the Web would allow for broader use of this methodology.

Objective: The objective of this study was to evaluate the acceptability and feasibility of the self-collection of DBS using newly developed multimedia training materials that were delivered through the Web. We also aimed to assess the usability of the collected DBS samples.

Methods: We recruited participants through Facebook advertising for two distinct studies. The first study evaluated the acceptability of our newly developed DBS training materials, while the second assessed the implementation of this protocol into a larger Web-based study.

Results: In the first study, participants (N=115) were aged, on average, 26.1 (SD 6.4) years. Training materials were acceptable (113/115, 98.2%, of participants were willing to collect DBS again) and produced usable samples (110/115, 95.7%, collected DBS were usable). In the second study, response rate was 25.0% (41/164), with responders being significantly younger than nonresponders (20.3 [SD 0.2] vs 22.0 [SD 0.4]; $P<.001$), and 92% (31/41) of collected DBS samples were usable by the laboratory.

Conclusions: Overall, while the protocol is acceptable, feasible, and produced usable samples, additional work is needed to improve response rates.

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KEYWORDS

dried blood spot; internet; feasibility studies

Introduction

Dried blood spots (DBS) are drops of whole blood that are collected on filter paper from a finger prick [1]. A wide range of biomarkers have been validated for assessment in DBS

([Multimedia Appendix 1](#)) [1-10]. The number of DBS biomarkers surpasses the number of validated biomarkers in urine or saliva samples alone [1,11]. The use of DBS in biomedical research has been growing as it allows objective measurement of variables that have been troubled by self-report

and recall bias (eg, biological confirmation of smoking status or medication compliance) [1]. Furthermore, the Centers for Disease Control and Prevention has stated that DBS "...has achieved the same level of precision and reproducibility that analytical scientists and clinicians have come to expect from standard methods of collecting blood such as vacuum tubes..." [12]. In addition to the wide range of applicable uses, DBS also provides other advantages over venipuncture and other biospecimen collection methods. DBS samples are stable at room temperature for a longer time period, and their collection is less costly and less burdensome for study participants [1,11].

A newly demonstrated benefit of biomarker analysis using DBS is the ability for the self-collection of samples by study participants. Successful self-collection of DBS has been reported in a wide variety of study samples from children with epilepsy [13] to individuals at high risk for HIV [14] and diabetics [15]. These studies have demonstrated high accuracy of collection as well as high satisfaction with the collection process. For instance, in a sample of adults with diabetes, 94% collected DBS correctly, and 97% reported that collection was easy [15]. Similarly, while 32% of individuals at high risk for HIV reported some discomfort with DBS collection, 92% reported that the process was easy and 93% indicated a willingness to collect DBS in the future [14].

Unfortunately, the use of DBS methodology is limited as nearly all studies have relied on in-person training for the self-collection of DBS. However, Roberts et al [4] recently utilized the self-collection of DBS after training via a printed brochure that was delivered through the mail. While 91% of their samples were usable, they recommended the use of a training video to reduce the number of suboptimal DBS specimens. We sought to eliminate the need for in-person training of accurate DBS self-collection by creating standardized written and video training materials that could be delivered through the Web. Therefore, the goal of this project was to evaluate the acceptability, feasibility, and usability of DBS samples that were collected after utilizing newly developed multimedia training materials delivered through the Web. To address this goal, we conducted two studies. In Study 1, we tested the newly developed training materials to determine the acceptability of the self-collection of DBS after exclusive Web-based training, as well as the usability of DBS samples. In Study 2, we implemented the DBS protocol within a larger ongoing study to assess the feasibility of our protocol. Eliminating the in-person training, in favor of Web-delivered training, will substantially reduce the logistical hurdles involved with collecting DBS samples. This will allow DBS collection to occur without any in-person interaction between study staff and participants, thereby allowing DBS to be collected with relative ease and be used for biomarker analysis in large, geographically diverse, population-based studies.

Methods

Development of Training Materials

To address our study goal, we created a video with corresponding written training materials. These items were modeled after previously created materials that were used to

train medical professionals for the collection of DBS [11] and those that have been previously used for in-person training for DBS collection in an ongoing HIV-related research project at Emory University (personal communication with Dr AD Mc Naughten, March 11, 2014; August 12, 2015; September 3, 2015). Initially developed materials were qualitatively reviewed by a small local sample (n=20) of male and female cigarette smokers (data not shown). After the identification of two major gaps in the training materials (clear instructions to not touch the filter paper and what to do if blood is not flowing enough), the training materials were revised. Final training materials can be found in [Multimedia Appendices 2 and 3](#). All study-related procedures were approved by the institutional review board at the University of Minnesota.

Study 1

Recruitment

Upon completion of the training materials, we recruited a convenience sample of study participants through advertising on Facebook. Recruitment advertising occurred for 1 week in April 2016 and was restricted to individuals in the United States between the ages of 18 and 35 years. After clicking on the advertisement, eligibility was assessed through a Research Electronic Data Capture (REDCap) survey [16]. To be eligible for the study, participants had to be between the ages of 18 and 35 years and self-report being a daily smoker at a rate of at least 5 cigarettes per day. These inclusion criteria were selected given a secondary goal of examining the relationship between sex hormones (eg, progesterone) and smoking-related biomarkers (eg, cotinine). Potential participants were excluded if they reported having difficulties (eg, feeling nauseous or dizzy) with the sight of blood.

Study Procedures

Upon confirmation of eligibility, participants provided informed consent and completed a pretest survey. In addition to information regarding demographics and smoking behavior, the pretest survey included 3 questions to assess expectations regarding expected difficulties with DBS collection, as well as confidence and willingness to complete DBS collection. Participants responded using a 100-point visual analog scale ranging from "very easy" or "not at all" to "very hard" or "very willing." In addition, we asked if participants had any prior experience with DBS collection (yes, no, not sure).

Next, participants viewed the 5-minute training video. We recorded the length of time the webpage displaying the video was open. Upon completion of the video, participants completed a posttest survey, which contained 3 sections. The first section was video response section in which participants answered 6 questions with 4 options (ranging from "strongly agree" to "strongly disagree") regarding the clarity of the video. The next section was the knowledge section that contained 6 true or false statements regarding the proper way to collect DBS (eg, "It is okay to touch my finger to the collection card"). The last section of the posttest survey assessed the willingness to collect DBS. Participants were asked if they would be willing to collect DBS and mail the DBS sample to the University of Minnesota in exchange for a US \$25 Amazon or Target e-gift card. Those

who indicated they would not be willing to collect were asked why they did not want to collect DBS. Those who indicated they would be willing to collect were routed to a survey in which they provided their mailing address. All data collection was completed through REDCap [16].

Finally, DBS collection materials were mailed to participants. The mailing included a letter, which contained a URL link to the training video, as well as a printed copy of the written instructions and placemat. Three DBS collection kits were sent to each participant—one kit, along with two back-ups to be used if necessary. Each kit contained 1 micro-lancet, 1 collection card (a 903 Protein Saver Card purchased from GE Healthcare Life Sciences), 2 gauze pads, 1 alcohol wipe, and 1 bandage. Furthermore, a postcollection survey was included to assess the overall impression of the process as well as the impression of the video and written materials. Additional materials included a pen, packaging materials (a desiccant packet, humidity indicator, and plastic biohazard bag), and a prepaid return envelope. The cost of supplies for each collection kit was US \$7.56 plus US \$5.34 in postage for a total of US \$12.90 per mailing.

We defined feasibility as the number of DBS samples received back from study participants. The laboratory staff then classified samples into one of four categories: excellent, satisfactory, poor, and not usable.

Study 2

Recruitment

From July to September 2016, we recruited a new and larger convenience sample including current smokers (defined as a self-report of smoking ≥ 100 cigarettes in their lifetime and smoking on at least 4 of the past 30 days) in the United States between the ages of 18 and 35 years through Facebook advertising to assess the role of hormonal contraceptive on smoking-related behaviors (results forthcoming). Per the goals of the parent project, participants were selected for this ancillary DBS project as follows: (1) all female participants who reported current use of any of the following types of hormonal contraceptives: Implanon ($n=14$), Mirena intrauterine device ($n=17$), or combination oral contraceptives with a stable daily ethinyl estradiol dose between 20 and 30 micrograms ($n=43$); (2) a simple random sample of 45 female participants who reported regular menstrual cycles and no use of exogenous hormones; and (3) a simple random sample of 45 male participants.

Study Procedures

Eligible participants were emailed an invitation to participate in this ancillary study, which contained a link to view the DBS training video as well as a link to a survey on REDCap [16], where interested participants would provide informed consent and their mailing address. After the original email invitation, eligible participants received an additional three reminder emails to participate in the ancillary study on 3, 6, and 14 days after the original invitation email was sent. All data regarding demographics and smoking behavior were collected from study participants through REDCap prior to the invitation to this ancillary study. All participants were paid a US \$10 Amazon

e-gift card for completion of this 20-minute survey. Participants who expressed an interest in completing the DBS protocol were sent the same materials as described above. Due to time restrictions with the study grant, participants were given 1 month to return completed DBS samples in exchange for a US \$50 Amazon e-gift card. Email reminders were sent 2 weeks and 5 days prior to the collection deadline.

Statistical Analysis

Descriptive statistics (means and SEs for continuous variables and percentages and counts for categorical variables) were computed to describe the demographics and smoking behavior of the study sample separately for both studies. In addition, descriptive statistics were computed for the following items collected in Study 1: (1) expectations from the pretest survey in Study 1; (2) the clarity of the video, knowledge of the process, and willingness to collect DBS from the posttest survey; and (3) receipt of DBS samples, responses to postcollection survey, and laboratory staff rankings of “usability.” In both studies, simple *t* tests and chi-square tests were performed to compare the demographics and smoking behavior between those who were willing to collect DBS versus those who were not, as well as those who returned their DBS samples versus those who did not. All analyses were conducted using SAS 9.3 (SAS Institute).

Results

Study 1

Study Sample

A total of 242 participants provided informed consent and completed the eligibility survey. A total of 28 were excluded due to the following reasons (items are not mutually exclusive): age ($n=12$), smoking < 5 cigarettes per day ($n=21$), or not being comfortable working with blood ($n=9$). Therefore, of all the participants enrolled into the study, 53.7% (115/214) completed the Web-based survey. The 115 participants who completed the survey were on average 26.1 (SD 6.4) years of age and smoked 17.4 (SD 9.7) cigarettes per day. Most (107/115, 93.0%) participants were white people and approximately half had at least some college education (58/115, 50.4%); 50.4% (58/115) participants were male and 49.6% (57/115) smoked their first morning cigarette within 40 minutes of waking. The sample was also geographically diverse (using the US Census definition)—17.4% (2/115) of participants from the West, 37.4% (43/115) from the Midwest, 20.0% (23/115) from the Northeast, and 25.2% (29/115) from the South. No significant differences were observed between those who completed the study ($n=115$) and those who did not ($n=99$) in terms of demographics or smoking behavior.

Previewing Survey

Prior to viewing the training video, 35.7% (41/115) participants indicated that they had some prior experience with the self-collection of DBS. On average, participants did not think the DBS self-collection would be difficult (25.1 [SD 24.8] on a 100-point visual analog scale with “0” indicating “not at all difficult”) and were confident that they would be able to successfully self-collect DBS (74.5 [SD 25.68] on a 100-point visual analog scale with “100” indicating “very confident”).

Upon completion of this survey, participants watched the training video. On average, the 5-minute video was viewed for 3.6 (SD 3.5) minutes, with 50.4% (58/115) of participants watching through the end of the instructions (4:38 minutes or more).

Postviewing Survey

After viewing the training video, most replied with “agree” or “strongly agree” to the following statements: (1) the instructions in the video were clear (113/115, 98.2%); (2) the video was enjoyable to watch (98/115, 85.2%); (3) after watching the video, I felt like I knew how to collect DBS (114/115, 99.1%); (4) after watching the video, I felt excited to collect DBS (89/115, 77.3%); (5) after watching the video, I felt more confident about my abilities to collect DBS (113/115, 98.2%); and (6) after watching the video, I felt more willing to collect DBS (104/115, 90.4%). As displayed in [Table 1](#), most participants responded to the true or false questions correctly.

A total of 106 participants (106/115, 92.1%, of those who completed the survey; 106/214, 49.5%, of the initially enrolled sample) indicated they would be willing to self-collect DBS for this study and 86.9% (100/115) provided us with a mailing address to send the collection materials. Among those who declined participation, 8 participants provided a reason for declining, which included (item not mutually exclusive) wanting more compensation (6/8, 75%), feeling uncomfortable sending blood to researchers (2/8, 25%), and feeling uncomfortable sending identifying information, such as mailing address, to researchers (2/8, 25%).

Usability of Dried Blood Spot Samples

Of all DBS kits mailed out, we received 51.0% (51/100) DBS samples back for analysis. A total of 96% (49/51) DBS samples were rated as “usable” by the laboratory staff. Two samples were rated as not usable because the drops of blood on the card were too small.

Table 1. Knowledge questions with participant response (n=115).

Question	Response, n (%)	
	True	False
The blood spots should fill most the collection circle.	113 (98.2) ^a	2 (1.7)
It is okay to touch my finger to the collection card.	110 (95.6) ^a	5 (4.3)
If my drop of blood does not fill the collection circle, I should add a second drop of blood.	22 (19.1)	93 (80.7) ^a
It is okay if my blood drop falls slightly outside the collection circle.	92 (80.0) ^a	23 (20.0)
If my blood stops flowing and I haven't filled all of the circles, I should prick another finger to try to fill all the circles.	67 (58.2) ^a	48 (41.7)
I should make sure the blood spots have dried for at least 4 hours before packaging the card.	109 (94.7) ^a	6 (5.2)

^aThe correct response.

Table 2. Postcollection survey (n=46).

Items and responses	Instructional booklet, n (%)	Video, n (%)
The instructions in the (instructional booklet or video) were clear.		
Strongly agree	44 (93)	41 (89)
Agree	2 (7)	4 (9)
Disagree	0 (0)	1 (2)
Strongly disagree	0 (0)	0 (0)
After (reading the instructional booklet or watching the video) I felt more willing to collect dried blood spots.		
Strongly agree	33 (71)	29 (63)
Agree	13 (29)	16 (35)
Disagree	0 (0)	1 (2)
Strongly disagree	0 (0)	0 (0)
After (reading the instructional booklet or watching the video) I felt confident about my abilities to collect dried blood spots.		
Strongly agree	41 (89)	38 (82)
Agree	5 (11)	7 (16)
Disagree	0 (0)	1 (2)
Strongly disagree	0 (0)	0 (0)

Among those who returned their DBS samples, 90% (46/51) also returned the postcollection survey. As displayed in [Table 2](#), participants thought the instructional materials were clear, increased willingness to collect DBS, and invoked feelings of confidence. Agreement with these items was slightly higher for the instructional booklet versus the video. Furthermore, these survey results indicated that most participants were “definitely” (41/46, 89%) or “probably” (4/46, 9%) willing to collect DBS again.

Study 2

Implementation

The email invitation was sent to a total of 164 eligible participants. Of them, 43.2% (71/164) provided informed consent and a mailing address. The nonresponders ($n=93$) were younger (20.3 [SD 0.2] vs 22.0 [SD 0.4]; $P<.001$), smoked on fewer days in the last 30 days (23.0 [SD 0.9] vs 25.9 [SD 0.8]; $P=.01$), and were more likely to be nonwhite people (25/93, 27%, vs 7/93, 7%; $P<.001$). There were no differences between responders and nonresponders in terms of gender, education, income, or cigarettes smoked per day.

Of the 71 DBS collection kits that were mailed to participants, 58% (41/71) returned DBS samples; 6% (4/71) kits were returned due to mailing or addressing errors and 37% (26/71) were not returned. Compared with those who returned the DBS kit ($n=41$), those who did not ($n=30$) were younger (22.9 [SD 0.5] vs 20.9 [SD 0.5]; $P=.01$). There were no differences in terms of gender, education, income, work status, race, ethnicity, or smoking behavior, including cigarettes smoked per day. Of the 41 samples received, 92% (38/41) were usable by the study laboratory.

Discussion

Principal Findings

Overall, the results of this project indicate that Web-delivered training on the self-collection of DBS was acceptable to study participants and that the protocol was feasible to implement. Specifically, the vast majority of participants indicated that both the instructional video and written materials increased their confidence and willingness to self-collect DBS. Furthermore, nearly all participants who self-collected DBS indicated they would probably or definitely be willing to collect again. Finally, nearly all self-collected DBS samples received were deemed usable by the laboratory staff. However, upon implementation of this protocol into a larger, ongoing study, our response rates remained low, despite increasing the financial incentives. This was especially true among the participants who were younger and of a racial minority.

Our observations regarding the usability of self-collected DBS are comparable to prior studies that used in-person training. For instance, in a study conducted by Fokkema et al [15] with an adult sample of diabetics who received in-person training on the self-collection of DBS, 95% of samples were collected correctly. Our laboratory staff determined that 95% (87 of 92) of our samples were collected correctly, which was slightly higher than the 91% rate observed in a recently published work

that used written training materials only [4]. Furthermore, the prior literature on self-collection of DBS that used in-person training reported high rates of willingness to self-collect DBS again (eg, 93% in a sample of HIV-infected individuals [14]). We reported that 98% (41/46) participants were “definitely” and 9% (4/46) were “probably willing to self-collect DBS again. Therefore, our Web-delivered training materials led to similar success and acceptability rates compared with in-person training.

Notably, only half of the study sample viewed the training video through the completion of the instructions. While participants who received the DBS self-collection kits through the US mail were instructed to view the video a second time prior to collection, it is unknown whether or not participants actually did this and, if so, how long they watched the video. Compared with the video, the written materials were indicated to be clear, as well as increasing the willingness and confidence to self-collect DBS, by more participants. Given that 95.7% (110/115) of DBS samples received by us were usable by the laboratory, suggests that written training materials may be more informative than the video. Overall, these observations suggest that the written training materials may be adequate on their own without the training video. However, we did not formally compare the usefulness of these materials.

Unfortunately, we observed a response rate of approximately 25.0% (41/164) when implementing this protocol into a larger, ongoing Web-based study; this was despite doubling the incentive for returning collected DBS samples from US \$25 to US \$50 from Study 1 to Study 2, which was the most common reason for declining in Study 1. There were a number of significant differences between responders and nonresponders; the latter were younger and more likely to be nonwhite people. Our response rate is quite a bit lower than that observed in a recently completed project with young adult cancer survivors, which paid participants US \$20 for completion [4]. It is likely that young adult cancer survivors are more motivated to participate in research than young adult smokers in the general population. Furthermore, the young adult cancer survivors were older and more educated than our sample. This suggests that in order to improve overall response rate, additional development in the protocol to encourage motivation for compliance is needed and study should be tailored to those who are younger or of a racial minority. For example, additional reminders (eg, via email, US mail, or texting) and more collection kits could be sent out to participants and a longer time for return of study samples could be provided. It may also be helpful to provide a small amount of initial compensation along with the mailed DBS collection kits to increase the incentive to return the completed DBS samples.

Although this study is the first to assess the feasibility of Web-delivered multimedia instructions for the self-collection of DBS, it is not without limitations. First, slightly less than half (99/214, 46.2%) of our participants discontinued the Web-based survey early in Study 1. Although those who discontinued the survey early were statistically comparable to those who completed the survey in terms of their demographics and smoking behavior, it is possible that selection bias is present in this study. Second, we limited our sample to individuals who were between the ages of 18 and 35 years and were daily

cigarette smokers. Therefore, it is unknown whether our observations are generalizable to other populations. Third, there are ethical considerations that need to be taken into account when performing research on Facebook (eg, verification of the age of consent). Next, in Study 2, we had a somewhat limited timeline due to funding restrictions. It is possible that our response rates would have been better if we allowed participants to return their DBS at a later date. Finally, we did not directly compare our training materials (eg, video and training booklet) to each other nor did we use a control group. Therefore, it is unknown which materials are driving our observations. These methodologies would be strengthened with this type of comparison; thus, future research should pursue this.

Conclusions

These newly developed multimedia training materials for the self-collection of DBS are acceptable to study participants, feasible to implement within a Web-based setting and yield usable self-collected DBS. However, response rates were low. Therefore, additional work is needed to improve response rates, especially among certain subgroups of the population. Future research pursuing improving the response rates would allow for the elimination of in-person training and, therefore, substantially expand the application of DBS to a variety of areas such as telemedicine, large population-based epidemiology studies, and Web-delivered intervention studies.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Biomarkers measurable in dried blood spots.

[[PDF File \(Adobe PDF File\), 72KB - formative_v2i2e11025_app1.pdf](#)]

Multimedia Appendix 2

Instructional video.

[[MP4 File \(MP4 Video\), 52MB - formative_v2i2e11025_app2.mp4](#)]

Multimedia Appendix 3

Written materials including the instructional booklet (3A) and placemat (4B).

[[PDF File \(Adobe PDF File\), 1MB - formative_v2i2e11025_app3.pdf](#)]

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Abbreviations

DBS: dried blood spots

REDCap: Research Electronic Data Capture

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Original Paper

Acceptance of Mobile Health Apps for Disease Management Among People With Multiple Sclerosis: Web-Based Survey Study

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Abstract

Background: Mobile health (mHealth) apps might have the potential to promote self-management of people with multiple sclerosis (MS) in everyday life. However, the uptake of MS apps remains poor, and little is known about the facilitators and barriers for their efficient utilization, such as technology acceptance.

Objective: The aim of this study was to examine the acceptance of mHealth apps for disease management in the sense of behavioral intentions to use and explore determinants of utilization among people with MS based on the Unified Theory of Acceptance and Use of Technology (UTAUT).

Methods: Participants for this Web-based cross-sectional study were recruited throughout Germany with the support of regional MS associations and self-help groups. To identify determinants of intention to use MS apps, a measure based on the UTAUT was adapted with 4 key determinants (performance expectancy, effort expectancy, social influence, and facilitating conditions) and extended by Intolerance of Uncertainty (IU) and electronic health literacy. Potential influencing effects of both MS and computer self-efficacy (C-SE) as mediators and fatigue as a moderator were analyzed using Hayes's PROCESS macro (SPSS version 3.0) for IBM SPSS version 24.0.

Results: A total of 98 participants (mean age 47.03 years, SD 10.17; 66/98, 67% female) with moderate fatigue levels completed the survey. Although most participants (91/98, 92%) were daily smartphone users, almost two-thirds (62/98, 63%) reported no experience with MS apps. Overall, the acceptance was moderate on average (mean 3.11, SD 1.31, minimum=1 and maximum=5), with lower scores among persons with no experience ($P=.04$) and higher scores among current users ($P<.001$). In multiple regression analysis ($R^2=63%$ variance explained), performance expectancy ($\beta=.41$) and social influence ($\beta=.33$) were identified as significant predictors of acceptance (all $P<.001$). C-SE was confirmed as a partial mediator in the relationship between IU and acceptance (indirect effect: $B=-.095$, 95% CI -0.227 to -0.01). Furthermore, a moderated mediation by C-SE was shown in the relationship between IU and behavioral intentions to use MS apps for low (95% CI -0.42 to -0.01) and moderate levels (95% CI -0.27 to -0.01) of fatigue.

Conclusions: Overall, this exploratory pilot study indicates for the first time that positive expectations about the helpfulness for self-management purposes and social support might be important factors to be considered for improving the acceptance of MS apps among smartphone users with MS. However, given some inconsistent findings, especially regarding the role of effort expectancy and IU and self-efficacy, the conceptual model needs replication with a larger sample of people with MS, varying more in fatigue levels, and a longitudinal assessment of the actual usage of MS apps predicted by acceptance in the sense of behavioral intentions to use.

KEYWORDS

multiple sclerosis; eHealth; mHealth, acceptability of health care; patient preference

Introduction

Multiple Sclerosis: Challenges for Self-Management

Multiple sclerosis (MS) is a chronic autoimmune disease of the central nervous system (CNS), which is characterized by exacerbations of neurological dysfunction [1]. Approximately 2.3 million people live with MS worldwide [2], of which half of those affected live in Europe [3] and about 200,000 people live in Germany [4]. Prevalence rates vary between region and registry. The onset of MS is usually between the 20th and 40th year of life, with women being affected more often than men at a ratio between 2:1 [5,6] and 3:1 [3]. Thus, MS is one of the most prevalent neurological disorders in young adulthood, leading to permanent disability and early retirement [3,4].

Principally, 4 major MS forms related to different challenges can be distinguished [6]: with 85% of cases, the most common MS form is relapsing-remitting MS, which is characterized by relapses and exacerbations as well as phases of remission. This form can transit to the secondary progressive form with continuing worsening. The primary progressive form of MS with gradual, continuous worsening from the onset affects approximately 10% of people with MS, whereas progressive relapsing MS with symptom progression from the onset without periods of remission represents less than 5% of cases [6]. Depending on the neuroanatomical localization of plaques of demyelination in the CNS, symptoms can be manifested as various motor, visual, cognitive, and sensory disturbances as well as fatigue [5], making it difficult to predict the individual MS course [6]. Therefore, coping with uncertainties is a key challenge of living with MS [7].

Because little is known about the etiology of MS [5] and there is currently no cure, the long-term MS treatment also has to focus on disease management or self-management and coping with uncertainties [7]. Self-management of a chronic illness can be defined as a dynamic process of actively coping [8]. Given that research has shown that people with MS prefer to take an active role in treatment decisions among most people with MS [9], self-help tools such as mobile health (mHealth) apps for MS could be useful for supporting disease management [10].

Multiple Sclerosis Apps as Self-Management Tools

Given that people with MS often experience issues in accessing health care services because of barriers such as mobility restrictions, mHealth and electronic health (eHealth) services represent a promising way to facilitate MS disease management [11]. In fact, the internet is the first source for health information for many people with MS [12].

Research suggests that modern technologies and new media in the health context (eHealth) may be helpful for people with MS by promoting adherence, self-management skills [10], mental health [13], physical activity [14-17], and fatigue management [18,19].

Many MS patients in Germany are familiar with using mobile phones for communication with health care providers [20]. Furthermore, a recent survey of the North American Research Committee on Multiple Sclerosis registry showed that 28.6% of participants with MS have used secure Web-based portals for the exchange of medical information with health care providers and that 46.2% of the smartphone and tablet users used an mHealth app [21].

Moreover, mHealth apps appear especially suitable for people with MS because of their location-independent and time-flexible accessibility [11]. There is also a growing number of positive economic evaluations on the cost-effectiveness of mHealth apps for medical conditions [22]. Hence, high-quality mHealth apps for MS can further help empower people with MS to be more active in their disease management and informed decision making [23].

The focus of existing apps and other stand-alone or blended care eHealth solutions lies in screening and assessment, disease monitoring and self-management, advice and education, as well as treatment and rehabilitation [11]. A narrative review of 28 eHealth and mHealth solutions for MS by Marziniak et al [11] showed that mHealth apps for MS patients such as Msdialog, COGNI-TRACK, or MyBetaApp usually address self-management and monitoring (eg, medication reminder and symptom tracking), whereas Web-based interventions such as Deprexis or MS Invigor8 focus on treatment and rehabilitation [11].

However, despite these advantages, the uptake of MS apps is poor. A scoping review [24] indicated that most MS apps for disease management failed to meet the needs and demands of users with MS. While advantages of eHealth and mHealth solutions include the possibility to connect with others [25], improved health care access or greater independence [26], perceived disadvantages involve the potentially poor usability for people with neurological impairments [25], and data security concerns [26]. However, especially in countries such as Germany with an early stage of eHealth adoption in routine care [27], little is known about the acceptance of mHealth services for MS as another barrier.

To shed light on the determinants of MS apps' uptake, technology acceptance models (TAM) [28] such as the Unified Theory of Acceptance and Use of Technology (UTAUT) [29] provide guidance as a validated framework. In these models, acceptance is operationalized as behavioral intention to use or actual usage of a technological innovation as dependent variables of a set of personal and interpersonal attitudinal factors. In the context of the TAM, Davis et al [28] argued that people form attitudes and intentions toward learning to use a novel technology, which are associated with uncertainties, before starting efforts aimed at performing. As an early form of acceptance, intention to use represents a well-established predictor of behavior, for instance, in terms of health behavior

[30] and the use of psychological services [31] as well as information technology [28]. In accordance with the Theory of Planned Behavior (TPB [30]), behavioral intention can be understood as an evaluation or attitude toward a behavior, affecting the likelihood of performing a particular behavior.

The UTAUT [29], which was evaluated in organizations in which learning to use a novel technology was either voluntary or mandatory for employees, is a synthesis of 8 validated models such as the TPB [30]; TAM [28,32]; the Diffusion of Innovation theory [33]; and the Social Cognitive Theory [34], hypothesizing a total of 32 constructs and up to 4 moderators (ie, gender, age, voluntariness, and experience) [29]. According to the UTAUT [29], performance expectancy (eg, perceived usefulness), effort expectancy (eg, ease of use), and social influence (eg, subjective norm) are predictors of the intention to use a technology, whereas facilitating conditions (eg, support and compatibility) and behavioral intention are direct determinants of usage behavior in business organizations.

In recent years, the UTAUT and TAM have been implemented in various medical settings [35-41]. However, to the knowledge of the authors, no study to date has modified the UTAUT model to the acceptance of MS apps.

On the basis of the theoretical considerations and empirical findings from other medical contexts [35], it can be hypothesized that the intention to use MS apps, as an early form of acceptance, is higher, in case of high degrees of the perceived usefulness of MS apps for self-management (*performance expectancy*), the expected ease of use (*effort expectancy*), the approval as being helpful by significant others (*social influence*), and available facilitating factors related to the use of MS apps such as technical support (*facilitating conditions*).

For the specific context of MS apps, further MS-related and technology-related variables could be relevant to understand their acceptance. For instance, research indicates that Intolerance of Uncertainty (IU) with respect to problem-focused coping [7] and eHealth literacy [42] might be additional predictors of health behavior and disease management in MS.

Moreover, self-efficacy, defined as the personal belief in one's capability to overcome challenges with respect to MS (multiple sclerosis self-efficacy, MS-SE [43]) and using technology (computer self-efficacy, C-SE [44]), might influence the acceptance of MS apps.

Fatigue is a common disabling condition in MS [45], with about three-thirds of people being affected by severe fatigue (compared to NARCOMS, 74% [46]). Hence, fatigue might play a moderating role in behavioral intention to use MS apps.

Goals of This Study

The purpose of this pilot study was to explore factors influencing the acceptance of MS apps among smartphone users with MS in Germany. We hypothesize that the expectations and beliefs associated with the use of MS apps, IU, and eHealth literacy will significantly predict the acceptance of MS apps. We assumed a significant predictive contribution of the following core UTAUT determinants in the behavioral intention to use MS apps (in the sense of early acceptance): (a) performance

expectancy, (b) effort expectancy, (c) social influence, (d) facilitating conditions as well as extended predictors, (e) IU, and (f) eHealth literacy. We expected significant positive associations between the predictors of the UTAUT determinants and eHealth literacy behavioral intention MS apps and a significant negative association between IU and behavioral intention MS apps. Our research questions are as follows: Does self-efficacy explain and fatigue influence the hypothesized relationships between the determinants proposed under hypothesis 1 and acceptance of MS apps? Consequently, another goal was to determine mediating effects of (a) MS-SE and (b) C-SE (research question 1a and b), and moderating effects of fatigue in the relationship between the 6 predictors and behavioral intentions to use MS apps (research question 2).

Methods

Study Design and Setting

We conducted a Web-based cross-sectional survey. Data were collected anonymously between March 8, 2017, and April 15, 2017, using Unipark (Enterprise Feedback Suite survey, version Spring 2017, Questback). No ethical approval was required by the institution of the principal investigators because it was an anonymously conducted, self-selected, and voluntary Web-based survey study that involved no intervention, no deception, and no potentially adverse or burdensome questions or tests. Participants were required to give informed consent to participate in the study using Unipark (click-to-agree). No monetary compensation was offered for participation. The average completion time was 15 min.

Participants and Recruitment

In this Web-based pilot study using convenience sampling, we were interested in the opinions of smartphone users with MS. As this study aimed to include only people with diagnosed MS over the age of 18 years, participants were recruited via a letter to the national associations of the German Multiple Sclerosis Society ("Deutsche Multiple Sklerose Gesellschaft" [DMSG]). Overall, 11 out of 16 regional associations accepted the invitation to share the link to the study via their websites, Facebook profiles, and newsletters. In the 5 other federal states, the recruitment took place by inviting 25 local MS self-help groups via email. In addition, there was a call via the online platform "MSlife" (Biogen, Germany).

A priori power analyses using G*Power, version 3.1 [47], (F tests, multiple regression: Omnibus, R^2 deviation from 0) yielded a required sample size of at least 77 participants to determine a moderate-to-high effect of $f^2=0.3$ ($\alpha=.05$; $\text{power}=0.95$) for the multiple regression model with 6 predictors (critical $F_{6,70}=2.23$, noncentrality parameter $\lambda=23.10$). The power of 0.95 was chosen based on the assumption of low risk of false negatives with this study design. The effect size was chosen based on a previous work on the UTAUT [48] and a study using a UTAUT-questionnaire design we adapted [35], showing high explained variance. Because there was no study using the same measure, we decided to use the squared correlation $R^2=.25$ to

calculate the effect size f^2 . This resulted in the effect size of $f^2=0.33$, which we rounded to $f^2=0.3$.

Formulation of a Conceptual Model for the Acceptance of Multiple Sclerosis Apps and Its Operationalization: Adaptation of the Unified Theory of Acceptance and Use of Technology Framework

Because the UTAUT [29] originates in organizational contexts, the constructs were adapted and extended to the context of MS apps (Figure 1). Items from the UTAUT model were adapted to MS apps for smartphones based on the original questionnaire [29] as well as an adapted measure for Web-based aftercare in Germany [35] and extended with the 2 additional predictors IU and eHealth literacy. To minimize the risk of overload because of an excessive number of items, truncated scales were used. For the items we adapted from the English version of scales, forward translation was used, which was checked independently by 3 professionals, of which 2 had a scientific or psychological background (PhD level and BSc level) and the other 1 was an English teacher. Furthermore, various items of prior studies using adaptations of the UTAUT measure were available in German through contacting the study’s authors [35]. The 8-item German eHealth Literacy Scale (G-eHEALS) [49] was also available in German. Testing the transadaptation was performed using cognitive debriefing. To ensure the comprehensibility of items adapted from scales available in German or English, 5 students were asked to give their feedback independently from each other. Furthermore, the final Web-based survey was pretested by 13 external persons from the personal network of the second author to avoid technical problems. All items we used to assess the conceptual model are presented in Multimedia Appendix 1.

Variables and Measures

Scales of the Adapted and Extended Unified Theory of Acceptance and Use of Technology Model

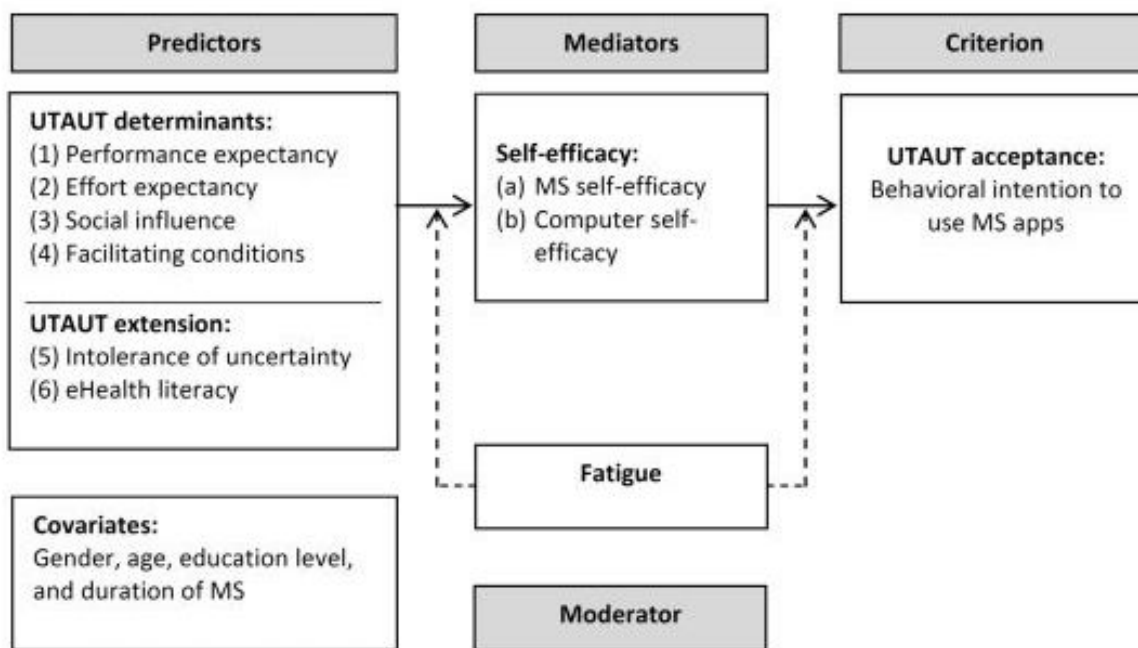
The overall survey consisted of 60 items, of which 40 items were used for the assessment of the model (16 items for UTAUT variables, 20 items for additional variables, and 4 items for the covariates).

In all adapted scales with numerical variables, participants were asked to indicate their agreement to statements on a 5-point Likert scale ranging from 1 (“fully disagree”) to 5 (“fully agree”).

Acceptance: Behavioral Intention to Use Multiple Sclerosis Apps as Criterion

As an indicator of early acceptance, behavioral intention was operationalized as the plan to use MS apps for disease management purposes. Behavioral intentions to use MS apps in general and within the next 4 weeks were measured using 3 items from the original UTAUT [29] we adapted. The sample was divided into 3 groups who received slightly modified items, considering actual use of MS apps in relation to intentions to use: participants who currently use MS apps (group 1=users), participants who have never used MS apps before (group 2=nonusers), and those who used MS apps in the past (group 3=past users). We asked current users if they would also use MS apps in the future, whereas past users were asked if they intend to use MS apps again. Nonusers received similar but more generally formulated items (Multimedia Appendix 1). A total scale score unifying the responses of the 3 groups was generated for the regression analysis, in which the mean value of the 3 items targeting acceptance for each participant was calculated and transferred to the total scale.

Figure 1. Conceptual study model: adapted and extended Unified Theory of Acceptance and Use of Technology for the acceptance of multiple sclerosis apps. UTAUT: Unified Theory of Acceptance and Use of Technology; MS: multiple sclerosis; eHealth: electronic health.



Predictors of Acceptance of the Extended Unified Theory of Acceptance and Use of Technology Model

Unified Theory of Acceptance and Use of Technology: Performance Expectancy

Performance expectancy is defined as the extent to which a person believes that using a technology could improve outcomes and has the strongest predictive value for acceptance in the UTAUT [29]. In this study, performance expectancy was operationalized as the expectation of a person with MS that using MS apps would be helpful for disease management purposes.

Performance expectancy was assessed with 4 items used by Hennemann et al [35], which we adapted to assess expected outcomes in connection to the perceived usefulness or helpfulness of MS apps. Because social participation is essential for successful adjustment to MS [50], a fifth item was added to the survey (“Using MS apps could help me maintain social contacts.”).

Unified Theory of Acceptance and Use of Technology: Effort Expectancy

Effort expectancy is one’s belief about how easy it is to use a technology, taking its complexity and difficulty into account [29]. In this study, effort expectancy is defined as the extent of perceived ease with which MS apps can be used.

Effort expectancy was evaluated with 2 adapted items based on studies in inpatient medical settings and the original UTAUT [29,35] (eg, “I suspect that using MS apps would be easy”).

Unified Theory of Acceptance and Use of Technology: Social Influence

Social influence refers to the extent to which a person believes that relevant others think one should perform the behavior in question and that the technical innovation could be useful in relation to a particular goal [29]. In this study, social influence in the sense of subjective norm was measured by asking participants to assess the extent to which (1) their close family members, (2) primary care provider, and (3) friends would consider the use of MS apps helpful for disease management. An *other* response option was provided so that respondents could add examples of other groups of people, but no additional groups were added.

Unified Theory of Acceptance and Use of Technology: Facilitating Conditions

Facilitating conditions are defined as a person’s belief that organizational and technical support is available when using a novel technology. This construct also involves the extent to which an innovation is experienced as compatible with personal values, needs, and experiences; perceived behavioral control; and objective factors [29]. Among people with MS, the plan to using a new technology despite a disabling long-term condition might be affected by perceived available resources, such as knowledge and support options.

Facilitating conditions were assessed based on 3 items, of which 2 items were completely adopted and adapted from a study in inpatient medical settings [35]. The third additional item was

created based on the original UTAUT [29], which considers social support as a facilitating condition (“If I had problems using MS apps, I would know where to get help.”).

Intolerance of Uncertainty

People with MS are confronted with numerous disease-related uncertainties [51]. High levels of IU are associated with increasing efforts to regain control of the uncontrollable situation, which can result in dysfunctional coping strategies [7]. IU is often related to incapacitation, stress-inducing perceptions, and a tendency to avoidance [52]. Under the assumption of using MS apps as a strategy for problem-focused coping with respect to disease management strategies, IU could have a negative influence on intentions to use.

Of the 27-item IU Scale (IUS [52]), this study used 4 items with the highest factor loadings per subscale from the primary study using a student sample (items 5, 12, 19, and 16). In total, 3 items were only translated, for instance, “My mind can’t be relaxed if I don’t know what will happen tomorrow” (item 12 of the IUS). We only adapted 1 item by adding a relationship to a *disease* (“When it’s time to act, uncertainty associated with my disease rather paralyzes me”).

Electronic Health Literacy

To be able to take an active role in medical decision making and self-management, people with MS require adequate information [51], which they often seek online [20]. eHealth literacy is defined as the ability to search, find, understand, evaluate, and use health information available via electronic resources [53]. As eHealth and mHealth tools for MS can improve self-management skills [10], it can be assumed that higher eHealth literacy may increase the likelihood of effectively using electronic resources such as MS apps [54].

eHealth literacy was measured using 4 slightly modified items of the 8-item G-eHEALS [49]. From the subscale *information search* (6 items), 2 items with the highest factor loadings were selected, whereas both items comprising the *information evaluation* were included.

Mediator Effects of Self-Efficacy Beliefs

Multiple Sclerosis Self-Efficacy

MS-SE can be understood as one’s confidence in the ability to handle challenges related to MS [43]. Self-efficacy has been shown to predict health-related behavior in people with MS, including physical mobility [55-57], psychosocial adjustment [43], or pain-related coping strategies [58], and to mediate health-related relationships [59,60]. Thus, it can be assumed that MS-SE can help explain problem-focused coping strategies such as using MS apps.

MS-SE was assessed using the 11-item Liverpool Self-Efficacy Scale [61]. For economic reasons, 2 items per subscale (control and personal agency) were chosen based on the criterion of face validity. We added the term *MS* in the German translation, for instance, “Despite my difficulties, I still manage to cope with daily life with MS.”

Computer Self-Efficacy

C-SE is defined as the personal belief regarding one's ability to use computer technology to perform specific tasks [62]. A meta-analysis of 102 studies [44] confirmed that C-SE is associated with behavioral intention and usage behavior as well as with components of technology acceptance such as perceived usefulness and ease of use. Therefore, we will examine the extent to which C-SE with respect to MS apps can explain the proposed relationships.

A measure of general computer self-efficacy (GCSE [63]) was used, but *computer* was replaced by *smartphone*. For economic reasons, the original 5-item scale was limited to the 3 items with the highest factor loadings (items 2, 3, and 5), for instance, "I believe I have the ability to remove apps from my smartphone I no longer need" (adapted item 5 of the GCSE).

Moderator Effects of Fatigue

Fatigue can be described as a state of subjective physical or mental exhaustion, varying largely in intensity over the day course [64,65]. Such fluctuations can hinder simple routines, job performance, and social activities, making fatigue one of the main reasons for incapacity to work [64,66]. On the one hand, MS apps such as *MoreStamina* [67] could be used on a compensatory basis for the management of fatigue. On the other hand, fatigue might also be one reason for the poor uptake of MS apps, for instance, because of negative effort expectancies. Hence, a moderating role of fatigue appears possible.

For the retrospective assessment of fatigue in the past 4 weeks, the 5-item Modified Fatigue Impact Scale [68] was used.

Control Variables

In the original UTAUT, age, gender, voluntariness (of learning to use a technology vs mandatory use in organizations), and experience were confirmed as moderators for the key relationships [29]. To control their influence in this study, age and gender were included as covariates in the mediation and moderation models. Gender as a categorical variable was included with dummy coding (0=male and 1=female). Age and duration of MS were included as numerical variables. Because using MS apps as a self-help tool is a voluntary choice, voluntariness was no applicable variable in this study. Experience was operationalized as the duration of MS, not as experience with MS apps. Due to the unclear proportion of MS app users in the target population, we found that the duration of living with MS might be a more meaningful indicator for experience with disease management. Furthermore, the education level was considered, as studies indicate a more likely use of eHealth services among higher educated people with MS [69]. An MS Registry survey [21] found a higher likelihood of smartphone, tablet, and mHealth app use being associated with younger age and higher education in people with MS. In line with the Comparative Analysis of Social Mobility in Industrial Nations (CASMIN-classification [70]), the educational attainment was assessed as an ordinal scale in 3 levels ranging from 1 ("low") to 3 ("high").

Procedure and Scale Metrics

The Web-based survey comprised a total of 60 items and optional commentary fields. The first part of the survey consisted of sociodemographic (6 items) and MS-related (4 items) questions using nominal scales.

Then, the MS-related constructs fatigue (5 items), IU (4 items), and MS-SE (4 items) were assessed on 5-point Likert scales. Smartphone use and frequency of use (2 items) as well as usage preferences (4 items) were asked using nominal scales. eHealth literacy (4 items) and C-SE (3 items) were evaluated on 5-point Likert scales. Use of MS apps (5 items) was assessed on a nominal scale. Overall, 3 optional questions (free text fields) were asked about subjective benefits, challenges, and suggestions for improvements regarding MS apps. To summarize the responses, the UTAUT model was used to map the responses to categories following the approach of a quantitative content analysis. Finally, 16 items on a 5-point Likert scale were used to measure UTAUT variables: behavioral intention to use (3 items), performance expectancy (5 items), effort expectancy (2 items), social influence (3 items), and facilitating conditions (3 items).

Statistical Analysis

Only completed surveys were considered for data analyses (listwise deletion). No imputation technique was used to compensate missing values because the vast majority of dropouts occurred after the first 3 demographic questions (missing not at random). Descriptive analyses were performed to obtain information on sociodemographics and usage of modern technology for MS-related purposes. Both simple and multiple linear regression analyses were conducted to determine predictors for the acceptance of MS apps. Due to the exploratory nature of this study and as the limited evidence base related to the proposed relationships in this specific model was too scarce, the predictors were included simultaneously in the multiple regression model. All analyses were performed using SPSS, version 24 (IBM Analytics), in which the macro PROCESS by Hayes [71] was implemented to test mediation (C-SE and MS-SE) and moderation hypotheses (fatigue). Before the analyses, the assumptions of multiple linear regression analysis were confirmed being sufficiently fulfilled to perform parametric tests. Data analyses were performed independently and cross-checked by 2 researchers. The significance level for all hypotheses was $\alpha < .05$.

Results

Descriptive Analyses

The survey platform was accessed 496 times. In total, 175 people agreed to participate (informed consent), of which 113 people fully completed the survey (attrition rate of 35.4%). Most participants (52/62, 84%) who dropped out of the survey did so after the first 3 demographic questions (ie, year of birth, gender, and postal code). The data of the other 15 participants were eliminated because of incomplete data because they indicated they did not possess a smartphone. Because the target sample was smartphone users, data from these participants were not included in the analysis.

Sample Characteristics

As shown in [Table 1](#), the final sample consisted of 98 people aged between 22 and 67 years (median 48.0 years, interquartile range 14.0 years). The CASMIN-based mean score (mean 2.23, SD 0.61) indicated a moderately high education level [70]. Detailed sample characteristics are presented in [Multimedia Appendix 2](#).

Frequency and Purposes of Mobile Phone Use

[Figure 2](#) shows the frequency of using the mobile phone or smartphone in general and for MS-related purposes.

In terms of MS-specific use, the mobile phone or smartphone was mostly used as internet access to search MS information or connect with others (51/98, 52%), scheduling (eg, for medical consultations, 45/98, 46%), making calls for medical purposes (44/98, 45%), MS-related emails or text messages (34/98, 35%), and for music or games (eg, for relaxation and cognitive training, 19/98, 19%). Other use (8/98, 8%) included apps as medication reminders. In total, 19% (19/98) did not answer this question.

Table 1. Sample characteristics (N=98).

Variables	Statistics
Age (years)	
All, mean (SD), range	47.03 (10.17), 22-67
Women, mean (SD), range	45.11 (10.09), 22-67
Men, mean (SD), range	51.0 (9.28), 22-66
20-35 years, n (%)	16 (16)
36-50 years, n (%)	43 (44)
51-67 years, n (%)	39 (40)
Gender, n (%)	
Female	66 (67)
Male	32 (33)
Secondary education, n (%)	
Certificate of secondary education ^a	8 (8)
General certificate of secondary education ^b	27 (28)
Advanced technical college entrance qualification ^c	19 (19)
General qualification for university entrance ^d	44 (45)
Vocational training and tertiary education, n (%)	
No professional qualification	4 (4)
Training qualification ^e	62 (63)
Polytechnic or college degree	9 (9)
University degree	23 (24)
Duration of multiple sclerosis (years)	
All, mean (SD), range	13.92 (9.84), 1-45
1-10, n (%)	43 (44)
11-21, n (%)	37 (38)
>21, n (%)	18 (18)

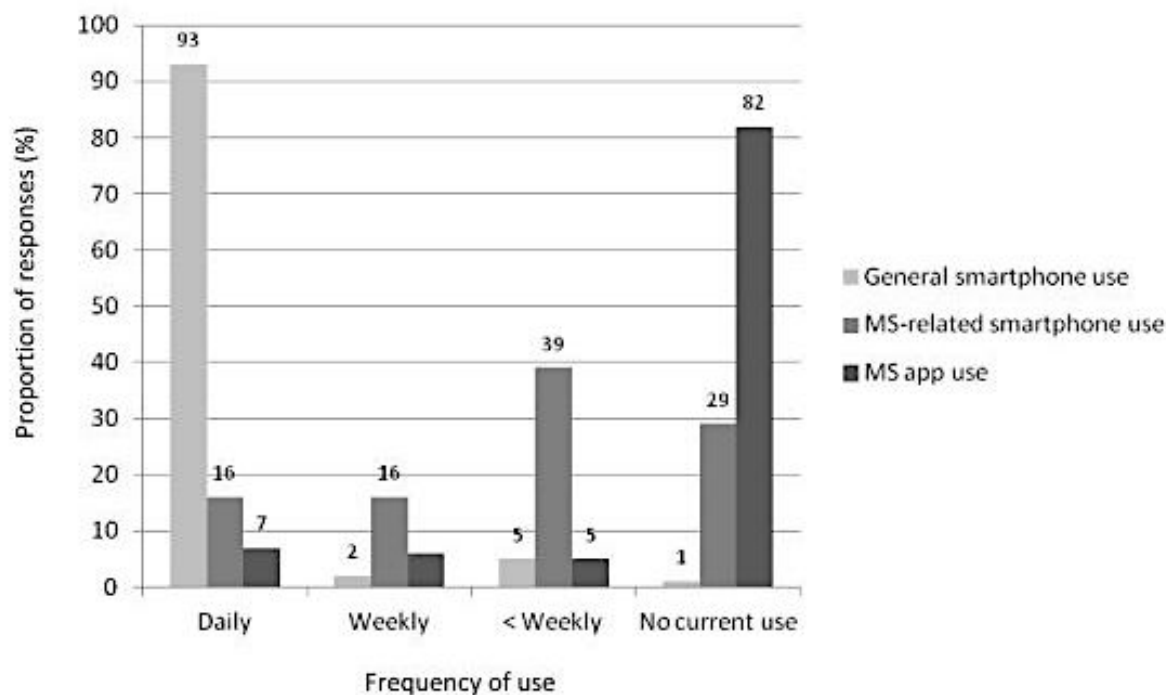
^aGerman "Hauptschulabschluss" as basic school qualification.

^bGerman secondary school level-I certificate ("Mittlere Reife").

^cGerman "Fachhochschulreife."

^dGerman "Allgemeine Hochschulreife" ("Abitur" or A Level).

^eGerman dual training model.

Figure 2. Frequency of general and multiple sclerosis–related smartphone use, proportions in percent (N=98). MS: multiple sclerosis.

Use of Multiple Sclerosis Apps for Disease Management Purposes

The majority of participants (62/98, 63%) reported no experience with MS apps. Of the 36 participants (36/98, 37%) reporting experience with MS apps, 18 people (18/36, 50%) were currently using them.

Most of the 36 participants with experience with MS apps indicated the use of the app *MS Kognition* (MS cognition) by the DMSG (15/36, 42%) in the comment field. Further apps reported by the participants are presented in [Multimedia Appendix 2](#). In addition, [Multimedia Appendix 2](#) provides a summary of optional free text responses on perceived benefits and challenges of MS apps as well as ideas for improvements.

Specific MS apps were used for purposes of cognitive training to improve attention or concentration (12/18, 67%), information and education about MS (9/18, 50%), reminders of appointments or medication intake (8/18, 44%), documentation (6/18, 33%), maintaining social contacts (6/18, 33%), and strengthening physical skills (3/18, 17%).

In addition to MS apps, 48% (47/98) participants also used other (non-MS-specific) mHealth apps for disease management, mostly for cognitive training (23/47, 49%); strengthening physical well-being, including yoga and fitness (12/47, 26%); orientation in public life (eg, finding barrier-free places, 10/47, 21%); nutrition (8/47, 17%); stress management (3/47, 6%); mood management (eg, anxiety and depression, 2/47, 4%); and other purposes (7/47, 14.9%). The awareness of the existence of internet-based therapies was low (aware: 25/98, 26%; not aware: 67/98, 68%; and not sure: 6/98, 6%).

Descriptive Analysis of the Scales Related to the Acceptance of Multiple Sclerosis Apps

[Table 2](#) summarizes the mean values, SDs, and Cronbach alpha for each numerical scale (N=98). As shown in [Table 2](#), the overall acceptance was moderate (mean 3.11, SD 1.31). When compared with the overall mean score, participants reporting no experience with using MS apps expressed significantly lower acceptance (mean 2.76, SD 1.32; $t_{61}=-2.100$; $P=.04$) and current users had significantly higher acceptance scores (mean 4.33, SD 0.79; $t_{17}=6.552$; $P<.001$), whereas the difference with former users was not significant (mean 3.11, SD 0.91; $t_{17}=0.005$; $P=.996$).

Principal Results of Regression Analyses

Multiple Regression Analysis

Correlation analyses and simple regression analyses ([Multimedia Appendix 3](#)) showed significant correlations between the variables and a significant contribution of the variables, except for eHealth literacy, in behavioral intentions to use.

According to the F test ($F_{6,91}=25.702$), the overall regression model contributes 63% of explained variance ($R^2=.625$; $P<.001$). The additional inclusion of the 4 control variables would have only yielded in a marginally increased explained variance of 1.3% (up to $R^2=.64.3\%$). As shown in [Table 3](#), with a regression coefficient of $B=.63$ ($\beta=.41$; $P<.001$), performance expectancy proved to be a significant predictor of intention to use as well as social influence with $B=.42$ ($\beta=.33$; $P<.001$). Contrary to hypothesized, the other predictors had no meaningful influence on acceptance in the multiple regression model (all $P>.05$).

Table 2. Mean values, SDs, and internal consistency of the scales of the conceptual study model (N=98).

Variable or scale ^a	Mean (SD) ^b	Cronbach alpha ^c
Behavioral intention to use overall (3 items per group, N=98) ^d	3.11 (1.31)	— ^e
Behavioral intention to use per group		
Group 1: current users (n=18)	4.33 (0.79)	.83 ^f
Group 2: nonusers (n=62)	2.76 (1.32)	.91 ^g
Group 3: past users (n=18)	3.11 (0.91)	.73 ^h
Performance expectancy (5 items)	2.81 (0.97)	.88 ^f
Effort expectancy (2 items)	3.80 (0.80)	.60 ⁱ
Social influence (3 items)	2.81 (1.02)	.90 ^g
Facilitating conditions (3 items)	4.45 (0.78)	.85 ^f
Intolerance of uncertainty (4 items)	2.61 (0.99)	.78 ^j
Electronic health literacy (4 items)	4.22 (0.70)	.87 ^f
Multiple sclerosis self-efficacy (4 items)	4.06 (0.80)	.85 ^f
Computer self-efficacy (3 items)	4.18 (0.94)	.84 ^f
Fatigue (5 items)	3.31 (1.17)	.89 ^f

^aItems were adapted from previous research ([Multimedia Appendix 1](#)).

^bScale range; minimum=1 to maximum=5. Item keying: higher scores mean a higher expression of the respective variable.

^cInternal consistency; classification according to Cohen criteria [72].

^dGroup 1=participants who are current users of MS apps, group 2=participants who never used MS apps, and group 3=participants who had used MS apps in the past. All assessed 3 items on behavioral intention that were modified based on the experience with MS apps.

^eNot applicable.

^fCronbach alpha: good.

^gCronbach alpha: excellent.

^hCronbach alpha: sufficient.

ⁱCronbach alpha: questionable.

^jCronbach alpha: acceptable.

Table 3. Coefficients in the multiple regression model of the adapted and extended Unified Theory of Acceptance and Use of Technology (N=98).

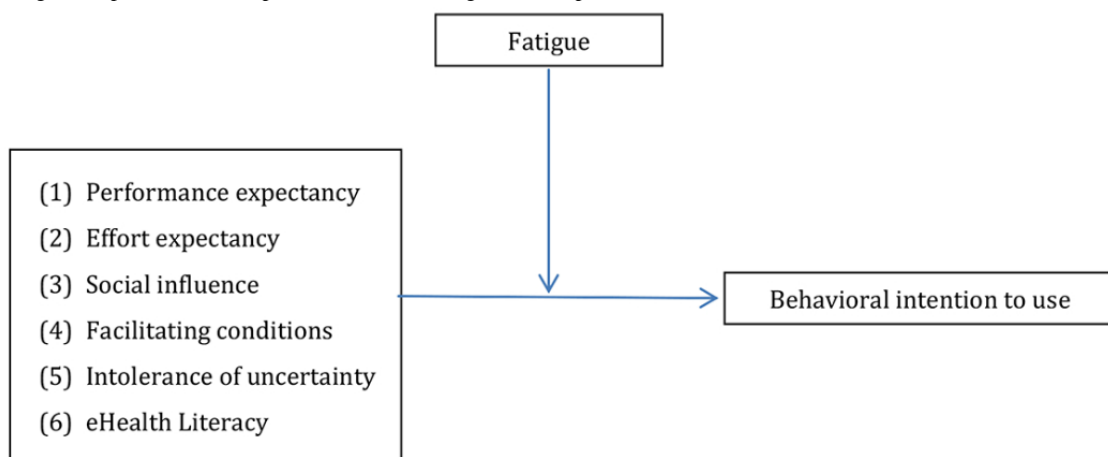
Predictors ^a	B	SE	Beta	t test	P value	Tolerance	VIF ^b
Constant	-.56	0.77	— ^c	-0.73	.47	—	—
Performance expectancy	.63	0.12	.47	5.32	<.001	.52	1.92
Effort expectancy	.09	0.13	.06	0.70	.49	.62	1.6
Social influence	.42	0.13	.33	3.33	.001	.42	2.40
Facilitating conditions	.07	0.13	.04	0.51	.61	.64	1.56
Intolerance of uncertainty	.09	0.09	.06	0.90	.37	.79	1.27
Electronic health literacy	-.04	0.14	-.02	-.030	.77	.78	1.28

^aCriterion: behavioral intention to use MS apps. All predictors were included simultaneously, without covariates.

^bVIF: variance inflation factor.

^cNot applicable.

Figure 3. Exploratory model for the assessment of the moderation hypotheses for fatigue. Criterion: behavioral intentions to use multiple sclerosis apps. The numbering of the predictors corresponds to the numbering of the 6 reported models. eHealth: electronic health.



Mediator Effects of Self-Efficacy

Mediation hypotheses were examined individually for each predictor (Multimedia Appendix 3). Due to the correlation of both mediators ($r=.289$; $P=.004$), a multiple mediation analysis was performed in which both C-SE and MS-SE were successively tested.

However, the assumption of mediation could only be confirmed for C-SE in the model specification with IU as a predictor of behavioral intention (model 5). Both the effect of IU on C-SE (a path, $B=-.23$; $P=.01$) and C-SE on behavioral intention (b path, $B=.42$; $P=.006$) were significant. The significant indirect effect of C-SE ($B=-.095$, 95% CI -0.227 to -0.01) suggests the reduction of the direct effect (c path, $B=.29$; $P=.046$) compared with the total effect (c path, $B=.30$; $P=.02$), indicating a partial mediation.

Furthermore, the control variable age showed significant influence on C-SE ($B=-.03$; $P=.003$), as did gender ($B=-.45$; $P=.02$), meaning that younger and male participants had a stronger expression of C-SE.

Moderator Effects of Fatigue

Simple regression analysis confirmed fatigue as a significant positive predictor of behavioral intention ($R^2=.05$; $B=.24$; $\beta=.21$; $SE=.11$; $P=.04$). As illustrated in Figure 3, each predictor was examined individually for the effect of fatigue.

Contrary to hypothesized, the interaction terms (predictor \times moderator) as an indicator for moderation effects of fatigue were not significant for performance expectancy ($B=-.01$; $P=.92$), effort expectancy ($B=.22$; $P=.08$), social influence ($B=-.07$; $P=.37$), facilitating conditions ($B=.05$; $P=.73$), IU ($B=-.06$; $P=.58$), and eHealth literacy ($B=.09$; $P=.57$). Because there was at least a marginal interaction effect ($P=.08$), inferential statistics were applied, which showed a significant fatigue-related effect of effort expectancy on behavioral intention for average (95% CI 0.23 to 0.86) and high levels of fatigue (95% CI 0.33 to 1.28; all $P<.001$), as shown in Multimedia Appendix 3.

As mediation effects of C-SE could only be confirmed in the relationship between IU and intentions to use MS apps, only

this model was tested for moderated mediation. For this purpose, the moderated mediation index was calculated for the moderator's mean score (± 1 SD). The results indicated a significant conditional indirect effect for both low (95% CI -0.42 to -0.01) and moderate levels (95% CI -0.27 to -0.01) of fatigue. Hence, the indirect effect of C-SE on the relationship between IU and behavioral intention varies depending on the levels of fatigue.

Discussion

Principal Findings and Comparison With Prior Work

The aim of this study was to assess determinants of acceptance of MS apps for disease-related self-management purposes, taking into account possible mediating effects of self-efficacy and a moderating role of fatigue.

Predictors of the Acceptance of Multiple Sclerosis Apps

Within the multiple regression analysis of the adapted UTAUT model, the explained variance of 63% proved to be relatively high but was lower than in the original UTAUT (70% [29]) and previous work (78% [35]). In line with previous research [29,48], performance expectancy was replicated as the strongest predictor in this model. Furthermore, the significant predictive contribution of social influence and the insignificant relationship between facilitating conditions and behavioral intention were also shown in a study investigating acceptance of medical aftercare in inpatients by Hennemann et al [35].

Considering the significant role of social influence in mHealth acceptance, an extension to digital sources of support could be considered such as social media. People with MS are usually well informed about the disease, but, at the same time, appear being vulnerable to scientifically not proven health information and hopes of cure, especially on social media websites [73]. Although most people with MS use the internet as the first choice for health information, their physician remains the most trusted source [12]. Furthermore, there is preliminary evidence that the spread of misinformation about MS therapy options is lower or less influential in social media networks for laypeople with MS under the presence of medical experts [74] than in open-access not moderated MS forums [75]. Social media

appears to be a relevant information source for people with MS, especially in terms of sharing opinions and experience with MS [75]. Hence, the beliefs and attitudes of other people with MS within social networks (bottom-up process) and health care providers (top-down process) should be considered in affecting the acceptance of MS apps.

Contrary to the previous empirical findings [76], effort expectancy proved to be an insignificant predictor in the multiple regression analysis, whereas it was significant as a single predictor. This is contrary to another study by Chua et al [77] that showed the relevant effect of effort expectancy besides social influence and performance expectancy in the acceptance of social media apps. One reason for this could be methodological shortcomings of the 2-item scale, given the questionable internal consistency ($\alpha=.60$), as well as common variance with other constructs. Another reason could be the low experience with the usability of MS apps. In addition, effort expectancy could be less relevant in this sample scoring relatively high on eHealth literacy and C-SE. With reference to Venkatesh et al's study [29], it can be further assumed that by including actual behavior, a stronger predictive weighting of effort expectancy could have been achieved.

Moreover, IU was not significant in the overall model anymore, which should be critically seen in view of methodological issues with this construct [78] and inconsistent findings regarding its effects on coping with MS [7].

Nonetheless, IU made at least a significant contribution to predicting acceptance in simple regression analysis. However, this relationship was positive and not negative as expected. This unexpected finding suggests that IU seems to be associated not only with incapacitation and avoidance [7,52,79] but may also result in functional problem-focused coping strategies such as increased willingness to use modern self-help tools. However, to identify which factors actually influence whether IU manifests itself through functional or dysfunctional outcomes needs further exploration [7]. It is also important to note that using mHealth apps could be emotion-focused, for instance, for stress management purposes [80]. Potentially, this study had an overly narrowed view of the problem-focused function of MS apps such as cognitive training or medication reminders.

In contrast, perceived eHealth literacy was the only variable without significant predictive value. Potentially, this construct is not suitable for the measurement of mHealth literacy in this specific context, as the construct validity has been debated [81]. Furthermore, the construct seems too restricted to Web-based information and not related to other Web-based self-management activities in long-term conditions. Another potential reason is ceiling effects with respect to the identified high eHealth literacy scores in this self-selected Web-based sample. A further investigation of health literacy in a more diverse population appears reasonable because research indicated that, for instance, functional literacy is associated with higher comfort levels and perceived skills with using eHealth information [42] and that many people with MS are quite willing to using eHealth services [21].

Taken together, the theoretical and empirical validation of an extended UTAUT model for MS apps and related innovative

tools can mainly rely on the classical determinants, when they are adapted to the MS context. In contrast, the current evidence base for further constructs appears too limited and inconsistent.

Mediating and Moderating Effects Involved in the Acceptance of Multiple Sclerosis Apps

Another aim of this study was to investigate the role of self-efficacy as mediator and fatigue as moderator. The findings suggest that the hypothesis of mediation for MS-SE must be rejected in all models. Evidence of partial mediation by C-SE was found in the case of IU predicting intentions to use MS apps. An explanation for this finding might be found in the social cognitive theory (SCT [34]). SCT proposes that the concept of self-efficacy is based primarily on the conviction that one is actually able to perform a certain behavior. It may be possible that the influence of self-efficacy has been mitigated by the decision to include only the intention to perform a behavior as a criterion in the model. William and Rhodes [82] argued that the self-efficacy construct is confounded and represents the motivation rather than one's perceived capability to perform a health-related behavior.

Although fatigue represents a common disabling symptom in MS [19], no moderation effect was identified. Only a marginally significant relationship between effort expectancy and behavioral intention was found, indicating that the expected ease of use related to using MS apps could be higher under the influence of average and higher levels of fatigue. In comparison with clinical samples, the moderate fatigue levels in the retrospective assessment observed in this study need to be considered. Interestingly, fatigue was a positive predictor of accepting MS apps. Potentially, the current need to manage subjective fatigue may have increased the general openness to use innovative self-help tools. Therefore, it would be conceivable that the intention to use MS apps may exist regardless of fatigue, whereas fatigue may represent a barrier for actually using MS apps. In this respect, the role of fatigue should be explored in the context of an actual behavior with a sample with more clinically relevant cases of fatigue. Potentially, people suffering from severe fatigue might have not participated.

Limitations

This study has different limitations. First, this observational study does not allow for causal conclusions because of the cross-sectional nature. Therefore, the results should be interpreted with caution. A next step would be to longitudinally assess the actual usage as predicted by acceptance. In line with prior research, we evaluated behavioral intention to use as a predictor of usage, but the direct translation to actual behavior is problematic (behavior-intention gap in technology use [83]). A next step for an observational study in cooperation with MS centers could be to include a follow-up assessment. Another option could be to conduct a randomized controlled trial to systematically assess the impact of acceptance interventions [84] on the actual uptake of MS apps in primary care (see the Implications section).

Second, the data were collected via a Web-based survey. Hence, disadvantages such as selection bias should be considered, as

well as the high attrition rate of about one-third. This might have also contributed to low variance of fatigue severity among survey completers. Besides fatigue, cognitive difficulties could be another reason for noncompletion. However, most participants who dropped out did so after the first 3 demographic questions (year of birth, gender, and postal code). This indicates further reasons such as decline of interest or motivation.

Furthermore, the sample was quite small and not representative, although the gender ratio, the mean age, and duration of MS were comparable with the Bavarian data from the German MS registry [85]. However, this anonymous survey provided no option to verify such self-reported outcomes. We collected no data (such as medical reports) to confirm the diagnosis of MS. We only asked for the year of diagnosis, but not for the exact diagnosis or subtype of MS. We tried to only reach people with MS by using a selective recruitment strategy with the support by a German MS society.

Third, the narrowed scope on MS apps in Germany restricts the generalizability to other eHealth contexts relevant for MS-related self-help activities. Future studies should use an umbrella term or involve more eHealth and mHealth options. As prevalence rates of MS are highest in Northern European countries [2,3], we are confident that our findings can be applied to a broader MS population.

Fourth, the majority of the assessed constructs were scored using translated and modified scales, which might have compromised the reliability of the scale effort expectancy. In this study, however, we avoided using longer scales to reduce participant burden and to minimize the attrition rate. A next step would be to assess the validity of the transadapted UTAUT-related measure using a larger sample.

Fifth, the experience with MS apps was rather low. However, we assume that the proportion of participants in this self-selected Web-based sample who know about mHealth apps and have previously used them is higher than that in a primary care setting. The study was conducted in Germany where the mHealth or eHealth adoption in health care is at an early stage, but as panel surveys show, there is already public awareness of digital self-help options to some extent [86]. Furthermore, on average, this sample reported receiving an MS diagnosis a decade ago. Therefore, this and the connection to MS self-help organizations indicate openness to (online) self-help.

Finally, it should be also mentioned that the retrospective assessment of subjective fatigue is subject to methodological limitations. Furthermore, fatigue can be associated with cognitive deficits [87]. For a more accurate assessment of fatigue in a target group with different manifestations of MS, the use of longer scales combined with neurological tests would be worth considering.

Implications

Although mobile phones belong to the everyday life of people with MS, their use in connection with MS seems relatively low [19]. In this Web-based study among smartphone users with MS, the vast majority (63.3%) reported no experience with MS apps. In contrast, the use of smartphones for MS-related purposes was higher. It can be assumed that the demand and

use of eHealth or mHealth services vary over time. For example, a qualitative study by Colombo et al [88] indicated that MS patients find the internet useful for disease management purposes, but there can be a barrier at the beginning and later stages of MS to actively search information online because it is perceived as stressful. Consequently, MS apps can not only be a resource, but at the same time, such tools can also provide a medium for illness representations. Vaughan et al [89] showed that illness representations in people with MS reflect the medical knowledge about MS, in which the consequences of impending degeneration and lacking prospect of cure are salient. Such representations are linked with the concept of pathogenesis, and labels such as *MS apps* could underline this deficient perspective.

In contrast, the concept of salutogenesis [90] does not deny the challenges of MS, but it raises awareness on how to use one's own resources to cope with them. In this sense, it can be assumed that a salutogenetic perspective could promote a greater motivation for health promotion, for instance, supported by apps. Possibly, the relatively high proportion of people in this sample who used nonspecific mHealth services rather than MS apps could indicate that they are avoiding stigmatization by the label *MS*. Hence, these considerations could be useful to improve the awareness of suitable apps and for the development of transdiagnostic apps for MS, with an emphasis on salutogenetic aspects. Another factor that should be considered is that there is not *one MS* but diverse manifestations that are related to different challenges and self-help preferences.

With performance expectancy being the strongest predictor of acceptance of MS apps, it can be suggested that the benefits of mHealth apps should be transparently communicated to potential users with MS [10]. Given the significant role of social influence in this study, it can be further recommended that such information should not just be provided via social media. In particular, a next step would be to rethink the integration of the social environment in the treatment of people with MS using eHealth and mHealth solutions.

In view of the limited experience with MS apps in this sample, before assessing the acceptance, more detailed information about digital self-management tools could be provided via acceptance-facilitating interventions (AFI). Short, video-based AFI have been shown to be effective in German primary care settings, for instance, in improving acceptance of digital interventions among patients with depression [84] and pain [91]. However, the results on the efficacy of AFI in Web-based study settings are inconsistent. For instance, a Web-based randomized controlled trial by Lin et al [92] showed no significant effects of a video-based AFI on the acceptance, adherence, and uptake rate of a mobile phone-based and Web-based intervention for chronic pain among people with long-term conditions. The (baseline) acceptance was, however, found to be higher than that observed in the target populations in primary care.

As there is a lack of such studies on the uptake of eHealth solutions for people with MS, it appears reasonable to develop AFIs with existing tools such as the commonly used *MS Kognition* in a routine care setting to assess the actual use predicted by acceptance. For this purpose, it is crucial to

consider quality standards of apps to identify appropriate tools via app stores [93,94], especially with regard to disease management for long-term conditions [95]. Moreover, it appears likely that people with different forms of MS experience different challenges that need to be considered when assessing the adoption of MS apps and other self-help services. Hence, the MS form should be considered in future studies. It is also possible that the low adoption rate is also associated with the poor quality of many mHealth apps available via app stores. Hence, it is crucial to understand and systematically involve the perspectives of users in the quality improvement of mHealth apps.

Finally, there is a lack of suitable measures to determine the acceptance of eHealth solutions in specific populations and contexts. In line with other research [35,36,84,91,96], we thus chose to adapt the UTAUT framework to our target population and service of interest. It is, thus, important to validate such adapted UTAUT measures with large samples in upcoming studies. This could be a first step to achieve methodological consensus on the assessment of the acceptance and use of mHealth apps for the disease management of MS and allow for comparisons with other research. Moreover, the UTAUT

framework is only one option to evaluate subjective views of people with MS on mHealth services. Attitudes may be more suitable for the assessment of early adoption of eHealth or mHealth [35]. In addition, other types of eHealth tools could be relevant for coping with MS in the target population, including psychological services. User perspectives could also be measured using validated measures such as the Attitudes towards Psychological Online Interventions [97]. Potentially, the evaluation of both acceptance and attitudes as well as related constructs could provide a more complete picture of the needs and preferences for different digital self-help tools among people with MS.

Conclusions

Taken together, this study suggests that the intention to use MS apps is rather poor among the majority of participants without usage experience and that positive expectations about the helpfulness and social influence are important predictors for the acceptance of MS apps. Moreover, noteworthy is the use of MS-unspecific apps by almost half of the participants. This finding makes the investigation of the acceptance and use of MS-specific mHealth services in comparison with other self-management options appear a logical next step.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire of the conceptual study model.

[PDF File (Adobe PDF File), 120KB - [formative_v2i2e11977_app1.pdf](#)]

Multimedia Appendix 2

Additional descriptive data.

[PDF File (Adobe PDF File), 1MB - [formative_v2i2e11977_app2.pdf](#)]

Multimedia Appendix 3

Additional regression analysis.

[PDF File (Adobe PDF File), 879KB - [formative_v2i2e11977_app3.pdf](#)]

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Abbreviations

AFI: acceptance-facilitating interventions
CASMIN: Comparative Analysis of Social Mobility in Industrial Nations
CNS: central nervous system
C-SE: computer self-efficacy
DMSG: Deutsche Multiple Sklerose Gesellschaft
eHealth: electronic health
GCSE: general computer self-efficacy
G-eHEALS: German eHealth Literacy Scale
IU: Intolerance of Uncertainty
IUS: Intolerance of Uncertainty Scale
mHealth: mobile health
MS: multiple sclerosis
MS-SE: multiple sclerosis self-efficacy
NARCOMS: North American Research Committee on Multiple Sclerosis
SCT: social cognitive theory
TAM: technology acceptance model
TPB: Theory of Planned Behavior
UTAUT: Unified Theory of Acceptance and Use of Technology

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Corrigenda and Addenda

Multimedia Appendix Correction: A Computer-Assisted Personal Interview App in Research Electronic Data Capture for Administering Time Trade-off Surveys (REDCap): Development and Pretest

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The authors of the paper “A Computer-Assisted Personal Interview App in Research Electronic Data Capture for Administering Time Trade-off Surveys (REDCap): Development and Pretest” (JMIR Formativ Res 2018;2(1):e3) made an error in [Multimedia Appendix 2](#). The original [Multimedia Appendix 2](#) contained the EQ-5D-5L in XML format which the authors did not have copyright permission to reproduce in the appendix. The EuroQol Group (owners of the EQ-5D) consider the original Multimedia Appendix a copyright infringement of the EQ-5D and asked for removal. The new version of [Multimedia Appendix 2](#) does not contain the EQ-5D-5L. The described app is designed to provide an electronic means of administering the time trade-off task in health economic studies. As such, the presence of EQ-5D in the Multimedia Appendix was illustrative and completely non-essential to the thrust and substance of the app and the article that has been published in the journal.

Editor and publisher remind authors to preferably use open, freely available research instruments and remind authors that JMIR Publications will no longer publish studies which report the development and validation of an instrument or scale without

making the instrument itself openly accessible (for example, under a Creative Commons license). The Committee on Publication Ethics (COPE) has also recently discussed the deplorable behavior of some scale developers which appear to comb the literature and ask those who used the scale for research to retract the paper or to pay for a retroactive license, sometimes asking for very large sums of money. COPE emphasized that “holding authors to ransom in this way is not good for the advancement of scientific knowledge or in the public interest,” and while the EuroQol Group has not asked for money in this specific case, the case serves as reminder for researchers to develop and use openly accessible instruments rather than copyrighted ones.

The corrected version of [Multimedia Appendix 2](#) is available below.

The corrected article will appear in the online version of the paper on the JMIR website on July 6, 2017, together with the publication of this correction notice. Because this correction was made after submission to PubMed or PubMed Central and other full-text repositories, the corrected article, with the updated Multimedia Appendix, has also been resubmitted to those repositories.

Multimedia Appendix 2

TTO-CAPI XML file.

[\[PDF File \(Adobe PDF File\), 10MB - formative_v2i2e11436_app2.pdf \]](#)

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