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Review

Original Paper

Mobile Phone Ownership Is Not a Serious Barrier to Participation in Studies: Descriptive Study

Emily J Harvey[1], MA; Leslie F Rubin[1,2], MS; Sabrina L Smiley[1], PhD, MPH, MCHES; Yitong Zhou[1], MS; Hoda Elmasry[1], MPH; Jennifer L Pearson[1,3], MPH, PhD

[1]Truth Initiative, Schroeder Institute for Tobacco Research and Policy Studies, Washington, DC, United States

[2]Department of Psychology, American University, Washington, DC, United States

[3]Department of Health, Behavior, and Society, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, United States

Corresponding Author:
Emily J Harvey, MA
Truth Initiative
Schroeder Institute for Tobacco Research and Policy Studies
900 G St NW Fourth Floor
Washington, DC, 20001
United States
Phone: 1 2024545768
Email: eharvey@truthinitiative.org

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Abstract

Background: Rather than providing participants with study-specific data collection devices, their personal mobile phones are increasingly being used as a means for collecting geolocation and ecological momentary assessment (EMA) data in public health research.

Objective: The purpose of this study was to (1) describe the sociodemographic characteristics of respondents to an online survey screener assessing eligibility to participate in a mixed methods study collecting geolocation and EMA data via the participants' personal mobile phones, and (2) examine how eligibility criteria requiring mobile phone ownership and an unlimited text messaging plan affected participant inclusion.

Methods: Adult (≥18 years) daily smokers were recruited via public advertisements, free weekly newspapers, printed flyers, and word of mouth. An online survey screener was used as the initial method of determining eligibility for study participation. The survey screened for twenty-eight inclusion criteria grouped into three categories, which included (1) cell phone use, (2) tobacco use, and (3) additional criteria

Results: A total of 1003 individuals completed the online screener. Respondents were predominantly African American (605/1003, 60.3%) (60.4%), male (514/1003, 51.3%), and had a median age of 35 years (IQR 26-50). Nearly 50% (496/1003, 49.5%) were unemployed. Most smoked menthol cigarettes (699/1003, 69.7%), and had a median smoking history of 11 years (IQR 5-21). The majority owned a mobile phone (739/1003, 73.7%), could install apps (86.8%), used their mobile phone daily (89.5%), and had an unlimited text messaging plan (871/1003, 86.8%). Of those who completed the online screener, 302 were eligible to participate in the study; 163 were eligible after rescreening, and 117 were enrolled in the study. Compared to employed individuals, a significantly greater proportion of those who were unemployed were ineligible for the study based on mobile phone inclusion criteria (P<.001); yet, 46.4% (333/717) of the individuals who were unemployed met all mobile phone inclusion criteria.

Conclusions: Inclusion criteria requiring participants to use their personal mobile phones for data collection was not a major barrier to study participation for most respondents who completed the online screener, including those who were unemployed.

Trial Registration: ClinicalTrials.gov NCT02261363; https://clinicaltrials.gov/ct2/show/NCT02261363 (Archived by WebCite at http://www.webcitation.org/6wOmDluSt)

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KEYWORDS

smoking; smartphone ownership; online survey screener; ecological momentary assessment; tobacco products/utilization; electronic cigarettes; observational study; United States

Introduction

Ecological momentary assessment (EMA), a real-time data capture method, has been increasingly used as a viable method to collect data from research participants over time and in various contexts outside of a research lab[1-3]. EMA focuses on collecting data and recording subject experiences at a particular moment in the context of the research participants' natural environment [4]. The types of devices used in EMA data collection have changed with the development of, access to, and utilization of new technology [5]. Whereas EMA once entailed that the participants keep written records, most real-time data is now collected via handheld electronic devices, such as tablets and cell phones[5-7]. Along with EMA, geotracking is another method that is being used more frequently to collect information regarding the participants' real-time physical location or surroundings (eg, Global Positioning System [GPS] coordinates, home, office) by obtaining GPS data from their mobile phones or other GPS-enabled devices. Geotracking also allows the identification and analysis of those locations in relation to ones' actions and/or experiences [8-10]. The technology used for both EMA and geotracking within public health research has developed alongside advancements in consumer electronics, and the methods can now be implemented through apps on the study participants' personal mobile phones [5,8].

The use of mobile phones has become a method for EMA and geotracking data collection over the past ten years [7,11,12]. Such a preference may be attributed to the surge in mobile phone ownership among the general population. Between 2011 and 2016, there was a 42% increase in mobile phone ownership, and 77% Americans now own a mobile phone [13]. The unique features of mobile phones include internet accessibility and the ability to download and install apps.

Instead of providing participants with study-specific handheld electronic devices, personal mobile phones are increasingly being used as a means for collecting EMA and geotracking data, providing a noncoercive (eg, no free phone for study participation), low-cost tool to collect data in real-time [1]. While the majority of US adults own a mobile phone, it cannot be assumed that a potential study participant will have access to a mobile phone [13]. Factors such as socioeconomic status (SES), which encompasses employment, income, and educational levels, may impact mobile phone ownership. Researchers must consider the potential participants' mobile phone ownership and usage when conducting studies utilizing EMA and geotracking methods. Thus, understanding a potential participant's access to a mobile phone is important for interpreting the generalizability of results when implementing these methods. The purpose of this study was to (1) describe the sociodemographic characteristics of respondents to an online survey screener assessing their eligibility to participate in the "Moment Study": a mixed methods study that examined e-cigarette initiation among adult cigarette smokers using geolocation and text message-based EMA data collected via the participants' personal mobile phones, and (2) examine how eligibility criteria requiring mobile phone ownership and an unlimited texting plan affected study eligibility.

Methods

Study Design

Data come from a parent study called the "Moment Study", a mixed method longitudinal study that examined factors influencing e-cigarette initiation using a convenience sample of adult daily smokers residing in Washington, DC [14]. Briefly, the parent study involved data collected over three-weeks, and included: 1) geotracking; 2) EMA; 3) individual interviews; 4) biosamples; and 5) an online follow-up survey 30-days after the participant's last study visit. Ethics approval for the study was obtained from the Chesapeake IRB (Pro00008526). Text message-based EMA data were collected via mobile phones. A secure, automated text message-based EMA system prompted participants to respond to 6 random text message surveys a day for 21 days. Participants also initiated text message surveys whenever they smoked a cigarette or used an e-cigarette. Geotracking data was collected via an app downloaded to participants' mobile phones. The app collected one tracking point every five minutes [14]. The analyses presented here include data from the online survey screener only.

Recruitment and Eligibility

We recruited a convenience sample of adult smokers via public advertisements, free weekly newspapers, printed flyers, and word of mouth. The advertisements included a link to an online survey, which was the initial screening tool. The online survey screened for twenty-eight inclusion criteria grouped into three categories, which included (1) mobile phone use, (2) tobacco use, and (3) additional inclusion criteria.

The inclusion criteria for mobile phone use derived from the technological needs for EMA and geotracking data collection. We required daily mobile phone use and a preexisting unlimited text messaging plan to ensure that participants were comfortable sending and receiving texts and the number of text messages sent and received over the course of three weeks did not pose a financial burden on the participants. We also required the participants to have an Android or iPhone mobile phone because the geotracking app was only available on these operating systems. Device requirements were not expected to be restrictive, as Android and iPhone are the leading mobile phone operating systems in the United States with Android holding 56.4% and iPhone accounting for 42% of the market as of January 2017 [15].

In addition to the mobile phone inclusion criteria, we also required that participants be adult (≥18 years) daily cigarette smokers with restricted past 30-day use of other tobacco products. Additional inclusion criteria included age, pregnancy status, and both physical and mental health status (Table 2).

Prior to study enrollment, participants deemed eligible by the online screener were re-screened via telephone by study personnel to confirm that they met the inclusion criteria.

Statistical Analyses

Descriptive statistics were used to summarize the sociodemographic characteristics of individuals who completed the online screener, overall and eligibility by virtue of mobile phone ownership, and to describe the frequency of respondents meeting the study criteria. Observations with missing data were listwise deleted. Chi square tests and Mood's median tests (a special case of chi square tests) were used to test the equality of proportions or medians. Statistical significance was set to a *P*-value of 0.05. All analyses were conducted using Stata 14.2 (Stata Corp, College Station, TX, USA).

Results

A total of 1003 individuals took the online screener. Most respondents were African American (605/1003, 60.3%), male (514/1003, 51.3%), and had a median age of 35 years (IQR 26-50). Nearly all the respondents lived in Washington, DC, Virginia or Maryland (976/1003, 97.3%), and approximately half (496/1003, 49.5%) were unemployed. Most smoked menthol cigarettes (699/1003, 69.7%) and had smoked for a median of 11 years (IQR 5-21) (Table 1).

Of the 1003 respondents to the online screener, 28.5% (286/1003) were ineligible because of mobile phone inclusion criteria. Differences by sociodemographic characteristics and mobile phone inclusion criteria were evident. African Americans (57.4% vs 70.5%, *P*<.001) and menthol smokers (72.0% vs 68.8%, *P*<.001) made up greater proportions of people who were ineligible owing to mobile phone inclusion criteria. Additionally, people who were ineligible owing to mobile phone inclusion criteria were older (median age of 47 vs 32, *P*<.001) and had smoked for more years (median years smoked being 20 vs 10, *P*<.001). Of those who met the mobile phone inclusion criteria, 53.6% (384/717) were employed; conversely, among those who did not meet mobile phone criteria, 68.9% (197/286) were unemployed.

Among the other inclusion criteria, 44.0% of the unemployed individuals met all tobacco use inclusion criteria, and 93.0% of unemployed individuals met all the additional inclusion criteria; there was no difference in eligibility by employment status for the tobacco use or all other inclusion criteria (results not shown).

Table 1. Characteristics of individuals who took the initial online screener, overall and by mobile phone inclusion criteria, in the Washington, DC area.

Characteristic	Mobile phone inclusion criteria			
	Overall (N=1003)	Met inclusion criteria (>N=717)	Did not meet inclusion criteria (N=286)	*P* value
Gender, n (%)[a]				<.001
Female	478 (47.7)	346 (48.3)	132 (46.2)	
Male	514 (51.3)	371 (51.7)	143 (50.0)	
Race, n (%)[a]				<.001
White	248 (24.7)	193 (27.0)	55 (20.0)	
African American	605 (60.3)	411 (57.4)	194 (70.5)	
Asian	39 (3.9)	35 (4.9)	4 (1.5)	
Native Hawaiian	1 (0.1)	1 (0.1)	0 (0)	
American Indian	2 (0.2)	1 (0.1)	1 (0.4)	
Other	52 (5.2))	41 (5.7)	11 (4.0)	
More than 1 race	44 (4.4)	34 (4.7)	11 (3.6)	
Hispanic, n (%)	77 (7.7)	58 (8.1)	19 (6.6)	.530
Age, median (IQR[b])[c]	35 (26-50)	32 (25-45)	47 (32-55)	<.001
Years smoking, median (IQR)[c]	11 (5-21)	10 (6-20)	20 (11-35)	<.001
Menthol smoker n (%)	699 (69.7)	493 (68.8)	206 (72.0)	<.001
Live in the DC metro area, n (%)	976 (97.3)	708 (98.9)	268 (93.7)	.201
Employment, n (%)[a]				
Employed	473 (47.2)	384 (53.6)	89 (31.3)	<.001
Not employed	496 (49.5)	333 (46.4)	197 (68.9)	

[a]The following variables had missing data: gender (1%), race (1.2%), employment (3.3%).

[b]IQR: interquartile range.

[c]Mood's median tests were used to test for differences in median age and years smoked.

Table 2. Percentage of screened individuals who satisfied mobile phone, tobacco use, or additional inclusion criteria in the online screener (N=1003).

Inclusion criteria	n (%)
Mobile phone criteria	
Have Android or iPhone	739 (73.7)
Mobile phone allows app installation	871 (86.8)
Use mobile phone daily	898 (89.5)
Unlimited text message plan	871 (86.8)
Meet all the mobile phone inclusion criteria	717 (71.5)
Tobacco use criteria	
Daily smoker	890 (88.7)
≥5 years of smoking	772 (77.0)
≥8 cigarettes a day	689 (68.7)
Use of little cigars no more than 5 times in the last 30 days	814 (81.2)
Use of cigars no more than 5 times in last the 30 days	998 (99.5)
Use of hookah no more than 5 times in the last 30 days	996 (96.3)
No use of pipe (with tobacco, not including hookah) in the last 30 days	995 (95.2)
No use of chewing tobacco in the last 30 days	995 (99.2)
No use of dip/snuff in the last 30 days	997 (99.4)
No use of snus in the last 30 days	1000 (99.7)
No use of nicotine products (like gum, patches) in the last 30 days	961 (95.8)
No use of e-cigarettes in the last 30 days	833 (83.1)
Interested in trying an e-cigarette	689 (68.7)
Meet all tobacco use inclusion criteria	426 (42.5)
Additional inclusion criteria	
Not on cessation medication	947 (94.4)
Not breastfeeding or planning to become pregnant	975 (97.2)
No heart disease/uncontrolled blood pressure	941 (93.8)
No psychosis	943 (94.0)
No suicidal thoughts	949 (94.6)
Not enrolled currently in an alcohol treatment program	940 (93.7)
Not out of town for more than 5 nights in the next 6 weeks	933 (93.0)
18 years or older	1002 (99.9)
Reside in the DC metro area	976 (97.3)
Willing to travel to data collection site four times in three weeks	949 (94.6)
Meet all additional inclusion criteria	916 (91.3)

The majority of the respondents owned an iPhone or Android mobile phone (739/1003, 73.7%) and could install apps on their mobile phone (871/1003, 86.8%). Many used their mobile phones daily (898/1003, 89.5%) and had an unlimited text messaging plan (871/1003, 86.8%). Most (717/1003, 71.5%) met the mobile phone inclusion criteria, and 91.3% met all the additional inclusion criteria; however, only 42.5% (426/1003) met all the tobacco inclusion criteria. Overall, 302 individuals were eligible to participate in the study with 163 eligible after being rescreened; 117 were ultimately enrolled in the study (Table 2).

Discussion

Principal Considerations

This study describes the sociodemographic characteristics of individuals responding to an online screener, and examines how eligibility criteria requiring mobile phone ownership affected study eligibility. A total of 1003 individuals completed the online screener of whom 73.7% (739/1003) owned a mobile phone; of the mobile phone owners, 86.8% (871/1003) could install apps, 89.5% (898/1003) used their mobile phones daily,

and 86.8% (871/1003) had an unlimited text messaging plan. While our mobile phone inclusion criteria were strict, 46.4% (333/717) of the unemployed respondents still met the criteria, suggesting that mobile phone ownership is not a major barrier to study participation, even for unemployed individuals.

These findings also have broader relevance for the tobacco control field, which increasingly uses mobile phone technology to examine tobacco product use, surveil tobacco retail environments, and deliver smoking cessation interventions [10,16,17]. Smoking is concentrated among low-SES groups with sometimes unstable employment; provision of a free mobile phone as part of study participation may be coercive for members of such vulnerable groups. Examination of who has access to a mobile phone is essential to assessing how planning a protocol using methods such as EMA or geotracking might affect ethical considerations, study recruitment, and generalizability of the findings.

Limitations

The study utilized an online screener, which may have been a barrier to individuals who lacked internet access. Had we initially screened potential participants via telephone, we may have found that a greater proportion of respondents were ineligible because of lack of mobile phone ownership. Additionally, given that this study was conducted in Washington, DC, our findings may not be generalizable to other settings. Moreover, it is important to consider that all data collected in this study were self-reported responses to the online screener questions. Therefore, the respondents' mobile phone and tobacco use may have been under- or over-reported owing to social desirability and recall bias.

Conclusions

This research suggests that using the participants' own mobile phones for data collection, including geotracking and text messaging, was not a barrier to study participation for the majority of the respondents who took the initial online screener. Employment was related to fulfilling the mobile phone inclusion criteria; however, nearly half of the eligible respondents were unemployed. As mobile phone ownership continues to grow, researchers should consider using the participants' own mobile phones as feasible data collection devices given their study's target population.

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Authors' Contributions

EH conceived the study design and the overall manuscript, led the data collection and analysis team, wrote the first draft of the paper, and worked as a research associate in the parent study. HE and YZ conducted the data analyses. SS and LR contributed to the analysis, interpretation of results, and manuscript writing. LR was involved as a research assistant in the parent study; SS was project director in the parent study, and JP was principal investigator in the parent study.

Conflicts of Interest

None declared.

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Abbreviations

EMA: ecological momentary assessment
GPS: Global Positioning System
IQR: interquartile range

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Original Paper

Mobile App Delivery of the EORTC QLQ-C30 Questionnaire to Assess Health-Related Quality of Life in Oncological Patients: Usability Study

Kerstin A Kessel[1,2], Dr Sc Hum; Marco ME Vogel[1,2], MD; Anna Alles[1], BSc; Sophie Dobiasch[1], MD; Hanna Fischer[1]; Stephanie E Combs[1,2], MD

[1]Department of Radiation Oncology, Technical University of Munich, Munich, Germany

[2]Institute for Innovative Radiotherapy, Helmholtz Zentrum München, Neuherberg, Germany

Corresponding Author:
Kerstin A Kessel, Dr Sc Hum
Department of Radiation Oncology
Technical University of Munich
Ismaninger Straße 22
Munich, 81675
Germany
Phone: 49 0894140 ext 4502
Fax: 49 08941404477
Email: kerstin.kessel@tum.de

Abstract

Background: Mobile apps are evolving in the medical field. However, ongoing discussions have questioned whether such apps are really valuable and whether patients will accept their use in day-to-day clinical life. Therefore, we initiated a usability study in our department.

Objective: We present our results of the first app prototype and patient testing of health-related quality of life (HRQoL) assessment in oncological patients.

Methods: We developed an app prototype for the iOS operating system within eight months in three phases: conception, initial development, and pilot testing. For the HRQoL assessment, we chose to implement only the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Core 30 (QLQ-C30; German version 3). Usability testing was conducted for three months. Participation was voluntary and pseudonymized. After completion of the QLQ-C30 questionnaire using iPads provided by our department, we performed a short survey with 10 questions. This survey inquired about patients' opinions regarding general aspects, including technical advances in medicine, mobile and app assistance during cancer treatment, and the app-specific functions (eg, interface and navigation).

Results: After logging into the app, the user can choose between starting a questionnaire, reviewing answers (administrators only), and logging out. The questionnaire is displayed with the same information, questions, and answers as on the original QLQ-C30 sheet. No alterations in wording were made. Usability was tested with 81 patients; median age was 55 years. The median time for completing the HRQoL questionnaire on the iPad was 4.0 minutes. Of all participants, 84% (68/81) owned a mobile device. Similarly, 84% (68/81) of participants would prefer a mobile version of the HRQoL questionnaire instead of a paper-based version. Using the app in daily life during and after cancer treatment would be supported by 83% (67/81) of participants. In the prototype version of the app, data were stored on the device; in the future, 79% (64/81) of the patients would agree to transfer data via the Internet.

Conclusions: Our usability test showed good results regarding attractiveness, operability, and understandability. Moreover, our results demonstrate a high overall acceptance of mobile apps and telemedicine in oncology. The HRQoL assessment via the app was accepted thoroughly by patients, and individuals are keen to use it in clinical routines, while data privacy and security must be ensured.

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KEYWORDS

radiation oncology; healthcare surveys; mobile applications; mobile apps; telemedicine; health-related quality of life; questionnaires; oncology

Introduction

Since the first smartphone was introduced by IBM in 1995 [1], the development of cell phones and mobile apps has been world-changing. The success of medical and health apps (labeled under mobile health [mHealth] or electronic health [eHealth]) is undeniable, with 165,000 programs in the respective leading app stores (Apple and Google) [2]. Apps for registering heart rate, blood pressure, and blood glucose are forthcoming, and apps for depression, body weight reduction, and diabetes are widely accepted. However, most of the apps are not scientifically validated [3-5]. To date, only a few apps in an oncological context exist, which allow for quality of life (QoL) assessment.

An essential key to everybody's well-being is QoL, which the World Health Organization defined in 1946 as an, "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [6]. This broad definition includes a holistic approach to QoL, which is rarely used in medical research. In the 1980s the concept of health-related quality of life (HRQoL) evolved [7]. HRQoL is a critical criterion in the therapeutic decision-making process undertaken by health care professionals (HCPs) who are torn between the patients' well-being, outcome, and economic considerations. Especially in oncology, where treatment is often only life-prolonging and not curative, HRQoL assessment is crucial to identify therapeutic benefit and need. The European Organization for Research and Treatment of Cancer (EORTC) developed a wide range of standardized and validated questionnaires to assess HRQoL in oncological patients. In this study we used the EORTC Quality of Life Questionnaire-Core 30 (QLQ-C30) [8], which is the core questionnaire that can be extended by cancer-specific modules.

In earlier series, we asked HCPs [9] and patients [10] about their attitudes regarding telemedicine and mobile apps in oncology. A total of 84.3% of HCPs supported the idea of an oncological app, and 97.8% found the HRQoL assessment very useful or useful. Approximately half of the patients asked were willing to use an oncological app; 75.3% of those patients were keen to send HRQoL data. In general, younger patients were more in favor of such an app (P=.032, r=-0.12).

Our previous results show an existing demand for oncological apps. Hence, we developed an app for HRQoL assessment in oncological patients. This work aims to present our results of the first prototype, the design/development, and patient testing.

Methods

For the first version of the app, we decided to develop the prototype for the iOS operating system (version 8 and later) optimized for iPads (generation 2 and later), but the app also worked on iPhones (generation 4s and later). Further operating systems and device options were scheduled after the first patient testing and validation results were obtained. The development was completed within eight months in three phases: conception, initial development, and pilot testing.

App Design and Development

Considering our previously published work on app use during cancer treatment [9-11], we specified primary functional requirements for the prototype listed in Table 1 with the following four main characteristics:

1. Clear interface and user-friendly design
2. The prototype should implement only the EORTC QLQ-C30 questionnaire (German version 3; Multimedia Appendix 1 [German], Multimedia Appendix 2 [English])
3. Data is locally stored on the device; no Internet connection or online data transfer were intended in this version
4. Login information (user identification [ID] and password) will be generated and provided by the department; this method ensured pseudonymization

The app was developed using Xcode 7.0 and Swift 2.2.

Table 1. Functional requirements for the prototype app.

Requirement	Details
User management	A user can register herself/himself with a given user ID and password on a device; after that, login and logout are possible on that specific device
Administration	The administrator can delete registered users on the device
	The administrator can review completed questionnaires and delete them
Questionnaire	A questionnaire can be filled out multiple times
	A questionnaire can be canceled at any time; results are not saved
	Questions can be skipped
	Answers can be changed
	Completed questionnaires can be saved (submitted) to store the results on the device
Data management	Questionnaires are stored with the information: user ID, date, given answers

Validation

As an empirical usability evaluation method, we used a questionnaire. The survey was conducted for three months at the Department of Radiation Oncology, Klinikum rechts der Isar, Munich, Germany. Participation was voluntary and pseudonymized. Inclusion criteria for participation were: age older than 18 years, German-speaking, and being physically and mentally able to fill out a structured questionnaire on a mobile device. Research assistants supervised the patients during app use and while completing the questionnaire. The Ethics Committee of the Technical University of Munich approved the nature and content of the study with the project number 321/16 S.

After completion of the QLQ-C30 questionnaire using iPads provided by our department, we conducted the short usability survey with 10 questions (Multimedia Appendix 3). This survey inquired about patients' opinions regarding general aspects, including technical advances in medicine, mobile and app assistance during cancer treatment, and the app-specific functions (eg, attractiveness, operability, and understandability). Statistical calculations were performed using SPSS Statistics v23 (IBM, Armonk, NY, USA) in a primarily descriptive way.

Results

App Design and Development

After launching the app, the login page appears (Figure 1, left). If accessing the app for first time, a user ID and password need to be registered on the device (Figure 1, right). After login, the start page appears (Figure 2, left). We decided to use a slide bar for the menu, as it is easily extendable for future additional functions of the app. Users can click the button in the top left corner or swipe left on the screen to open the menu. For the prototype, the functions for starting a questionnaire, reviewing answers (administrator only), and logging out were implemented (Figure 2, right).

Figure 3 (left) shows the start page of the EORTC QLQ-C30 questionnaire. We displayed the same information that is written on the paper-based version of the questionnaire. Likewise, all 30 questions were copied from the original QLQ-C30 sheet. No alterations in wording or answers were made. Figure 3 (right) shows the first question. On the bottom of each page, the user can go back to the previous question or skip the current question. After the last question, the user is asked to save the completed questionnaire. These answers can be reviewed by the administrator (Multimedia Appendix 4).

Figure 1. Screenshot of the login (left) and registration (right) page.

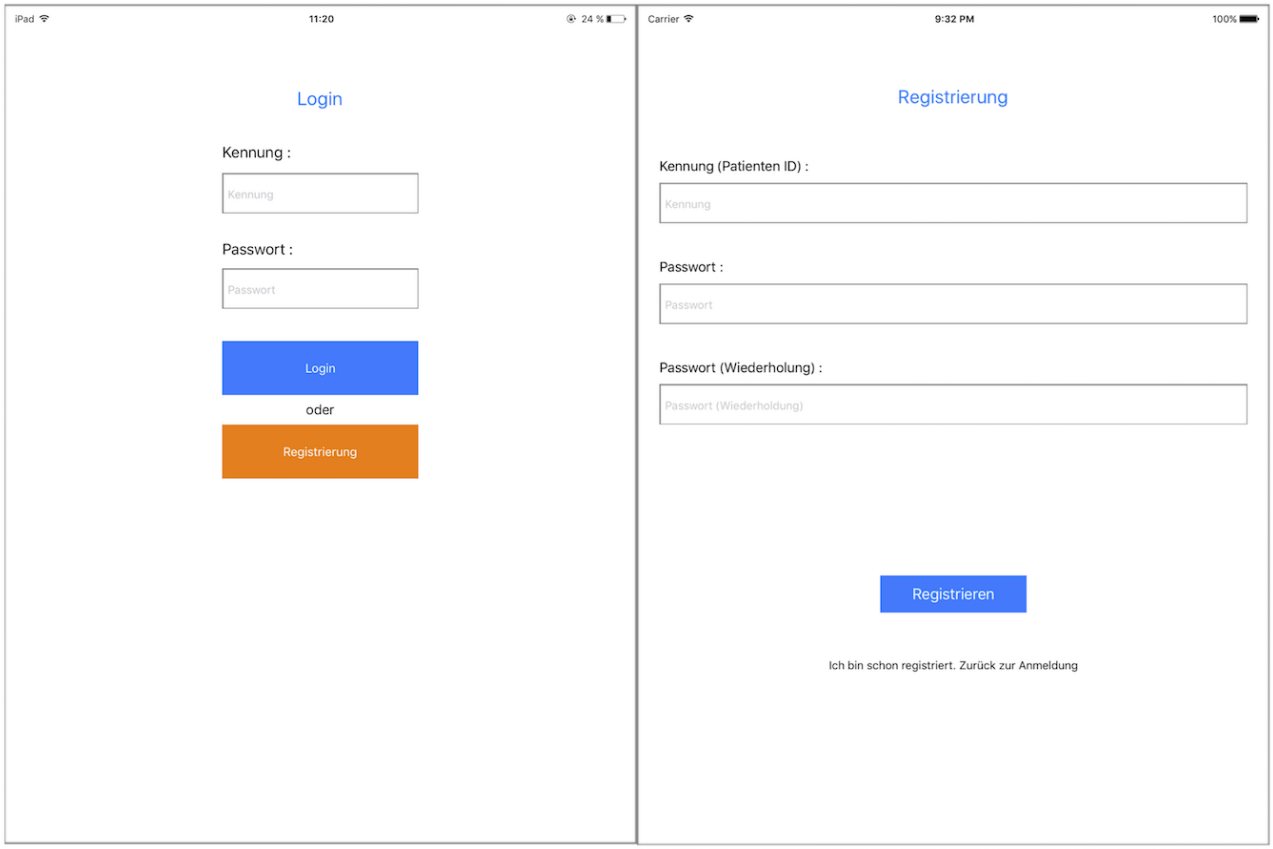


Figure 2. Screenshot of the start page (left) and slide bar of the menu (right). Administrator view is displayed.

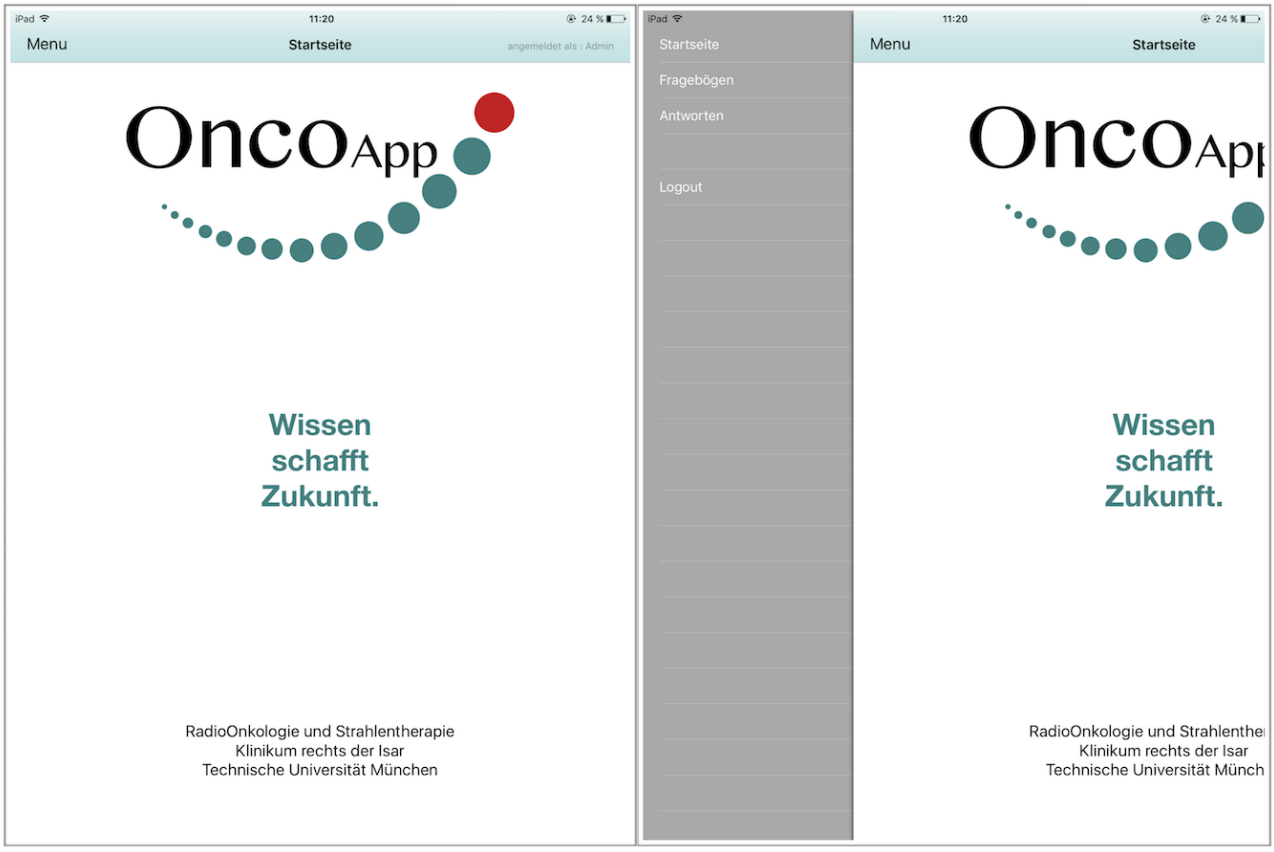


Figure 3. Screenshot of the start page of the European Organization for Researchand Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30; left) and the first question (right).

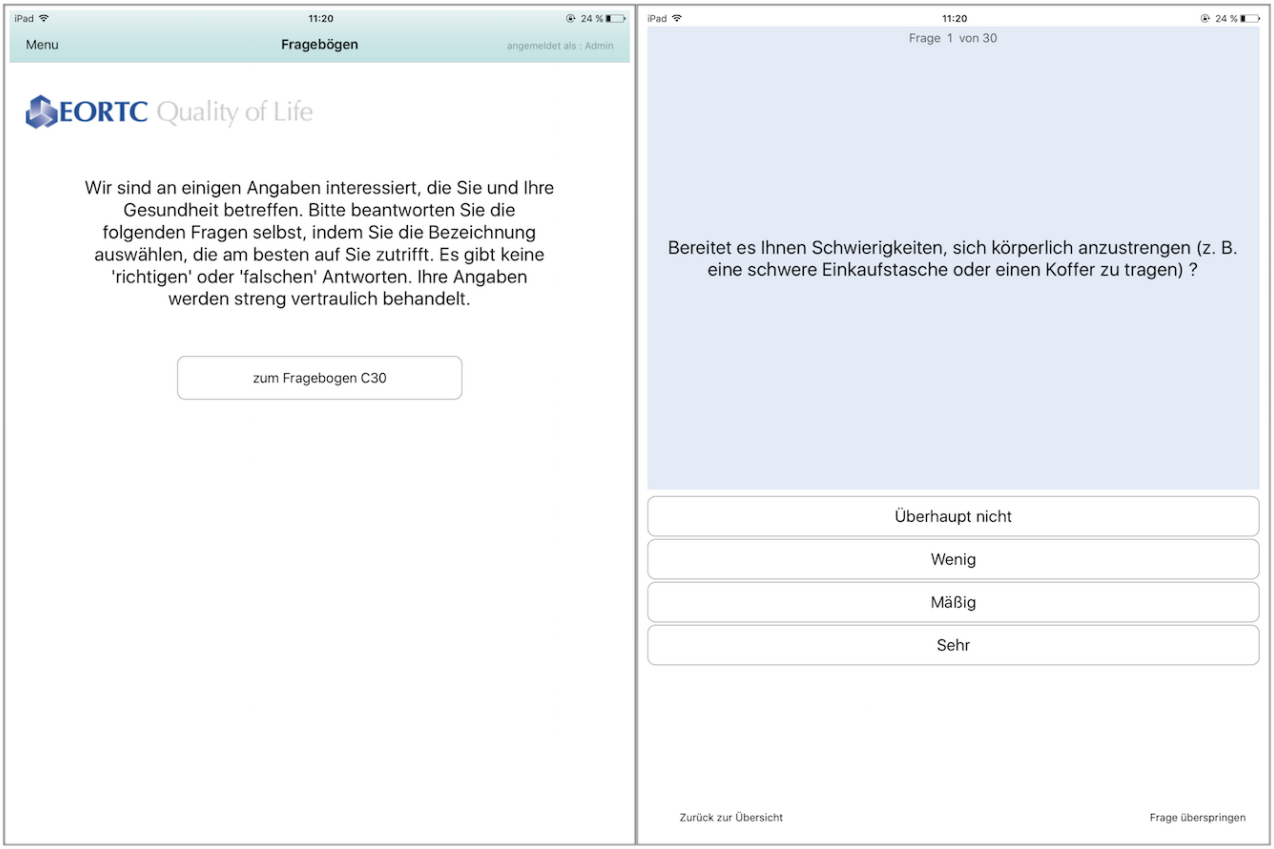


Figure 4. Patient opinion about mobile technologies in medicine (scale from 1 = “I like the development” to 6 = “I don’t like the development”).

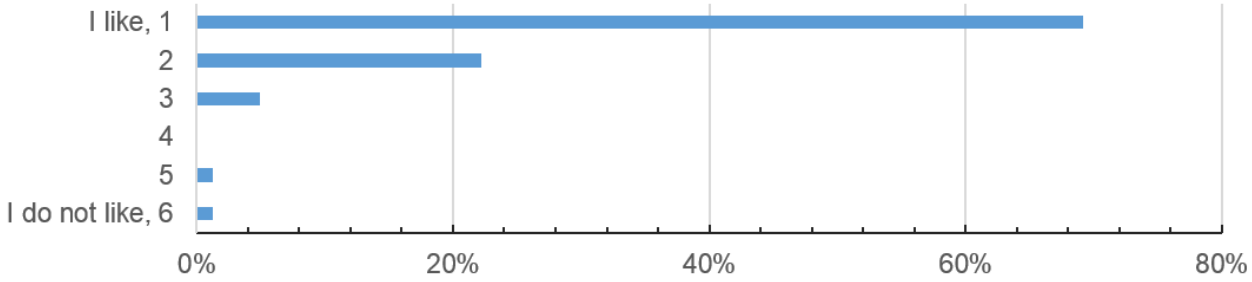
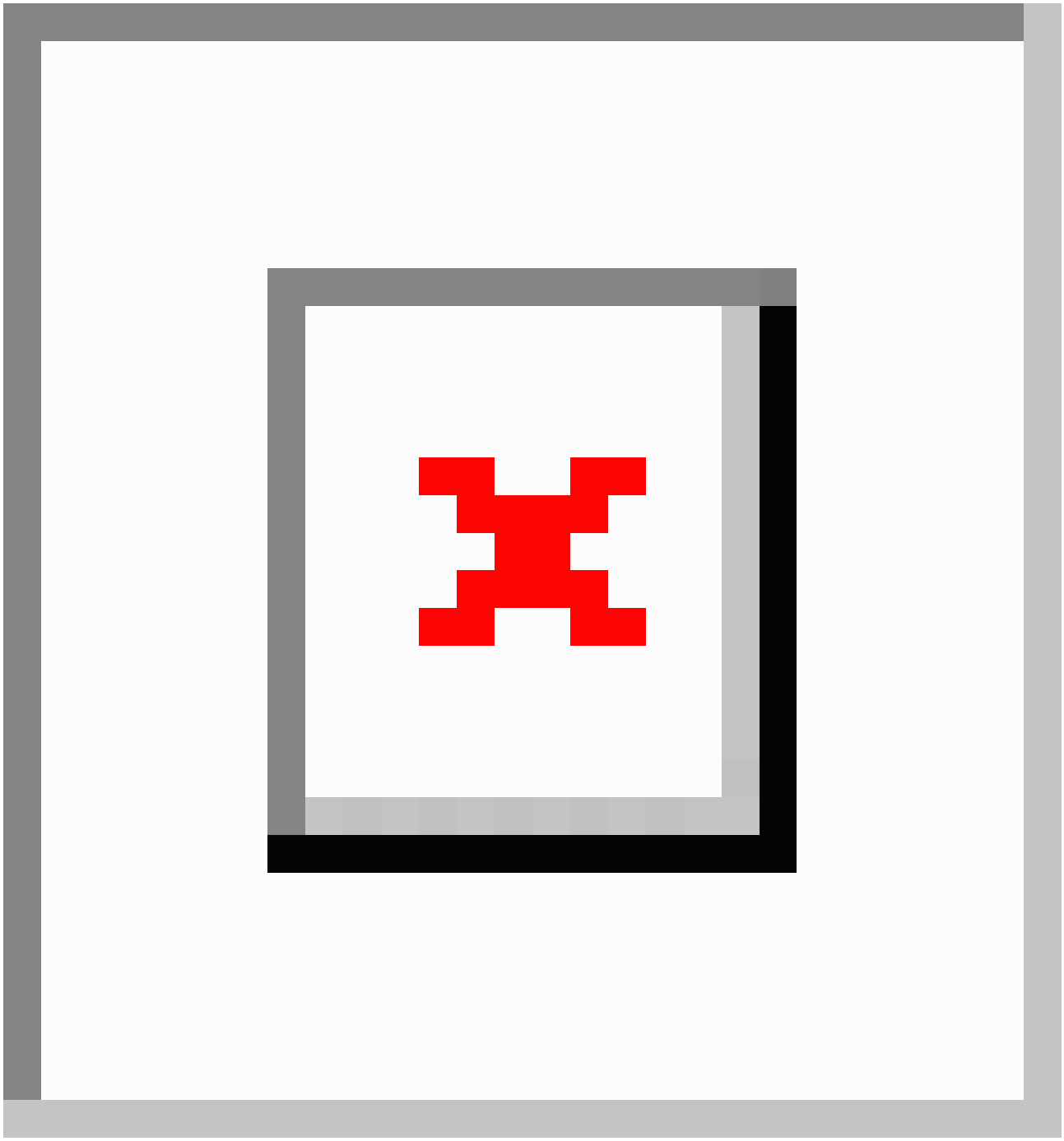


Figure 5. Patient opinion about the app design in terms of color, text and button size, content, and the amount of content per page (scale from 1 = “I like it” to 6 = “I don’t like it”).



Validation

The usability of the app was tested with 81 patients (44 male, 37 female); median age was 55 years (range 21-80 years). When using the app, older patients (>60 years old) distinguished themselves from younger patients (<60 years old). The research assistants observed that while the elderly users had to ask questions about where to click and swipe on the screen, the younger users intuitively knew how to navigate through the app.

The median time for completing the HRQoL questionnaire on the iPad was 4.0 minutes (range 1.5-8.0 minutes). Of all participants, 84% (68/81) owned a mobile device. Similarly, 84% (68/81) would prefer the mobile version of the HRQoL questionnaire instead of the paper-based version that they usually get during a clinical visit. Using the app in daily life during and after cancer treatment would be supported by 83% (67/81) of participants, which corresponds with their general opinion about mobile technologies in medicine (described in Figure 4). Patients were satisfied with the current development and the introduction of the app into clinical life. In the prototype version of the app, data were stored on the device; in the future, 79% (64/81) of the patients would agree to transfer data via the Internet.

The operability and navigation of the app were rated as intuitive by 95% (77/81) and 93% (75/81) of participants, respectively. Six participants stated opportunities for improvements regarding the HRQoL questions. However, these cannot be changed as they follow a standardized structure and wording that has been established by the EORTC. Regarding the attractiveness, two patients wished for a setting option to change the font size; five had difficulties finding the menu at first. Figure 5 shows the patients' opinions on the app interface and design.

Discussion

The long-term aim of app-assisted care is to generate higher treatment quality and HRQoL for our patients. In this study, we present our first app-prototype for regular HRQoL assessment, along with the patient usability testing. Most of the participants (84%, 68/81) owned a mobile device and therefore were appropriately equipped to use an app. Similarly, 84% (68/81) of participants would prefer a mobile version of HRQoL assessment instead of a paper-based version, while 83% (67/81) would use it in daily life. Such an app would increase clinical efficiency by reducing paperwork and costs, and enhance patient empowerment. Our results show that mobile technologies are widely accepted; 96% (78/81) of the patients scale their opinion about telemedicine as *positive* (scale 1-3; Figure 4).

The users in this study were cancer patients, and the concept of the prototype was to implement a clean and simple app, with the primary goal to be user-friendly. The oncological patient population includes individuals of young and old age. While implementing apps in clinical routine, age and technical skills always seem to be a problem. In our study, patients >60 years old needed more assistance than younger patients. However, Smith et al showed a growing trend of smartphone use amongst elderly people (>65 years) in the United States, with 18% in 2014 [12] and 27% in 2015 [13]. Older individuals incrementally adapt to mobile technology. Nevertheless, it is essential to develop apps for older patients with a focus on operability and understandability. Intensive preuse teaching might be necessary in some cases.

Although we recently showed a higher usage of Android phones (52.9%) than iOS phones (37.2%) in our patient population [10], we rationally decided to develop the first version of the app for iPhones and iPads. iOS development is cheaper [14] and more comfortable, as apps only need to meet the criteria of two model types. However, a version of our app for Android is planned in the near future.

The interface was designed in light, cool colors and we omitted any animation or gamification. Overall, we used hues of the blue and green family, which tend to psychosocially calm down the already anxious cancer patients [15]. We chose to use dark characters on white background. Piepenbrock et al [16] showed an advantage in positive display polarity for young and old adults. Font size 12 was chosen to be readable by older patients with visual impairment. Darroch et al [17] showed that font size does not affect reading accuracy in both young and old adults, but young adults preferred size 8 and 10 while older adults preferred slightly bigger sizes of 8 to 12. Darroch et al recommend offering a setting option for font size, which was requested by two of our patients.

Button size for the questionnaire was chosen to be 20 pixels high. Anthony [18] recommends a target width of 45-57 pixels wide to allow the user's finger to fit in the target while the edges are visible when tapping. We chose the width to be the full size of the screen, as our app needs to be comfortable for older patients with visual impairment and lower touch accuracy. After pretesting, we decided to implement a button for skipping questions, as patients can do the same in the paper-based version. Patients who do not want to (or cannot) answer one of the questions can still complete the survey.

Overall, patients were in favor of the presented app design (Figure 5); operability (95%) and navigation (93%) were rated excellent. These factors play a critical role in patient compliance, as poor user-friendliness will automatically lead to reduced usage. Completion time of the paper-based EORTC QLQ-C30 questionnaire was reported by Aaronson et al [8] as approximately 11 minutes, while our mobile version only took median 4 minutes. Both patient populations were different (median age 55 vs 63 years, international multicenter study vs in-house study) [8]. However, our study shows that patients with cancer disease are compliant with an app-based HRQoL assessment, and it is an efficient method.

To date, data are only stored locally on the device and can be transferred via a cable. In the future, patient data will be sent online, and the treating physicians will have access to the data (eg, at aftercare appointments). Here, it is crucial to guarantee data protection and security. We showed previously that 85.2% patients marked pseudonymization and data security as very important/important [10]. As health data is always highly sensitive, data security was the most crucial requirement for using an oncological app [11,19].

The first version of the app only contains the EORTC QLQ-C30 questionnaire. Future functions are planned and in progress. A multilingual approach (English, French, Italian, Russian, Arabic) is necessary, as our department is frequented by many international patients, and furthermore German is not the mother tongue of some local patients (eg, refugees). Moreover, cancer-specific modules such as the EORTC QLQ-BR23 [20] for breast cancer or QLQ-PR25 [21] for prostate cancer will be implemented next. HRQoL data from cancer patients can be used to adjust the individuals' treatment or offer supportive therapy. Surveys on therapy satisfaction will help to improve the departments' workflow and the patients' contentment.

Another function of the app will be the documentation of treatment-related side effects and symptoms. The course of a disease will be monitored and chronicled. This feature can also be used to register study parameters in app-assisted randomized controlled trials (smartRCTs). SmartRCTs can reduce study duration, costs, and subject bias, as well as collect a broader range of data [11]. Certainly, a workflow regarding how to check patient answers regularly and how to handle severe entries by the patients must be developed. However, we could recently show that 94.3% of HCPs were willing to contact the patient [9], which may lead to a quicker detection of progress, as recently stated by Denis et al [22,23]. This group demonstrated that using a Web-based app resulted in a significant improvement in overall survival (12 months vs 19 months) in patients with high-risk lung cancer, and relapses were detected five weeks earlier that the control group [23].

Our usability test showed good results for the presented app. Moreover, our results demonstrate a high overall acceptance of mobile apps and telemedicine in oncology, which is in line with our previous results [9,10]. The HRQoL assessment via the app was accepted thoroughly by patients, and individuals are keen to use it in clinical routine, while data privacy and security must be ensured. Digital medicine (medicine 4.0) is an unstoppable trend and will play a significant role in the future of clinical health care.

Conflicts of Interest

None declared.

Multimedia Appendix 1

QLQ-C30 questionnaire paper based version (German).

[PDF File (Adobe PDF File), 141KB - mhealth_v6i2e45_app1.pdf]

Multimedia Appendix 2

QLQ-C30 questionnaire paper based version (English).

[PDF File (Adobe PDF File), 20KB - mhealth_v6i2e45_app2.pdf]

Multimedia Appendix 3

Patient usability survey (German).

[PDF File (Adobe PDF File), 303KB - mhealth_v6i2e45_app3.pdf]

Multimedia Appendix 4

Screenshot of the review screen with completed questionnaires (administrator view).

[PNG File, 399KB - mhealth_v6i2e45_app4.png]

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Abbreviations

eHealth: electronic health
EORTC: European Organization for Research and Treatment of Cancer
HCP: health care professional
HRQoL: health-related quality of life
ID: identification
mHealth: mobile health
QLQ-C30: Quality of Life Questionnaire-Core 30
QoL: quality of life
smartRCT: smart randomized controlled trial

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Original Paper

Cardiac Auscultation Using Smartphones: Pilot Study

Si-Hyuck Kang[1], MD; Byunggill Joe[2], MS; Yeonyee Yoon[1], MD, PhD; Goo-Yeong Cho[1], MD, PhD; Insik Shin[2], PhD; Jung-Won Suh[3], MD, PhD

[1]Division of Cardiology, Department of Internal Medicine, Seoul National University Bundang Hospital, Seongnam-si, Republic Of Korea

[2]School of Computing, Korea Advanced Institute of Science and Technology, Daejeon, Republic Of Korea

[3]Division of Cardiology, Cardiovascular Center, Seoul National University Bundang Hospital, Seongnam-si, Republic Of Korea

Corresponding Author:
Jung-Won Suh, MD, PhD
Division of Cardiology
Cardiovascular Center
Seoul National University Bundang Hospital
166 Gumi-ro
Bundang-gu
Seongnam-si, 13620
Republic Of Korea
Phone: 82 31 787 7016
Fax: 82 31 787 4051
Email: suhjw1@gmail.com

Abstract

Background: Cardiac auscultation is a cost-effective, noninvasive screening tool that can provide information about cardiovascular hemodynamics and disease. However, with advances in imaging and laboratory tests, the importance of cardiac auscultation is less appreciated in clinical practice. The widespread use of smartphones provides opportunities for nonmedical expert users to perform self-examination before hospital visits.

Objective: The objective of our study was to assess the feasibility of cardiac auscultation using smartphones with no add-on devices for use at the prehospital stage.

Methods: We performed a pilot study of patients with normal and pathologic heart sounds. Heart sounds were recorded on the skin of the chest wall using 3 smartphones: the Samsung Galaxy S5 and Galaxy S6, and the LG G3. Recorded heart sounds were processed and classified by a diagnostic algorithm using convolutional neural networks. We assessed diagnostic accuracy, as well as sensitivity, specificity, and predictive values.

Results: A total of 46 participants underwent heart sound recording. After audio file processing, 30 of 46 (65%) heart sounds were proven interpretable. Atrial fibrillation and diastolic murmur were significantly associated with failure to acquire interpretable heart sounds. The diagnostic algorithm classified the heart sounds into the correct category with high accuracy: Galaxy S5, 90% (95% CI 73%-98%); Galaxy S6, 87% (95% CI 69%-96%); and LG G3, 90% (95% CI 73%-98%). Sensitivity, specificity, positive predictive value, and negative predictive value were also acceptable for the 3 devices.

Conclusions: Cardiac auscultation using smartphones was feasible. Discrimination using convolutional neural networks yielded high diagnostic accuracy. However, using the built-in microphones alone, the acquisition of reproducible and interpretable heart sounds was still a major challenge.

Trial Registration: ClinicalTrials.gov NCT03273803; https://clinicaltrials.gov/ct2/show/NCT03273803 (Archived by WebCite at http://www.webcitation.org/6x6g1fHIu)

(JMIR Mhealth Uhealth 2018;6(2):e49) doi:10.2196/mhealth.8946

KEYWORDS

cardiac auscultation; physical examination; smartphone; mobile health care; telemedicine

Introduction

Cardiovascular diseases are the most common causes of death, accounting for 31.5% of all deaths globally [1,2]. In 2015, in the United States, 92.1 million adults were estimated to have cardiovascular diseases, and 43.9% of the adult population is projected to have some form of cardiovascular disease by 2030 [3].

The stethoscope has played a key role in the physical examination of patients with cardiac disease since its invention by Rene Laënnec in 1816 [4]. The opening and closing of the heart valves, as well as blood flow and turbulence through the valves or intracardiac defects, generate rhythmic vibrations, which can be heard via the stethoscope [5]. Cardiac auscultation using the stethoscope enables hemodynamic assessment of the heart and can help in the diagnosis of cardiovascular diseases [6].

Recently, the advent of noninvasive imaging modalities has dwarfed the importance of cardiac auscultation in clinical practice [7,8]. Devices such as the handheld ultrasound have enabled detailed on-site visualization of the cardiac anatomy and are further threatening the role of the stethoscope as a bedside examination tool [9,10]. In this way, there has been a decrease in the appreciation of the importance of cardiac auscultation, and physicians are decreasingly proficient and confident in their examination skills [11-13]. Studies have also suggested a low level of interobserver agreement regarding cardiac murmurs [14].

The smartphone has become a popular device. As of 2015, 64% of Americans and 88% of South Koreans were reported to own a smartphone [15]. Smartphones are frequently used for health purposes, such as counseling or information searches [16]. The modern smartphone has excellent processing capability and is equipped with multiple high-quality components, such as microphones, display screens, and sound speakers. There have been efforts to use smartphone health apps for self-diagnosis [17]. However, some of these software apps have shown poor credibility, and their role in health care is not yet established [18].

Therefore, we sought to develop a smartphone app for cardiac auscultation that could be used by non–medical expert users. Although the importance of cardiac auscultation is declining in the hospital setting, it could serve as a screening tool at the prehospital stage if it can be performed easily by smartphone users themselves. This was a pilot study to test the feasibility of cardiac auscultation using the built-in microphones of smartphones without any add-on devices. The study tested (1) whether heart sound recording using a smartphone is feasible, and (2) whether an automated diagnostic algorithm can classify heart sounds with acceptable accuracy. Heart sounds were recorded using the smartphone microphones and processed electronically. We developed a diagnostic algorithm by applying convolutional neural networks, which we used for the diagnosis of the recorded heart sounds. In this study, we assessed the diagnostic accuracy of the algorithm.

Methods

Description of the App

We developed a smartphone app named CPstethoscope for this study (Figure 1). The app runs on the Android operating system (Google Inc) and is used for research purposes only. Heart sounds were recorded by placing the phone on the skin of the chest, using the built-in microphone. In most smartphones, microphones are located on the lower border of the device. Heart sounds can be best heard in the intercostal spaces. The instructions for this app indicated the anatomical landmarks and auscultation areas. While maintaining the contact of the lower margin of the smartphone with the chest wall, users are required to manipulate the device to start and stop recording. Users can see on the screen whether their heart sounds are properly being captured.

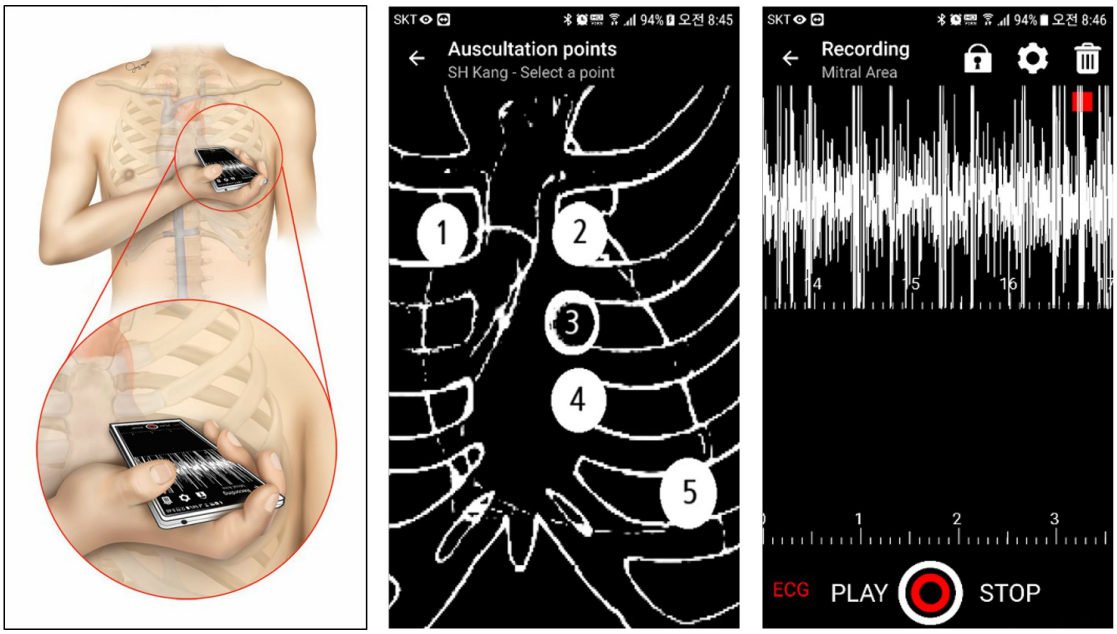
Study Design

This was a pilot study designed to demonstrate the feasibility of smartphone-based recording and identification of heart sounds. We sought to enroll 50 participants who were 18 years of age or older and had undergone an electrocardiogram (ECG) and echocardiography within the previous 6 months at Seoul National University Bundang Hospital, Seoul, Republic of Korea. Ultimately, we sought to develop an app for self-diagnosis that could be performed by users. However, for this pilot study, heart sounds were recorded by researchers who were familiar with the use of the app and understood the principles of cardiac auscultation. The investigators who recorded heart sounds were not aware of the patients' diagnoses. Eligible patients were invited to participate in the study by the research doctors at the outpatient clinics or on the wards. After participants provided informed consent, their heart sounds were recorded in a quiet room that was free from environmental noises.

Reference heart sounds were recorded by participating cardiologists (SHK, YY, GYC, and JWS) using an electronic stethoscope (3M Littmann Electronic Stethoscope Model 3200; 3M, St Paul, MN, USA). Study devices were the Samsung Galaxy S5 (model SM-G900) and Galaxy S6 (SM-G920; Samsung Electronics, Suwon, Republic of Korea), and LG G3 (LG-F400; LG Electronics, Seoul, Republic of Korea).

We chose the best site for recording from among the aortic, pulmonic, mitral, and tricuspid areas. The built-in microphones were placed directly on the skin of the chest wall for detection of the heart sound. We tested all 3 devices with all study participants. There were no prespecified orders for tested devices. No add-on devices were used. Recordings were made for approximately 10 seconds after stable heart sounds were displayed on the screen. Final diagnoses of the reference heart sounds were confirmed by a second cardiologist (SHK and GYC) by listening to the audio files and matching them with the echocardiography reports.

Figure 1. Heart sound recording using a smartphone app. Left: illustration of how the heart sounds were recorded in this study. Smartphones were placed directly on the chest wall; a dedicated app was used with no add-on devices. Middle and right: representative screenshots of the app (called CPstethoscope) developed for this study. ECG: electrocardiogram.



This study was approved by the Seoul National University Bundang Hospital institutional review board on August 24, 2016 (B-1609-361-303), and all participants provided written informed consent. We registered this study protocol (ClinicalTrials.gov NCT03273803). The corresponding author had full access to all the data in the study and takes responsibility for its integrity and the data analysis.

Data Processing and Identification

We transferred the recorded audio files to a desktop computer for data processing. After subtracting environmental and thermal noises using fast Fourier transformation, we constructed time-domain noise-reduced heart sounds. We detected the first and second heart sounds without an ECG reference, using a previously reported algorithm [19]. Time-domain signals were transformed into frequency-domain spectrogram features. We developed a diagnostic algorithm using convolutional neural networks, a variant of an artificial neural network that mimics the connections of neurons in the visual cortex of the brain. The convolutional neural network was constructed from 40×40 heart sound spectrogram matrices through 1 input layer. We processed these matrices with 2 convolution-max pool layers whose kernel size was 5×5. Moreover, the number of kernels for each of the 2 convolutional layers was either 8 or 16. Next, a dense, fully connected layer followed the second convolution–max pool layer, and we appended the last readout layer with 5 nodes that corresponded to each disease. We calculated the training loss of function of the network as soft maximum cross-entropy using the values from the readout layer. Finally, we trained the network with the Adam optimizer at a learning rate of 0.001 [20]. We used the TensorFlow version 1.2 Python library to compose this network [21]. Training was conducted using demonstration heart sounds obtained from open databases (The Auscultation Assistant, C Wilkes, University of California, Los Angeles, Los Angeles, CA, USA; Heart Sound & Murmur Library, University of Michigan Medical School, Ann Arbor, MI, USA; Easy auscultation, MedEdu LLC, Westborough, MA, USA; 50 Heart and Lung Sounds Library, 3M, St Paul, MN, USA; and Teaching Heart Auscultation to Health Professionals, J Moore, Rady Children's Hospital, San Diego, CA, USA). We classified heart sounds into 5 categories: normal, third heart sound, fourth heart sound (S_4), systolic murmur, and diastolic murmur. The algorithm showed 81% diagnostic accuracy with the training sets. Testing was performed with the samples acquired from this study.

Statistical Analysis

We calculated continuous variables as mean (SD), and categorical variables as counts and percentages. Reference heart sounds were adjudicated by experienced cardiologists. The primary end point of the study was the diagnostic accuracy of the system for heart sound classification. We considered the diagnosis to be accurate when the algorithm classified a heart sound into the correct category with 50% or more probability. We also estimated the performance of the system using sensitivity, specificity, positive predictive value, and negative predictive value. We defined the study end points were as follows: diagnostic accuracy = (TP+TN)/(TP+FP+FN+TN); sensitivity = TP/(TP+FN); specificity = TN/(TN+FP); positive predictive value = TP/(TP+FP); and negative predictive value = TN/(TN+FN), where TP indicates true positive; TN, true negative; FP, false positive; and FN, false negative. We calculated the diagnostic values as simple proportions with corresponding 95% confidence intervals. Statistical analyses were performed using the R programming language version 3.2.4 (The R Foundation for Statistical Computing). A 2-sided $P<.05$ was considered statistically significant.

Results

Patient Profiles

A total of 46 patients participated in this study. Multimedia Appendix 1 shows the Standards for Reporting of Diagnostic Accuracy Studies checklist and flow diagram for the study. Similar numbers of men and women were enrolled, and their median age was 65.5 years. Table 1 describes the participants' characteristics: 20 (44%) had systolic murmurs, 20 (44%) had normal heart sounds, 5 (11%) had diastolic murmurs, and 1 (2%) had S_4.

After audio file processing, including noise reduction, we confirmed 30 of 46 heart sounds (65%) as interpretable. The reasons for failure to acquire interpretable heart sounds included the small amplitude of the acquired heart sounds, background noise, and the participant's poor cooperation. Younger age tended to be associated with better interpretability, while body mass index had no impact. Significant factors for uninterpretability included atrial fibrillation and diastolic murmur.

Diagnostic Performance

Figure 2 shows the performance of the diagnostic algorithm by device. Heart sounds recorded with the 3 different study devices yielded consistently high diagnostic accuracy: Samsung Galaxy S5, 90% (95% CI 73%-98%); Samsung Galaxy S6, 87% (95% CI 69%-96%); and LG G3, 90% (95% CI 73%-98%). The Samsung Galaxy S5 and S6 showed a high sensitivity (S5: 94%, 95% CI 70%-100%; S6: 94%, 95% CI 70%-100%), while the LG G3 showed a high specificity (100%, 95% CI 68%-100%). The diagnostic performance did not vary significantly according to the study participants' age or sex (Table 2). Figure 3 shows representative waveforms and spectrograms of heart sounds (audio files are provided in Multimedia Appendix 2,Multimedia Appendix 3, and Multimedia Appendix 4). No meaningful adverse events occurred during the study.

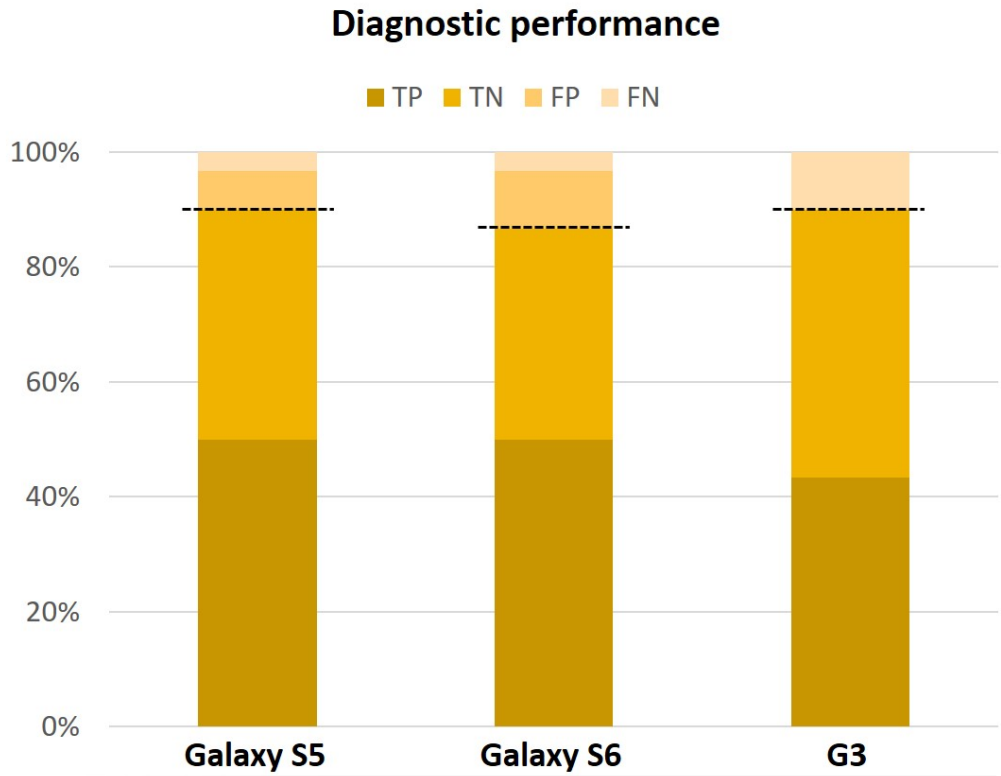
Table 1. Characteristics of study participants.

Characteristics	Interpretable heart sounds		Total	*P* value[a]
	Yes	No		
Number of participants, n (%)	30 (65)	16 (35)	46	
Male sex, n (%)	14 (47)	7 (44)	21 (46)	>.99
Age (years), median (range)	62.5 (22.0-90.0)	72.0 (27.0-88.0)	65.5 (22.0-90.0)	.07
Body mass index (kg/m^2), mean (SD)	23.8 (3.9)	23.4 (3.3)	23.7 (3.7)	.69
Hypertension, n (%)	14 (47)	9 (56)	23 (50)	.76
Diabetes, n (%)	4 (13)	5 (31)	9 (20)	.24
Atrial fibrillation, n (%)	0 (0)	5 (31)	5 (11)	<.001
Primary diagnosis, n (%)				.005
Aortic stenosis	11 (37)	2 (13)	13 (28)	
Aortic regurgitation	0 (0)	2 (13)	2 (4)	
Mitral stenosis	0 (0)	4 (25)	4 (9)	
Mitral regurgitation	2 (7)	0 (0)	2 (4)	
Hypertrophic cardiomyopathy	1 (3)	1 (6)	2 (4)	
Others	16 (53)	7 (44)	23 (50)	
Heart sounds, n (%)				.007
Systolic murmur	15 (50)	5 (31)	20 (44)	
Diastolic murmur	0 (0)	5 (31)	5 (11)	
S_3/S_4[b]	1 (2)	0 (0)	1 (2)	
Normal	14 (47)	6 (38)	20 (44)	

[a]Comparisons were performed using Student *t* test or Mann-Whitney *U* test for continuous variables, and chi-square test or Fisher exact test for categorical variables.

[b]S_3/S_4: third and fourth heart sounds.

Figure 2. Diagnostic performance of each study device. Bold broken lines indicate diagnostic accuracy. FN: false negative; FP: false positive; TN: true negative; TP: true positive.

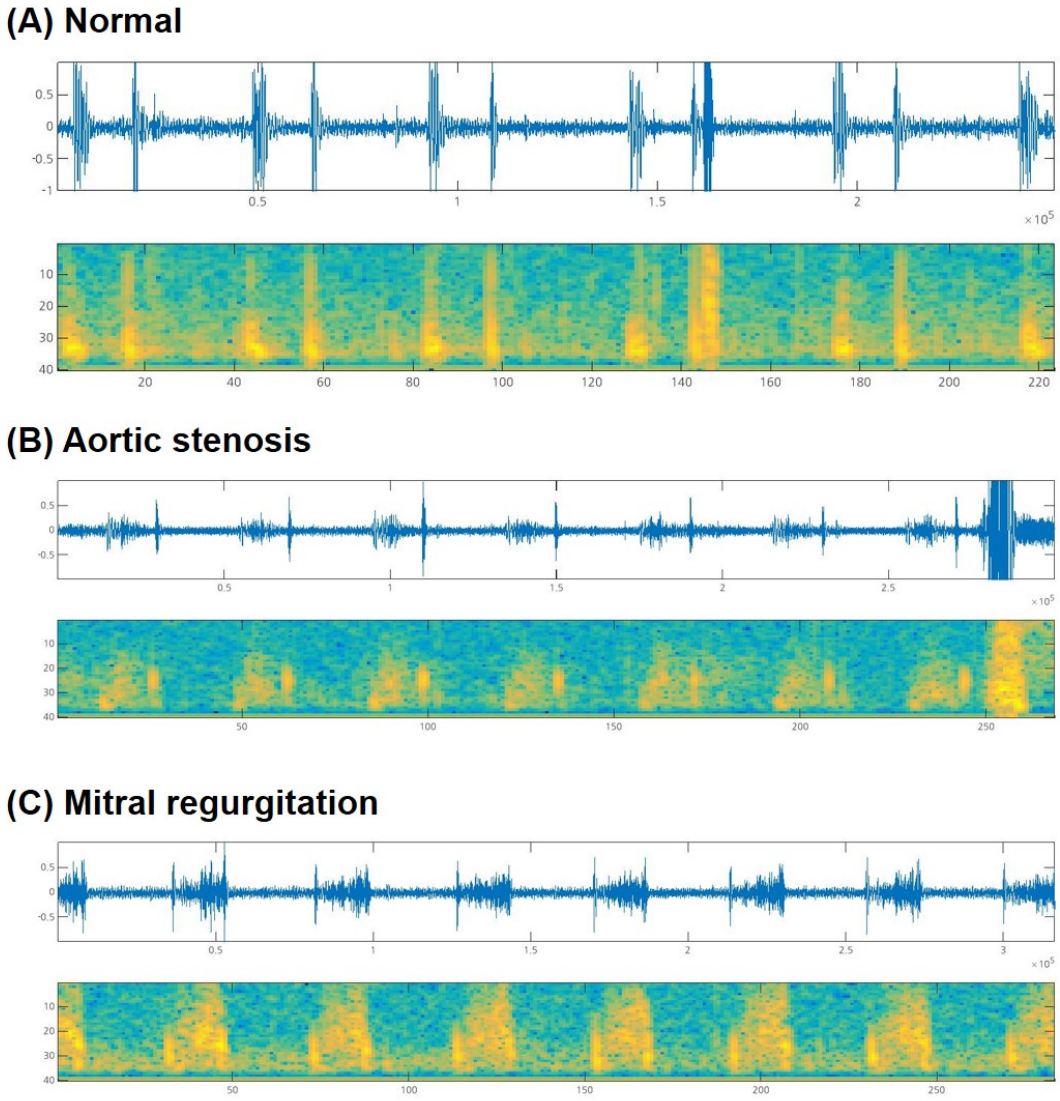


	Galaxy S5	Galaxy S6	G3
Diagnostic accuracy (%)	90 (73–98)	87 (69–96)	90 (73–98)
Sensitivity (%)	94 (70–100)	94 (70–100)	81 (54–96)
Specificity (%)	86 (57–98)	79 (49–95)	100 (68–100)
Positive predictive value (%)	88 (64–99)	83 (59–96)	100 (66–100)
Negative predictive value (%)	92 (64–100)	92 (62–100)	82 (57–96)

Table 2. Diagnostic performance (%) of each study device.

Participants grouped by age and sex	Study device		
	Galaxy S5 estimate (95% CI)	Galaxy S6 estimate (95% CI)	G3 estimate (95% CI)
Total (n=30)			
Diagnostic accuracy	90 (73-98)	87 (69-96)	90 (73-98)
Sensitivity	94 (70-100)	94 (70-100)	81 (54-96)
Specificity	86 (57-98)	79 (49-95)	100 (68-100)
Positive predictive value	88 (64-99)	83 (59-96)	100 (66-100)
Negative predictive value	92 (64-100)	92 (62-100)	82 (57-96)
Men (n=14)			
Diagnostic accuracy	79 (49-95)	79 (49-95)	93 (66-100)
Sensitivity	83 (36-100)	83 (36-100)	83 (36-100)
Specificity	75 (35-97)	75 (35-97)	100 (52-100)
Positive predictive value	71 (29-96)	71 (29-96)	100 (36-100)
Negative predictive value	86 (42-100)	86 (42-100)	89 (52-100)
Women (n=16)			
Diagnostic accuracy	100 (71-100)	94 (70-100)	88 (62-98)
Sensitivity	100 (59-100)	100 (59-100)	80 (44-97)
Specificity	100 (42-100)	83 (36-100)	100 (42-100)
Positive predictive value	100 (59-100)	91 (59-100)	100 (52-100)
Negative predictive value	100 (42-100)	100 (36-100)	75 (35-97)
Elderly (≥65 years; n=12)			
Diagnostic accuracy	100 (64-100)	92 (62-100)	83 (52-98)
Sensitivity	100 (55-100)	100 (55-100)	78 (40-97)
Specificity	100 (19-100)	67 (9-99)	100 (19-100)
Positive predictive value	100 (55-100)	90 (55-100)	100 (47-100)
Negative predictive value	100 (19-100)	100 (9-100)	60 (15-95)
Young (<65 years; n=18)			
Diagnostic accuracy	83 (59-96)	83 (59-96)	94 (73-100)
Sensitivity	86 (42-100)	86 (42-100)	86 (42-100)
Specificity	82 (48-98)	82 (48-98)	100 (62-100)
Positive predictive value	75 (35-97)	75 (35-97)	100 (42-100)
Negative predictive value	90 (55-100)	90 (55-100)	92 (62-100)

Figure 3. Representative phonocardiograms and spectrograms. (A) Normal heart sounds from the aortic area of a 22-year-old man with a history of vasovagal syncope. (B) Midsystolic ejection murmur from the aortic area of an 83-year-old woman with aortic stenosis, which was classified as a systolic murmur. (C) Systolic murmur from the mitral area of a 63-year-old woman with mitral valve prolapse and mitral regurgitation, which was classified as a systolic murmur.



Discussion

Principal Findings

This was a pilot study to assess the feasibility of heart sound recording and identification using smartphones. We found that reliable heart sound recording was the most important difficulty encountered. However, the results of this study suggest that, once interpretable heart sounds are acquired, cardiac murmur diagnosis using convolutional neural networks yields high diagnostic accuracy.

Implications

With the widespread use of smartphones, an increasing number of health care apps have been developed. There were approximately 165,000 health-related apps available in 2016 [22]. These health care-related apps comprise a variety of aspects of medicine, including prevention, diagnosis, monitoring, treatment, compensation, and investigation [23]. However, there are concerns that many of these apps are not evidence based, and it is difficult to find any information on the research used in their development [18]. This study was a part of our effort to develop a diagnostic app that can differentiate normal and abnormal heart sounds. We sought to validate the diagnostic performance of the recording and identification system among patients in real-world clinical practice.

There have been attempts to use add-on gadgets in conjunction with smartphones for health care use, but most of these have not been accepted widely. Modern smartphones are equipped with high-quality built-in microphones that can capture low-pitch, low-amplitude heart sounds. We presumed that an app working solely with the featured specifications would have advantages with respect to accessibility and acceptability. However, this study implied that the acquisition of good-quality heart sounds is still far from perfect. A variety of factors were suggested to affect the heart sound recording. First, background noise is difficult to reduce systematically and, thus, should be avoided during recordings. It was necessary to record on the skin of the chest wall, and the choice of the appropriate location

was essential. Second, respiration was not as important as expected. The frequency spectrum of lung sounds (100-2500 Hz) is usually distant from that of heart sounds (20-100 Hz) [24]. Thus, lung sounds were easily attenuated by applying a simple band-pass filter. Third, patient factors, such as age, body mass index, and the presence of arrhythmia, were also crucial. Fourth, our system failed to recognize heart sounds with diastolic murmur, although the sample size was small.

The use of machine learning in clinical medicine is rapidly increasing, with a marked increase in the amount of available data [25]. The interpretation of digitized images and development of prediction models are the leading applications of machine learning in the field of medicine [26,27]. This study suggests that the interpretation of audio signals derived from humans may be a potential application of artificial intelligence.

Comparison With Prior Work

To our knowledge, this study is the first attempt to discriminate heart sounds using a deep learning–based diagnostic algorithm. We showed that the diagnostic algorithm was feasible and reproducible. We found only 1 app for cardiac auscultation that enables heart sound recording, which is called the iStethoscope [28]. It amplifies and filters heart sounds in real time for better quality, but it is not capable of diagnosing heart murmurs. AliveCor Kardia, a device approved by the US Food and Drug Administration, enables ECG monitoring and, according to 1 clinical trial, significantly improves the detection of incident atrial fibrillation [29]. Azimpour et al performed an elegant study in which they used an electronic stethoscope to detect stenosis of coronary arteries [30]. Although the study idea was interesting, it may be difficult to use in commonly available smartphones due to the deep location of the coronary arteries and the low amplitude of the acoustic signals. There are several apps that enable heart rate monitoring. Some require specialized devices, and others simply use built-in smartphone cameras and flashes, also known as photoplethysmography. However, their accuracy and clinical application still require further investigation [31,32].

Limitations

This study had several limitations. First, the sample size was too small to represent a variety of cardiac murmurs. Second, the enrollment of study participants was selective rather than consecutive; thus, there is a possibility of a selection bias of participants with clear and unambiguous heart sounds. Third, we used the app developed for this study only to record heart sounds. In this pilot study, the audio files were moved to a central server and subsequently analyzed. Therefore, the app needs to be improved such that it can be used in the real world, such as an all-in-one system from acquisition to diagnosis. Fourth, we obtained the heart sounds ourselves, although we ultimately seek to develop an app that can be used by members of the general population.

Fifth, this study showed variations in performance with different devices, which seem to be caused by the differing specifications of each smartphone. This is one of the major hurdles in the development of an app that can be used in a variety of smartphones from different manufacturers. Our pilot testing indicated that the quality of recorded heart sounds depended on the quality of the built-in microphones. For this reason, we included 3 high-end smartphones for this study. System performance may be worse with inexpensive devices. In addition, we tested only devices running the Android operating system in this study, but not the Apple iPhone, which is one of the most widely used smartphones worldwide.

Future Research Steps

The app described in this study requires further development. An all-in-one system is crucial, comprising recording, audio processing, and a diagnostic algorithm. Instructions that help users record their heart sound by themselves are also needed. We are improving the ability of the app to acquire interpretable heart sounds and to diagnose atrial fibrillation. Another potential application is the use of a diagnostic algorithm with commercialized electronic stethoscopes performed by medical personnel [33]. This may improve the quality of clinical practice by assisting early-career doctors or nurses to assess patients.

Conclusions

The concept of cardiac auscultation using smartphones is feasible. Indeed, diagnosis using convolutional neural networks yielded a high diagnostic accuracy. However, use of the built-in microphones alone was limited in terms of reproducible acquisition of interpretable heart sounds.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Standards for Reporting of Diagnostic Accuracy Studies study checklist and study diagram.

[PDF File (Adobe PDF File), 963KB - mhealth_v6i2e49_app1.pdf]

Multimedia Appendix 2

Audio file 1 (normal heart sound).

[WAV File, 573KB - mhealth_v6i2e49_app2.wav]

Multimedia Appendix 3

Audio file 2 (aortic stenosis).

[WAV File, 672KB - mhealth_v6i2e49_app3.wav]

Multimedia Appendix 4

Audio file 3 (mitral regurgitation).

[WAV File, 704KB - mhealth_v6i2e49_app4.wav]

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Abbreviations

ECG: electrocardiogram
FN: false negative
FP: false positive
S4: fourth heart sound
TN: true negative
TP: true positive

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Original Paper

Mobile Diabetes Intervention Study of Patient Engagement and Impact on Blood Glucose: Mixed Methods Analysis

Charlene Connolly Quinn[1], RN, PhD; Erin C Butler[2], MD; Krystal K Swasey[1], MPH; Michelle D Shardell[3], PhD; Michael D Terrin[1], MPH, MD; Erik A Barr[1], MS; Ann L Gruber-Baldini[1], PhD

[1]Department of Epidemiology and Public Health, University of Maryland School of Medicine, Baltimore, MD, United States

[2]Department of Emergency Medicine, Wellspan York Hospital, York, PA, United States

[3]National Institute on Aging, Baltimore, MD, United States

Corresponding Author:
Charlene Connolly Quinn, RN, PhD
Department of Epidemiology and Public Health
University of Maryland School of Medicine
Howard Hall Suite 200
660 W Redwood Street
Baltimore, MD,
United States
Phone: 1 410 706 2406
Fax: 1 410 706 4433
Email: cquinn@som.umaryland.edu

Abstract

Background: Successful treatment of diabetes includes patient self-management behaviors to prevent or delay complications and comorbid diseases. On the basis of findings from large clinical trials and professional guidelines, diabetes education programs and health providers prescribe daily regimens of glucose monitoring, healthy eating, stress management, medication adherence, and physical activity. Consistent, long-term commitment to regimens is challenging. Mobile health is increasingly being used to assist patients with lifestyle changes and self-management behaviors between provider visits. The effectiveness of mobile health to improve diabetes outcomes depends on patient engagement with a technology, content, or interactions with providers.

Objectives: In the current analysis, we aimed to identify patient engagement themes in diabetes messaging with diabetes providers and determine if differences in engagement in the Mobile Diabetes Intervention Study (MDIS) influenced changes in glycated hemoglobin A_{1c} (HbA_{1c}) over a 1-year treatment period (1.9% absolute decrease in the parent study).

Methods: In the primary MDIS study, 163 patients were enrolled into 1 of 3 mobile intervention groups or a usual care control group based on their physician cluster randomization assignment. The control group received care from their physicians as usual. Participants in each intervention group had access to a patient portal where they could record monitoring values for blood glucose, blood pressure, medication changes, or other self-management information while also assigned to varying levels of physician access to patient data. Intervention participants could choose to send and receive messages to assigned certified diabetes educators with questions or updates through the secure Web portal. For this secondary analysis, patient engagement was measured using qualitative methods to identify self-care themes in 4109 patient messages. Mixed methods were used to determine the impact of patient engagement on change in HbA_{1c} over 1 year.

Results: Self-care behavior themes that received the highest engagement for participants were glucose monitoring (75/107, 70.1%), medication management (71/107, 66.4%), and reducing risks (71/107, 66.4%). The average number of messages sent per patient were highest for glucose monitoring (9.2, SD 14.0) and healthy eating (6.9, SD 13.2). Compared to sending no messages, sending any messages about glucose monitoring (P=.03) or medication (P=.01) led to a decrease in HbA_{1c} of 0.62 and 0.72 percentage points, respectively. Sending any messages about healthy eating, glucose monitoring, or medication combined led to a decrease in HbA_{1c} of 0.54 percentage points compared to not sending messages in these themes (P=.045).

Conclusions: The findings from this study help validate the efficacy of the mobile diabetes intervention. The next step is to determine differences between patients who engage in mobile interventions and those who do not engage and identify methods to enhance patient engagement.

Trial Registration: ClinicalTrials.gov: NCT01107015; https://clinicaltrials.gov/ct2/show/NCT01107015 (Archived by WebCite at http://www.webcitation.org/6wh4ekP4R)

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KEYWORDS

mobile health; diabetes; engagement; randomized clinical trial; qualitative; digital health

Introduction

Type 2 diabetes is a growing national health concern affecting an estimated 10% of the US population [1]. It is a costly disease that requires an intricate self-management regimen including regular self-glucose monitoring, healthy eating, exercise, regular physician examinations, and specialist visits. Many patients, however, miss recommended screenings and lack diabetes self-management education (DSME) leading to higher rates of poor glycemic management and associated complications [2-7].

Several studies have previously documented the efficacy of lifestyle modifications and drug therapy to prevent and treat type 2 diabetes, with many finding that lifestyle modifications are more effective at long-term prevention compared to metformin therapy [5,8-10]. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) study suggested that intensive drug therapy could increase risk of adverse events and death, although mechanisms of the adverse events remain unknown [11-13].

One approach to facilitate self-management and lifestyle changes is behavior intervention technology, which uses technology and mobile health to target specific short- and long-term treatment and management goals [14]. There have been numerous phone-, text-, and Web-based intervention studies in recent years that demonstrate mixed impact when compared to traditional phone call or face-to-face intervention strategies. One personal digital assistant–based intervention found some improvement in glycated hemoglobin A_{1c} (HbA_{1c}) management during a 9-month study, and another found improvement with an intervention based on regularly scheduled telephone calls depending on patient risk level [15,16]. Although some short message service interventions have been shown to help prevent and manage diabetes [17,18], other studies have found that strictly phone-based applications have minimal impact on glycemic management compared to traditional intervention methods [19]. Furthermore, many studies on Web-based interventions, including components for tracking blood glucose readings, medications, diet, exercise, and weight loss through an online portal system, had varying degrees of success at helping participants lose weight and improve glycemic management [20-24].

A promising future direction of mobile diabetes management may be an integrated system that uses multiple means of access via Web portals or mobile apps and provides people with feedback based on their tracking data [7,21,25-27]. A particularly effective component of many recent studies is patient interaction with certified diabetes educators (CDEs) via phone, email, or other messaging systems. Regardless of medium, patient engagement and the ability to communicate with a diabetes educator helped improve outcomes across a variety of mobile health interventions [23,28-32]. Yet, less than 20% of currently available diabetes management applications have a motivational feedback component to them [32]. These cost-effective, easy-to-implement measures could help patients avoid expensive hospitalizations and diabetes complications by allowing them to manage their diabetes at home. Feedback components may also increase the efficiency for primary care physicians who manage patients with diabetes most often [29].

The messaging component of studies such as the DiabetesCoach intervention [31] show that patients are responsive to both automated and personalized messages, and an individualized, personal message option is effective at helping reach a given treatment outcome. However, further research into the impact of patient engagement and best practices to engage patients is needed before standards of care can be amended [32]. In this study, we identified patient engagement messages and assessed patient engagement in the Mobile Diabetes Intervention Study (MDIS) to determine if differences in engagement were related to changes in HbA_{1c}.

Methods

Study Design and Eligibility

A detailed description of the Mobile Diabetes Intervention Study was published previously [33]. The study was a cluster-randomized clinical trial including 26 primary care physician groups across 4 geographic areas of Maryland. Randomization took place at the practice level to avoid contamination among physicians regarding care of their patients.

Eligible patients followed physician randomization assignment. Inclusion criteria for patients included diagnosis of type 2 diabetes at least 6 months prior to enrollment in the study, HbA_{1c} ≥7.5%, and age 18 to 64 years. Patients who were uninsured or Medicare or Medicaid beneficiaries were not included. Baseline data was collected from all participants, including demographic information, health history, current health status (including HbA_{1c}) and medications, risk factors for complications associated with poor diabetes management, and lifestyle and self-management behaviors.

The MDIS enrolled 163 patients across 3 intervention groups and 1 control group. The control group received care from their physicians as usual. Participants in each intervention group had access to a patient portal where they could record self-care behavior while also assigned to varying levels of physician access to patient data. In the most complex intervention group, physicians could review raw patient data, see analyzed patient data reports every 3 months, and make treatment recommendations based on these summaries. All patients

received their choice of 1 of 2 smartphones with an unlimited 1-year data plan as well as a OneTouch Ultra 2 (LifeScan Inc) glucose meter and enough testing supplies for the duration of the 1-year study.

For this secondary analysis of the MDIS, group 1 data was not evaluated because control patients were not able to message their providers.

Patient Engagement

In addition to tracking information related to self-management of their diabetes, the secure patient portal allowed participants to communicate with CDEs throughout the study. When patients input data into the system, the computer would automatically generate feedback messages with encouragement or advice based on recently recorded data. For example, if a participant input a low blood glucose value, the system would provide a feedback message such as "This blood sugar is low! Eat 15 grams of carbs and recheck in 15 minutes." Additionally, the data would be reviewed by the patient's assigned CDE who could provide feedback intermittently. Most patients used the portal messaging system to communicate with educators over the course of the study, seeking advice, feedback, and answers to questions; however, using the messaging feature was not required for patients, and there was no set schedule of communication as part of the study intervention. The portal contained a variety of diabetes education materials including information on healthy eating, counting carbohydrates, being active, self-monitoring blood glucose, medications, and coping with and adjusting to living with diabetes.

Patients covered a wide variety of content in their messages to the CDEs from asking questions about healthy eating to changing medications to optimizing their medication schedule. To investigate the association of patient engagement with improved patient outcomes observed in previous studies [23,28-32], we evaluated patient engagement in our study through a qualitative analysis of messages sent through the secure patient portal.

For this analysis, we used the grounded theory approach [34] to analyze patient messages. As its name suggests, the theory is grounded in the observation of qualitative data and is used (for the purpose of this study) to categorize the data into core concepts. Based on review of a few sample patients, we created a coding scheme based on the 7 self-care behaviors for healthy living recommended by the American Association of Diabetes Educators (AADE) and the American Diabetes Association (ADA) [35,36]. After a pilot coding of 2 complete patient files, additional codes to account for patient-reported motivation and learning as well as general discussion about diet, medication, or self-monitoring of blood glucose were added (27 codes). Patient messages were then coded by EB and CQ (team members) based on the 27 codes developed for this project, with the appropriate codes assigned to each patient message, allowing for multiple codes assigned to a single message depending on content. Each team member independently coded the same message narrative line by line in Atlas.ti (ATLAS.ti Scientific Software Development GmbH), a qualitative data management program. Messages were coded individually without accounting for message threads on a single subject.

Study Oversight

The Institutional Review Board of the University of Maryland, Baltimore approved this study. A data and safety monitoring board was designated to review the study procedures and adverse events. After enrollment was closed, errors in consent were found and all participants, both physicians and patients, were asked to sign consent forms again as recommended by the Institutional Review Board. All patients in the final analysis were reconsented.

Statistics

The frequency of message themes was computed based on coding to categorize messages using Atlas.ti. Baseline characteristics are expressed as mean and standard deviation for continuous variables comparing users versus nonusers with 2-sample *t* tests or frequencies and proportions for categorical variables comparing users with nonusers with chi-square tests. A mixed methods approach was used to determine the effect of patient engagement on HbA_{1c}. Using qualitative analysis data, regression models were developed to determine the predicted change in HbA_{1c} for a patient based on the number and theme of messages sent over the 1-year study period. SAS 9.2 (SAS Institute Inc) was used to perform all statistical analyses. A $P<.05$ was considered statistically significant.

Results

There were 107 patients in this secondary analysis of MDIS. Among intervention participants, 76.6% (82/107) messaged at any time during the year (users), and 25 participants never messaged during the intervention year (nonusers). Males and females were equally represented. Although not statistically significant, participants who messaged (users) had more education, lower baseline HbA_{1c}, and lower body mass indexes (BMIs) than nonusers (Table 1). Users were significantly older (53.5 [SD 7.5] years vs 49.6 [SD 8.9] years, $P=.03$) and more likely to be white (62.2% versus 37.8%, $P=.02$) compared to nonusers.

Table 2 shows the 7 self-care behaviors for healthy living with diabetes as recommended by the AADE plus 2 additional messaging domains. Patients sent messages in an average of 4.3 behavior themes throughout the study. Among all participants, 76.6% (82/107) sent messages in at least 1 behavior theme, and each patient sent an average of 38.4 messages over the 1-year treatment period. Patient engagement was highest for glucose monitoring (75/107, 70.1%), medication (71/107, 66.4%), and reducing risks (71/107, 66.4%) themes and lowest for being active (44/107, 41.1%) and healthy coping (63/107, 58.9%). On average, most messages sent per patient were related to glucose monitoring (9.2, SD 14.0) and healthy eating (6.9, SD 13.2), while patients sent few messages about being active (2.2, SD 5.2) or healthy coping (4.4, SD 8.1).

Table 1. Baseline characteristics.

Baseline characteristics	Users (n=82)	Nonusers (n=25)	*P* value
Glycated hemoglobin A_{1c}, n (%)			.78
7.5 to 8.9%	42 (51.2)	12 (48.0)	
≥9.0%	40 (48.8)	13 (52.0)	
Age, years, mean (SD)	53.5 (7.5)	49.6 (8.9)	.03
Sex			.28
Male	43 (52.4)	10 (40.0)	
Female	39 (47.6)	15 (60.0)	
Race			.02
Nonwhite	31 (37.8)	16 (64.0)	
White (non-Hispanic)	51 (62.2)	9 (36.0)	
Duration of diabetes, years, mean (SD)	7.8 (5.4)	7.6 (4.9)	
Education, n (%)			.36
High school or less	24 (29.3)	11 (44.0)	
Some college or associates	34 (41.5)	9 (36.0)	
Bachelor's degree or higher	24 (29.3)	5 (20.0)	
Body mass index (kg/m^2), mean (SD)	35.7 (7.2)	36.8 (9.9)	.61
Normal or underweight (16.5 to 24.9 kg/m^2), n (%)	2 (2.4)	2 (8.0)	
Pre-obese (25 to 29.9 kg/m^2), n (%)	18 (22.0)	5 (20.0)	
Obese class 1 (30 to 34.9 kg/m^2), n (%)	20 (24.4)	5 (20.0)	
Obese class 2 (35 to 39.9 kg/m^2), n (%)	20 (24.4)	5 (20.0)	
Obese class 3 (≥40 kg/m^2), n (%)	22 (26.8)	8 (32.0)	

Table 2. Mobile communication messages by patient diabetes behaviors over 1-year treatment period.

Messaging domain	Number	Any messages sent		Messages per patient[a]
		% of total	% of users	Mean (SD)
Domains				
Healthy eating	67	62.6	81.7	6.9 (13.2)
Being active	44	41.1	53.7	2.2 (5.2)
Monitoring	75	70.1	91.5	9.2 (14.0)
Medication	71	66.4	86.6	6.1 (9.3)
Problem solving	70	65.4	85.4	5.0 (8.2)
Healthy coping	63	58.9	76.8	4.4 (8.1)
Reducing risks	71	66.4	86.6	4.5 (6.4)
Any of above behaviors	82	76.6	100.0	38.4 (60.6)
Healthy eating, monitoring, medications	60	56.1	73.2	13.9 (20.7)

[a]Mean messages per patient is calculated for all patients in group, both those that did send messages in this theme and those that did not send messages in this theme.

Table 3. Effect of domain messaging on hemoglobin A_{1c}.

Message domain	Sent no messages by domain	Sent messages by domain	*P* value
Healthy eating, n	40	67	
Baseline, mean (SD)	9.8 (2.1)	9.4 (1.9)	
12-month, mean (SD)	8.2 (1.7)	7.6 (1.3)	
Change, mean (SD)	–1.6 (2.2)	–1.7 (1.7)	.10
Being active, n	63	44	
Baseline, mean (SD)	9.7 (2.0)	9.4 (2.0)	
12-month, mean (SD)	7.9 (1.6)	7.7 (1.4)	
Change, mean (SD)	–1.7 (1.9)	–1.7 (1.8)	.60
Monitoring, n	32	75	
Baseline, mean (SD)	9.8 (2.2)	9.5 (1.9)	
12-month, mean (SD)	8.3 (1.7)	7.6 (1.4)	
Change, mean (SD)	–1.4 (2.2)	–1.8 (1.7)	.03
Medication, n	36	71	
Baseline, mean (SD)	9.8 (2.1)	9.5 (1.9)	
12-month, mean (SD)	8.4 (1.6)	7.6 (1.3)	
Change, mean (SD)	–1.4 (2.1)	–1.9 (1.7)	.01
Problem solving, n	37	70	
Baseline, mean (SD)	10.1 (2.2)	9.3 (1.9)	
12-month, mean (SD)	8.3 (1.6)	7.6 (1.4)	
Change, mean (SD)	–1.7 (2.3)	–1.7 (1.6)	.12
Healthy coping, n	44	63	
Baseline, mean (SD)	9.8 (2.1)	9.4 (1.9)	
12-month, mean (SD)	8.1 (1.6)	7.6 (1.4)	
Change, mean (SD)	–1.6 (2.1)	–1.7 (1.7)	.21
Reducing risks, n	36	71	
Baseline, mean (SD)	9.9 (2.2)	9.4 (1.9)	
12-month, mean (SD)	8.2 (1.7)	7.6 (1.4)	
Change, mean (SD)	–1.6 (2.2)	–1.7 (1.7)	.12
Message on any behavior, n	25	82	
Baseline, mean (SD)	9.8 (2.3)	9.5 (1.9)	
12-month, mean (SD)	8.5 (1.8)	7.6 (1.3)	
Change, mean (SD)	–1.2 (2.2)	–1.8 (1.7)	.02

Participants who sent messages about glucose monitoring (*P*=.03) or medication (*P*=.01) decreased their HbA_{1c} significantly more than those who did not send messages related to those themes (Table 3). Individual theme regression models in Table 4 show that sending any messages lowered HbA_{1c} 0.75 percentage points (95% CI 0.13 to 1.36, *P*=.02) compared to sending no messages. Likewise, sending any messages about glucose monitoring was associated with a decrease in HbA_{1c} of 0.62 percentage points (95% CI 0.05 to 1.19, *P*=.03) and sending any messages about medication was associated with a decrease in HbA_{1c} of 0.72 percentage points (95% CI 0.17 to 1.26, *P*=.01). Based on the top 3 significant themes presented in Table 4, the composite of healthy eating, glucose monitoring, and medication was also tested to determine its combined predictive power. Sending any messages about healthy eating, glucose monitoring, or medication combined significantly decreased HbA_{1c} by 0.54 percentage points (95% CI 0.01 to 1.08, *P*=.02) compared to messages not including these themes (not shown in table).

Table 4. Effect of domain messaging (both count and dichotomous) on hemoglobin A_{1c}.

Message domain	Message count (continuous)			Any message sent (dichotomous)		
	Estimate[a]	95% CI	*P* value	Estimate[a]	95% CI	*P* value
Healthy eating	–0.005	–0.025 to 0.015	.62	–0.469	–1.020 to 0.083	.10
Being active	–0.017	–0.067 to 0.033	.50	–0.146	–0.692 to 0.399	.60
Monitoring	–0.010	–0.029 to 0.010	.32	–0.624	–1.193 to –0.054	.03
Medication	–0.015	–0.043 to 0.013	.30	–0.717	–1.264 to –0.171	.01
Problem solving	–0.014	–0.047 to 0.019	.40	–0.452	–1.018 to 0.115	.12
Healthy coping	–0.020	–0.053 to 0.014	.25	–0.344	–0.886 to 0.198	.21
Reducing risks	–0.025	–0.070 to 0.019	.26	–0.445	–1.010 to 0.120	.12
Any message	–0.002	–0.007 to 0.002	.35	–0.748	–1.363 to –0.132	.02

[a]Point estimates are per message.

Discussion

Principal Findings

Among adults with type 2 diabetes, engagement in the portal messaging system of the MDIS was associated with an absolute decrease in HbA_{1c} of 0.75 percentage points. A 0.5 to 1.0 percentage point change in HbA_{1c} is considered clinically significant to reduce risk of comorbid conditions [37,38]; the US Food and Drug Administration requires a 0.4 percentage point change in HbA_{1c} for drug evaluations [39]. Although any sending of messages was related to a reduction in HbA_{1c}, glucose monitoring and medication use themes were also associated with decreases in HbA_{1c}. Patients sent the most messages on glucose monitoring, medication use, and reducing complication risks themes. The average number of messages sent per patient was highest for glucose monitoring, medication use, and healthy eating themes.

Self-Care Behaviors and Hemoglobin A1c

The AADE and the ADA provide patients, researchers, and clinicians with current self-care and lifestyle behavior guidelines for the management of diabetes and the prevention of its complications [35,36]. These guidelines, developed from the findings of the UK Prospective Diabetes Study [40], supply individuals with type 2 diabetes the knowledge needed to better understand their disease. Physicians in this study were given current ADA patient care guidelines but were not explicitly told to use them to care for study patients. Our findings support other studies that have shown the benefits of lifestyle interventions on diabetes outcomes [41-45]. In particular, digital health interventions targeting behavior change have shown lower HbA_{1c} levels, lower random [43] and postprandial [44] plasma glucose levels, and lower body weight [43] as well as improved self-efficacy [45].

Among the behavior themes measured, most messages contained either monitoring, healthy eating, or medication themes. Since messages sent regarding the medication and glucose monitoring themes also significantly decreased HbA_{1c}, patients may need more education surrounding medication use and monitoring blood glucose to ensure HbA_{1c} goals can be achieved effectively on their own.

Patient Engagement

Previous studies that assessed patient engagement in telemedicine and digital health interventions showed that race, age, and health literacy all play significant roles in patient participation [46-48]. Racial minorities, older patients, and patients with low health literacy showed the least engagement in telemedicine and digital health interventions [46,48]. In a 3-month mobile health intervention involving adults with type 2 diabetes, Nelson and colleagues [47] found that those who were younger or were diagnosed with type 2 diabetes closer to the start of the intervention displayed higher engagement activities and had more favorable experiences than older individuals or those with a longer diabetes duration. Our results are consistent with others, showing that nonwhite patients were less likely to send messages to assigned CDEs. Likewise, among participants who did not use the messaging portal, most had a high school education or less, perhaps also indicating a lower health literacy rate. However, unlike previous studies, we observed that users of the messaging portal tended to be older than nonusers. This suggests that older age does not imply disengagement from mobile health technology [49-51]. In fact, in a study evaluating the self-efficacy and use of a mobile health diabetes intervention among older adults, we previously concluded that participants experienced high self-efficacy in making changes to manage their diabetes and demonstrated their ability to use the intervention and communicate with educators [52]. We recommend including older adults and nonwhite individuals in mobile technology development with specific aims to evaluate improving patient engagement.

Other studies concluded that patients' high engagement in digital health interventions was related to feedback received from physicians or assigned caregivers. From this feedback, patients felt more motivated and were able to attain higher self-efficacy [53,54]. Patients in this study who elected to send messages regarding any self-care behavior reported significant decreases in HbA_{1c}. Although the influence of CDE messages on patients' outcomes was not examined, knowing a diabetes educator was

available may have improved patient confidence and encouraged them to participate.

Mixed-Methods Approach to Analysis

We believe that patient engagement in an intervention cannot be determined simply by a quantitative value but must also include qualitative data that demonstrates the effectiveness of the intervention from the participants' perspectives. To accurately interpret the extensive data collected from digital health studies, it is important to include a qualitative component [55], as information on individual experience influences the effectiveness of the intervention. We used a mixed-methods approach to evaluate patient engagement data for participants in MDIS. We identified coding themes reflecting patient messages sent to CDEs and analyzed these themes against changes in patient HbA_{1c} values. Results of this study reinforce findings from previous mobile health investigations that use a mixed-methods approach to examine data, collecting self-care behavior and self-efficacy data to measure outcomes [47,56,57]. These studies add valuable knowledge about the usability of digital health applications for the management of diabetes and reveal areas lacking in development that, if revised, could enhance patient user experience and improve diabetes outcomes. This secondary analysis of the MDIS affirms that it is not enough to simply give patients information about diabetes; patients must also be given actionable items that drive behavior change.

Strengths, Limitations, and Future Directions

The secondary data analysis is, to our knowledge, the first of its kind. Few previous studies have used a mixed-methods approach to evaluate patient engagement. While prior interventions included a patient messaging component [48] or analysis of self-management behaviors [58], none performed a qualitative evaluation of patient messages that was then used to create models predicting the impact on patient clinical outcomes. Furthermore, previous studies show that although participants preferred to use mobile health applications for diabetes management, currently available apps do not offer functions that would allow proper disease monitoring and management [59,60]. Results of this analysis may help pinpoint behavioral features that could improve existing mobile health technologies and satisfy the lack in functionality.

There are a few limitations of this secondary analysis. One is that although the models give a statistically significant prediction of change in HbA_{1c} based on certain message themes, it cannot be definitively stated that this is a direct result of solely the message content. It is important to consider the other aspects of the intervention, such as tracking data, accessing the learning library, or receiving directed care from their primary care physicians as also potentially influencing the patient's outcome. Also, engagement was not randomized, so there is potential for confounding.

It is also important to note that based on the structure of the program, some patients engaged in external email and phone messages with the CDEs that are not in the portal message records; without knowing the content of these messages, it is impossible to get a complete picture of patient engagement over the year of the study. Furthermore, the role that messages from the diabetes educators play in patient outcome is unknown. While a future analysis may explore the impact of CDEs on patient outcomes, this analysis cannot account for the influence of the content of those messages on patient engagement or overall patient outcomes.

Since each message was analyzed and coded individually, we did not account for message threads. A conversation spanning several messages could have been counted each time the patient mentions the subject when really it is all part of the same conversation on the subject. Our analysis of dichotomies may be based on more tenable assumptions than the analysis per message.

Conclusion

In this study, messages sent in the combined healthy eating, monitoring, and medication themes or monitoring and medication themes separately significantly improved HbA_{1c} over the study period. Our results provide insight into the importance of health provider feedback and essential self-care behaviors that require greater emphasis when developing mobile health technologies for diabetes populations.

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Authors' Contributions

CCQ was principal investigator for these studies. CCQ, EB, KKS, MDS, MLT, and ALG-B were responsible for the design, data analyses, writing, and review of the manuscript. EB and CQ were responsible for the qualitative message data coding. EAB was responsible for the data analyses and manuscript review. KKS contributed to the writing and review of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AADE: American Association of Diabetes Educators
ACCORD: Action to Control Cardiovascular Risk in Diabetes
ADA: American Diabetes Association
BMI: body mass index
CDE: certified diabetes educator

DSME: diabetes self-management education
HbA1c: glycated hemoglobin A1c
MDIS: Mobile Diabetes Intervention Study

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Original Paper

Exploring the Influence of a Smartphone App (Young with Diabetes) on Young People's Self-Management: Qualitative Study

Gitte Reventlov Husted[1], RN, MScN, PhD; Janne Weis[2], RN, MScN, PhD; Grete Teilmann[1], MD, PhD; Pernille Castensøe-Seidenfaden[1], MD, PhD

[1]Pediatric and Adolescent Department, Nordsjællands Hospital, University of Copenhagen, Hillerød, Denmark

[2]Department of Neonatology, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark

Corresponding Author:
Pernille Castensøe-Seidenfaden, MD, PhD
Pediatric and Adolescent Department
Nordsjællands Hospital
University of Copenhagen
Dyrehavevej 29, 1511
Hillerød, 3400
Denmark
Phone: 45 48294650
Fax: 45 48293034
Email: pernille.castensoee-seidenfaden@regionh.dk

Abstract

Background: Adequate self-management is the cornerstone of preventing type 1 diabetes mellitus (T1DM) complications. However, T1DM self-management is challenging for young people, who often struggle during the transition from childhood to adulthood. The mobile health (mHealth) app Young with Diabetes (YWD) was developed in collaboration with young people to enhance their T1DM self-management during this transition.

Objective: The purpose of this study was to explore the influence of YWD on young people's self-management during a 12-month period.

Methods: A qualitative explorative approach was used, comprising a purposive sample of 20 young people (11 females and 9 males, ages 15 to 23 years, with app use of 3 to 64 days) from 3 pediatric and 3 adult departments. Participants were interviewed individually using a semistructured interview guide. Data were collected from January to March 2017 and analyzed using thematic analysis.

Results: A total of 5 themes were identified: (1) not feeling alone anymore ("we are in this together"); (2) gaining competence by sharing experiences and practical knowledge ("they know what they are talking about"); (3) feeling safer ("it's just a click away"); (4) breaking the ice by starting to share thoughts and feelings and asking for help ("it is an outstretched hand"); and (5) lack of motivating factors ("done with the app"). Young people reported that YWD promoted self-management by peer-to-peer social support, exchanging messages with health care providers, and sharing YWD with parents. Participants recommended YWD as a supplement to self-management for newly diagnosed young people with T1DM and suggested improvements in app content and functionality.

Conclusions: The mHealth app YWD has the potential to support self-management. In particular, peer-to-peer support reduced feelings of loneliness and helped young people to gain knowledge and skills for managing T1DM. A need exists for alternative ways to train health care providers in using YWD and to support collaboration between young people and their parents to further improve young people's self-management of T1DM.

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KEYWORDS

mHealth; diabetes mellitus, type 1; youth; self-management; qualitative research

Introduction

Background

Type 1 diabetes mellitus (T1DM) is a demanding disease for young people, who struggle to learn to self-manage their condition during the transition from childhood to adulthood [1,2]. As young people gradually become more independent, they are expected to take on responsibility for T1DM management that includes administering daily insulin, measuring blood sugars, and counting carbohydrates to meet the recommended glycemic control target [3]. However, new lifestyles and physical, cognitive, and social changes challenge daily T1DM self-management routines [4]. This often results in impaired glycemic control [5,6], increased risk of acute complications [7], and early onset of long-term complications [8,9]. In addition, young people with T1DM often skip clinical visits, endangering their current and future health [5]. Flexible engagement and continuity with health care providers and ongoing support from parents are still needed [10,11]. However, current routine care [5,6] does not seem to meet young people's need for T1DM self-management support [12-14].

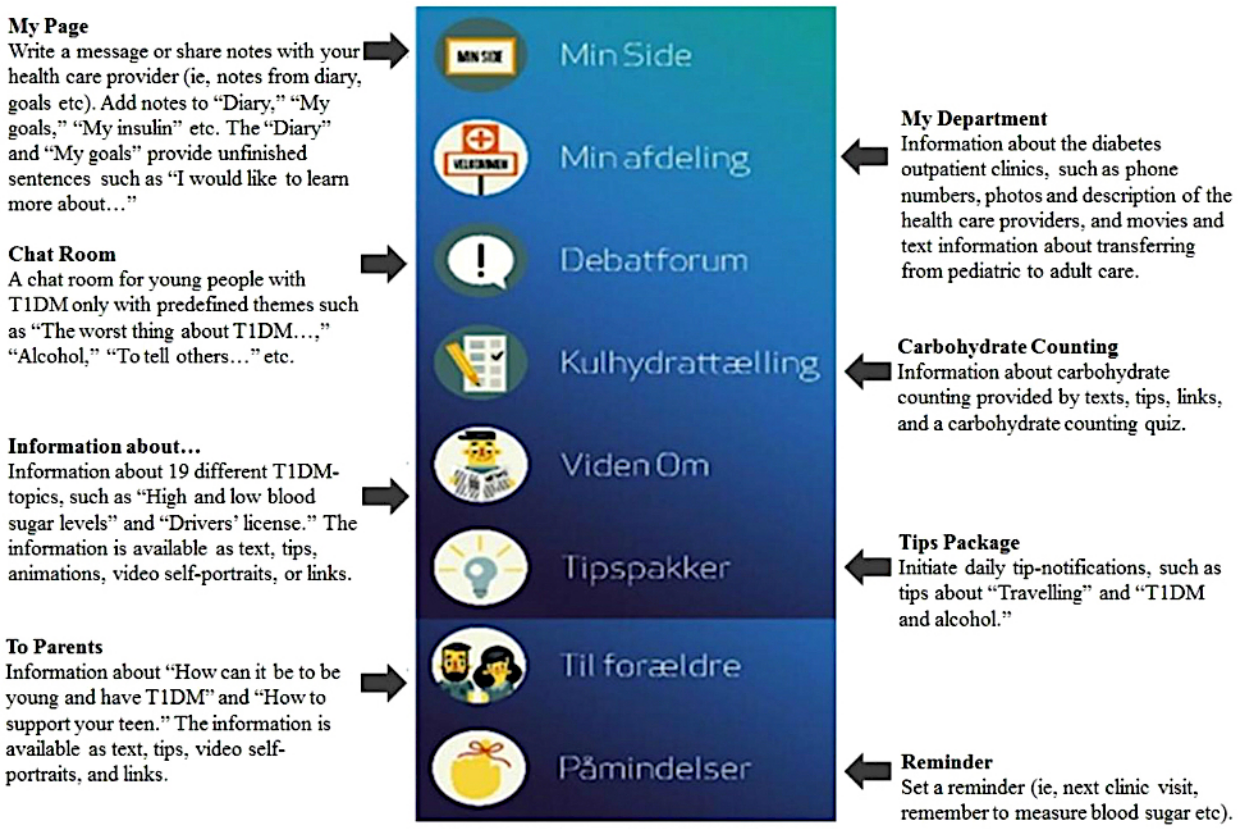
Mobile health (mHealth) apps seem to be suitable tools for engaging young people in self-management by providing information and optimizing interaction with health care providers and parents [15-19]. However, most mHealth studies to date have been conducted among adults. A review of mHealth apps identified 2 apps only that support T1DM self-management among adolescents [20]. Cafazzo et al showed an improvement in the frequency of blood glucose monitoring when testing an app to facilitate feedback on automated blood glucose readings [21], whereas Frøisland et al demonstrated an increased understanding of applied knowledge when testing the combination of a picture-based diabetes diary and a text messaging service [22]. Finally, a recent study by Holtz and colleagues reported that a patient-centered mHealth app for adolescents with T1DM and their parents seemed to enhance their collaboration [18]. In conclusion, the use of apps appears to have the potential to improve current patterns of providing self-management support [19]; however, there is a lack of evaluation studies focusing on the effect of mHealth apps on young people's management of their long-term conditions.

Young With Diabetes App

The Young with Diabetes (YWD) mHealth app was developed in a mixed-methods design based on a participatory and iterative approach [23] in collaboration with young people with T1DM, parents, health care providers, a team of health researchers, and information technology (IT) consultants. The goal of YWD was to provide a supplemental tool to support young people in developing T1DM self-management knowledge and skills during the transition from childhood to adulthood.

YWD is based on a family-centered approach [24] as recommended by transition guidelines [3,25,26] to improve self-management [1], defined as "an active, daily and flexible process in which youths and their parents share responsibility and decision-making for achieving disease control, health, and well-being through a range of illness-related activities" (p 92) [27]. Acquiring self-management in living with T1DM is a gradual process.

Figure 1. The eight main functions of the Young with Diabetes app. T1DM: type 1 diabetes mellitus.



YWD comprises 8 main functions (Figure 1): (1) My Page enables users to contact their health care provider and write notes, (2) My Department contains information about diabetes outpatient clinics, (3) Chat Room offers peer-to-peer interaction, (4) Carbohydrate Counting, (5) Information about T1DM, (6) Tips Package provides daily T1DM tips, (7) To Parents provides information for parents on how to support their teen, and (8) Reminder. Further details are provided elsewhere [23]. The YWD content did not change during the test period.

Young people, their parents, and health care providers received the same version of YWD, except the Chat Room that was only available for young people. Anonymity in the Chat Room was encouraged with the use of nicknames.

The aim of this study was to explore YWD's influence on young people's self-management during a 12-month period.

Methods

Design and Participants

A qualitative exploratory interview study was embedded in a 12-month randomized controlled trial (RCT) testing the effect of YWD on young people's self-management skills. A purposive sample [28] of young people with T1DM who had completed the RCT study in the intervention group was recruited from January to the end of March 2017. They were invited to participate by the last author at the final data collection visit.

Young people and their parents were randomized to the intervention group (YWD, n=76) or control group (n=75), and participants in the YWD group downloaded the app on their mobile phone or tablet. PC-S provided an initial 10 min introduction of the app to the participant in person or by telephone. Participants were encouraged to use YWD between clinical visits and in collaboration with parents and health care providers. No prompts or reminders triggered app use. All young people had a mobile phone.

Health care providers were encouraged to use the app in the outpatient clinic. YWD-trained diabetes team members, including physicians, nurses, and dieticians (n=39) with at least 1 year of diabetes outpatient clinic experience, provided the YWD intervention as part of usual practice. Monthly face-to-face sessions were offered to refresh the use of YWD, and a telephone hotline was available in case of technical issues.

Data Collection

Individual interviews were conducted between January and March 2017 from 1 to 3 weeks after the RCT was completed. The interviews were conducted by GRH (an experienced female researcher who did not know the participants). GRH interviewed participants independently of their parents in their homes (n=19) or at school (n=1), using a semistructured interview guide (Multimedia Appendix 1) that included exploring individual reasons for variations in outcomes. The interview guide was inspired by an empowerment approach as defined by Anderson and Funnell [29]. The process of empowerment is defined as: "...the discovery and development of one's inborn capacity to be responsible for one's own life. People are empowered when they have enough knowledge to make rational decisions, control, resources to implement their decisions and experience to evaluate the effectiveness of their actions" (p 11) [29]. Interviews lasted for 35-60 min and were digitally recorded, transcribed verbatim, and checked for accuracy [30] by the first author. Transcripts were uploaded to NVivo software (QSR International version 11, QSR International Pty Ltd, Doncaster Victoria, Australia) to organize data and support the analysis.

Outcomes measures for the RCT included posttrial hemoglobin A_{1c} (HbA_{1c}) levels (primary outcome) and scores on 3 psychometric scales (secondary outcome): Perceived Competence in Diabetes (PCD) [31], Health Care Climate Questionnaire (HCCQ) [31], and Problem Areas in Diabetes (PAID-20) [32]. These scores, along with baseline characteristics, were used to characterize interview participants.

The study was approved by the Danish Data Protection Agency (no. 04015 NOH-2015-031) and performed in accordance with the ethical recommendations of the Helsinki Declaration. Ethical approval of interview studies by Research Ethics Committee is not necessary in Denmark (no. 15000468). An information leaflet to participants stated that data would be treated confidentially and anonymously and that they could withdraw from the study without consequences for their treatment and care at the outpatient clinic. Written consent was obtained from all participants and from parents if participants were younger than 18 years. After each interview, GRH spent some time with participants to make sure they felt comfortable having shared their experiences with app use.

Data Analysis

Data were analyzed using a 6-phase thematic analysis provided by Braun and Clarke [33]: (1) familiarization with the data, (2) generating initial codes, (3) interpreting and sorting codes into themes, (4) reviewing themes for coherent patterns, (5) defining and naming the themes, and (6) producing the report [33]. GRH analyzed all interviews, generating initial codes and potential themes before discussing them with coauthors.

Subsequently, GRH and JW refined the categorization of codes into potential themes. Initially, this was an inductive process, followed by applying a more deductive approach during steps 3 and 4 to explore whether the app content and functions met young people's needs [1,5]. Throughout all phases, constant checking of data extracts, codes, and themes against each other and the entire dataset was performed.

Credibility was addressed by researcher triangulation throughout the analysis, with GRH, PC-S, and GT having experience with T1DM and GRH, JW, and PC-S having experience with qualitative research. Feedback from the researchers was discussed at meetings until consensus was reached. Bias was diminished by having a coresearcher, who had not participated in the development of the app, to handle the analysis. Transferability was ensured by offering thick descriptions, dependability by providing quotes from informants, and confirmability by thoroughly describing the processes of sampling, data collection, and analysis [34].

Results

In total, 22 young people were invited to participate; 2 (1 female) declined due to exams or illness. The final sample comprised 20 young people (11 females and 9 males; age range, 15-23 years). They differed in app use and in the primary and secondary outcome measures (Tables 1 and 2).

Although young people still found daily self-care tasks difficult, YWD was experienced as a valuable tool to support T1DM self-care:

> *You damn need to do something [to self-manage T1DM]...but it [YWD] has helped me to do some of the daily work.* [20-year-old female, ID17]

This was identified through 5 themes: (1) not feeling alone anymore ("we are in this together"); (2) gaining competence by sharing experiences and practical knowledge ("they know what they are talking about"); (3) feeling safer ("it's just a click away"); (4) breaking the ice by starting to share thoughts and feelings and asking for help ("it is an outstretched hand"); and (5) lack of motivating factors ("done with the app"). In the following section, the findings are detailed.

Theme 1: Not Feeling Alone Living With T1DM Anymore—"We Are in This Together"

The Chat Room proved to be the most important function of YWD. Finding peers who faced the same challenges in T1DM self-management was enlightening for all interview participants; they felt that:

> *...we are in this together.* [20-year-old female, ID1]

Feelings of loneliness were relieved when young people became aware that their struggles were familiar issues among their peers. The possibility of contact with peers made their current challenges and worries easier to bear, as did knowing that they were not alone in having these burdens. Some participants had never met other young people living with T1DM, as illustrated here by a male:

> *I have gained a slightly better understanding, because before I had the app it was a little difficult to realize how others my age felt because there is no one at my school...that has diabetes...I think it is good to know that I am not the only one that has these problems or thinks about the same things, like the future with diabetes and all that.* [18-year-old male, ID15]

Table 1. Participant characteristics (n=20).

Characteristic	Value
Gender, n (%)	
Female	11 (55)
Age in years, mean (SD, range)	
At baseline	18 (2.60, 14-22)
At diagnosis with diabetes	9 (3.95, 2-16)
Diabetes duration at baseline in years, mean (SD, range)	9 (4.62, 3-18)
Insulin regimen, n (%)	
Multiple daily injections of insulin	11 (55)
Pump	9 (45)
Parental involvement, n (%)	
Participant lives with both parents	9 (45)
Divorced	10 (50)
At least 1 participating parent	13 (65)[a]
Pediatric site, n (%)	
Pediatric and Adolescent Department, Nordsjællands Hospital, Hillerød	4 (20)
Pediatric and Adolescent Department, Herlev	5 (25)
Pediatric Department, Roskilde	1 (5)
Adult site, n (%)	
Department of Cardiology, Nephrology and Endocrinology, Nordsjællands Hospital, Hillerød	2 (10)
Steno Diabetes Center	6 (30)
Department of Endocrinology, Køge	2 (10)
Transfer to adult care, n (%)	2 (10)
Active app days, mean (SD, range)	19 (15.87, 3-64)

[a]Mother (n=8), father (n=1), both mother and father (n=4).

Table 2. Participant scores at baseline and at the end of the 12-month trial (n=20).

Outcome measures	Range of possible scores	Baseline, mean (SD)	12 months, mean (SD)
HbA_{1c}[a]	-	83 (20)	82 (19)
PCD[b]	5-35	27 (8)	28 (7)
PAID[c]	0-100	27 (21)	28 (19)
HCCQ[d]	5-35	28 (7)	29 (6)

[a]HbA_{1c}: hemoglobin A_{1c}, mmol/mol; assesses blood sugar control.

[b]PCD: Perceived Competence in Diabetes; assesses patients' experience of feeling able to successfully manage diabetes; higher scores represent greater perceived competence.

[c]PAID: Problem Areas in Diabetes; assesses diabetes-related distress; higher scores indicate greater emotional distress, and a score ≥30 indicates elevated distress.

[d]HCCQ: Health Care Climate Questionnaire; assesses the degree to which patients perceived their health care providers as supporting their autonomy; higher scores indicate a high level of perceived support for autonomy.

The possibility of participating in chats or simply observing chat comments helped young people acknowledge that it was not always easy to self-manage T1DM. They realized that peers were familiar with their concerns, frustrations, and challenges, which helped reduce feelings of loneliness, as expressed by a female:

> *[I]t is good to know that you are not the only one with it...of course you have the support from your family and your friends, who say that you will get through it...but hearing it from someone who also has it and knows what you are going through and...to have others you can talk to, that is very, very nice.* [18-year-old female, ID14]

Feeling like everyone else and "being normal" (16-year-old female, ID9) occurred when young people were in the Chat Room. By reflecting on their peers' ways of living, young people experienced normalization of T1DM into everyday life. This contrasted with the feeling of being different that often arose when spending time with friends without T1DM:

> *[O]ften you feel that you are walking around in your own little world, because you are surrounded by people that don't have diabetes.* [18-year-old female, ID14]

The Chat Room provided a safe, closed space where a spirit of companionship arose even though the young people did not know each other. A female described the experience:

> *[O]ften when you are at school, you are reminded that you have diabetes...But when you are in that diabetes chat room, then you are among others, and it is like the diabetes things are something that you have in common with the others.* [18-year-old female, ID14]

Theme 2: Gaining Competence by Sharing Experiences and Practical Knowledge—"They Know What They Are Talking About"

Young people shared T1DM experiences in the Chat Room, which helped them gain new knowledge and skills for managing their disease . They became aware of the difference between advice and information they received at outpatient clinic visits and the insights and real-life knowledge they received in the Chat Room:

> *...they know what they are talking about.* [22-year-old male, ID3]

They experienced health care providers as being unable to provide the person-specific information they sought. On the contrary, health care providers often discussed T1DM in general ways, for example, by looking at blood sugar curves trying to figure out the cause of fluctuations. The young people found that sharing experiences with peers provided valuable and reliable person-specific information, such as how to manage hypoglycemia or deal with challenges when traveling. This knowledge improved their self-management competencies, as described by a male:

> *[O]ne way is that a physician tells you how to do it, another thing is when the ones that have [T1DM], tell what they do to make their blood sugar levels drop or what they do when they travel, so that has helped me quite a lot.* [18-year-old male, ID15]

Young people became confident about trying out new ways of handling T1DM. They exchanged tips and tricks, such as precautions for driving, how to regulate blood sugar in relation to sports, and how to use the different functions of the insulin pump around meals to avoid fluctuating blood sugars.

> *There are people who have solutions to problems that you might not be able to find yourself.* [16-year-old male, ID13]

Easy access to the Chat Room provided young people with opportunities to immediately change self-care practices. As a female described:

> *There was one person who wrote that she used the basal [rate] in the pump...and I didn't know that you could turn up the basal, then she wrote how to do it...that has helped me a lot, now it [the blood sugar level] doesn't fluctuate as much.* [19-year-old female, ID6]

Young people gained practical knowledge that supported their participation in social life, such as going out with friends, while still feeling confident about taking care of their T1DM.

Exchanging experiences in the Chat Room provided them with real-life scenarios of risky situations, such as drinking alcohol. They did not receive this type of information from their health care providers. From their peers, they received concrete instructions about how to act and cope, as described by a female:

> *...it has also helped me a lot with what to do if things go wrong when I drink and am at a party...* [18-year-old female, ID14]

Most young people had not used the Information about...section, often because they felt they knew everything about T1DM after having been diagnosed years previously:

> *Maybe sometimes it is just the words, "Information About," where I think I don't need to read that.* [20-year-old female, ID17]

Therefore, they did not consider the informational part of the app as an option for obtaining advice about how to self-manage different situations in real-life contexts. However, they were convinced that the information function of YWD would be very useful for young people newly diagnosed with T1DM. As a male put it:

> *...The category "Information About" would be real smart for new diabetics who don't have any idea as to how the different things affect your body.* [17-year-old male, ID18]

Theme 3: Feeling Safer Having the App—"It's Just a Click Away"

Young people felt safer living with T1DM knowing that all the information they needed about their disease was available in YWD. This gave them a sense of freedom and peace:

> *It has been a relief for me that all my diabetes things are gathered in one location.* [18-year-old female, ID14]

Before using the app, they had often had difficulty maintaining an overall perspective on their T1DM while taking care of school, work, and youth life. Ready access to information and knowledge made self-management easier:

> *It's just a click away.* [20-year-old female, ID5]

For instance, some young people used links in the app to figure out how to count carbohydrates, some gained new perspectives by watching video self-portraits, and some reached out to peers or health care providers . YWD functioned as a kind of "back up" (16-year-old male, ID13) in almost all aspects of life with T1DM from minor concerns to acute issues. Young people viewed the app as a lifeline and felt safe just having it, as described by a female:

> *...then it is more reassuring with the app...let us say you have a situation, and then you can quickly...sit and look it up.* [20-year-old female, ID1]

A few young people benefited from writing personal notes in the My Page function to organize their life with T1DM. Before using the app, they had expended a great deal of energy figuring out how their blood sugar responded to activities and food intake. By making notes about their reactions during different activities and in various circumstances, they gradually developed a personal guide to rely on in similar situations. This app function provided a *parking lot* for speculation and worry, helping ease their minds. As a female explained:

> *I have gotten a better perspective on it, so I don't have so many different thoughts...and I have gotten it all gathered so I can access it directly and see, that is what I did the last time and create my own guides to what I need to do, so that has helped me a lot.* [18-year-old female, ID14]

Young people appreciated that the app's informational sections were easy to understand and focused on the most important aspects of T1DM. They had greater confidence in the information presented by YWD than in information they had previously located online. This gave them a sense of safety, as expressed by a male:

> *Information about...," that is professionals that have written that, it is not someone off some Google home page...so that makes it a lot more reassuring to have this app.* [17-year-old male, ID13]

Theme 4: Breaking the Ice by Starting to Share Thoughts and Feelings and Asking for Help—"It Is an Outstretched Hand"

For some young people, YWD became a way to break the ice with their health care providers and parents. It supported them in sharing thoughts and feelings about their challenges of living with T1DM and asking for help.

Young people found that contacting health care providers through YWD was very informal, which facilitated writing messages:

> *I communicate with my nurse in a completely different way—I can be much more honest.* [20-year-old female, ID17]

Young people primarily wrote about practical things such as scheduling appointments or new prescriptions. They emphasized that health care providers did not introduce YWD during outpatient clinic visits or only referred to it superficially, such as by asking whether they had used the app. Young people had the impression that the app was not meant for collaboration. However, YWD made a profound difference in the few instances in which young people used it in collaboration with health care providers. For example, they used it to ask for help to lose weight or help to manage an eating disorder, topics that had not been discussed during clinic visits. A female described it this way:

> *I have had difficulties with my eating disorder, and that has not been something I have told my practitioners, so the app gave me an opportunity...to write them, because it was hard for me to say, either over the phone or face-to-face.* [23-year-old female, ID10]

Other young people used the "Unfinished sentences" in the My Page function as a way to break the ice and address unspoken difficulties in living with T1DM. They felt that doing so made it possible to talk openly about their thoughts and feelings:

> *The thing that I am worst at, regarding my diabetes...*" *that is a very accurate sentence, because it is like taboo.* [20-year-old female, ID17]

By sharing their thoughts and feelings with health care providers, young people suddenly experienced more continuity in those relationships. This promoted sharing successes and failures and receiving ongoing support, which not had been possible before.

It motivated young people to improve their self-management because health care providers immediately responded to their actions. A female explained it this way:

> *The thing about how many blood sugar levels I have measured in so and so many days, that I would never have told her, but she sees the progress and tells me about it and praises me for it and that would not have happened without the app.* [20-year-old female, ID17]

YWD also became a way for young people to break the ice and start to share thoughts and feelings about the challenges of living with T1DM with their parents and to ask for help when needed. Some young people and their parents looked at the video self-portraits or at posts in the Chat Room, competed in the Carbohydrate Counting Quiz, or looked at the information sections separately or together. They then began to talk about topics that previously had been difficult to discuss openly, as in the example of a male who had talked about sex with his father for the first time while looking at the app together:

> *[M]e and my dad, we talked about the issue of having sex with diabetes...that is probably not something I would have thought about normally—if there is a difference there...so because of the app we actually talked about some stuff.* [17-year-old male, ID18]

Young people described their parents as gaining a deeper and more nuanced perspective on the difficulties they faced in trying to self-manage T1DM. This changed the way parents and young people interacted about their self-management. Young people described their parents as seeming more eager to provide appropriate autonomy support, rather than admonishing or comforting them. As a girl describes:

> *We talk about it in a different way, because they are informed about it, and they have asked... "Have you had it like that...?" and I have said "I think, like all the others, that it is a shitty thing to have" ...then they have said: "If there is something we can do [as opposed to everything will be all right], we would like to help." They somehow better understand how it works in our minds...how we feel about our diabetes.* [18-year-old female, ID14]

Young people felt that their parents started to show greater confidence in them, and they had the impression that their parents suddenly took their situation and frustrations more seriously. In some cases, this led to changes in their parents' point of view, including relaxing rules as they became more confident that the young person could handle, for instance, alcohol. A boy stated the following:

> *Here in the beginning of last year, my parents wouldn't allow me to drink, and now I have just gotten permission since we looked at the app together, there was a chat concerning alcohol and that has helped us a lot.* [15-year-old male, ID20]

Theme 5: Lack of Motivating Factors—"Done With the App"

Despite the fact that young people appreciated YWD, some also expressed being "done with the app" after the first few months because no new information, quizzes, or video self-portraits were added during the trial. A male said:

> *It would be nice if it [YWD] was updated...it's like Wikipedia, when you have read it, then you have read it, new knowledge won't suddenly appear.* [17-year-old male, ID18]

Moreover, they noticed decreased activity in the Chat Room, which reduced their motivation for keeping the app. A male described the lack of motivating factors:

> *There aren't enough who write, so it is kind of like...it is hard to see where the app is supposed to take us, when there aren't enough who use it to answer and write.* [22-year-old male, ID3]

However, young people wanted to keep YWD, except for 3 male participants, aged 20 to 22 years, who no longer wanted it due to the static content. All participants had many suggestions for improvements to content and functionality to ensure more activity and make YWD more useful (Table 3).

Table 3. Suggestions for improving Young with Diabetes content and functionality. T1DM: type 1 diabetes mellitus.

Main function	Suggestions for improvements
My Page	Share the notes, diary, and messages with parents
	Visualize blood glucose readings in a graph and compare the readings with recommendations
	Set a blood glucose level goal and receive motivating feedback notifications
	Access your medical record, such as information about treatment and hemoglobin A_{1c}
My Department	Automatic information from the hospital database about your health care provider, department, and phone number
Chat Room	Add a parent chat room
	Add closed chat rooms
	Add invitations to events
	Create your own chat themes and change the order of the predefined themes
	Include the opportunity to chat with a diabetes physician
	Create a profile similar to Instagram
Carbohydrate Counting	Include specific amount of carbohydrates
Information about T1DM	Continuously updated information, such as the newest research in T1DM
	Detailed information about treatment options, such as photos of devices
	Include quizzes on T1DM topics with varying levels. Upload new quizzes regularly
	Add an introduction to the video self-portraits and place the video self-portraits in front with a more obvious play button
	Improve the overview and shortcuts to the most frequently used T1DM apps
To Parents	Include information about what it is like to be a parent of a young person with T1DM
Other suggestions	Quick introduction to Young with Diabetes by a short animation describing content and functionality
	Customization, such as choosing the background, the start page, and placing the favorite sections in front
	Improve the intuitive interface by adding more visual icons and small information boxes
	Reduce scrolling of long text sections and reduce the number of “clicks.” Add shortcut options
	Add a narrator button to read the text for people with reading difficulties
	Fingerprint login

Discussion

Principal Findings

This qualitative study provides insight into the mHealth app YWD as a motivating factor and a supplemental tool to self-manage T1DM. In particular, young people experienced interactions in the Chat Room, exchanging messages with health care providers, and looking at the YWD with parents as useful features. Our findings show the importance of helping young people communicate with like-minded peers to share feelings, practical knowledge, and experiences. In addition, the findings indicate that YWD is a promising supportive tool to change communication patterns between young people and health care providers during and between outpatient clinic visits and between young people and their parents. Finally, YWD could be a tool for health care providers to address sensitive topics in outpatient clinic visits. However, improvements are also needed to maintain young people’s motivation for self-management.

Comparison With Prior Studies

The Chat Room was found to be the most important part of the app, providing an online community for young people struggling with the same feelings, thoughts, and practical issues related to T1DM self-management. Young people felt they received support for self-managing specific diabetes situations and experienced diminished feelings of loneliness. Previous research has identified this kind of interaction as diabetes-specific social support [35], which is associated with reduced loneliness in living with T1DM [36]. Social support organized by health care providers as a kind of peer-to-peer support [37] has proven effective in preventing loneliness [38]. However, the literature on diabetes-specific peer support addresses a wide range of peer interactions and interventions [39,40], and the evidence is insufficient to determine the types of peer interactions, elements, and interventions most applicable to young people with T1DM [39]. YWD seems to have the potential to reduce loneliness, as compared with traditional outpatient clinical visits. Our findings emphasize that young people need help to connect with peers to share their experiences in a way that they cannot with parents, health care providers, and other social networks, as identified by Mayer et al [41].

In addition, untreated loneliness is known to contribute to diabetes distress [36,42]. Diabetes distress is high among young people emerging into adulthood [43]. In our study, young people experienced a slight increase in diabetes distress (PAID-20) scores (Table 2). The lack of effect on diabetes distress in our

study could be explained by decreasing activity in the Chat Room during the trial period. Another potential explanation is that YWD alone does not provide sufficient support for young people with T1DM. Finally, it could be a result of the researchers bringing attention to the feelings of distress, supporting participants in identifying and reporting these feelings.

It is well known that health care providers play a significant role in supporting young people's self-management [44]. However, not all health care providers feel confident using mHealth apps [45], and some may feel uncomfortable engaging with young people through technology [46,47]. This may explain why some young people perceived little interest from their health care providers in using the app collaboratively. Overall, YWD could not overcome barriers to frank discussions about sensitive topics, such as sex and alcohol, with which young people often struggle [38]. These topics should be addressed regularly in clinic visits [1]. However, the slight increase in HCCQ scores (Table 2) indicate that YWD may have the potential to complement health care providers' traditional self-management support when used as an ongoing autonomous support in collaboration with the young people. In addition, YWD was able to slightly increase young people's perceived competences in diabetes self-management identified by the PCD scores (Table 2).

Health care providers' training in how to use YWD was very brief, lasting a single hour. This may not have been sufficient to help them feel confident in using the app in collaboration with young people and their parents [23]. Adaption and adoption of new technology require serious implementation work, including developing health care providers' competence at performing new tasks and using the technology as intended [48]. Our study demonstrates that a critical need exists for guidelines on how to optimally train health care providers to use self-management apps as currently recommended [3,25,26].

Interestingly, we found that YWD use often changed interaction patterns between young people and their parents. The app created a platform for young people and parents to approach each other in a more constructive way and enable them to talk about sensitive topics by sharing video self-portraits or posts in the Chat Room or looking at the To Parents section. Parents often face challenges when trying to support their child in achieving self-management [18,49]. New ways of facilitating interactions that engage parents and young people during the transition from childhood to adulthood are needed [50,51]. YWD seems to have the potential to complement this process, but methods for encouraging collaborative use of mHealth apps by young people and their parents are needed; only 13 of 20 young people used YWD with their parents (Table 1). However, our findings suggest that combining an online space for exchanging peer support with support from health care providers and parents seems to facilitate more successful self-management, as also identified by Kowitt et al [52].

Implications

The findings highlight the importance of addressing communication about illness in any patients with long-term conditions by focusing on improving peer-to-peer support as well as supporting the digital communication with health care providers. However, there is a need to focus on health care providers' competence at using mHealth apps. Given the many available mHealth apps, it may be worthwhile to introduce a course during health education programs, such as in medical and nursing schools, focusing on how to use technology collaboratively with patients. This is supported by a recent study [53] in which medical students reported improved understanding of the involved issues and procedures and greater confidence in conducting a telehealth consultation after a course in telehealth skills [53].

In addition, YWD may be a valuable tool for people with newly diagnosed T1DM as recommended by participants in the study. The informational functions of the app may be most useful at an early stage of the disease. We intend to incorporate young people's feedback and suggestions for improvements in content and functionality (Table 3) before testing YWD in a group of participants with newly diagnosed T1DM. Because the age at diagnosis of T1DM may be different compared with participants' age in this study, further revision would be of interest to meet the needs of younger participants.

YWD may have the potential to provide a generic model for supporting young people with other chronic conditions and their parents and helping health care providers to engage with young people in ways that provide ongoing support. Despite disease-specific differences, young people with chronic conditions and their parents share many commonalities [16].

Strengths and Limitations

One of the strengths of our study is the recruitment of participants with a variety of app use, age, gender, T1DM duration, affiliation with diabetes departments, and outcome measures. We consider this population as representative of the entire study group. In addition, patient-centered methods were used to assess YWD. Furthermore, the study used a rigorous qualitative methodology (thematic analysis), as described by Braun and Clarke [33], to provide rich and detailed data, rendering the freedom of combining an inductive and a deductive analysis to identify patterns within data. A limitation is the short-term nature of the study (app use range 3-64 days) and the varying levels of health care provider collaboration. Furthermore, we did not report parents' and health care providers' perspectives on using YWD and its impact on young people's self-management. Currently, parents' and health care providers' perspectives are being explored in questionnaires and focus group interviews, respectively, to make a more informed case about the implications of YWD on all groups of users.

Conclusions

The YWD app appeared to be a motivating factor in young people's self-management of T1DM. In particular, peer-to-peer support, exchanging messages with health care providers, and looking at the YWD with parents were useful in supporting self-management. YWD changed communication patterns between young people, health care providers, and parents and provided young people with ongoing support. YWD is not effective as a stand-alone intervention, but it seems to have the

potential to help young people, parents, and health care providers optimize T1DM self-management. A need exists to refine YWD according to users' suggestions, to optimize and standardize health care providers' use of YWD, and to further investigate how the app can be used collaboratively by young people, their parents, and health care providers.

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Conflicts of Interest

YWD was developed in cooperation with the IT enterprise Mobile Fitness A/S and the project group (including GRH, GT, and PCS). The project group owns the national rights.

Multimedia Appendix 1

Interview guide.

[PDF File (Adobe PDF File), 58KB - mhealth_v6i2e43_app1.pdf]

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Abbreviations

HbA_{1c}: hemoglobin A_{1c}
HCCQ: Health Care Climate Questionnaire
IT: information technology
PAID-20: Problem Areas in Diabetes
PCD: Perceived Competence in Diabetes
mHealth: mobile health
RCT: randomized controlled trial
T1DM: type 1 diabetes mellitus
YWD: Young with Diabetes

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Original Paper

Exploring the Specific Needs of Persons with Multiple Sclerosis for mHealth Solutions for Physical Activity: Mixed-Methods Study

Guido Giunti[1,2], MD; Jan Kool[3], PhD; Octavio Rivera Romero[4], PhD; Enrique Dorronzoro Zubiete[4], PhD

[1]Salumedia Tecnologias, Seville, Spain
[2]University of Oulu, Oulu, Finland
[3]Kliniken Valens, Valens, Switzerland
[4]Universidad de Sevilla, Seville, Spain

Corresponding Author:
Guido Giunti, MD
Salumedia Tecnologias
Avda Republica Argentina nº 24
Edificio Torre de los Remedios 5ª Planta Modulo A
Seville, 41011
Spain
Phone: 34 717702622
Email: drguidogiunti@gmail.com

Abstract

Background: Multiple sclerosis (MS) is one of the world's most common neurologic disorders, with symptoms such as fatigue, cognitive problems, and issues with mobility. Evidence suggests that physical activity (PA) helps people with MS reduce fatigue and improve quality of life. The use of mobile technologies for health has grown in recent years with little involvement from relevant stakeholders. User-centered design (UCD) is a design philosophy with the goal of creating solutions specific to the needs and tasks of the intended users. UCD involves stakeholders early and often in the design process. In a preliminary study, we assessed the landscape of commercially available MS mobile health (mHealth) apps; to our knowledge, no study has explored what persons with MS and their formal care providers think of mHealth solutions for PA.

Objective: The aim of this study was to (1) explore MS-specific needs for MS mHealth solutions for PA, (2) detect perceived obstacles and facilitators for mHealth solutions from persons with MS and health care professionals, and (3) understand the motivational aspects behind adoption of mHealth solutions for MS.

Methods: A mixed-methods design study was conducted in Kliniken Valens, Switzerland, a clinic specializing in neurological rehabilitation. We explored persons with MS and health care professionals who work with them separately. The study had a qualitative part comprising focus groups and interviews, and a quantitative part with standardized tools such as satisfaction with life scale and electronic health (eHealth) literacy.

Results: A total of 12 persons with relapsing-remitting MS and 12 health care professionals from different backgrounds participated in the study. Participants were well-educated with an even distribution between genders. Themes identified during analysis were MS-related barriers and facilitators, mHealth design considerations, and general motivational aspects. The insights generated were used to create MS personas for design purposes. Desired mHealth features were as follows: (1) activity tracking, (2) incentives for completing tasks and objectives, (3) customizable goal setting, (4) optional sociability, and (5) game-like attitude among others. Potential barriers to mHealth apps adoption were as follows: (1) rough on-boarding experiences, (2) lack of clear use benefits, and (3) disruption of the health care provider-patient relationship. Potential facilitators were identified: (1) endorsements from experts, (2) playfulness, and (3) tailored to specific persons with MS needs. A total of 4 MS personas were developed to provide designers and computer scientists means to help in the creation of future mHealth solutions for MS.

Conclusions: mHealth solutions for increasing PA in persons with MS hold promise. Allowing for realistic goal setting and positive feedback, while minimizing usability burdens, seems to be critical for the adoption of such apps. Fatigue management is especially important in this population; more attention should be brought to this area.

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KEYWORDS

multiple sclerosis; telemedicine; fatigue; mobile applications; video games; qualitative research; exercise; chronic disease

Introduction

Background

Multiple sclerosis (MS) is one of the world's most common neurologic disorders. MS is an unpredictable, often disabling disease of the central nervous system that can adversely affect body functions, and it is the leading cause of nontraumatic neurologic disability in young adults in many countries [1]. The most common symptoms are overwhelming fatigue, visual disturbances, altered sensation, cognitive problems, and difficulties with mobility [2]. There are pharmacological treatments for the condition as well as other strategies to manage MS symptoms. Quality of life is often impacted in many ways, and MS symptoms often lead to embarrassment and avoidance of social situations [3]. MS has a median survival time of around 40 years from the time of diagnosis [4]; therefore, issues regarding progressive physical and cognitive disability, psychosocial adjustment, and social reintegration are likely to affect persons with MS for a long time. Living with MS often requires individuals to self-manage and to be more engaged in their care [2]. Evidence suggests that physical activity (PA) helps people with MS stay active, reduces MS symptoms such as fatigue, and improves cognitive abilities but still many individuals with MS avoid PA [5-9]. Engaging individuals in specific behaviors involves understanding what motivates them to act in a certain way. Self-determination theory (SDT) is a macro theory of human motivation that establishes three psychological needs that motivate the self to initiate behavior and include the need for competence, autonomy, and psychological relatedness [10]. The implications of living with MS for patients, caregivers, treating clinicians, and society represent an opportunity for other modalities of care.

Connected health (CH) is a new model of health management in which patients become the center of the health care system with the support of new information and communications technologies (ICTs) [11]. The delivery of health care through mobile devices is known as mobile health (mHealth) [12] and is included in CH. The use of mobile software apps for health and well-being promotion has grown in recent years [13,14]. The use of mHealth for behavioral interventions has many potential advantages because of their ubiquity, cost-effectiveness, less invasive nature to participants, ability to provide immediate feedback, and track activities [15-17]. Persons with MS may benefit from the use of mHealth solutions supporting them in the management of their condition. However, to be effective, interventions need to reach the intended audience in a way that is meaningful to them. Condition-specific mHealth interventions require in-depth understanding of the patient and condition's needs, barriers, and facilitators [18,19]. The process of tailoring refers to creating individualized communications by gathering and assessing personal data related to a given health outcome to determine the most appropriate strategy to meet patient's unique needs [20,21]. The important role that health care professionals have in the care of chronic patients is in contrast with their lack of involvement in mHealth apps development [22-27].

There are emerging trends in software development such as user-centered design (UCD) that try to address these problems, with the goal of creating solutions specific to the characteristics and tasks of the intended users [28]. Following UCD design principles generates systems that are easy to learn, have higher user acceptance and satisfaction, and lower user errors. UCD involves end users and relevant stakeholders in the different phases of software development process [28-30]. Access to mHealth end users, however, is not always easy or cost-effective; so, user representations such as personas are sometimes used. Personas are a common tool used in UCD to represent a target population and are created using information obtained through interviews, focus groups, and demographic data among others. These personas typically comprehend short descriptions that include the behavioral patterns, goals, skills, and attitudes of these user types [30]. Personas can be role-played to act as a vehicle to communicate user needs and requests to the designers and developers. Having personas helps designers focus on the users' needs in a more concrete way, so that they can center their design on them.

Research in MS so far has focused on various health-promoting behaviors rather than specifically on PA [31-35]. In our preliminary study of commercially available MS mHealth apps [27], we encountered only a handful of apps (n=25), which is in stark contrast with the reality for other conditions such as cancer (n=295 in 2013) [36], diabetes (n=137 in 2009) [37], or human immunodeficiency virus (n=124 in 2013) [38] among others. To our knowledge, no study has explored what perspectives persons with MS and their formal caregivers have with regard to using mHealth solutions for PA.

To address the gap in the literature, we conducted a mixed-methods research with the goal of understanding the potential benefits of mHealth in individuals living with MS from two perspectives: the patient side (persons with MS) and the health care provider (HP) side (those professionals who work with them).

Objectives

The aim of our study was to (1) explore MS-specific needs for MS mHealth solutions for PA, (2) detect perceived obstacles and facilitators for such mHealth solutions from persons with MS and health care professionals, and (3) understand motivational aspects that could facilitate development of mHealth solutions for MS.

Methods

Study Design

This study adopted a mixed-methods design: a qualitative part comprising focus groups and interviews, and a quantitative part comprising structured surveys and standardized tools.

Qualitative inquiries are useful to provide insight into complex and multifaceted experiences of individuals when a rich description is the main goal of the study [39]. On the patient side, focus groups and individual interview sessions were conducted to gather information on their use of ICT, health literacy, perceived obstacles and facilitators for PA and the use of mHealth solutions, and possible motivational aspects. On the HP side, focus groups' individual interview sessions were conducted to explore what in their expert opinions are barriers and facilitators that could help patients with MS adopt healthier behaviors and what elements should mHealth solutions feature to be of use for patients with MS and health care professionals.

The quantitative part consisted of demographic questionnaires, satisfaction with life scale (SWLS) assessments [40], measurements of electronic health (eHealth) literacy (eHEALS) [41], and questionnaires on technology use. These quantitative assessments were used to contextualize the results obtained from the qualitative methods.

Setting

Kliniken Valens is a center specialized in neurological rehabilitation services located in Valens, Switzerland. Kliniken Valens employs a multidisciplinary staff, including neurologists and physio-, occupational, speech, and sports therapists. In 2016, a total of 2451 patients with neurological conditions were admitted for neurological rehabilitation, of which 586 suffered from MS.

Recruitment

Persons with MS from Kliniken Valens patient database were invited to participate in the study. Inclusion criteria required that each participant should (1) be older than 18 years, (2) have been diagnosed with MS, (3) have none to moderate physical disability (Expanded Disability Status Scale [EDSS]<4.5) at the time of recruiting, and (4) ownership and usage of a mobile phone. Participants were coded as PWMS from 01 to 12, that is, *PWMS01*.

For the HP side, physicians, physio-, occupational, and sports therapists who worked at Kliniken Valens were detected. Inclusion criteria were as follows: (1) be older than 18 years (2) have been working with persons with MS for more than 2 years, and (3) be a mobile phone user. Participants were coded as HP from 01 to 12, that is, *HP01*.

To ensure that the sample was rich for analysis, purposive sampling was used. The sampling was based on several factors such as EDSS scores, age group, and ICT familiarity for persons with MS; health care profession and years of experience, among other factors, were considered for HPs. Recruitment continued until saturation of results was reached.

Ethical Approval and Informed Consent

Ethical approval for this study was obtained from the Swiss Ethics Committee on Research Involving Humans ID #2016-00529. Before agreeing to participate, all subjects were informed about the nature of the research project; the reasons for their subjectability; risks, benefits, and alternatives associated with the research; and their rights as research subjects.

Data Collection

We used a semi-structured approach led by facilitators with experience in qualitative research providing trigger questions to participants; initially, questions were more general and gradually became more specific. The facilitators were GG and JK, physician and physiotherapist, respectively, who were present in all sessions. The questions derived from relevant points in the literature and UCD techniques [42]. See Multimedia Appendix 1 for guiding questions.

As the study progressed, emerging issues were explored with subsequent participants to refine categories and themes. Focus groups and interviews were conducted in German and English; German transcripts were later translated to English. Translated transcripts were linguistically and culturally validated through back-translation techniques and evaluated by bilingual professional translators.

The eHEALS scale attempts to determine a person's combined knowledge, confidence, and perceived skills in finding, evaluating, and applying electronic health information to health problems [41]. The measure consists of 8 items scored on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Higher scores on the eHEALS indicates higher eHealth literacy (total score range: 5-40). The SWLS is intended to represent a broad, reflective appraisal of a person's life as a whole without differentiating between different domains [40]. This measure consists of 5 items scored on a 7-point Likert scale anchored by the extent of agreement with each statement. Items of the SWLS are summed to create a total score that can range from 5 to 35. Culturally and linguistically validated versions of the SWLS [43] and eHEALS [44] tools were used in this study.

Data Analysis

Focus groups and interviews were audiotaped, transcribed verbatim, and coded using the qualitative data analysis management program NVivo (QSR International, Melbourne, Australia). Data analysis was conducted by 2 reviewers independently (GG and OR). Through iterative process, recurring themes and subthemes were identified and coded. During a deductive phase, coders matched each participant's comment categorizing them as barriers or facilitators. An inductive phase came later where thematic content analysis was performed [45]. Further refinement was conducted by merging and removing redundant themes until consensus was reached.

The results of the standard structured questionnaires were analyzed according to their respective evaluation matrices.

Persona Creation

To create personas that could work as intermediate constructs in the task of designing mHealth solutions for persons with MS, we used the information and insights generated in this study. The research team revisited observation notes, interviews and focus transcripts, and survey responses to define specific characteristics of the study participants and generate profiles. The initial profiles were refined and reviewed to generate personas as seen in other studies [46,47]. Additional characteristics such as stories were incorporated for further

understanding of a user representation. Personas were then validated by HPs with experience treating persons with MS. With these personas in mind, specific strategies or tools can be created that fit the needs, goals, and tasks of these individuals.

Results

For the patient side, we conducted 3 focus groups with 10 participants in total and 2 individual interviews. For the HP side, 2 focus groups with 8 participants in total and 4 individual interviews were conducted.

Participant Characteristics

Table 1 provides a summary of participant characteristics for this study for the patient side (persons with MS). The patient side ages ranged from 35 to 62 years, with a median of 43.5 years (interquartile range [IQR] 40.25-50). Participants were well educated with an even distribution between genders. In terms of eHealth literacy, according to the eHEALS scale, the median score was 17.75 (IQR 11-28.50). The most common type of MS present was relapsing-remitting multiple sclerosis (RRMS), and the patients were being treated with immunomodulators. Participants had been living with MS for a median of 17 years (IQR 10.50-21.50), and according to the SWLS, most participants were dissatisfied with their lives (SWLS<14 [IQR 9-14]).

In Table 2, we can see characteristics of the HPs. In addition, ages of the HPs ranged from 26 to 64 years with a median of 40 years (IQR 28-53.25), and genders were equally distributed. The median of years of experience dealing with persons with MS was over 15 years (IQR 4.50-23). ICT ownership and use were very high in this group.

Ownership of ICTs was high as most individuals had laptops, desktops, and mobile phones and were frequent users of mobile phones (Figures 1 and 2).

Thematic Analysis

Certain themes were identified during analysis: MS-related barriers and facilitators, mHealth design considerations, and general motivational aspects. Subthemes were also found and are presented in this study. Each theme and subtheme are presented mainly from the perspective of patient and bringing the HPs' side to either reinforce or contrast relevant points.

A general overview of all barriers and facilitators to PA for persons with MS can be found in Textboxes 1 and 2.

Multiple Sclerosis–Related Barriers and Facilitators

To understand which, if any, specific MS barriers and facilitators there are to PA, we discussed general attitudes toward PA and how they coped with living with their condition. This produced certain subthemes:

Specific to Physical Activity

An important deterrent of PA was the diminishing sense of self-efficacy and the impact MS symptoms directly have in the enjoyment of PA. According to *PWMS02*, there are times when:

> *You don't know how much confidence to have in yourself.*
>
> *I used to do a lot of sports. 80 km of jogging a week, tennis, cross-country...Over time, it became less and less. My motivation has decreased because of MS. I still enjoy it, but not quite like I used to. Now, it feels like work.* [PWMS09]

HPs own assessments of the situation were in agreement:

> *Since everything requires exertion, the fun factor and enjoyment are missing somehow, so why [should they] do it?* [HP08]

The need for goal-setting and proper feedback was deeply emphasized in this part of the conversation. Being able to understand when progress is being achieved was considered key as the subjective experiences differed from what they actually accomplished:

> *[In general, if you want] to convince people that physical activity is the key, we need to give them targets. Having feedback to how you are doing is good. We need to know we are doing something right.* [PWMS06]
>
> *If you ask them, "how do you feel," they will always say, "I don't feel good." Interestingly, this feeling doesn't change, they may train over 3, 4, or 5 weeks and they will feel the same. However, if you look at the parameters that you normally assess, you will see that they have improved. VO_2, oxygen uptake, or maximum heart rate will have gone up. They objectively improve but subjectively still feel bad.* [HP11]
>
> *The important thing is that we have to show [them] clear goals. These goals have to be realistic, measurable, and achievable. [...] you have to work toward that step by step.* [HP10]

Persons with MS and HPs were in agreement: customizing PA to meet a patient's individual need determines the success or failure of an exercise program. Flexibility and engagement are required.

Fatigue Management

Fatigue and fatigue management issues were raised over and over again. Persons with MS reported that, as they went along their activities of daily life, they *accumulated* more and more fatigue. In this way, one participant stated that, "Fatigue ate away their life."

Participants claimed that they had to resort to "strange strategies" to be able to keep up:

> *I use one trick, I move all my appointments to the morning; so, people around me don't realize that I'm not well. I then take a break in the afternoon, and if someone wants to do something, I just say that my calendar will free up again in the evening.* [PWMS02]

Table 1. Participant characteristics: persons with multiple sclerosis.

Characteristics	Persons with MS[a] (n=12)
Gender, n (%)	
Female	6 (50)
Age (median, IQR[b])	43.5 (40.25-50)
Education[c] , n (%)	
High school	2 (17)
Higher education	6 (50)
University or college	4 (33)
Marital status, n (%)	
Single	2 (17)
Married	8 (66)
Divorced	2 (17)
Employment status, n (%)	
Not working	1 (8)
Unable to work	2 (17)
Employed	9 (75)
Type of MS, n (%)	
Relapsing-remitting MS	7 (58)
Secondary-progressive MS	3 (25)
Primary-progressive MS	2 (17)
Progressive-relapsing MS	—
Years since MS diagnosis (median, IQR)	17 (10.50-21.50)
EDSS[d] score (median, IQR)	4 (3.75-5.12)
Pharmacological treatments, n (%)	
Immunomodulators	7 (58)
Muscle relaxants	4 (33)
Antidepressants	3 (25)
Vitamin supplements	5 (42)
None	2 (17)
SWLS[e] score (median, IQR)	12 (9-14)

[a]MS: multiple sclerosis.

[b]IQR: interquartile range.

[c]Categories were simplified from the Swiss Education System.

[d]EDSS: Expanded Disability Status Scale.

[e]SWLS: satisfaction with life scale.

Table 2. Participant characteristics: health care providers.

Characteristics	Health care providers (n=12)
Gender, n (%)	
Female	6 (50)
Age (median, IQR[a])	40 (28-53.25)
Health care profession, n (%)	
Physiotherapists	6 (50)
Occupational therapists	2 (17)
Sport therapists	1 (8)
Physicians	3 (25)
Years of experience (median, IQR)	15.5 (4.50-23)

[a]IQR: interquartile range.

Figure 1. Information and communications technologies ownership.

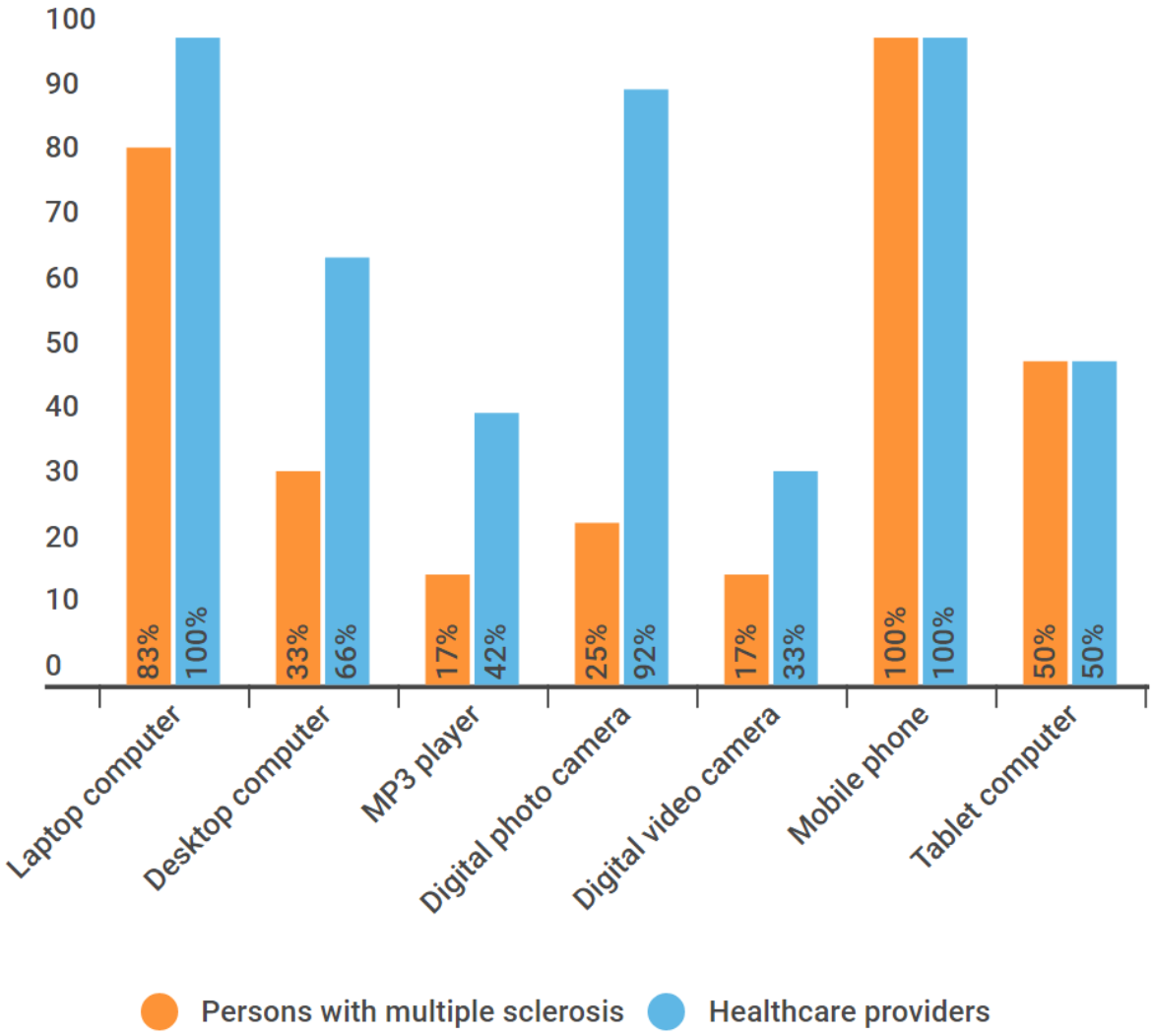
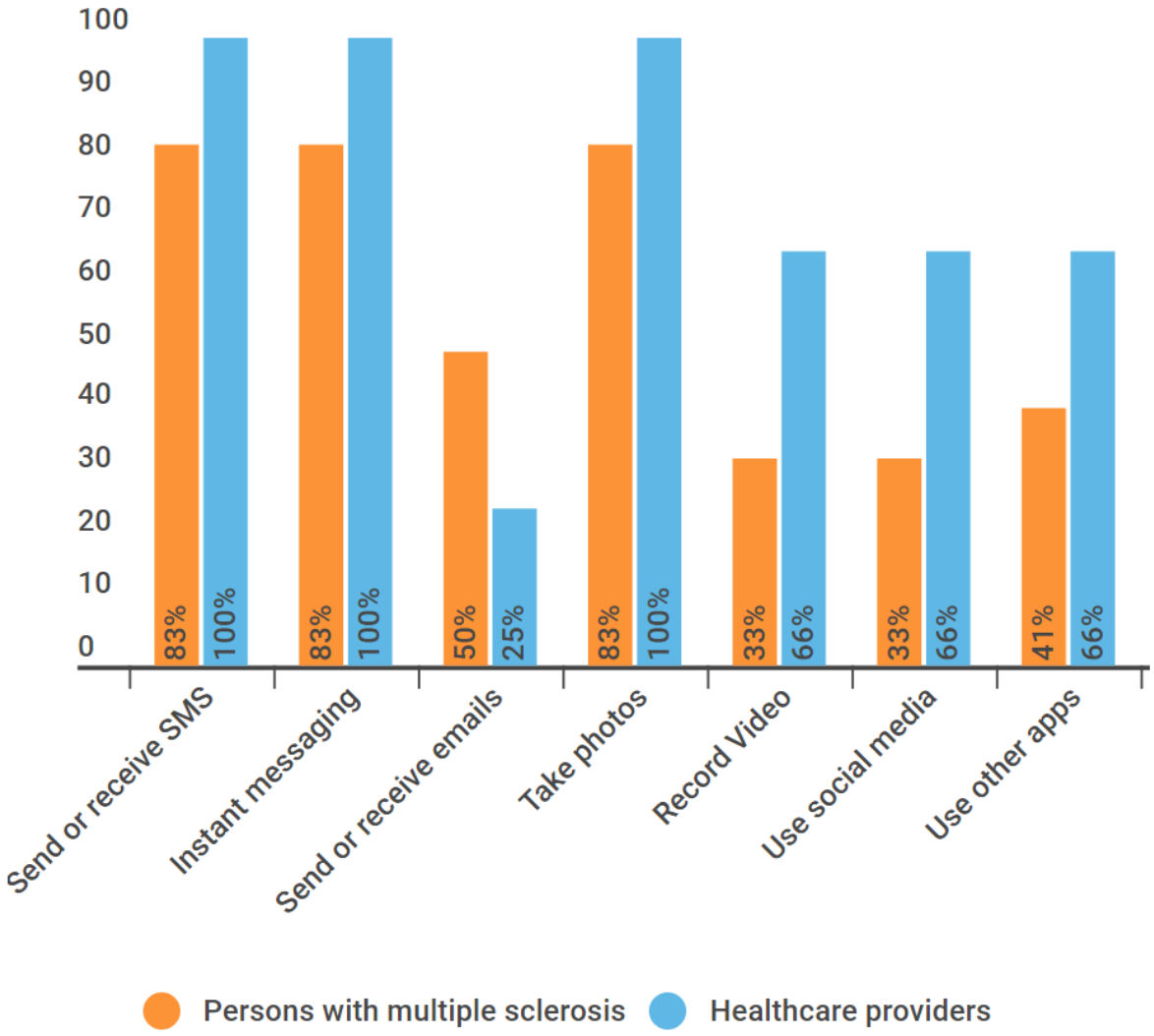


Figure 2. Mobile phone usage. SMS: short message service.



Textbox 1. Overview of barriers for physical activity in persons with multiple sclerosis.

Motivational aspects

- Social comparison with others with multiple sclerosis
- Negative feedback from their environment
- Self-motivation issues

Multiple sclerosis symptom burden

Balance problems

- Muscle weakness and fatigue
- Bladder control
- Medication side effects
- Unpredictable course

Physical activity misconceptions

- Fear of triggering a relapse
- Poor understanding of benefits
- Unrealistic expectations

Textbox 2. Overview of facilitators for physical activity in persons with multiple sclerosis.

Motivational aspects

- Social support from loved ones
- Collaboration with other persons with multiple sclerosis
- Clear goals
- Reminders from third parties

Physical activity promoters

- Reserved dedicated time for physical activity
- Personalized training routines
- Sufficient recovery time
- Noticeable benefits

HPs commented that sometimes it is helpful for persons with MS to create some sort of visual representation of the body's energy sources. *HP07* related this with patients' difficulty *determining how much energy they will need for [doing] something*. According to *HP05*, resources are limited in patients with MS; so, they have to learn how to manage them. Another HP stated:

> *If we had an app that would allow patients to manage their energy as a resource, [now] this would be a great thing.* [HP10]

When asked about what they would feel about such a "fatigue management solution," patients responded very positively:

> *That would be awesome, yes, definitively. If there would be something that would measure how much energy I have left for the day and how much I've already used so far. That would be excellent. It would be amazing.* [PWMS06]

Living With Multiple Sclerosis

MS conditioned the way persons with MS live their life; not only in that they have to consider their energy as resources that need managing but also in more subtle ways. Many persons with MS report that weather conditions and warmer temperatures worsens their symptoms; *PWMS07* stated: "Heat makes me sluggish."

Some experience bladder and bowel problems that shape how they plan their daily routine.

The progressiveness of the disease acts as a strong barrier and reduces motivation for acquiring healthier behaviors. One participant stated:

> *I don't want to change the way [I live my life] because a relapse may happen and then what [was the point of changing them]?*
>
> *MS gets in the way of doing things* [PWMS02]

HP03 suggests that this is because:

> *They don't want to grapple with the disease and just want to do things like other people of their age, […] patients often struggle with themselves and give the disease very little room [in their life].*

HP03 recommends professionals who wish to work with persons with MS to pay special attention and make an extra effort to understand the psychological distress they may experience:

> *MS isn't always easy to understand for us. MS patients are more sensitive because of the condition, one wrong word can be enough to demotivate them.*

Both sides felt that persons with MS would benefit more if they had some form of cognitive activity they could do to stimulate them and prevent further deterioration.

mHealth Design Considerations

The following were design considerations of interest to designers of mHealth solutions. They identify barriers to adapt design approaches. Although the exploration was focused on mHealth solutions, it was common for participants to use the word "app" interchangeably; this change in terminology has been kept intact when quoting participant's views. A summary of suggested mHealth solution features and characteristics that emerged from our interactions is presented in Textbox 3 in order of feature priority. An overview of barriers and facilitators can be found in Textboxes 4 and 5.

Attitudes Toward mHealth

On this topic, both sides were interested but hesitant. The main concern was regarding the value an mHealth solution could hold. ICT usage barriers were mentioned as *those who are not interested in technology would never use an app anyway*.

Textbox 3. Potential features and characteristics for multiple sclerosis mobile health (mHealth) solutions.

Customizable goal setting

- Challenges need to be tailored to the specific person with multiple sclerosis characteristics

Energy profiles and fatigue management

- Information and tools that help users in managing their day-to-day activities

Patient education

- Offer verified information that is helpful and reliable

Data visualization

- Information must be presented in a way that is meaningful to persons with multiple sclerosis

Positive feedback system

- Rewards and incentives for completing tasks and objectives

Activity tracking

- Register metrics such as steps, calorie consumption, heartbeat, and quality of sleep among others

Exercise library

- An array of different activities specific to multiple sclerosis such as fitness or relaxation techniques that can be selected

Game-like attitude

- Engaging in a playful mindset in a way that is highly pleasurable and motivating

Strong evidence base

- Features and information offered should have a solid scientific foundation

Remote monitoring

- Health care providers can follow persons with MS progress and give feedback

Optional sociability

- Ability to opt-out of social media features such as messaging, feeds, or other types of social comparisons

Reminders systems

- Notifications that reminds persons with MS to engage in activities

Personal data management

- Access to personal information and data defined by the user case by case

Textbox 4. Overview of barriers to the adoption of multiple sclerosis mobile health (mHealth) apps.

Social Factors

- Negative word of mouth from peers or health care providers
- Disruption of the health care provider-patient relationship
- Promotes competition among multiple sclerosis peers

Reliability of the solution

- Unrealistic promises
- False information
- Inaccurate measurements

User experience

- Rough on-boarding experience
- Obvious or excessive advertising
- Constant notifications or reminders

Usability

- Unattractive design
- Confusing interface
- Accessibility issues

Value proposition

- Solution does not fit the needs of users
- Unclear purpose
- Overall lack of personalization

Data ownership and access by third parties

Refusal to use information and communications technologies

When confronted with the question of whether they would use a mobile solution for MS, many were intrigued but unsure about *how an app would benefit* them:

> *The effectiveness isn't clear to me.* [PWMS01]
>
> *That's what I can't think of. What does the app give them?* [HP11]
>
> *It maybe true that we [health care professionals] are not likely to recommend or suggest technology-based solutions. I've never thought about it. Maybe because there is still no clear answer as to how apps can help. Perhaps, we feel that the personal relationship that we form with our patients is not something we can replace with technology.* [HP05]

Items that increased the intent of downloading and using mHealth solutions were knowing that experienced professionals were involved in the design and having endorsements from recognized MS institutions. A point where all HPs agreed on was that mHealth solutions for MS should be based on solid scientific information and theory. For health care professionals, it was a matter of tool validation, whereas for patients, it seemed to be more about effective word of mouth. The strongest motivators for downloading or recommending an mHealth solution were clarity in its features and promises, and solid scientific backing:

> *[I read] the description and what it offers [to me]. [I like it] if there are bullet points about what it will give me. Perhaps something like having a manual about how to use it. […] I think that's something that I look for before installing.* [PWMS06]
>
> *If an app has theoretical basis behind it and it's useful for the patient, I would feel comfortable [recommending it]. Even if it doesn't have publications [proving it works].* [HP05]

The main deterrents for installing, and most influential factors preventing HP recommendation of an mHealth solution, were the presence of false information and negative experiences from acquaintances or read on the news.

Textbox 5. Overview of facilitators to the adoption of multiple sclerosis mobile health (mHealth) apps.

Social factors

- Endorsements from experts and patient associations
- Reinforces the health care provider-patient relationship
- Allows collaboration and support amongst multiple sclerosis peers
- Integration of family and friends in the solution use and flow

Reliability of the solution

- Up-to-date information
- Friendly language
- Theory and evidence based

User experience

- Customizable features
- Variety of options
- Playfulness

Usability

- Simple to use
- Attractive design
- Consistent interface

Value proposition

- Benefits of use must be evident
- Provides incentives and motivation
- Specific to persons with multiple sclerosis needs

Data ownership and access management

Designed and developed in collaboration with health care providers

A shared view among HPs was that these solutions should not get in the way of standard care, rather they should act as additional support tools that could let professionals guide patients from the distance:

> *An app can be used to motivate people. The app can be like a kind of coach. A virtual coach that gives them a task and if they do it, they've reached a partial goal, for example, [they get some incentive]. And they know how many points they earned by the end of the month. That could be an incentive.* [HP08]

This sentiment was in line with what persons with MS were expressing, for example:

> *[an app could present something like] an obstacle course that you have to get through. [Something] that you tackle daily. The app would have to give you an alert that says you have to walk 2 km today, for example. And you have to be able to set [your own] goals. The patient should try how long he or she can walk and then perhaps increase the amount. That would maybe make people use it more. In a game, there are also tasks that you have to do. If you finish them, you get something.* [PWMS02]

This game-like attitude heavily resonated in several other patients and even some HPs:

> *For me, it's important that (the app) is playful. We all remain children deep down. It should have colors, some music and be attractive.* [HP03]

Personalization and customization was regarded highly in both groups, yet as *PWMS07* says it is important to remember that:

> *Everyone is as active as they want to be. The app is of no use if the person doesn't want to do things.*

eHealth and Health Literacy

Participants with MS held in high regard the opinion of their HPs, often consulting them for information validation or seeking advice. A common concern was not about finding information on the Web, but rather making sure that it was right for them.

> *There are a lot of types of MS and what may help one person might harm another one* [PWMS06]

HPs were reticent on directing their patients to any online sources:

> *They can find information online, so there's no need for a special app for that I think. However, you can*

> *get lost in the sea of the Internet and you may need an expert to guide you.* [HP10]

The need for reliable information regarding other symptoms was mentioned:

> *We may need information about incontinence. What to do if your bladder cramps up? Maybe knowing about pelvic exercises [would be useful].* [PWMS11]

There was a lot of uncertainty about which activities would be beneficial and not harmful to them. Because of their condition, participants with MS feared engaging in new activities as these are "untested waters." This was seen not only in terms of PA but also for nutrition:

> *I have equipment for training at home, but I don't know if I use it correctly or at the right time. I want to exercise a group of muscles but I don't know if that will hurt another group [of muscles]. What should I be eating now? I don't know what to do.* [PWMS07]

The health care community seemed to be in part to blame for these anxious feelings. MS misconceptions and outdated knowledge among professionals played a role in fostering this uncertainty:

> *I have a doctor who tells me that I have to do less, as less as possible. […] Otherwise, I might do too much and put too much strain on my body, and this could possibly trigger a relapse.* [PWMS02]

> *Many neurologists are telling patients that they shouldn't do much physical activity, or that they are not allowed to do some sports. [in the past] patients and medical reports have described a deterioration of symptoms due to PA and the main view was to not recommend training to avoid this deterioration. But now, we know that this is only a temporal setback, just for a few hours and then people recover completely. It has no lasting effect on MS symptoms; after a resting period, functions are restored to normal level. There is also no risk to induce a relapse. A recent study, published last year I think, shows that there is no correlation between physical training, even in higher intensities, and a risk of inducing a relapse, but not all of us [professionals] stay updated.* [HP05]

Privacy and Data Ownership

Participants with MS and HPs had negative perceptions of third party involvement in mHealth projects. For the patient side, the main objection was in terms of pharmaceutical or insurance companies taking advantage of their medical and personal data. They saw their participation in mHealth projects as some sort of a warning sign and expected their involvement to be explicitly clear upfront:

> *I'd like to know who's getting the data and what for. It's my personal data.* [PWMS07]

> *If everyone could see my data, I wouldn't give [the app] a chance.* [PWMS01]

The HPs were less opposed to hearing about pharmaceutical companies being involved but still were concerned. HPs wondered whether it would be possible to restrict these companies from accessing sensible data:

> *I don't want to have these [pharmaceutical] companies having access to that information. The commercial interest is dangerous in this way. I feel reluctant to give too much information […] to health insurance companies even. I think it's an aspect that needs discussion and setting up clear rules for all participants.* [HP05]

General Motivational Aspects

Using SDT as lenses, we coded participants with MS' comments and responses with regard to competence, autonomy, and relatedness.

Autonomy

Autonomy within SDT concerns a sense of volition or willingness when doing a task; events or conditions that diminish the sense of choice interfere with perceived autonomy. All participants with MS wanted to, in some degree, be able to influence their condition treatment. They wanted to be able to set their own goals or decide what activity to do at a given time. They wanted to feel that they have a choice in the matter. For example, *PWMS04* said he needs to find a way in which doing the task is his decision:

> *[I am doing it] not because I have to do it, but because I want to do it. And [only] then I can do it.*

The loss of perceived autonomy seemed to play an important role. It was often mentioned as barrier and facilitator at the same time. It presented itself as a cause for concern and depression for some and as a motivator for others:

> *I can't do everything I did before [I was diagnosed].* [PWMS03]

> *Self-motivation is very difficult. I always need something that I can't do anymore and then I want to be able to do it again.* [PWMS01]

Competence

Competence refers to the need for challenge and feelings of effectance; opportunities to acquire new skills or to receive positive feedback increase perceived competence. For participants with MS, acknowledgment of their progress and tracking was very important:

> *At first, I could only walk 6 meters and now I can do 180 meters without taking a break. That makes me happy. I feel more like doing something.* [PWMS03]

Presenting situations as challenges to overcome was highly motivating for them, but there were some caveats. *PWMS06* stated:

> *I'd rather be amongst healthy people and have the challenge to keep up with them.*

PWMS07 remarked that in his case, he needed:

> *To surpass his limits every day but that it was important to understand that you shouldn't be in competition with other persons with MS. We need to be supportive [to each other].*

Relatedness

Relatedness is experienced when a person feels connected with others, positive social interactions enhance the feeling of relatedness. The way participants seemed to discuss social interactions required a clear distinction between how they engage with others with MS and with people without MS.

Others With Multiple Sclerosis

The relationship participants with MS have with others with MS is complex. Interacting with those who share their condition had a very strong negative impact as evidenced by comments such as:

> *I don't want to speak to everyone who has the same disease. That doesn't help me. If you get to talk with someone who shares the same values and goals, that's good. But if you wear glasses, you don't want to speak with everyone just because they wear glasses too.* [PWMS01]

> *It's very depressing. It doesn't really help me [seeing others with MS], let's put it this way. People with MS tell me "Oh, you can still do this, I can't anymore" or "Oh, I can't sleep because everything hurts." They tell me that they are always exhausted and are always tired. It just drains me [to hear them]. It takes away all my energy.* [PWMS06]

> *I always saw other patients and heard many bad stories. I feel that having a negative or positive attitude is what determines things. I once received a request for a forum where you sit in a circle and talk with other MS patients. I don't need such a self-help group.* [PWMS08]

This particular aspect was very much so present for the HPs as they noticed that:

> *There are patients who tell us that they don't want to see other patients with MS [with more advanced MS than them] because they don't want to see their future.* [HP12]

However, spending time with other people with MS was not always a negative thing. Going through the same experience provides a common ground that they share:

> *I'm in a regional [MS] group. We go on excursions or meet for coffee. Then, we talk about everything but the disease.* [PWMS05]

> *I don't stress when I'm with them [persons with MS], [I don't think] about the weakness in my legs or [the way I look with] my walking. I know that they experience the same problems that I do or worse; so, it takes some of the stress out because I don't feel like I'm being watched.* [PWMS06]

> *It's important to distinguish how you're connected. I don't want to compete [with other persons with MS].* [PWMS07]

> *It's important to do things in a group. It's much better than being alone. The motivation is stronger that way.* [PWMS09]

People Without Multiple Sclerosis

Having a social circle of family and friends who provide support was a determining factor for motivating persons with MS to take better care of themselves. This was present in all interviews and participants. HPs had a slightly different take on this, as family members' expectations can have their downsides:

> *If the partner is healthy, they [persons with MS] often put themselves under too much pressure [to perform].* [HP08]

The way strangers look at them had a big effect on participants with MS, to the point that some of them try not to move just to limit what can be seen and criticized:

> *If I'm not having a good day, I won't leave the house. I'd know early on in the morning. [I know that] I'll have balance problems…I've been told a few times by strangers that "I should drink less." If I'm really having a bad [symptoms] day and someone comes and says something like that, it gets to me.* [PWMS10]

However, friends and family remind them that:

> *We're not alone with our MS. There are people thinking about what they can do to help us.* [PWMS08]

Persona Creation

The information collected from the questionnaires, structured surveys, focus group, and individual interviews was reviewed and used to devise case profiles. We identified specific characteristics of our participants, such as age, level of PA, ICT usage, and general motivations, and used clustering to create 4 MS persona types: (1) high ICT, medium PA; (2) medium ICT, high PA; (3) medium ICT, medium PA; and (4) low ICT, low PA.

Personas created represent potential persons with MS and highlight their individual barriers and facilitators to mHealth adoption:

- Demographic information from our participants was used to generate socioeconomic traits.
- Medical information from the participants was summarized and grouped to create medical profiles.
- eHEALS scores were converted to persona traits that represented the eHealth and health literacy levels.
- SWLS and interviews helped define personality traits such as a life perspectives or sociability.
- Data from the focus groups and interviews helped create the different stories.

Figure 3 shows an example of our MS personas. See Table 3 for a synopsis of all MS personas; full versions can be found in Multimedia Appendix 2.

Table 3 presents a summarized version of the MS personas; for the full version, please see Multimedia Appendix 2.

Figure 3. Multiple sclerosis persona with high information and communications technologies and medium physical activity.

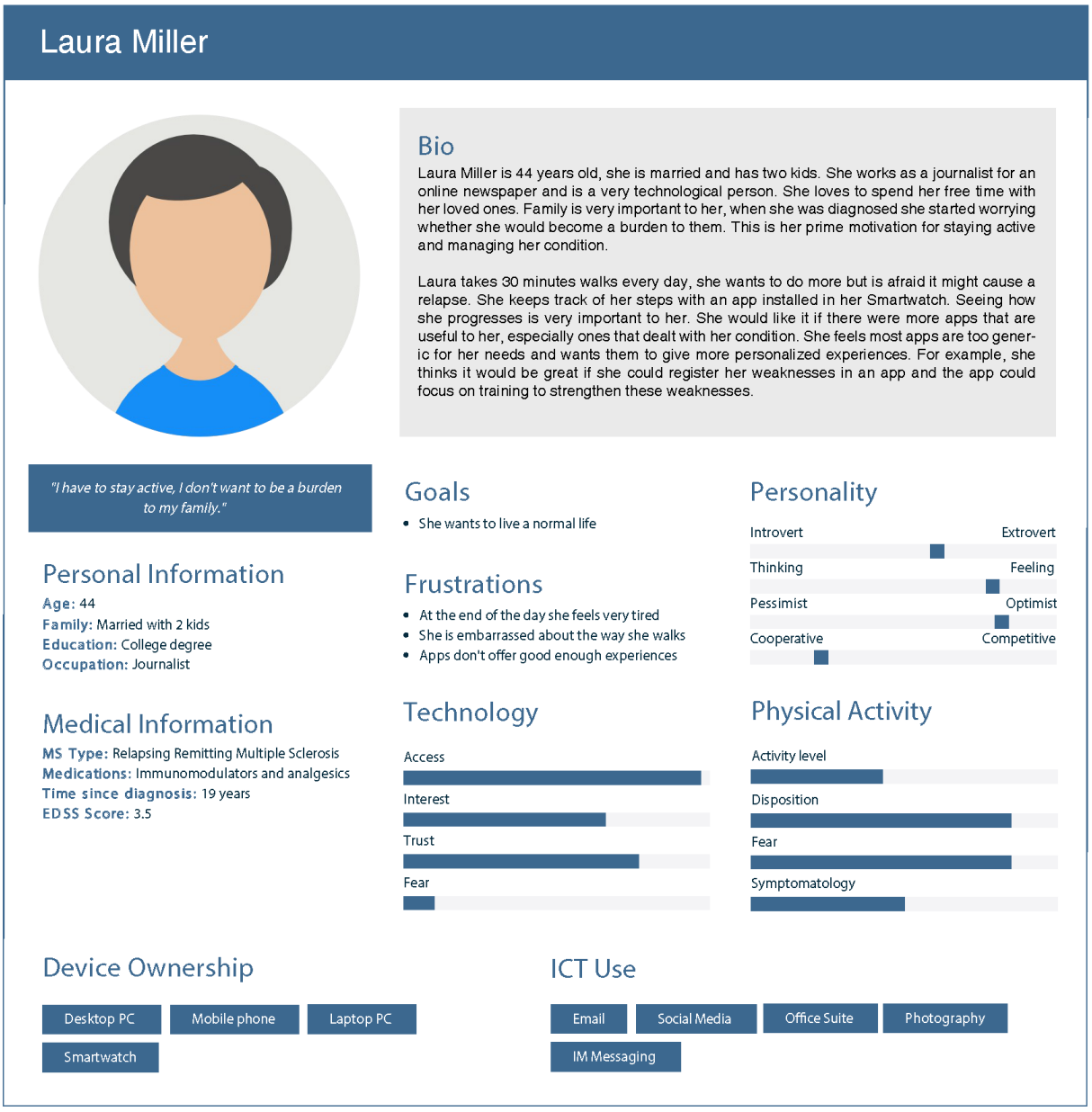


Table 3. Multiple sclerosis personas' synopsis.

Persona name	Age	Gender	Years with MS[a]	Type	Description
Laura Miller	44	Female	19	High ICT[b], medium PA[c]	Laura is married with 2 kids, and her family is very important to her. She is afraid that MS will make her a burden to those around her. She understands she should work out more but feels tired all the time. She likes to use technology and has a smartwatch.
Tim Smith	42	Male	5	Medium ICT, high PA	Tim is an elementary school teacher. He is married to Margaret who always wants to go for walks with him. He likes to stay positive so he tried not to talk about MS. He likes using step counters because he feels he achieves things that way.
John Peterson	38	Male	12	Medium ICT, medium PA	John is an office clerk and not a big fan of technology. Things are complicated enough as they are. He has been having problems with his eyesight. He does not work out because he is afraid to trigger a relapse. His wife tells him that he gets too competitive sometimes.
Amanda Palmer	47	Female	15	Low ICT, low PA	Amanda is divorced and does not like to exercise. She does housework and feels that is enough. She does not really understand technology or why people would use it except for the basics. Friends are very important to her.

[a]MS: multiple sclerosis

[b]ICT: Information and Communications Technologies

[c]PA: physical activity

Discussion

Principal Findings

We conducted a series of focus groups and interviews with persons with MS and health care professionals in charge of their care, and identified specific needs and characteristics for mHealth solutions. We also identified possible obstacles and facilitators for mHealth adoption. To our knowledge, this is the first study to bridge this gap in the literature. We analyzed four overarching themes (MS-related barriers and facilitators, mHealth design considerations, and general motivational aspects) with their respective subthemes. Important findings from this study include the identification of desired features in mHealth solutions for persons with MS such as: (1) activity tracking, (2) incentives for completing tasks and objectives, (3) customizable goal setting, (4) optional sociability, and (5) game-like attitude among others (Textboxes 4 and 5). Potential barriers to MS mHealth adoption such as rough on-boarding experiences, lack of clear use benefits, and disruption of the HP-patient relationship are identified; potential facilitators were also identified such as: (1) endorsements from experts, (2) playfulness, and (3) tailored to specific persons with MS needs (Textboxes 4 and 5). We also explored barriers and facilitators for PA in persons with MS (Textbox 3). Lastly, we used this understanding to develop a set of personas that represent male and female versions of persons with MS, to provide designers additional means to help in the creation of mHealth solutions for MS.

Comparison With Prior Work

Physical Activity and Fatigue

Only a small proportion of individuals with MS report meeting the minimum guidelines for PA for patients with MS [7,8]. PA and exercise have been the subject of much discussion in the MS literature, with attention to engaging patients in health behaviors aimed at reducing their physical limitation and improve their overall health and well-being [48]. However, persons with MS have a different attitude toward PA [49] and are typically less active compared with healthy persons [50]. This was also the case in our study, as patients expressed how working out now entails a new range of obstacles. The overall fear of triggering a relapse and further harm themselves was very much present. The outdated belief that "exercise is dangerous for patients with MS" has been demonstrated as incorrect, as symptoms' impairment after exercise is only temporary and does not affect the disease course [51]. However, this continues to stop physical exercise prescription [52]. Findings also remark the importance of realistic goal setting and feedback on achieving progress, which is consistent with a meta-analysis on the effectiveness of setting goals for health [53]. The most common facilitator for PA was adjusting the type of exercise modality and intensity to the individual; this is in line with what has been called "appropriate exercise for physical capabilities" [54]. Accommodating for preferences, allowing persons with MS to select from a variety of activities may help foster autonomy and increase their enjoyment of PA. Several studies suggest that providing participants with opportunities to set priorities in choosing which health behaviors to focus on result in better outcomes [55,56].

The general lack of enjoyment of PA was a big demotivator for persons with MS. Including game elements or a game-like feel to PA was seen as positive and a desirable feature. Gamification is often defined as "the use of game design elements in nongame contexts" [57]. The use of gamification and serious games is a popular strategy in mHealth [58]; it would be interesting to explore its effectiveness in this population. However, as competition with others was viewed negatively, game features should be implemented with care to avoid mechanics that could be adversely received in this population.

Fatigue is a subjective sensation, with objective changes in mental or physical performance conceptualized as fatigability [59]. It was perceived as both an important adverse consequence of PA and a barrier to PA. Fatigue is typically worst for patients with MS in the later part of the day [60,61] and is exacerbated by psychosocial stress [62]; this phenomenon was experienced by several of our participants. An interesting point, frequently remarked on by HPs and persons with MS during this study, was the need for enforcing strategic "energy" management, which could be supported by ways to visualize "energy" expenditure.

mHealth Considerations

Health literacy is the degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services to make appropriate health decisions [63]. Nowadays, health information also includes electronic resources such as the Internet and other technologies that now play an increasing role in consumer health [41]. Studies show that a prior use is the most important predictor of accepting new media for communication with HPs [64]. Participants in our group had already a widespread adoption of new communication technologies (computers, websites, emails, and mobile phones). MS online information sources are reported to have variable quality [65]. As with most long-term conditions, persons with MS information-searching habits vary depending on the time since diagnosis. Information needs vary along the course of the condition [66]. Persons with MS in this study valued their lead physician's opinion above information found online. Official "professional endorsement" was high on their list of priorities for accepting online health information or mHealth solutions.

The idea of mHealth solutions for MS management was positively received; however, our preliminary study showed that there are very few mHealth solutions for persons with MS currently available [27]. The deciding factor for mHealth adoption seemed to be having a clear value proposition. Persons with MS held pleasant user experience in high regard to their engagement with mobile apps; apps should be simple and intuitive to use, which aligns with Nielsen's findings on usability [67]. HPs felt that having theoretical background was essential. User privacy and ownership of user-generated data remains an underexplored territory from policy and regulatory perspectives [68]. HPs and persons with MS were concerned about data confidentiality, and how the use of mHealth solutions could impact on the doctor-patient relationship; this is in line with other findings in the literature [24,69-73].

Persons with MS are known to modify their social relationships and free-time activities as a result of their diagnosis, switching from group activities to individual exercises, resulting in worsening of their social life [49]. Feelings of frustration and loss of control may be the most commonly experienced self-evaluative negative consequence from participation in PA in persons with MS. Engaging with others with MS was easier for participants with MS because they felt less conscious about their limitations; however, it also served as a reminder of the uncertain progression of the condition. Most participants preferred to avoid discussion of MS and staying away from health-related topics. This aversion should be kept in mind when designing ICT interventions that include socialization features.

Designers of mHealth solutions for MS should also take into account condition-specific disabilities, such as reduced fine motor skills or blurry vision, to increase the chances of adoption. Besides having solid scientific content, these apps need to be designed to consider individual needs. The list found in Textboxes 4 and 5 of suggested mHealth solutions features provides an interesting starting point for exploration. It would be beneficial for future MS mHealth designers and developers to have the facilitators and barriers presented in Textboxes 4 and 5 in mind during the creation of new MS mHealth interventions.

The use of personas is relatively new in the field of mHealth and is being used to support the development process of health information technologies [28]. The MS personas we created and provided here (Table 3 and Appendix 2) can be used to guide designers in the creation of mHealth solutions but should be used considering their limitations.

Limitations

This study has limitations that are inherent to qualitative research methods. The sample size is not large enough to be representative of a larger population. A potential limitation of this study is the recruitment method, as participants came from a single center from a highly developed country such as Switzerland; steps were taken to make the sample as diverse as possible, but the risk of selection bias is present. The level of education, economic status, etc, will surely be different in a sample from a different center in another country. HPs had different backgrounds, so, the resulting views represent an interdisciplinary perspective and not those of a single discipline in particular. Likewise, MS treatment and care services available vary depending on the country; so, persons with MS will have different views on how to manage their condition.

Exploring persons with MS mHealth needs is difficult as the distinction between "user needs" and "user wants" is not clear. This should be taken into account as interviewed subjects may inadvertently respond "needs" questions with their "wants." Also, MS unpredictable progression influences the generalizability of this study, as the experiences differ from patient to patient; however, this limitation is inherent to MS.

Personas generated in this study need to be contextualized as coming from a high-income country and not addressing younger adults with MS; their use is limited and would require refining to better suit other populations.

Finally, our findings may be limited by the fact that the majority of participants were enrolled in a PA rehabilitation treatment plan from the clinic; so, their awareness to PA benefits may be positively biased.

Conclusions

mHealth solutions have been advocated as a modality with the potential to increase efficiency within medical practice, and their use for increasing PA in persons with MS holds promise. Critical issues to address for an improved adoption of MS health solutions seem to be allowing users realistic goal setting,

providing them with positive feedback, and minimizing usability burdens. Fatigue management is especially important in this population; more attention should be brought to this area. Results of this study provide valuable information that could help designers and developers of mHealth solutions for MS. It would be advisable that future mHealth interventions for MS consider the facilitators and barriers highlighted in this study. We are currently exploring how commercially available MS health apps contrast the findings of this study, aiming to understand how the current supply meets the demand. The combination of persons with MS-positive predisposition for specialized solutions for MS and the gap in mHealth solutions provides an interesting opportunity to explore. In the words of *PWMS10*: "There aren't many apps yet for MS; so, it's time to make an app."

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Authors' Contributions

GG conceived, designed, led overall study conduct, carried out the data collection, led analysis and interpretation of the data, and drafted the manuscript. JK participated in overall study conduct, collection, analysis, and interpretation of study data. GG and OR carried out the data coding and data interpretation. ED contributed to the analysis and interpretation of study data, and conceptualized, reviewed, and suggested modifications to presentation of results. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Question guide.

[PDF File (Adobe PDF File), 28KB - mhealth_v6i2e37_app1.pdf]

Multimedia Appendix 2

Multiple sclerosis (MS) personas.

[PDF File (Adobe PDF File), 1MB - mhealth_v6i2e37_app2.pdf]

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Abbreviations

EDSS: Expanded Disability Status Scale
eHEALS: eHealth Literacy Scale
eHealth: electronic health
HP: health care provider
ICT: information and communications technologies
IQR: interquartile range
mHealth: mobile health
MS: multiple sclerosis
PA: physical activity
PWMS: person with multiple sclerosis
RRMS: relapsing-remitting multiple sclerosis
SDT: self-determination theory
SWLS: satisfaction with life scale
UCD: user-centered design

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Original Paper

Digital Peer-Support Platform (7Cups) as an Adjunct Treatment for Women With Postpartum Depression: Feasibility, Acceptability, and Preliminary Efficacy Study

Amit Baumel[1,2], PhD; Amanda Tinkelman[2], MD; Nandita Mathur[2], MA; John M Kane[2], MD

[1]Department of Community Mental Health, University of Haifa, Haifa, Israel

[2]Psychiatry Research, Zucker Hillside Hospital, Glen Oaks, NY, United States

Corresponding Author:
Amit Baumel, PhD
Department of Community Mental Health
University of Haifa
Abba Khoushy Ave 199
Haifa,
Israel
Phone: 972 482 4011
Email: abaumel@univ.haifa.ac.il

Abstract

Background: Peer support is considered to be an important framework of support for mothers experiencing postpartum depression (PPD); however, some barriers exist that may limit its use including peer availability and mothers' lack of time due to child care.

Objective: This non-randomized study was designed to examine the feasibility, acceptance, and preliminary clinical outcomes of using 7 Cups of Tea (7Cups), a digital platform that delivers self-help tools and 24/7 emotional support delivered by trained volunteers, as an adjunct treatment for mothers diagnosed with PPD.

Methods: Mothers with PPD were referred during intake to the study coach who provided guidance about 7Cups. 7Cups features included self-help tools and chats with trained volunteers who had experienced a perinatal mood disorder in their past. Acceptability was measured by examining self-reports and user engagement with the program. The primary outcome was the Edinburgh Postnatal Depression Scale (EPDS) change score between pre- and postintervention at 2 months, as collected in usual care by clinicians blinded to the study questions. Using a propensity score matching to control for potential confounders, we compared women receiving 7Cups to women receiving treatment as usual (TAU).

Results: Participants (n=19) proactively logged into 7Cups for a median of 12 times and 175 minutes. Program use was mostly through the mobile app (median of mobile use 94%) and between 18:00 and 08:00 when clinicians are unavailable (68% of total program use time). Participants chatted with volunteers for a total of 3064 minutes and have indicated in their responses 0 instances in which they felt unsafe. Intent-to-treat analysis revealed that 7Cups recipients experienced significant decreases in EPDS scores (P<.001, Cohen d=1.17). No significant difference in EPDS decrease over time was found between 7Cups and TAU, yet the effect size was medium favoring 7Cups (P=.05, Cohen d=0.58).

Conclusions: This study supports using a computerized method to train lay people, without any in-person guidance or screening, and engage them with patients diagnosed with mental illness as part of usual care. The medium effect size (d=0.58) favoring the 7Cups group relative to TAU suggests that 7Cups might enhance treatment outcomes. A fully powered trial has to be conducted to examine this effect.

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KEYWORDS

mhealth; postpartum depression; perinatal mood disorder; peer support; online; self-help

Introduction

Overview

Postpartum depression (PPD) affects 10% to 15% of mothers within the first year after giving birth [1]. While untreated depression and anxiety are associated with low productivity and quality of life [2], PPD carries additional risks due to the baby's vulnerability to the mother's state, which may result in a poor mother-child relationship [3] and increased psychopathology in childhood or adolescence [4]. Psychosocial and psychological interventions were shown to be effective treatments for women with PPD [5]; however, some barriers exist that may limit the uptake of evidence-based interventions, including lack of time and child care needs [6]. Technology-based interventions, providing easily accessible services anywhere and anytime needed, could be particularly helpful for these women. In previous studies, it was demonstrated that Internet interventions for mothers with PPD have the potential to significantly reduce depressive symptoms, yielding small to large effect sizes [7-11]. These interventions used mostly principles derived from cognitive behavioral therapy providing users with relevant information, guidelines, and exercises.

Peer support is considered to be another important framework of support for mothers experiencing PPD [12-14]. For example, in a quantitative longitudinal study of 512 first-time mothers, Leahy-Warren et al [15] examined the relationships between social support and PPD and found that at-birth emotional functional support was predictive of PPD at 12 weeks. Websites or virtual communities enabling mothers to easily receive peer support have been studied in the last decade [16-18]. In particular, Evans et al [19] examined the perceived value of women participating in PPD online discussion groups, finding that these groups provide a safe place to connect with others and receive information, encouragement, and hope. Findings suggest that mothers with PPD may find online peer support to be helpful. However, using the Internet as a venue to provide peer support to those who were clinically diagnosed with PPD and as an integral part of mental health care was not fully examined. In addition, technology-based products have yet to demonstrate in real-world settings a scalable way to recruit, train, and engage relevant peers with mothers experiencing PPD.

Supplementing Treatment With 7Cups, A Digital Platform That Delivers Just-in-Time Peer Support and Self-Help Tools

7 Cups of Tea (7Cups) was chosen for this project because its solution enables, in a scalable way, training users from the community and engaging them with those who seek their support. Another reason to choose 7Cups was the high volume of available volunteers on the platform [20], opening new avenues for providing peer-based emotional support in real-world settings. 7Cups provides free self-help tools and 24/7 emotional support to members through an app or Web-based messaging system. The emotional support is provided by trained volunteers (listeners), who complete a computerized training course on active listening that includes video, text, role-play, and quiz components. A previous study demonstrated that 7Cups users find the listeners' support to be helpful. Moreover, users found that listeners' advantages in comparison to psychotherapists lie in their ability to provide sincere care and support without being paid for it ("you got someone who cares enough to listen") and in listeners' stand as peers who may better relate to users' difficulties [21].

Working in collaboration between researchers, clinicians, and patients, we adapted 7Cups to supplement treatment for women with perinatal mood disorders [22]. The first stage enlisted clinicians to identify program modifications necessary to use 7Cups to supplement existing treatment resources. Based on clinician reviews, guidelines for referring patients to use 7Cups were gathered, and a computerized training model was developed to provide listeners with relevant information for supporting women who are coping with perinatal mood disorders. In the second stage, patients with perinatal depression or anxiety used the platform for a single session and provided their evaluation of usefulness and usability and overall impressions of the program. Patients noted a need for support outside the scheduled therapy time and believed that freely available online emotional support could help meet this need. Most patients were interested in receiving support from first-time mothers and those who suffered from perinatal mood disorders in the past [22].

Study Design

Based on the previous study results, modifications were made, including (1) recruitment of women listeners who had a personal experience of perinatal mood disorders, (2) providing group support tools, (3) integrating relevant evidenced-based self-help tools within the platform, and (4) appropriately presenting relevant information about the listener. Once we were satisfied with the modification process we conducted this pilot study. The primary objectives were to examine (1) whether using 7Cups as an adjunct to treatment is feasible in terms of patient recruitment and timeline (ability to offer the intervention as planned shortly after diagnosis and to assess study outcomes), (2) program acceptability by obtaining participant attitudes toward the use of 7Cups as an adjunct to treatment and examining user behavior on the platform (ie, use patterns), and (3) preliminary efficacy using standardized outcome measures. Our secondary objectives were to explore use patterns in order to understand user preferences and examine whether the experience of receiving lay people's support felt safe to participants of the study. Patients were referred to use 7Cups in their own environment. We set ourselves the aim of keeping the referral process as close as possible to real-world settings such that patients learned about 7Cups enhancement option as part of their regular intake process.

Methods

Participants

Participants were recruited from December 2015 to May 2017 from the perinatal program at the Adult Outpatient Department in the Zucker Hillside Hospital. We aimed to recruit more than 15 participants to enable identify a medium (0.5) pre to post effect size with 90% power and 2-sided 5% significance [23]. Outpatient clinicians, who conducted most of the intakes to the perinatal program, were provided inclusion and exclusion

criteria and recruitment material informing participants about the study. Included patients were diagnosed with PPD as indicated by a psychiatrist during intake and recorded in their electronic medical record, 18 years of age or older, treated at the Zucker Hillside Hospital, spoke English, and had home access to the Internet through a computer or mobile phone. Patients were excluded if they had a severe medical disorder, homicidal or suicidal intent or plan, or a history of mental retardation or autism spectrum disorder.

Procedure

The Feinstein Institute for Medical Research Institutional Review Board approved the study. Patients meeting eligibility criteria who consented to participate came for an in-person meeting with a health technology coach who guided them through the use of 7Cups. Participants completed assessments at baseline and 30 days after. They received up to US $110 compensation for completing assessments, regardless of their use of either 7Cups or usual care.

Description of 7Cups

The adaptation of 7Cups as part of the program to supplement treatment for perinatal mood disorders was described in a previous paper [22]. 7Cups provides several components that were introduced to the patients in this study. The first component is the ability to connect with people from the community, mostly listeners. Participants could connect with listeners who opted in specifically to support women with perinatal mood disorders through a designated URL (Figure 1). To be included in this group, listeners had to complete a computerized training course that was developed to provide them with relevant information for supporting women who are coping with perinatal mood disorders [22], and they were required to have a 4.5 average star review based on more than 20 different prior chats. We included only listeners who reported being "past survivors"—that is, to have experienced a perinatal mood disorder themselves.

Study participants had the option to browse through the list of general listeners allowing them to filter listeners based on different categories (Figure 2). Participants could also join support groups moderated by listeners. These support groups were accessible 24/7 through open chat rooms that are focused on many topics related to emotional support (eg, anxiety, depression, acceptance and gratitude, disability). Once users chose a support group they would like to join, the chat room would be opened and they could join the conversation.

The second component is a personalized growth path (eg, Perinatal Mood Disorder: Growing Mother; Panic Attacks: Overcoming Panic; Exercise Motivation). Growth paths provide users with a tailored map to help them go from their current state to feeling better (Figure 3). They provide a step-based path to activities or information meant to be therapeutic including gratitude exercises, psychoeducation, exercises drawn from principles of acceptance and commitment therapy, assessments, and feedback. Users can also choose to try something else if they do not like the suggested step. For example, users choosing "Perinatal Mood Disorder" would receive psychoeducational material about how to cope with this disorder as a first step, as a second step would be given an opportunity to try a relaxation exercise, and at the third step would be directed to try one of the support groups embedded within the platform.

The third component is audio-based mindfulness exercises covering topics taken from the mindfulness and relaxation world such as calming meditation and acceptance of thoughts. Enrolled participants could access 7Cups whenever and wherever they chose, through the 7Cups app installed on their device or by computer log-in. The use of 7Cups was completely on demand and patients were not automatically prompted to use it in certain times or situations.

Figure 1. Designated webpage pointing patients to study listeners.

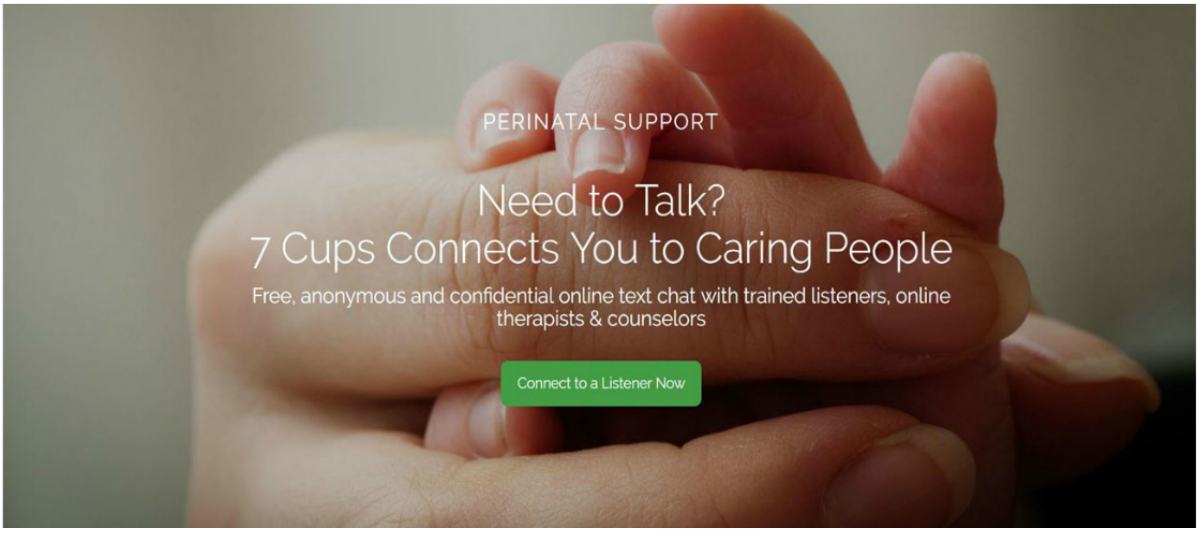


Figure 2. 7Cups Browse Listeners feature: mobile (left) and computer (right).

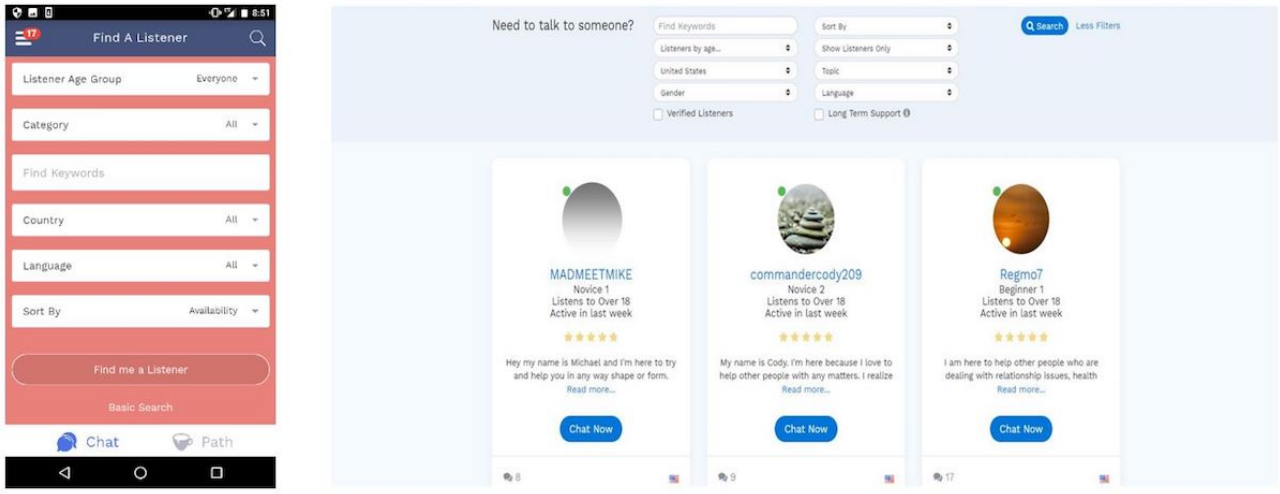
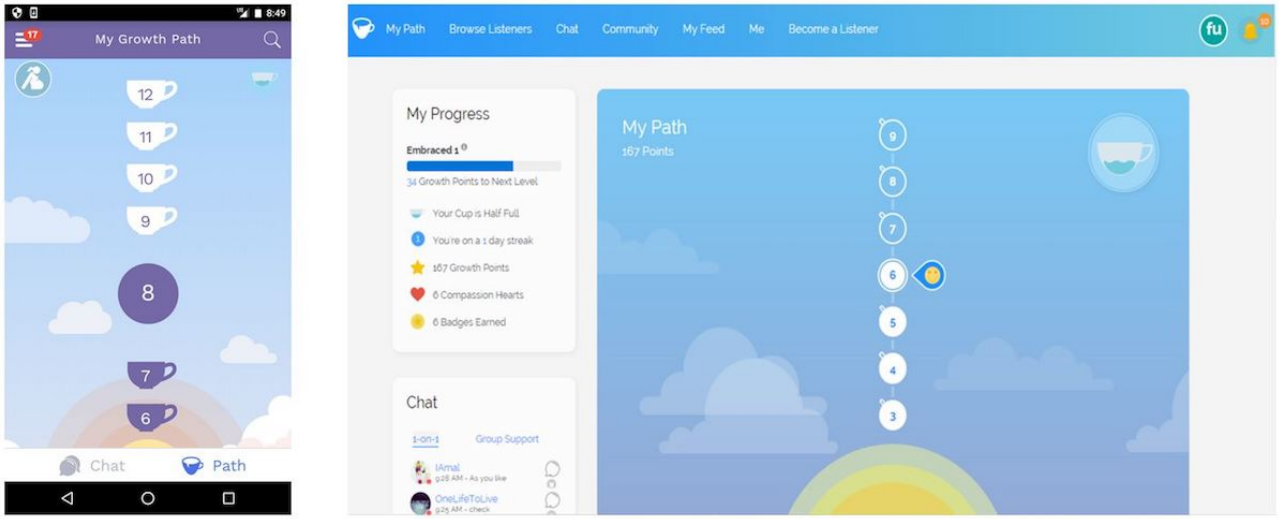


Figure 3. 7Cups Growth Path feature: mobile (left) and computer (right).



Health Technology Coaching

Coaching had several aims: installing the app and guiding participants on the program features, tackling any technical difficulties, and encouraging beneficial use through constructive feedback. To enable proper feedback, the coach had access to a platform that presented all user activity in 7Cups. Coaching included 30 minutes in-person guidance (mostly conducted before or after a meeting scheduled for the patient with her clinicians) where users signed in to 7Cups on a computer and then installed it on their mobile device. The health technology coach also proactively contacted each participant 2 to 4 days after enrollment to address any technical difficulties that may have emerged and encourage users to find the features that are most beneficial for them. If, based on program use pattern, patients were not engaged, the coach tried to reach them 1 additional time. Thereafter, participants received 1 to 2 texts within the first 30 days to encourage use and check in on any difficulties that may occur. The study coach had a master's degree in clinical psychology and did not have any prior clinical experience.

Assessments and Measures

In this pilot study, we aimed to collect relevant data while keeping the use of the program as close as possible to real-world conditions. Therefore, assessments and analysis were based on 2 paths. First, all participants enrolled into this study received 7Cups as an adjunct to treatment and were measured at preintervention and 30 days after. Second, in order to examine whether 7Cups enhances treatment outcomes, we compared 7Cups users to a different group of patients based on one outcome measure that was available to us. These assessments and analysis are further described in details below.

At baseline, participants completed a demographic questionnaire (age, race, ethnicity, education, employment status, family status, history of mental illness). At baseline and 30 days after enrollment, participants completed online versions of the Beck Depression Inventory II (BDI-II), Edinburgh Postnatal Depression Scale (EPDS), and Beck Anxiety Inventory (BAI). Participants were asked to complete the BAI since symptoms of anxiety might be more common in the perinatal period than in other depressions [24]. EPDS scores are also regularly recorded by psychiatrists during each patient visit for all patients in the perinatal program. We therefore recorded the EPDS score

at baseline and 2 months after as collected by physicians or nurse practitioners blinded to the study questions.

Following recommendations of assessing feasibility in applied intervention research [25,26], we evaluated the feasibility of 7Cups as an adjunct treatment based on (1) recruitment (participation) and (2) timeline (ability to offer the intervention as planned shortly after diagnosis and assess study outcomes). Acceptability was measured by examining users' self-reported attitudes and satisfaction toward using 7Cups as an adjunct to treatment and analyzing program use patterns. Usability (eg, "I find/found 7Cups program easy to use"), attitudes toward 7Cups (eg, "7Cups is/was useful in helping me feel better"), and satisfaction questionnaires (eg, "I would recommend using 7Cups to women who suffer from perinatal mood disorders") [27-30] that had been adjusted and used in prior studies of 7Cups [21,22,31] were measured at 30 days. 7Cups use data was collected passively. Since the analytical platform did not enable us to effectively differentiate between growth paths use and mindfulness exercises use (which are sometimes also embedded within the growth paths), we examined 7Cups use separated into self-help tools (eg, growth path, mindfulness) and online chat communication (which also included support group use). The length of program use in minutes per session was measured from first log-in until the last event in a given session. When the time between 2 events exceeded more than 5 minutes, a new session was created where the previous session end was the time of the last event recorded in it.

Data Analysis

Data analysis included descriptive statistics of the multiple-choice questions and program use patterns. Pre-post analysis of self-reported symptoms in BDI-II, EPDS, and BAI were conducted using *t* tests for paired samples.

Comparison With Treatment as Usual Using a Propensity Score Matching

As described above, the 7Cups enhancement group also received usual care; therefore, it would be difficult to determine whether recorded pre-post effect was only the natural result of usual care. To account for that effect, we created a retrospective comparison group of patients receiving treatment as usual without 7Cups (TAU). As an outcome measure we used the difference in EPDS scores between baseline and 2 months as recorded by the treatment team on a usual basis for all patients in the perinatal program. To control for potential confounders between the groups, several steps were carried out. First, only patients who were not offered 7Cups and met eligibility criteria could be included in TAU group. This condition was possible because different staff members and hospital residents conducted intakes but only some of these "intakers" received guidance and therefore offered patients the use of 7Cups. Second, only patients who had an intake during the study time period could be included in the TAU.

Of these remaining patients, a propensity score matching paradigm with the nearest neighbor matching was used to balance the groups across potential covariates [32,33]. Potential covariates for study outcomes were chosen—EPDS score at intake, diagnosis group (eg, depression, depression and anxiety), age at admission, marital status, race, and ethnicity—and then used to calculate the propensity score for each participant in 7Cups and the TAU prospective sample using SPSS 22.0 (IBM Corp). For each participant in 7Cups, a patient from the TAU prospective sample with the most similar propensity score was selected, without replacement. Balance of the baseline characteristics was assessed postmatching using a measure of standardized bias (similar to an effect size, it is defined as the mean difference divided by the common standard deviation). All standardized biases were acceptable at <0.2 [34,35].

Pre-post analysis of the difference in documented EPDS scores for 7Cups and TAU was conducted using *t* tests for paired samples. Due to the pilot nature of the study and limitations in statistical power, between-group effect size (small 0.20-0.49, medium 0.50-0.79, and large ≥0.80) was also used to compare 7Cups and TAU [36]. Whereas significance testing conveys the likelihood that study results differ from chance expectations, effect-size calculations convey the relative magnitude of the experimental effect and, therefore, provide the opportunity to compare the magnitude of treatment effects within and across studies [37]. We also examined the percentage of participants who experienced a drop in at least 1 level of symptom severity during the 2-month examination based on established severity ranges for EPDS: none or minimal depression (0-6), mild depression (7-13), moderate depression (14-19), and severe depression (19-30) [38].

Results

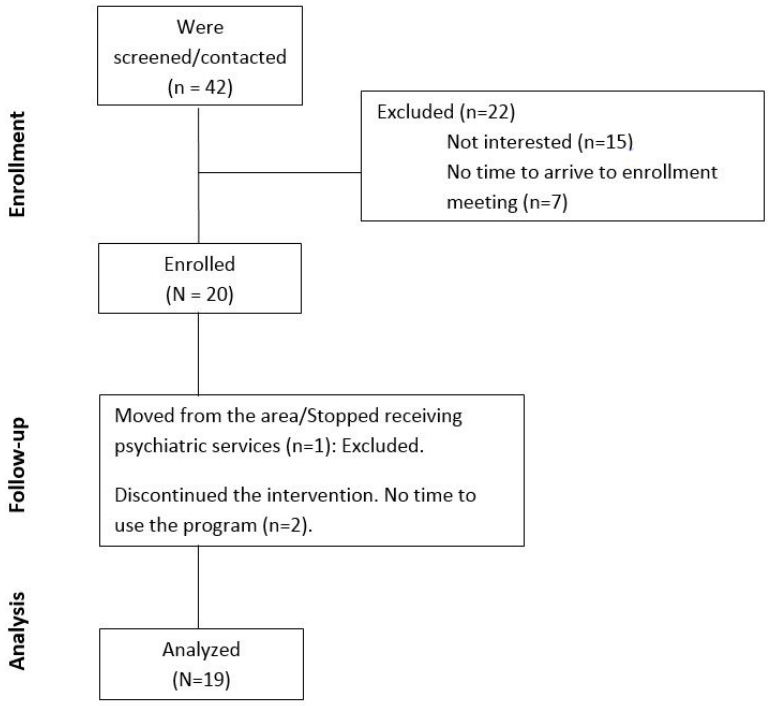
Participants

A total of 20 patients consented and were enrolled into this study (see Figure 4). Of those patients, 1 participant dropped out due to a move to a different state within the United States and was therefore not included in the analysis. Two participants withdrew from the study voluntarily, however, and were included in the results when applicable based on intent-to-treat analysis. The mean age of participants was 31.95 (SD 5.57) years. All other baseline characteristics of patients can be viewed in Table 1. Of the study sample, 40% (8/20) were black or African American and 15% (3/20) were Hispanic or Latino, most women were married or in conjugal relationships, most women were first-time mothers, and most women had a history of mental illness prior to this treatment period. In terms of usual care, all but 1 participant received antidepressants and most received either individual or group psychotherapy, with a median of 2 in-person meetings within the first 30 days after intake.

7Cups Use

7Cups use during the 30-day examination can be viewed in Table 2. Participants proactively logged in to 7Cups a median of 12 times and used the program a median of 175 minutes. Participants used 7Cups mostly through mobile devices (median 93.7%). Finally, the median use (in percentages) of listeners' support was 41.7%. Figure 5 presents the proportion of 7Cups use by daily hours. The data shows that 75% of program use was during evening and nighttime, between 18:00 and 08:00. No significant difference was found between program use in the first 2 weeks and the last 2 weeks of the examination.

Figure 4. Consolidated Standards of Reporting Trials diagram of participant flow.



Usability and Acceptability

Participant responses to the usability and acceptability measures are reported in Table 3. A total of 88% (15/17) of study participants found 7Cups to be useful in helping them to feel better, 70% (12/17) indicated that 7Cups emotional support was useful at times when the clinicians were not available, 82% (14/17) indicated they would use 7Cups in the future when needed, and 88% (15/17) indicated they would recommend using 7Cups to women who suffer from perinatal mood disorders. More than 80% (14/17) of study participants indicated they consider 7Cups to be a confidential and safe place. The participants chatted with listeners for an accumulated time of 3064 minutes and indicated in their responses 0 times in which they felt unsafe (ie, feeling any sort of emotional distress or threat caused by listeners' inappropriate reactions during the chat). One participant wrote she was worried someone from her home might see the data and that a passcode to her mobile phone would be helpful.

Efficacy

Self-reported outcome measures are presented in Table 4. Paired samples *t* tests indicated significant reductions in symptoms from baseline to post (30 days) in depression on the BDI-II (P=.01) and EPDS (P=.005). Scores on the BAI did not significantly change. To examine whether there was an association between symptom change and the frequency with which participants used the intervention, we conducted Spearman correlations between changes in BDI-II, EPDS, and BAI scores and the total minutes of use. No significant association was found between these variables.

Comparison with TAU

This comparison eventually included 17 participants from each group since 2 participants who used 7Cups (2/19, 11%) did not have postintervention clinician-based assessment documented at 2 months after enrollment. These 2 participants did not differ from other participants in their use patterns and self-reports. Intent-to-treat analysis of EPDS scores administered by clinicians revealed that patients in the 7Cups (t_{16}=4.83, P<.001, Cohen d=1.17) and TAU (t_{16}=3.24, P=.003, Cohen d=0.79) groups experienced significant decreases in depressive symptom severity over the 2-month period. A *t* test for independent samples comparing pre- to posteffect sizes revealed no significant difference between the 7Cups (mean difference 6.29 [SD 5.37]) and TAU (mean difference 3.47 [SD 4.42]) groups, yet the effect size was medium: t_{32}=1.67, P=.05, Cohen d=0.58. The percentage of participants who experienced a drop in at least 1 level of symptom severity during the 2-month examination was 71% (12/17) for 7Cups and 47% (8/17) for TAU.

Table 1. Sample characteristics (n=20).

Variable	n (%)
Race and ethnicity	
Black or African American	8 (40)
White	5 (25)
Hispanic or Latino (white)	3 (15)
Asian	2 (10)
Multiracial	2 (10)
Marital status	
Married or in conjugal relationship	16 (80)
Never married/single	3 (15)
Divorced/separated	1 (5)
Highest education	
Some high school	1 (5.0)
Completed high school	1 (5.0)
Postsecondary school	5 (25)
Completed 4-year college	7 (35)
Completed postgraduate training/advance degrees	6 (30)
Employment status 6 months prior	
Employed	14 (70)
Unemployed	6 (30)
Number of children	
1	11 (55)
2	7 (35)
3	1 (5)
Preferred not to answer	1 (5)
History of mental illness	14 (70)
Treatment	
Psychotherapy or group therapy	17 (85)
Pharmacotherapy	19 (95)

Table 2. Use of 7Cups enhancement during the 30-day examination (n=19).

Use	Median (IQR[a])	Mean (SD)
7Cups log-ins	12.0 (18.5)	18.0 (16.9)
7Cups use, minutes	175.0 (327.0)	301.7 (412.3)
Proportion of online chat use[b]	41.7 (67.9)	47.0 (36.6)
Proportion of use through mobile	93.7 (18.5)	79.9 (27.2)

[a]IQR: interquartile range.

[b]Calculated based on the time in minutes dedicated to this activity as opposed to self-help. Use of support groups was sparse and accounted for 5% out of the total online chat use.

Figure 5. 7Cups use by daily time windows.

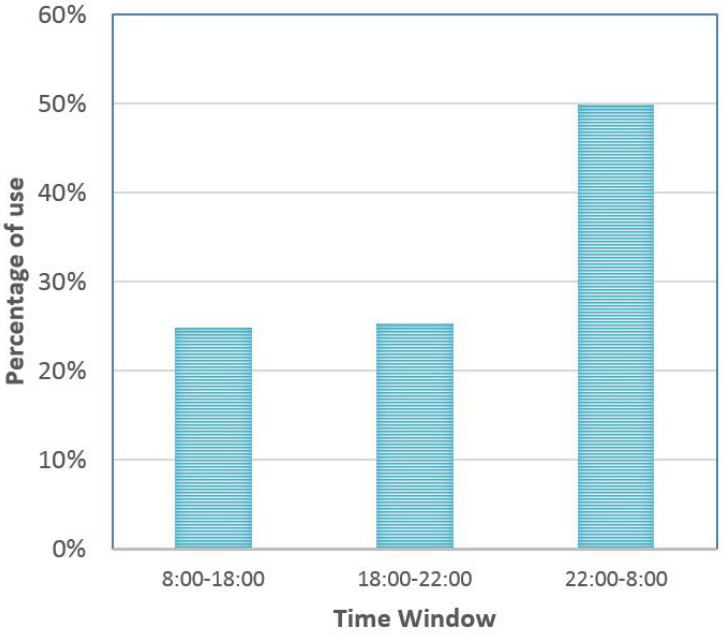


Table 3. Participant responses to usability and acceptability measures (n=17).

Statement	Strongly disagree n (%)	Disagree n (%)	Slightly disagree n (%)	Neutral n (%)	Slightly agree n (%)	Agree n (%)	Strongly agree n (%)
I find/found 7Cups program easy to use	0 (0)	0 (0)	0 (0)	3 (18)	2 (12)	9 (53)	3 (18)
I learned to use 7Cups quickly	0 (0)	0 (0)	0 (0)	4 (24)	3 (18)	6 (35)	4 (24)
7Cups is/was useful in helping me to feel better	0 (0)	0 (0)	0 (0)	2 (12)	1 (6)	13 (77)	1 (6)
The emotional support provided by 7Cups is/was useful in helping me when clinicians weren't available	0 (0)	1 (6)	0 (0)	4 (24)	2 (12)	5 (29)	5 (29)
7Cups significantly increases/increased the social support I receive/received	0 (0)	2 (12)	0 (0)	3 (18)	3 (18)	8 (47)	1 (6)
I would probably use 7Cups in the future when needed	0 (0)	0 (0)	0 (0)	3 (18)	1 (6)	5 (29)	8 (47)
I would recommend using 7Cups to women who suffer from perinatal mood disorders	0 (0)	0 (0)	0 (0)	2 (12)	0 (0)	6 (35)	9 (53)
I would like to join 7Cups as a listener	1 (6)	2 (12)	0 (0)	7 (41)	1 (6)	2 (12)	4 (24)
I consider 7Cups a safe place	0 (0)	0 (0)	0 (0)	3 (18)	1 (6)	5 (29)	8 (47)
I consider 7Cups a confidential place	0 (0)	0 (0)	0 (0)	3 (18)	1 (6)	5 (29)	8 (47)

Table 4. Intent-to-treat (n=19) means and standard deviations of self-reported outcome measures filled by intervention group over a 30-day period.

Measure	Baseline mean (SD)	After 30 days mean (SD)	*t* (pre-post)	*P* value	Pre-post effect size (Cohen *d*)
BDI-II[a]	26.11 (13.34)	19.18 (9.23)	2.48	.01	0.57
EPDS[b]	17.32 (5.96)	13.53 (4.65)	2.88	.005	0.66
BAI[c]	20.47 (13.15)	16.65 (7.52)	1.29	.11	0.30

[a]BDI-II: Beck Depression Inventory II.

[b]EPDS: Edinburgh Postnatal Depression Scale.

[c]BAI: Beck Anxiety Inventory.

Discussion

Principal Findings

This study demonstrates that a mobile intervention providing peer support and supplementary self-help tools as an adjunct treatment for women with PPD is feasible and acceptable and suggests that this intervention might also be clinically helpful. Women with PPD used 7Cups more than regular services and mostly when services would not likely be available. Most program use occurred during the evening and nighttime, based on mothers' (or babies') schedule. It is also worth noting that while mothers received equivalent guidelines about the use of 7Cups via computer and mobile device, most program use was through mobile device (median of mobile use 93.7%), probably since mobile phones are more accessible when needed. Finally, about a third of mothers who chose not to participate in the study explained they did not have time to attend the enrollment meeting. Overall, these findings are congruent with a previous study showing that for mothers with PPD, one of the main perceived advantages of an online program revolves around its flexibility and accessibility, due to the mothers' need to manage themselves around the children's schedules [39].

This study also demonstrated that women with PPD find online peers who have been recruited, trained, and screened using only a computerized program to be helpful and find the experience safe. Participants chatted for a total of 3064 minutes with not one noted incident of feeling unsafe. While a previous study demonstrated that people in emotional distress may find online peer support to be helpful, that study sample was biased as it was composed only of 7Cups native users [21]. Our study provides evidence about the acceptance of a volunteer-based support program from an unbiased sample, which converges with findings from previous studies demonstrating that online peer support can be beneficial for women experiencing depression [19,40]. It is worth noting that the use of support groups was sparse and accounted for 5% out of the total online chat use. It might be that participants would use this feature much more in the presence of an ongoing support group in which the same users attended, as happens in outpatient settings. This, however, raises more complications in terms of product design.

While 7Cups had a very large pre to post positive effect on symptoms of depression (d=1.17), the results did not indicate a significant difference between 7Cups enhancement and TAU groups. Since the perinatal program at Zucker Hillside Hospital provides evidence-based care including pharmacologic and psychosocial interventions (eg, psychotherapy, group support), it was expected that TAU would yield significant improvement in symptoms of depression as well. However, the medium effect size (d=0.58) favoring 7Cups relative to TAU suggests that 7Cups might improve treatment outcomes. A fully powered trial must be conducted to examine this effect. It is also worth noting that participants did not report a significant drop in symptoms of anxiety, although this may be attributed to lower rates of experienced anxiety (BAI mean 20.47) in comparison to depression (BDI-II mean 26.11) at preintervention.

Using Technology in the Service of Human Connection

This study presents an intervention that uses a computerized method to train lay people without any in-person guidance or screening and then engages them with people diagnosed with mental illness. While previous studies demonstrated positive outcomes for the use of peer-assisted interventions [41,42] and family involvement [43], their impacts were limited by the need to develop and implement practical methods to engage, screen, and train lay people from the community to support others. Other programs that leverage peer-based support showed positive results in terms of user engagement [44] and efficacy [45] but did not demonstrate ability to empower a large number of peers to enroll and provide support to the extent demonstrated by 7Cups [21].

The approach demonstrated by 7Cups takes into account safety and therapeutic considerations by the way the platform is designed to collect and present listeners' reputations. Listeners are being continuously evaluated by members for their listening skills and commitment to the 7Cups community, and these evaluations are then presented online for all members to view (in our program only listeners with high evaluation scores were presented in the designated program page). Listeners can also receive a verified listener badge, which means that they were inspected for their listening skills by an experienced listener and passed this inspection. In terms of safety and therapeutic effectiveness, our study was focused on the use of 7Cups as an adjunct to treatment and not as a standalone, which largely affects the safeguards in place. More has to be discussed and examined when it comes to whether there should be other methods for supervision and/or evaluation of actual conversations that occur based on the settings in which such programs are being used.

Limitations

This study has several limitations. First, while the difference in EPDS scores between 7Cups and TAU was not small (d=0.58), it was not significant (P=.05). This is not surprising given that the nature of this study was more focused toward evaluation of potential effects, which could be helpful for researchers prior to the initiation of a fully powered examination. Second, the difference in outcomes between the groups is not based on a randomized controlled trial. While the propensity matching paradigm did account for several confounders, there might be other confounders affecting the results. For example, it is possible that there are other factors related to patients enrolling in the study, such as readiness to change, that affected outcomes but could not be balanced (since such factors are not collected in usual care). We believe, however, that the large effect size found for the study group as well as the self-reported effects provide sufficient evidence that could be further investigated using a randomized controlled trial. Third, it might be that study compensation contributed to engagement with the program; however, this is unlikely given that participants were clearly informed that they would receive their compensation regardless of their use of 7Cups and that they would be compensated approximately 4 months after enrollment.

Conclusions

This study provides data regarding the potential value of 7Cups within the therapeutic process by retrieving user-based empirical data in real-world conditions [46]. Given the development costs of technological resources and the evolving technological landscape, studies that use existing tools rather than developing and evaluating completely new products might be more likely to influence current clinical practices. This study also demonstrated that technology can not only facilitate an unprecedented increase in supportive human resources but also that the quality of emotional support received through this avenue is deemed adequate by people with mental illness. Given that safety controls are adequate, technology could be used across all levels of community, from volunteers, to neighbors, and family members, to provide a novel model of care, where mental illness and mental health needs are not solely addressed behind the closed doors of health care providers.

Conflicts of Interest

None declared.

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Abbreviations

7Cups: 7 Cups of Tea
BAI: Beck Anxiety Inventory
BDI-II: Beck Depression Inventory II
EPDS: Edinburgh Postnatal Depression Scale
PPD: postpartum depression
TAU: treatment as usual

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Review

Mobile Phone Apps for Behavioral Interventions for At-Risk Drinkers in Australia: Literature Review

Carol C Choo[1], DPsych (Clin); André A D Burton[2], MCouns

[1]College of Healthcare Sciences, James Cook University, Singapore, Singapore

[2]School of Psychology, Murdoch University, Perth, Australia

Corresponding Author:
Carol C Choo, DPsych (Clin)
College of Healthcare Sciences
James Cook University
149 Sims Drive
Singapore, 387380
Singapore
Phone: 65 67093760
Fax: 65 67093889
Email: carol.choo@jcu.edu.au

Abstract

Background: The mobile technology era has ushered in the use of mobile phone apps for behavioral intervention for at-risk drinkers.

Objective: Our objective was to review recent research relevant to mobile phone apps that can be used for behavioral intervention for at-risk drinkers in Australia.

Methods: The inclusion criteria for this review were articles published in peer-reviewed journals from 2001 to 2017 with use of the search terms “smartphone application,” “alcohol,” “substance,” “behavioural intervention,” “electronic health,” and “mobile health.”

Results: In total, we identified 103 abstracts, screened 90 articles, and assessed 50 full-text articles that fit the inclusion criteria for eligibility. We included 19 articles in this review.

Conclusions: This review highlighted the paucity of evidence-based and empirically validated research into effective mobile phone apps that can be used for behavioral interventions with at-risk drinkers in Australia.

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KEYWORDS

problem drinking; alcohol drinking; eHealth; telemedicine; smartphone; mobile applications; behavioral intervention; risk reduction behavior; review

Introduction

In Australia, alcohol is a common substance of dependence for which individuals seek treatment [1]. Reducing the risk of alcohol-related harm is important in Australia, with a government that takes a harm minimization approach [2-4]. The preferred approach for alcohol interventions in Australia has been to prevent the adverse consequences associated with alcohol consumption rather than banning drinking altogether [5]. Psychological interventions informed by the stages of change model [6,7], as well as therapeutic techniques from motivational interviewing [8], cognitive behavioral approaches [9], and self-management strategies [8,10], hold promise to change problematic behaviors [7,11] and address adverse consequences related to drinking [12].

In recent decades, the advent of mobile phone technology has transformed the mode of delivery of psychological treatment [13]. Through promotion of the accessibility of interventions via mobile phone apps, alcohol dependence interventions may be enhanced and the adverse consequences of risky drinking may be reduced [6]. The demand for electronic health apps across Australia and the world is mirroring larger societal trends wherein consumer acceptance of technology has grown [14,15]. Community interest has increased in Australia regarding the use of mobile phone apps to address substance abuse [16], health monitoring, and self-management [17]. Some clinics in Australia

have implemented conjunctive treatment modalities in guided programs such as cognitive behavioral therapy and psychoeducation apps alongside face-to-face therapy sessions [17]; for example, the DBT Diary Card & Skills Coach [18] was designed as an adjunctive tool to therapy for individuals recovering from substance abuse. However, research examining its effectiveness lacked conclusive evidence due to the lack of distinction made between the different types of substance use [19,20].

Our aim was to review research relating to the evidence for mobile phone apps that can be used for behavioral intervention for at-risk drinkers in Australia.

The literature positions mobile phone apps under the umbrella of mobile health and its subcategory electronic health, which is defined as health care practice supported by electronic processes and communication [21]. For this review, smartphone refers to a mobile phone that performs many of the functions of a computer. This typically includes having a touchscreen interface, Internet access, and an operating system capable of running downloaded apps. A mobile app is a computer program designed to run on mobile devices such as smartphones and tablet computers. It allows for third parties to design software and apps that can then be downloaded by the user at their discretion.

At-risk drinker is defined as a heavy drinker who consumes 5 or more drinks on the same occasion on each of 5 days or more in the past 30 days [22]. In contrast to a binge drinker, who has a pattern of drinking that brings blood alcohol concentrations up rapidly after consuming alcohol in one go, an at-risk drinker displays consistency in their heavy drinking levels.

Methods

The inclusion criteria for this review were publication in peer-reviewed journals from 2001 to 2017 with use of the search terms “smartphone application,” “alcohol,” “substance,” “behavioural intervention,” “electronic health,” and “mobile health.” The databases we searched were PsycINFO, Scopus, Google Scholar, and PubMed.

We initially used the PsycINFO database to identify peer-reviewed articles with the inclusion criteria named above; this yielded 11 results. The Scopus database search yielded 19 articles. We then conducted hand searches: a backward search using the reference lists of relevant articles and a forward search that checked publications from authors who had cited these relevant articles. The backward and forward searches generated 11 more articles. The focus was on recently published articles in peer-reviewed journals that fit the inclusion criteria and were relevant to a mobile phone app that could be used for behavioral intervention for at-risk drinkers in Australia.

We retrieved articles if they related to interventions provided via a mobile phone app for at-risk drinkers. The strategy for evaluating eligibility for inclusion involved the following: recent articles that contained original work published in peer-reviewed journals after the year 2001; and articles related to use of a mobile phone app by clinicians for therapeutic purposes. We excluded articles that did not refer to the use of mobile phone apps by clinicians for therapeutic purposes.

Results

A total of 103 articles satisfied all inclusion criteria in the original search across all the databases. Of the original 103 search results, we screened 90 articles, after which we assessed 50 full-text articles against the inclusion and exclusion criteria, and then deemed 19 of these to be suitable for inclusion in this review [17,23-40]. Multimedia Appendix 1 presents the results of the review.

Overall, the articles show a lack of convincing evidence of effective mobile phone apps that can be used for behavioral intervention for at-risk drinkers in Australia. Randomized controlled trials did not yield significant results on the primary outcome [23,24]. Other studies were limited by small sample sizes [25,26] or only reviewed mobile phone apps [27] and did not specifically address our research question [17] of whether the mobile phone app was effective for behavioral intervention for at-risk drinkers in Australia. Although qualitative studies are not typically included in a systematic review, we decided to include these in our table (Multimedia Appendix 1) to illustrate the state of research in Australia, that convincing evidence is still lacking. A study in Australia conducted by Weaver and colleagues [26] reviewed available mobile phone apps and then used a qualitative methodology of focus groups, which offers preliminary exploration. However, it does not offer evidence for their use within the demographic group most at risk for developing alcohol problems in Australia, namely men aged 20 to 29 years and indigenous youths [22,41], who often develop dysfunctional drinking habits that maintain their dependence [42]. Risky drinking in younger demographics is known to be a risk factor for suicidality [43] and other adverse mental health outcomes.

Discussion

As younger demographics are more likely to access online information relating to mental health problems [44-46], mobile technologies can enhance patient-centered care for youths and young adults in an increasingly technology-savvy society [28], highlighting a growing need to offer electronic interventions as an adjunctive tool to face-to-face therapy [47,48]. Evidence for the use of mobile phone apps has been demonstrated in many other areas [49-54] but not for at-risk drinking in Australia. Internet-based interventions have been found to be efficacious for mental health issues [3] in young adults [45,47,55]. Behavioral monitoring apps have been used for mental health interventions [29,56] in addition to face-to-face therapy. Positive outcomes were shown in overall motivation [57], and in maintaining and reinforcing behavioral changes [16,57,58]. These apps show promise for use with ethnically diverse and low-income populations [59] to enhance support [17], help them to cope, and aid in recovery [60,61]. Behavioral data can be quantified into graphs [56] and used by clinicians [29,62]. However, youths view apps as a form of entertainment rather than therapeutic tools [26]. The focus could be shifted with an emphasis on behavioral modification instead [63] and apps

could be used as an adjunctive tool to complement face-to-face therapy delivered by qualified health professionals [2,15,64]. More research is needed to support the effectiveness of such apps for use with indigenous youths and young adults in Australia.

Mobile phone interventions have been used for drinking problems in a few clinics in the United States [29] but with less compelling evidence for clinics in Australia. Behavioral monitoring apps are being used for digital behavior change interventions that provide goal setting and behavior monitoring [30], which also allow for triggers to be detected. The AlcoDroid Alcohol Tracker [65] allows for tracking alcohol consumption, as does the Alcohol Tracker [66]. Most of these apps are based on simple features that estimate the amount of alcohol in the blood [67-70], which could be used to set specific drinking targets but do not constitute the most important element for the monitoring of risky drinking [26].

Despite a large increase in research on electronic interventions in recent years (refer to Multimedia Appendix 1), gaps in knowledge remain. Specifically, there is a lack of strong evidence examining the efficacy of mobile phone apps that have been empirically validated with rigorous scientific methods for at-risk drinkers in Australia, especially young males [4,29] and indigenous youths. Youths can be impressionable consumers, and principles of rigorous scientific inquiry should be applied to explore the benefits of the use of health-related apps in this population [71]. Research aimed at examining low-cost mobile phone apps that are efficacious as an adjunctive tool to therapy would add significantly to the literature [29]. Considering the prevalence of alcohol problems [22], especially in young males and indigenous youths in Australia, research is much needed to explore alternative ways to deliver effective interventions [72].

It is important to understand that any therapy or medical treatment has the potential to cause harm, and that any device can cause adverse effects if used incorrectly. Some critiques of the mobile phone app movement have focused on the ethical importance of protecting consumers from potential harm. There should be laws and regulations [73] governing the operation of mobile phone app stores, and steps should be made available to legislators to protect consumers. This argument follows that if apps were to be used in health care settings for therapy, it is important that the stores be reputable and that the apps be created by legitimate third-party software developers [73]; for example, iTunes App Store currently contains 20,000 apps in the Medical category, yet it is not clear what is precisely relevant for clinical decision making with specific at-risk groups [31].

The critical issue for clinicians using mobile phone apps with their patients is the risk to benefit ratio with such a large selection of apps [73]. During this fledgling stage of exploration when apps are yet to be rigorously assessed and curated formally based on their content, clinicians should carefully consider safety issues. In Australia, it is a prerequisite in the Therapeutic Goods Act [74] for health apps to ensure data security and that all claims made regarding the app comply with the Australian consumer law that they are not misleading the consumer [74]. No apps in Australia fall under the label of medical device, which requires registration under the Therapeutic Goods Act [74]. If apps could be registered as medical devices, perspectives toward privacy may change, since data security would be mandated as a part of the registration [75]. This would also allow regulatory action to be followed through if there were legal issues that needed attention.

There is concern over accessibility in terms of limitations of digital cover in remote communities [75,76]. A difference in network coverage and affordability of the type of mobile phones that can be used to host the app may disadvantage Australians who already experience significant socioeconomic disadvantage and who are also at risk of higher rates of alcohol use [77]. Additionally, a critique has been made on whether youths could become somewhat dependent on apps [78]. However, problem drinkers or those at risk of alcohol addiction are not a homogeneous group, and this must be considered when clinicians are deciding on app suitability for use with their patients. The needs of the patient need to be carefully considered.

In summary, there is consensus that alcohol misuse is a widespread problem in Australia [79]. The health and social consequences resulting from the misuse of alcohol have been widely reported [32,80]. Reducing the risk of alcohol-related harm is important for affected individuals and society at large [2,3]. Enhancing the delivery of interventions may reduce the adverse consequences of alcohol misuse [6]. The potential use of mobile phone apps in the delivery of behavioral interventions tailored for at-risk drinkers remains promising, but evidence to support their use is lacking in Australia. More research is needed to address the gaps in knowledge and to provide an evidence base for the implementation of mobile phone technologies. Developing mobile tools for young users with substance and alcohol abuse issues requires careful ethical consideration regarding the patient-practitioner relationship, the logic of self-surveillance, and overall best practice.

More rigorous research and evaluations are needed to ascertain the efficacy of and establish evidence for best practice for use of such mobile phone apps [17]. The real-time delivery of interventions aimed at reducing risky drinking holds promise to support people who are seeking to change their behavior [32]. Although drinking apps do exist, there are many inconsistencies in their features [26]. Apps that are designed specifically for behavioral interventions for at-risk drinking have not been empirically studied in Australia. Quality and ethical issues relating to the use of such technology need to be considered on a deeper level.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of evidence.

[PDF File (Adobe PDF File), 112KB - mhealth_v6i2e18_app1.pdf]

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Original Paper

Peer Coaching Through mHealth Targeting Physical Activity in People With Parkinson Disease: Feasibility Study

Cristina Colón-Semenza[1], PT, MPT; Nancy K Latham[2], PT, PhD; Lisa M Quintiliani[3], PhD; Terry D Ellis[1], PT, PhD

[1]Center for Neurorehabilitation, Department of Physical Therapy & Athletic Training, College of Health & Rehabilitation Sciences: Sargent College, Boston University, Boston, MA, United States

[2]Boston Claude D Pepper Older Americans Independence Center, Research Program in Men's Health: Aging and Metabolism, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, United States

[3]School of Medicine, Department of Medicine, Section of General Internal Medicine, Boston University, Boston, MA, United States

Corresponding Author:
Terry D Ellis, PT, PhD
Center for Neurorehabilitation, Department of Physical Therapy & Athletic Training
College of Health & Rehabilitation Sciences: Sargent College
Boston University
635 Commonwealth Ave
Boston, MA, 02215
United States
Phone: 1 6173537571
Email: tellis@bu.edu

Abstract

Background: Long-term engagement in exercise and physical activity mitigates the progression of disability and increases quality of life in people with Parkinson disease (PD). Despite this, the vast majority of individuals with PD are sedentary. There is a critical need for a feasible, safe, acceptable, and effective method to assist those with PD to engage in active lifestyles. Peer coaching through mobile health (mHealth) may be a viable approach.

Objective: The purpose of this study was to develop a PD-specific peer coach training program and a remote peer-mentored walking program using mHealth technology with the goal of increasing physical activity in persons with PD. We set out to examine the feasibility, safety, and acceptability of the programs along with preliminary evidence of individual-level changes in walking activity, self-efficacy, and disability in the peer mentees.

Methods: A peer coach training program and a remote peer-mentored walking program using mHealth was developed and tested in 10 individuals with PD. We matched physically active persons with PD (peer coaches) with sedentary persons with PD (peer mentees), resulting in 5 dyads. Using both Web-based and in-person delivery methods, we trained the peer coaches in basic knowledge of PD, exercise, active listening, and motivational interviewing. Peer coaches and mentees wore FitBit Zip activity trackers and participated in daily walking over 8 weeks. Peer dyads interacted daily via the FitBit *friends* mobile app and weekly via telephone calls. Feasibility was determined by examining recruitment, participation, and retention rates. Safety was assessed by monitoring adverse events during the study period. Acceptability was assessed via satisfaction surveys. Individual-level changes in physical activity were examined relative to clinically important differences.

Results: Four out of the 5 peer pairs used the FitBit activity tracker and *friends* function without difficulty. A total of 4 of the 5 pairs completed the 8 weekly phone conversations. There were no adverse events over the course of the study. All peer coaches were "satisfied" or "very satisfied" with the training program, and all participants were "satisfied" or "very satisfied" with the peer-mentored walking program. All participants would recommend this program to others with PD. Increases in average steps per day exceeding the clinically important difference occurred in 4 out of the 5 mentees.

Conclusions: Remote peer coaching using mHealth is feasible, safe, and acceptable for persons with PD. Peer coaching using mHealth technology may be a viable method to increase physical activity in individuals with PD. Larger controlled trials are necessary to examine the effectiveness of this approach.

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KEYWORDS

Parkinson disease; exercise; telemedicine; social support; fitness tracker

Introduction

Background

For persons with Parkinson disease (PD), exercise and physical activity reduce impairments, improve function, enhance quality of life, and potentially modify disease progression [1-4]. Despite this evidence and recommendations by neurologists to exercise [5], most individuals with PD are physically inactive [6]. Walking, a highly accessible form of physical activity, has been shown to decline early in the course of the disease and therefore is an important target of intervention [7,8]. Results of exercise trials in PD reveal the benefits of moderate-intensity walking to reduce disability [9,10]. Although the optimal dose of moderate-intensity exercise in PD is not known, exercise guidelines published by the American College of Sports Medicine [11] for older adults are routinely applied to persons with PD [12,13]. Recommendations consist of 150 min of moderate-intensity exercise per week, the equivalent of approximately 30 min, 5 days per week [11,14]. Studies in PD reveal a pattern of sedentary behavior with 73% failing to reach this recommendation [15]. Studies that have successfully engaged participants with PD in exercise have typically done so under highly controlled conditions, in a clinical setting, under the direct supervision of a health care professional [10,13,16]. However, it is often not feasible or cost-effective for health care professionals to administer exercise programs on an ongoing basis, and clinic-based programs present many logistical barriers over the long term (ie, time constraints, transportation) [17].

A sustainable, scalable approach to increasing participation in long-term physical activity is needed to reduce disability in people with PD. We propose that training peers as coaches, using mobile health (mHealth) technology to facilitate remote interactions, may be a viable approach to help motivate people with PD to participate in exercise over the long term [18]. Peer coaching is a form of support in which peers with the same condition share disease-specific information, strategies for implementing lifestyle changes, and provide psychosocial support to overcome challenges associated with living with a particular condition [19,20]. Peer coaches who successfully participate in regular exercise could support sedentary peers to increase physical activity through cooperative goal setting, modeling the desired behavior, and providing regular feedback toward goals via shared mHealth platforms [20,21].

A growing knowledge base supports the use of peer coaching for people with chronic health conditions [20,21]. For example, those who underwent coronary artery bypass graft surgery experienced increased physical activity and self-efficacy with peer coaching [22]. Studies suggest that peer-led interventions in older adults and in individuals with type 2 diabetes were just as effective in increasing physical activity as professionally delivered interventions [23,24]. A significantly greater effect for long-term maintenance of physical activity (including walking) was found for a peer-led physical activity intervention compared with a control group that received pedometers and access to an exercise facility [25]. In a systematic review of peer-delivered physical activity interventions, increases in physical activity with peer mentoring were greater than those of an attention-matched control group and a no-intervention control group [19].

No theoretically based peer-led program for increasing physical activity currently exists for people with PD. A training program for peer mentors is needed to provide people with PD the skills, knowledge, and support needed to begin this new role [23]. Mentoring people with progressive neurological diseases, such as PD, to increase their physical activity presents several challenges, such as addressing problems with motor skill loss, the nonmotor symptoms such as apathy, as well as the progressive nature of the disease.

Higher self-efficacy for exercise among people with PD has been associated with successful participation in physical activity and therefore may be an important target of treatment [26]. Vicarious experiences, goal setting, and the provision of regular feedback have all been identified as important elements in increasing self-efficacy for exercise [26,27]. Integrating mHealth technology into the peer-mentoring approach could provide a means of incorporating the critical self-efficacy elements into daily life. Previous peer-mentored interventions have used pedometers to increase physical activity; however, the use of an activity tracker that also allows for real-time sharing of accumulated walking data (via FitBit *friends*) provides a more robust mechanism to increase self-efficacy. Using an activity tracker (FitBit) and becoming FitBit *friends* allows for remote interaction while simultaneously providing a medium for vicarious experiences, social comparison, and daily feedback on walking goals.

Objectives

The purpose of this study was to develop a PD-specific peer coach training program and a remote peer-mentored walking program using mHealth technology with the goal of increasing physical activity in persons with PD. Moreover, we set out to examine the feasibility, safety, and acceptability of the programs along with preliminary evidence of individual-level changes in walking activity, self-efficacy, and disability in the peer mentees.

Methods

Development of the Peer Coach Training Program (Peer Coaches Only)

Theoretical Framework

A peer coach training program was developed by the authors based on the self-determination theory and Bandura's social cognitive theory [28,29]. The self-determination theory proposes that autonomy (supported through individualized goals in partnership with coach and by enhancing empowerment), competence (supported through coach focusing on acceptance and affirmations of previous and ongoing successes and strengths with physical activity), and relatedness (supported

through FitBit *friends* and weekly phone conversations) drive motivation for behavior. The social cognitive theory is focused on building self-efficacy through social structures and experiences to drive behavior change. Peer mentoring, with the addition of regular mHealth interactions, may increase social comparison and enhance self-efficacy, leading to the adoption of increased physical activity. The program incorporated key elements from other successful peer coach training programs [20,22,23,30] as well as content that was identified as being important to persons with PD.

Training Program

Before the in-person training, peer coaches were asked to review printed and Web-based educational materials independently over a 1- to 2-week period in their homes at a self-selected pace (approximately 3-4 hours). Educational materials were provided in both hard copy (printed material, handbooks) and on a flash drive with links to websites that provided an overview of PD, the benefits of exercise, strategies to improve motivation, and the benefits of social support as well as an introduction to the activity tracker and peer support [16,31-34]. Information on ethics, roles, and responsibilities of being a peer mentor, and community resources were also provided. Next, peer coaches participated in two, 4-hour, in-person training sessions, separated by 1 week, at the Center for Neurorehabilitation at Boston University. The training program was administered by a physical therapist who was board certified in neurology (CCS). The topics included motivational interviewing, active listening, action plans, and instruction on the technology used in this study and were presented through lectures, discussions, and role-playing (Textbox 1). Case examples related to living with PD were used to integrate these concepts and strengthen skill acquisition.

Study Design and Participants

Trained peer coaches were matched with peer mentees of the same sex based on previous successful peer support programs that matched peer pairs by sex [20,22,35]. Each peer dyad participated in the walking program. All outcomes were assessed at baseline and post intervention with the exception of walking activity, which was measured with the activity tracker at baseline and then during the final 7 consecutive days of activity tracking (Figure 1).

Adults with idiopathic PD were recruited through a patient registry at the Center for Neurorehabilitation at Boston University and postings in the newsletter of the American Parkinson Disease Association, MA Chapter, Information and Referral Center. Interested individuals were screened in person for eligibility. Inclusion criteria included a diagnosis of idiopathic PD (using UK Brain Bank Criteria), Hoehn and Yahr stage of 1-3, Montreal Cognitive Assessment (MOCA) >24, a stable dose of Parkinson's medications for at least 2 weeks before study onset, able to walk without physical assistance or an assistive device for at least 10 continuous minutes, and able to effectively communicate with recruitment personnel. Exclusion criteria were a diagnosis of atypical Parkinsonism, more than 2 falls in the previous month (due to safety reasons), a score of 3 or greater on item number 3 of the Freezing of Gait questionnaire (often or always freezing with walking), and serious comorbidities (ie, heart failure, diabetes mellitus, or cancer) that may interfere with the ability to participate in a walking program. Trained research assistants, who were not involved in the intervention, completed the assessments. Those participants who were meeting or exceeding national exercise guidelines [11,14] by engaging in brisk walking greater than or equal to 150 min per week, measured by self-report, before study onset, were designated as peer coaches. Those who were not walking or walking below this level, before study onset, were designated as peer mentees. This study was approved by the Institutional Review Board at Boston University. Informed consent was obtained from all study participants.

Peer-Mentored Walking Program

Initial Setup

The peer coaches and mentees were given a wireless activity tracker (FitBit Zip) and were instructed on how to use the device during their initial visit to the Center for Neurorehabilitation at Boston University. Participants were instructed on how to view their daily accumulated steps on the activity tracker screen. They were assisted with syncing this tracker with their device(s) (smartphone, tablet, or laptop). Coaches were instructed on how to become *friends* on the Fitbit mobile app, so they were prepared to instruct mentees during their initial interaction.

Walking Goal, Action Plan, and mHealth Interactions

The peer coach contacted the peer mentee, either by phone or email, within 1 week of completing the peer coach training to schedule an initial conversation. This initial conversation focused on establishing rapport, jointly determining the 8-week walking goal for the mentee, and developing the initial action plan. The walking goals for mentees were increased from the step averages obtained via the activity tracker during the baseline period. There was no predetermined increase for the walking goal, as this was individualized and based on the peer coach and peer mentee's mutually agreed-upon goal and action plan. The peer *coach* did not have an explicit step goal. The action plan specified the location, days of the week, time of the day, duration, and with whom the peer mentee would engage in walking activity. The peer coach and peer mentee did not walk together, and instead, they each walked in their own self-selected environment. The action plan also included an assessment of the participant's confidence in their ability to reach their goal. If their confidence to achieve the goal was lower than 80%, the goal was revised until their confidence in achieving the goal was elevated to 80% or greater. The peer coach also instructed the peer mentee on how to become FitBit *friends* during the initial interaction and explained how they could assess the walking goal and view each other's steps remotely. Peer pairs viewed the steps they accumulated over the week using the FitBit *friends* option. The FitBit *friends* feature allows for remote interaction between the peer coach and peer mentee, providing an opportunity for regular feedback (ie, cheering with an emoji or instant messaging) on progress toward goals. Mentees could see the coach's step counts, providing a social comparison and vicarious experiences leading to greater self-efficacy among mentees.

Textbox 1. Peer coach training program: in-person skill-based learning components.

Motivational interviewing

- Spirit
  - Partnership
  - Empowerment
  - Acceptance
  - Compassion
  - Evocation
- Skills
  - Open-ended questions
  - Affirmations
  - Reflections
  - Summaries
- Processes
  - Engaging
  - Focusing
  - Evoking
  - Planning
- Goals
  - Specific
  - Measurable
  - Achievable
  - Relevant
  - Timed

Active listening

- Building rapport
- Enhancing understanding
- Establishing trust

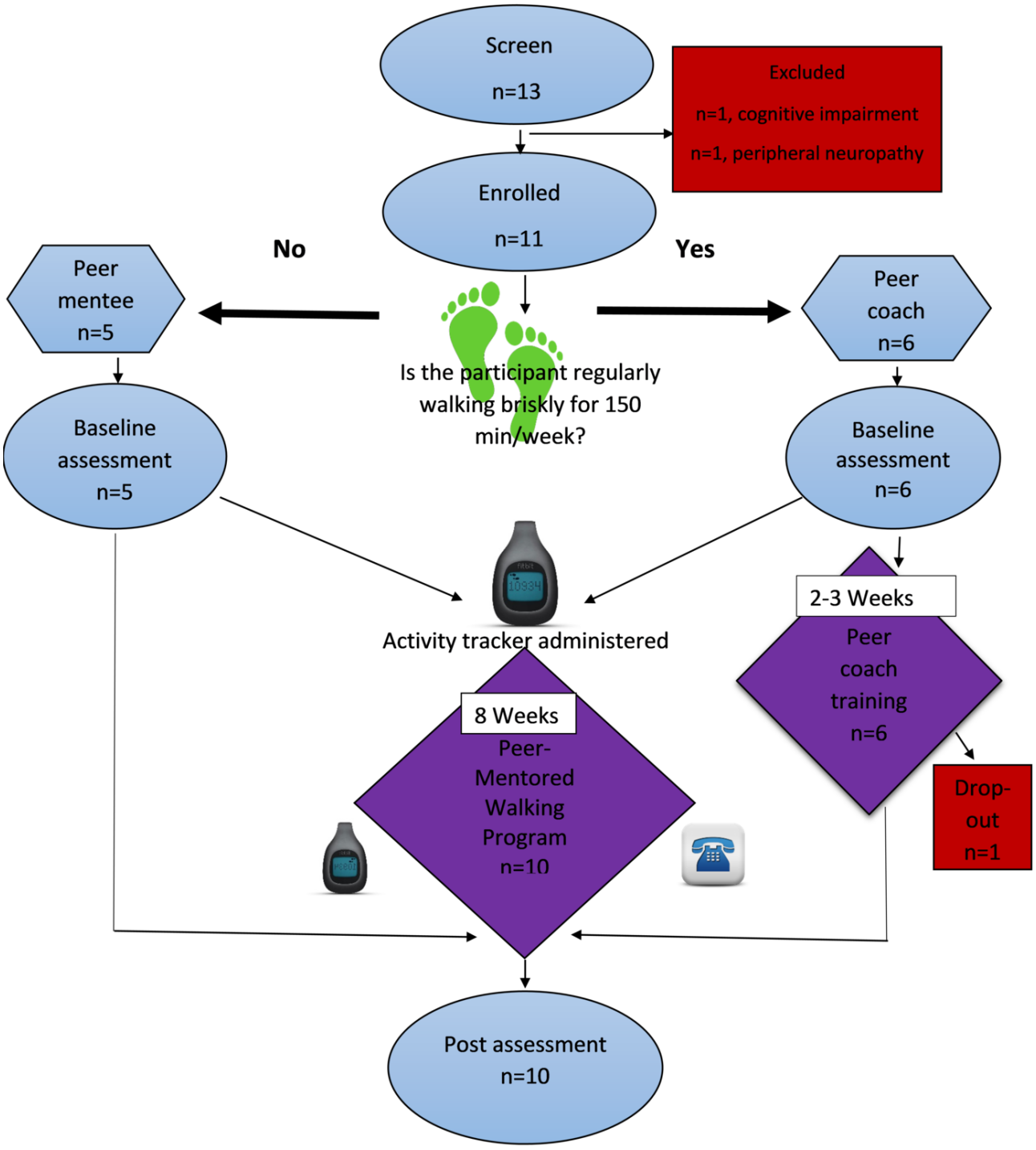
Technology

- FitBit management
  - Donning
  - Changing batteries
  - Syncing with personal device
  - Using the app
  - Using the *friends* function

Action plans

- Self-management
- Assist with specifics (day, time, location, duration, with whom)
- Identifying barriers
- Dealing with conflict

Figure 1. Participant flowchart.



Weekly Phone Calls

The peer coach and mentee engaged in phone conversations weekly over the 8-week study period from the convenience of their own homes. Peer coaches were given paper calendars for scheduling weekly phone calls and guiding checklists to guide peer discussions to ensure that they were adhering to the recommended techniques for peer mentoring. Peers discussed the following elements on the guiding checklist: assessing the walking activity goal of the peer mentee, progress made, problems encountered, strategies to overcome barriers, and resources available. They jointly solved the problem about how to increase participation in walking activity within daily life at home and in the community.

Guidance and support was provided by the physical therapist on the research team to the peer coaches via conference calls, following the initial and 4-week mentor-mentee conversations. This included reinforcing the role of the peer coach, ensuring successful use of the activity tracker, and strategies to assist coaches with potential challenges encountered when mentoring the peer mentee.

Outcomes

Feasibility

Feasibility was determined by examining recruitment, participation, and retention rates. Recruitment was assessed by examining recruitment rates and the sample characteristics of those recruited. Participation was assessed by monitoring the completion of phone calls between the peer coach and peer mentee, which were recorded by the peer coaches on a calendar (63%, 5/8 calls set as criteria), and use of the mHealth platform (80%, 4/5 peer pairs as criteria). Retention was assessed by tracking the number of participants who completed the peer coach training program (coaches only) and mentored walking program (coaches and mentees) (80%, [5/6] retention for peer coach training program and 80% [9/11] retention for mentored walking program set as criteria).

Safety

Adverse events were monitored throughout the study period. Participants were instructed to contact a research assistant if there were any falls or a change in status that led to medical attention. Contacts were to be recorded in a database by the research assistant.

Acceptability

At the final assessment, peer coaches responded to 12 questions about their satisfaction with the training program and 7 questions about their perception of the effectiveness of the training program. Acceptability criteria were set as 80% (4/5) of participants were satisfied to very satisfied, agreed that the training was clear , and had confidence in their ability to coach after the training . A 1-hour focus group was conducted with all peer coaches 1 week after the last peer interaction to discuss successes, challenges, and reactions to the peer coaching experience. A research assistant took detailed notes throughout the session. Peer mentees responded to 13 questions about their satisfaction with the peer-mentored walking program (80% satisfied to very satisfied, endorsed the peer interaction was enjoyable, and built confidence to manage physical activity were set as criteria).

Walking Activity

Using the activity tracker, walking was measured as average steps per day for 7 days, active minutes per week, and the frequency of achieving 30 min of fairly active to very active minutes over 7 days before the peer-mentored walking program began and again over the last 7 consecutive days in which the activity tracker was worn. Research assistants downloaded all activity data during the participants' last study visit.

Self-Efficacy

Self-efficacy was measured using the Self-Efficacy for Walking-Duration, a 10-item questionnaire that assesses self-efficacy for walking moderately fast for 5-min increments, beginning with 5 min and increasing to 40 min. For each item, participants indicated their confidence to execute the behavior on a 100-point percentage scale comprising 10-point increments, ranging from 0% (not at all confident) to 100% (highly confident). The internal consistency of this scale has been found to be excellent (alpha>.95) [36].

Disability

Disability was measured using the Late Life Function and Disability Instrument (LLFDI), which assesses disability in community-dwelling older adults [37]. The 16-item disability component has the participant rate activities, in terms of frequency and difficulty, for each item in this section (eg, How often do you participate in a given activity; to what extent do you feel limited in doing a particular activity?) The LLFDI limitation-scaled score ranges from 0-100 points. A score of 0 indicates no to low participation, whereas a score of 100 indicates high levels of participation in socially defined life tasks.

Data Analysis

Feasibility, safety, and acceptability measures were analyzed using descriptive statistics. Mean changes were calculated for all secondary outcomes, and individual change scores were assessed to determine if they exceeded the minimal detectable change (MDC) or minimally clinically important difference (MCID), if known.

Data collected from peer coaches during the focus group and responses to open-ended questions in the satisfaction surveys were analyzed and coded for themes. Data from peer mentees' open-ended questions within the satisfaction surveys were also analyzed and coded for themes. Coding for themes was completed by 1 researcher (CCS) with review by 2 additional researchers (TE and LQ).

Results

Feasibility: Recruitment Capability, Participation, and Retention

A total of 15 potential participants expressed interest in taking part in the study. In addition, 2 individuals did not agree to participate because they had pre-existing conflicts with the scheduled peer coach training sessions. Of the 13 that agreed to participate, 1 participant was excluded due to lower extremity peripheral neuropathy and the other due to cognitive impairment. This resulted in 11 participants enrolled in the study. One peer coach dropped out of the study due to time constraints. A total of 5 peer coaches completed the peer coach training. In summary, 10 individuals participated in the study, 5 peer coaches and 5 peer mentees (Figure 1). All individuals that finished the peer coach training (n=5) completed their roles as peer coaches over the 8-week intervention period. All peer mentees (n=5) completed the 8-week mentored walking program. All peer coaches and peer mentees exceeded the 80% criteria for retention. In all, 4 out of the 5 peer pairs completed 100% of weekly calls. Moreover, 1 peer pair missed 2 weekly calls due to scheduling conflicts. All peer dyads reached the 63% criteria for participation. A total of 4 out of the 5 peer pairs used the FitBit activity tracker and *friends* function without difficulty. Furthermore, 1 peer pair had technological difficulties (loss of the FitBit device, management of the battery, or syncing the activity tracker with a personal device).

Resulting Sample Characteristics

The majority of the participants were male and highly educated. Participant characteristics are presented in Table 1.

Table 1. Demographics of participants.

Variable	Peer coach (n=5)	Peer mentee (n=5)
Age in years (SD)	64.6 (4.04)	63.4 (2.06)
Education in years (SD)	18.0 (0.89)	16.8 (1.02)
Male, n (%)	3 (60)	3 (60)
Race (white), n (%)	5 (100)	4 (80)
Disease duration in years (SD)	5.2 (1.24)	6.2 (2.2)
Hoehn and Yahr stage, n (%)		
Stage 1	3	1
Stage 2	1	3
Stage 3	1	1

Safety

No adverse events occurred over the duration of the study.

Acceptability

All peer coaches (100%, 5/5) agreed that the material presented in the training was clear; however, some (40%, 2/5) reported difficulty with the length of the in-person training sessions and had suggested shorter sessions. The majority (80%, 4/5) of the peer coaches felt confident in their ability to be a peer coach after the training; however, 1 individual (20%) was neutral in their confidence to be a peer coach. All peer mentees (100%, 5/5) enjoyed interacting with their peer coaches. The majority (60%, 3/5) of peer mentees agreed that their peer coaches helped them to become confident to manage their walking activity; however, 2 (40%) of the peer mentees were neutral about the peer coach building their confidence. All participants (100%, 10/10) who participated in the peer interaction would recommend this peer coaching program to others with PD. All participants (100%, 10/10) were satisfied or very satisfied with the peer coach training or peer-mentored walking program.

Participant Perspectives (Focus Group and Open-Ended Questions)

Peer Coach Training

Peer coaches recommended shorter in-person training sessions due to fatigue and difficulty learning new material all at one time. Peer coaches had a positive reaction to learning coaching skills, which included active listening, and being flexible and nonprescriptive. Coaches reported ease of use with the training manual and Web-based resources that were completed independently in the home environment.

Peer-Mentored Walking Program

Themes that emerged from peer coaches and peer mentees included factors that enhanced or deterred rapport or communication as well as factors that enhanced or deterred physical activity. Rapport and communication enhancers included sharing feelings, goals, and experiences. All peer coaches reported being able to successfully interact with their peer mentee via the mHealth platform. Some participants desired face-to-face interactions to enhance rapport. One example of this theme was a participant stating:

> *Starting with a face-to-face meeting establishes rapport and would be helpful.*

Others indicated that they "would have liked to meet the person" and that they would have liked to "do some things together." Rapport and communication deterrents included time constraints, power dynamics, and difficulties hearing over the phone. This theme, specifically power dynamics, was illustrated by 1 peer coach stating:

> *She [mentee] kept changing subjects and not answering questions that I [coach] asked.*

Physical activity enhancers included competition and activity monitoring by peer pairs using the activity tracker and mHealth app. Peer coaches described the effect of sharing walking data via the mHealth platform as creating a "friendly competition," a "gentle rivalry," and "encouraging each other."

One participant commented when asked about what was positive about the peer interaction:

> *...the competitive nature was even more motivating than just using the FitBit [alone].*

Physical activity deterrents included time constraints with 1 peer coach stating:

> *I was going through a really busy time at work and so I was much less active.*

The themes from the peer coaches and peer mentees were consistent between pairs and reflected what the opposite member reported.

Walking Activity

In the peer mentees, mean steps per day increased by 31% from 5428 (SD 2440) to 7115 (SD 1291) steps. The increase in 4 of the 5 peer mentees exceeded the MCID of 779 steps per day reported for individuals with a chronic neurological condition [38] (Figure 2). In all peer mentees, mean active minutes (fairly active to very active minutes) per week increased by 42% from 199 (SD 95) to 282 (SD 83) min per week. The change in these active minutes ranged from a decline of 89 min to an increase

of 193 min per week, in the peer mentees (Figure 3). The MCID for active minutes in those with PD has yet to be determined. At baseline, peer mentees were achieving the recommended daily 30 min of fairly active to very active minutes 43% of the week (~3/7 days per week). After participating in the intervention, they were achieving this recommended activity level 63% of the week (~4/7 days per week).

Figure 2. Peer mentees' initial and post average steps per day.

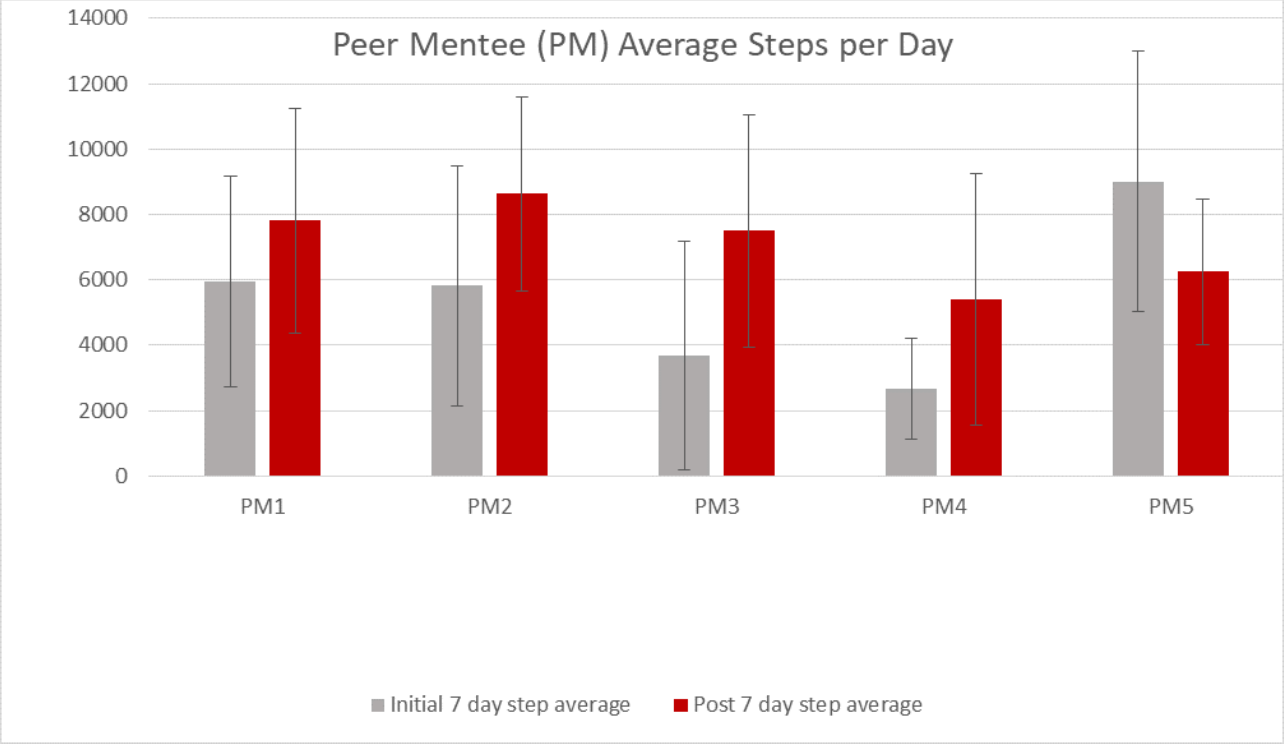
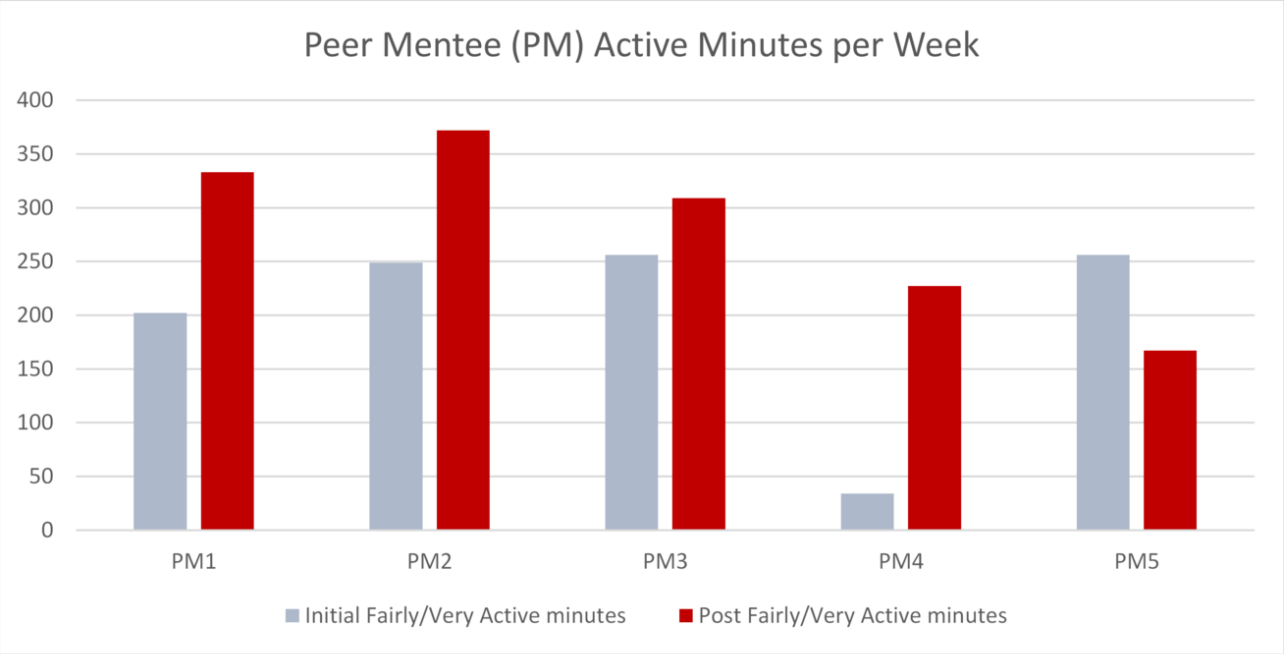


Figure 3. Peer mentees' initial and post fairly to very active minutes per week.



Self-Efficacy

The mean self-efficacy for peer mentees increased from 66.8 (SD 25.7) points at baseline to 70 (SD 25.9) points post intervention. Clinically important differences were not established for this measure.

Disability

For the LLFDI, the mean score (limitation score) was 72.2 (SD 5.9) points at baseline and increased (improved) to 73.7 (SD 10.0) post intervention. A total of 3 of the 5 peer mentees had an increase or improvement (1.76-9.28 points); however, these changes did not exceed the MDC (MDC 90) of 11.62 points,

suggesting that changes in disability were not clinically meaningful [37].

Discussion

Principal Findings

The purpose of this study was to develop and evaluate the feasibility, safety, and acceptability of a peer coach training program and a remote peer-mentored walking program to promote physical activity for persons with PD. In addition, we sought to examine preliminary evidence of individual-level changes in walking activity, self-efficacy, and disability in the peer mentees. This study revealed that people with PD could be successfully trained as coaches with the goal of increasing physical activity in peers with PD. The remote peer-mentored walking program was feasible with 4 out of the 5 peer pairs completing all 8 phone calls and most (4 out of the 5) peer coaches successfully using the mHealth platform to share walking data. The program was safe with no adverse events reported during the study period. The peer coach training program was acceptable with 100% of the coaches reporting being satisfied to very satisfied with the coaching program and feasible with 5 out of the 6 peer coaches completing the training program. Both programs were acceptable to peer coaches and peer mentees, with 100% recommending peer coach training/peer-mentored walking program to others with PD. Clinically meaningful gains in walking occurred in 4 out of the 5 peer mentees with low levels of physical activity (<6000 steps per day) at baseline, suggesting the potential benefits of a peer mentoring approach to improve physical activity in persons with mild to moderate PD who are physically inactive.

Comparison With Prior Work

Peer coaches, in this study, were individuals with PD who were consistently walking briskly for greater than or equal to 150 min per week, based on the national physical activity guidelines [11,14]. However, it is unknown if the best person to be a coach is one who has already reached the targeted goal or one that is concurrently working on a target goal with the peer mentee. Sharing both stressful and rewarding experiences creates successful peer relations; therefore, the optimal walking physical activity criteria for a peer coach require further exploration [39]. In addition, research regarding the best method to match peer coaches and mentees is in its infancy [40,41]. Peer mentees were matched with a peer coach based on sex only, based on previous successful peer coaching interventions [20,22] and qualitative data indicating this preference [35]. However, peers expressed a desire for matching based on other potentially important characteristics (ie, career, education level, exercise mode, and geography). Other studies matched peers on sociocultural characteristics such as race [42,43] and revealed improvements in glucose control in those with diabetes [42] and decreased depressive symptoms in breast cancer survivors [43]. Different forms of peer matching have yet to be directly compared.

The majority (4 out of the 5) of peer mentees increased their steps per day (1864-3794 steps per day) and exceeded the MCID of 779 steps per day suggested for individuals with chronic progressive neurological disease [37]. Our finding of a 31% increase in mean steps per day among peer mentees is important because a 30% deficit has been reported in steps per day in people newly diagnosed with PD (compared with those without PD)[8]. The increase in active minutes per week is encouraging due to the large decline in active minutes per week (nearly 45 min per week) found in a previous 12-month observational study of walking activity in people with PD [7]. Finally, two of the peer mentees were no longer categorized as sedentary by week 8 [44]. Although gains in walking cannot be attributed to the peer mentoring program in this uncontrolled study, these results suggest the potential of this approach in persons with PD. Larger controlled trials in PD are needed to determine the effectiveness of this approach in increasing physical activity.

Although 4 out of the 5 peer mentees did experience increased daily step averages, there was not a commensurate decrease in disability. Given the relatively slow progression of PD that occurs over many years, it is likely that active engagement with increased levels of physical activity over longer periods would be necessary to reduce disability. In addition, the responsiveness of the LLFDI in PD is not known. Given that the intervention specifically targets walking, measures that focus on walking-related changes in disability (ie, 6-min walk test, 10-meter walk) may be more responsive and should be included in future studies.

We targeted self-efficacy through the FitBit *friends* feature and through motivational interviewing during phone conversations. Remote interactions between the peer coach and peer mentee provided an opportunity for goal setting and feedback on whether goals were attained. Peer coaches provided affirmations to increase empowerment and self-management of physical activity levels while living with PD. Mentees could see the coaches' step counts, providing a social comparison and vicarious experiences that may have contributed to the positive but small increase in self-efficacy observed over the course of this study. Further investigation in a larger controlled trial is necessary to determine if self-efficacy is an important mediator of change in physical activity levels.

Although other studies have reported successful strategies to increase physical activity levels in persons with chronic neurological conditions, they rely on health care professionals to deliver the intervention. In a study that aimed to increase physical activity in individuals with multiple sclerosis, the behavioral coach was a graduate student with expertise in behavior change and physical activity [45]. A behavioral intervention delivered by physical therapists in persons with PD resulted in an increase in physical activity as measured by activity monitors [46]. Reliance on health care professionals may be cost-prohibitive for long-term application. A remote peer-mentoring approach using mHealth technology also allows for social modeling and shared experiences of living with the same condition, a potentially important element to facilitate meaningful lifestyle changes over the long term [27,47]. The use of remote peers, rather than health care professionals, offers a potentially cost-effective and scalable option to reduce sedentary behavior in those with PD and other chronic neurological conditions [48]. Embedding peer coaching within a preexisting health care structure (eg, partnering with physical therapists, neurologists, or movement disorder specialists) may

optimize broader implementation and requires further investigation [49].

Limitations

There are several limitations of this study. Considering the long-term nature of PD, the feasibility of peer coaching was examined over a relatively short period (8 weeks). The long-term feasibility of peer coaching in PD requires further investigation. In addition, this study did not have a control group; therefore, the increases in physical activity cannot be attributed to the peer coaching intervention. In addition, our sample was small, highly educated, and lacking in racial diversity; therefore, the results may not be generalizable to the broader population of people with PD. Selection bias may also limit generalizability of our results as participants were volunteers interested in participating in an exercise study. Although consumer-based activity trackers (FitBit) have been shown to be reasonably accurate in measuring step counts in the healthy population, the accuracy in those with PD has not been established [50]. Despite this limitation, waist-worn commercially available accelerometers are ecologically valid tools that are supported for use in clinical trials assessing walking activity in those with neurological conditions [51].

Conclusions

Training people with PD to provide coaching targeting physical activity in persons with PD is a feasible approach. In addition, a remotely delivered peer-mentored walking program using mHealth technology is a feasible, safe, and acceptable approach in persons with mild to moderate PD. Larger controlled trials over longer periods are needed to further investigate the effect of peer coaching on increasing physical activity with the goal of improving function and reducing disability in those with PD.

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Conflicts of Interest

None declared.

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Abbreviations

LLFDI: Late Life Function and Disability Instrument
MCID: minimally clinically important difference
MDC: minimal detectable change
mHealth: mobile health
MOCA: Montreal Cognitive Assessment
PD: Parkinson disease

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Original Paper

A Smartphone App to Promote an Active Lifestyle in Lower-Educated Working Young Adults: Development, Usability, Acceptability, and Feasibility Study

Dorien Simons[1,2], MSc; Ilse De Bourdeaudhuij[3], Prof Dr; Peter Clarys[2], Prof Dr; Katrien De Cocker[3,4], Dr; Corneel Vandelanotte[5], Prof Dr; Benedicte Deforche[1], Prof Dr

[1]Health Promotion and Education Unit, Department of Public Health, Ghent University, Ghent, Belgium

[2]Physical Activity, Nutrition and Health Research Unit, Faculty of Physical Education and Physical Therapy, Vrije Universiteit Brussel, Brussels, Belgium

[3]Department of Movement and Sport Sciences, Faculty of Medicine and Health Sciences, Ghent University, Ghent, Belgium

[4]Physically Active Lifestyles Research Group, Institute for Resilient Regions, University of Southern Queensland, Springfield Central, Australia

[5]Physical Activity Research Group, School for Health, Medical and Applied Science, Central Queensland University, Rockhampton, Australia

Corresponding Author:
Dorien Simons, MSc
Health Promotion and Education Unit
Department of Public Health
Ghent University
Corneel Heymanslaan 10
Ghent, 9000
Belgium
Phone: 32 498457442
Email: dorien.simons@ugent.be

Abstract

Background: Physical activity (PA) levels are problematic in lower-educated working young adults (18-26 years). To promote PA, smartphone apps have great potential, but there is no evidence for their effectiveness in this population. To increase the likelihood that a newly developed app will be effective, formative research and user testing are required.

Objective: The aim of this study was to describe the development, usability, acceptability, and feasibility of a new theory- and evidence-based smartphone app to promote an active lifestyle in lower-educated working young adults.

Methods: The new app was developed by applying 4 steps. First, determinants important to promote an active lifestyle in this population were selected. Second, evidence-based behavior change techniques were selected to convert the determinants into practical applications. Third, a new smartphone app was developed. Fourth, volunteers (n=11, both lower and higher educated) tested the app on usability, and lower-educated working young adults (n=16) tested its acceptability and feasibility via (think aloud) interviews, a questionnaire, and Google Analytics. The app was accordingly adapted for the final version.

Results: A new Android app, *Active Coach*, was developed that focused on knowledge, attitude, social support, and self-efficacy (based on outcomes from step 1), and that applied self-regulation techniques (based on outcomes from step 2). The app consists of a 9-week program with personal goals, practical tips, and scientific facts to encourage an active lifestyle. To ensure all-day and automatic self-monitoring of the activity behavior, the Active Coach app works in combination with a wearable activity tracker, the Fitbit Charge. Issues detected by the usability test (eg, text errors, wrong messages) were all fixed. The acceptability and feasibility test showed that participants found the app clear, understandable, and motivating, although some aspects needed to be more personal.

Conclusions: By applying a stepwise, user-centered approach that regularly consulted the target group, the new app is adapted to their specific needs and preferences. The Active Coach app was overall positively evaluated by the lower-educated working young adults at the end of the development process.

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KEYWORDS

mHealth; young adult; mobile applications; physical activity; active transport; health promotion

Introduction

Emerging adulthood is a period ranging from the late teens through the twenties and comprises various turning points in life such as changes in education, employment, or place of residence [1,2]. These changes have shown to be associated with a decrease in physical activity (PA) and active transport (AT) levels [3-6], making young adults (18-26 years) an important target group for the promotion of an active lifestyle. Additionally, young adults' PA and AT choices are likely to remain stable over time and provide long-term health benefits in adulthood [7,8]. In Belgium, approximately 50% of 15-24 year olds does not reach the recommended 30 min of moderate PA a day [9], which increases their all-cause mortality risk with 11.4% [10]. AT represents an opportunity to include PA into young adults' busy daily life [11]. Young adults who started working around the age of 18 years and who did not complete higher education (college or university) have an even higher risk for inactivity because of their lower educational attainment. Among adults of all ages, lower levels of education have been associated with lower levels of general PA [2,12], less AT [13,14], and higher levels of overweight and obesity, and prevalence of common chronic diseases [15]. As such, there is a clear need to promote an active lifestyle in lower-educated working young adults.

Recent technologies such as smartphones, health and fitness apps, and consumer wearable activity trackers have great potential as tools for assessing and promoting PA in all age groups [16-20]. Smartphone apps can measure PA and AT and provide feedback in real time; provide interactive, individualized, and automatically generated content; and deliver materials on a device (ie, smartphone) that is already carried by the individual [21]. In addition, consumer wearable activity trackers are a popular and growing market for monitoring PA and can be used in combination with smartphones [20]. Smartphones are gaining popularity worldwide, and they are most popular among young adults. In the United States [22] and Belgium [23], respectively, 85% and 80% of young adults own a smartphone. Young adults and lower socioeconomic subgroups in high-income countries tend to use mobile phones more compared with other age groups and high socioeconomic subgroups [22,24-26]. Due to their potential and popularity, smartphone apps might be a good tool to promote an active lifestyle in lower-educated working young adults.

Many PA apps are already available through app stores such as Apple App Store and Google Play Store. However, most of these apps are not developed in collaboration with health professionals or academics, do not incorporate theoretical content, and have a relative absence of evidence-based behavior change techniques (BCTs) [27-32]. Additionally, the existing PA apps might not be appropriate for certain target groups such as lower-educated working young adults, as they are not specifically adapted to their lifestyle and cognitive capacities. Therefore, developing a new theory- and evidence-based PA app tailored to the needs of this target group is necessary.

Developing a new theory- and evidence-based smartphone app requires conceptualization (reviewing evidence, understanding of the needs and perspectives of the intended users, deciding on the theoretical basis, planning the developmental process), formative evaluation, and pretesting the acceptability (is the target group willing to receive the strategies?) and feasibility (is it realistic to consider implementing the proposed strategies?), before evaluating its effectiveness [33-38].

Only a few mobile health (mHealth) studies have described these developmental steps in detail [34]. It is important to present this process to help others in developing effective tools to improve health [33]. Therefore, the aim of this study was to describe the development, acceptability, and feasibility of a new smartphone app (Active Coach) to promote an active lifestyle in lower-educated working young adults.

Methods

Approach

A stepwise approach, consisting of 4 steps, based on the Intervention Mapping Approach and the developmental steps for mHealth interventions, was used in the development of the new app [34,39]. In step 1, determinants important to promote an active lifestyle among low-educated working young adults were selected. In step 2, evidence-based BCTs [40] were selected to convert the determinants into practical applications. In step 3, a new smartphone app called "Active Coach" was developed. In step 4, the Active Coach app was tested on errors, acceptability, and feasibility and accordingly adapted for the final version. In this chapter, only the methods of the 4 steps will be described. The results (including the content of the app) will be described next in the *Results* section. This study was approved by the ethics committee of the university hospital of Ghent University (B670201525362) and by the ethics committee of the Vrije Universiteit Brussel (BUN 143201112745).

Step 1: Selecting Determinants

To develop an evidence- and theory-based app, determinants important to promote an active lifestyle in lower-educated working young adults need to be selected. The selection was based on the existing literature, previous studies from our research group, a theoretical health behavior change model, and an exploratory qualitative study among lower-educated working young adults (see Results step 1 [4,41-57]).

In the qualitative study, focus groups were conducted among lower-educated working young adults to assess determinants of an active lifestyle (PA and AT). In addition, opinions about mobile technologies (eg, smartphones, tablets, apps, fitness trackers) and valuable features of PA apps and their use to promote an active lifestyle were explored. Eligible participants had to be employed, aged between 18 and 26 years, and without a university or college degree (lower educated). Participants (n=34, mean age: 24.0 [SD 3.0] years, 59% [20/34] men, mean years of employment: 3.0 [SD 2.0]) were recruited throughout Flanders (northern part of Belgium). Snowball and convenience

sampling, two nonprobability approaches often used in qualitative research [58], were used to recruit participants via the personal network of researchers and assistants and via social media. Five focus groups (6-10 participants per group) were conducted at places that were most convenient for the participants. Focus groups were conducted until saturation, which is the point at which all questions have been thoroughly explored in detail and no new concepts or themes emerge in subsequent sessions [59]. All focus groups were held in Dutch and lasted approximately 60 min. A focus group protocol and a semistructured discussion guide (Table 1) were developed consistent with the recommended focus group methodology [60]. The guide consisted of several questions, including an introduction question, a transition question, key questions, and an ending question. For some questions, participants were asked to write down an answer. This method allows participants to think and reflect about a question before starting a group discussion and not to copy other participants' answers or opinions. Before the discussion started, the participants provided informed consent and completed a brief questionnaire obtaining sociodemographic information. The discussions were led by a moderator. Notes were taken by an observer. With permission of the participants, all conversations were audiotaped for transcription. The focus group interviews were transcribed verbatim, and the texts were incorporated into a qualitative processing program (NVivo 9 qualitative software, QRS International). The data were analyzed based on grounded theory. Grounded theory is a method of analyzing qualitative data without preconceived theories and is characterized by intensively analyzing data, often sentence by sentence or phrase by phrase [61]. During the transcription of the conversations, we developed codes according to the responses and the themes that arose frequently and were relevant to the aim of the study. Data obtained by the questionnaire were entered into SPSS (version 23.0) to calculate descriptive statistics.

Step 2: Selecting Behavior Change Techniques

BCTs were used to translate the selected determinants into practical applications that will be used in the new app [40]. BCTs are the active component of an intervention designed to change behavior [62]. Michie et al [40] developed a BCT taxonomy of 93 hierarchically clustered techniques. BCTs were selected based on their previously demonstrated effectiveness and on the focus group results (see Results step 2 [25,39,40,63-70]).

Step 3: Developing the App

On the basis of the translation of the BCTs into practical applications and on the basis of the results from the focus groups, a new app was developed in cooperation with a commercial mobile app development company (Cucumber Apps). It is a native Android app (only developed for the Android operating system), which means that it is completely compatible with the smartphone's native features and hardware (eg, accelerometer, camera, GPS) and ensures the best user experience [71]. In 2015, Android was the operating system with the highest penetration rate in the smartphone market worldwide (80% Android vs 19% IOS) [72] and among 15- to 35-year-olds in Belgium (57% Android vs 37% IOS) [23]. Moreover, developing an app for iPhone (IOS) would be too expensive and too time-consuming.

The content of the app was developed to incorporate an autonomy-supportive communication style, based on the self-determination theory [73]. Self-determination theory suggests that the content of goals (ie, intrinsic vs extrinsic) and the way goal contents are communicated (ie, autonomy-supportive vs controlling) explain variance in people's motivation and performance [74]. Autonomy-supportive includes a more motivating language (can, may, want) instead of a controlling language (should, have to). The first version of the intervention content was read and evaluated by junior and senior researchers in the field of public health (n=19, mean age: 26.2 [SD 5.1] years, 26% [5/19] men). They were consulted because of their experience and knowledge regarding public health interventions. After adapting the first version, interviews were held with lower-educated working young adults (n=10, mean age: 23.0 [SD 2.0] years, 50% [5/10] men) to check the usefulness, applicability, and understandability of the content. Participants were recruited using convenience sampling, and the interviews were audiotaped and transcribed verbatim. Analyses were conducted as described in step 1.

Step 4: Testing the App on Usability, Acceptability, and Feasibility

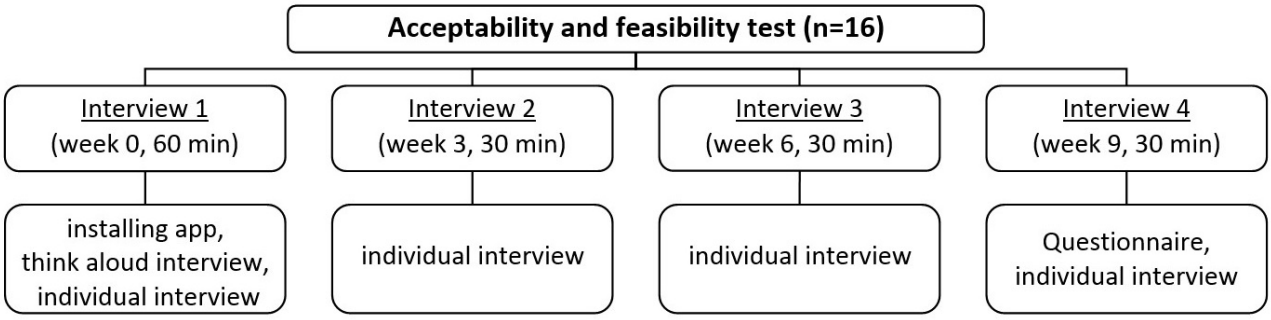
First, usability of the app was tested by a small group of volunteers (n=11, mean age: 28 [SD 10] years, 55% [6/11] men, both lower and higher educated) who checked the app for faults and errors (also known as "bugs"). Nielsen et al [75] showed that conducting usability testing with only 5 participants will reveal 85% of usability problems. These volunteers (all different from the focus group participants recruited in step 1) needed to own an Android smartphone and were recruited via the personal network of researchers and colleagues in 2016 (convenience sampling). They installed the app and used it for approximately 5 weeks. All problems mentioned by the volunteers were collected by the researchers via an issue list and passed on to the developers. Accordingly, the app was adapted.

Next, the adapted version of the app was tested on acceptability and feasibility by lower-educated working young adults. A contact list of the previously conducted focus groups (see step 1) was used as a basis to recruit participants via snowball and convenience sampling. In addition, participants were recruited via a social employment business with several projects for lower-educated people (VZW Ateljee, Ghent). A total of 4 participants of the acceptability and feasibility test had participated in the previously conducted focus groups; all other participants were new. Participants (n=16, mean age: 24.4 [SD 2.3] years, 63% [10/16] men, mean years of employment: 3.7 [SD 2.3] years) had to possess an Android smartphone. During the acceptability and feasibility test, 4 interviews were conducted with each of the participants during a 9-week period (1 interview every 3 weeks; see Figure 1).

Table 1. Focus group semistructured discussion guide. PA: physical activity.

Question type	Purpose	Question
Intro	To begin discussion of topic	Write down 5 reasons why you are or would like to be physically active.
Transition	To move toward the key questions	Now we are going to discuss your answers.
		How much or how often do you think you need to be physically active to stay healthy?
		Do you think you are physically active enough to stay healthy?
		Is your amount or level of PA changed since you started working? Why?
Key	To obtain insight about determinants of PA	Would you like to be more physically active?
		Write down 3 activities that involve PA and that you would like to do, but that you do not do for one reason or another.
		Write down 5 reasons why you would not be physically active enough or difficulties you have to be regularly physically active.
		Now we are going to discuss your answers.
		Which solutions may help you to overcome these barriers that you just summed up?
		Have you ever tried to be more physically active? How?
Transition	To move toward the key questions on mobile technologies and PA apps	Do you have a smartphone? How often do you use your smartphone?
		Why do you use your smartphone? (short message service, calls, apps, internet, etc)
		Do you use PA apps, such as Runkeeper, runtastic? Why (not)? What do you think of those apps?
		Does anyone use a fitness tracker, a device or bracelet that tracks your activity? Do you know it? What do you think of it?
Key	To obtain insight about mobile technologies and PA apps	This is an example of a smartphone app (Stappenteller) that tracks your daily steps. • What do you think of it? • What do you think of the design of this app? • Do you think this app is clear, do you understand everything? • This app can only work when you have your smartphone with you. Do you always have your smartphone with you? Yes or No? Why (not)? Is it feasible for you to always carry your smartphone with you? • Would you like to use this app? Why (not)? • Could this app help you to become more active? Why (not)?
		Do you have a computer, laptop or tablet at home? (How often) do you use it? Do you have Internet access on those devices?
		Who has a Facebook account? How often do you use it? Do you also use other social networks such as Twitter, Instagram, LinkedIn, Google Plus...?
		Would you like to get information about the importance of PA and how you can increase your PA? Why (not)? • What information would you like? • Would you prefer reading that information on your computer (website) or on your smartphone (app)?
		Here is an example of a page (Can be a website or an app) on which information and tips about PA are shown. On this page a few questions are asked so that the information and tips can be personalized. A PA goal is also set. • Would you fill in those questions to receive personalized information? • What do you think about the question to fill in your step count? (would you fill it in? Would you cheat? Does it need to be automatic?) • What do you think about the goal that is set? Would you rather choose your own goal? • What do you think of the information displayed here? • Do you think this page should be linked to Facebook or another online social network? • Would you like to share your results or progress with others? Why (not)? • If this page was a website, how much would you use it? Why? • How long would you use the page and the given information? Why?
Ending	To bring closure to the discussion	Does anyone have suggestions or additions?

Figure 1. Flowchart of the acceptability and feasibility test (Step 4).



During the first interview (week 0), participants were informed about the purpose of the study. They were asked to sign an informed consent form and to complete a questionnaire about sociodemographics. A think-aloud interview was conducted during the download, install, registration, and first use of the app. In the think-aloud interview, participants were asked to use the app and say out loud any thoughts that came to mind. This is particularly useful as people give their immediate reactions to every element of the app, and it allows researchers to observe how it was used [76]. Afterward, a brief semi-structured interview (Table 2) was conducted to discuss issues that came up during the think-aloud interview and to ask additional questions. During the second (week 3) and the third (week 6) interview, the same semistructured interview was conducted to obtain intermediate information about participants' experiences with the app (Table 2). During the fourth interview (week 9), a paper-and-pencil questionnaire, based on existing questionnaires assessing acceptability and feasibility, was used to evaluate specific elements of the app [77,78]. Moreover, 4 questions on a 5-point scale from 1 (strongly disagree) to 5 (strongly agree) were used to assess general opinions about the app (ie, clear, fun, user-friendly, attractive), opinions about the tips and facts (ie, interesting, motivating, boring), and opinions about the goals received (ie, motivating, useful, tried to achieve it). After completing the questionnaire, a semistructured interview was held to discuss the answers of the questionnaire in more detail (Table 2). All interviews were held in Dutch and were audiotaped for transcription with permission of the participant. Analyses were conducted as described in step 1. In addition, Google Analytics [79] was used to obtain app usage statistics and evaluate how participants used the Active Coach app. Google Analytics offers free tools to measure website and app data to gain usage insights.

Table 2. Semistructured discussion guide.

Questions during interview 1, 2, 3, and 4	Additional instructions
So far, what do you like or dislike about the Active Coach app?	What did you find good or not good?
	Why do you think that was good or not good?
	Can you tell a bit more about that?
Are there certain parts of the app that you find confusing or that you do not understand?	Which parts are confusing?
	Can you tell me more about that?
	Why do you think that?
	How could this be improved?
What change(s) would you recommend to improve the app?	Design, color, font, content, ease of use
	Why do you think that would improve the app?
	Can you tell me more about that change?
Are there certain parts of Active Coach app that definitely should stay the same?	What are they?
	Can you tell me a bit more about that?
	Why do you think that?
What do you think of the use of the Fitbit Charge?	Why do you think that?
	Can you tell me a bit more about that?
Are there any problems or difficulties while using the Active Coach app or the Fitbit?	Which one?
	Can you tell me a little more about that?
What do you think of the daily and weekly goals?	Do you manage to achieve your goal?
	How useful do you find these goals?
	Have these goals helped you to be more active?
	What do you like or dislike about the goals?
	Can you tell me a little more about that?
What do you think of the tips you get each Monday and Friday?	Have you read the tips and facts?
	Do you sometimes reread the tips and facts?
What do you think of the facts you get each Wednesday?	How useful do you find these tips and facts?
	Do these tips or facts help you to be more active?
	What do you think of the amount of tips and facts?
	Would you like to get more or less?
	What do you like or dislike about the tips and facts?
	Can you tell me a little more about that?
Do you use the app regularly?	Do you use the app more, the same, or less than in the beginning? Why?
What makes you continue to use the app?	Would you continue to use the app if you were not participating in a study? Why (not)?
What would be the main reason for you to stop using the app?	Why?
	How could we change this?

Results

Step 1: Selecting Determinants

From the existing literature, self-efficacy has been shown to be one of the most important determinants of PA [41-43] and AT [44-46] among (young) adults. Social support was positively associated with PA and AT in adolescents [42] and young adults [4,47]. A review also showed that social support and having a companion for PA were positively associated with different types of PA, including AT [57]. Attitude has been an inconsistent determinant in the literature [42]. However, important perceived benefits and barriers of PA and AT have been mentioned in recent studies. Health benefits, recreation (releasing tension), social contact, and body image have shown to be important benefits for young adults' PA participation

[52,53]. Important benefits of AT among young adults are low costs, autonomy and flexibility, and a short travel time in urban areas [47,49]. Barriers of PA are lack of time, lack of motivation, and lack of money [50,51]. Barriers of AT are bad weather, practicality (eg, how to deal with luggage), comfort (eg, sweating), and lack of facilities such as bicycle parking or showers and changing rooms at work [44,47,48]. Although knowledge might not be sufficient to change behavior, it is a necessary prerequisite to an individual's positive motivation to engage in more PA [56]. It has been shown that knowledge of PA guidelines in Irish and English adults is very low and that lower education is associated with not knowing the guidelines [54,55].

In the focus groups conducted in this study, these results were confirmed by the target group. For example, lower-educated working young adults mentioned similar perceived benefits and barriers of PA and AT as found in the existing literature. They also indicated to have a lack of knowledge regarding an active lifestyle, and they were very interested in information and advice. Other results of the conducted focus groups (regarding mobile technologies, valuable app features, and app use to promote an active lifestyle) are discussed in steps 2 and 3 of the results section.

As a result, following determinants of an active lifestyle in lower-educated working young adults were selected: knowledge, attitude (perceived benefits and perceived barriers), social support, and self-efficacy. Therefore, the attitude–social influence–self-efficacy (ASE) model [80] was used as a base to develop an app for the promotion of an active lifestyle. The ASE model is a theoretical model that describes the processes wherein health behaviors, such as an active lifestyle, are shaped. It states that an active lifestyle is defined by intention to act, whereas intention, in turn, is determined by attitudes (ie benefits and barriers), social influences, self-efficacy, and the knowledge and skills needed to achieve an active lifestyle [80]. The ASE model has been used in the development of previous health interventions [81-84].

Step 2: Selecting Behavior Change Techniques

BCTs were used to translate the selected determinants into practical applications [40] (Table 3). Multiple self-regulation techniques were selected (self-monitoring, goal-setting, feedback on behavior, review of behavior goals, instruction on how to perform the behavior) as it has been shown that these techniques are important to target the selected determinants to increase PA in interventions [63-66]. Moreover, both in qualitative and quantitative studies, young adults rated self-regulation techniques (especially self-monitoring and goal-setting) as most valuable features to increase self-efficacy among health behavior apps [25,85]. In addition, participants of the focus groups conducted for this study also mentioned self-regulation techniques (self-monitoring, goal-setting, and instruction on how to perform the behavior) as valuable app features. Furthermore, to encourage self-efficacy regarding the (re)use of the app, "prompts/cues" was selected as a BCT. Providing prompts or cues (notifications in an app) has had a positive effect on reuse of intervention websites among adults, adolescents, and children, particularly those with low socioeconomic status [68-70]. A qualitative study among young adults also found that relevant and timely (but not too frequent) alerts and reminders are valuable features of health behavior apps [25]. Furthermore, participants of the current focus groups mentioned push notifications as necessary to not forget an app.

The BCTs "instruction on how to perform the behavior" and "information about health consequences" were selected to increase knowledge and to encourage a positive attitude toward PA and AT. A qualitative study among young adults showed that providing feedback and advice to guide people about how they can change behavior was evaluated as a valuable app feature [25]. Participants of the focus groups conducted in this study also indicated to be interested in information and advice regarding an active lifestyle:

> *I would find it interesting to know how active I need to be to be healthy. But I need encouragement. And people need guidelines and ideas on how to be active.*

Finally, the BCT "enhancing network linkages" was selected. This BCT focuses more indirectly on social support by advising on mobilizing and maintaining social networks (eg, tips on being active together) [39,67]. Although social support is positively associated with an active lifestyle, it has been found that smartphone users do not like apps that link and share (health) information with social network sites [25,67]. In the conducted focus groups, Facebook was indicated as the most popular social network. Participants used it daily for communication or games, but they did not want to post or share health-related information on Facebook via an app.

Step 3: Developing the App

The new native Android app, Active Coach, aims to promote an active lifestyle in lower-educated working young adults via a 9-week program. There is no consensus on the optimal duration of app programs to ensure user engagement [18]. However, in a recent review on app interventions to improve health behavior (ie, PA), intervention durations longer than 8 weeks tended to be effective [18]. Nevertheless, very lengthy app programs might not be useful, as app use often declines rapidly because people lack commitment and use apps in a transient, casual way [25,86].

Users of the Active Coach can choose how they want to make their lifestyle more active, through general PA or through AT. Participants of the focus groups conducted in this study agreed that a smartphone app would be used more and more suitable to promote an active lifestyle than a website:

> *...a smartphone is way easier than a computer. You always have it by your side and you don't have to wait until it's ready to be used.*

Although focus group participants used their smartphone on a daily basis, many of them indicated that they were not allowed to carry their smartphone with them during working hours. However, they clearly preferred automatic tracking of their activity behavior:

> *I don't want to enter anything myself. It takes time and you could cheat and maybe you do it ones, or twice, but not more.*

Therefore, to ensure all-day and automatic self-monitoring of the activity behavior, the Active Coach app works in combination with a wearable activity tracker, the Fitbit Charge. The Fitbit Charge is a wrist-worn activity tracker that uses a 3-axis accelerometer to track a person's movement [87]. The wristband can track the number of steps walked, active minutes, floors climbed, the quality of sleep, and other personal metrics. For the Active Coach app, only the number of steps walked was used. Fitbit trackers are valid and reliable devices for measuring step counts in healthy young adults [20,88].

The Active Coach app includes a registration process and 7 other components, each with their own influence on the determinants (Table 3). In the focus groups conducted in this study, participants said they were willing to go through a registration process at the beginning of an app to receive more personal information:

> *...the more personal an app, the better. You need to register for almost every site or app, I don't mind. As long as it's not a whole questionnaire.*

However, participants indicated that the questions of the registration process should not be too detailed, too long, or go back too far in the past. Therefore, the registration process consists of only 3 screens. First, personal questions (name, email-address, password, gender, date of birth) are asked. Second, it is asked what kind of job the user has (mostly sitting or mostly standing or walking), and how the user would like to become more active (PA or AT). Third, perceived benefits are asked regarding the chosen behavior. If a user chooses PA, answer options are as follows: (1) being fit and healthy, (2) looking good (weight maintenance, appearance), and (3) relaxing, having distraction and/or social contact. If a user choses AT, answer options are as follows: (1) being fit and healthy, (2) saving money (no fuel costs), and (3) practical reasons (no traffic jams, not searching for parking spots).

After completing the registration, the Active Coach app consists of a 9-week program. During those 9 weeks, user's PA behavior is being tracked by the Fitbit Charge (step count) and their AT behavior is being tracked by mobile smartphone sensors (GPS and accelerometer). Regardless of the activity choice (PA or AT), both behaviors will be tracked automatically and will be visible for the user in the app on a graphical display (steps/day [PA] and minutes/day [AT] per day, week, month, and year) in the app (Figure 2). However, the goal setting and the information received will differ according to the chosen behavior.

Table 3. The 8 components of the Active Coach app with their behavior change techniques (BCTs) and determinants.

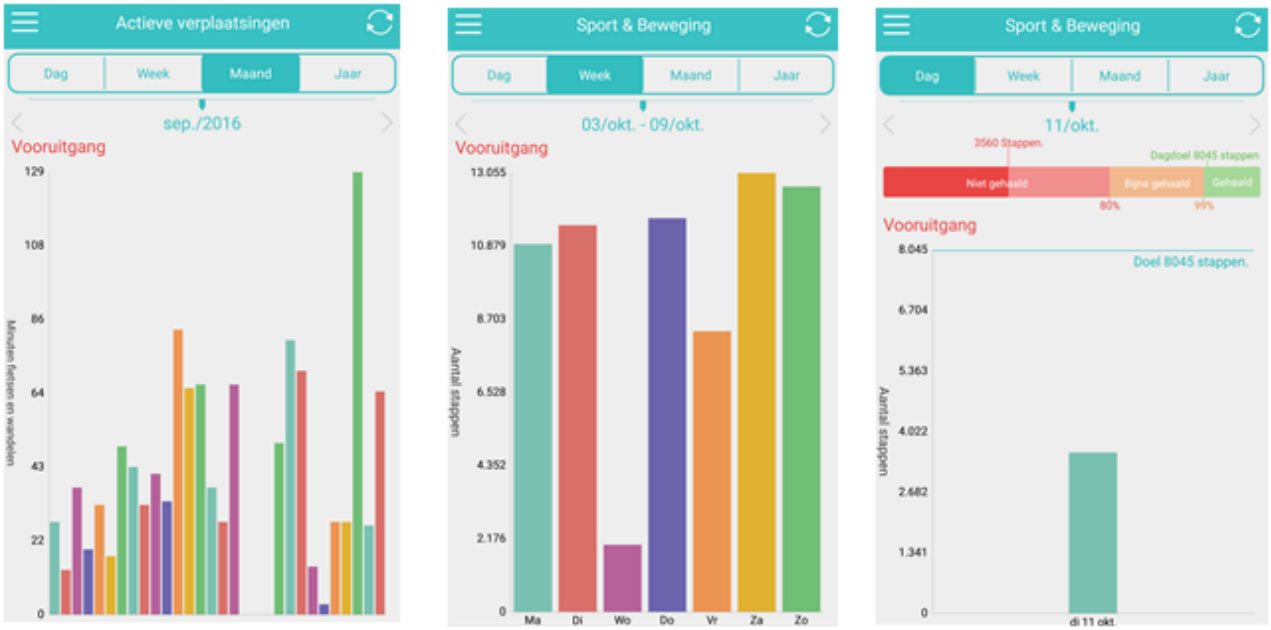
Active Coach component	Behavior change techniques	Determinants
Registration process	N/A[a]	N/A
Tracking of PA[b] (via Fitbit) and AT[c] (via mobile sensors) + graphical display	Self-monitoring	• Self-efficacy • Knowledge
1 week baseline activity level measuring	Self-monitoring	• Self-efficacy • Knowledge
Weekly goal (steps/day or min AT[c]/day) (set by app)	Goal-setting	Self-efficacy
End of each week: feedback on goal achievement • goal achieved: option to increase goal (user's choice) • goal not achieved: perceived barriers option to decrease goal (user's choice)	• Feedback on behavior • Goal-setting • Review behavior goals	Self-efficacy
	Prompts/cues	Self-efficacy (app use)
Daily visual feedback on goal achievement	Feedback on behavior	Self-efficacy
Practical tips: 2 per week	Instruction on how to perform the behavior	• Self-efficacy • Knowledge • Attitude
	Enhancing network linkages	Social support
	Prompts/cues	Self-efficacy (app use)
Facts: 1 per week	Information about health consequences	• Knowledge • Attitude
	Enhancing network linkages	Social support
	Prompts/cues	Self-efficacy (app use)

[a]N/A: not applicable.

[b]PA: physical activity.

[c]AT: active transport.

Figure 2. Active Coach app screenshots with (a) month overview of AT in min per day, (b) week overview of PA in steps per day, and (c) day overview of PA in steps PA per day and a personal goal line and bar.



The first week of the 9-week program is a baseline week during which the baseline activity level of the user is measured. At the end of this week, a personal goal dependent on the chosen behavior (PA in steps/day or AT in min/day) is set by the app for the following week (eg, Your goal for next week is to try and walk 6000 steps each day). The goal was based on mean steps per day or min AT per day of at least 3 of the 7 baseline days, which was increased by 10%. Participants of the focus groups conducted in this study agreed that there should be a goal or a target to reach for. Some wanted it to be set automatically, whereas others wanted to choose their own goal.

Therefore, the app provides both automatic and individually set goals. The focus group participants also liked receiving rewards (eg, virtual rewards such as a medal) or positive feedback when they achieve a goal or target. Therefore, every day during the following 8 weeks, users receive a notification on whether or not they achieved their day goal. They can also see their daily and weekly goal progression on the graphs in the app (Figure 2). In addition, users receive feedback on their goal achievement at the end of each week (Sunday). If they achieve their goal, they can increase it with 10%, 25%, or 50% or they can maintain the same goal for the next week. If they do not achieve their goal, they can choose to decrease it with 10%, 25%, or 50% or they can maintain the same goal for the next week. Additionally, users are asked why they did not achieve their goal (perceived barriers). For a user who chooses PA, answer options are as follows: (1) lack of time, motivation, energy, etc; (2) lack of money, sports equipment, etc; (3) no sports partner; and (4) bad health (sick, injury, tired). For a user who chooses AT, answer options were as follows: (1) feeling unsafe (dangerous traffic, bike theft), (2) practical reasons (bad weather, luggage), (3) laziness or habit of taking the car, and (4) bad health (sick, injury, tired). This information is being used to give users more personal feedback.

Every Monday and Friday during the 8 weeks after the baseline week, users receive a notification with a practical tip, and every Wednesday, they receive a notification with a scientific fact to help and motivate them to reach their goal. The content of the tips and facts is tailored based on information from the registration process (gender, sitting or standing job, PA or AT, selected benefits), on goal achievement, and on the selected barriers. If users achieve their goal from the previous week, they receive 1 general tip (eg, Naviki is a very practical app to help plan your route with information on slopes and the weather on the road) and fact (eg, Did you know that being active when you're young decreases the risk of heart disease later in life?) and 1 tip adapted according to the benefits selected during the registration (eg, benefit: staying fit and healthy, tip: You can stay fit and healthy together with your colleagues by joining a fun biking contest). If users do not achieve their goal from the previous week, they receive 2 tips adapted according to the barriers selected at the end of the previous week (eg, barrier: high costs, tip: By asking your colleagues to make a walk during lunch break, you can be more active at work without any extra costs). Users can select the preferred time to receive these notifications. When pretesting the tips and facts with lower-educated working young adults, they indicated that some tips and facts were too long, too commanding, and too obvious. With their suggestions, tips and facts were adapted to be shorter, more powerful, and more supportive. New information was also added, and some written messages were replaced by figures.

Step 4: Testing the App on Usability, Acceptability, and Feasibility

The volunteers (n=11) who tested the Active Coach app for technical errors and faults all owned different brands of Android smartphones. Several problems occurred such as too small fonts, errors in texts, not receiving messages, receiving wrong messages, receiving notifications at the wrong time, and error messages. All these problems were fixed. The main change was adding an extra page in the app to collect all received notifications about tips, facts, and goals, so that the users could consult these again at any moment.

Next, lower-educated working young adults (n=16) tested the app on acceptability and feasibility. Two participants dropped out due to a damaged smartphone. On the basis of the interviews, participants were very positive about the simplicity of the Active Coach app. They used and understood the app without any problems:

> *I think the app is easy and very clear. And there is not too much in it. With some apps you are like "Where do I find that again?", but that is not a problem with this one.*

Participants were also positive about the design of the app:

> *I think it is very clear, neat and with nice colors. Modern, also.*

Participants had no problems with the registration process: they liked that it was not too long and they understood all the questions. Although they did not want more questions during the registration process, it was said that the app (particularly the tips) should be more tailored:

> *Some tips you can actually use, but other tips are not very applicable for you. Those are more general tips. It would be better if they were more personal.*

However, they really liked the scientific facts and thought they were very interesting. In addition, participants also liked that they received the tips and facts as notifications, because it reminded them to have a look at the app. Participants indicated that they regularly looked at the notifications page to reread some tips and facts.

Participants were positive about the goals. They particularly liked the weekly possibility to increase or decrease their goal:

> *I really like the goals, it motivates you. And it is good that you can change your goal each week, with the 4 options.*

They also liked the graphical display of the tracked behavior and the goals ("It is very clear, with all the different colors. And also divided in day, week, month, year. That's good."), although they had some suggestions for improvement:

> *You can only see your current goal. It would be practical if, when you look at the month, it would display multiple marks for the goals of each week.*

In the beginning, participants complained about battery drainage, mostly because their Bluetooth, GPS, and/or Internet connection was switched on the entire day. However, they quickly fixed this problem themselves:

> *I always have my GPS switched on, but not my Bluetooth. I just switch it on once a day, in the evening, to sync everything. So now my battery use is under control.*

Finally, participants really liked the Fitbit wearable:

> *You don't even feel it, it doesn't bother me at all. And it is very secure, it doesn't come off easily.*

However, they found it to be a disadvantage that it is not waterproof and they could not wear it while swimming. Some participants also looked at the native Fitbit app, mainly to check additional features such as calories burned or sleep.

Results from the questionnaire during the fourth and last interview showed that 11 of the 14 participants thought that they were more active because of the Active Coach app and also 11 of the 14 would recommend the app to others. Furthermore, as shown in Table 4, almost all participants (13 of 14) agreed or strongly agreed that the app was clear and understandable and that the tips and facts were understandable. In addition, more than half agreed or strongly agreed that it was motivating to have a goal and useful to receive weekly feedback about that goal. On the basis of these results, adaptations were made to the app. Some minor problems with the notifications page were fixed, and the list of practical tips was re-evaluated.

Results from Google Analytics showed that the Active Coach app was most used on days and hours that users received notifications with tips, facts, and weekly feedback on goal achievements (Monday, Wednesday, Friday, and Sunday between 8 and 10 PM). It also showed that they used the app on average 1 min per session. The app was visited by minimum 1 and maximum 14 users on each day of the acceptability and feasibility testing period with a minimum of 5 sessions a day and a maximum of 31 sessions a day.

Table 4. Experiences with the Active Coach app (results from the questionnaire at week 9). Response categories: 5-point scale, from 1 (strongly disagree) to 5 (strongly agree).

Active Coach app	Strongly disagree (n)	Disagree (n)	Sometimes (dis)agree (n)	Agree (n)	Strongly agree (n)	Mean (SD)
What did you think about the Active Coach app?						
Clear		1		11	2	4.0 (0.7)
Pretty		1	5	6	2	3.6 (0.8)
Boring	1	5	5	2	1	2.8 (1.1)
Understandable			1	8	5	4.3 (0.6)
Fun		2		9	3	3.9 (0.9)
Attractive		2	5	6	1	3.4 (0.9)
User-friendly		1	2	8	3	3.9 (0.8)
What did you think about the tips you received?						
Interesting		3	4	4	3	3.5 (1.1)
Motivating		3	6	3	2	3.3 (0.9)
Boring	2	5	4	3		2.6 (1.0)
Useful	1	1	5	5	2	3.4 (1.1)
Understandable		1		6	7	4.5 (0.8)
Commanding	5	7		1	1	2.0 (1.2)
What did you think about the facts you received?						
Interesting	1		3	7	3	3.8 (1.1)
Motivating	1	2	5	5	1	3.2 (1.1)
Boring	5	3	4	2		2.2 (1.1)
Believable	1		1	7	5	4.1 (1.1)
Understandable	1			4	9	4.4 (1.1)
Educational	1	1	4	5	3	3.6 (1.1)
What did you think about the goals you received?						
I tried to achieve my daily goal			7	6	1	3.6 (0.6)
I found it motivating to have a goal			5	4	5	4.0 (0.9)
I found it useful to receive daily feedback	1	4	2	6	1	3.1 (1.1)
I found it useful to receive weekly feedback	1		1	8	4	4.0 (1.0)
I liked it that I could adjust my goal weekly	1	1	1	6	5	3.9 (1.2)

Discussion

This study aimed to describe all steps of the development (including the usability, acceptability, and feasibility testing) of a new smartphone app (Active Coach) that will be used, in combination with a wearable activity tracker, in an intervention to promote an active lifestyle in lower educated working young adults. It is important to use a stepwise and iterative approach when developing new smartphone apps. The literature in this area clearly emphasizes the importance of formative research and pretesting and indicates they are necessary steps before conducting a pilot test or RCT [34]. In this study, exploratory focus groups during the formative research revealed characteristics of the target group that were not known beforehand. For example, wrist-worn activity trackers were only included after statements of focus group participants that they were not allowed to carry their smartphone with them during working hours. Lower-educated working young adults often have blue-collar jobs during which it is prohibited to carry a smartphone, thus relying on the built-in sensors of smartphones to track activity would have resulted in incomplete and incorrect data. An Australian study on interest and preferences for using activity tracking devices [89] showed that activity trackers should indeed align with the characteristics of a target group. They found that accelerometers (eg, Fitbit) are preferred, especially among younger people, because of their wearing position (ie, wrist), features (ie, measures steps), and characteristics (ie, accuracy) [89].

The use of the Fitbit Charge wearable activity tracker was positively evaluated in the acceptability and feasibility test of this study. Cadmus-Bertram et al [90,91] also found low barriers and very high adherence regarding Fitbit use in an RCT among

obese, middle-aged women. Lower-educated working young adults in this study found the Fitbit Charge easy and comfortable to wear and use, and they liked the long battery life. It automatically tracked their activity behavior all day, even during working hours and during (sport) activities when they did not carry their phone with them. A disadvantage was that it is not waterproof [87], which means that swimming cannot be tracked. However, this issue might be resolved soon as future generations of activity trackers will probably be waterproof. Next, because of the relatively high cost, lower-educated working young adults might not own a Fitbit tracker or are not willing to purchase it in the future. Nevertheless, a study among Australian adults found that cost is not a significant barrier to the use of activity trackers [89]. Additionally, it is expected that prices of wearable activity trackers will drop quickly in the future, as this technology continues to evolve rapidly [92].

Focus group participants also indicated that they prefer information in apps to be personal. Previously, it has been shown that individually tailored feedback and advice (ie, based on the user's own characteristics [93]) is more likely to be effective than generic information about PA [94-96]. The use of the wearable activity tracker allowed the Active Coach app to provide personal activity information (eg, graphs, goals), without manual user input, which is a great strength of the developed app [67,97]. It has been shown that that user engagement in health behavior programs is much better when automatic tracking is applied [97]. Providing tailored advice (personal tips and facts) remains more difficult, as it requires knowledge about people's characteristics. In computer-tailored interventions, tailored advice is based on participants' answers to a predefined diagnostic questionnaire. However, a recent US study on health app use found that the primary reason respondents stopped using health-related apps was the demanding nature of manual data entry [98]. In this study, focus group participants said that, although they were willing to complete a registration process to receive more personal information, questions should be limited in number and should not be too long or too detailed. Therefore, the provided advice in the Active Coach app (tips and facts) is only tailored to a certain extent, by using information from the concise registration process, the weekly goal achievements, and the reported barriers. Results from the acceptability and feasibility test showed that participants had no problems with the registration questions, but they thought the tips needed to be more personal. This indicates the difficult balance between manual data entry burden and providing app users with tailored advice. A possible solution would be to provide tailored advice based on automatically gathered information. Klein et al [67] described the use of location data (GPS) to monitor user's actual location and to identify frequently visited locations to send timely and context-specific messages. A very advanced example of this is Google Now, which is an intelligent virtual assistant app that learns from user's behaviors, habits, and preferences (based on location data, weather information, Internet search history, online agenda, email data, etc) and shows relevant information without the user asking for it [99]. This information might also cover other health behaviors besides PA, such as healthy nutrition or sleep quality, depending on the interests of the user. The feasibility and acceptability test showed indeed that some lower-educated working young adults expressed interest in other health features of the Fitbit app, such as burned calories or sleep. However, this type of automatically generated tailored information would require expert technological knowledge and skills, a lot of time, and extensive financial means to add this to the existing app. Although the Active Coach app was developed in cooperation with a commercial mobile app development company, the available time and limited financial means only allowed for concise tailoring of advice. Future mHealth interventions should keep the importance of both tailored health information and tailored advice in mind while attempting to limit data entry burden as much as possible.

A limitation of this study is that some app features could not be realized because of limited time and financial means, regardless of the target group's interest in it, such as highly personalized advice and virtual rewards for goal achievement. Future mHealth studies might want to include these elements. Next, the choice to develop a native Android app ensures the best user experience and compatibility with smartphone's native features and hardware [71]. However, this means that people with iPhone (IOS) or Windows phone cannot use the Active Coach app. The app is specifically adapted to the Flemish lower-educated working young adults, which limits its generalizability. However, targeting apps to specific population groups may also enhance their efficacy [18]. Furthermore, it is possible to adjust elements of the app (eg, translate it to other languages, adapt the tips and facts) to make it useable for other target groups.

This study includes some important strengths. The stepwise development process, during which lower-educated working young adults were regularly consulted, resulted in a new PA app that is adapted to the needs and preferences of an under-researched target group at high risk for physical inactivity. The app was specifically adapted for the Flemish lower-educated working young adults on several levels such as language (eg, simple and understandable), layout (eg, tested by the target group to ensure user-friendliness, attractiveness), content (eg, tips on benefits of AT or PA focused on benefits that were important for the target group), and their lifestyle (eg, use of wearable activity trackers because the target group was not allowed to carry their smartphone with them during working hours). To the best of our knowledge, this is the first app aiming to promote an active lifestyle that is specifically developed for lower-educated working young adults. Several qualitative and quantitative research methods (focus group discussions, think-aloud interviews, semi-structured interviews, questionnaires, Google Analytics) were used to test and adapt multiple versions of the Active Coach app. As a result, many technical errors and faults could be eliminated to maximize the user-friendliness of the app. Furthermore, by identifying the theoretical constructs that needed to be targeted, integrating them into the ASE-model, and by using multiple self-regulatory BCTs, a theory- and evidence-based app was developed, which is important to increase effectiveness [37,96]. Finally, the use of a Fitbit wearable activity tracker allowed the Active Coach app to provide personal activity information (eg, graphs, goals), without manual user data input. As recommended in previous research [33], it is important to present the process of developing

a new health app to help others in developing effective tools to improve health. The next step in this process is to test the efficacy of the Active Coach app in an RCT.

Research showed that formative research and pretesting before conducting a pilot test or RCT ensures the best chance of developing new and effective tools to improve health. Therefore, we used a stepwise and iterative approach during which the target group was regularly consulted to develop an evidence- and theory-based smartphone app promoting an active lifestyle that is adapted to the specific needs and preferences of lower-educated working young adults. At the end of the development process, the Active Coach app was overall positively evaluated by the target group.

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Conflicts of Interest

None declared.

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Abbreviations

AT: active transport
ASE: attitude–social influence–self-efficacy
BCTs: behavior change techniques
PA: physical activity

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Original Paper

Feasibility of Virtual Tablet-Based Group Exercise Among Older Adults in Siberia: Findings From Two Pilot Trials

Svetlana Nikitina[1,2*], MS (Comp Sc); Daniele Didino[1,3*], PhD; Marcos Baez[1,2*], PhD; Fabio Casati[1,2*], PhD

[1]Tomsk Polytechnic University, Tomsk, Russian Federation

[2]Department of Information Engineering and Computer Science, University of Trento, Trento, Italy

[3]Department of Psychology, Humboldt-Universität zu Berlin, Berlin, Germany

[*]all authors contributed equally

Corresponding Author:
Svetlana Nikitina, MS (Comp Sc)
Department of Information Engineering and Computer Science
University of Trento
Via Sommarive, 9 - Povo
Trento, 38123
Italy
Phone: 39 0461 28 5299
Fax: 39 0461 28 3166
Email: svetlana.nikitina@unitn.it

Abstract

Background: Regular physical activity has a positive effect on physical health, well-being, and life satisfaction of older adults. However, engaging in regular physical activity can be challenging for the elderly population because of reduced mobility, low motivation, or lack of the proper infrastructures in their communities.

Objective: The objective of this paper was to study the feasibility of home-based online group training—under different group cohesion settings—and its effects on adherence and well-being among Russian older adults. We focused particularly on the technology usability and usage and on the adherence to the training (in light of premeasures of social support, enjoyment of physical activity, and leg muscle strength). As a secondary objective, we also explored the effects of the technology-supported intervention on subjective well-being and loneliness.

Methods: Two pilot trials were carried out exploring two different group cohesion settings (weak cohesion and strong cohesion) in the period from 2015 to 2016 in Tomsk, Russian Federation. A total of 44 older adults (59-83 years) participated in the two pilots and followed a strength and balance training program (Otago) for 8 weeks with the help of a tablet-based virtual gym app. Participants in each pilot were assigned to an interaction condition, representing the online group exercising, and an individual condition, representing a home-based individual training. Both conditions featured persuasion strategies but differed in the ability to socialize and train together.

Results: Both interaction and individual groups reported a high usability of the technology. Trainees showed a high level of technology acceptance and, particularly, a high score in intention to future use (4.2-5.0 on a 5-point Likert scale). Private texting (short service message [SMS]) was used more than public texting, and the strong cohesion condition resulted in more messages per user. Joint participations to training sessions (copresence) were higher for the social group with higher cohesion. The overall adherence to the training was 74% (SD 27%). Higher levels of social support at baseline were associated with higher adherence in the low cohesion condition ($F_{1,18}=5.23$, $P=.03$), whereas in the high cohesion, such association was not found. Overall improvement in the satisfaction with life score was observed between pre and post measures ($F_{1,31}=5.85$, $P=.02$), but no decrease in loneliness.

Conclusions: Online group exercising was proven feasible among healthy independently living older adults in Russia. The pilots suggest that a physical training performed in a virtual environment positively affect the life satisfaction of the trainees, but it does not provide support for a decrease in loneliness. High cohesion groups are preferable for group exercising, especially to mitigate effects of low social support on adherence. Further research in motivating group interactions in training settings is needed.

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KEYWORDS

physical fitness; exercise training; tablet computers; elderly; social support

Introduction

Background

Regular physical activity is a key factor to a successful aging, contributing to positive outcomes in health and well-being in later life [1-4]. It can improve physical function [4], slow the progression of degenerative diseases [3], reduce risk of falls [1], and also improve cognitive performance, mood, and quality of life (QoL) of older adults [2,4]. A physically inactive lifestyle, on the contrary, can increase the risk of developing chronic diseases, one of the leading causes of death and disability in older adults [5,6].

Engaging in regular physical activity can be challenging. Older adults might suffer from reduced mobility, low self-efficacy, lack the proper infrastructures in their communities, or simply find it difficult to leave home and participate in physical activities on a regular basis [7,8]. For these and many other reasons, physical inactivity is still prevalent in older adults [9], leading to the undesired effects on health and well-being.

Intervention programs to promote physical activity have shown to be effective in increasing and maintaining physical activity [10]. In particular, group-based interventions have shown promising results in long-term settings with higher adherence compared with individual home-based interventions. Studies have also reported a preference by older adults for group exercising [11] and discussed the potential of the social context to stimulate social interactions and increase social well-being [12].

However, despite the body of literature on the topic, little attention has been paid on populations living under difficult environmental conditions and undergoing complex social changes, such as the Siberian community. Seasonal fluctuation has been found to determine the level of physical and social activities of older adults [13] leading to less opportunities to go out and interact, especially in high latitudes where winter can result in a decline of physical functions of older adults, such as ankle strength [14]. Recent history has also shaped the lives of older adults in Russia. The breakup of Soviet Union in the early 90s, and the difficult years that followed, negatively affected the social and economic well-being of the Russian population: the life expectancy of men is 14 years lower than in the European Union [15], and loneliness levels are among the highest in Europe [16]. The social, political, and economic uncertainty also deeply affected QoL, with a decrease in life satisfaction and happiness [17].

The above observations point to the need for solutions that can help older adults living under the above conditions to keep physically and socially active. Technology-supported interventions have been shown in the past to be successful in this goal [18].

Related Work

Recent research has demonstrated an effectiveness of technology-supported exercise interventions for older adults in terms of physical fitness [18]. However, although there is an ongoing discussion on whether group exercising or home-based individual exercising is more effective in increasing adherence of individuals to training programs (eg, [19,20]) and despite calls for analysis focusing on understanding group-based exercising in terms of *cohesiveness* (frequency of contact and group dynamics) [21], no intervention has compared the effectiveness of individual and (different types of) group settings in a technology-supported intervention.

Research has also shown a preference by older adults in group training [11,12]. However, implementing group exercising can be challenging, especially in a heterogeneous elderly population, with individual differences leading to motivational issues and problems in tailoring the training [11].

Fitness apps for home-based training have been widely explored in technology-supported interventions (see [22] for a review); however, we are not aware of interventions supporting online group exercising for individuals of different levels of fitness. Consequently, there is very limited research on the effects of level of fitness, social support, and subjective well-being in online group settings. The exception comes from a recent study on an Internet-based group training intervention [23] relying on a general-purpose teleconference software to deliver real-time exercises to older adults in rural areas. Although targeting homogeneous groups, focused on physical fitness outcomes, and limited to a small sample of 10 older adults, the study highlights some interesting challenges in deploying this type of technology.

In our previous study [12,24], we made some steps to test the feasibility of a tool for online group exercising, namely Gymcentral, that allows individual of different levels of fitness to follow exercises with the remote company of others. We conducted an 8-week pilot study exploring the effects of online group exercise training in Trento, Italy, with 37 adults, 65 years and above, who followed the Otago exercise program [25] aiming at strength and balance improvement in older age. The specific focus of the study was on technology acceptance, attitude, and preference toward group training and its effects on physical and social well-being; in comparison with a traditional tablet-based individual training program implementing no persuasion strategies.

Still, despite the prior work and the extensive existing literature, open questions remain:

1. How does the online group exercising translate to other cultural and environmental settings?
2. How effective is online training with groups of different levels of cohesion?
3. How does online group exercising compare with individual training featuring persuasion strategies?

Objectives

This paper reports on two pilot studies of an online exercise intervention with older adults living in Tomsk, Siberian Federal District (Russia). The aim of the intervention was to enable older adults of different levels of fitness to follow a personalized exercise program from home, with the (virtual) company of training companions and under the supervision of a remote coach. This was done with the support of a tablet app offering group exercising in a virtual gym while leveraging on the social context of the group exercising to enable social interactions and feedback.

The main objective of the pilot was to study the feasibility of online group exercising under different cohesion settings among Siberian older adults. We focused on the technology acceptance, on the adherence to the training (especially in light of pre-measures of social support, as well as on the enjoyment of physical activity and leg muscle strength). As a secondary objective, we also explored the effects of the technology-supported intervention on subjective well-being and loneliness.

Methods

Training Apps

The technology support was provided by Gymcentral, a tablet and Web app that allows trainees of different functional abilities to follow online group exercises from home, under the supervision of a remote coach [26]. Gymcentral serves the needs of trainees and coach via the *trainee* and *coach* apps (see Figure 1).

The design of the trainee app is based on a virtual gym environment that provides the following main features:

- Tailored training program. It delivers video exercises that are tailored to the abilities and progress of individual trainees. Trainees may receive exercises of different intensity level or not receive some exercises depending on their condition and the coach assessment.
- Online group exercising. It allows trainees to participate in online group exercise sessions in a virtual classroom. Trainees can see the video of the coach and also the presence of other trainees via avatars. However, differences in functional abilities or the intensity level of the exercises remain hidden.
- Persuasion strategies. It provides individual persuasion features such as positive and negative reinforcement and self-monitoring (implemented using a growing garden metaphor), as well as social persuasion features such as social learning, social support, social facilitation, and normative influence.
- Remote monitoring and feedback. Participation to training sessions and completeness of exercises are recorded by the app and made available to the training coach. The coach can act on this data to provide feedback (using the communication features) and increase or tailor the intensity of the training program.
- Communication features. It enables trainees to share public messages with all the other trainees in a bulletin board or to exchange private messages with individual trainees (or the training coach) using an internal messaging feature.

The monitoring and feedback is supported by the coach app, a companion Web app for the training expert.

Details about the features of the Gymcentral app are discussed in detail in the study by Báez et al [26] and the underlying conceptual model in the study by Far et al [27].

Research Questions

In this work, we studied the feasibility and effectiveness of the online group exercise intervention and its effects on the well-being of Siberian older adults by addressing the following specific research questions (RQ):

RQ1. Is the online group exercising technology usable and accepted by older adults? We aimed at exploring the perception of older adults toward the technology by measuring the usability and acceptance. More importantly, we also explored how the app was used in practice and how the usage relates to the observed effects of the.

RQ2. How do online group exercising and baseline measures influence the adherence of older adults to a training program? Previous research suggests that exercising in a group results in higher adherence and preference by older adults [7,11]. However, research also points to major obstacles when delivering group exercises to heterogeneous populations, which can make training in this setting difficult and less motivating [11]. In this study, we explored how a virtual group environment influences the adherence of older adults under different measures of known determinants of physical activity.

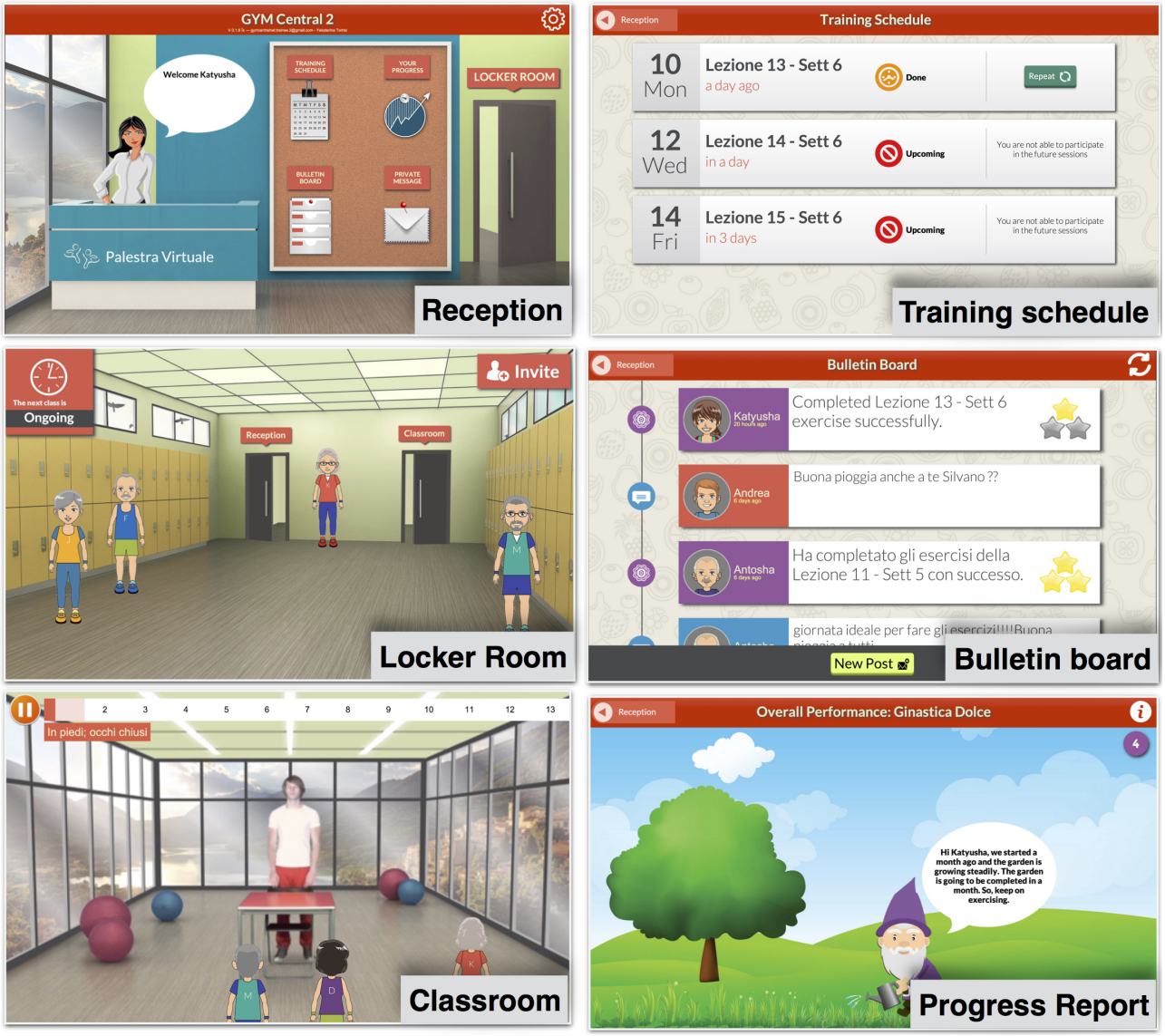
RQ3. Does online group exercising affect the well-being of older adults? We explored the effects of physical training via a virtual social environment on the subjective well-being and social well-being of older adults. By addressing this question, we aimed at contributing to the existing research on the association between physical training and well-being [1-4].

Study Design

We explored the above questions in two pilot studies in Tomsk, Siberian Federal District (Russian Federation) that adhered to the same protocol and conditions, except for the group cohesion setting:

- Tomsk1 (July 2015-September 2015). Participants with high group cohesion, recruited from two organizations, and with the majority performing shared activities (computer courses and hobbies classes).
- Tomsk2 (April 2016-June 2016). Participants with low group cohesion, recruited from various organizations, with weak or no ties with each other.

Figure 1. Features of the virtual gym environment of the trainee app.



As seen above, we explored two group cohesion settings: participants with *strong group cohesion* and participants with *low group cohesion*. Thus, for the reasons explained above, candidate participants from Tomsk 1 had a stronger cohesion than Tomsk 2 at recruitment time, regardless of the treatment they ended up receiving. We did so to understand the effect of the prior connectedness among participants on the observed outcomes.

Both pilot studies were follow-ups to a previous pilot performed in Trento, Italy, and so they follow the same study design [12]. An overview of the study flow in consolidated standards of reporting trials–compliant format is shown in Figures 2 and 3.

In both studies described here, participants were assigned to an interaction group (online group exercise condition) or to an individual group (individual exercise condition) using a random assignment procedure, with age and participants' frailty level as random assignment variables. In Tomsk 1, the process was slightly different as to ensure a high level of cohesion after randomization: pairs of friends, identified during the informative meeting, were treated as single elements during randomization. In this modified process, we firstly followed the randomization procedure for participants *without friends*, assigning participants to interaction and individual treatments, and then repeating the process for the friend pair units. Thus, friends were assigned to the same treatments, contributing to the overall group cohesion in Tomsk 1.

The two studies and the two treatment conditions defined four effective groups (see Table 1). Participants in the interaction groups have access to online group exercising with social interaction and persuasion features, whereas in the individual groups, participants have access to individual training with persuasion features but with social interactions limited to contacts with the coach. Details about the group cohesion and features available to each group can be seen in Table 1.

Figure 2. Study flowchart for Tomsk1 (July 2015-September 2015).

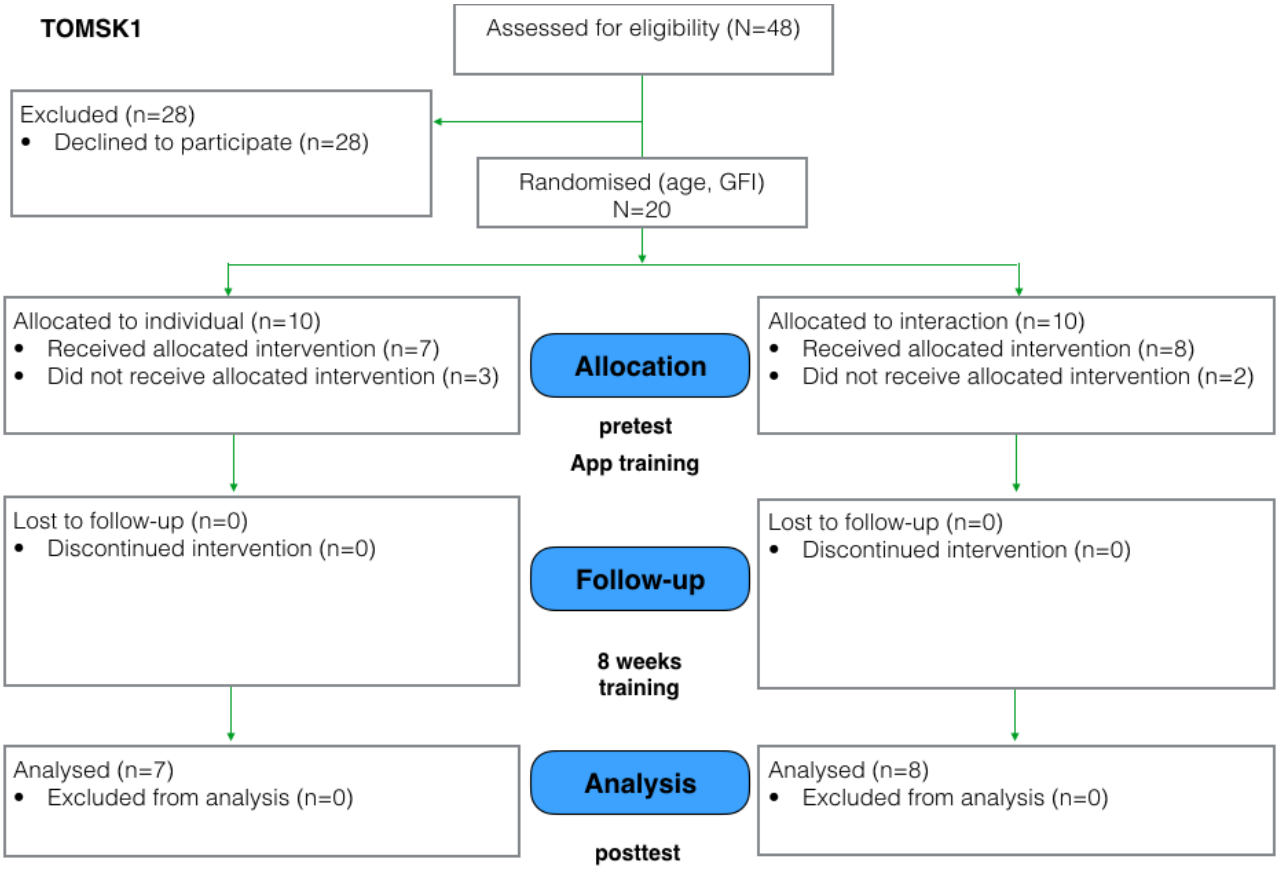


Figure 3. Study flowchart for Tomsk2 (April 2016-June 2016).

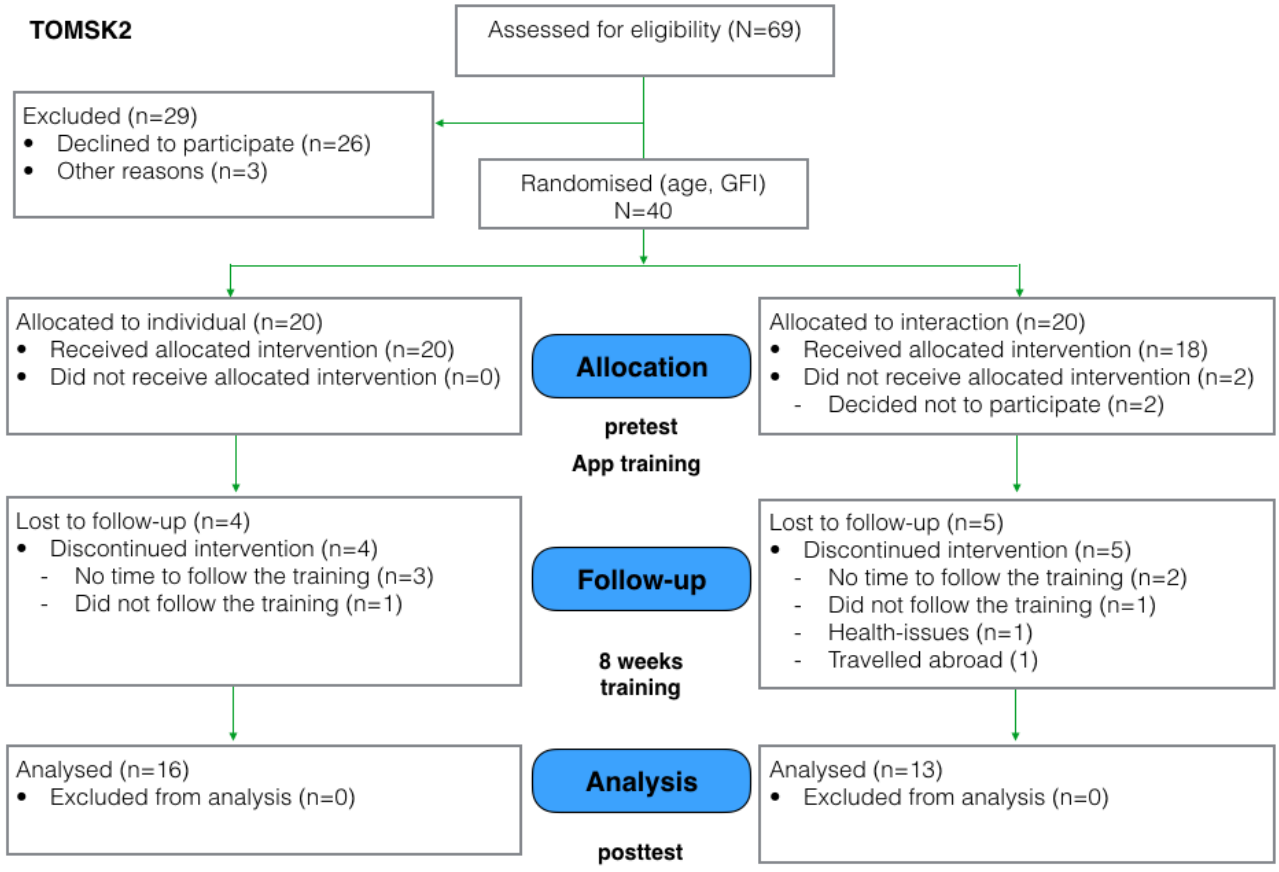


Table 1. Group cohesion and features of the trainee app available to each study group. Presence of the features in the version of gymcentral application used in each study group are denoted by checkmarks (✓).

Groups	Tomsk 1		Tomsk 2	
	Interaction	Individual	Interaction	Individual
App features availability				
Tailored exercises program (Otago)	✓	✓	✓	✓
Training with others in the classroom	✓		✓	
Invitation to join a training session	✓		✓	
Self-monitoring progress (garden metaphor)	✓	✓	✓	✓
Positive or negative reinforcement	✓	✓	✓	✓
Sharing of training activity the in bulletin	✓		✓	
Contextual messages in the locker room	✓		✓	
Public messages in the bulletin board	✓		✓	
Private messages with other trainees	✓		✓	
Private messages with the coach	✓	✓	✓	✓
Group cohesion				
Weak group cohesion			✓	✓
Strong group cohesion	✓	✓		

Both versions of the app implemented the same training program, developed on the basis of the Otago exercise program [25], which includes a set of muscle strengthening and balance-retraining exercises. The training program was designed with a standard set of exercises to be performed in each training session, varying in intensity each week according to the performance of the trainees. In the app, each exercise had 10 levels of intensity based on the duration and the number of repetitions. At the beginning of the study, a personal trainer (who was also the coach in the virtual gym) performed a physical assessment, which was used to set the starting intensity level of the program.

Participants received an iPad Air tablet (9.7-inch) preinstalled with the assigned version of the app and Internet access, a case to support the vertical positioning of the tablet, an activity monitoring sensor (Misfit Shine), one pair of ankle weights (0.5 Kg each), and the telephone number of the support team.

Before the start of the training program, participants joined pretest and technology training meetings: (1) an initial meeting where they signed the informed consent and filled out enrollment questionnaires, (2) a session with a medical doctor to evaluate eligibility, (3) a technology training session in the use of tablets and the assigned version of the app, and (4) a session for the physical assessment with the coach and pretest measures. The technology training followed a workshop format and was done in small groups of 10 participants each. Participants assigned to individual and interaction conditions attended workshops separately as they were provided with different versions of the app.

In the 8 weeks of the training, participants performed the home-based training activity with the monitoring of the coach and of the support staff. The training schedule offered three exercise sessions per week, and participants were required to perform at least two exercise sessions every week. The duration of the training session ranged from 30 to 40 min depending on the intensity level. Participants were free to join the training sessions at any time. Posttest measures took place on the week after the training.

The coach guiding the participants during the training was a practicing doctor with a primary care doctor degree and had over 10 years of experience in gymnastics, rehabilitation exercises, and yoga for older adults. Before the beginning of experiment, the coach was acquainted with the Otago training program and Gymcentral app settings.

During the training period, the coach had the task of progressing the intensity of the exercise program and providing feedback. At the end of every week, the coach could maintain or increase the intensity level of each trainee according to the attendance and completeness of the training sessions in the week. The coach was also instructed to contact trainees at least once a week to provide feedback and to respond to any question from the trainees. The coach was not aware of the difference between the interaction and individual groups, and both received the same amount of technical support.

The pretest measures included the *Groningen Frailty Indicator* [28], the *Rapid Assessment of Physical Activity Questionnaire* [29], demographic information, and questionnaires concerning psychological and social well-being. The posttest measures included the *System Usability Scale* (SUS) [30], a set of questions on the acceptance of the app, the *Satisfaction with Life Scale* (SWLS) [31,32], the medical outcomes survey (*MOS) Social Support Scale* [33,34], and the 3-item *revised University of California, Los Angeles (UCLA) Loneliness Scale* (R-UCLA Loneliness Scale) [35,36]. The participants filled in all the questionnaires by themselves in pencil-and-paper format.

The study protocol received ethical approval from the CREATE-NET Ethics Committee on ICT Research Involving Human Beings (Application N. 2014-001) in Trento, Italy. The studies reported in this paper—as follow-ups to our previous study—comply with this protocol, with the informed consent and informational materials translated into the Russian language.

Participants

We considered eligible for the study: participants aged 59 years or older, independent living, self-sufficient, and with a nonfrail, transitionally frail or a mild frailty level. These criteria were measured by self-reports. All participants had to pass a doctor assessment to ascertain the absence of conditions that would prevent them from performing light physical exercises. Participants wearing pacemakers were considered not eligible as the study required the use of an activity sensor (Misfit shine monitor). The specifics of baseline measures for each study site are described in Table 2.

Table 2. Baseline measures for study site. Tomsk1 and Tomsk2.

Measures	Individual	Interaction	*P* value[a]
Pre allocation test			
Age (years), mean (SD)			
Tomsk1	65.0 (6.1)	68.2 (7.8)	.71
Tomsk2	68.8 (7.2)	67.6 (6.2)	.48
Females, n (%)			
Tomsk1	100 (100)	90 (90)	
Tomsk2	100 (100)	100 (100)	
Groningen frailty indicator, mean (SD)			
Tomsk1	4.2 (2.04)	4.5 (2.42)	.99
Tomsk2	3.6 (2.54)	3.56 (2.5)	.91
Rapid Assessment of Physical Activity Questionnaire, mean (SD)			
Tomsk1	5.78(1.79)	5.9 (1.73)	.72
Tomsk2	5.15(2.41)	5.13(1.96)	.84
Post allocation tests—Self-reported			
Physical Activity Enjoyment Scale, enjoyment, mean (SD)			
Tomsk1	50.0 (3.5)	50.0 (4.8)	.99
Tomsk2	49.9 (5.4)	47.8 (4.2)	.49
R-UCLA [b] Loneliness Scale, loneliness, mean (SD)			
Tomsk1	4.2 (1.6)	5.4 (1.4)	.18
Tomsk2	4.3 (1.1)	4.0 (1.2)	.35
MOS [c] Social Support Scale, social support, mean (SD)			
Tomsk1	4.0 (1.5)	5.1 (1.6)	.99
Tomsk2	4.3 (1.1)	4.0 (1.2)	.55
SWLS [d], well-being, mean (SD)			
Tomsk1	4.0 (1.5)	5.4 (1.4)	.52
Tomsk2	4.3 (1.1)	4.1 (1.2)	.35
Post allocation tests—Physical assessment			
Leg muscle strength, mean (SD)			
Tomsk1	13.6 (2.2)	12.9 (1.4)	.49
Tomsk2	16.5 (3.8)	16.5 (3.0)	.96

[a]Differences computed using independent samples *t* test for age and leg muscle strength; all the other variables were analyzed with Mann Whitney tests.

[b]R-UCLA: revised-University of California, Los Angeles.

[c]MOS: Medical Outcomes Survey.

[d]SWLS: Satisfaction with Life Scale.

Participants in both studies were contacted through retirement organizations in Tomsk, Russia. In the first study, Tomsk1, participants were mainly invited through organization offering computer-learning classes and hobbies activities for seniors. In the Tomsk2 study, the recruitment was carried out through three organizations organizing social activities and events. We conducted presentations explaining the project and their expected involvement and handed out printed bulletins. Older adults interested in participating provided their phone numbers and were later on contacted by the project coordinator. Details about the retirement organizations and the number of candidates reached can be seen in Table 3.

In the Tomsk1 study, 20 participants were found eligible for the study (mean age individual group=65, SD 6.1; interaction group: mean 68.2, SD 7.8; 19 females and 1 male). In the Tomsk2 study, 40 participants were accepted according to the inclusion criteria (mean age individual group=68.9, SD 7.2; interaction group: mean 67.6, SD 6.2; all 40 female). The difference in the number of male and female participants is because of the demographics of the study location and the availability of male candidates at the retirement organizations. In Siberia, lifespan gap between males and females is one of the biggest in the world: life expectancy at birth for men is 64.7 years, whereas for women it is 76.3 years [37]. These demographics posed difficulties in recruiting male participants from the retirement organizations. The study flow for Tomsk1 and Tomsk2 is depicted in Figures 2 and 3. After the recruitment, participants in both studies signed the informed consent before participating in the experiment.

In the Tomsk 1 study, out of 20 participants, 5 withdrew before the start of the study for health problems or personal reasons; therefore, data of 15 participants was included in the analysis. In the Tomsk2 study, out of 40 participants, 2 withdrew before the beginning of the training because of travel plans. During the training program, 4 participants in the individual group and 5 participants in the interaction group dropped out because of health issues, travels, or reported lack of time for participation. Thus, in the Tomsk2 study, a total of 29 participants were included in the analysis (individual: 16, interaction: 13).

There were no statistical differences between individual and interaction groups in term of initial measures (Table 2). These baseline comparisons have been performed on participants that finished the training program.

Outcome Measures

Acceptance and Usability

We focus on the usability, acceptance of the technology, and preference to train together:

- Usability: The usability of the app was evaluated by means of the SUS [30]. This scale includes 10 items rated on a 5-point Likert scale (from 1="completely disagree" to 5 ="completely agree"). The SUS score ranges from 0 (low usability) to 100 (high usability). However, in a pretest of the scale, older adults found difficult to understand two items ("I found the various functions in this system were well integrated" and "thought there was too much inconsistency in this system." Therefore, we decided to exclude these two items in the questionnaire we administered to our participants. This means that the SUS score in our study ranged from 0 to 80.
- Acceptance: Acceptance was measured with a set of questions designed to evaluate positive ("I enjoy using the app") or negative feelings ("The app makes me nervous") associated with the use of the apps, the response to the communication feature ("It is easy to communicate with other people with the app"), the intention to use it ("I would like to use the app in the future"), and the perceived ease of use ("It is easy to use the virtual gym to perform exercises"). These questions were rated on a 5-point Likert scale (from 1="completely disagree" to 5="completely agree"). The questionnaire was developed by our team on the basis of previous literature [38]. Each question has been separately analyzed.
- Copresence: Participants had the choice to train at any time, but they could also coordinate to train at the same time via texting or using the *invite user to join* feature. To capture the preference of users for group training, we logged the attendance to the training sessions to compute for each user whether he or she trained alone (individual attendance) or together with another trainee (joint attendance). We then define copresence of a group as the ratio of joint attendances with respect to the total number of attendances.

Table 3. Senior citizen organizations contacted and candidates reached in each study.

Retirement organization	Study	Size of groups reached
Tomsk union of retirees	Tomsk 1	Large organization providing courses to around 600 retirees per year. Four active courses at the time (approximately 20 members each) were contacted, reaching around 80 older adults in total
Veterans council of Tomsk Polytechnic University (TPU)	Tomsk 1	Small organization of around 80 retirees. The invitation was extended to all members
Veterans Council of Tomsk Scientific Center	Tomsk 2	Small organization of around 80 retirees. The invitation was extended to all members
Tomsk region veterans council	Tomsk 2	Small organization of around 100 retirees. The invitation was extended to all members
Veterans council of TPU	Tomsk 2	Small organization of around 80 retirees. The invitation was extended to all members

Adherence to the Training

Measured with:

Persistence: Persistence was computed considering the ratio between the number of attendances to exercise sessions by a participant and the number of the exercise sessions planned in the program. Participation was measured by logging the attendance to the scheduled training sessions in the virtual classroom. For persistence, a rate equal to 100% was considered as participation in all three sessions per week, for all 8 weeks of training. Participants were not aware of how the persistence was scored but could monitor the individual progress in the garden (self-monitoring feature).

Subjective Well-Being, Social Support, and Loneliness

To measure if there was an improvement in the well-being outcomes as a result of training (secondary outcomes), we relied on the following instruments:

- SWLS [31]: Five questions rated on a 7-point Likert scale (from 1=”Strongly disagree” to 7=”Strongly agree”). The SWLS was translated and adapted to the Russian language by Tucker et al [32]. The total score ranges from 5 to 35, with higher scores indicating higher levels of life satisfaction.
- Loneliness: To measure loneliness, we used a shorter version of the R-UCLA Loneliness Scale [35] developed by Hughes et al [36]. The scale used includes 3 items scored on a 5-point Likert scale, with the total score ranging from 3 to 15 and higher scores indicating higher levels of loneliness.

Determinants of Physical Activity

In the analyses explained in the following sections, we use the following determinants of physical activity as covariates:

- Physical Activity Enjoyment Scale (PACES) [39]: This scale includes 16 items scored on a 5-point Likert scale (from 1=“disagree a lot” to 5=“agree a lot”). The PACES total score ranges from 16 to 80 (maximum enjoyment).
- MOS Social Support: [33,34]: Eight questions scored on a 5-point Likert scale (from 1=“None of the time” to 5=“All of the time”). This scale was translated by us according to the international guidelines [40]. It aims at measuring the social support provided by others. The total score ranges from 1 to 8, with higher scores indicating higher levels of social support.
- Leg muscle strength: Measured with the 30-second chair stand test [41]. The purpose of this test is to evaluate leg strength and endurance. From a seated position, the participant rises to a full standing position and then sits back down again for 30 seconds. The outcome measure is the number of times the participant comes to a full standing position in 30 seconds.

Statistical Analysis

We analyzed the difference between the interaction and the individual groups in terms of the SUS score with two Mann Whitney tests, whereas for the difference in the percentage of copresence, we use *t* tests.

We analyzed adherence (measured as rate of persistence) to the training program with an analysis of covariance (ANCOVA) with group (interaction vs individual) and study (Tomsk1 vs Tomsk2) as between-subject factors and leg muscle strength, social support (MOS score), and enjoyment of physical activity (PACES score) as covariates.

For well-being measures, we selected the SWLS score and R-UCLA Loneliness Scale score as dependent variables to be used in two separate repeated-measures analysis of variance (ANOVA). We used the same independent variables in both ANOVAs: time (pretest vs posttest) as within-subject factor and group (interaction vs individual) and study (Tomsk1 vs Tomsk2) as between-subject factors.

The statistical analyses were performed using the open source statistical software R (R Studio Team) [42], using the ggplot2 package to create plots [43].

Results

Perception and Adoption of the Technology

A starting point to understand the feasibility of the technology for our target population was to address (RQ1) and investigate the perceived usability, acceptance, and usage of the online group exercising technology.

Usability

Nine participants did not answer to some of the questions of the SUS and thus have been excluded by the analysis on this account. On average, the SUS score (on an 80 points scale, as we excluded two questions) was very similar between the interaction group (mean 63 [SD 9]; N=19; range 48-80) and the individual group (mean 66 [SD 14]; N=15; range 40-80). From a more detailed perspective, a Mann Whitney test showed that neither in the Tomsk1 study (W=11, $P \geq .99$) nor in the Tomsk2 study (W=89.5, $P=.32$) the SUS scores were different between the two groups (individual vs interaction) despite the higher complexity of the app assigned to the interaction groups.

Acceptance

Table 4 reports the results for the questions concerning acceptance (A). Consistently with the SUS score, trainees showed a high level of acceptance of the app. In fact, as the Table shows, trainees reported high levels of enjoyment (A1) and low levels of nervousness (A2) in using the app. Training with the app was perceived as very easy to do (A4) as well as communicating (A3), but with a lower score by 1 point. Trainees also reported with a high score their intention to use the app in the future.

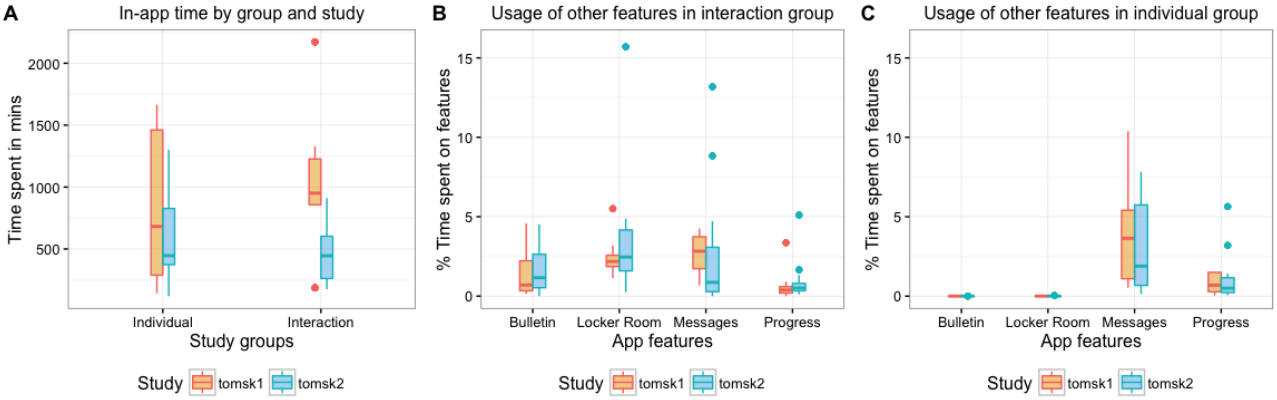
Characterization of App Usage

To characterize the usage of the various features of the app, we analyzed the app logs to derive how participants spent their time in the app. Overall, the mean time spent in-app was higher in Tomsk1 (16 hours) compared with Tomsk2 (9 hours), the difference being marked by a higher time spent by the interaction group in the first study (see Figure 4).

Table 4. Mean (SD) of the technology acceptance (A) responses for each group and study (range:1-5).

Features	Tomsk1		Tomsk2	
	Interaction, mean (SD)	Individual, mean (SD)	Interaction, mean (SD)	Individual, mean (SD)
A1 (feel joy)	3.9 (1.4)	3.9 (1.6)	2.8 (1.9)	3.3 (1.9)
A2 (feel nervous)	2.3 (1.2)	1.2 (0.4)	1.4 (0.8)	1.1 (0.3)
A3 (easy social)	4.4 (0.9)	3.0 (2.3)	3.1 (1.7)	4.1 (1.5)
A4 (easy train)	4.9 (0.4)	4.6 (1.1)	4.7 (0.5)	5.0 (0)
A5 (future use)	4.9 (0.4)	4.2 (1.8)	4.6 (0.7)	5.0 (0)

Figure 4. App usage by group and study. (A) Total time (in min) spent by user in the app during the experiment, (B) Usage of the app features in the interaction group, and (C) Usage of the app features in the individual group, % from total time spent in the app.



Not surprisingly, most of the time was spent training in the classroom, as the duration of exercise session ranged from 20 to 40 min depending on the intensity level. Looking at the time spent in the classroom relative to the time spent in-app by each participant, we can see that participants of the individual group in both studies spent nearly the same percentage of their time (Tomsk1=95.3%, Tomsk2=95.6%) in the classroom. Participants in the interaction groups spent a little less on the classroom—especially in Tomsk2 (Tomsk1=92.5%, Tomsk2=81.4%). The lower use in the interaction app is because of the presence of extra features and in the case of Tomsk2, because of the lower time spent training.

Analyzing the usage of the other features, we observe that participants spent a significant percentage of their time messaging, particularly those in the individual groups (see Figure 4). We can derive that the individual group not only used the training feature but also the messaging tool to interact with the coach and to check their progress. The bulletin board and the locker room were not available for the individual group.

The interaction group also used the social features (see Figure 4). The messaging feature was used to send private messages to other participants and the coach, especially in Tomsk1. The bulletin board was also used, although visits were more related to a *lurking* behavior rather than actual contributions. We attribute this to automatic sharing of the participant's performance (as a 3-star rating based on completeness) on the bulletin board (*social learning* persuasion strategy [12]). The locker room comprises also an important percentage but it is mostly because of the fact that it preceded the classroom in the navigation. No important interactions or invitation to the join the classroom were registered from this virtual space.

Online Interactions

Participants in the interaction group had the possibility of exchanging public and private messages either with the coach or other trainees, whereas in the individual group, the interactions were limited to private messages with the coach. Table 5 summarizes the exchanges among participants of both groups in the two pilot studies.

Participants in the social condition made significantly more use of private messages compared with public messages. This was the case even for participants in Tomsk1 (strong group cohesion), with 4.4 private messages compared with only 0.6 public messages per user. Not surprisingly, participants of Tomsk1 interacted significantly more among themselves (4.4 messages per user compared with only 0.4 in Tomsk2).

It is also noteworthy the asymmetry between sent and received messages when including messages by the coach. This is because of the scheduled messages by the coach who reached participants on a weekly basis but was not always reciprocated, as well as to the interaction behavior of the coach, that is, sending more than one messages per interaction.

Copresence in the Training

Participants in the interaction group were able to see each other, train together, and coordinate their participations. Participants in the individual group were not. Thus, copresence in the individual group is only an indication of meetings by chance

and used for comparisons. The copresence by study and group is shown in Figure 5.

The copresence in the Tomsk1 study was on average significantly higher in the interaction group: 36.25% (SD 17.25%) in comparison with 10.71% (SD 4.15%) for the individual group. A *t* test showed a significant difference between the interaction and individual groups ($t_{7.9}$=−4.05, *P*=.004) in favor of the group training condition.

In the Tomsk2 study, the copresence was of 16.38% (SD 11.44%) in average in the interaction group and 19.4% (SD 11.13%) in the individual group. A *t* test showed no significant difference between groups ($t_{25.22}$=0.7, *P*=.49).

Program Adherence

The overall persistence rate was of 74% (SD 27%) when considering the number of sessions available in the 8 weeks of training. Breaking down this number by group treatment, we observe a persistence rate of 75% (SD 28%) for the individual groups and 74% (SD 26%) for the interaction groups, whereas the result by study shows a persistence rate of 82% (SD 24%) for Tomsk1 and 70% (SD 28%) for Tomsk2. In the study Tomsk1, the persistence rate was 77% (SD 25%) for the individual group and 87% (SD 23%) for the interaction group; in Tomsk2, it was 74% (SD 30%) for the individual group and 65% (SD 25%) for the interaction group.

An ANCOVA was performed to compare the persistence of participants of individual and interaction groups in the two studies while controlling for the initial baseline measures of leg muscle strength, social support, and PACES. The results show neither a significant main effect for group ($F_{1,18}$<1, *P*=.74) or for study ($F_{1,18}$=1.46, *P*=.24), nor interaction between study and group ($F_{1,18}$=1.15, *P*=.30).

Considering the baseline measures, the results show a significant interaction between study and the initial social support score ($F_{1,18}$=5.23, *P*=.03). As observed in Figure 6, part A, in Tomsk2, participants with higher social support level showed higher adherence to the training, whereas in Tomsk1, the adherence is not significantly associated with by the initial social support score.

Table 5. Mean (SD) messages exchanged among all users (including the coach) and only trainees.

Messages exchanged	Tomsk1		Tomsk2	
	Interaction, mean (SD)	Individual, mean (SD)	Interaction, mean (SD)	Individual, mean (SD)
Private messages sent				
All users	8.4 (6)	8.1 (7)	4.3 (6)	5.7 (4)
Only trainees	4.4 (3)	Not applicable (N/A)	0.4 (1)	N/A
Private messages received				
All users	13.5 (2)	13.1 (7)	11.1 (3)	10.9 (1)
Only trainees	4.3 (2)	N/A	0.5 (1)	N/A
Public messages posted				
Trainees	0.6 (1)	N/A	0.5 (1)	N/A

Figure 5. Copresence by study and group.

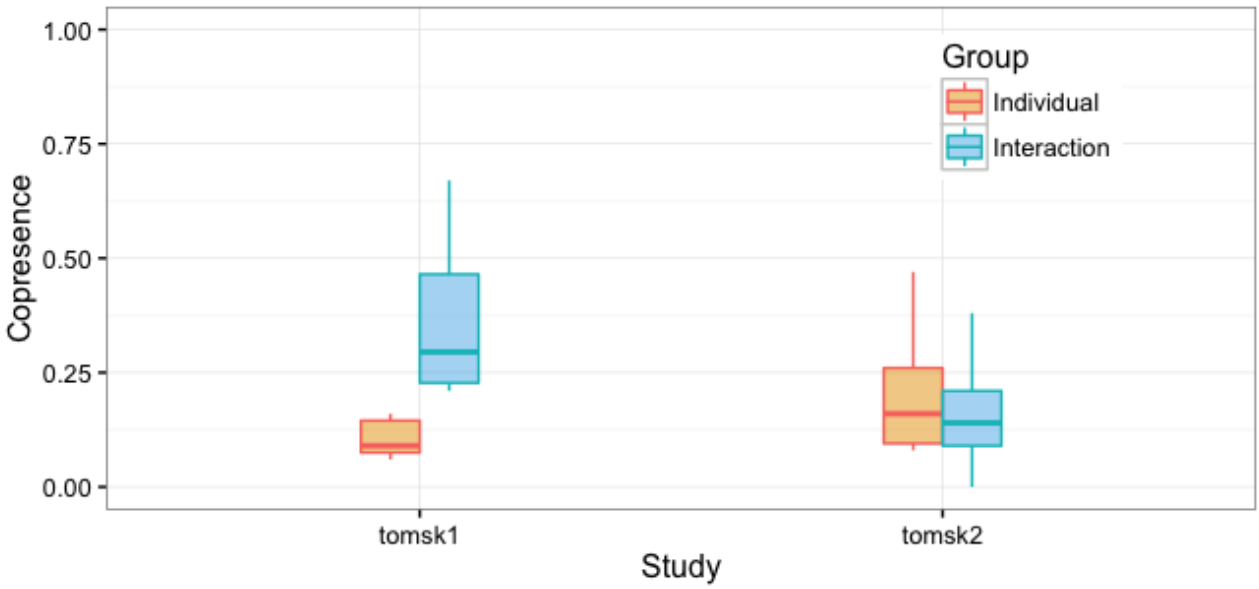
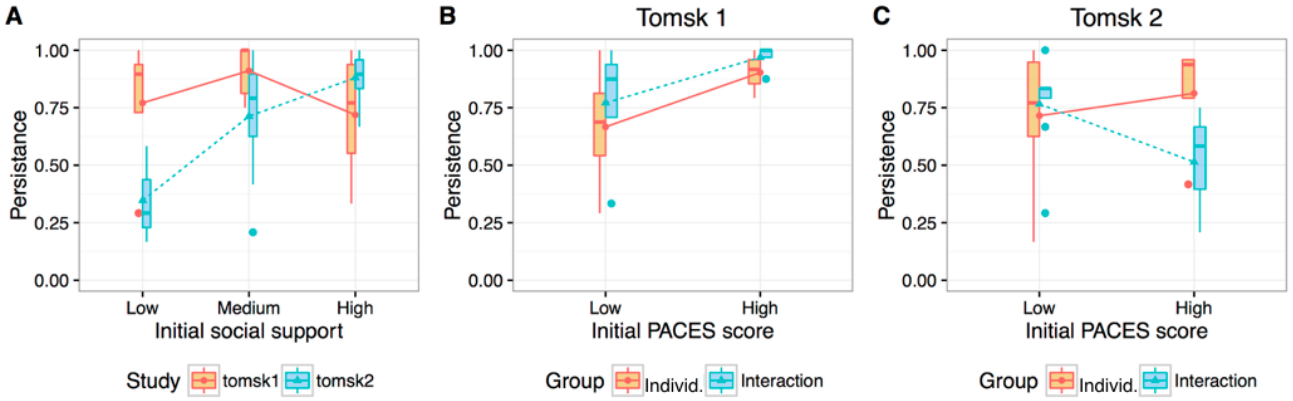


Figure 6. Interaction plots for persistence and baseline measures. (A) Interaction between study and initial level of social support (medical outcomes survey, MOS score has been grouped in three equally distributed intervals: low, medium, and high). (B) Interaction between group and initial PACES score in Tomsk1. (C) Interaction between group and initial PACES score in Tomsk2.



No significant effects were found for the initial scores of leg muscle strength.

The interaction between PACES score and group was also significant ($F_{1,18}$=6.001, P=.03). As shown in Figure 6, in Tomsk2, participants with higher enjoyment of physical activity had a higher adherence level (Figure 6, part B), whereas in Tomsk1, enjoyment of physical activity had a negative effect on the interaction group (Figure 6, part C).

Well-Being Outcomes

Eight participants did not answer to one or more questions of the SWLS and thus, have been excluded by this analysis. On the subset of participants without missing answers, SWLS score was analyzed with a repeated measure ANOVA with time (pretest vs posttest) as within-subject factor, and group (individual vs interaction) and study (Tomsk1 vs Tomsk2) as between-subject factors. Only the main effect of time was significant ($F_{1,31}$=5.85, P=.02). Participants reported high satisfaction in the posttest questionnaire (mean 23.8 [SD 6.2]) compared with the pretest measures (mean 21.34 [SD 5.8]).

The same analysis was performed on R-UCLA Loneliness Scale. Eight participants were excluded from the analysis because of missing values in the pretest or posttest questionnaires. Only the main effect of study showed a tendency toward significance ($F_{1,31}$=3.55, P=.07). Participants reported a lower level of loneliness in the Tomsk1 study (mean 4.77 [SD 1.7]) compared with the Tomsk2 study (mean 4 [SD 1]).

Discussion

Principal Findings

Online Group-Exercising Tool Rated as Highly Usable (Research Question 1)

Participants' rating on the usability of the app shows that the group exercise app (assigned to the interaction group) has a high usability and that the added complexity in relation to the more traditional home-based version (assigned to the individual group) did not significantly affect its usability.

When asked in detail, participants reported the training feature as very usable, whereas the messaging as usable but with a lower score (1 point lower), possibly because of the typing. The intention to use the app in the future was also very high, which along with the analysis of the actual usage, points to the feasibility of using the online group-exercising tool for training in a social context. These results are in line with a previous usability study and usage behavior analysis done on the Gymcentral tool [26].

Private Messages as Preferred Interaction Channel Among Trainees, Even in the Strong Cohesion Group (Research Question 1)

As in our previous study analyzing online interactions in a training context among Italian older adults [26], we expected to observe a higher usage of public messages for communication among trainees. Surprisingly, however, participants exchanged more private messages among themselves than public ones, even in the strong cohesion group. The high cohesion setting only accounted for more exchanges per user, not for group-level interactions. This result suggests different attitudes toward group interactions possibly because of cultural differences. In fact, the usage logs suggest mainly a lurking behavior, possibly because of the automatic sharing of the participant's performance—a social learning feature. Thus, further studies are required to design better online interaction tools that would motivate group building in the cultural context of reference.

Copresence Higher in the Strong Cohesion Group (Research Question 1)

The results of copresence show us that participants from the interaction group in Tomsk1 (strong cohesion group) participated in significantly more training sessions with the company of others compared with the meetings by chance in the individual group. We have seen the same effect in our previous study [12] featuring a high-cohesion group of Italian older adults. This effect was not observed in Tomsk2 (low cohesion group), suggesting that training together is not necessarily a preference in groups with low cohesion, and thus, the cohesion level might affect the willingness to train together.

Online Group Exercising Did Not Result in Higher Adherence When Compared With Individual Training With Persuasion Features (Research Question 2)

We have observed a higher adherence for the groups with high cohesion, and in particular, under the group-exercising treatment (interaction: mean 87% [SD 23%]; individual: mean 77% [SD 25%]). However, the ANCOVA showed neither a significant main effect for group or for study, nor interaction between study and group. This suggests that the added group exercising feature did not account for a significant difference in persistence rate compared with the individual training with persuasion features (interaction: mean 65% [SD 25%]; individual: mean 74% [SD 30%]).

In our previous study with Italian older adults [12], we observed a higher adherence to the online group-exercising compared with individual training (with no persuasion strategies). Here, we did not observe the same effect when comparing online group exercising with individual training (with persuasion strategies). We attribute this effect to (1) Persuasion features in the individual training condition that raised the adherence by 10% compared with our previous study [12]. This increase made the difference in favor of the group exercising condition nonsignificant and (2) Weaker cohesion among participants in Tomsk2, which might have reduced the effect of normative influence and peer support, resulting in a 20% drop in adherence compared with Tomsk1 and our previous study [12].

These results contribute to the ongoing discussion on the differences between individual and group training (see [21] for the most recent meta-analysis on the topic). First, it adds to the evidence that group-exercising in low cohesion groups results in an adherence comparable to that of individual training with contact (with a coach), extending the evidence to online settings. Second, it partially supports the evidence that group exercising in high-cohesion groups results in higher adherence than individual training with contact. On this point, we have seen evidence only when comparing group exercising with individual training with no persuasion strategies, which is indeed closer to the individual condition explored in [21]. The possibility of incorporating persuasion strategies in online setting adds a new dimension that requires further investigation.

Social Support Can Predict Adherence to a Training Program When Social Connections are Weak or Absent (Research Question 2)

In analyzing the effects of social support on adherence, we have seen a significant interaction between study and the initial social support score at baseline. In Tomsk2, participants with higher social support level showed higher adherence to the training. This suggests that higher level of social support is associated with higher levels of adherence when the connection among participants is weak (Tomsk2). This observation is in lines with the literature highlighting the social support structure as an important determinant of adherence [7,8]. Interestingly, Tomsk1 did not show a significant association between initial social support and adherence. This suggests that low levels of external social support (as measured at baseline) can also be compensated with the social dynamics of an online group with strong cohesion (Tomsk1).

Enjoyment of Physical Activity With Contradicting Effects on Adherence for Groups With Weak and Strong Cohesion (Research Question 2)

Enjoyment of physical activity is described as determinant of physical activity [7,8] and is associated with positive attitudes toward exercise, intrinsic motivation, and consequently long-lasting adherence to physical activity [44,45]. We have seen, however, some conflicting effects of this variable—as measured with the PACES scale—on the adherence of the groups with weak and strong cohesion: all groups showed higher adherence for higher PACES score except for the interaction group with low cohesion that showed the opposite effect. This negative effect on adherence in the latter group came as a surprise, and it requires further study to investigate its roots and whether it is because of negative social dynamics in low cohesion settings.

Initial Level of Fitness With Nonsignificant Effect on Adherence of Online Group Exercising and Individual Training With Persuasion Strategies (Research Question 2)

Implementing group exercising can be challenging, especially in heterogeneous populations. Individual differences among older adults can lead to motivational issues and problems in tailoring the training [11]. In addition, perceived barriers such as lack of skills, pain, fear of injuries, and falls can also constitute obstacles to the motivation of older adults to exercise.

In our previous study with Italian older adults [26], we observed that the initial level of fitness could predict the adherence of older adults to an individual training (without persuasion strategies). It was also observed that the online group exercising tool—the same used in the pilots reported in this paper—was effective in mitigating that effect. In lines with this prior study, the results from our two pilots showed that the initial level of fitness did not have a significant effect on adherence of the interaction group but neither on the adherence of the individual group. One potential explanation is the presence of individual persuasion strategies in the version of the app used by the individual group, which might have leveled the effect. This suggests that more studies are needed to better understand the roots of the observed effects of the initial level of fitness, as well as the effects of individual and social persuasion in mitigating them.

Seasonal Fluctuations and Its Influence on Availability of Candidate Participants (Research Question 2)

Seasonal fluctuation has been found to determine the level of physical and social activities of older adults [13], especially in high latitudes where winter can result in a decline of physical functions of older adults [14]. In Siberia, these fluctuations greatly influence the activities of the daily living and the opportunities to engage in activities in general.

Although our studies were set in spring and summer periods, we did experiment the effects of the seasonal fluctuation but at recruitment and for quite the opposite reasons. June to

September is gardening season, and independent living older adults usually engage in this activity, spending most of the period in their summer houses (Dacha). This influenced the availability of participants in our study as it created obstacles for some candidates that showed initial interest in participating (eg, finding time to train and worries of bringing tablets with them outdoors or to the Dacha). After this experience, the second study was moved to earlier spring months (April-June) to increase the pool of potential candidates. However, we did not see a significant difference in the program adherence that could be explained by these two different seasons. Further studies are needed, especially to understand the effects of the extreme winter season.

Increase in Life Satisfaction as a Result of the Training, Regardless of the Version of the App (Research Question 3)

Recent history, along with current social, political, and economical factors have impacted negatively in life satisfaction and happiness of older adults in the Russian Federation [17]. Thus, devising and studying solutions aiming increasing the happiness and well-being of older adults in this region is of paramount importance.

In investigating the impact of physical training, we have seen an overall improvement in the SWLS score for all participants, regardless of the version of the tool used. This is consistent with our previous study with Italian older adults [26], where we observed an improvement in the subjective well-being of the participants regardless of being part of the individual or group condition. Furthermore, these results are in line with previous literature on the benefits of physical activity on the QoL of older adults [46,47], and contribute with additional evidence in favor of technology-supported interventions and their benefit for older adults in the Siberian region.

No Significant Decrease in Loneliness, Despite Social Features (Research Question 3)

Participants did not observe any decrease in the loneliness score as a result of the training, not even those in the online group exercise condition. This is contrary to our expectations, given the social context provided by the group-exercising and the social interaction features. In Trento, Italy [26], we did observe a significant decrease in the loneliness score, but compared with this study, the usage of social interaction tools and adherence to the training was much higher. This difference in the usage of social interaction features, possibly because of cultural differences as reported earlier, could have limited the effectiveness of the medium.

Limitations

Gender Imbalance

The lifespan gap between males and females in the Siberian region is one of the biggest in the world: life expectancy at birth for men is 64.7 years, whereas for women it is 76.3 years [37]. These demographics limit the availability of male candidates in the senior citizen organizations, and therefore, our ability to recruit more male participants. However, previous studies suggest that male and female participants may have the same reactions to sport activities despite differences in motives to participation [45,48]. Still, further studies are needed to see if these observations can be translated to the intervention described in this paper.

Group Size Difference

The amount of participants in the Tomsk2 study was twice bigger than in the first Tomsk1 study, 40 and 20 participants, respectively.

The difference in the group size between the two studies is because of (1) the complexity of the study design and (2) the difficulty in finding participants of older age willing to participate, given the specific social characteristics of the region (older adults living in Siberia are not used to participate in studies). Therefore, we were able to involve only 20 participants for the study Tomsk 1. The following year, as we built better contacts with various retirement organizations and local organizations became more familiar with the project, we were able to involve 40 people in the study (Tomsk 2).

No Quantitative Measures of Group Cohesion

Group cohesion was defined as a property of the pool of candidates: participants acquainted with each other and engaging in joint activities. This property was maintained during randomization by ensuring that pairs of friends would end up in the same groups. While being a solid definition, the fact that cohesion was not qualitatively measured should be noted as a limitation.

Scales Validation in Russian Language

There is a lack of translations of international standardized measure in Russia. Therefore, except the SWLS (which has already been validate in Russian language), no translation was available for the measures used in the study. These measures were translated and adapted to Russian language and culture by our research group by using the standard translation or bask-translation procedure. During this procedure, we ensured to reach semantic, idiomatic, and conceptual equivalence between the original English and final Russian versions.

Although, without a validation study, we cannot be completely sure that these instruments fully fit the socioeconomic characteristics of Siberia, we believe that the standard procedure adopted to translate these instruments provided reliable results. This should be considered as the limitation of the study.

Validity of the System Usability Scale

Two questions were excluded from the SUS because in the pretest of the prefinal version of the scale (during the translation or back-translation procedure), older adults found it difficult to understand them (“I found the various functions in this system were well integrated” and “I thought there was too much inconsistency in this system”). Therefore, whereas in the original scale the total SUS score ranged from 0 to 100, in our study it ranged from 0 to 80. This is a limitation of our study and could make it difficult to interpret the usability results. However, it is worth noting that no usability scale suitable for older adults existed in Russian language, and our study provides the first adaptation for this culture. Future studies should investigate the validity of this short version of the SUS.

Conclusions

The results point to the feasibility and effectiveness of technology-supported physical interventions, and in particular, of online group exercising among Siberian older adults. High cohesion groups are preferable for group exercising, especially to mitigate effects of low social support on adherence. Cultural differences might explain the preference of private messages over public ones. Results in terms of subjective well-being are promising, but enabling interaction has proved not to be enough to observe a decrease in loneliness. Thus, further research is needed to understand how to better enable community-building interactions.

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Conflicts of Interest

None declared.

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Abbreviations

ANCOVA: analysis of covariance
ANOVA: analysis of variance
MOS: medical outcomes survey
PACES: Physical Activity Enjoyment Scale
QoL: quality of life
RQ: research question
R-ULCA: revised University of California, Los Angeles
SUS: System Usability Scale
SWLS: Satisfaction with Life Scale

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Original Paper

Feasibility of a Mobile Phone App to Support Recovery From Addiction in China: Secondary Analysis of a Pilot Study

Hui Han[1*], MD; Jing Ying Zhang[1*], MD; Yih-Ing Hser[2], PhD; Di Liang[2], PhD; Xu Li[1], MD; Shan Shan Wang[1], MD; Jiang Du[1,3], MD, PhD; Min Zhao[1,3], MD, PhD

[1]Collaborative Innovation Center for Brain Science, Shanghai Mental Health Center, Shanghai Jiao Tong University School of Medicine, Xu Hui District, Shanghai, China

[2]Los Angeles Integrated Substance Abuse Programs, The University of California, Los Angeles, CA, United States

[3]Shanghai Key Laboratory of Psychotic Disorders, Shanghai, China

[*]these authors contributed equally

Corresponding Author:
Jiang Du, MD, PhD
Collaborative Innovation Center for Brain Science
Shanghai Mental Health Center
Shanghai Jiao Tong University School of Medicine
600 Wan Ping Nan Road
Xu Hui District, Shanghai, 200030
China
Phone: 86 18017311220
Email: dujiangdou@163.com

Abstract

Background: Mobile health technologies have been found to improve the self-management of chronic diseases. However, there is limited research regarding their feasibility in supporting recovery from substance use disorders (SUDs) in China.

Objective: The objective of this study was to examine the feasibility of a mobile phone-based ecological momentary assessment (EMA) app by testing the concordance of drug use assessed by the EMA, urine testing, and a life experience timeline (LET) assessment.

Methods: A total of 75 participants dependent on heroin or amphetamine-type stimulant (ATS) in Shanghai were recruited to participate in a 4-week pilot study. Of the participants, 50 (67% [50/75]) were randomly assigned to the experimental group and 25 (33% [25/75]) were assigned to the control group. The experimental group used mobile health (mHealth) based EMA technology to assess their daily drug use in natural environments and received 2 short health messages each day, whereas the control group only received 2 short health messages each day from the app. Urine tests and LET assessments were conducted each week and a post-intervention survey was administered to both groups. The correlations among the EMA, the LET assessment, and the urine test were investigated.

Results: The mean age of the participants was 41.6 (SD 8.0) years, and 71% (53/75) were male. During the 4 weeks of observation, 690 daily EMA survey data were recorded, with a response rate of 49.29% (690/1400). With respect to drug use, the percent of agreement between the EMA and the LET was 66.7%, 79.2%, 72.4%, and 85.8%, respectively, for each of the 4 weeks, whereas the percent of agreement between the EMA and the urine test was 51.2%, 65.1%, 61.9%, and 71.5%, respectively. The post-intervention survey indicated that 46% (32/70) of the participants preferred face-to-face interviews rather than the mHealth app.

Conclusions: This study demonstrated poor agreement between the EMA data and the LET and found that the acceptance of mHealth among individuals with SUDs in China was not positive. Hence, greater efforts are needed to improve the feasibility of mHealth in China.

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KEYWORDS

mHealth; substance use; heroin dependence; amphetamine-type stimulant (ATS) dependence; mobile app; China

Introduction

Substance use disorder (SUD) is a major public health issue, not only in China but worldwide as well [1,2]. Based on the report from the United Nations Office on Drugs and Crime (UNODC), approximately 290 million people worldwide use illicit drugs, and marijuana heads the list as the most popular drug used throughout the world [3]. China, the largest developing country, faces serious drug problems. Between 2000 and 2016, the number of registered people in China with a drug addiction increased sharply from 0.86 to 2.50 million [4]. Although the number of users of club drugs, such as methamphetamine, ecstasy, and ketamine, has increased since the last decade, heroin remains a major drug problem, with 49.3% of people registered with a drug addiction being addicted to it [5]. To control the problems of heroin abuse and HIV and AIDS infection, harm-reduction programs, including methadone maintenance treatment (MMT) clinics, have been established throughout China beginning in 2004 [6,7]. By the end of 2014, there were more than 300 MMT clinics providing services to 344,254 addicts [8]. Although the effectiveness of MMT has been demonstrated, its implementation still faces certain problems, including the high cost of MMT, a lack of psychotherapy, and the low dosage of methadone, which contributes to high rates of drop-out and relapse [9,10]. Together, these conditions suggest the need to develop new intervention strategies that meet the needs of people with drug addiction in China [11,12].

A large body of studies has demonstrated that drug addiction is a chronic relapsing brain disease that features cycles of relapse and remission [13]. A chronic condition means that those with SUDs require a chronic care model that can provide an integrated care system that includes services and self-management tools designed to prevent relapse [14,15].

Mobile health (mHealth) service is a new technology that has been widely used in the health care service field as well as in substance abuse treatment programs in western countries [16]. Service providers integrate a tailored mHealth self-management app for patients and collect data from the app to help them monitor their patients' behaviors [17]. For example, a mobile phone can be programmed to send a message when people with a drug addiction enter a high-risk area that can lead to relapse. Other functions include improving disease management, delivering therapeutic interventions, and increasing healthy behavior [18].

Recently, the mobile phone-based ecological momentary assessment (EMA) began to be used in the field of medical treatment. The EMA is a mHealth technology that is capable of collecting individuals' data in real time. Compared to other retrospective surveys, the EMA is thought to substantially improve the accuracy of reporting since self-reporting sometimes requires participants to recall events over long periods, a situation that may introduce a systematic bias [19,20].

A few studies have compared the accuracy of the EMA with other measures to assess drug use behaviors. Kranzler [21] assessed the amount of drinking SUDs using a timeline follow-back method (TLFB) and a daily interactive voice recording (IVR) and found poor agreement between the two approaches. Similarly, Searles and Lincoln's results revealed poor agreement between daily drinking recall and IVR measures [22,23]. Conversely, other researchers [24-26] conducted a set of outcome-based analyses using both the TLFB and the IVR drinking outcomes and found no differences between the two measures.

To our knowledge, there are no published studies that address the feasibility and acceptability of this novel technology among individuals with SUDs in China. This lack of evidence hinders the implementation of mHealth in China. To address this knowledge gap, we conducted secondary analyses based on a pilot study of a mobile phone-based intervention designed to support recovery from addiction. The aims of the present study were to test the concordance of drug use collected via the EMA, urine testing, and a retrospective self-report survey instrument, and to investigate the acceptability of mHealth in China. The overall goal was to provide evidence for the future use of mHealth technology in drug relapse prevention.

Methods

Sample Recruitment and Study Procedures

Participants were recruited from 3 MMT clinics and the Zi-Qiang social work consortium. The social work consortium is a community-based social work service network with approximately 500 social workers hired from eligible individuals in the community to help clients living within the same community. All participants were recruited through advertisements in the MMT clinics and the social work consortium. Inclusion criteria were (1) aged 18 to 65 years; (2) above primary education; (3) able to use a mobile phone with app capabilities; (4) a newly enrolled patient in an MMT clinic or social work consortium or relapsed (positive urine test) within the past 30 days; (5) met the Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV) criteria for heroin dependence or amphetamine-type stimulant (ATS) dependence; and (6) consent to participate in the study. Exclusion criteria were (1) a main substance that was not heroin or ATS; and (2) diagnosis of serious mental illness and inability to complete the evaluation. Protocols for this study were approved by the institutional review board (IRB) of Shanghai Mental Health Center (No 2012-56C2) and the University of California, Los Angeles (12-000809).

From June 2015 to April 2016, 89 clients were screened at baseline. Of the clients, 7 (8% [7/89]) reported that they had no mobile phone, and 5 (6% [5/89]) refused to participate in the study. Thus, 75 participants were recruited and assigned to either the experimental group (n=50) or the control group (n=25), resulting in a 2:1 ratio.

All participants were required to install the app and were given instructions on how to use it. The app for the experimental group included 6 functions: surveys (daily survey and self-initiated survey), messages, settings, profile, craving, and help. The app for the control group included messages, settings, profile, and help. Participants in the experimental group were asked to complete a daily survey on the app and they received 2 health

messages every day for 4 weeks. Participants in the control group only received 2 health messages from the app. Demographics, substance abuse histories, and clinical scale data were collected at baseline. Whether participants engaged in drug use was assessed using the EMA app, the urine test, and the LET once a week during the study period.

Description of the Mobile Health-Based App

The mHealth was developed specifically to help individuals with SUDs achieve and maintain recovery. Thus far, it is the first mobile app designed for people with SUDs in China. The mechanism of the mHealth app is based on cognitive behavior therapy (CBT) and self-determination theory (SDT). CBT emphasizes triggers and coping strategies for relapse prevention, whereas SDT is a theory that motivates people to change and act for themselves. mHealth is combined with CBT and SDT to create 3 main tools: surveys, messages, and cravings, to foster positive behavior and manage behavior. These tools provide timely assessment and intervention and help individuals with SUDs to control their cravings and prevent relapses.

Surveys

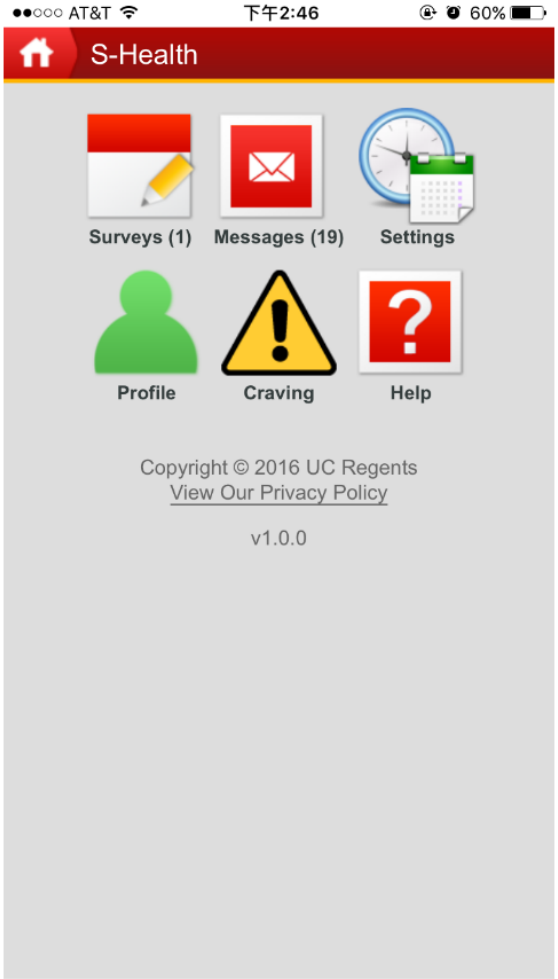
There are 2 types of surveys built into the app: the daily survey and the self-initiated survey. Participants were alerted to complete the daily survey every 24 hours. This survey required them to report their alcohol, tobacco, and drug use as well as their cravings, triggers, emotions, coping strategies, and daily goal progress for the last 24-hour period. Once participants completed the daily survey, it was no longer available to the participant until the next day at the scheduled time, which was set by the participant. It took 1 to 2 minutes to complete the daily survey. The self-initiated survey was available to participants at any time. The questions on this survey addressed cravings, triggers, and drug use. Once the participant indicated a craving for a drug, he or she could complete the survey and received messages to help control the craving, to a certain extent. A screenshot of the mHealth app home screen is shown in Figure 1.

Data Collection

Ecological Momentary Assessment

The EMA data were collected from the experimental group using the survey function in the app. The daily situation (eg, drug use, craving, coping) was collected by the daily survey, which was conducted every day at a scheduled time. Before the scheduled time, a reminder message was sent to the participants to remind them to complete the daily survey. Craving status was collected by the self-initiated survey, which could be completed any time the participant experienced a craving for a drug. A guide message was then sent to the participant to help control the craving.

Figure 1. Home screen of the mobile health (mHealth) app.



Life Experience Timeline Assessment

The LET was developed by the University of California, Los Angeles (UCLA) and exhibited good reliability and validity [27,28]. The questionnaire consists of 20 items that record 20 events (eg, substance use, emotion, coping, and craving) over the past week. Participants were requested to complete the LET survey at baseline and each week during the study period. The outcomes collected by the LET indicated whether the individual used any of the identified substances in the last week and, if so, how many days they used drugs in last week.

Urine Test

The urine test board was used to test drug use at baseline and each week during the study period. The test identified heroin, ATS, marijuana, cocaine, and ketamine use.

Post-Intervention Survey

To measure the acceptability of the electronic mobile (e-mobile) method among individuals with SUDs, the participants were asked to respond "agree" or "disagree" for each of the following items:

It is easy for me to understand these questions.

I feel okay when I answer questions about drug use.

I can recall the days I used drugs during the last week.

It is fine for me to answer the same questions each year.

This mHealth app is easy to use.

Compared to a face-to-face interview, I prefer to use the mHealth app.

An informal group discussion was conducted with 7 participants who voluntarily attended the discussion. The main purpose of the group discussion was to collect supplementary information as to why individuals with SUDs did not want to use the mHealth app.

Data Analysis

All statistical analyses were conducted using the Statistical Package for Social Science (SPSS, version 22.0). The differences in characteristics between the experimental group and the control group were analyzed using the *t* test for continuous measures and the chi-square test for categorical measures. Statistical significance was set at alpha=.05. Cohen kappa was conducted to measure the correlations among the 3 measures. Concordance correlation coefficients less than 0.20 were regarded as poor, 0.21 to 0.40 as fair, 0.41 to 0.60 as moderate, 0.61 to 0.80 as good, and 0.81 to1.00 as very good. The chi-square test was used to compare the consistency of the EMA and the LET data. A logistic regression was conducted to explore the factors that influenced the correspondence between the EMA and the urine test during the study period. Only non-missing data during the whole week were included in the analysis.

Results

Baseline characteristics of the participants of the experimental and control groups are shown in Table 1. The mean age of the participants was 41.6 (SD 8.0) years, and 71% (53/75) of the participants were male. Among the experimental group, 76% (38/50) were heroin users and 24% (12/50) were ATS users, whereas among the control group, 80% (20/25) were heroin users and 20% (5/25) were ATS users. There were no significant differences between the groups in terms of the type of drug, age, gender, education, marriage, employment status, initial age of use drug, or length of main substance used. Drug use test results are summarized in Table 2.

Table 1. Baseline characteristics of the participants (N=75).

Characteristic	Total	Experimental group (N=50)	Control group (N=25)	t/F/Z	*P**
Age, mean (SD)	41.6 (8.0)	41.7 (8.7)	41.3 (6.8)	0.235	.815
Male, n (%)	53 (71)	35 (70)	18 (72)	0.138	.858
Education, n (%)				0.538	.463
≤Middle school	32 (43)	23 (46)	9 (36)		
≥High school	43 (57)	27 (54)	16 (64)		
Marital status, n (%)				0.001	.972
Married	32 (43)	20 (40)	12 (48)		
Single	43 (57)	30 (60)	13 (52)		
Employment, n (%)				2.600	.107
Employed	45 (61)	33 (67)	12 (48)		
Initial age of use drug, mean (SD)	26.1 (8.9)	25.9 (8.8)	26.4 (9.2)	-0.211	.834
Length of main drug used (months), mean (SD)	15.5 (6.0)	15.8 (6.1)	14.9 (6.0)	0.615	.541

*Significant at *P*<.05.

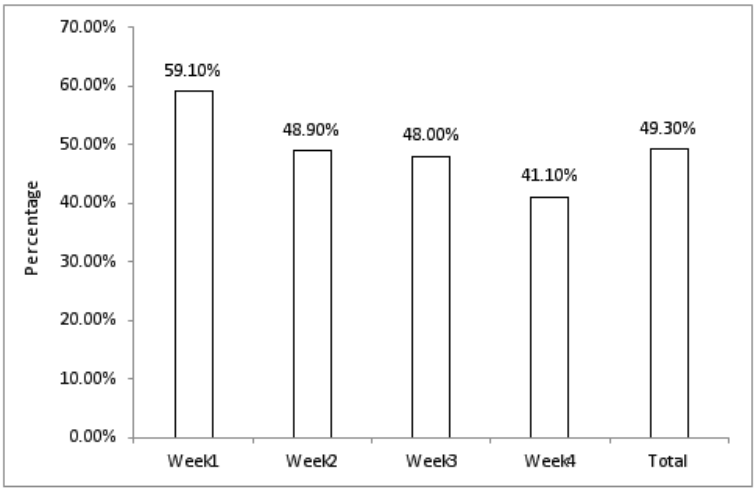
Table 2. Drug use test results by week.

Test	First week (n)	Second week (n)	Third week (n)	Fourth week (n)
Urine test				
Use	24	21	15	11
No use	19	22	27	31
Total	43	43	42	42
Self-report LET[a]				
Use	15	12	10	7
No use	33	36	38	41
Total	48	48	48	48
EMA[b]				
Use	12	10	6	5
No use	28	25	26	25
Total	40	35	32	30

[a]LET: life experience timeline.

[b]EMA: ecological momentary assessment.

Figure 2. The weekly ecological momentary assessment (EMA) data in the experimental group.



Ecological Momentary Assessment Data Description

The EMA data were collected from the experiment group. A total of 350 EMA daily surveys were expected each week (50 times 7). The daily survey data received was 59.1% (207/350) the first week; 48.9% (171/350) the second week, 48.0% (168/350) the third week, and 41.1% (144/350) the fourth week. The average response rate was 49.29% (690/1400). These results indicated that the daily survey response rates were generally low (Figure 2).

Methods of Measuring Drug Use

Three methods (ie, EMA, LET, and urine test) were used to assess drug use each week. The correspondence between the EMA and the LET over the 4 weeks was 67% (32/48), 79% (38/48), 72% (35/48), and 86% (41/48), respectively. The correspondence between the EMA and the urine test was 51% (22/43), 65% (28/43), 62% (26/42), 72% (30/42), respectively (Figure 3). The agreement between the EMA and the LET was not good, with Cohen kappas of 0.128, 0.412, 0.111, and 0.241, respectively. With respect to the agreement between the EMA and the urine test, the results were not optimistic according to Cohen kappas, which were 0.076, 0.292, 0.017, and 0.103, respectively. The logistic regression analysis revealed that work and age were correlated with correspondence between the EMA and the urine test during the study period (odds ratio [OR]=0.167, 1.137, 0.195; P<.05), as shown in Table 3 and Figure 3.

Post-Intervention Survey

The post-intervention survey was conducted with all participants to evaluate their attitude toward the mHealth-based app (Table 4). Even though most of the participants (72% [51/71]) admitted that the mHealth app was easy to use, almost half of them (46% [32/70]) stated that compared to the mHealth data collection method, they preferred a face-to-face interview.

Figure 3. The concordance of test results.

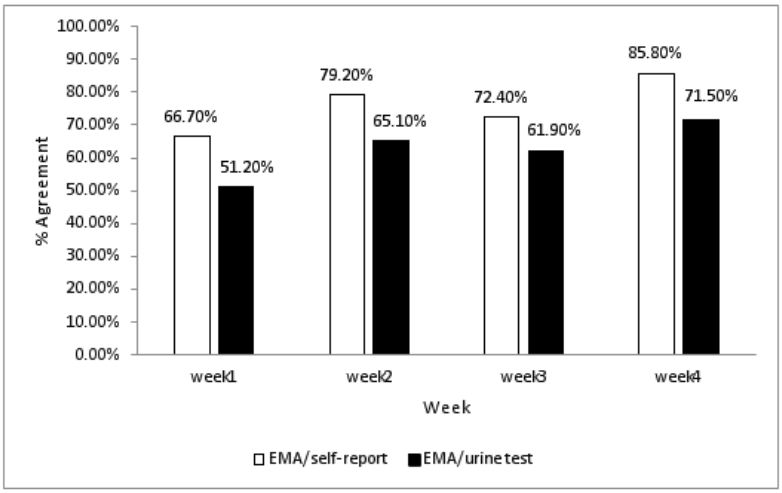


Table 3. Logistic regression of concordance between the ecological momentary assessment and the urine test.

Week	Factor	β	SE	Chi-square	*P*	OR[a]	95% CI
1	Job	-1.792	0.755	5.625	.018	0.167	0.038-0.733
2	Age	0.129	0.048	7.074	.008	1.137	1.034-1.251
3	Job	-1.636	0.854	3.670	.034	0.195	0.037-1.038

[a]OR: odds ratio.

Table 4. Post-intervention survey results.

Item	Agree, n (%)	Disagree, n (%)
1. It is easy for me to understand these questions[a].	44 (67)	22 (33)
2. I feel comfortable when I answer these questions[b].	49 (69)	22 (31)
3. I can recall the days I used drugs during the last week[b].	42 (59)	29 (41)
4. I prefer to answer these questions each year[b].	51 (72)	20 (28)
5. The mHealth app is easy to use[b].	51 (72)	20 (28)
6.Compared to a face-to-face interview, I prefer to use the mHealth app[c].	38 (54)	32 (46)

[a]N=66.
[b]N=71.
[c]N=70.

Discussion

Principal Findings

The purpose of this study was to investigate the feasibility and acceptability of mHealth among individuals with SUDs in China. The findings from our study demonstrated that the veracity and acceptability of the EMA was not optimistically received among those with SUDs in China.

In China, people with drug addiction are treated as immoral. Poor adherence to treatment is the primary problem when dealing with substance-related issues [29] because it leads to relapse. Schomerus [30] found that the stigma associated with alcohol dependence was higher than it was for other mental disorders in general population studies and created a barrier for people to routinely enter treatment [31,32]. Thus, mHealth-based data collection methods hold a unique place among people with drug addiction. Nonetheless, our findings indicated that the response rate for EMA data collection was low, with an average response rate of 49.29% (690/1400), and half of the participants preferred face-to-face interviews. The reasons for the low response rate were drawn from the post-intervention survey. Patients who were unwilling or hesitant to use mHealth expressed concerns with privacy. Some mentioned that the mHealth-based app was not safe and they were afraid of being arrested because they thought the police could obtain information about their relapse from the app. They also expressed concerns about the Global Positioning System (GPS) function of the app, claiming that it made them uncomfortable.

Moreover, because most of the individuals with SUDs were isolated from society and their relatives, they preferred the face-to-face interviews because they perceived them as a way to communicate with the public. Another factor that affected the response rate is age [33]. Compared to older patients, young patients are more inclined to accept novel technologies, such as mHealth. Conversely, older patients are more conservative and tend to be more concerned about their privacy. Although age was not mentioned as a barrier in this study, it should be considered in future research and in clinical applications.

Another aim of the study was to explore the veracity of the EMA data. The EMA aims to minimize recall bias, maximize ecological validity, and enable the study of behavior in the real world. Our study results indicated that the correlations between the EMA and the LET and the EMA and the urine test were poor. These results are similar to those of previous studies. For example, Pearson [34] compared the accuracy of self-reported electronic cigarette (e-cigarette) puff counts using the EMA to objective puff count data collected by a Bluetooth-enabled e-cigarette device and found poor agreement between the device data and the self-reported data. Solhan [35] examined the discrepancies among trait questionnaires, retrospective reports, and EMA measures of affective instability in psychiatric outpatients and found poor agreement between recalled mood changes and the EMA. Griffith [36] also found poor agreement between the TLFB and the EMA with respect to heavy smokers.

Regarding the impact factors, Patrick [37] found that gender moderated the 3 methods of data collection. Our work indicated that job and age were predictors of the correspondence between the EMA and the urine test. With respect to the influence of employment, people with a job were found to exhibit better correspondence between the EMA and the urine test. This may be because people who have jobs are better able to cooperate with others and are more likely to engage in honest communications and receive assistance from others.

Limitations

Limitations to our study included a convenience sample that may not be representative of other areas in China or of foreign countries. However, our findings may still be beneficial to those with similar situations. Second, self-reporting and the response to the text message could have been inaccurate due to a number of factors. Third, the low response rate to the EMA daily diaries indicated poor acceptance of mHealth among individuals with SUDs. A future study could combine pre-intervention education and EMA technology to improve the response rate. Finally, because the technology was limited, we were unable to provide accurate feedback or interventions to participants when a craving arose. Despite these limitations, the study presents valuable information regarding the feasibility of electronic health (e-health) among individuals with SUDs.

Conclusions

Mobile phones have been widely used among the Chinese population, with 1.3 billion mobile phone users in 2016. Thus, mobile phones provide a potential opportunity for the development of mHealth in China. The current study demonstrated poor agreement among the data from the EMA, the LET assessment, and urine testing. Hence, the acceptance of mHealth among individuals with SUDs in China was not enthusiastic. This indicates that more work is needed to optimize the mHealth app and improve its acceptance among individuals with SUDs in China as well as in other countries that are experiencing similar issues.

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Conflicts of Interest

None declared.

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Abbreviations

ATS: amphetamine-type stimulant
CBT: cognitive behavior therapy
e-cigarette: electronic cigarette
EMA: ecological momentary assessment
IVR: interactive voice recording
LET: life experience timeline
mHealth: mobile health
MMT: methadone maintenance treatment
SDT: self-determination theory
SUD: substance use disorder
TLFB: timeline follow-back method

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Original Paper

Feasibility and Efficacy of a Parent-Focused, Text Message–Delivered Intervention to Reduce Sedentary Behavior in 2- to 4-Year-Old Children (Mini Movers): Pilot Randomized Controlled Trial

Katherine L Downing[1], BAppSc (Ex&SS) (Hons); Jo Salmon[1], PhD; Trina Hinkley[1], PhD; Jill A Hnatiuk[1], PhD; Kylie D Hesketh[1], PhD

Institute for Physical Activity and Nutrition, School of Exercise and Nutrition Sciences, Deakin University, Burwood, Australia

Corresponding Author:
Katherine L Downing, BAppSc (Ex&SS) (Hons)
Institute for Physical Activity and Nutrition
School of Exercise and Nutrition Sciences
Deakin University
221 Burwood Hwy
Burwood, 3125
Australia
Phone: 61 392446088
Email: k.downing@deakin.edu.au

Abstract

Background: Despite public health guidelines to limit sedentary behavior, many young children spend large amounts of time sedentary (eg, screen and sitting time) during waking hours.

Objective: The objective of this study was to test the feasibility and efficacy of a parent-focused, predominantly text message–delivered intervention to support parents to reduce the amount of time their children spend in sedentary behavior.

Methods: Mini Movers was a pilot randomized controlled trial delivered to parents of 2- to 4-year-old children in Melbourne, Australia. Participants were recruited through playgroups, social media, and snowball sampling. Eligibility criteria were having an ambulatory child (2-4 years), English literacy, and smartphone ownership. Participants were randomized to intervention or wait-list control on a 1:1 ratio after baseline data collection. The 6-week intervention was predominantly delivered via text messages, using a Web-based bulk text message platform managed by the interventionist. Intervention strategies focused on increasing parental knowledge, building self-efficacy, setting goals, and providing reinforcement, and were underpinned by the Coventry, Aberdeen & London-Refined taxonomy of behavior change techniques and social cognitive theory. The primary outcome was intervention feasibility, measured by recruitment, retention, intervention delivery, and fidelity; process evaluation questionnaires; and qualitative interviews with a subsample of participants. Secondary outcomes were children's screen and restraint time (parent report), sitting time (parent report, *activ*PAL), and potential mediators (parent report). Linear regression models were used to determine intervention effects on secondary outcomes, controlling for the child's sex and age and clustering by playgroup; effect sizes (Cohen's *d*) were calculated.

Results: A total of 57 participants (30 intervention; 27 wait-list control) were recruited, and retention was high (93%). Process evaluation results showed that the intervention was highly acceptable to parents. The majority of intervention components were reported to be useful and relevant. Compared with children in the control group, children in the intervention group had significantly less screen time postintervention (adjusted difference [95% CI]=−35.0 [−64.1 to −5.9] min/day; Cohen's *d*=0.82). All other measures of sedentary behavior were in the expected direction, with small to moderate effect sizes.

Conclusions: Mini Movers was shown to be a feasible, acceptable, and efficacious pilot intervention for parents of young children, warranting a larger-scale randomized control trial.

Trial Registration: Australian New Zealand Clinical Trials registry: ACTRN12616000628448; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12616000628448p (Archived by WebCite at http://www.webcitation.org/6wZcA3cYM)

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KEYWORDS

child behavior; children; mHealth

Introduction

Early childhood (ie, birth through 5 years) is recognized as a critical period in which sedentary behavior habits (eg, time spent sitting, screen time) are established [1,2]. In young children, sedentary behavior includes screen time, quiet play, and time spent in situations that restrict movement (eg, in car seats or prams). In early childhood, there is inconsistent evidence on the health and developmental outcomes associated with objectively assessed sedentary time (herein referred to as sedentary time) or time spent in situations that restrict movement (eg, in a car seat or pram). Some studies report no associations between sedentary time and adiposity [3,4] or psychosocial health [5], or between time spent restrained and motor development outcomes [6]. On the other hand, studies have reported unfavorable associations between girls' total sedentary time and waist circumference [7] and between total percentage of time spent sedentary (for boys and girls) and locomotor skills [8]. For screen time, the evidence is more consistent. Television viewing, one of the most commonly studied sedentary behaviors in this age group, has been associated with unfavorable levels of adiposity and decreased psychosocial health and cognitive development [9,10], and total screen time has been associated with poorer well-being [11].

On the basis of these adverse health and cognitive outcomes, and given that some sedentary behaviors track over time [2], recommendations to limit sedentary behavior have been developed in several countries. These recommendations suggest that children aged 2 to 5 years should have less than 1 hour per day of screen time [12,13] and that situations that restrict movement, for example, in a car seat or pram, should be minimized for children aged 5 years and younger [12-14]. However, contrary to these recommendations, many young children are spending large amounts of time in these behaviors [6,15-18]. Feasible, acceptable, and effective interventions to reduce sedentary behaviors are therefore necessary during this early childhood period.

A systematic review and meta-analysis of interventions to reduce sedentary behavior during early childhood found that previous interventions can reduce both children's screen time and sedentary time [19]. A majority of interventions included in that review were conducted in the preschool or child care setting, with comparatively few conducted in the home or in a community-based setting. However, subgroup analyses revealed that interventions conducted in the home setting, and including parent involvement, had the largest effects on screen time outcomes [19], suggesting this may be the most effective approach for modifying children's screen behaviors. That review also highlighted the paucity of interventions targeting time spent in front of screens other than television or time spent restrained [19]. Furthermore, a limitation of existing interventions is that many, particularly those delivered to parents, have limited scalability (ie, the ability to be widely distributed at a population level). There is therefore a need to trial interventions that include parent involvement and have the potential for scalability and broad reach.

Population strategies that incorporate access to the home environment are challenging. In recognition of its potential reach, mobile phone technology is increasingly being used to deliver health behavior programs [20]. Text messages, or short message services, are particularly useful in this instance. They are a wide-reaching, low-cost channel for the delivery of health behavior programs and can be individually tailored, which has been shown to have positive effects on behavior change and to reduce attrition [21]. Few programs targeting child and adolescent health behaviors have used text messages to deliver intervention messages to parents [22], with only one targeting the early childhood population. Militello et al [23] conducted a pilot intervention using twice-weekly text messaging that focused on healthy lifestyle behaviors for parents of overweight and obese preschoolers. Results from that study showed significant improvements in parental knowledge regarding nutrition and physical activity. Additionally, the intervention was found to be feasible and acceptable for parents of young children [23], suggesting that this delivery mode holds promise in this population group. However, that intervention did not report on changes in children's behaviors. No studies have utilized text messages to change sedentary behavior in this population; thus, it remains to be explored whether interventions delivered via text messages are feasible and can change sedentary behavior in this population. This study aimed to pilot test (1) the feasibility and (2) the potential efficacy behavior change strategies delivered predominantly by text message to support parents to reduce the amount of time their children spend in prolonged sedentary behavior.

Methods

Overview

This study was a two-arm pilot randomized controlled trial to evaluate a parent-focused, predominantly text message–delivered intervention to reduce sedentary behavior in 2- to 4-year-old children. The primary outcome was feasibility of the intervention. Secondary outcomes were changes in child sedentary behaviors (objectively assessed sitting time, and parent proxy-reported screen time) and potential mediators. The study protocol has been previously published [24] and is briefly outlined below. The study complied with the Consolidated Standards of Research Trials (CONSORT)-EHEALTH guidelines [25], including relevant items from the extension for pilot trials [26]. The Deakin University Human Research Ethics Committee granted ethics approval for the study (2016-103). This study was prospectively registered on May 16, 2016. Participants provided written, informed consent to participate on behalf of themselves and their children.

Participants and Recruitment

Participants were recruited in Melbourne, Australia, through playgroups, social media (namely Facebook), and snowball sampling. In Australia, playgroups are informal gatherings for parents/caregivers and their children aged from birth to 5 years before the commencement of primary school. Snowball sampling included participating parents (recruited either through playgroups or on Facebook) passing on study information to friends and family (either hard copy flyers or by sharing information on Facebook). Inclusion criteria for parents were having an ambulatory child aged 2 through 4 years (ie, up to the age of 4.99 years); able to freely give informed consent; able to speak, read, and write fluent English; and smartphone ownership. The intervention was delivered to participants individually, regardless of recruitment method.

Sample Size and Randomization

As the main outcome of this study was feasibility, no sample size power calculations were undertaken. Initially, this study aimed to recruit 100 participants. Participants were randomized to the intervention or wait-list control on a 1:1 ratio after baseline data collection. If more than one parent was recruited from a particular playgroup, randomization occurred at the group level to avoid potential contamination. A computer-generated random number schedule was developed by a researcher (not part of the research team) who had no contact with the participants. Group allocation was concealed in sealed, opaque envelopes, which were opened and revealed to the researcher and the participant(s) after baseline data collection to minimize selection and measurement bias. Participants were informed that they were either in Group 1 (intervention group; receiving the program immediately) or Group 2 (wait-list control group; receiving the program in 7 weeks).

Mini Movers Intervention

The Mini Movers intervention was a predominantly text message–delivered intervention that aimed to provide parents with information and practical support to minimize the amount of time their children spend being sedentary and in screen time. The intervention was developed based on evidence-based guidelines for sedentary behavior in early childhood [12] and guided by the Coventry, Aberdeen & London-Refined (CALO-RE) taxonomy of behavior change techniques [27] and social cognitive theory [28]. Intervention strategies mapped to theoretical constructs are presented in the previously published study protocol [24]. Strategies focused on increasing parental knowledge, building self-efficacy, setting goals, and providing reinforcement. Participants in the intervention group received their intervention materials, including a Mini Movers information booklet, goal-checking magnet, and a Move and Play Every Day: National Physical Activity Recommendations for Children 0-5 Years brochure [12] either in person or by mail after baseline measures and allocation had been completed. The interventionist then had a one-on-one discussion with each participant individually, either in person or over the phone, to set their goals for the program. In total, 2 goals were set around reducing their child's sedentary behavior; specifically, 1 screen time goal (eg, to limit their child's screen time to 60 min or less per day) and 1 overall sedentary behavior goal (eg, to change an activity their child normally does sitting down, such as painting, to a standing activity). The goal-checking magnet aided participants to track their progress with their 2 goals for the duration of the program (6 weeks).

After the materials were given to participants and the goal-setting discussion was complete, the personalized, interactive text messages (ie, the main mode of intervention delivery) began the following day. Text messages were delivered using a Web-based bulk text message platform, managed by the interventionist. Participants received a welcome text message at the commencement of the program, followed by 3 standard text messages per week for 6 weeks (19 texts in total). The standard text messages included 2 behavioral messages with practical ideas and suggestions for limiting and displacing their child's screen and sitting time, active play ideas, and monitoring and encouraging achievement of individual goals. Some text messages included links to reputable websites for further information.

The text messages were tailored to the participant's name, child's name, behavior goals, and the interventionist's name. Participants were not required to respond to the text messages, with the exception of those texts used for goal monitoring, sent at the end of each week. These 2-way goal-monitoring text messages required participants to respond to let the interventionist know whether they had met their goal. On the basis of whether the response indicated the goals were achieved or not, parents were sent a predefined response, encouraging them to revisit their materials and keep trying the following week (if goals were not met) or congratulating them and encouraging them to keep going (if goals were met). Multimedia Appendix 1 shows examples of the types of text messages that were sent to participants.

Wait-List Control

Participants randomized to the wait-list control group received the full intervention after postintervention assessments were completed.

Measures

Data collection occurred pre- and postintervention. Measures included children's height and weight (preintervention only), *activ*PAL (PAL Technologies Ltd, Glasgow, UK) accelerometers (worn for 7 days to objectively assess sitting time), and parent surveys.

Primary Outcome

Intervention feasibility was measured by recruitment numbers, retention of participants, program metrics, and self-reported participant data, as described below.

Recruitment and Retention

Recruitment was measured by the proportion of contacted playgroups interested in the study (ie, the proportion of playgroups allowing a visit by the research team or distribution of flyers), the number of eligible parents within playgroups consenting, the number of parents recruited via social media and snowball sampling, and the time taken to recruit the sample. Retention was measured by the proportion of recruited participants providing measures at the end of the study.

Intervention Delivery and Fidelity

Intervention delivery and fidelity, that is, successful delivery to protocol, was measured by system reports (eg, delivered text messages) and auditing of protocol compliance in delivery of one-on-one goal-setting discussions by a single researcher.

Engagement in the Intervention and Acceptability

Engagement in the intervention was measured by the number of replies received from participants to the 2-way goal-monitoring messages and participant self-reported usage of and engagement with different components of the intervention, as reported in the postintervention survey. A subsample of randomly selected participants in the intervention group were invited to participate in qualitative telephone interviews (with a researcher other than the interventionist) to provide more detailed feedback about what they found useful and what they liked or disliked about components of the program. These participants were contacted after the program via mail and asked to return a separate consent form. Telephone interviews were scheduled for days and times convenient to the parents. Interviews included questions such as: "What did you find useful or most relevant to you about Mini Movers? How/why was that useful for you?"; "What did you think about the frequency of the text messages you received?"; and "How would you suggest we could improve the resources/materials so parents might be more likely to use them?"

Secondary Outcomes

Children's Objectively Assessed Sitting Time

Participating children wore an *activ*PAL for 7 consecutive days pre- and postintervention to objectively measure sitting time. The *activ*PAL has been shown to be valid, reliable, and feasible in young children [29]. The *activ*PAL was worn in the middle of the anterior aspect of the right thigh; monitors were sewn into purpose-made pouches affixed to leggings/bike shorts with Velcro, worn underneath normal clothes. Data were collected in 15-second epochs, and nonwear time was defined as 10 min of consecutive zero counts and removed from daily wear time. Children were asked to wear the monitors during waking hours (except for water-based activities such as bathing or swimming). To be included in analyses, children were required to have at least 6 hours of wear time on at least 4 days, including 1 weekend day. Nonwear time and minimum inclusion criteria were based on reliability criteria for ActiGraph (Pensacola, FL, USA) accelerometers [30], as no studies have examined reliability criteria for *activ*PAL accelerometers in this population. These criteria have been used previously in a pilot randomized control trial to reduce electronic media use in 2- to 3-year-old children [31].

Parent Proxy-Reported Sedentary Behavior and Screen Time

During each of the weeks that the children wore the *activ*PAL (ie, pre- and postintervention), parents completed Web-based surveys delivered via Qualtrics (Qualtrics Labs, Provo, UT). Parents with incomplete surveys (ie, missing responses) were followed up with an email and text message to prompt them to complete their survey. Parents reported their child's usual time in the last week in a range of sedentary behaviors including sitting down for reading/quiet play/craft activities; situations that restrict movement (eg, in a car seat or stroller); and screen behaviors (ie, television viewing, computer and electronic games use, handheld electronic games use, smartphone use, and tablet computer use). Responses were open-ended (ie, hours and/or minutes per day). Parents also reported the number of days that their child watched television/DVDs or played video or computer games or used other electronic devices for entertainment for less than 1 hour (ie, met screen time recommendations). A 2-week test-retest reliability was conducted in a separate sample of 50 participants to test the reliability of these items (intraclass correlations=.07-.82 for continuous variables; kappa=.25 and percent agreement=52.3 for meeting recommendations question). Screen behaviors were examined individually as outcomes and also summed to give average daily minutes in total screen time (intraclass correlation=.98).

Potential Mediators

Parents were asked to report: their child's preferences for sedentary behavior (sum of 3 items; 5-point Likert scale from *Never* to *Always*); their concerns about their child's screen time use (sum of 4 items; 4-point Likert scale from *Strongly disagree* to *Strongly agree*); their use of screens to distract or occupy their child (sum of 6 items; 4-point Likert scale from *Never/rarely* to *All the time*); their views about screen time occupying children (sum of 4 items; 4-point Likert scale from *Strongly disagree* to *Strongly agree*); their self-efficacy for limiting sedentary behavior (sum of 5 items; 5-point Likert scale from *Not at all confident* to *Extremely confident*); logistic support for their child's screen time (sum of 4 items; 5-point Likert scale from *Never or rarely* to *Several times each day*); and their beliefs/knowledge of screen time for young children (sum of 12 items; 4-point Likert scale from *Strongly disagree* to *Strongly agree*). The majority of these individual items had previously established reliability [32,33]. The reliability of new items was tested as described above; kappa=.22-.89 and percent agreement=33.4-97.7.

Internal reliability of all summed scores was tested using Cronbach alpha. Scores with reliability ≥.70 were included [34]. Of the 10 scales, 8 had acceptable reliability. The 2 remaining scales (child preferences for sedentary behavior=.64, and parental concerns about their child's screen time use=.67) had moderate reliability; however, a decision was made to still include them as they made sense conceptually. Parents also reported their own frequency and duration in moderate- to vigorous-intensity physical activity (MVPA) in the previous week using the Active Australia Survey [35] and their usual week and weekend day television viewing [36], both collapsed to average minutes per day. Mediation analyses were not undertaken because of the small sample size.

Sample Characteristics and Child and Parent Adiposity

Parents reported their own and their child's demographic information (eg, date of birth, parent education, parent employment status) and their child's usual sleep duration (including daytime naps). Parents self-reported their height and weight, whereas children's height and weight were measured

before intervention by trained researchers using a Wedderburn portable rigid stadiometer, Wedderburn Tanita portable digital scales, and standardized measurement procedures [37,38]. Body mass index (BMI) was calculated by standard formula (weight in kilograms divided by height in meters squared); BMI categories (healthy weight, overweight, obese) were determined using age- and sex-specific international cutoff points for children [39] and World Health Organization's classifications for parents [40].

Statistical Analysis

All analyses were conducted using Stata 14 (StataCorp, College Station, TX, USA). Descriptive statistics were used to describe the baseline characteristics of the sample. Feasibility and acceptability were assessed using percentages and by analyzing qualitative data, as appropriate. Qualitative interviews were recorded, transcribed verbatim, and analyzed using NVivo (QSR International, 2002) qualitative software package. Participants' responses to questions were coded to identify key themes. Linear mixed models were used to determine the effect of the intervention on the secondary outcomes (including children's sedentary behavior and potential mediators), controlling for the child's sex and age and clustering by playgroup. Given the small sample size, effect sizes (Cohen's *d*) were calculated. Values around .20 represent small, .50 moderate, and ≥.80 large effect sizes [41].

Results

Primary Outcome

Recruitment and Retention

Recruitment was undertaken from June to October 2016. Figure 1 presents the flow of participants through the study. A total of 39 playgroup leaders were contacted initially. Of these, 10 leaders (26%) agreed to have a researcher visit the playgroup to talk to parents or put up flyers, 5 leaders (13%) declined participation, and 24 leaders (61%) did not respond (after a maximum of 2 emails and 2 phone calls). Of the 10 playgroups that received a recruitment visit, 7 had consenting parents (mean number of consenting parents per group=3.6, range=2-7; n=23 parents in total). A further 34 parents were recruited via Facebook and snowball sampling, resulting in a final sample of 57 participants who provided written, informed consent to participate in the study. Due to study time constraints, recruitment was planned for a set period of time (5 months) and was closed as planned, despite the recruitment target of 100 participants not being met.

All of the 57 consenting participants provided baseline data and were randomized to the intervention (n=30) or wait-list control (n=27) groups. One participant in the intervention group was uncontactable post baseline measures and hence did not receive the intervention; 1 participant from the intervention and 2 from the wait-list control group were uncontactable post intervention and hence did not provide follow-up data (93% retention). Acceptability questions were completed by 20 intervention participants postintervention. In total, 18 intervention (60%) and 20 (74%) control participants had complete proxy-reported child screen time data at both time points, and 19 participants from each group (63% and 70%, respectively) had valid *activ*PAL data at both time points and were included in efficacy analyses.

Child and parent characteristics are presented in Table 1. The average age of children was 3 years and just under half the sample were boys. One parent was the father of the child in the study and the remainder were mothers. The majority of parents were born in Australia, had a university degree, and were married/in a de facto relationship.

Intervention Delivery and Fidelity

The goal-setting discussions were all delivered; just over half (59%) were conducted in person with the remainder conducted over the phone. All of the standard text messages (ie, the welcome text message plus 2 behavioral and 1 goal-monitoring text message per participant per week; 19 text messages in total per participant) were also successfully delivered (n=551 text messages in total).

Engagement in the Intervention and Acceptability

Of the 174 goal-monitoring text messages sent in total, 145 (83.3%) received a response. Results of the self-reported usage of and engagement with the text messages, as well as perceived usefulness and relevance of different components of the intervention, are presented in Multimedia Appendix 2. The majority of participants (19/20; 95%) reported reading at least 9 of the 12 behavioral text messages. In terms of the 2 behavioral text messages that contained links to videos, 5 of the 20 participants (25%) reported watching none in full, 9 (45%) reported watching one of them in full, and 6 (30%) reported watching both in full. Five participants (25%) reported watching at least one of the videos more than once. In terms of the 5 behavioral text messages containing links to images or other websites, 1 participant (5%) clicked through to none, 11 participants (55%) clicked through to at least 3, and 5 (25%) clicked through to all 5 links. The majority of participants reported that the overall information, the goal planning, the booklet, and the text messages were very or extremely useful (10-13/20; 50%-65%) and very or extremely relevant (10-12/20; 50%-60%). Slightly fewer participants reported that the links to videos or other websites were very or extremely useful or relevant (both 9/20; 47%).

Of the 25 intervention participants invited to participate in the qualitative interviews, 10 participants provided written, informed consent (40% response). Interviews lasted 17 min on average. Overall, parents were very positive about the program:

> *I thought it was fantastic. We (the playgroup) were all really keen to participate, for the children...for their awareness and for our learning and I don't have a criticism—I just thought it was lovely to promote... (an) active lifestyle and I think it's really good that those things start young for children.*

> *I thought it was a really great program. I think it had a lot of potential to really educate parents just about being aware of their kids' activity and the consequences of inactivity...And it was very simple, like it wasn't incredibly...complex or anything.*

When asked about what components of the program they enjoyed specifically, many parents commented that the goal-setting was their favorite part. Parents thought that the goal-setting was particularly useful to keep them on track:

> *I think the thing that was most useful and I enjoyed the most was the goal-setting. So we had some goals around more physical activity in our day and also switching off the TV [television]...and so I liked being able to check off the goals and make sure that we met them every day.*

Parents were also positive about the text messages, reporting that they were an easy and convenient way to receive the information. All parents reported that the frequency of receiving the text messages was acceptable; one parent suggested that they would have been happy to receive more (ie, 1 text message per day). Parents also liked the practical ideas and suggestions received in the text messages:

> *The information you gave around very practical ideas...rather than just sort of saying you know, they shouldn't be sedentary and they shouldn't be sitting and watching TV and screen time and things like that. You actually then provided alternatives...which I think sometimes as a parent, it's not that you run out of ideas, but you do get stuck in old ways.*

Figure 1. Trial flow diagram.

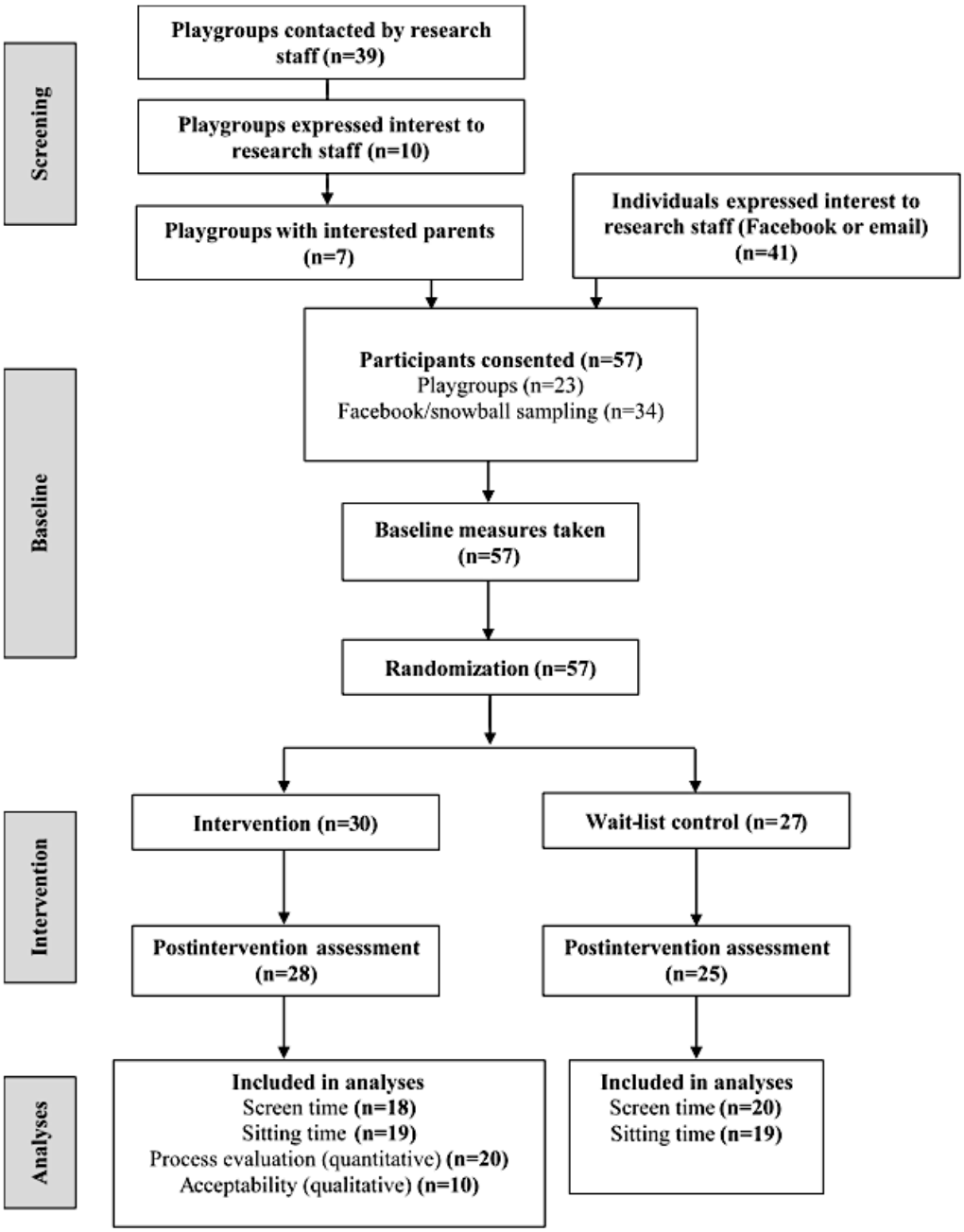

Table 1. Participant baseline characteristics.

Characteristics	Intervention (n=30)	Control (n=27)
Child characteristics		
Sex (male), n (%)	15 (50)	11 (41)
Age in years, mean (SD)	3.2 (0.8)	2.9 (0.7)
Sleep duration in hours/day, mean (SD)	11.8 (1.1)	11.9 (1.0)
BMI category, n (%)		
Healthy weight	24 (80)	20 (74)
Overweight	6 (20)	6 (22)
Obese	0 (0)	1 (4)
Siblings (yes), n (%)	20 (77)	16 (67)
Parent characteristics		
Relation to child, n (%)		
Mother	26 (100)	23 (96)
Father	0 (0)	1 (4)
Age in years, mean (SD)	36.1 (3.9)	34.1 (3.7)
BMI category, n (%)		
Healthy weight	14 (56)	18 (78)
Overweight	6 (24)	3 (13)
Obese	4 (20)	2 (9)
Born in Australia, n (%)	20 (77)	18 (78)
Education level, n (%)		
Year 12 or equivalent	1 (4)	0 (0)
Trade/certificate/diploma	1 (4)	6 (26)
University degree/postgraduate	24 (92)	17 (74)
Marital status, n (%)		
Never married	0 (0)	1 (4)
Married/de facto	26 (100)	22 (96)
Work status, n (%)		
Maternity/paternity leave	9 (35)	7 (30)
Student	1 (4)	0 (0)
Home duties full time	4 (15)	7 (30)
Part-time work	12 (46)	6 (26)
Full-time work	0 (0)	3 (13)

[a]BMI: body mass index.

When prompted about the links in the text messages, some parents reported that they only clicked through a few of them. All parents were positive about the content of the links, but some reported that they often did not have time to click through and then would forget to go back:

> *A couple of times I couldn't (click through) at the time, on my phone, for whatever reason...but they were all quite good actually...the ones that I saw. There was a couple I certainly didn't delve into 'cos I either forgot to go back to it...or at the time I couldn't access it so I'd sort of put it on the backburner and then...the next week evolved I suppose.*

When asked whether they thought the program had changed the way they do things in their family, parents commented that the program had made them more conscious of screen and sedentary time, and in some cases had other flow-on effects such as spending more time with their children:

> *I do tend to spend more time with the kids...because one of the goals was to reduce TV time, I have found that I do spend more time with them. So I will try and keep the TV reduced as much as possible, like*

switched off as long as I possibly can. And yeah, I do end up spending more time playing with them because you know, I want him to stand and I want him to move around and things like that.

It definitely made me rethink TV time...and use it a bit more sparingly I guess, instead of a babysitter.

We've definitely increased physical activity levels in our kids and we're walking to kinder, and we're walking to the shops a lot more and we're relying on the car a lot less...And...we kind of had iPads, but we've pretty much decommissioned our iPads now so they're not existing in our house anymore and we just switch off the TV a lot more. So that's definitely been a sustained effect of the program.

There were also some suggestions from parents on how to improve the program. Some parents suggested that a website or Facebook page would be beneficial as a central place for all of the information provided. One parent also suggested that Facebook would be useful for allowing parents in the program to chat to each other. Some parents also thought that revisiting their goals halfway through the program may have been beneficial:

Maybe...for the first few weeks start off with a more lenient goal and then make your way to a more...a stricter goal to yourself.

Finally, some parents reported that although they liked the premise of the program, they found that the information provided was not necessarily new to them and that they already did many of the things suggested:

The text messages, maybe for people who weren't active, would be a good reminder to be active...(but) the suggestions weren't particularly relevant for me...like we already did a lot of that stuff.

I walk the dogs 7 days, every morning...she walks with me or she's in the trike, we can be gone for half an hour or an hour each morning. And then she'll come with me to the gym and then we'll do...another gym training class where mums and the kids are there in a big hall, and the kids just jump around the whole time. And then we do swimming another day...so I guess that I feel like over the week, there's activity every day...um, there's play with other children, there's awareness...there's a focus on us being out. So, I didn't feel our lives were very sedentary before the program.

Table 2. Baseline and postintervention values, adjusted differences, and effect sizes for sedentary behavior outcomes.

Outcome variable (all min/day unless otherwise specified)	Baseline, mean (95% CI)		Post intervention, mean (95% CI)		Adjusted mean difference (95% CI)[a]	Effect size (Cohen's *d*)
	Control	Intervention	Control	Intervention		
Parent reported						
Total screen time[b]	92.0 (68.1 to 115.9)	109.7 (78.2 to 141.3)	99.5 (69.2 to 129.8)	79.2 (53.2 to 105.1)	−35.0 (−64.1 to −5.9)	0.82
TV/DVD viewing	77.5 (57.5 to 97.5)	88.1 (54.9 to 121.2)	78.0 (57.4 to 98.6)	69.2 (43.1 to 95.2)	−15.0 (−34.3 to 4.3)	0.61
Computer/e-game[c] use	0.0 (0.0 to 0.0)	0.6 (−0.6 to 1.7)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	—	—
Handheld e-game use	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	—	—
Smartphone use	4.8 (0.1 to 9.4)	5.9 (1.3 to 10.4)	5.8 (−1.0 to 12.5)	3.5 (−0.5 to 7.6)	−1.9 (−7.2 to 3.4)	0.38
Tablet use	10.3 (0.02 to 20.5)	15.0 (2.8 to 27.2)	7.1 (−2.0 to 16.2)	6.7 (1.5 to 11.9)	−8.2 (−23.0 to 6.6)	0.21
Time restrained	63.2 (39.6 to 86.9)	74.7 (46.2 to 103.2)	64.3 (49.7 to 78.8)	57.5 (37.3 to 77.7)	−16.2 (−39.3 to 7.0)	0.48
Time sitting	127.3 (82.5 to 172.0)	126.7 (97.8 to 155.5)	118.5 (83.3 to 153.7)	106.1 (75.2 to 137.0)	−13.5 (−63.4 to 36.4)	0.15
Days/weekdays child has <1 hour screen time	3.5 (2.4-4.6)	3.6 (2.3 to 4.9)	3.6 (2.6 to 4.6)	3.4 (2.2 to 4.7)	−0.1 (−1.7 to 1.4)	0.11
activPAL						
Sitting time	265.8 (212.4-319.2)	281.7 (223.6 to 339.9)	262.1 (209.6 to 314.6)	256.0 (205.6 to 306.3)	−22.3 (−80.8 to 36.3)	0.26

[a]Adjusted for child sex, child age, and clustering by playgroup.

[b]Sum of individual screen behaviors.

[c]e-game: electronic game.

Secondary Outcomes

Children's Sedentary Behavior

Table 2 presents the mean minutes per day parents reported their children spent in each of the individual screen behaviors, total screen time, and time spent restrained and sitting, as well as *activ*PAL assessed sitting time, at baseline and post intervention.

Adjusted mean differences between intervention and control groups were all in the expected direction (favoring the intervention group), with a significant difference seen for child total screen time only. Intervention participants reduced their total screen time by 30.6 min/day (from 109.7 to 79.2 min/day), whereas screen time for control participants increased by 7.5 min/day (from 92.0 to 99.5 min/day; *d*=0.82). Reductions in individual screen behaviors resulted in small to medium effect sizes (*d*=0.21-0.61). Time spent restrained was reduced in the intervention group by 17.2 min/day (from 74.7 to 57.5 min/day) and increased in the control group by 1.0 min/day (from 63.2 to 64.3 min/day; *d*=0.48). Parent-reported sitting time was reduced in both the intervention and control groups, by 20.6 min/day (from 126.7 to 106.1 min/day) and 8.8 min/day (from 127.3 to 118.5 min/day), respectively (*d*=0.15). Sitting time, as measured by *activ*PAL, was reduced in the intervention group by 25.8 min/day (from 281.7 to 256.0 min/day) and in the control group by 3.7 min/day (from 265.8 to 262.1 min/day; *d*=0.26).

Potential Mediators

Changes in potential mediators from baseline to post intervention for the intervention and control groups are reported in Table 3. The largest effect (*d*=0.93) was seen for parental logistic support for their child's screen time (eg, putting the television on for their child, buying DVDs), with a significant adjusted mean difference between intervention and control groups post intervention. Moderate effects were also seen for parent MVPA (not in the expected direction; *d*=0.66), parental views about the use of screen time for occupying children (*d*=0.61), and parental self-efficacy to limit their child's sedentary behavior (*d*=0.43).

Table 3. Baseline and postintervention values, adjusted differences, and effect sizes for potential mediators.

Outcome variable	Baseline mean (95% CI)		Postintervention mean (95% CI)		Adjusted mean difference (95% CI)[a]	Effect size (Cohen's *d*)
	Control	Intervention	Control	Intervention		
Child preferences for sedentary behavior (eg, more likely to watch TV than be active); possible range, 0 to 12	3.5 (2.4 to 4.5)	3.8 (3.0 to 4.6)	3.4 (2.6 to 4.1)	3.2 (2.4 to 4.1)	−0.5 (−1.6 to 0.6)	0.26
Parental concerns about child's screen time (eg, child watches too much TV); possible range, −8 to 8[b]	−4.8 (−6.1 to −3.5)	−4.0 (−5.2 to −2.8)	−5.4 (−6.5 to −4.3)	−5.4 (−6.3 to −4.6)	−0.9 (−2.4 to 0.5)	0.40
Parent use of screens to distract or occupy child (eg, uses TV to distract child when he/she is being difficult); possible range, 0 to 18	3.5 (2.2 to 4.8)	4.4 (2.6 to 6.1)	3.0 (1.7 to 4.3)	3.4 (1.6 to 5.3)	−0.8 (−2.1 to 0.4)	0.23
Parental views about screen time occupying children (eg, has difficulty getting child to eat without screens as distraction); possible range, −8 to 8[c]	−4.5 (−6.1 to −2.8)	−3.2 (−5.3 to −1.0)	−4.7 (−6.2 to −3.1)	−4.8 (−6.7 to −2.9)	−1.3 (−2.8 to 0.2)	0.61
Parental self-efficacy to limit child's sedentary behavior; possible range, 0 to 20	14.8 (13.6 to 15.9)	12.9 (11.0 to 14.9)	14.8 (13.5 to 16.0)	14.2 (12.6 to 15.7)	1.2(−0.5 to 2.9)	0.43
Parental logistic support of screen time (eg, number of times in the last week parent put the TV on for child); possible range, 0 to 20[c]	5.3 (3.8 to 6.7)	5.8 (4.1 to 7.6)	5.3 (3.5 to 7.2)	3.9 (2.3 to 5.5)	−1.7 (−3.0 to −0.4)	0.93
Parental beliefs/knowledge of child screen time (eg, TV is educational for children); possible range, −24 to 24[d]	2.6 (−3.0 to 8.2)	2.3 (−2.3 to 6.8)	1.7 (−3.1 to 6.5)	3.1 (−2.2 to 8.4)	3.0 (−0.7 to 6.8)	0.27
Parent moderate- to vigorous-intensity physical activity (min/day)	27.1 (12.0 to 42.2)	38.2 (−20.3 to 96.6)	43.2 (25.4 to 61.1)	41.2 (−4.6 to 87.0)	−16.6 (−35.7 to 2.6)	0.66
Parent TV viewing (min/day)	70.3 (38.4 to 102.1)	91.8 (52.1 to 131.5)	64.1 (44.9 to 83.3)	83.2 (57.5 to 108.9)	6.8 (−21.5 to 35.2)	0.05

[a]Adjusted for child sex, child age, and clustering by playgroup.

[b]Lower score indicates fewer concerns.

[c]Lower score indicates more favorable outcome.

[d]Lower score indicates parental beliefs/knowledge consistent with evidence.

Discussion

Principal Findings

This study aimed to test the feasibility and efficacy of a parent-focused, predominantly text message—delivered intervention to support parents to minimize the amount of time their children spend in sedentary behavior. Results show that the intervention was largely feasible and acceptable to parents of young children. The study also showed a statistically significant and meaningful reduction in children's total screen time in the intervention group compared with the control group, with promising results for the other secondary outcomes.

Recruitment was particularly difficult through playgroups compared with the other recruitment strategies utilized in this study (eg, social media). Initial contact with playgroup leaders was challenging; many did not reply to multiple phone calls or emails. Leaders who declined participation (n=5) cited reasons, including participation in other research, their playgroup potentially disbanding, or simply that they were not interested. Within playgroups, there was also evidence of peer influence, whereby if 1 or 2 parents were very interested initially, it would often prompt other parents to read the information and potentially consent to participating. Conversely, if no one initially expressed interest, then other parents would not consent. Future studies may benefit from exploring other recruitment avenues in this population. In particular, Facebook seemed to be a useful platform for recruiting parents in this study. This is consistent with reports of recruitment from other studies. For instance, an mHealth intervention delivered to parents of infants (<3 months) targeting infant feeding practices recruited more than 50% of the intervention group online (compared with around 30% recruited by practitioners and 7% recruited face-to-face by researchers) [42]. This suggests that Web-based methods may be more appealing to parents of young children, perhaps given that they are able to read about the study and consent in their own time. Despite these difficulties, and although recruitment targets were not met, a sufficient sample was recruited for a pilot study. Previous feasibility studies targeting screen time in this population have included similar or smaller samples [31,43]. Moreover, despite the small sample, a significant reduction in total screen time was observed and effect sizes showed favorable effects.

The acceptability of the intervention overall was high. In both the quantitative process evaluation and the qualitative phone interviews, parents reported that the goal-setting and the text messages were very useful and relevant. Many parents noted that the goal-planning magnet was useful to help keep them on track. It has been suggested that higher parental compliance with behavior change techniques such as goal-setting and self-monitoring results in better child outcomes [44]. It was encouraging that a number of parents reported in the qualitative interviews that they had continued to try to meet their goals and that the changes in their families were sustained once the intervention ended. However, parents reported using the text messages containing links to images and other websites less frequently and also reported finding them less useful and relevant, compared with the goal-setting and behavioral text messages. Parents of young children are likely to be time-poor, and, as some parents noted in qualitative interviews, if they were not able to click through immediately, they would often forget to go back. A pilot text message intervention focusing on healthy lifestyle behaviors for parents of overweight and obese preschoolers reported that parents wanted a short, easy-to-read, and strong message [23]. It may be that providing links to more information or to videos may not be necessary or feasible in this population.

The efficacy results are also encouraging. In addition to the statistically significant reduction and large effect in total screen time in the intervention group compared with the control group, a moderate effect was seen for television viewing. Given that television viewing constitutes around 80% of total screen time in this sample and in previous studies [15], it is important that interventions target this behavior. An intervention conducted in preschools reported very similar results, with a significant reduction in total screen time of almost 30 min a day but no effect on television viewing [45]. A home-based intervention reported a significant reduction in television viewing in the intervention compared with control group of 37 min a day; however, that intervention specifically targeted television viewing rather than total screen time [46]. Small effects were seen for smartphone use and tablet use in this study; however, use of these screens was relatively low compared with television viewing, leaving little scope to reduce those behaviors. It may be that specific strategies are needed to target children's use of these newer devices. Although the effect size was small, it was promising to see a reduction in objectively assessed sitting time of more than 20 min per day in the intervention group compared with the control group. A previous intervention targeting only screen time use found no effect on objectively assessed sitting time [31] and suggested that specific strategies should be included to target reductions in sitting time. Results from this study support this, showing that, by providing parents with strategies to reduce sitting time, potentially positive outcomes can be observed.

There was a significant reduction in parental logistic support for screen time (eg, putting the television on for the child) in the intervention group compared with the control group. This suggests that the strategies used in the intervention were effective at changing parents' behavior around their child's screen time. Potentially, the practical strategies around alternatives to screen time may have resulted in this change; in qualitative interviews, some parents reported that they switched off the television more and used it less as a babysitter. Moderate effects were also seen for parental views about screen time occupying children and parental self-efficacy to limit their child's sedentary behavior. This is particularly promising given that the intervention was theoretically based on the social cognitive theory [28], in which there is a strong focus on self-efficacy. Previous cross-sectional studies have reported that higher parental self-efficacy is associated with lower amounts of screen time in preschool-aged children [47-49], suggesting that future interventions would benefit from continuing to target self-efficacy as a mediator of children's screen time.

There was also a moderate effect on parent's self-reported MVPA; however, the adjusted mean difference was in the unexpected direction, in that parents in the intervention group reduced their MVPA by almost 17 min per day compared with the control group. A possible explanation for this is that many parents set their overall sedentary behavior goal as walking to local destinations without the pram (ie, to decrease their child's time spent restrained). As a result, in trying to achieve this goal by having their child walk more, the parents themselves may have ended up walking more slowly than usual. Future research should consider objectively measuring parents' physical activity to examine potential changes in sedentary time and light-intensity physical activity, in addition to MVPA.

Strengths and Limitations

Limitations of this study include the small sample size and the number of participants without full outcome data. This is mostly because of parents not completing, or only partially completing, Web-based surveys, despite reminders to do so. It may be that Web-based surveys are not practical for parents of young children, as there is more opportunity for them to be distracted or forget to come back to it. Additionally, a number of children did not have valid *activ*PAL data. Although the *activ*PAL accelerometers (sewn into a pouch and affixed to leggings) were predominantly acceptable for the children and parents, many parents noted that they often forgot to put the leggings back on after naps or bathing. This may have resulted in fewer valid hours of wear time on particular days, potentially excluding them from analyses.

It was a reasonably homogenous sample with a high percentage being very highly educated (>75% with a university degree or higher). Although over-representation of higher-educated women in research is common [50,51], the outcomes observed in this study may not have been observed in a sample of parents with lower educational attainment. Finally, intervention fidelity may have been somewhat compromised as a number of parents reported, both quantitatively and qualitatively, that they did not click through to all of the links provided in the text messages. Many parents also reported that they did not watch the videos provided in these links in full, suggesting that different strategies may be needed for some parents to increase compliance. However, given that a significant intervention effect was seen for children's screen time, the text messages alone may have been sufficient to elicit behavior change and the links may not have been necessary.

There are also a number of strengths of this study. Comprehensive measures of sedentary behavior were included, including parent proxy report of specific screen-based behaviors, time spent restrained, and sitting time, in addition to children's objectively assessed sitting time. The intervention was developed based on the social cognitive theory [28] and targeted specific behavior change mediators from the CALO-RE taxonomy of behavior change techniques [27]. Interventions are more likely to be effective if they are theory-based [52] and are closely aligned with behavior change techniques [53].

Conclusions

Mini Movers was found to be a feasible and acceptable intervention for parents of 2- to 4-year-old children. Moreover, child sedentary behavior was reduced, suggesting that the intervention was efficacious. It will be important for future studies to measure individual screen behaviors; results from this study support previous findings that although at this age screen time consists largely of television viewing, there is some evidence of use of smartphones and tablets and so targeting these behaviors specifically in interventions may be efficacious. The findings and learnings from this pilot study show sufficient promise to inform the development of a future large-scale trial adequately powered to determine impacts on children's sedentary behavior and to explore the mediators of behavior change. If effective, the main delivery mode (ie, text messages) means that this intervention has the ability to be scaled up and widely disseminated.

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Authors' Contributions

KLD conceived the study, composed the content for the intervention, drafted the manuscript, and was the project manager/interventionist. JS, TH, JAH, and KDH provided substantial contributions to the conception, design, and content of the study and reviewed and critically appraised the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Examples of text messages.

[PDF File (Adobe PDF File), 17KB - mhealth_v6i2e39_app1.pdf]

Multimedia Appendix 2

Parent self-reported usage of and engagement with text messages and perceived usefulness and relevance of the intervention.

[PDF File (Adobe PDF File), 25KB - mhealth_v6i2e39_app2.pdf]

Multimedia Appendix 3

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 537KB - mhealth_v6i2e39_app3.pdf]

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Abbreviations

BMI: body mass index
MVPA: moderate- to vigorous-intensity physical activity

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Original Paper

A Text Message Intervention with Adaptive Goal Support to Reduce Alcohol Consumption Among Non-Treatment-Seeking Young Adults: Non-Randomized Clinical Trial with Voluntary Length of Enrollment

Brian Suffoletto[1], MSc, MD; Tammy Chung[2], PhD; Frederick Muench[3], PhD; Peter Monti[4], PhD; Duncan B Clark[2], MD, PhD

[1]Department of Emergency Medicine, University of Pittsburgh, Pittsburgh, PA, United States

[2]Department of Psychiatry, University of Pittsburgh, Pittsburgh, PA, United States

[3]Center for Psychiatric Neuroscience, The Feinstein Institute for Medical Research, Northwell Medical Center, Great Neck, NY, United States

[4]Center for Alcohol and Addiction Studies, Brown University, Providence, RI, United States

Corresponding Author:
Brian Suffoletto, MSc, MD
Department of Emergency Medicine
University of Pittsburgh
Suite 400, Iroquois Building
3600 Forbes Avenue
Pittsburgh, PA, 15261
United States
Phone: 1 412 901 6892
Email: suffbp@upmc.edu

Abstract

Background: Stand-alone text message–based interventions can reduce binge drinking episodes (≥4 drinks for women and ≥5 drinks for men) among nontreatment-seeking young adults, but may not be optimized. Adaptive text message support could enhance effectiveness by assisting context-specific goal setting and striving, but it remains unknown how to best integrate it into text message interventions.

Objective: The objective of this study was to evaluate young adults' engagement with a text message intervention, Texting to Reduce Alcohol Consumption 2 (TRAC2), which focuses on reducing weekend alcohol consumption. TRAC2 incorporated preweekend drinking-limit goal-commitment ecological momentary assessments (EMA) tailored to past 2-week alcohol consumption, intraweekend goal reminders, self-efficacy EMA with support tailored to goal confidence, and maximum weekend alcohol consumption EMA with drinking limit goal feedback.

Methods: We enrolled 38 nontreatment-seeking young adults (aged 18 to 25 years) who screened positive for hazardous drinking in an urban emergency department. Following a 2-week text message assessment-only run-in, subjects were given the opportunity to enroll in 4-week intervention blocks. We examined patterns of EMA responses and voluntary re-enrollment. We then examined how goal commitment and goal self-efficacy related to event-level alcohol consumption. Finally, we examined the association of length of TRAC2 exposure with alcohol-related outcomes from baseline to 3-month follow-up.

Results: Among a diverse sample of young adults (56% [28/50] female, 54% [27/50] black, 32% [12/50] college enrolled), response rates to EMA queries were, on average, 82% for the first 4-week intervention block, 75% for the second 4-week block, and 73% for the third 4-week block. In the first 4 weeks of the intervention, drinking limit goal commitment was made 68/71 times it was prompted (96%). The percentage of subjects being prompted to commit to a drinking limit goal above the binge threshold was 52% (15/29) in week 1 and decreased to 0% (0/15) by week 4. Subjects met their goal 130/146 of the times a goal was committed to (89.0%). There were lower rates of goal success when subjects reported lower confidence (score <4) in meeting the goal (76% [32/42 weekends]) compared with that when subjects reported high confidence (98% [56/57 weekends]; P=.001). There were reductions in alcohol consumption from baseline to 3 months, but reductions were not different by length of intervention exposure.

Conclusions: Preliminary evidence suggests that nontreatment-seeking young adults will engage with a text message intervention incorporating self-regulation support features, resulting in high rates of weekend drinking limit goal commitment and goal success.

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KEYWORDS

binge drinking; young adult; text messaging

Introduction

Young adults have the highest prevalence of hazardous alcohol consumption among all age groups [1], largely due to binge drinking (defined as consuming ≥4 drinks for women or ≥5 drinks for men on any drinking occasion [2]), yet numerous barriers prevent them from seeking help to reduce alcohol consumption [3]. Mobile digital interventions could help provide evidence-based support to young adults who would not otherwise seek help. Systematic reviews suggest that mobile digital interventions can reduce alcohol use in adults [4] and that text message (short message service, SMS) interventions reduce alcohol consumption among young adult populations [5]. Our group has spent the past 6 years iteratively designing and testing a text message alcohol intervention (Texting to Reduce Alcohol Consumption: TRAC), which uses ecological momentary assessments (EMA) to assist self-monitoring, tailor goal support, and provide performance feedback and relevant protective behavioral strategies. In a large trial, we found that young adults exposed to the first TRAC intervention, TRAC1, reported greater reductions in alcohol consumption and alcohol-related injuries compared with control and assessment-only groups up to 6 months after intervention completion [6]. Still, effects of TRAC1 were small, indicating the intervention was not optimized.

One design feature potentially limiting TRAC1's effectiveness was that drinking limit goal support was not optimized. In examining EMA data collected from those exposed to TRAC1, we found that subjects declined to commit to a weekend drinking limit goal based on the binge threshold roughly 40% of the times they were prompted and that goals were met only 65% of the time [7]. In examining latent classes of individuals exposed to TRAC1, we found that the class with higher baseline drinking had lower probability of committing to weekend drinking limit goals and had no discernible reduction in drinking over time [8]. Finally, in focus groups, several TRAC1 subjects reported ignoring goal prompts or declined goal commitment because they felt consuming <4 or 5 drinks was unreasonable based on the amount they drank, which was typically >10 drinks [9]. Together, these results provided evidence that design features focused on personalizing goal support, especially for heavier drinkers, needed to be improved.

To improve context-specific goal support, we incorporated drinking limit goal commitment EMA tailored to past 2-week alcohol consumption, intraweekend goal reminders, self-efficacy EMA with support tailored to goal confidence, and maximum weekend alcohol consumption EMA with drinking limit goal feedback into the TRAC intervention (now called TRAC2).

Our primary aim was to evaluate young adult engagement with the TRAC2 goal support features. Specifically, we examined responses to goal commitment and goal self-efficacy EMA, and how responses related to event-level alcohol consumption. We hypothesized that the percentage of responses indicating a willingness to commit to a weekend drinking limit goal tailored to past drinking (adaptive goal prompts) would be higher compared with the 60% willing to commit to the fixed binge threshold used in TRAC1. Our secondary aim was to examine the association of length of TRAC2 exposure with alcohol-related outcomes from baseline to 3-month follow-up, including maximum drinks per drinking occasion on weekends, prevalence of reporting a binge drinking episode on a typical drinking week, and alcohol-related consequences. We hypothesized that subjects who used the TRAC2 intervention for longer periods would have greater reductions in alcohol-related outcomes than those who used it for shorter periods.

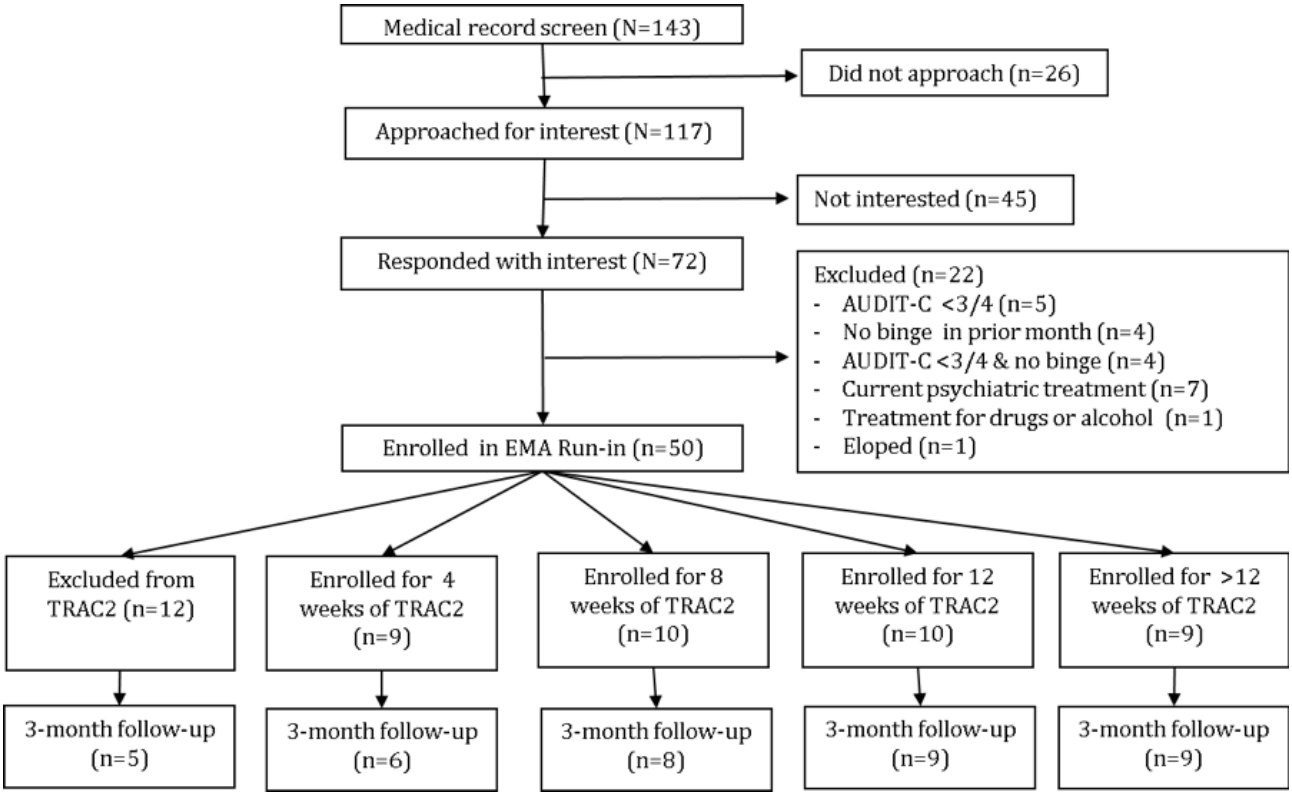
Methods

Procedures

Recruitment and Enrollment in the Emergency Department

From April 1 to June 9, 2016, a convenience sample of 143 patients aged 18 to 25 years who presented to an urban emergency department (ED) were identified through medical record review. Following introduction by a member of the care team, 117 young adults who were medically stable and not seeking treatment for substance use disorder were approached by research staff and 72 (66.7%) of them provided consent to complete a questionnaire, including assessments of alcohol use severity. Young adults reporting recent hazardous alcohol consumption based on an Alcohol Use Disorder Identification Test for Consumption (AUDIT-C) score of ≥3 for women or ≥4 for men [9] and at least 1 binge drinking episode in the prior month were eligible to participate. Young adults were excluded if they reported past treatment for drug or alcohol use, reported current medical treatment for psychiatric disorders, or did not own a mobile phone with SMS. Excluded young adults (n=22) did not differ in age or sex from those included (n=50). All subjects provided written informed consent and completed a baseline survey in the ED, for which they were compensated US $20. All procedures were approved by the university's institutional review board. The flow diagram of subject recruitment, enrollment, and retention is shown in Figure 1.

Figure 1. CONSORT diagram (EMA, ecological momentary assessments; AUDIT-C, Alcohol Use Disorder Identification Test for Consumption; TRAC2, Texting to Reduce Alcohol Consumption 2).



Text Message Run-In

Following enrollment (n=50), each Thursday at 5 pm for 2 weeks, subjects received the following EMA: "Do you plan on drinking this weekend?" Each Sunday at 1 pm for 2 weeks they received: "Between Thursday and today, what is the MOST drinks you had on any occasion?" When a subject responded, he or she received a text: "Thanks for completing this assessment. We will check in with you on [Thursday and Sunday]." If subjects completed at least 50% of EMA during the 2-week run-in, they were offered the option of enrolling in the TRAC2 intervention by texting "Go." We included the run-in period to exclude those individuals who expressed initial willingness in participation but did not exhibit adequate engagement through texting.

Texting to Reduce Alcohol Consumption 2 Intervention

Subjects who met the run-in eligibility criteria and opted in (n=38) were sent EMA each Thursday, Friday, Saturday, and Sunday. On Thursdays, subjects were queried about their weekend drinking plans and willingness to commit to a drinking limit goal. Instead of asking individuals to commit to a weekend drinking limit goal based on the binge threshold (as done in TRAC1), we used an algorithm that prompted a drinking limit goal based on the running average of the largest number of drinks consumed by that individual on any occasion in the prior 2 weekends. When the average number of drinks in prior 2 weeks was greater than 10, the drinking limit goal was set at 10. When the average number of drinks in prior 2 weeks (#) was reported as less than or equal to 10 but greater than binge (>4/5 drinks), their drinking limit goal was (#) minus 1. This adaptive goal prompt feature fits with harm reduction principles [10] to meet individuals "where they are at" and the theory of behavioral shaping, where individuals with higher drinking amounts make small, successive approximations to an ultimate low-risk drinking goal (eg, binge threshold) [11].

To increase goal salience proximal to contexts of high cue reactivity and peer pressures [12], we sent goal reminders on Friday and Saturday evening (if they had committed to a drinking limit goal). We also queried their confidence in meeting this goal and tailored self-efficacy support based on their reply. This feature fits with prior research showing the importance of self-efficacy as a predictor of heavy drinking [13]. On Sundays, we queried the maximum number of drinks consumed on any occasion and, based on whether they committed to a goal, sent goal-relevant feedback (success or failure reframing) [14] or feedback on amount consumed.

In addition to these goal support features, we chose to provide individuals more control over how long they use the TRAC2 intervention using enhanced active choice [15], where at the end of each 4-week block, individuals were offered the choice to opt in for continued voluntary enrollment. Following each 4-week block, all existing TRAC2-enrolled subjects were given the opportunity to re-enroll by texting "Go," up to a maximum of six 4-week blocks. A flow diagram of the TRAC2 intervention is provided in Multimedia Appendix 1.

Web-Based Follow-Up

All subjects, including those enrolled in the ED but not exposed to TRAC2, were asked to complete a follow-up Web-based survey 3 months after baseline assessments and were compensated US $40 upon completion. Subjects were notified by SMS to access the survey website and those who did not

complete their Web-based follow-up within 1 week were contacted once through email as a reminder.

Measures

Demographic Characteristics

At baseline, subjects reported their age, sex, race, ethnicity, and education (college enrolled: yes/no).

Alcohol-Related Characteristics

During screening, we asked subjects the AUDIT-C and the question: "How many days have you had ≥4 (for women) or ≥5 (for men) standard alcoholic drinks in the past month?" At baseline and at 3-month follow-up, subjects were presented with a calendar and a visual reference displaying standard drink amounts and were asked to report their alcohol consumption by day of the week for both a typical and heavy drinking week (Daily Drinking Questionnaire [16]). We used data from the heavy drinking week to calculate the maximum drinks consumed over any weekend day, and we used data from the typical week to calculate the percentage of subjects reporting any binge drinking episode. The 24-item Brief Young Adult Alcohol Consequences Questionnaire [17] was used to assess the number of negative alcohol-related consequences experienced during the past month. Items were dichotomous (no/yes) and summed. We used the Alcohol Ladder [18] to measure an individual's motivation to change their drinking. The Alcohol Ladder is a visual analog scale that consists of 10 rungs, each with a corresponding statement (eg, "I never think about changing the way I drink, and I have no plans to change"). We coded responses to fit the stage of change [19] continuum (precontemplation, contemplation, preparation, action, and maintenance).

Drug Use

At baseline, subjects were asked to report frequency of other drug use over the past 3 months using the NIDA Modified Alcohol, Smoking, and Substance Involvement Screening Test (NM-ASSIST [20]). Cigarette use was recoded as less than daily=0 and at least daily use=1. Marijuana use and opioid use were recoded into dichotomous variables (none=0; any=1).

Ecological Momentary Assessments

Drinking intentions were measured each Thursday through responses to: "Do you plan on drinking this weekend?" coded as no=0 and yes=1. Willingness to commit to a drinking limit goal was measured through responses to: "Would you be willing to commit to a goal to drink less than [X] drinks on any occasion this weekend?" coded as no=0; and yes=1. Drinking limit goal self-efficacy was measured through responses to: "How confident are you that you will meet this goal on a scale from 1 (not at all) to 5 (completely)?" For the purposes of this study, we used the lowest value reported over the weekend as a measure of self-efficacy vulnerability. Finally, we measured the maximum number of drinks consumed each weekend through responses to: "Between Thursday and today, what is the MOST drinks you had on any occasion? " reported as a continuous variable. We used this value to calculate whether they met their drinking limit goal (when made), coded as did not meet goal=0 and met goal=1.

Data Analyses

We first examined baseline characteristics of enrolled subjects, identifying any differences across groups of different durations of TRAC2 engagement (number of 4-week blocks enrolled) using analysis for variance for mean comparisons, Kruskal-Wallis test for medians, and chi-square test for categories. We then calculated EMA response rates across weeks by group. To understand changes in alcohol consumption over weekends, we visually inspected distribution of maximum drinks consumed on any weekend day across groups and modeled data by group using repeated-measures linear regressions. We first declared data as a panel to account for clustering within individuals. We specified "max drinks" as a count variable with a Poisson distribution and modeled random effects, given the variability in maximum drinks consumed by subjects in week 1 (intercept). We specified that residuals were autoregressive. To understand predictors and processes influencing goal success, we used chi-square tests to examine univariate associations between selected correlates of drinking behavior and drinking goals being met. Finally, we tested the significance of differences between baseline and 3-month follow-up reports using Wilcoxon signed-rank tests (for maximum drinks and negative consequences) and 2-sample test of proportions (for prevalence of any binge drinking episode in a typical week). All statistical tests were conducted using Stata 14.0 (StataCorp, Inc, College Station, TX).

Results

Texting to Reduce Alcohol Consumption Subjects

A total of 50 subjects were enrolled in the ED. Baseline descriptive statistics are reported in Multimedia Appendix 2. There was a wide range of drinking severities, with 12% (6/50) of subjects scoring ≥10 on the AUDIT-C, indicating high probability of alcohol dependence [21]. There was also a wide range of stages of change, with 38% (9/50) of subjects being precontemplative. All subjects reported at least one negative consequence related to alcohol consumption in the last 3 months (median=9; interquartile range= 4-12). Substance use was common: around a quarter (26%, 13/50) of subjects smoked cigarettes at least daily, half (50%, 25/50) reported cannabis use, and 10% (5/50) used some form of opioid recreationally in the past month.

Texting to Reduce Alcohol Consumption 2 Engagement

Opting in to Texting to Reduce Alcohol Consumption 2 Over Six 4-Week Intervention Blocks

Among the 50 enrolled subjects, 38 (76%) completed the run-in successfully and enrolled in TRAC2. Comparing those who were excluded during the run-in with those who successfully enrolled in the intervention period, there was a higher percentage of Hispanic subjects (25% [3/12] vs 8% [1/38]; *P*=.01) and lower percentage of college-enrolled subjects (8% [1/12] vs 32% [12/38]; *P*=.12). The percentage of subjects who continued to enroll in TRAC2 was 76% (29/38) after the first 4-week block, 50%(19/38) after the second 4-week block, 24% (9/38) after the third 4-week block, 16% (6/38) after the fourth 4-week block, 5% (2/38) after the fifth 4-week block, and 2% (1/38)

after the sixth 4-week block. The only significant differences in baseline characteristics between subjects based on length of TRAC2 enrollment were higher prevalence of cannabis use among subjects enrolled for 4 weeks and higher prevalence of opioid use among those enrolled for 12 weeks. Stage of change was not associated with length of voluntary TRAC2 enrollment (see Multimedia Appendix 2).

Ecological Momentary Assessment Compliance Over the First 12 Weeks

The percentage of subjects responding to EMA queries on Thursday and Sunday by length of TRAC2 enrollment is shown in Figure 2. Response rates to EMA queries were, on average, 82.3% for the first 4-week intervention block, 75.3% for the second 4-week block, and 72.8% for the third 4-week block. Those subjects who opted in to TRAC2 for longer periods also had higher overall EMA completion rates. Response rates were lowest on Friday and Saturday evenings to goal self-efficacy EMA, where only 58% of EMA were responded to.

Changes in Drinking-Related Outcomes

Ecological Momentary Assessment: Drinking Cognitions

In week 1, 78% (29/37) of subjects reported a plan to drink over the weekend, which decreased to 46% (15/33) by week 4. Among subjects who reported a plan to drink over a given weekend in the first 4 weeks of the intervention, on average reported being willing to commit to the proposed drinking limit goal 96% (68/71) of weekends. The percentage of subjects being prompted to commit to a drinking limit goal above the binge threshold was 52% (15/29) in week 1 and decreased to 0% (0/15) by week 4. The percentage of weekend days where subjects reported high confidence (score 4 or 5) in meeting their drinking limit goals on both Friday and Saturday in the first 4 weeks of the intervention was, on average, 60% (68/71 weekends), with no changes in confidence across time.

Ecological Momentary Assessment: Weekend Drinking and Goal Success

The median number of maximum drinks consumed on any weekend day by length of TRAC2 enrollment and regression model output is shown in Figure 3 and Table 1. In Poisson regressions, all groups, except for those enrolled >12 weeks, significantly reduced their drinking over time. However, those enrolled >12 weeks had a lower starting point (intercept) for maximum drink count.

Figure 2. Ecological momentary assessment (EMA) completion rates by intervention block (TRAC2, Texting to Reduce Alcohol Consumption 2; CIs and/or standard errors are not included to allow for clarity).

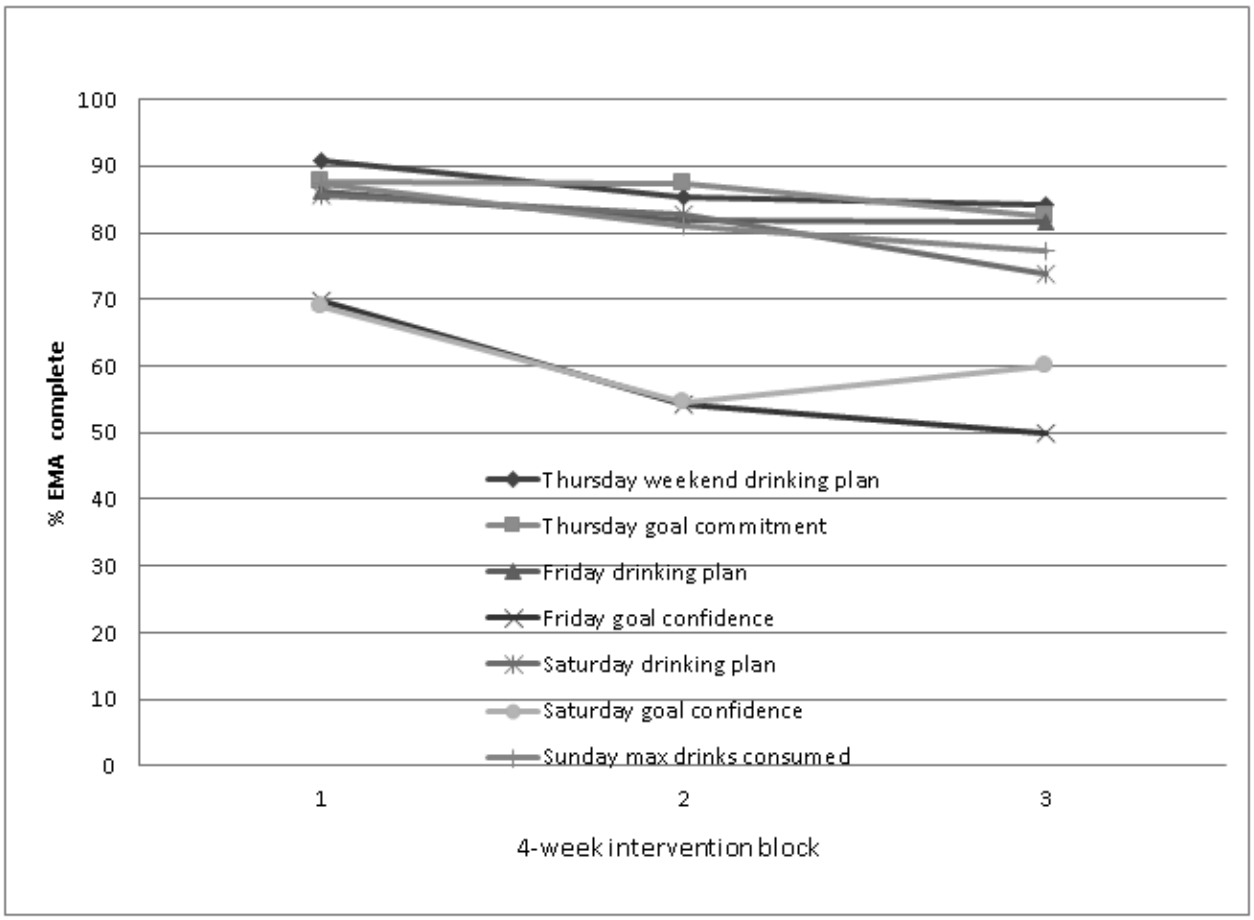


Figure 3. Median maximum drinks consumed over weekends by length of intervention engagement. Included are ecological momentary assessment (EMA) reports over the 2-week run-in to show changes that occurred before Texting to Reduce Alcohol Consumption 2 (TRAC2) intervention exposure (assessment reactivity).

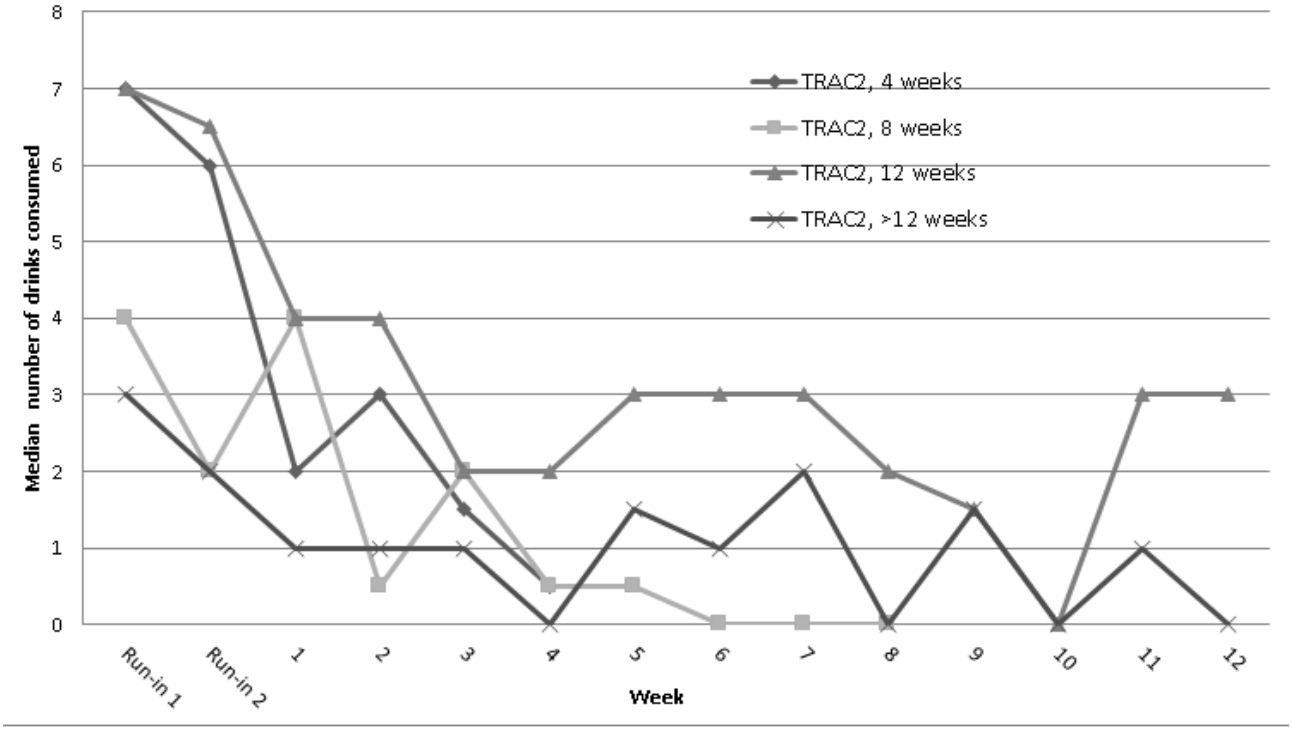


Table 1. Output from Poisson repeated-measures regression models of maximum drinks consumed over weekends using ecological momentary assessment (EMA) reports. Coefficient=beta coefficient.

TRAC2	Coefficient	95% CI	*P* value
4 weeks (n=6)			
Intercept	2.82	2.18 to 3.46	<.001
Rate of Change	–0.34	–0.47 to –0.21	<.001
8 weeks (n=8)			
Intercept	1.6	0.87 to 2.32	<.001
Rate of Change	0.17	–0.26 to –0.09	<.001
12 weeks (n=9)			
Intercept	1.99	1.58 to 2.4	<.001
Rate of Change	–0.13	–0.16 to –0.09	<.001
>12 weeks (n=9)			
Intercept	0.61	0 to 1.21	.05
Rate of Change	–0.03	–0.06 to –0.01	.10

Table 2. Change in alcohol-related outcomes from baseline to 3-month follow-up (Wilcoxon signed-rank tests for max drinks and negative consequences and 2-sample test of proportions for prevalence of any binge drinking episode in a typical week). Text in italics represents a summary of the other categories.

Outcome and TRAC2[a] exposure	Baseline	3 months	*P* value
Maximum drinks on any weekend day, median (IQR[b])			
None (n=5)	6 (2-8)	9 (2-10)	.89
4 weeks (n=6)	5 (3-10)	4 (2-7)	.29
8 weeks (n=8)	5 (3-7)	5 (3-7)	.94
12 weeks (n=9)	5 (4-6)	5 (3-8)	.6
>12 weeks (n=9)	6 (3-6)	2 (1-5)	.09
Any (n=32)	*5 (3-6)*	*5 (2-7)*	*.31*
Any binge drinking episode in a typical week, n (%)			
None (n=5)	2 (40)	2 (40)	.99
4 weeks (n=6)	4 (67)	2 (33)	.32
8 weeks (n=8)	3 (38)	2 (25)	.56
12 weeks (n=9)	3 (33)	4 (44)	.65
>12 weeks (n=9)	4 (44)	1 (11)	.08
Any (n=32)	*14 (44)*	*9 (28)*	*.19*
Number of negative consequences, median (IQR)			
None (n=5)	9 (3-9)	3 (0-9)	.41
4 weeks (n=6)	11 (3-14)	5 (1-7)	.4
8 weeks (n=8)	9 (4-13)	2 (0-3)	.09
12 weeks (n=9)	10 (4-13)	3 (1-6)	.009
>12 weeks (n=9)	6 (4-11)	2 (0-3)	.05
Any (n=32)	*9 (4-13)*	*3 (0-6)*	*.004*

[a]TRAC2: Texting to Reduce Alcohol Consumption 2.

[b]IQR: interquartile range.

The percentage of weekends where the drinking limit goal was met was, on average, 89.0% (130/146 weekends), with no significant change over time. When examining factors associated with goal success, we found that goal success rates were higher among black subjects (98% [51/52 weekends]) than white subjects (84% [58/69 weekends]; *P*=.01). There were lower rates of meeting drinking limit goals when the goal prompt was greater than binge levels (77% [26/34 weekends]) than when the goal was at the binge threshold (92.9% [104/112 weekends]; *P*=.01). Finally, there were lower rates of goal success when subjects reported lower confidence (score <4) in meeting the goal on either Friday or Saturday (76% [32/42 weekends]) compared with that when subjects reported high confidence (98% [56/57 weekends]; *P*=.001).

Web-Based Retrospective Reports

A total of 37 out of 50 subjects (n=32 exposed; n=5 excluded from TRAC2) completed Web-based follow-up surveys at 3 months. No baseline factors including sex, college education, race, baseline alcohol use severity (AUDIT-C score), or stage of change were associated with attrition. There were trends indicating reductions in maximum drinks consumed over typical weekends and prevalence of binge drinking in all groups exposed to TRAC2. There were significant reductions in the number of alcohol-related consequences among TRAC2-exposed participants (see Table 2).

Discussion

Main Findings

In this study, we found high levels of engagement with a text message intervention incorporating adaptive goal support features among a racially diverse sample of nontreatment-seeking young adults at varying stages of change. Among subjects who met run-in criteria, there were high response rates to EMA during TRAC2 exposure. Consistent with our a priori hypothesis, we found that there was a high willingness to commit to adaptive drinking limit goals (96% of time), which is higher than the 40% goal commitment willingness when we used a fixed “binge” threshold with a similar cohort of young adults in TRAC1 [7]. This suggests that individuals find that goals for limiting drinks close to, but less than, typical drinking amounts are found to be more palatable than drinking limits that require larger reductions from typical drinking amounts. We also found that the proportion of weekends when goals were met was significantly higher than

that found in TRAC1. This is likely due to the smaller "step-down" for each week, and could reduce the possibility of "limit violations," which can be detrimental to future self-regulation of behavior [22]. Finally, we found that lower confidence in meeting drinking limit goals was associated with a lower probability of goal success. This finding supports the role of self-efficacy in drinking self-regulation [23].

Regarding the safety of prompting individuals to commit to goals to limit drinks at levels found to be associated with negative outcomes, we found that it was a time-limited issue. Despite more than half of subjects being prompted in week 1 to commit to a drinking limit goal above a binge threshold, by week 4 no subject was being prompted to limit drinks above binge threshold. We also recognize that the binge threshold is a somewhat arbitrary cutoff and that there is a linear relationship with escalating blood alcohol content and consequences [24], thus supporting goal prompts that work to assist any reduction in alcohol consumption from typical amounts.

To our knowledge, this is the first published report of an alcohol intervention that incorporates an algorithm that gradually steps an individual down gradually over time. We focused on goal support, given the importance of goals in behavior change generally [25] and for self-regulation of substance use among young adults specifically [26]. Although there have been no prior alcohol interventions that use adaptive goal prompts, behavioral studies outside the alcohol field have used adaptive goal algorithms to improve step counts among obese adults [27] and reduce smoking by using a criterion based on percentile carbon monoxide levels [28].

Secondary Findings

We found that 76% (29/38) of enrolled subjects chose to continue the TRAC2 program after the first 4 weeks. We were surprised that a third of subjects chose to continue the program after 12 weeks, with 1 individual continuing the program up to 28 weeks. These findings suggest that most individuals exposed to TRAC2 find it valuable. It also highlights the importance of choice architecture in behavioral intervention designs and supports "enhanced active choice" [15] where users control length of participation. We did not find that subjects who used the TRAC2 intervention for longer periods had greater reductions in drinking than those who used it for shorter periods. This may be due to the fact that those who used TRAC2 for longer periods had lower alcohol consumption at the start of the intervention, as evidenced through EMA reports in the >12 week group. It may also be that those individuals who did not re-enroll in TRAC2 had made desired reductions in their drinking over a short period and did not need further support, as evidenced through the rapid reductions in weekend maximum drink reports seen in the 4-week group. If this is true, then not all who drop out of mobile behavioral interventions should be considered "failures."

Limitations

This was a pilot study with a small number of participants. As such, differences may exist that we were not powered to detect. Subjects were sampled from an urban ED and therefore may not represent young adults broadly. All outcome data were self-reported and subject to possible bias. A quarter of young adults who expressed interest in study participation in the ED did not complete at least half of EMA sent over the first 2 weeks and were thus excluded from receiving the TRAC intervention. This may indicate that not all young adults with hazardous alcohol use are willing or interested in interacting through digital modalities such as SMS to improve health behaviors. We did not use randomization procedures, given the primary aim of determining acceptability, and therefore, cohorts may differ in both measured and unmeasured ways. Finally, the response rates to goal self-efficacy EMA were significantly lower than other EMAs. This may have been due to the fact that either the timing of the messages was not optimal (eg, received during socializing times) or the nature of the query was unacceptable.

Conclusions

Preliminary evidence suggests that, among a diverse sample of nontreatment-seeking young adults with past hazardous alcohol consumption, adaptive goal support text message intervention features are acceptable and potentially effective in supporting short-term reductions in alcohol consumption. Future research is needed to replicate findings in a larger cohort and determine which features of adaptive goal support optimize behavioral change.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Flow diagram of Texting to Reduce Alcohol Consumption-2 (TRAC2).

[PDF File (Adobe PDF File), 120KB - mhealth_v6i2e35_app1.pdf]

Multimedia Appendix 2

Baseline characteristics by length of enrollment.

[PDF File (Adobe PDF File), 77KB - mhealth_v6i2e35_app2.pdf]

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Abbreviations

AUDIT-C: Alcohol Use Disorder Identification Test for Consumption
ED: emergency department
EMA: ecological momentary assessment
TRAC: Texting to Reduce Alcohol Consumption

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Original Paper

Activity Monitors as Support for Older Persons' Physical Activity in Daily Life: Qualitative Study of the Users' Experiences

Maria Ehn[1], MSc, PhD; Lennie Carlén Eriksson[1], MSc; Nina Åkerberg[2], PT; Ann-Christin Johansson[3], PT, PhD

[1]School of Innovation, Design and Engineering, Mälardalen University, Västerås, Sweden

[2]Västerås Municipality Care and Welfare, Västerås Municipality, Västerås, Sweden

[3]School of Health, Care and Social Welfare, Mälardalen University, Västerås, Sweden

Corresponding Author:
Maria Ehn, MSc, PhD
School of Innovation, Design and Engineering
Mälardalen University
Box 883
Västerås, S-721 23
Sweden
Phone: 46 21 107093 ext 107093
Fax: 46 21 101450
Email: maria.ehn@mdh.se

Abstract

Background: Falls are a major threat to the health and independence of seniors. Regular physical activity (PA) can prevent 40% of all fall injuries. The challenge is to motivate and support seniors to be physically active. Persuasive systems can constitute valuable support for persons aiming at establishing and maintaining healthy habits. However, these systems need to support effective behavior change techniques (BCTs) for increasing older adults' PA and meet the senior users' requirements and preferences. Therefore, involving users as codesigners of new systems can be fruitful. Prestudies of the user's experience with similar solutions can facilitate future user-centered design of novel persuasive systems.

Objective: The aim of this study was to investigate how seniors experience using activity monitors (AMs) as support for PA in daily life. The addressed research questions are as follows: (1) What are the overall experiences of senior persons, of different age and balance function, in using wearable AMs in daily life?; (2) Which aspects did the users perceive relevant to make the measurements as meaningful and useful in the long-term perspective?; and (3) What needs and requirements did the users perceive as more relevant for the activity monitors to be useful in a long-term perspective?

Methods: This qualitative interview study included 8 community-dwelling older adults (median age: 83 years). The participants' experiences in using two commercial AMs together with tablet-based apps for 9 days were investigated. Activity diaries during the usage and interviews after the usage were exploited to gather user experience. Comments in diaries were summarized, and interviews were analyzed by inductive content analysis.

Results: The users (n=8) perceived that, by using the AMs, their awareness of own PA had increased. However, the AMs' impact on the users' motivation for PA and activity behavior varied between participants. The diaries showed that self-estimated physical effort varied between participants and varied for each individual over time. Additionally, participants reported different types of accomplished activities; talking walks was most frequently reported. To be meaningful, measurements need to provide the user with a reliable receipt of whether his or her current activity behavior is sufficient for reaching an activity goal. Moreover, praise when reaching a goal was described as motivating feedback. To be useful, the devices must be easy to handle. In this study, the users perceived wearables as easy to handle, whereas tablets were perceived difficult to maneuver. Users reported in the diaries that the devices had been functional 78% (58/74) of the total test days.

Conclusions: Activity monitors can be valuable for supporting seniors' PA. However, the potential of the solutions for a broader group of seniors can significantly be increased. Areas of improvement include reliability, usability, and content supporting effective BCTs with respect to increasing older adults' PA.

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KEYWORDS

exercise; behavior; aged; seniors; mobile applications; fitness trackers

Introduction

Background

Physical activity (PA) has numerous health benefits in all age groups. For older persons, it can contribute to maintenance of autonomy and quality of life. Older adults value their independence, but health-related consequences from fall injuries pose an immediate threat to their ability to remain self-sufficient. Hence, falls are a major health concern, which needs to be prevented in the old population. Moreover, successful fall prevention can reduce large economic costs for the society.

There exists evidence that 40% of all fall injuries can be prevented by regular PA [1]. For this purpose, exercise programs including training of balance, muscle strength, endurance, and aerobic exercises are recommended [2,3]. In addition, general PA, which can be defined as "any bodily m ovement produced by skeletal muscles that results in energy expenditure above the basal resting level" [4] can delay functional decline and reduce the risk of premature mortality of the old population. Walking activities are major contributors to general PA among healthy older adults [5]. Compliance to exercise programs is generally low in the old population; Riebe and Burbank report a 30% decrease of exercise activities only 4 weeks after an exercise program was introduced [6]. Different approaches have been tried to increase the adherence of older adults to exercise programs: technology-based interventions (mainly with commercially available gaming technology) have shown promising results in terms of adherence at least throughout the first 12 weeks of the intervention [7]. However, to increase long-term exercise compliance and also general physical activity, a behavior change process is required; in this process support from caregivers are decisive [8]. Here, different types of technical support systems can be of value [9,10].

Prior Work

Persuasive technology is designed to change people's attitudes and behaviors [11]. Persuasive systems have been used in health care to increase patients' adherence to Web-based interventions [12] and to promote PA [13,14]. Most likely, this type of systems can be useful for promoting seniors' PA contributing to fall prevention. However, the systems need to support behavior change techniques (BCTs) effective for the specific target behavior and intended user group [15]. Furthermore, the systems must meet users' needs and preferences. Here, aspects critical for usability [16] and user acceptance [17] are important to gather.

Commercial activity monitors (AMs) are examples of persuasive technology for increasing people's PA [18-20]. However, the available AM products have proven to be insufficient for monitoring PA of older adults with reduced walking speed and with varying gait pattern [21]. Moreover, BCTs supported by current AMs (mainly self-monitoring and self-regulation techniques) have proven as less efficient for supporting behavioral change among older adults than for younger adults [22,23]. It has been suggested that wearable AMs should be enriched with additional BCTs that are specifically efficient for increasing older adults' PA [23]. Examples of such BCTs are "provide rewards contingent on successful behavior," "barrier identification or problem solving," and "model or demonstrate the behavior." Recently, a quantitative investigation of older peoples' experiences with commercially available AMs for self-tracking PA behavior was performed in terms of drivers technology use according to the Technology Acceptance Model (TAM) [24,25]. However, a review of empirical research on technology acceptance by older people concludes that, to better understand older people's acceptance behavior, additional variables should be included in TAM [26]. Qualitative studies of older person's experiences in using AMs are important for understanding users' acceptance of the technology. A mixed-methods study has assessed the acceptance and usage of wearable activity trackers among Canadian community-dwelling adults in the age range of 55 to 84 years [27]. Previous studies have investigated the acceptance of AMs among persons with chronic illness [28] and the usability of AMs among patients with chronic obstructive pulmonary disease [29].

To prepare for user-centered design [30] of new solutions supporting seniors in increasing their PA behavior, we investigated how a group of persons in the age range of 75 to 90 years experienced using currently available AMs in daily life. Our intention was to perform the study in a setting very similar to the real life of a senior that has acquired an AM and tries to use it as support for daily PA.

The aim of this study was to explore senior users' experiences in using the current AMs and from that learn more about users' requirements and preferences related to motivation, meaningfulness, usefulness, and usability.

Methods

An overview of the applied study design is presented in Figure 1.

Study Design

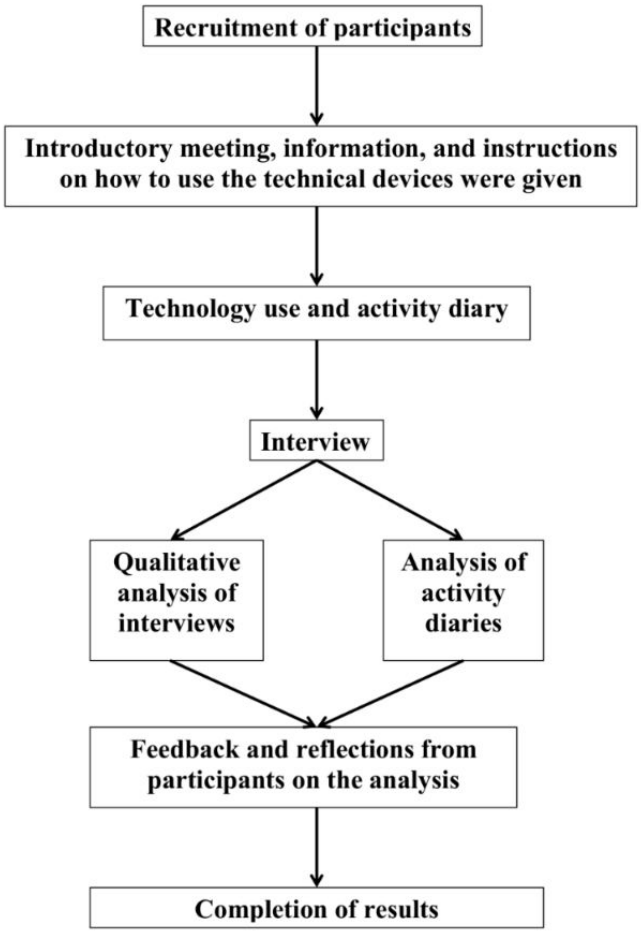
The study was descriptive with a qualitative inductive approach [31] to gain understanding of older persons' experiences in using for measuring their daily PA in terms of steps per day.

Data on users' experiences have been collected from different sources including interviews, activity diaries, and documentation of group discussions with the participants on the analysis result.

Participants and Recruitment

A total of 8 participants, 75 years or older were recruited, of which 6 had recently finished participating in a study in which exercises to prevent falls had been evaluated [32]. Two participants responded positive to participation via an advertisement in a meeting place for old people in the community. Six of the participants had light walking disabilities and used walkers on wheels, and 2 participants walked without aid.

Figure 1. Overview of the applied study design.



All 8 individuals who were asked for participation responded positively, and written consent was collected from them.

Inclusion criteria included being 75 years or older and living in an ordinary home in the community. Exclusion criteria included not being able to move independently at home and cognitive disability, both of which were considered as threats to validity for experience evaluations. Participants who had finished the previous exercise study had all a score of 25 or more at the Mini Mental State Examination [33]. They were all tested during the latest year, and experienced physiotherapists in the field judged the participants who responded to the advertisement as having sufficient cognitive function.

Activity Monitors and Tablet-Based Apps

Two commercially available bracelets for monitoring PA were used in the tests, namely Withings Activité Pop (Withings) and Jawbone UP3 (Jawbone), together with corresponding software (apps) accessible on a tablet (iPad, Apple). The devices (wearables and iPad) were selected as they were considered to be user-friendly, hygienic, and enabled storing activity data only locally on the tablet. To keep data locally, social features of the solutions were not enabled and therefore, not used. Moreover, the inclusion of two different products makes our results representative for more than one specific AM.

The Withings wearable has the design of an analog wristwatch with a major dial displaying current time and a smaller dial giving real-time feedback in terms of percentage of daily activity goal achieved. The Jawbone wearable is designed as a bracelet with three icons (status light) that can be lit up. Different kinds of notifications can be given to the users on the band. In this study, the Jawbone bracelet was used for monitoring purposes, and users were instructed to access activity results in the app.

Both wearables monitor PA and sleep cycles. In addition, the Jawbone bracelet continuously monitors resting pulse. As a consequence of this, the battery of the Jawbone bracelet needs to be charged every 3 to 4 days, whereas the battery of the Withings bracelet lasts for 8 months.

Each wearable is packaged with a specific app to be used on a tablet or a smartphone.

The Withings app gives the user an overview of daily activity data, both current and historical. Data shown include total amount of steps taken (absolute number and percentage of the daily activity goal) and steps taken per hour over the day visualized in a bar diagram. If sleep has been measured, total hours of sleep, percentage of sleeping goal, and a graph showing sleeping activity per night hour is also shown. Moreover, if specific activities (such as running and swimming) have been identified, a corresponding summary of the measured activity is shown (duration, energy consumption, and if applicable, also distance). If the user receives badges as rewards for healthy days (eg, if the activity goal had been reached), this is also shown in the summary. The start page of the Jawbone app shows a daily overview of accomplished PA (steps taken) and total

sleep time. Furthermore, the user can get feedback on trends of different behavior over longer times. In addition, the user can receive feedback on measurements related to PA (including total amount of steps, % of activity goal and total active time, longest active period, and longest active idle period in terms of duration and energy consumption) and resting pulse. Sleep analysis is also summarized and visualized. The app allows the user to set quantitative goals for target behaviors including steps per day and sleep hours per night. General recommendations for each goal are given.

Intervention

Two participants came to the university to meet physiotherapists and to receive the technical devices, additional information, and instructions. At this occasion, the participants responded to some questions regarding short personal information, general health, and activity habits. The participants received thorough oral and written information about the technology and were introduced to handling the devices and charging the batteries. Questions and comments were encouraged to elucidate unclear information and doubts in relation to the devices. All participants tested the use of both the bracelets and the iPad on this occasion. The participants borrowed the devices and started to use them the following day. In addition, the participants received an activity diary in which they were requested to estimate their physical effort each day during the test period. Here, the participants could also note additional information about experienced difficulties with the technology and activities performed.

Participants were instructed to pursue daily activities as usual, wear the activity bracelet all day and preferably also at night, fill information in the activity diary on estimated physical effort daily, and whether the technology had been functional. Moreover, participants were instructed to open the app on the tablet once a day to look at the results from their registered activity.

Six participants were in the same manner informed at their home by the physiotherapist that they had been in contact with during the previously finished study [32]. They also borrowed the devices, were requested to fill in the activity diary, and started to use the devices the day after the visit.

During the test period, each physiotherapist kept in contact with her participants to check if the testing went on well and if the technology was OK. The participants also had the opportunity to call the physiotherapists for support during the test period, if needed. The participants tested the technology for 9 to 10 days.

Data Collection

Background Characteristics

Age, gender, length, general health, medications, use of walking aid, help in daily life, perceived memory capacity, and PA level were collected through a questionnaire at the initial meeting. Participants estimated their PA level by using the five-level scale that is frequently used by the Public Health Agency of Sweden. It is further developed into a compatible seven-level scale, which is recently validated with a correlation coefficient of .7 with AMs [34]. The participants' previous experiences from using mobile phones, tablets, phone-based pedometers, and computers, respectively, were collected in the interviews.

Activity Measurements

During the test period, activity was monitored and data for each participant was saved in the corresponding app on the tablet. Data from each participant (mainly in terms of number of steps/day, in some cases also sleep hours and activities identified by the technology) was moved from the tablet to a local data server.

Activity Diary

Each participant was asked to self-report in a diary both daily physical effort by giving a score on a scale from 0 to 10 (where 0=no effort at all and 10=maximum effort) in a diary and technology functioning feedback (yes or no). Participants were also asked to report descriptions of activities performed and experienced problems with the technology. Moreover, when reporting technology malfunctions, participants were asked to describe what kind of problem they had experienced.

Interviews

Individual semistructured interviews were conducted by one of the authors (ACJ). Each interview lasted for approximately 30 min. The participants were preliminary informed that the purpose of the interview was to explore their experiences with the technical devices and to share their experience of using the technology in their daily lives. A semistructured interview guide [35] was used, containing five main questions supported by follow-up questions to initiate reflections and to obtain descriptions of the experience of using the technical devices. The interview guide is presented in Multimedia Appendix 1. The interviews were audiorecorded and transcribed verbatim.

Meeting With the Users

The participants were invited to a meeting where the results from the interviews and the technical measurements were presented by the researchers. At this meeting the participants were also encouraged to make reflections, give feedback, and completions of presented results. Group discussions at the meeting were documented.

Data Analyses

Background Characteristics

The quantitative data related to the participants' background information were analyzed by means of descriptive statistics.

Activity Diary

The quantitative data self-reported in the activity diaries were analyzed through descriptive statistics. These data included scored daily physical effort and daily report on the technology functioning. Qualitative data in the diaries included comments on experienced problems with the technology and examples of performed activities. These data were summarized for the study group.

Interviews

A qualitative content analysis was conducted by adopting an inductive approach [31]. Throughout the analysis, categories and subcategories were generated from the interview text. The analysis began with ACJ reading all transcripts, thoroughly several times. Next, to capture the key concepts and thoughts, the text was read word by word to extract meaning units, with a focus on the experiences of measuring PA with the adopted technical devices. The text was condensed into meaning units by ACJ and ME and subsequently coded by all authors. Codes were discussed and finally set in agreement with all authors; the codes emerged from the content of condensed meaning units. The coded meaning units were grouped into categories based on similarities in the content and subcategories, which reflected different aspects of the content. A coding scheme was used. Finally, the analysis resulted in descriptions of three categories with 13 related subcategories. During the analysis process, all authors discussed units, codes, and categories until agreement was reached. All authors followed every step in the analysis, confirmed, or raised questions, which needed to be discussed. The final version of the analysis was read by all authors to ensure the rigor of the described categories and subcategories [36]. In addition, quotations were used to illustrate the text and to give examples from the interviews, with the aim of achieving trustworthiness.

In striving for trustworthiness and credibility, reflexivity was used in the analysis. The authors strived to become aware of their preunderstandings how those might influence the emerging findings toward how the categories covered the data. The categories were thoroughly discussed to elicit differences between and similarities within the categories. In striving for credibility, methods the selection of participants, data collection, and data analysis are presented as thoroughly as possible. All authors were aware of the preunderstanding and existing knowledge about the context. The researcher ACJ performing the interviews was also aware of the physiotherapist lens, which she possessed.

Meeting With the Users

Notes from the meeting were read by all authors and analyzed in comparison to the interviews. Analysis was performed through group discussions between the authors.

Ethics

The study was approved by the regional ethics committee in Uppsala (Dnr 2015/372). All participants were given both verbal and written information about the study; then, informed consent was obtained from all participants.

Results

Participants

Eight eligible participants, all in independent living, were included according to the inclusion and exclusion criteria. Their mean age was 83 years (range 77-90 years), and the mean of medications used per person was 3 (range 1-8). Descriptive statistics from background information of participants are presented in Table 1.

All participants were familiar to and used mobile phones, no one had previously used an iPad, and two had used an app-based pedometer on a smartphone. Two participants were familiar to and used computers, mainly for mail correspondence.

All participants completed the testing period. However, one participant became sick during the test period and therefore, only wore the AM and filled in the notebook during 5 days.

Activity Measurements

All the participants performed activity measurements during the whole testing period; however, one person became sick and 3 participants experienced technical problems during the tests. As a consequence, PA information (monitored by AMs) about those four persons is missing for several days in the test period. However, all participants wore the monitors and filled in information in the diaries during the whole period.

As the aim of the study was to investigate the users' experiences in using AMs, results from the activity measurements have only been used for comparison with self-reported data in the diaries. Moreover, the amount of measurement data was very limited. Therefore, the AM results are not presented in the paper. Comparisons of AM data and the activity diaries indicated that the measurement correspond to the self-reported daily physical effort to a certain extent. Moreover, the comparisons indicate that reliability of measurements related to some types of physical activities such as biking and walking with a walker need to be further explored. Indeed, in the interviews, participants raised questions and comments regarding the reliability of measurements for these types of activities.

Activity Diary

All participants completed diaries. One participant was sick during the testing period and therefore, only reported 5 days.

Self-estimated daily physical effort was in mean score 4 (standard deviation 2, range 1-9). Mean score per day for each participant varied between 2.2 and 7.1. Activities reported in the diaries included walks, biking, gym training, shopping, and cooking, and one participant had extra work serving in a café.

Out of 74 total test days, participants had perceived that the technology had been working 58 days (78%); nonworking 14 days (19%); 2 days (3%) lacked this information. Problems reported were difficulties in getting the app window in the right orientation (was now upside down), failure in charging the bracelet (only Jawbone), lost Bluetooth connection between bracelet and tablet, difficulties in finding training results in the app, and unwanted popping-up of text messages on the tablet. In several cases, participants reported nonworking technology without adding further details describing how. One participant also described to be insecure about whether the technology had been functional, as previous experience in using computers was very limited.

Table 1. Descriptives of the participants.

Participant characteristic	Total, n (%)
Age (years)	
75-80	3
80-85	3
85-90	2
Gender	
Female	6
Male	2
Use of walking aid	
No	3
Only outdoors	3
Both indoors and outdoors	2
Use of medications	
1-4 medications	4
5-8 medications	4
Weekly amount of activity causing increased body temperature	
>5 hours/week	3
3-5 hours/week	3
1-3 hours/week	1
Missing data	1
Physical activity performed over the last 6 months	
2-4 hours/week of lighter physical effort	7
>3 hours/week of more intense physical activity	1
Experiences of using technical platforms	
Mobile phones exclusively for making calls	8 (100)
Computers	2 (25)
Tablet	0 (0)

Interviews

The participants' overall experiences in using the monitors were investigated through qualitative analysis of the whole interviews. Three main categories and 13 subcategories emerged from the interviews. Main and subcategories are presented in Multimedia Appendix 2 (Main and subcategories based on the interviews).

Influence on the Individual

The participants expressed that the activity monitors had, to varied extent, influenced their motivation, awareness, emotions, and behavior related to daily PA.

The degree to which the users' motivation for PA had increased when using the monitors varied in the group. Some users saw that the monitors had motivated them to be more physically active and encouraged PA:

> *I was motivated by the technology, that I freely admit.*

On the other hand, other participants described that they were already motivated for PA, and this was not changed because of the monitors:

> *The technology has no impact on my motivation, I am physically active anyway. I am on the verge to getting diabetes, that is what motivates me the most.*

It was also pointed out that using the monitors requires a basic degree of motivation for PA and interest in progress:

> *If you are interested in making progress with exercises and things like that, it is good (the technical support). But for those who are not really motivated, it is a matter of motivating people.*

Furthermore, using the monitors and apps provoked different emotions among the participants: some participants found it enjoyable and interesting to measure and get feedback on performed physical activities. Hence, PA was perceived funnier when the user could see how active he or she had been, for example when an activity goal had been reached:

> *You could see how far you have walked, I have not registered that previously. It was fun.*

Different results of the activity measurements could cause different kinds of feelings among the users, for example, low activity feedback could cause feelings of embarrassment:

> *It was irritating when it is visible that I had been so damn lazy. But it is good to have (the technology).*

Likewise, the user could be positively surprised if the measured activity was higher than expected:

> *Yes, I was positively surprised over that I had taken so many steps. I hadn't walked that much (laugh). I was positively surprised.*

Negative feelings were also provoked in situations when the devices failed to work as expected:

> *I was disappointed when it stopped working.*

Participants described that their awareness of how active they actually were had increased because of using the monitors: the measurements clearly reflected whether the user had been active or inactive during the day. Furthermore, users perceived interests in comparing measurement results in terms of steps from different activities. Here, some participants were surprised to see that also indoor activity could lead to high number of registered steps:

> *I was surprised that I got the highest number of steps during the day that I spent indoors. But I was active 8-9 hours in a row. Out buying cream, in again, up and down.*

> *I found it interesting to see the results from different activities performed. The difference between an active and inactive day was clear.*

Some users experienced that the activity measurements had an effect on their PA behavior in the sense that they increased their PA:

> *I have walked a little more while being monitored.*

The participants emphasized the impact of the monitors as reminders and a push forward to increase PA. They described that feedback in terms of reminders was important for behavioral change toward a more active life style. Additionally, goal setting was perceived important for increasing active behavior: a quantitative activity goal was helpful for the user by clarifying if the current activity level was too low. In addition, reminders about the goal could stimulate the user to increase and maintain activity:

> *Setting goals has importance, I get pushed if I have been too lazy.*

Some participants described that they were already active to a certain level in their daily lives. They had their own considerations, decisions, and habits related to PA, and those were not affected by measuring the activity:

> *I did not change my exercise habits during the monitoring, I took the same walk as usual in the morning or in the afternoon. It is a goal I have and as a pensioner, I have plenty of time.*

Experiences From Being Monitored

The participants expressed their experiences from being monitored in terms of limitations, possibilities, integrity, reliability, and feedback.

Some participants envisioned that the activity monitors and apps might have a limitation in their usability and usefulness for senior persons: Participants saw that, for senior persons less vigorous than themselves, everyday use of the devices could be difficult, cumbersome, and demanding:

> *It is more difficult for a person less alert than me maybe also using walking aids. It might be tough for them to register like this every day.*

Furthermore, the usefulness of the monitors and apps could also be limited to persons with certain attitudes and mentality.

Some users had perceived the devices as fragile and had therefore limited their use and own experimentation with the technology to avoid destroying it. For example, some persons had abandoned opening the app on the tablet for studying activity results.

Furthermore, technical limitations of the devices were described: the users highlighted that tested monitors were limited in their capability of measuring different kinds of activities. For example, gym and household activities such as baking had not been registered. This was disappointing for persons that had performed these activities.

The possibility of increasing the users' PA by means of the monitors was discussed. In particular, feedback on current activity in relation to a goal was seen helpful and enabling the user's self-control: by increasing the user's awareness on whether current activity behavior is sufficient, the person can be stimulated to increase his or her PA. Additionally, the feedback might encourage and promote the user to increase PA. However, the participant describing this possibility was at the same time expressing doubts on how efficient the devices would be in this aspect:

> *I think it would spur others that don't move so much. Because he or she would then need to present something. And that I think can be a real spur. So for many people it will probably be a spur because I don't want to appear worse than others.*

Another enhancement possibility of the monitoring technology proposed by the participants was the combination of PA measurements and health parameters (such as pulse and blood pressure). Moreover, the users discussed improvement possibilities for the tested monitors. For example, the Jawbone bracelet could be redesigned to better instruct and facilitate charging:

> *There should have been an instruction saying "Check charging here" and a symbol on the bracelet that could be clicked on in order to see the charging level.*

In general, participants perceived no problems concerning integrity associated with having their personal PA measured by the monitors. However, it was envisioned that other persons might feel controlled if being monitored:

> *Someone really sensitive in terms of integrity might feel controlled, but for me it is only positive.*

Furthermore, one participant described that she felt afraid of being pushed into something she had not decided herself:

> *I want to decide myself how many steps I should take. I don't think I need a specific goal.*

One important aspect of users' experience related to the measurements was reliability, both of the measurements, and the devices, Problems with the devices negatively affected the participants' motivation in continuing with their use:

> *I wore the bracelet during the first night but when problems began to occur, I didn't bother using it at night.*

The users' perception of the measurements reliability was highly dependent on how well the measurement results correlated with the individual's own estimation of activity level. In fact, some participants suspected that the measurements had failed to work properly and questioned whether the result was correct. This reduced their motivation for being monitored.

User experiences from getting feedback on accomplished activity in terms of steps taken varied among participants. Although some participants questioned the importance of feedback, others were positive:

> *It would feel great, because it is what you need. You need the push that you should walk.*

The participants reflected on what type of feedback might be most helpful for them to increase their PA: seeing the activity results was perceived interesting and appreciated in terms of receipt confirming how active one has actually been. Especially, the feedback should clearly confirm the user whether a daily activity goal had been reached or not:

> *I think the idea is great. At least for me because I want confirmation of my outdoor walks. So it was actually perfect.*

Moreover, the importance of praise in terms of feedback was emphasized—even in cases when the progress was modest.

Participants perceived that the measurements enabled self-monitoring. However, all participants expressed low interest in seeing their accomplished PA on a screen. It was pointed out that software providing feedback must be very easy to use and navigate in. For example commands must be in the user's native language.

Experiences in Using the Technical Devices

Users' experiences in using the technical devices were mainly related to handling, insecurity, learning, and wearing the monitors.

In general, the users perceived handling the monitors easy. However, the users described that they had felt insecure on whether the communication between the monitor and app would work. Moreover, participants had felt insecure on whether the monitors could be damaged if worn while taking a shower. Furthermore, the Jawbone users had felt insecure on whether they had handled the charging of the bracelet correctly:

> *I was of course a bit worried initially about not being able to handle it. That I would push the wrong button and things like that. But then I thought it worked as the physiotherapist had taught me and I tried to remember that. Yes, it has worked well. I think.*

Handling the tablet could cause frustration and insecurity: the participants felt insecure on how to interact with the touch screen as they lacked previous experience of swiping hand or fingers over the screen and found the movement being difficult to perform. The participants had felt inexperienced in handling the technical devices and therefore had felt insecure on whether they were doing this correctly. In addition, there were occasions when the technology had not worked properly, and this made the users wonder if the problems experienced were because of incorrect handling or to technical failure:

> *I wish I would be because it is really good to know these things. Without knowledge, help is needed for everything. If you want...if you can manage a personal computer, you are able to proceed directly. So I wish, and if I had known more, then this would have...then I would have felt more confident and then it would have worked although I feel a bit hesitant.*

The users expressed a desire to learn more about how to use the technical devices. Moreover, they would have preferred increased access to help in the early phases of learning the practical handling. Here, some participants had experimented on their own to learn how to handle the technology. Meanwhile, others had refrained from doing this as they were afraid of damaging something:

> *If I would change anything, it would be that I should have learnt more so that I had felt more confident in the beginning.*

The written instructions provided to the participants contained English terms. As the participants have another native language, learning and following the written instructions was perceived difficult:

> *Then I read the written instructions but they contained a lot of English, there shouldn't be English terms there.*

The wearable bracelets were in general perceived user-friendly, unobtrusive, and easy to wear. However, the Jawbone bracelet was perceived stiff and the Withings watch was found large, uncomfortable, and difficult to match with different types of clothes:

> *...of course it was large and awkward sometimes. When wanting dress nicely, it was of course not so neat.*

Furthermore, the watch was described as difficult to put on, and help from another person had been needed to lock the wristband:

> *I once took off the watch while taking a shower, but after that I have worn it during showers because it was very difficult to put on. It was hard to hook, I had to take help.*

The participants wore the monitors during daytime. Some users also wore the bracelets at night while others took them off at

night, mainly as they found the wearables uncomfortable or were used to sleeping without watch. Although the participants had been instructed to wear the monitors during showers, several users took them off while showering. Furthermore, users who had worn the bracelets in the shower described that they had still somehow been careful not to get the device wet:

> *I have worn the watch in the shower but have been careful so that it wouldn't get too wet. I was a little careful with it.*

Meeting With the Users

All 8 participants were invited to a meeting with the research group where results from the data analysis were presented and discussed. Five participants could not attend because of various reasons; 3 participants came to the meeting. The results from the interviews were presented and discussed.

In discussions on being monitored, the participants confirmed that they had been surprised when seeing that outdoor activities performed with walker resulted in fewer steps than indoor activities without walker. There were also participants that had continued measuring PA after the study by using a mobile phone.

In discussions on handling the technology, participants emphasized that the technology must be easy to handle. In fact, it was expressed that the technology has to be "so user-friendly that the user doesn´t even perceive it as technology." Furthermore, the participants emphasized the importance of access to practical training on how to handle the technology together with another person.

In discussions on feedback from the technology, the participants expressed the desire of being informed in case they had moved too little. Feedback on insufficient activity should preferably be presented directly on the wearable monitor so that no extra screen is needed. Participants also described that it would be interesting to monitor and get feedback on different health parameters. Additionally, information on available basic fall preventive exercises was found valuable.

Different aspects of the technology's quality were discussed: the participants pointed out usability and intelligibility as most important. Access to personal support was also described as highly important, especially for long-term use.

Discussion

Principal Findings

This study has provided insight on how community-dwelling older adults experienced using commercial activity monitors for a relatively short time period with limited access to help and support. The study setting is comparable to the real-world situation of senior citizens acquiring a commercially available support for PA in daily life. More specifically, the addressed research questions were as follows:

- What are the overall experiences of senior persons, of different age and balance function, in using wearable AMs in daily life?
- Which aspects did the users perceive relevant to make the measurements as meaningful and useful in the long-term perspective?
- What needs and requirements did the users perceive as more relevant for the activity monitors to be useful in a long-term perspective?

PA has many health benefits for the increasing old population [37]. However, a major challenge is to achieve and maintain increased PA among older adults. Support for behavioral change can contribute here. Persuasive technology is designed to support behavioral change including increasing PA [11,38]. Current products for promoting PA are well adopted in the younger population but are not in their current state suitable for the old population [18,27,39]. In our study, the activity measurements terminated because of technical problems for 3 out of 8 participants. Although the study sample was small, this indicates that current AMs can be challenging to handle for senior users.

To design new persuasive systems, the users' needs and preferences must be understood, for example, regarding motivation and usability [16]. This is often obtained by codesigning new solutions in cooperation with end users [30]. The activity monitors in the study support several BCTs including goal setting, discrepancy between current behavior and goal, feedback on behavior, and self-monitoring of target behavior [9]. Although these BCTs have been shown effective for increasing younger adults PA, their effectiveness for increasing older adults PA has been questioned: for example, a systematic review [22] has identified three BCTs (namely "provide rewards contingent on successful behavior," "barrier identification or problem solving," and "model or demonstrate the behavior") as significantly effective for increasing older adults' PA. Due to the qualitative approach of our study in combination with a limited sample and short intervention time, no conclusions can be drawn from our results regarding the efficiency of BCTs supported by the monitors for this user group. However, the qualitative investigation of the users' experiences in our study has enabled us to identify aspects important for the measurements' meaningfulness and usefulness, as well as needs and requirements of the supporting technology.

The users' descriptions about how the measurements had influenced their motivation, awareness, emotions, and behavior illustrated that the monitoring of PA had increased their awareness on own PA behavior. In addition, users had started to explore and reason about how many steps each of the different activities could correspond to. As a consequence, PA could become funnier and some persons had increased their PA. Persons reaching their PA goal experienced feelings of enjoyment, whereas other people felt embarrassed for having low PA. Hence, measurements were perceived meaningful and useful for the users as they provided a receipt on whether users' efforts to perform different activities were sufficient for reaching the activity goals. Needless to say, this requires that the measurements of different activities are reliable and that the devices must be robust in their functioning. Additionally, it is important that the goal set is reasonable for the individual. This indicates that the used AMs could support the users own exploring of PA behavior. Therefore, we believe that the AMs shall support the BCT "model or demonstrate the behavior." In

this respect, we see room for improvements of the devices to strengthen their support for this BCT. Additionally, the AM app could be enriched with features supporting the BCT "barrier identification or problem solving," which could be critical for individuals that for different reasons were hindered in exploring PA behavior.

Users' experiences about being monitored include valuable information about preferences for support, as well as preferred key values of the technical devices. Here, the users described their need for feedback on accomplished PA as a positive receipt on their efforts during the day. Additionally, they liked to be praised for having been active. Hence, this illustrated the importance of the BCT "rewards contingent on successful behavior" for seniors striving toward increasing their PA. High reliability of the measurements is a necessary prerequisite such that users would perceive them useful and meaningful. Moreover, using the wearable must be perceived as smooth, comfortable, and nondemanding for the users to accept the devices in a long-term perspective.

Finally, users' experiences related to handling the technology contains valuable information on user requirements related to usability. Here, the users stressed that the devices must be easy and robust to use. They argued that the technology should be comprehensible, intuitive, and self-instructive to prevent users feeling insecure on the handling.

Limitations

These results cannot be generalized to all community-living older adults as further described below. Hence, the following limitations of the study have been identified.

Participants

The number of participants was few but considered as sufficient because of the relative homogeneity of the group [40]. The analysis of the interviews indicates that saturation in terms of emerging categories was obtained. Moreover, all recruited participants were positive toward technical support and/or fall prevention training. Hence, for studying experience of persons reluctant to using technology or being physically active, this group of participants might not be representative. Analysis of the activity diaries showed large variance in self-estimated daily physical effort between the participants. Additionally, self-estimated daily effort varied over time for each person. This can be explained by the participants' different physical conditions. Both individuals who were users and nonusers of walking aids were included.

Activity Monitors and Tablet-Based Apps

Only two different monitors were tested in the group; both of them were used together with a corresponding specific app on a tablet. User experience may vary over time and by model of monitor. However, the inclusion of two different products makes our results not just representative for one specific AM.

Intervention

Participants tested the technology for 9 to 10 days. Experience and acceptance vary over time and the period used is short. However, the used length of testing period enabled us to identify key challenges and experiences by new users in the critical initiation phase. Recommendations on aspects related to long-term usage were deduced from the users' perceptions of the short-term usage.

Comparison With Prior Work

Persuasive technology is designed to support behavioral change [11]. In our study, the participants described that the technology increased their awareness of how active they actually were. Increased self-awareness of PA has also been described in other studies of older adults' acceptance of wrist worn AMs [27]. However, the technology's influence on motivation and behavioral change related to PA varied between participants in our study. The ability of AMs to provide more awareness than motivation in PA with goal setting and progress monitoring has been demonstrated in other studies with younger users [41]. In addition, it has been suggested that current AMs need to be enriched with additional BCTs that are more likely to appeal to senior users [23]. French and coworkers have identified "provide rewards contingent on successful behavior," "barrier identification or problem solving," and "model or demonstrate the behavior" as the most effective for increasing older adults' PA [22].

In our study, some of the participants were already motivated for being physically active and had already included regular PA in their daily lives. At least partly, this could be referred to as sample selection bias as the participants had already shown some interest for PA. These persons had their own views on adequate activity behavior and own personal aims. Furthermore, if hinders had occurred to them, they had been able to manage them. Meanwhile, other participants had low motivation for being physically active, something that was not affected by the monitors. It is possible that some of these participants did not perceive the technology as motivational. Possible reasons for this are that the BCTs incorporated in the products were insufficient for supporting and motivating those persons [9,22,23]. For example, barrier identification or problem solving might be highly valuable for persons experiencing different kind of hinders for PA. Other explanations can be poor usability and insufficient comprehensibility of the devices. For example, several participants perceived the provided feedback as difficult to interpret and value. Moreover, some participants had difficulties in handling the devices and therefore missed out on the motivating feedback. This confirms the information processing theory [42] describing that a person must both receive and comprehend the persuasive message to be able to change attitude. In addition, participants identified users' personal interest in and motivation for progress as a prerequisite for using AMs as support for PA. Patel has similarly pointed out this opinion [39]. This indicates that for persons with low PA levels, low motivation, and low interest in progress, current AMs might not be suitable. For them, new persuasive solutions meeting their needs for motivation are necessary.

The emotions expressed in relation to the technology were described as enjoyable, positively surprising, but also embarrassing if it was related to feedback of low PA. Some participants perceived PA as funnier when being monitored. Positive emotions are important to notice as emotional meaning is prioritized and valued as more relevant than instrumental

gains in the old population. The emotional meaning is also closely related to motivation in this age group [43]. Negative emotions expressed were connected to disappointment when the measurements failed. In this respect, the importance of the technology's reliability was emphasized. This opinion relates to theoretical models of technology adoption [44] and efficient persuasive technology [11]. A systematic review of older adults' perception of technologies aimed at fall prevention, detection, and monitoring has identified that the technology must be simple, reliable, effective, and tailored to individual need [45].

Our study adds new knowledge to prior work on older people's experiences in using AMs. Recently, a quantitative study measured older users' experiences of commercial AMs for self-monitoring of PA in terms of drivers for technology use from TAM [25]. It has been suggested that additional variables should be included in TAM for better reflecting older people's technology acceptance behavior [26]. Our qualitative methodology enabled us to identify motivational aspects as highly relevant. Here, we found that the measurements' impact on motivation for PA varied between participants.

Moreover, our study has applied a different setup during the technology intervention compared with the study by McMahon and coworkers [25]: the technology used in their study comprised one type of activity bracelet (without tablet) that was used for a significantly longer period of time together with extensive access to support for the users. Our study confirms that older adults perceive activity bracelets easy to use. Moreover, the tablet was perceived difficult to maneuver by our participants who had a median age of 83 years. This confirms previous studies reporting that using tablets among individuals older than 60 years can be associated with problems [46]. As support, our participants had received written information on how to handle the technology. Despite this, they realized that they would have needed more support for learning the handling. In earlier studies, it has been highlighted that older adults need support through the process of learning how to use new technology [47]. We now realize that our participants needed more supported learning time, even if this was not requested when the participants met the physiotherapist. In this respect, we believe that our study setting is closer to the real-life situation of a senior person starting to use any commercially available AM as support for PA.

Furthermore, mixed-methods evaluations of usability, usefulness, and acceptance of wearable AMs for adults over 50 years with chronic illness [28] and community-dwelling adults between 55 and 84 years have been performed [27]. In the study by Mercer [28], users with chronic illness tested five AMs for 3 days and evaluated the devices' usability and usefulness by questionnaires based on TAM. Moreover, qualitative data was collected in focus groups and subjected to thematic analysis. Despite differences in age and health status between these users and the participants in our study, similarities in the users' experiences can be identified: both groups described that using the AMs increased awareness of their PA levels. However, the users with chronic illness [28] had already been asked by a physician to exercise more. Hence, the increased self-awareness contributed increased motivation for PA. When aiming at increasing peoples PA for preventing future disease, the potential risks because of current behavior and the potential benefits gained through altered behavior need to be perceived by the user.

In the study by Puri [27], the users tested two different AMs for 3 weeks. A questionnaire gathered users' experience and acceptance after each testing period. The users expressed moderate levels of acceptance. In addition, semistructured interviews were conducted with 4 participants and analyzed with regards to qualitative content. Here too, participants described that the AMs had increased their self-awareness and motivation for behavioral change. The AM's impact on motivation for behavioral change varied among participants in our study.

An unexpected finding was that the participants in our study did not experience any problem related to integrity when using the technology. In fact, usually privacy concerns are significantly associated with wearable technology acceptance in health care in the general population [48]. However, the view of the participants in our study regarding integrity has also been described in the study performed by Puri [27] and in reviews of studies on ethical considerations concerning assistive technology [49]: the majority of older people state that the needs for devices overrule any possible privacy concerns, and as long as there is a balance between needs and privacy, they do not feel that their privacy is violated. This opinion could possibly also reflect that the users, who had limited previous experience of using the Internet, had limited knowledge and awareness of integrity aspects related to recording of PA. This question needs to be addressed in future studies.

Conclusions

The study investigated senior users' experience in using AMs as support for PA in daily life. Conclusions to be drawn from the study are as follows:

- AMs can increase senior users' awareness of own PA behavior.
- The influence of AMs on older users' motivation and/or PA behavior varies between different senior users: although some users started to explore how different activity behavior affected PA levels, other persons maintained their daily PA habits.
- For the measurements to be perceived meaningful and useful for the users, they have to be reliable and give the user a receipt on whether the daily PA has been enough in relation to a quantitative goal. Feedback in terms of praise is also appreciated.
- For AMs to be useful in the long-term for senior users, the devices must be easy to use, intuitive, robust, and reliable. Deficiencies in these areas significantly reduce the users' motivation in using the AMs.
- Current AMs partly support BCTs effective for increasing older adults' PA. However, the devices should be further developed and enriched to better support effective BCT for the target group.
- Participants in the study expressed no problems related to integrity when using the AMs. Whether this experience reflects limited awareness of integrity issues related to

Internet-based registration of PA needs to be addressed in future studies.

In summary, this study has provided insights on how senior community-living adults with little or no experience of information and communication technology perceived using AMs. AMs can be valuable for supporting some older adults' PA. However, currently available products are not ideal for broader groups of older users.

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Authors' Contributions

ME was the main researcher responsible for the study. ME and ACJ were the main authors of the manuscript and designed the study. ACJ and NÅ were responsible for the intervention and data collection. LCE was responsible for the technology. ME analyzed the notebooks and background information. All authors participated in the qualitative analysis and critical review and revision of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide.

[PDF File (Adobe PDF File), 15KB - mhealth_v6i2e34_app1.pdf]

Multimedia Appendix 2

Main and subcategories based on the interviews.

[PDF File (Adobe PDF File), 11KB - mhealth_v6i2e34_app2.pdf]

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Abbreviations

AM: activity monitor
BCT: behavior change technique
PA: physical activity
TAM: technology acceptance model

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Original Paper

Patterns of Fitbit Use and Activity Levels Throughout a Physical Activity Intervention: Exploratory Analysis from a Randomized Controlled Trial

Sheri J Hartman[1,2], PhD; Sandahl H Nelson[1,2], MS; Lauren S Weiner[1,2], BA

[1]Department of Family Medicine and Public Health, University of California San Diego, La Jolla, CA, United States

[2]University of California San Diego Moores Cancer Center, University of California San Diego, La Jolla, CA, United States

Corresponding Author:
Sheri J Hartman, PhD
Department of Family Medicine and Public Health
University of California San Diego
3855 Health Sciences Drive
La Jolla, CA, 92093
United States
Phone: 1 8585349235
Email: sjhartman@ucsd.edu

Abstract

Background: There has been a rapid increase in the use of technology-based activity trackers to promote behavior change. However, little is known about how individuals use these trackers on a day-to-day basis or how tracker use relates to increasing physical activity.

Objective: The aims were to use minute level data collected from a Fitbit tracker throughout a physical activity intervention to examine patterns of Fitbit use and activity and their relationships with success in the intervention based on ActiGraph-measured moderate to vigorous physical activity (MVPA).

Methods: Participants included 42 female breast cancer survivors randomized to the physical activity intervention arm of a 12-week randomized controlled trial. The Fitbit One was worn daily throughout the 12-week intervention. ActiGraph GT3X+ accelerometer was worn for 7 days at baseline (prerandomization) and end of intervention (week 12). Self-reported frequency of looking at activity data on the Fitbit tracker and app or website was collected at week 12.

Results: Adherence to wearing the Fitbit was high and stable, with a mean of 88.13% of valid days over 12 weeks (SD 14.49%). Greater adherence to wearing the Fitbit was associated with greater increases in ActiGraph-measured MVPA ($b_{interaction}$=0.35, *P*<.001). Participants averaged 182.6 minutes/week (SD 143.9) of MVPA on the Fitbit, with significant variation in MVPA over the 12 weeks (F=1.91, *P*=.04). The majority (68%, 27/40) of participants reported looking at their tracker or looking at the Fitbit app or website once a day or more. Changes in Actigraph-measured MVPA were associated with frequency of looking at one's data on the tracker (b=−1.36, *P*=.07) but not significantly associated with frequency of looking at one's data on the app or website (*P*=.36).

Conclusions: This is one of the first studies to explore the relationship between use of a commercially available activity tracker and success in a physical activity intervention. A deeper understanding of how individuals engage with technology-based trackers may enable us to more effectively use these types of trackers to promote behavior change.

Trial Registration: ClinicalTrials.gov NCT02332876; https://clinicaltrials.gov/ct2/show/NCT02332876?term=NCT02332876&rank=1 (Archived by WebCite at http://www.webcitation.org/6wplEeg8i).

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KEYWORDS

physical activity; technology; activity tracker; self-monitoring; adherence

Introduction

The ubiquity of technology in day-to-day life is paving the way for new and emerging tools that can easily monitor physical activity. Use of commercially available, technology-based wearable activity trackers such as a Fitbit or Garmin is growing. A 2016 analysis revealed that 45% of American adults own at least one activity tracker, up from 21% in 2014 [1]. Trackers have been incorporated into several interventions that have successfully increased physical activity [2,3]. However, little is known about how individuals use trackers in a physical activity intervention to support behavior change.

Self-monitoring is defined as the observing and recording of one's own behavior [4]. In the context of a behavioral intervention, the goal of self-monitoring is to increase self-awareness of target behaviors and outcomes, which has been shown to promote a range of healthy behaviors including smoking cessation [5], healthy eating and physical activity [6-8], weight management [9,10], and reducing excessive alcohol consumption [11]. There may be several benefits to self-monitoring physical activity with technology-based trackers compared with traditional self-monitoring techniques such as pedometers or self-reported recall [12,13]. Technology-based trackers automatically capture activity data, minimizing participant burden and recall bias compared with traditional paper and pencil journaling. In addition, these trackers can simultaneously monitor many indicators including steps, distance, moderate to vigorous physical activity (MVPA), heart rate, and sleep [3]. With the growing use of trackers in physical activity interventions, it is important to understand how they may help individuals self-monitor their behavior.

Trackers, and their associated mobile apps and websites, support many theory-based techniques proven to increase activity in behavioral interventions [7,8,12-17]. The behavior change techniques framework proposed by Michie and colleagues suggests that self-monitoring is the skill most strongly associated with intervention success when combined with at least one other self-regulatory technique from control theory (eg, receiving feedback on performance and reviewing progress toward goals) [7,13,15,18]. According to control theory, feedback loops provide awareness of discrepancies between performance and goals that can encourage behavior change [18]. Trackers facilitate feedback loops by providing information about physical activity behaviors in relation to individual goals. Although a key benefit of these trackers is the automatic recording of activity and personalized feedback with little burden for the wearer, it also could result in minimal engagement with the activity information. That is, simply recording activity without attending to the feedback and using additional self-regulatory techniques (ie, *passive* self-monitoring) may be insufficient to change behavior [12,15,19]. Conversely, trackers may encourage greater awareness of behavior when an individual attends to feedback provided on the tracker itself or associated mobile apps and websites (ie, *active* self-monitoring) [9,12,20-22].

Adherence to wearing a tracker may also be important for behavior change. A large body of literature suggests that strong adherence to self-monitoring of weight [23-27], diet [22,28], and physical activity [9,28] is associated with greater weight loss and improved weight control. Similarly, a systematic review found that consistent use of a pedometer is associated with higher activity levels [29]. Although some intervention studies report overall adherence or compliance to wearing a tracker (ie, proportion of total study days worn) [30-32], few have assessed patterns of adherence to tracker use *throughout* a physical activity intervention. A recent intervention trial by Cadmus-Bertram and colleagues that used a Fitbit activity tracker is one of the only published studies to take an in-depth look at adherence to wearing the Fitbit throughout the intervention [19,33]. They found adherence to wearing the Fitbit to be high and stable over time; however, it is unknown how or if participants were attending to the information collected by the trackers. There is also a lack of research examining how adherence to wearing a technology-based tracker relates to increasing physical activity. Additional research is needed to understand how best to utilize trackers in interventions to support self-monitoring and effectively change behavior.

A recently published study by Robertson et al [34] examining intervention delivery preferences found that cancer survivors are highly interested in using technology-based trackers to increase their activity. This is important as physical activity can decrease cancer recurrence [35,36], mortality [37], and improve quality of life [38,39], but unfortunately, many breast cancer survivors decrease their activity levels as much as 50% from pre- to postdiagnosis [40] and for several months to years following diagnosis [41]. Up to 65% of breast cancer survivors do not meet Centers for Disease Control and Prevention physical activity guidelines of 150 min of aerobic activity and 2 days of strength training per week [42,43]. It is important to understand how emerging, scalable intervention modalities such as technology-based trackers can be used to help cancer survivors increase their physical activity.

The goal of the current analysis was to conduct an in-depth examination of data collected from the Fitbit tracker daily for 12 weeks among a sample of breast cancer survivors enrolled in a physical activity intervention, where 7 days of ActiGraph-measured physical activity was also collected at baseline and end of study. The primary aims of this analysis were as follows: (1) examine patterns of adherence to wearing the Fitbit, (2) test the association of adherence to wearing the Fitbit with changes in ActiGraph-measured MVPA, (3) examine patterns of Fitbit-measured MVPA, (4) examine frequency of self-reported checking of data on the tracker and on the mobile app or website, and (5) test the association between self-reported checking of data on the tracker and on the mobile app or website with changes in ActiGraph-measured MVPA. We hypothesized that higher adherence to wearing the Fitbit and greater checking of the data would be associated with greater increase in ActiGraph-measured MVPA.

Methods

Participants and Design

Participants in this secondary data analysis were enrolled in a randomized controlled trial of a 12-week physical activity

intervention. Data were collected from February 2015 to July 2016. The University of California, San Diego institutional review board approved all study procedures, and all participants provided written informed consent. The trial was registered with Clinicaltrials.gov (NCT 02332876). Eligible participants were female breast cancer survivors, in the age range of 21 to 85 years, who were diagnosed less than 5 years before study enrollment, had completed chemotherapy or radiation treatment, were sedentary (defined as self-reporting less than 60 min of MVPA in 10 min bouts per week), and had access to the Internet and a Fitbit-compatible computer, tablet, or phone. Exclusion criteria included any medical condition that could make it potentially unsafe to be in an unsupervised physical activity intervention (determined by the Physical Activity Readiness Questionnaire [44]), other primary or recurrent invasive cancer within the last 10 years, and unable to commit to a 12-week intervention.

Out of 911 women who were screened for eligibility, 108 were eligible, and 97 came to the baseline visit. Most common reasons for being ineligible included being too active (n=225), unable or unwilling to attend clinic visits (n=106), breast cancer surgery more than 5 years ago (n=81), and medical exclusion (n=36). At the baseline visit, 10 women were deemed ineligible (high blood pressure, n=8; physical limitation, n=2). A total of 87 participants were randomized to the exercise arm (n=43) or the control arm (n=44). One participant from each arm was lost to follow-up, resulting in a 97.7% retention rate (exercise n=42, control n=43) [45]. The current analyses comprise data from the 42 participants who were randomized to the exercise arm and completed the study.

A detailed description of the protocol was previously published [46]. Briefly, participants were predominantly recruited via cancer registry lists. Potential participants were telephone-screened to determine eligibility. Interested and eligible women were scheduled for an in-person visit where they were given an ActiGraph GT3X+ accelerometer to wear for 7 days and bring back to the randomization visit. At the randomization visit, participants in the exercise arm were given a Fitbit One as part of the intervention. Participants were instructed to use their Fitbit to self-monitor their physical activity. As the intervention focused on Fitbit's "Active Minutes," which consists of MVPA and did not focus on steps, participants were encouraged to wear the Fitbit when engaging in MVPA but were not instructed to wear it for a minimum amount of time each day. Participants were informed that their Interventionist would check their Fitbit data at least once a week and that they may be contacted by the interventionist if it seemed that they were struggling or having a great week. All participants received intervention phone calls around the 2-week and 6-week time points and automatic emails every 3 days throughout the 12-week intervention, which included reminders to sync and wear their Fitbit. One week before their final study visit, participants were mailed the ActiGraph GT3X+ and asked to wear it for 7 days, concurrently with the Fitbit, and to bring the ActiGraph to the in-person visit. At the final in-person visit, participants completed a questionnaire regarding their use of the Fitbit tracker and the Fitbit app and website.

Measures

The Fitbit One, a commercially available accelerometer-based activity tracker, was used to examine patterns of physical activity throughout the 12-week intervention. Fitbit uses a proprietary algorithm to classify each minute as being in sedentary, light, moderate, or vigorous activity and provides metabolic equivalent of tasks (METs) for each minute. Data were wirelessly uploaded to the user's fitbit.com account and then downloaded by the research team through a database called Fitabase (Small Steps Lab, San Diego, CA), which allows for collecting data at the minute level. Daily adherence to wearing the Fitbit tracker was defined as wearing the tracker for >10 hours in a day or logging at least some activity (>1 min MVPA). This definition for a valid Fitbit wear day was used because participants were not instructed to wear the Fitbit all day; rather they were instructed to use the Fitbit to track activity. Thus, wearing the tracker specifically to log MVPA was deemed to be valid wear based on these instructions. Fitbit wear time was determined by processing of minute level Fitbit data using the R function *accel.weartime* within the "accelerometry" package [47]. Nonwear was classified using both steps and METs. Consistent with standard protocols for ActiGraph wear time [48], greater than 90 consecutive minutes of 0 steps or METs, with 2-min tolerance (ie, for 2 min with nonzero counts during nonwear intervals) was deemed nonwear.

The ActiGraph GT3X+, a well-validated research grade accelerometer [49], provided frequency, duration, and intensity of physical activity for 7 days at baseline (prerandomization) and at week 12. Using standard guidelines, sufficient ActiGraph wear time was classified as >10 hours of wear a day for at least 5 days or >50 hours across 4 days and screened for in the ActiLife software (ActiGraph, Pensacola, FL) using guidelines outlined by Choi et al [48]. All complete and valid data were processed in ActiLife software using the low frequency extension and aggregated to 60-second epochs so that published physical activity cut points could be applied [50]. MVPA was defined as 1952 or more counts per minute (3.00-7.00 METs).

Self-report questionnaires at follow-up (12 weeks) were used to determine participants' frequency of looking at their activity data on the Fitbit tracker itself and (in a separate question) the Fitbit app or website. These questions used an 8-point Likert scale with the following response options: more than once per day, once per day, 4-6 times per week, 2-3 times per week, once per week, 2-3 times per month, once a month or less, and never.

Statistical Analysis

The distribution (mean [SD] and n [%]) of participant demographics and breast cancer characteristics were calculated at baseline for the analytic sample. ActiGraph-measured physical activity, measured at baseline and follow-up, was described using mean (SD). The agreement between ActiGraph- and Fitbit-measured MVPA was assessed by calculating the concordance correlation in days with overlapping wear.

Examine Patterns of Adherence to Wearing the Fitbit

Overall adherence to wearing the Fitbit was analyzed by determining the percent of days in the 12-week intervention period that the participant logged a valid day of wear (>10 hours

wear or >1 min MVPA). Syncing errors occurred for 2 participants resulting in no data for 64 days for 1 participant and 21 days for the other participant; this data was considered missing and not classified as nonvalid.

To graphically display patterns of adherence over time, rolling adherence was calculated by determining the percent valid days in the past 6 days + the current day. To examine differences in weekly adherence, we calculated the mean (SD) of weekly adherence from the end of each week (1,...,12) and carried out a mixed effects ANOVA, with a subject level random intercept and slope and using a variance components covariance structure, to detect an omnibus difference in adherence between weeks. The subject level random intercept and slope models were used to account for the correlated nature of the weeks nested within each individual.

Test the Association of Adherence to Wearing the Fitbit With Changes in ActiGraph-Measured Moderate to Vigorous Physical Activity

The association between Fitbit adherence and change in ActiGraph-measured MVPA was assessed using a linear mixed effects model with a subject level random intercept. The model regressed ActiGraph-measured MVPA on overall Fitbit adherence, time (baseline vs follow-up), and the interaction between adherence and time.

Examine Patterns of Fitbit-Measured Moderate to Vigorous Physical Activity

Overall, Fitbit-measured MVPA was assessed by calculating the mean (SD) of day level MVPA for each participant across all valid days in the 12-week study and transforming to the week level.

To graphically display patterns of physical activity over time, rolling MVPA was calculated by summing the minutes of physical activity in the past 6 days + the current day. To examine differences in weekly MVPA, we calculated the mean (SD) of weekly MVPA from the end of each week (1,...,12) and carried out a mixed effects ANOVA, with a subject level random intercept and slope and variance components covariance structure, to detect an omnibus difference in Fitbit-measured MVPA between weeks. As before, the subject level random intercept and slope allowed us to account for the correlated nature of the weeks nested within each individual.

Test the Association Between Self-Reported Checking of Data on the Tracker, Mobile App, or Website With Changes in ActiGraph-Measured Moderate to Vigorous Physical Activity

Associations between physical activity self-monitoring and changes in ActiGraph-measured MVPA were analyzed using a linear mixed effects model with a subject level random intercept. The model regressed ActiGraph-measured MVPA on the self-monitoring score, time (baseline vs follow-up), and the interaction between the self-monitoring score and time. There were two "self-monitoring scores," each based on an 8-point Likert score (one for looking at information on the Fitbit tracker and the other for looking at information on the app or website). In addition, we created a combined binary variable to assess the proportion of participants who looked at both the Fitbit tracker and the app or website daily (≥once per day) versus those who did not. The mixed effects model was run individually for each of the self-monitoring questions, with the Likert questions treated as continuous. Questions were treated as continuous because the Likert measure had 8 points, there was an underlying continuous concept (time), and low skew when the distribution was treated as continuous.

Results

Participant Characteristics

Participants were 42 female breast cancer survivors who were predominantly diagnosed at stage 1 (62%, 26/42). About half had received chemotherapy, and about three-fourths were currently taking an aromatase inhibitor or tamoxifen. They were an average of 58 years old (SD 11.3), with the majority being non-Hispanic (81%, 34/42), white (83%, 35/42), and having a college education or greater (69% [29/42]; Table 1). The intervention group significantly increased ActiGraph-measured MVPA from baseline (93.8 min/week, SD 90.79) to 12 weeks (195.3 min/week, SD 105.9, P<.001) [45]. Minutes of ActiGraph-measured MVPA at week 12 was highly correlated with Fitbit MVPA collected on overlapping days (r=.81: ActiGraph MVPA/day mean 29.9, SD 25.90, Fitbit MVPA/day mean 25.8, SD 28.76).

Patterns of Adherence to Wearing the Fitbit

Adherence to wearing the Fitbit was high, with a mean number of valid days across the 12-week intervention period of 88% (SD 14), median of 95%, and range of 31% to 100% of intervention days. Each week, participants wore the Fitbit on average 6.2 out of 7 days (88.5% per week, SD 1.8). Although adherence to wearing the Fitbit appeared to decrease in the middle of the intervention period (Figure 1), adherence did not significantly differ across the 12 weeks (P=.71).

Overall Adherence to Wearing the Fitbit and Associations With ActiGraph-Measured Moderate to Vigorous Physical Activity

Greater adherence to wearing the Fitbit was associated with greater increases in ActiGraph-measured MVPA ($b_{interaction}$=0.35 P<.001). Someone with the median amount of valid wear days (95%) had an expected ActiGraph-measured MVPA increase of 109.8 min/week, whereas someone with the first or third quartile amount of valid wear days (80% and 98%, respectively) had an expected ActiGraph-measured MVPA increase of 73.3 min/week and 117.2 min/week, respectively.

Patterns of Fitbit-Measured Moderate to Vigorous Physical Activity

Across the 12 weeks, participants averaged 182.6 minutes/week (SD 143.9) of MVPA on the Fitbit. Minutes of MVPA per week significantly differed over the 12 weeks ($F_{11/392}$=1.91, P=.04; Figure 2). Weeks 3 and 9 had the highest average MVPA with 222.9 min/week (SD 173.4) and 198.4 min/week (SD 167.9), respectively. Weeks 12 and 5 had the lowest average MVPA with 159.7 min/week (SD 128.4) and 168.1 min/week (SD 123.5), respectively.

Table 1. Baseline characteristics (N=42).

Characteristic	Value
Age in years, mean (SD)	57.9 (11.3)
Married or living with partner, n (%)	31 (73)
Body mass index, kg/m^2, mean (SD)	26.7 (6.3)
Education, n (%)	
Some college or less	13 (31)
College graduate	18 (43)
Master's degree or higher	11 (26)
Ethnicity, n (%)	
Not Hispanic/Latino	34 (81)
Hispanic/Latino	8 (19)
Race, n (%)	
White	35 (83)
Nonwhite	7 (17)
Cancer stage, n (%)	
Stage I	26 (62)
Stage II	12 (29)
Stage III	4 (10)
Received chemotherapy, n (%)	22 (52)
Current aromatase inhibitor or tamoxifen, n (%)	30 (71)
Time since surgery, months, mean (SD)	29.5 (17.6)

Figure 1. Rolling weekly percent adherence to wearing the Fitbit, averaged across study participants (standard error), reference line at overall 12 week average, n=42.

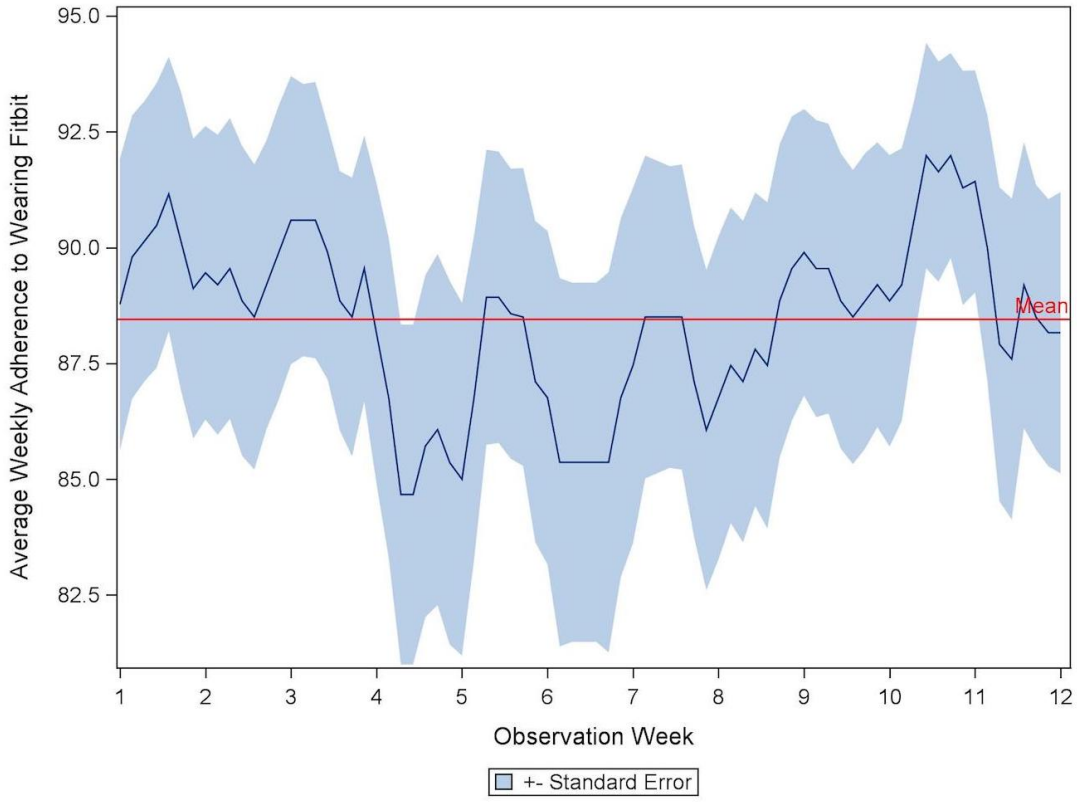
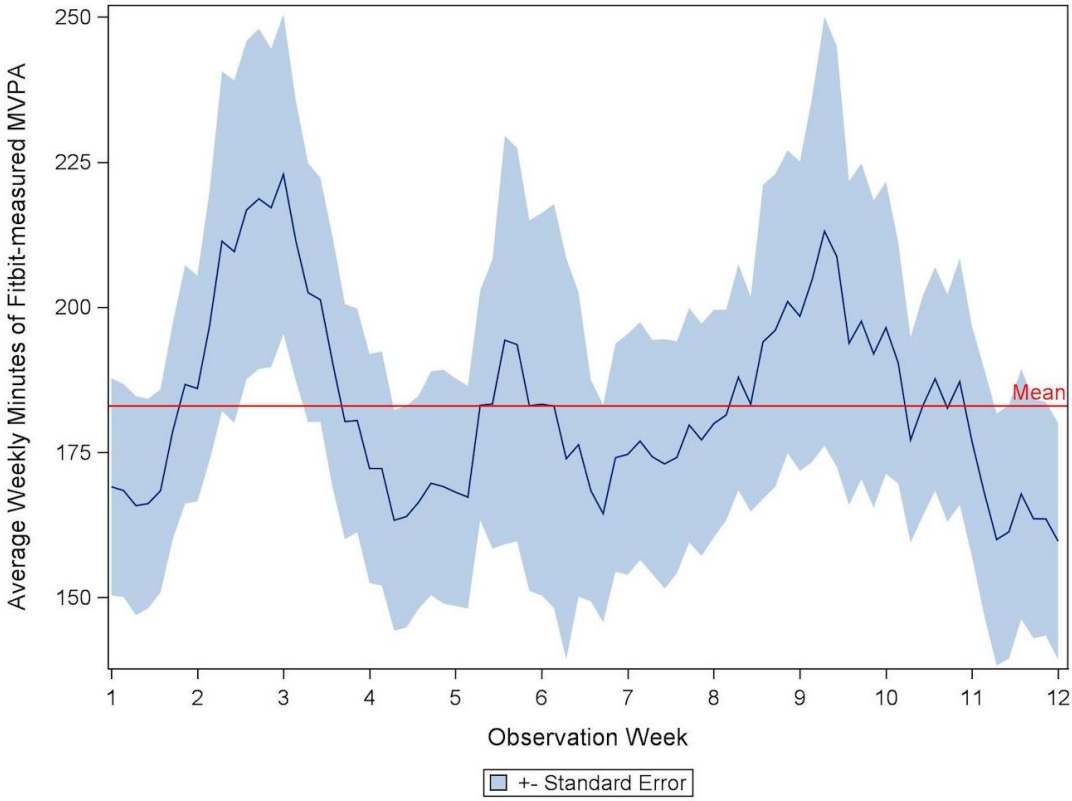


Figure 2. Rolling weekly minutes of Fitbit-measured MVPA, averaged across study participants (standard error), reference line at overall 12 week average, n=42.



Use of the Fitbit Tracker, App, or Website

At study completion, participants answered a series of questions regarding use of the Fitbit tracker and Fitbit website or mobile app. Two participants did not answer these two items. Of the 40 participants who answered these items, 68% (27/40) reported looking at their activity data on the Fitbit app or website once a day or more; 13% (5/40) reported looking at the app or website less than once a week; 68% (27/40) of participants reported looking at the Fitbit tracker itself once a day or more, whereas 10% (4/40) reported looking at it less than once a week. Exactly half (50%, 20/40) of the participants reported looking at both the Fitbit tracker and the app or website at least once per day (Table 2).

Association of Use of the Fitbit Tracker, App or Website With ActiGraph-Measured Moderate to Vigorous Physical Activity

Frequency of looking at one's data on the Fitbit app or website, controlling for adherence to wearing the Fitbit, was not associated with change in ActiGraph MVPA (*P*=.36). There was a negative association between looking at one's data on the Fitbit tracker and change in ActiGraph MVPA (b=−1.36, *P*=.07), controlling for adherence to wearing the Fitbit. Participants who reported looking at the tracker more frequently had smaller increases in MVPA than those who looked less often. When this analysis was carried out on the combined binary variable of looking at the Fitbit tracker and the app or website at least daily, we found no association with change in ActiGraph MVPA (*P*=.87).

Table 2. Fitbit self-monitoring questionnaires (N=40).

Question	Frequency
Looked at information on the app or website	
Never	0 (0)
Once a month or less	2 (5)
2-3 times per month	3 (8)
Once per week	3 (8)
2-3 times per week	3 (8)
4-6 times per week	2 (5)
Once per day	6 (15)
More than once per day	21 (53)
Looked at information on the Fitbit tracker	
Never	2 (5)
Once a month or less	1 (3)
2-3 times per month	1 (3)
Once per week	2 (5)
2-3 times per week	3 (8)
4-6 times per week	4 (10)
Once per day	7 (18)
More than once per day	20 (50)
Looked at information on the app or website and on the Fitbit tracker	
Less than once a day	20 (50)
Once a day or more	20 (50)

Discussion

Principal Findings

This study is one of the first to take an in-depth look at use of a commercially available wearable activity tracker and how it relates to changes in physical activity. Using minute level data collected from the Fitbit, adherence to wearing the tracker was high and stable across the 12-week intervention period. This is generally consistent with previous research [30,33,51]; however, one recent observational study found linear decreases in Fitbit use over a year [52]. This suggests that Fitbit use long term and not within an intervention may be different than was seen in this study. One challenge of comparing Fitbit use across studies is that how adherence to wearing the tracker was calculated or defined is often not reported [30,33,51,52]. To our knowledge, this is also one of the first studies to explore the relationship between use of a commercially available activity tracker and success in a physical activity intervention where the physical activity was also measured by an ActiGraph, the gold standard measure for free-living physical activity in research. The positive association between wearing the Fitbit and increased MVPA suggests that using the real-time data to determine if someone is wearing their tracker could help to identify individuals who may need additional support, or possibly other self-monitoring methods, to support behavior change.

In our analyses, MVPA significantly varied throughout the intervention. Interestingly, the highest minutes of MVPA occurred at week 3, immediately after the intervention call, which typically occurred around the end of week 2, and at week 9, which was around when participants were contacted to confirm their final visit at 12 weeks. This highlights the importance of personal contact with participants in a physical activity intervention and is consistent with research that has found greater benefit for combining technology-based self-monitoring with counseling than using technology alone [53].

A novel aspect of wearable trackers is that they can provide objective feedback on MVPA. Previous studies with traditional pedometers could only provide feedback on steps, which captures activities of all intensities. We identified only two other published physical activity interventions in which participants set goals explicitly on Fitbit's active minutes and examined changes in Fitbit-measured active minutes as one of the primary study outcomes [33,54]. Given the numerous benefits of MVPA [55-57], the capability of trackers to automatically collect information on MVPA may be useful in helping individuals meet physical activity guidelines [13].

While technology-based activity trackers make self-monitoring less burdensome compared with traditional tracking methods, they also do not require a person to attend to the information being collected by the monitor. Overall, self-reported viewing

of activity data on the Fitbit itself, or on the Fitbit website or app was very high. Looking at activity data on the app or website was not associated with changes in ActiGraph-measured MVPA. Surprisingly, more frequent looking at data on the Fitbit tracker itself was associated with smaller changes in ActiGraph-measured MVPA. One reason for this finding may be that the Fitbit One tracker did not show minutes of MVPA; that information was only available on the app or website. These results could also indicate that checking one's own data is not as important as being accountable to someone else for increasing physical activity. In this study, it was stressed that the Fitbit would be used so that the interventionist could see the data and provide support. It may be that being accountable was a greater motivating factor for increasing MVPA than being self-aware of one's own activity levels. Much of the field's understanding of the importance of self-monitoring is based on active self-monitoring, which typically require a person to think about their day and record their minutes of activity, but this record is often not easily or immediately shared. As technology-based trackers become more common place in interventions, we need to continue exploring the impact of active versus passive self-monitoring and the role of accountability on behavior change so that our understanding of the role of monitoring physical activity is consistent with new and emerging technologies.

Limitations

Although this in-depth analysis of daily activity data from a commercially available activity tracker is an important addition to our understanding of how trackers are associated with behavior change, several limitations should be noted. This study comprised a small sample of a relatively homogenous group of breast cancer survivors, and results may not be generalizable. Fitbit does not share information on number of times a person checks the Fitbit app or website; therefore, checking of app or website relied on self-report, which unfortunately had little variation, with most participants reporting looking at their Fitbit or the app or website daily. Additionally, self-report questions assessing use and engagement with the tracker were only asked at the end of the intervention, limiting our ability to examine trends in engagement throughout the intervention. In addition, we used a question combining website and app use and could not examine those two modalities separately. The intervention period was relatively short—long-term use of an activity tracker and its relationship with increasing physical activity could not be assessed. Although we also used standard cut-points for determining ActiGraph-measured MVPA, future studies should consider using machine learning algorithms to classify ActiGraph-measured behaviors. Finally, the intervention included many reminders to wear the Fitbit, so adherence results may not be representative of what would happen outside of an intervention protocol.

Conclusions

With the continued emergence of new technologies for self-monitoring physical activity, it is important to understand how people use these new devices and how use of these devices can support behavior change. These insights may enhance our ability to effectively utilize activity trackers to promote behavior change.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT E-HEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 430KB - mhealth_v6i2e29_app1.pdf]

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Abbreviations

MET: metabolic equivalent of task
MVPA: moderate to vigorous physical activity

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Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org