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Original Paper

A Dietary Management System Using Radio-Frequency Identification Technology to Collect Information on Chinese Food Consumption: Development and Feasibility Study

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Abstract

Background: Dietary management is important for personal health. However, it is challenging to record quantified food information in an efficient, accurate, and sustainable manner, particularly for the consumption of Chinese food.

Objective: The objective of this study was to develop a dietary management system to record information on consumption of Chinese food, which can help in assessing individuals' dietary intake and maintaining healthy eating behaviors. We proposed to use plates embedded with radio-frequency identification chips to carry Chinese foods and collect food consumption data.

Methods: We obtained food composition and nutrient (eg, carbohydrate, fat, fiber) data from the Chinese Recipe Database and China Food Composition Database. To test the feasibility of the dietary management system at a population level, we applied it to collect data on 489 Chinese foods that were consumed at lunchtime across 7 weeks by 10,528 individuals. To test individual-level output, we selected an individual participant with completed 20-day dietary data for analysis. We examined the system's nutrient calculation performance by comparing the nutrient values of 3 selected Chinese dishes calculated by our method with the results of chemical measurements.

Results: We collected the dietary intake for a group of 10,528 individuals aged from 20 to 40 years having lunch in a restaurant across 7 weeks. A total of 489 Chinese dishes were identified. We analyzed a specified customer's diet recordings and broke his or her 20 lunch diet recordings down to ingredients and then to nutrient intake. We compared the nutrient value of a given Chinese dish (eg, garlic puree cooked pork leg) calculated by our method with the results of chemical measurements. The mean absolute percentage deviation showed that our method enabled collection of dietary intake for Chinese foods.

Conclusions: This preliminary study demonstrated the feasibility of radio-frequency identification–based dietary management for Chinese food consumption. In future, we will investigate factors such as preparation method, weight of food consumed, and auxiliary ingredients to improve dietary assessment accuracy.

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KEYWORDS

diet records; RFID technology; radio frequency identification device; food consumption; Chinese foods

Introduction

Dietary Assessment

Diet is an important risk factor or prevention-related factor for health management and disease treatment. Healthy eating behaviors can help decrease the burden of chronic diseases such as overweight, cardiovascular disease, liver disease, and diabetes [1-4]. Accurate methods to record food consumption and assess dietary intake are essential in health-related research and health care interventions.

Commonly used dietary assessment methods include dietary records, 24-hour dietary recall, food frequency questionnaires, and brief dietary assessment instruments [5]. In the dietary record approach, individuals must record each of the consumed foods in detail (eg, food name, preparation methods) and their amounts measured by scales or estimated by models. To complete a dietary record, individuals are required to describe these details at the time of food consumption. In the 24-hour dietary recall, individuals are required to remember the foods consumed in the past 24 hours. This is traditionally conducted by a trained interviewer in person or by telephone. In the food frequency questionnaire method, individuals are required to report the frequency of their consumed foods from given checklists. Brief dietary assessments are developed for situations that do not require either assessment of the total diet or quantitative accuracy in dietary estimates. For example, brief instruments have been used for population surveillance in the Behavioral Risk Factor Surveillance System [6].

Technical advances in information and communication technology have improved the automatic collection of self-reported dietary data by means such as standardized question sequencing, fasting data processes, and increased flexibility [7]. In recent years, new technology-based dietary assessments have included online (Web-based) methods, mobile methods, and sensor technology, thus assisting clinical studies and nutritional epidemiology research. These new information and communication technology-based efforts are at various stages of development [8]. For instance, the Graphical Food Frequency System was developed to address the food frequency questionnaire's limitations inherent in paper questionnaires [9]. A mobile app, Diet-A, was developed for self-monitoring dietary intake [10].

Objective

In this study, we proposed to apply a sensor technology, radio-frequency identification (RFID), to collect information on consumption of Chinese food.

RFID technology enables information interaction or exchange without human intervention and awareness [11]. RFID-based systems have been used in health care environments [12] and the food industry [13,14]. Recently, RFID chips have been embedded in plates for dietary recording [15,16]. Wireless interaction between the RFID-embedded plates and RFID readers facilitates automatic collection of food consumption information with supporting dietary assessment.

In Chinese diets, foods are cooked according to numerous recipes, and are classified as staple foods (eg, rice, steamed buns), cooked dishes (eg, cooked tomato with eggs), and soups (eg, egg drop soup). In this study, the RFID plates were used to carry the Chinese foods. We developed our dietary management system to automatically collect food consumption information (ie, food names and food frequency) but no personal information of the consumers (eg, sex, age, and smoking habits). The system further provided functions of food frequency statistics, food composition overview, and proxy indicators of dietary intake.

Methods

Participants

A total of 10,528 participants took part in this study. Participants' ages ranged from 20 to 40 years, and all had access to a restaurant equipped with a dietary management system for lunch. Each of them was assigned a unique identification (ID) the first time they had meals in the restaurant.

Dietary Management System Design

We designed and implemented a dietary management system for the collection of Chinese food information (see Figure 1). It comprises 3 key components: the RFID-based dietary data collection module, the Chinese food composition analysis module, and the nutrient analysis module.

Radio-Frequency Identification–Based Dietary Data Collection

We used iPlate (Hangzhou Sovell Technology Development Company Limited), a research and development solution for dietary management, which provides an open platform supporting Chinese nutrient research [17]. A standard iPlate set comprises 3 components: 3 types of plates embedded with RFID chips, which provided information such as what kinds of foods were on the plate and their corresponding weights; a production bench, which can erase and rewrite the RFID chips embedded in the plates, and a settlement bench, with an RFID reading function.

We classified foods into 3 categories, put onto 3 types of plates: staple foods (eg, rice) are on plate 1, cooked dishes (eg, cooked tomato with eggs) are on plate 2, and soups (eg, egg drop soup) are on plate 3. The RFID chips embedded in the plates recorded information about the foods, including their name, price, and weight. When a diner checked out after choosing a plate of food, the RFID reader interacted with the plate, recording food consumption information by connecting the consumer's ID with the food information.

Each plate contained 1 type of food or dish. The weight of food in each plate was set by the restaurant according to the food itself and the type of plate. Dietary information (cooked food price, food name, consumer ID, and time of meal: breakfast, lunch, or supper) was stored in the individual food consumption database.

Chinese Food Composition Analysis

To analyze the composition of the chosen foods, we developed 2 databases: a recipe database and a nutrient intake database.

The recipe database stored the Chinese food recipes, including the food names, main ingredients and their corresponding weights, and preparation methods. The function of the recipe database was to break down the Chinese foods on the RFID plates into their ingredients.

The function of the food composition database was to break down the ingredients into their nutrient components. We used the China Food Composition Database [18,19] as the data resource, which includes 23 nutrients for 1400 food ingredients.

Nutrient Analysis

We selected 3 specific Chinese dishes for nutrient calculations. We first broke down their ingredients according to the recipe database. Then, we calculated the dishes' total nutrients by summing the nutrients of each food ingredient according to the China Food Composition Database. We coded Chinese food in the food composition table. Our previous studies on data representation for food nutritional composition [20] and development of a nutrient content retrieval-oriented search engine for Chinese recipes [21] laid the foundation for the nutrient analysis.

Figure 1. A radio-frequency identification (RFID)–based dietary management system for Chinese foods.

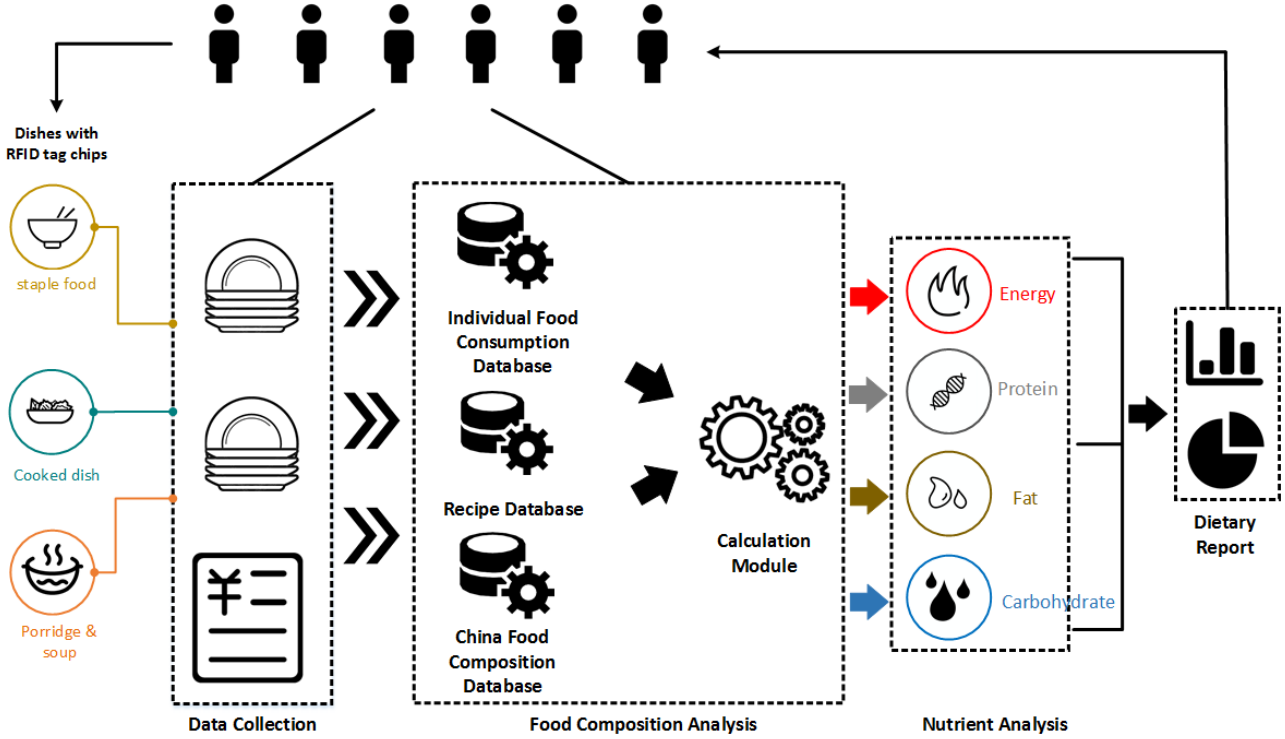
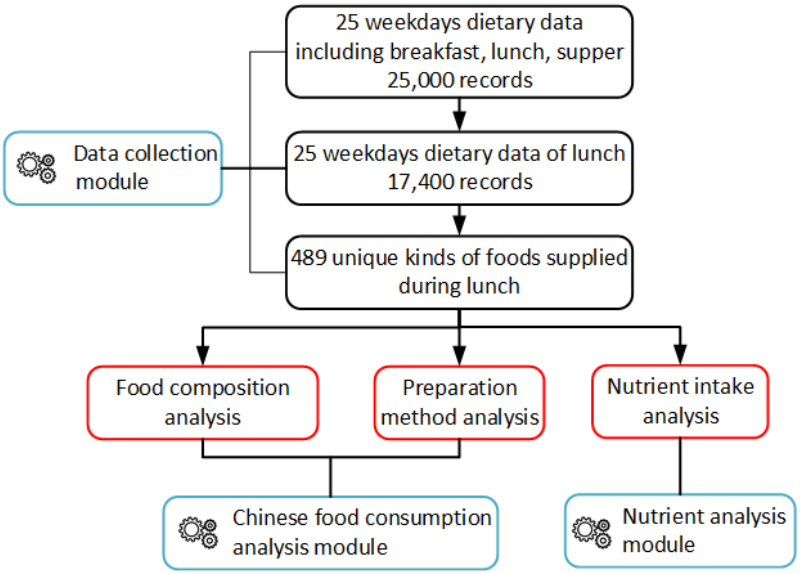


Figure 2. Data selection process for dietary records.



Data Selection Criteria

We used the following criteria to select RFID-collected data for further analysis, as Figure 2 shows: (1) dietary data records collected at lunchtime, (2) Chinese foods on the RFID-embedded plates, (3) the chosen food recipes included in the recipe database, (4) the chosen food ingredients included in the composition database.

Feasibility Testing

To test the feasibility of the dietary management system, we applied it to collect data on 489 kinds of Chinese foods, which were consumed at lunchtime by our study participants from January 5 to February 15, 2016. We used these examples to test our system output at the population level, including consumed food distribution and preparation method distribution. To test our system at an individual level, we selected one participant who completed 20-day dietary data.

Results

Food Consumption Distribution

We obtained 489 kinds of unique Chinese dishes eaten by diners at lunchtime. The system monitored the distribution of the ingredients of all the dishes provided, as Figure 3 illustrates. We can see that vegetables and vegetable products (eg, tomato, cabbage) made up 21% (20 kinds of vegetables out of 91 kinds of ingredients) of the dishes monitored. Tubers, starches and their products, meat and meat products, poultry and poultry products, fungi and algae, and fish, shellfish and molluscs all account for over 10% of all of the dishes consumed.

Preparation Method Distribution

Following Chinese dietary habits, we divided the 489 dishes of consumed Chinese foods into 3 types: staple food (83/489, 17.0%), cooked food (391/489, 80.0%), and porridge and soup (15/489, 3.0%).

The proportion of cooked food is 80% (n=391), which means it is an indispensable component of Chinese food. Based on the cooked food recorded, we analyzed the distribution of preparation methods at the population level (see Figure 4). This group of diners preferred the stir-fried dishes.

Personalized Nutrient Analysis

To demonstrate the individual-level system output, we selected an individual with completed 20-day dietary data for analysis. Figure 5 shows the individual's consumed food frequency at lunch over 20 days. This person liked to eat rice together with soups, having chosen rice and soup 15 times within the 20 days.

Figure 6 shows this sample individual's eating preferences for food composition (left) and preparation methods (right). Compared with the population-level distribution (see Figure 3 and Figure 4), this individual preferred vegetables and steamed foods.

Figure 7 shows the proxy indictors of dietary intake over the 20 working days from January 5 to February 4, 2016. The figure shows caloric intake at lunch (left) and nutrient intake (right) in the form of carbohydrate (blue), fat (orange), protein (gray), and fiber (green).

Figure 3. Example of system output: distribution of consumed foods.

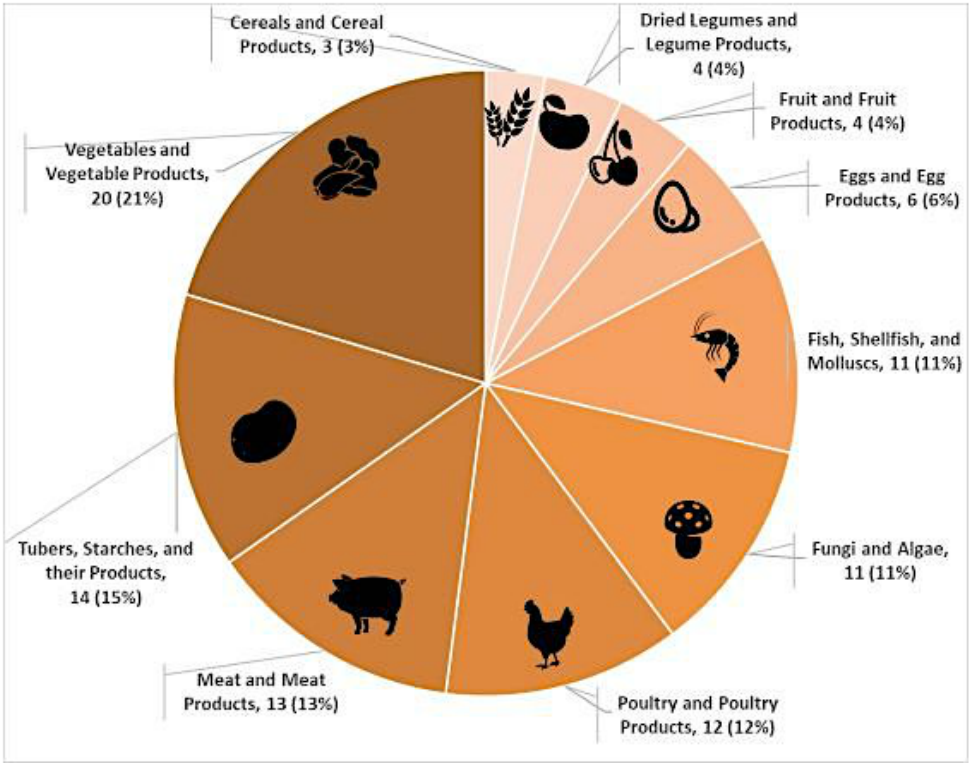


Figure 4. Example of system output: distribution of preparation methods.

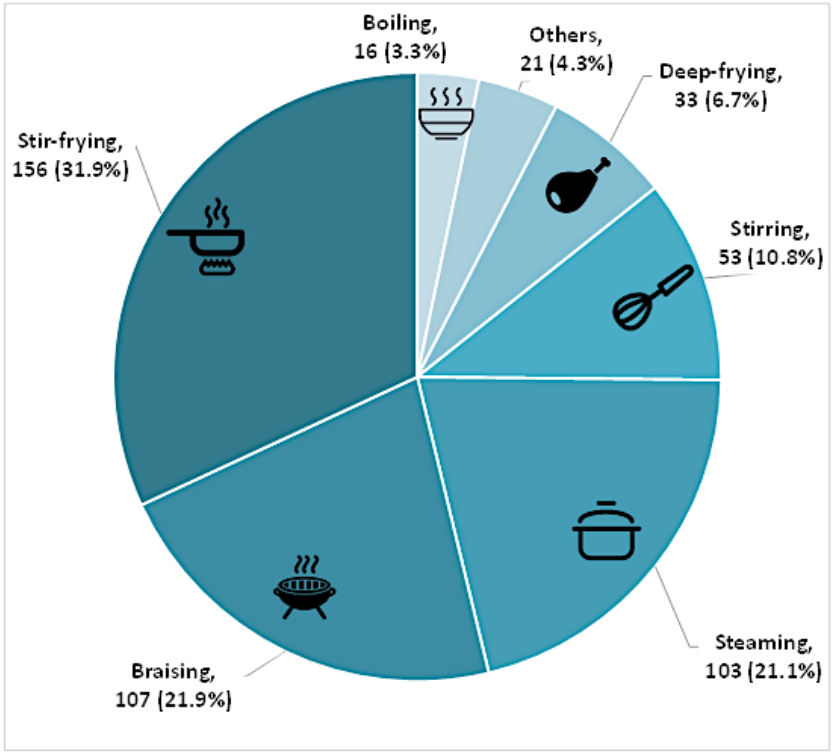


Figure 5. Example of system output: frequency of foods consumed by 1 sample participant.

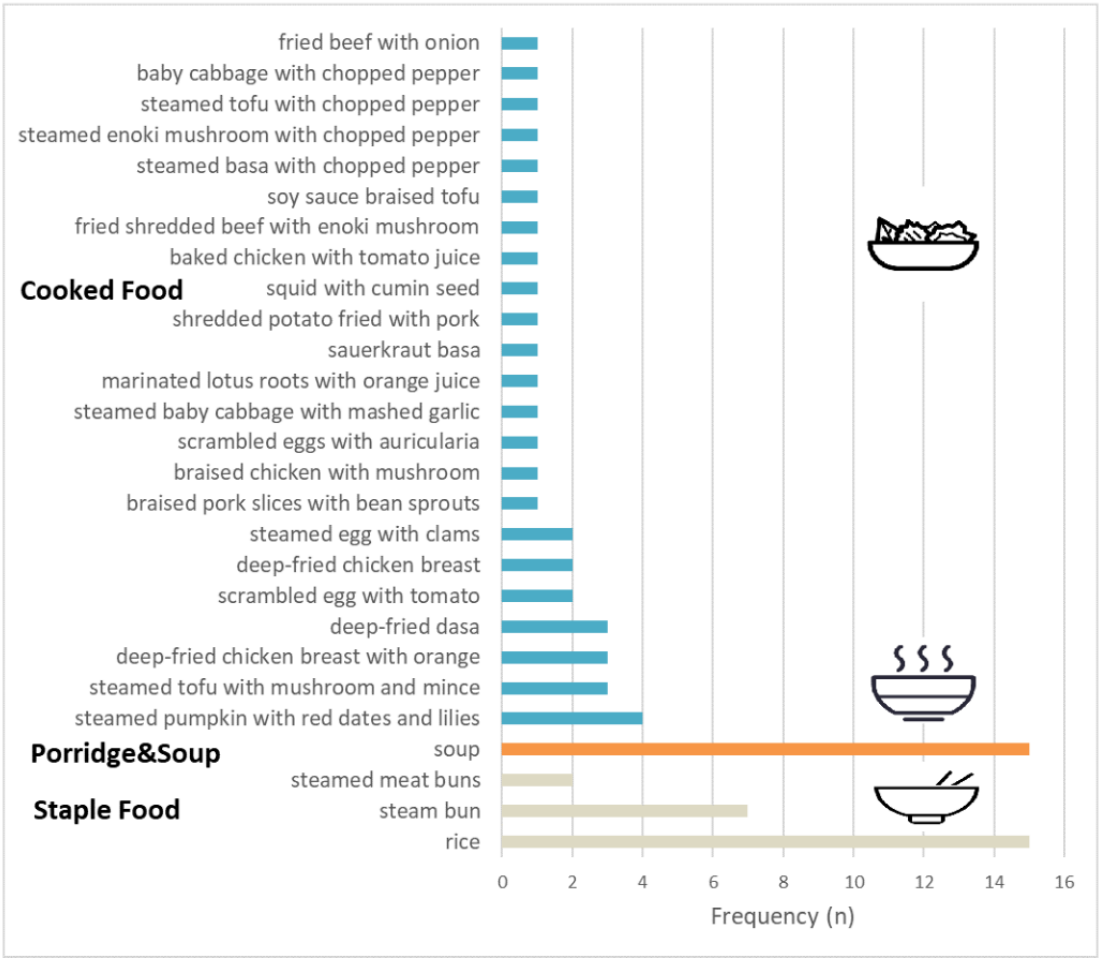


Figure 6. Example of system output: a sample individual's preferred food composition (left) and preparation methods (right).

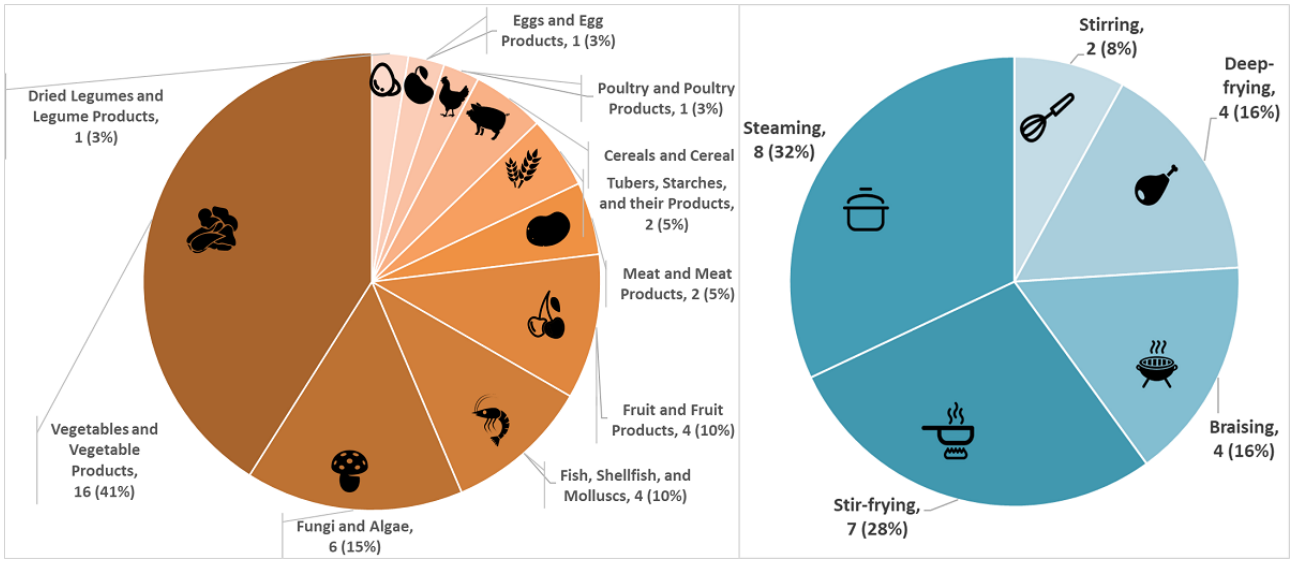
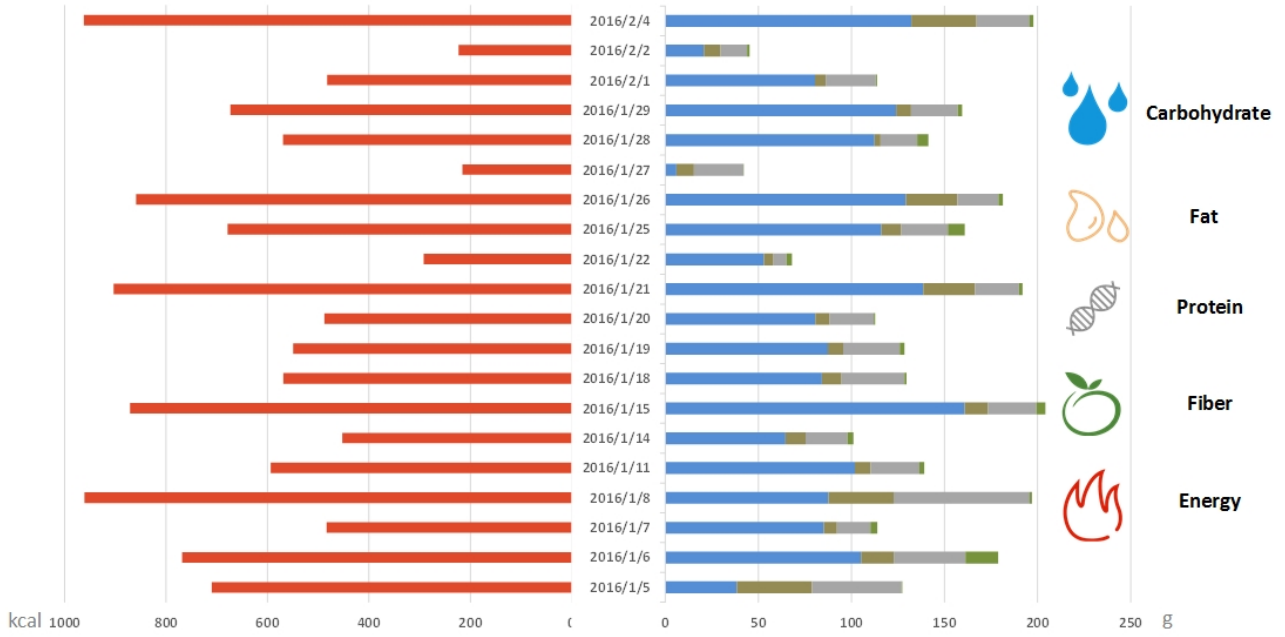


Figure 7. Example of system output: energy (left) and nutrient calculation results (right) for a sample individual. Blue: carbohydrate; orange: fat; gray: protein; green: fiber; red: energy (kcal).



Initial Indications of Nutrient Calculation

To examine our nutrient calculation performance, we selected 3 Chinese food dishes for comparison analysis. The 3 dishes were garlic puree cooked pork leg, dry-fried string beans, and roast lamb, which were measured by chemical methods in a previous study [22]. Given a dish of Chinese food (weight = 100 g), we calculated its nutrient content as C={c_1, c_2, ..., c_n}, where c_x is a nutrient such as energy, protein, fat, or carbohydrate. We used mean absolute percentage deviation (MAPD) [23] to express the difference between our calculation results and the measurement M={m_1, m_2, ..., m_x} obtained by chemical methods, where the Kjeldahl nitrogen method was applied to evaluate the protein content and the acid hydrolysis method was used to evaluate the fat content [22].

Table 1 shows the results of the comparison between our calculated nutrient values and the chemical measurements for the 3 selected Chinese cooked dishes. The MAPD of each nutrient value pair showed that our calculation method achieved comparable results to the chemical measurements, when considering the complexity and variety of Chinese food cooking.

Table 1. Nutrient calculation results compared with chemical measurements.

Chinese food dishes, ingredients and preparation method	Nutrient	Nutrient content measure		
		c_x [a]	m_x [b]	MAPD[c] (%)
Garlic puree cooked pork leg				
Pork, garlic, scallions, pepper; steaming	Energy (kcal)	288.1	253	13.87
	Protein (g)	25	22	13.64
	Fat (g)	20.9	18.3	14.21
	Carbohydrate (g)	0	0	—
Dry-fried string beans				
String beans, minced pork, dried chilies, garlic, scallions; stir frying	Energy (kcal)	210.7	229	7.99
	Protein (g)	9.25	10.8	14.35
	Fat (g)	18.2	16.7	8.98
	Carbohydrate (g)	5.73	9	36.33
Roast lamb				
Lamb, onion, cumin, oil; roasting	Energy (kcal)	133.4	162	17.65
	Protein (g)	19.4	21.5	9.77
	Fat (g)	6.2	8.1	23.46
	Carbohydrate (g)	0	0.8	100.00

[a]Nutrient content calculated in this study.

[b]Measurement obtained by chemical methods (Kjeldahl nitrogen method for protein content and acid hydrolysis method for fat content).

[c]MAPD: mean absolute percentage deviation.

Discussion

Principal Results

We developed a dietary management system to collect information on Chinese food using RFID technology. We applied the system to process real-world dietary data to test its feasibility. As shown in the preliminary results, the system can automatically record the Chinese foods carried by RFID-embedded plates and generate food frequency reports. With the support of the Chinese Recipe Database and China Food Composition Database, our dietary system broke down the cooked Chinese foods into their ingredients and nutrients. The system outputs included data on the frequency of the foods consumed and an overview of the composition of chosen foods, at both a population level and an individual level.

We compared the nutrients calculated for 3 selected Chinese foods with those measured by chemical methods. The result showed that the deviation was less than 20%. This deviation in calculated nutrients may have been caused by the instability in ingredient proportions and the change in food ingredient compositions according to location, season, and weather. The estimated weight of each dish and the ingredients may also result in deviation. However, comparison of 3 samples was insufficient to established a solid conclusion. More samples should be included for calculating c_x to compare against the reference standard set by chemical methods.

Limitations

Our study had 3 main limitations. First, we estimated the weight of the food on each kind of plate by the type of plate and the food itself. We did not weigh exactly the consumed part on each plate. This may have affected the accuracy of our nutrient intake calculation. Second, the preparation methods used in Chinese cuisine affected the nutrient calculation results. Recent studies investigated the effects of cooking methods on specific foods [24,25]. We have not yet considered the effects of cooking method. Third, in Chinese food recipes, small amounts of auxiliary ingredients (eg, ginger and garlic) are commonly used. In this study, we ignored their nutrient contents in our calculation, which may have affected the nutrient analysis results. In our future work, we will consider the above factors such as precise weights and auxiliary ingredients to improve nutrient intake calculation accuracy. As the dietary management system was designed for clinical research and health consumers, user tests should also be conducted in future.

Conclusions

In this study, we used an RFID-based system to track and record the foods and their corresponding weight eaten by our study group. We used 2 databases, a recipe database and a food composition database, to obtain the distribution of ingredients consumed by the group and to validate the calculated nutrients.

In future research, we will consider more factors (eg, preparation method, weight of the consumed portion, and auxiliary ingredients) in the nutrition calculation and improve the accuracy of our results. Additionally, we will combine the nutrition analysis with the consumer's information, including

health condition and demographic information such as age, sex, and birthplace. All of these efforts aim to provide more personalized dietary management.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

ID: identification
MAPD: mean absolute percentage deviation
RFID: radio-frequency identification

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Original Paper

mHealth Tools for the Self-Management of Patients With Multimorbidity in Primary Care Settings: Pilot Study to Explore User Experience

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Abstract

Background: Given the complex and evolving needs of individuals with multimorbidity, the adoption of mHealth tools to support self-management efforts is increasingly being explored, particularly in primary care settings. The electronic patient-reported outcomes (ePRO) tool was codeveloped with patients and providers in an interdisciplinary primary care team in Toronto, Canada, to help facilitate self-management in community-dwelling adults with multiple chronic conditions.

Objective: The objective of study is to explore the experience and expectations of patients with multimorbidity and their providers around the use of the ePRO tool in supporting self-management efforts.

Methods: We conducted a 4-week pilot study of the ePRO tool. Patients' and providers' experiences and expectations were explored through focus groups that were conducted at the end of the study. In addition, thematic analyses were used to assess the shared and contrasting perspectives of patients and providers on the role of the ePRO tool in facilitating self-management. Coded data were then mapped onto the Individual and Family Self-Management Theory using the framework method.

Results: In this pilot study, 12 patients and 6 providers participated. Both patients and providers emphasized the need for a more explicit recognition of self-management context, including greater customizability of content to better adapt to the complexity and fluidity of self-management in this particular patient population. Patients and providers highlighted gaps in the extent to which the tool enables self-management processes, including how limited progress toward self-management goals and the absence of direct provider engagement through the ePRO tool inhibited patients from meeting their self-management goals. Providers highlighted proximal outcomes based on their experience of the tool and specifically, they indicated that the tool offered valuable insights into the broader patient context, which helps to inform the self-management approach and activities they recommend to patients, whereas patients recognized the tool's potential in helping to improve access to different providers in a team-based primary care setting.

Conclusions: This study identifies a more explicit recognition of the contextual factors that influence patients' ability to self-manage and greater adaptability to accommodate patient complexity and provider workflow as next steps in refining the ePRO tool to better support self-management efforts in primary care ahead of its application in a full-scale randomized pragmatic trial.

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KEYWORDS

primary care; mHealth; self-management; multimorbidity

Introduction

Individuals with multimorbidity often require personalized, multifaceted self-management support to facilitate the acquisition of varying and evolving patient-centered goals [1-8]. Self-management is conceived as both an outcome, that is, positive health behaviors that individuals perform, such as exercise and medication adherence, as well as a process by way of the actions that individuals undertake to sustain health behaviors, such as goal setting, monitoring progress toward goals, and identifying barriers to self-management [1].

Primary care providers play a central role in collaborating with patients to help them successfully manage their multimorbidity [9,10]. Supporting self-management efforts involves collaboratively helping patients and their caregivers acquire the skills and confidence to manage their chronic conditions and regularly assessing progress toward patient goals and addressing any challenges faced [11]. Providers in primary care settings have indicated that conflicting symptom profiles, uncertainty around treatment regimens, and the absence of guidelines around managing patients with multiple chronic conditions affects their ability to effectively support self-management in adults with multimorbidity [12]. This is further complicated by a number of challenges, including the compound effects of different conditions and medications, emotional strain, and diminished motivation that patients' may experience as they try to manage competing health conditions and issues of social complexity such as low-income status and limited health literacy [13,14].

The use of mHealth is demonstrated to be an effective means to support self-management efforts to help mitigate the challenges that patients and primary care providers experience [10,15-19]. mHealth technology can enable the integration of self-management support into an individual's daily routine by allowing them to access educational materials, record health behaviors, track health data (blood glucose or blood pressure readings) on an ongoing basis and share that information with their primary care providers [20] to allow for collaborative management of their chronic conditions [21]. The adoption of mHealth tools in primary care settings has received considerable attention in the literature, given the central role that the primary care sector plays in supporting community-dwelling adults with chronic conditions [10,22,23]. To date, however, much of the existing exploration around the influence of mHealth apps in facilitating self-management has focused on patient experience involving a single chronic condition, such as diabetes [24,25], hypertension [26], asthma [27,28], and chronic obstructive pulmonary disease [29], with provider perspectives receiving considerably less attention [30,31].

As such, our understanding of the effectiveness of mHealth apps in supporting self-management and their impact on outcomes in adults with multiple chronic conditions remains in its early stages [3,32]. In light of the growing prevalence of multimorbidity among patients being managed in primary care settings [33-35] and the unique challenges in self-management faced by individuals with multimorbidity [8], a more targeted effort toward exploring the development, uptake, and outcomes associated with using mHealth apps to support self-management in this particular patient group is increasingly needed.

The electronic patient-reported outcomes (ePRO) tool is among a small number of mHealth tools developed using a user-centered design approach [36] with an explicit focus on facilitating self-management in patients with multiple chronic conditions. An initial usability assessment of the ePRO tool was conducted, and findings suggested relatively low usability and feasibility of the ePRO tool [37]. To build on the results obtained from the usability pilot, this paper aims to examine patient and provider views and experiences pertaining to the use of the ePRO tool to better understand how the tool supports self-management among patients with multimorbidity. Our analysis was informed by the Individual and Family Self-Management Theory (IFSM), a well-recognized theory that highlights key aspects of successful self-management, which has previously been used to assess self-management efforts aided by technology [38,39]. IFSM posits 3 constructs related to self-management including contextual aspects, that is, individual and external factors that might challenge or enhance the patient's ability to successfully self-manage, and the provider's capacity to support self-management efforts; procedural aspects of self-management, including self-regulation (goal setting, self-evaluation, and self-monitoring), self-efficacy, and social facilitation (social support for self-management); and proximal or short-term and distal outcomes such as changes in health behaviors, reduced health system utilization, and costs [40]. Multimedia Appendix 1 presents a visual depiction of the IFSM theory.

Methods

Design

This study was based on a secondary analysis of data from a usability pilot of the ePRO tool and sought to assess the user (patient and provider) experience of the tool in supporting self-management for patients with multimorbidity in an interdisciplinary primary care team.

Setting and Participant Recruitment

At the time of the study, the primary care team was composed 5 family physicians, 1 nurse practitioner, 1 social worker, 2 registered nurses, 2 medical assistants, 2 diabetes educators, and 6 administrative staff members. Patients had a lead provider (physician or nurse practitioner) that managed care, although patients could also receive care from other providers (social worker and dieticians) on the primary care team [41]. The focus of this study was patients with multiple chronic conditions and social complexity.

Provider recruitment was initiated through the managing director of the primary care team who was asked to identify providers that would be interested in participating, given the tool's intended functionality and focus on patients with multimorbidity.

A summary of the research study and consent form was sent to those providers identified by the managing director. Following the completion of consent forms, providers from the primary care team shared the names and contact information of potential participants with the research team.

Patient participants had to meet the following eligibility criteria [37]: 1) patient was considered to be multimorbid, which could include physical chronic illness as well as social complexity and mental health issues, and 2) they had the physical capability to use a tablet or have a caregiver with the physical capability to use a tablet to input data on behalf of the patient. Eligible patient participants were contacted directly by the primary care team's administrative staff over the phone or when they checked in for appointments. Patients were informed of the study and provided consent to be contacted by the research team if they were interested in participating [37]. Patients provided informed consent to participate in the study by signing consent forms when they received training on how to use the ePRO tool before starting the study. Patient information, including age, comorbidities, birthplace, and comfort with technology, was collected at the outset of the study to provide contextual information for later analyses. Furthermore, full ethics approval for recruitment was obtained and data were collected from the Joint Bridgepoint Hospital-West Park Healthcare Centre-Toronto Central Community Care Access Centre-Toronto Grace Health Centre Research Ethics Board.

Electronic Patient-Reported Outcomes Tool Features

The ePRO tool was developed by a group of primary care providers and patients in an interprofessional primary care team based in Toronto, Canada; a detailed description of the development process has been published elsewhere [37,42]. The tool includes a mobile platform that is linked to a Web-based portal system and has 2 key components (1) goal setting to develop and track self-management goals, and (2) a hospital checkout function to notify providers of hospital visits. Goals were focused on 5 key themes: physical and social well-being, mental well-being (specifically mood and memory), mobility, pain management, and weight/diet management. Goal themes were linked to a designated monitoring protocol based on indicators from a variety of validated scales, including the Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health Scale, PROMIS Pain Interference Scale, PROMIS Health Assessment Questionnaire, Generalized Anxiety Disorder Scale, and the Patient Health Questionnaire, which are considered to be valid and reliable in the context of patients with chronic conditions [43-45]. The weight and diet theme allowed patients to take photos of their food and track their weight on an ongoing basis. In addition, the tool had a hospital checkout feature that allowed patients to notify their provider when they had visited and been discharged from a hospital. Of note, the ePRO system is compliant with the relevant Canadian and American health information and security laws. All system use data from the mobile phone app and web portal was linked to a secure server, which was managed by the technology partner QoC Health Inc (Toronto, Canada), and a confidentially agreement was also completed by QoC Health Inc.

Training

The technology partner (QoC Health) offered providers two 1-hour hands-on training sessions (facilitated by the research team) on the mobile phone app and portal to provide a walk-through of the ePRO tool before starting the study, whereas, patients received one-on-one training through a 30-minute hands-on session with a member of the research team at the time when patients gave consent to participate in this study.

On-Boarding and Electronic Patient-Reported Outcomes Tool Use

Each participating patient received a Samsung Core mobile phone (including 3G data coverage) that had the ePRO mobile app preloaded. In addition, patients had the option to enter monitoring data through the portal instead of the mobile device. Providers could access the desktop version of the app through the portal system, which allowed them to collaboratively establish goals with patients, track patients' progress over time, and access the hospital checkout alerts. The portal system was generally expected to be used primarily by providers when establishing goals and to review patient progress.

At the outset of the study, patients and providers met to collaboratively determine what goals (and associated monitoring protocols) they wanted to establish and track over the course of the study. During the initial 30-minute consult, patients and providers discussed their existing and evolving needs as they relate to managing their multimorbidity, collaboratively established goals, and identified relevant monitoring protocols pertaining to their self-management goals. After this initial meeting, patients tracked their progress toward goals for 4 weeks using the mobile phone app or the portal, following which they met with their provider to view their results and discuss progress to date. Furthermore, patients could see their providers on a more frequent basis if needed (and discuss results or adjust goals, etc), but the initial set-up meeting and final results debriefing were mandatory for all participants.

Data Collection and Analysis

Upon completion of the 4-week study period, patients and providers were invited to participate in separate focus groups involving semistructured questions to offer feedback on their experience. Patients were asked whether the tool addressed pertinent issues, what improvements could be made, and whether they felt the tool was easy to use. The patient focus group (PTFG) was conducted in December 2014 and moderated by a member of the research team (CSG). A total of 5 patients participated in the PTFG, which lasted 75 minutes. In addition, 3 patients were unable to attend the PTFG and were interviewed separately (interviews lasted 45-60 minutes). Conversely, the provider focus group (PRFG) was conducted by CSG in January 2015 (lasted 60 minutes) and included all 6 providers who participated in this study. Providers were asked about the ease of use, whether they could incorporate the tool into the workflow, and what improvements could be made.

Initially, members of the research team (AIK, AG, CSG, and PH) independently reviewed transcripts and then met iteratively to achieve consensus around a common coding scheme [46].

Following the completion of the qualitative descriptive stage where common themes were identified using a thematic content analysis approach [46], 2 members of the research team (AIK and AG) individually mapped emerging themes pertaining to patient and provider experiences of using the ePRO tool onto the context, process, and outcomes domains of the IFSM theory [40] via the framework method for qualitative data analysis [47] to better understand how the ePRO tool supports each of these components in facilitating self-management for adults with multimorbidity. Following this initial conceptualization, the authors held a consensus meeting to address any gaps or discrepancies in the mapping procure. A description of the IFSM's core domains is available below:

1. *The context* domain encompasses individual, family, and environmental factors that may challenge or enhance a patient's ability to successfully self-manage and provider capacity to support self-management efforts [40]. Contextual factors pertaining to both patients and providers who participated in this study were identified through interview and focus group transcripts.
2. *The process* domain refers to procedural aspects of self-management, including self-regulation (goal setting, self-evaluation, and self-monitoring), self-efficacy (which refers to the degree of confidence an individual has in their ability to adjust or alter behavior successfully), and social facilitation (ie, social support for self-management and the interplay between the perspectives of patients, families, and providers on goals and techniques for self-management) [40]. Patient and provider feedback was assessed using this process lens to explore the tool's role in supporting or inhibiting key self-management processes.
3. The *outcome* domain includes short-term outcomes, such as successful symptom management and changes in health behaviors, which over time might result in distal outcomes, including reduced health system utilization and costs [40]. Interview and focus group transcripts were reviewed to explore patient and provider perceptions of outcomes pertaining to their experience of using the ePRO tool over the duration of the study.

Results

Sample Characteristics

A total of 12 patient participants were identified and agreed to participate in this study. Over the course of the study, 3 patients dropped out owing to health concerns. Patient participants were on average aged 58 years (range 35-72 years) with an equal ratio of males to females. Patients presented with both medical and social complexity—a typical patient in the sample could be described as a female aged 58 years with multiple chronic conditions, including hypertension, chronic obstructive pulmonary disease, arthritis, and depression. Half of the patient group (n=6) reported feeling comfortable with hand-held devices and technology. Most patients tracked one or two goals, and physical health was the most commonly tracked goal. In addition, 6 providers participated in this study, including family physicians, a registered nurse, dietician, social worker, and diabetes educator. Table 1 presents a summary of patient characteristics and system use. The key themes that were drawn from the PRFG and PTFG as well as interviews were mapped onto the core domains of the IFSM framework and are summarized in Table 2.

Self-Management Context

Contextual factors that both user groups identified as important considerations in developing mHealth tools for self-management included the expansion of the tool's scope to allow for comprehensive self-management and linkages with programs and services offered at the practice. In addition, providers described a gap between the tool's design and provider workflow and an underlying disconnect between the goals established at the outset and the monitoring protocols available in the tool, indicating that many questions lacked specificity and were not adequately personalized to align with individual patient context.

Patient Views

Patient interviews indicated that they perceived the ePRO tool as a means to manage their conditions and health behaviors more holistically and as such, they felt the tool had limitations in terms of the comprehensiveness of its scope. Given the wide range of conditions and symptoms patients are attempting to monitor and regulate as part of their self-management efforts, features such as appointment and medication reminders, blood sugar reporting, pedometer functionality, and links to other mHealth apps (such as Sugars and FitBit) were identified as necessary in expanding the tool's scope to reflect the broader individual context within which patients were hoping to self-manage their conditions and symptoms. In addition, patients stressed the need for greater personalization and customizability of goals and monitoring protocols. The questions in the ePRO tool appeared to lack the depth that was considered vital to incorporating patient context into self-management activities:

> *For the mood one, the questions I got asked...would have been okay for somebody that didn't have much of a mood problem.* [Patient 05, PTFG]

> *Not everybody needs the same questions. Everybody's case is different...but we got the exact same questions.* [Patient 11, PTFG]

> *I think the bottom line that comes out of my disconcertedness about it was that the questions were too broad. They weren't specific enough.* [Patient 09, Interview]

Table 1. Participant characteristics.

Characteristics	Value
Age (years), n (%)	
35-54	5 (46)
55-65	4 (36)
>65	3 (27)
Sex, n (%)	
Female	6 (50)
Male	6 (50)
Reported ease with technology, n (%)	
Previous experience	6 (50)
Little experience	2 (17)
Not reported	4 (33)
Chronic conditions, n (%)	
Arthritis	2 (17)
Cardiovascular	3 (25)
Chronic pain	5 (42)
Diabetes	5 (42)
Mental health	10 (83)
Obesity	2 (17)
Renal failure	2 (17)
Chronic obstructive pulmonary disease	1 (8)
Other	2 (17)
Goals tracked, n (%)	
Physical health	6 (50)
Mood and memory	3 (25)
Pain	2 (17)
Diet	2 (17)
Mobility	1 (8)
Questions per module and number of unique completions[a]	
Physical health	9-76 completions
Mood and memory	8-70 completions
Pain	8-53 completions
Diet	3-9 completions
Mobility	25-3 completions
Hospital alert	2-1 completions

[a]Unique completions refers to the frequency of times patients completed a full report of protocol questions.

Table 2. Summary of themes observed across user groups.

IFSM[a] domains	Thematic mapping	Key themes	
		Patient views	Provider views
1. Context: Individual, family, and environmental factors that might challenge or enhance patient ability to successfully self-manage and provider capacity to support self-management efforts	• Contextual aspects pertaining to users (patients and providers) that inhibit (or facilitate) self-management efforts	• Expansion of tool scope to promote comprehensive self-management • Need for improved alignment between the tool's design and patient complexity	• Linkage with existing programs and practice approaches • Tool responsiveness to challenges presented by self-management in patients with multimorbidity
2. Process: Procedural aspects of self-management, including self-regulation (goal setting, self-evaluation, and self-monitoring), self-efficacy (ie, the degree of confidence an individual has in their ability to adjust or alter behavior successfully), and social facilitation (eg, social support for self-management and the interplay between the perspectives of patients, families and providers on goals and techniques for self-management)	• ePRO[b] tool's role in supporting or inhibiting key self-management processes	• Limited progress toward self-management goals further inhibits a patient's sense of self-efficacy • Need for more active feedback and support from providers for self-regulation activities	• Challenges in promoting self-efficacy for patients with multimorbidity • Concerns with offering active social support through the tool
3. Outcomes: Proximal or short-term outcomes, such as changes in health behaviors, as well as distal outcomes, such as reduced health system utilization and costs	• The impact of the ePRO tool on self-management efforts—patient and provider perspectives on the tool's effectiveness	• Capacity building for expanded self-management support across providers in the primary care team	• Key insights into broader patient context and its underlying impact on patient ability to self-manage

[a]IFSM: Individual and Family Self-Management Theory.

[b]ePRO: electronic patient-reported outcomes.

Provider Views

Providers acknowledged the challenges that multimorbidity presents for patients engaged in self-management and suggested expanding the tool's capabilities to account for how complexity attributed to multimorbidity dominates decisions around which self-management strategies providers adopt in caring for these patients. Providers emphasized the need for greater connectivity with existing mHealth apps and services offered by the primary care practice:

> *Align it with...programs that we're doing already. Like Her Story or She Rose, Craving Change...the Stop Study...Every single one of the patients that [are] coming... to see me is very complicated–medically, socially and psychologically...Smoking cessation, changing your behavior around eating, tracking food and how you're feeling...would align [with patient needs]...and those are already people, that are engaged in the sense that they are coming to those groups.* [Provider 04, PRFG]

Providers noted that individual complexity profiles along with variability in patient readiness for behavioral change requires a flexible approach toward self-management. As such, the adoption of the ePRO tool might not be appropriate for all patients. In fact, one provider offered the example of a patient who they felt was not ready for an active self-management intervention.

> *If I had been able to think about it more in advance or understood this better in the beginning, I would not have chosen that participant because he needed a lot more motivational interviewing to get to the point where we could do that kind of goal setting. He wasn't an ideal candidate for this kind of test. But it was very difficult for him...he found having to look at that information depressing...all of which points to the fact that he was not ready to set those goals.* [Provider 05, PRFG]

Several providers revealed that the ePRO tool did not match existing approaches to goal setting used in the primary care practice. Providers were accustomed to using the "specific, measurable, attainable, realistic, and timely" (SMART) goals approach [48] to guide goal setting efforts and expressed that the format and process for goal setting built into the tool was not aligned with the SMART framework. Multiple providers expressed that this disconnect along with limited connectivity with electronic medical records restricted the extent to which they could adopt the tool as a standard part of care.

> *[The tool] has to be tailored to work flow, I would like that the visit could be somehow linked into our electronic medical record. Because I was documenting...I was like dealing with the [ePRO] template and setting the goal. But then that doesn't document it in the patient's chart.* [Provider 04, PRFG]

Although providers indicated that the tool could be a useful component in supporting self-management in this patient population, self-management for patients with multimorbidity is an inherently long-term and multilayered process due to the

compounding of medical and social complexity that commonly occurs in this patient group. As one provider stated:

> *...What I usually do with people is just layers and layers and layers and layers of therapy...And you can't even get to the therapy because... they're at risk for homelessness. Then they're not getting their Ontario Works cheque. And so you're just kind of going along and along. It takes me a long time to meet with somebody once you get through all of that stuff and then go, "Let's set some goals.*" [Provider 06, PRFG]

Self-Management Processes

Patient views pertaining to how the ePRO tool supports self-management processes revolved around the patient's desire for more active engagement and support from providers directly through the tool and how limited progress toward self-management goals detracted from the patient's sense of self-efficacy and self-regulation activities. However, providers indicated concerns with offering active social support directly through the tool and discussed the challenges that multimorbidity presents in promoting self-efficacy.

Patient Views

Several patients described how monitoring their limited progress toward goals through the tool actually led them to feel discouraged and demotivated, thereby hindering confidence in their ability to self-regulate and meet intended self-management goals. As several participants noted:

> *...It's going to take weeks before I might move up to the next level. All you're doing in that case for me is reminding me that my fitness...is crappy... If I had to answer that question every day that my fitness was bad, it's not motivating. It's sort of sinking into my head that my fitness is crappy...It's continuing to be crappy. So depending on the person that might get you depressed.* [Patient 012, PTFG]

> *You know, you go up and down. I mean even in a day, I could go down, you know. And I was told, you know, just put it in at nighttime...But you know, if I put it in at nighttime, probably from night to night, it would change if I just rate it at that minute. But throughout the whole day...there was nothing to say, you know, I'm on a total rollercoaster ride.* [Participant 05, PTFG]

Patients identified gaps in the tool's ability to promote self-efficacy in terms of the adherence to self-regulation activities because of limited feedback on their progress from providers. Patient-reported data were not reviewed by providers in real time nor were providers able to comment on patient progress directly through the tool; this gap in functionality led to patients feeling isolated and discouraged.

> *The problem is I don't know what the picture [refers to uploading photos of meals consumed to better track their diet to manage their diabetes] is doing. Like there's no one analyzing the picture—is there?* [Patient 012, PTFG]

Patients suggested the use of alerts in the form of reminders (that could be sent by the provider or programmed into the ePRO tool) for logging data to support self-regulation. Patients also suggested that providers use the tool to offer direct encouragement and acknowledgment of patients' progress and monitor patient-reported data in real time (and intervene in a timely manner if needed). As one patient expressed:

> *Your provider should be able to trigger an event because you weren't answering a question...But there's no ability to...I got no feedback from my provider until today. And it was useful feedback...So how do you keep up on your goal? Because the onus was on you* [Patient 012, PTFG]

Patient expectations around social facilitation and social support indicated that they were expecting a more active role in self-management efforts from providers. Patients felt the tool should supplement patient-provider interaction through regular feedback and encouragement as an "add-on" to existing in-person appointments rather than a replacement for in-person interaction and consults with their providers.

Provider Views

Provider interviews indicated that careful attention and adjustment is vital in ensuring that self-regulation activities and subsequent monitoring protocols are appropriately selected. Limited progress toward self-management goals inhibits self-efficacy and leaves patients feeling unmotivated and unlikely to continue with self-regulation and monitoring activities. As one provider explained:

> *A lot of times when people set goals, it doesn't work, especially the first time or couple of times...A lot of people set goals that are way too big, way too out there, or not realistic until they actually apply it...So then that sets them up for dropping out maybe. Because they're like, oh, I can't do this goal, I failed, I suck.* [Provider 04, PRFG]

Providers also indicated that self-management is a fluid process and as such, the tool must be more responsive to the changing self-management needs of this patient subgroup. As one provider said:

> *For concrete goals, this can be a useful tool. Patients who can set those kind of concrete goals can implement them. They probably don't need the tool...Most of the goals I set are not like that...they'refluid and they change. And I didn't find this tool to be responsive enough to offer that.* [Provider 05, PRFG]

In contrast to patient views, provider expectations pertaining to how the tool would be operationalized in the daily practice were centered on the tool's potential in remotely monitoring patient progress. Providers envisioned the tool being used to flag problems or lapses in patient adherence to self-regulation activities (rather than a mechanism for active social facilitation of self-management efforts), such that providers only intervene as needed, thereby reducing the need for in-person appointments. As one provider noted:

> *One of the things that I do is tell people who are initiating insulin to increase their dose. And I have to be in regular contact with them a lot. Like way too much. If this tool could tell me the information, they could just punch it in—what their blood sugar was that day, how much insulin they took. And the only time we would have to be in touch would be if there was a problem until there was regular follow-up scheduled. That would be perfect.* [Provider 05, PRFG]

Providers had concerns about active engagement and communication with patients through the tool; in particular, they highlighted challenges with information overload related to reviewing patient-reported data in real time and associated liabilities from a medical and legal perspective. Overall, they envisioned the tool as more of a means to allow for remote monitoring (when patients readiness to self-manage was evident).

Proximal or Short-Term Outcomes

Patient and provider views on the ePRO tool's impact on enabling self-management efforts indicated that both user groups felt that the tool had made important contributions in terms of proximal or short-term outcomes pertaining to successful self-management. Patients described the tool's potential in enabling wider support for self-management from multiple providers in the primary care team. Conversely, providers stated that the tool offered important insights into the contextual aspects that inhibit a patient's ability to engage in self-management activities. Specifically, access to patient-reported data, that is, mood, health behaviors, etc, had helped them to explore trends in self-regulation and goal attainment over time and more easily identify the underlying motivations and barriers that patients may face in self-management.

Patient Views

Patients acknowledged the potential of the ePRO tool in building capacity to support self-management in a team-based care environment by helping to better distribute the workload across providers to meet the evolving needs of patients. As one patient expressed:

> *It could be really valuable in terms of...balancing the time of those professionals in a way that could help the patient...with that goal but also manage the time of the professionals on the team in the most appropriate way...Instead of someone saying I need to see my doctor every week...as you're seeing those results, you could see, well, basically the issue here is with what I'm eating. I need to talk to the dietician. So they wouldn't be going back to the physician every week. You would have other people stepping in when they would see from the tracking that you needed support.* [Patient 02, Interview]

Provider Views

Providers emphasized the value of the ePRO tool in helping to generate insights into underlying patient context (ie, patient preferences and readiness) to offer a fulsome sense of how patients are coping, and thereby adjust goals and self-management activities as needed. One provider describes how data obtained through the tool offered a sense of the challenges that her clients face, and this helps to contextualize overall progress toward goals and allows for the timely identification of barriers to self-management:

> *When [the patient] was experiencing a lot of pain...the other goals drop off because she's not going to be attempting those. And even if [the patient] hadn't linked those then we could have linked them at the visit. But [the patient] had already obviously linked those two things together. So it was kind of nice to have that pain data, to see that...* [Provider 02, PRFG]

Discussion

Principal Findings

In light of the growing prevalence of individuals with multimorbidity being managed in primary care settings [1], the development, refinement, and evaluation of mHealth tools to better assist patients and primary care providers in effectively self-managing chronic conditions is an important research priority [17]. Findings indicated that both patients and providers recognized that the nature of self-management support a patient requires varies based on their medical and social complexity as well as readiness for change. As such, both user groups expressed the importance of greater alignment between tool capabilities and underlying self-management context in light of the complex and evolving nature of self-management needs for patients with multimorbidity. In addition, providers emphasized the need to recognize practice context and better integrate the tool into workflow (ie, linkage with electronic medical records and consistency with goal-setting procedures used in practice such as the SMART goals framework). Some dissonance emerged between the expectations of patients and providers around the role of the tool in providing social support for self-management processes, wherein providers see the tool as a possible mechanism to reduce in-person appointments and patients expect more active feedback, social support and facilitation from providers through the tool. Both patients and providers acknowledged the tool's value in supporting self-management efforts; patients felt that the tool could help to better distribute the workload across providers in an interdisciplinary team setting, and providers acknowledged that the tool offers critical insights into how patient context influences progress toward goal attainment and helps inform provider approaches toward self-management.

Connectivity with existing mHealth apps (ie, fitness tracking and blood sugar monitoring) was strongly emphasized by both patients and providers, which is an important finding, given that among patients managing multiple conditions [8], the disproportionate effect of a single condition can adversely impact their physical or psychosocial functioning and capacity to self-manage [3,6,14]. As such, both user groups highlighted the potential of the ePRO tool in serving as a comprehensive hub for self-management support where they could conceivably input data from other sources (ie, other mobile phone apps, etc)

to manage multiple goals and track symptoms and progress over time.

Patients and providers both highlighted the need to adopt a more patient-centered approach for self-management activities (ie, monitoring protocols offered in the tool) for greater alignment between the tool's functionality and individual patient context, citing a disconnect between patient goals and the monitoring protocols available in the tool and emphasizing the need for more personalized content [49,50] and realistic goal setting [51]. Moreover, these findings reflect existing research, which has found that mHealth solutions are likely to have greater uptake when they allow for personalization [52] and can be integrated into workflow [30,53]. In addition, proactively identifying and adjusting patients' expectations around the pace of self-management progress and challenges must be considered when determining whether the tool is an appropriate fit [16]. Fit is particularly important for individuals with multimorbidity, who often experience symptoms that may be interdependent and impart a compounded effect on their ability to self-manage [3,8,54-56]. As such, the use of mHealth tools to support self-management in patients with multimorbidity must reflect the complexity and inherent variability in each patient's experience of multimorbidity [55].

From the perspective of providers, improving the tool's alignment with current workflow (such as the incorporation of the SMART goals approach) and integration with electronic health records were key aspects of suggested improvements, indicating the need for proactive consideration of organizational context and provider workflow when developing and implementing mHealth tools [16,53,57,58]. In addition, ensuring that providers have adequate time to acquire training on the tool's functions [59,60], minimizing clinical and workflow redesign [30,60], and financial compensation for the extra time and effort required of providers to incorporate mHealth tools into standard practice are key considerations in improving uptake and acceptance among providers [60,61]. Furthermore, although providers suggested linkages with electronic medical records to improve the tool's functionality, issues pertaining to breaches of privacy, secure transmission of data, devices getting lost or stolen, and user data being accessed in an unauthorized or unsecure manner must also be considered [62,63].

In this study, both user groups recognized that goal setting and self-management is a fluid process that varies according to a patient's social and medical complexity and readiness [3,8,64]; thus, self-management processes, including decisions around goal setting and the selection of monitoring protocols, must be adaptive to that complexity [6,65]. Providers acknowledged the ePRO tool's potential in identifying important contextual information, including patient readiness, preferences, and barriers to self-care, and also emphasized the importance of understanding the impact of these contextual factors on influencing the patient's ability to self-manage [57,66,67]. Compared with previous research, which found that providers tend to view self-management from a biomedical lens with a strong emphasis on individual responsibility [68], in this study, both user groups recognized how medical, psychological, and social aspects collectively inform patient ability to self-manage.

Patient feedback indicated they wanted providers to have a more "active" presence through the ePRO tool; the suggestions included push factors, such as regular feedback and encouragement from providers, and alerts if providers observe deviations in results, which is consistent with other studies of self-management using mHealth tools [17,69-73]. Patients viewed the tool as a supplement rather than a replacement to existing care, which resonates broadly with patient perspectives on the role of eHealth tools in influencing care [65,73,74]. This particular finding also reflects previous research on patients with multimorbidity and their preferences around collaborative care management involving primary care providers, which found that participants indicated a willingness to use technology for monitoring or educational purposes if it did not eliminate or inhibit human contact with their providers [54]. Findings suggested that patients expressed fears of feeling isolated or being abandoned (by their providers) as a function of adopting a mHealth tool for self-management, which is also consistent with previous research in this topic area [73].

In contrast, providers perceived the ePRO tool as a way to enable remote monitoring of patients and intervene as needed, highlighting an important disconnect in expectations between the 2 user groups. This observation differs somewhat from previous research, which found that providers are often concerned about placing too much responsibility around self-management on patients without adequate guidance, emphasizing the need to strike a balance between patient autonomy and provider support [51,58]. Furthermore, this finding warrants the importance of examining how technologies to support self-management are developed in terms of whether they promote a patient-driven or provider-centered view of self-management and being aware of possible dissonance between user groups to adjust the tool accordingly [66,70].

Limitations

The challenge of small sample sizes is a common aspect of many studies focused on pilot-testing of mHealth interventions [75]; thus, we cannot make generalizations about observed findings. A small number of dropouts occurred during the study, highlighting the challenges of working with patients with multimorbidity and issues of attrition that are commonly observed in mHealth and Web-based interventions [76-78], including interventions involving self-management [78,79]. However, in alignment with past formative work around the development of mHealth tools, this study offers a detailed comparison of patient and provider perspectives around the use of a mHealth tool to support self-management with respect to a patient group with a unique set of needs. Owing to time and resource constraints, the provider on-boarding meeting was not observed by a member of the research team, which is an important limitation of our design. In addition, although proximal outcomes were identified based on the user feedback, clinical or long-term outcomes were not assessed. A randomized pragmatic trial is underway to examine the impact of the ePRO tool on clinical and system-level outcomes. Another limitation involves the challenges of working with a complex patient subgroup, which often involved dealing with issues regarding recruitment, including attrition and difficulty with follow-up, owing to challenges stemming from their medical and social

complexity [80]. It can also be difficult to engage providers because of their limited availability, which can affect their ability to actively participate in development and testing phases despite their enthusiasm and interest.

Conclusions

Past research has mostly focused on the use of mHealth tools for patients in a single disease group [29,53,81-84]. Multimorbidity can complicate approaches to self-management because of complex (and often conflicting) clinical practice guidelines and competing priorities that providers and patients often face [6]. Incorporating a user-centered design approach in developing and refining mHealth tools is critical to ensure alignment with underlying user context and processes pertaining to self-management support [25,85]. Broadening the tool's scope to allow for greater customizability of content to enable personalized goal-oriented care [86], and the addition of features, such as secure communication, between patients and providers through the tool, and connectivity with other mHealth apps are some aspects that are under consideration in terms of refinement of the tool prior to a full-scale application in the upcoming randomized pragmatic trial.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Model of the Individual and Family Self-management Theory.

[PDF File (Adobe PDF File), 87KB - mhealth_v6i8e171_app1.pdf]

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Abbreviations

ePRO: electronic patient-reported outcomes

IFSM: Individual and Family Self-Management
PRFG: provider focus group
PROMIS: Patient-Reported Outcomes Measurement Information System
PTFG: patient focus group
SMART: Specific, measurable, attainable, realistic, and timely

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Original Paper

Implementing eHealth Technology to Address Gaps in Early Infant Diagnosis Services: Qualitative Assessment of Kenyan Provider Experiences

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Abstract

Background: Literature suggests that electronic health (eHealth) interventions can improve the efficiency and accuracy of health service delivery and improve health outcomes and are generally well received by patients; however, there are limited data on provider experiences using eHealth interventions in resource-limited settings. The HIV Infant Tracking System (HITSystem) is an eHealth intervention designed to improve early infant diagnosis (EID) outcomes among HIV-exposed infants.

Objective: We aimed to compare provider experiences with standard EID and HITSystem implementation at 6 Kenyan hospitals and 3 laboratories. The objective of this study was to better understand provider experiences implementing and using the HITSystem in order to assess facilitators and barriers that may impact adoption and sustainability of this eHealth intervention.

Methods: As part of a randomized controlled trial to evaluate the HITSystem, we conducted semistructured interviews with 17 EID providers at participating intervention and control hospitals and laboratories.

Results: Providers emphasized the perceived usefulness of the HITSystem, including improved efficiency in sample tracking and patient follow-up, strengthened communication networks among key stakeholders, and improved capacity to meet patient needs compared to standard EID. These advantages were realized from an intervention that providers saw as easy to use and largely compatible with workflow. However, supply stock outs and patient psychosocial factors (including fear of HIV status disclosure and poverty) provided ongoing challenges to EID service provision. Furthermore, slow or sporadic internet access and heavy workload prevented real-time HITSystem data entry for some clinicians.

Conclusions: Provider experiences with the HITSystem indicate that the usefulness of the HITSystem, along with the ease with which it is able to be incorporated into hospital workflows, contributes to its sustained adoption and use in Kenyan hospitals. To maximize implementation success, care should be taken in intervention design and implementation to ensure that end users see clear advantages to using the technology and to account for variations in workflows, patient populations, and resource levels by allowing flexibility to suit user needs.

Trial Registration: ClinicalTrials.gov NCT02072603; https://clinicaltrials.gov/ct2/show/NCT02072603 (Archived by WebCite at http://www.webcitation.org/71NgMCrAm)

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KEYWORDS

early infant diagnosis (EID); HIV/AIDS; eHealth; mHealth; implementation science; Kenya

Introduction

In East Africa, electronic health (eHealth) interventions are increasingly being integrated into health care settings to support a range of HIV-related services and improve patient outcomes. In Kenya, where approximately 7000 children were infected with HIV in 2015 [1], we piloted an eHealth intervention called the HIV Infant Tracking System (HITSystem). The HITSystem aims to retain mother-infant pairs through the 18-month early infant diagnosis (EID) process or until an infant is identified as positive and treatment is initiated. The EID provider initiates enrollment in the HITSystem at the first EID visit, but laboratory technicians and mothers/caregivers are also active in the process. Algorithms driven by the infant's date of birth and age-specific EID guidelines generate electronic alerts to inform clinical providers when a patient misses a key EID service and clinical and laboratory providers when polymerase chain reaction (PCR) sample processing is delayed. Additionally, the HITSystem sends short message service (SMS) texts to mothers alerting them when results are available at the hospital and serving as a reminder or cue to action for upcoming retesting services or when any service is missed. These processes are automated and may result in up to 14 provider alerts per infant enrolled (average of 3 to 5) and 3 or more SMS messages to mothers over the course of EID services, depending on infant test results and timeliness of seeking care.

Pilot data suggest that the HITSystem improves retention in EID services at 9 months, decreases turnaround times for PCR sample processing and mother notification of infant's result, and increases the proportion of HIV-positive infants who achieve timely antiretroviral therapy (ART) initiation [2]. To date, over 10,000 mother-infant pairs have enrolled in the HITSystem at 30 hospitals in Kenya since its introduction in 2011. Hospitals using the HITSystem display moderate to high levels of ownership and adoption of the innovation [3]. A randomized controlled trial (RCT) is underway at 3 intervention and 3 control hospitals to rigorously evaluate the impact of the HITSystem on EID outcomes in Kenya [NCT02072603] [4].

While many eHealth interventions have reported on health outcomes [4-10] and patient acceptability or satisfaction [11-15] in Eastern Africa, few have reported extensively on the provider experience [16,17]. Health care providers are the key to the development and implementation of many eHealth interventions; thus, understanding their experience is critical in assessing factors that may facilitate or impede sustainable integration of new eHealth interventions into health care systems. This study describes the results from qualitative interviews conducted with hospital and laboratory providers involved in EID service provision as part of the ongoing RCT to evaluate the HITSystem [4]. The objective of this study was to better understand provider experiences implementing and using the HITSystem in order to assess facilitators and barriers that may impact the adoption and sustainability of this eHealth intervention. We drew upon constructs from implementation [18], technology acceptance [19,20], and diffusion models [21], which suggest that perceived usefulness and perceived ease of use play significant roles in a person's intention to use a technology.

Methods

Study Setting

This process evaluation using qualitative methods was embedded within the RCT to evaluate the HITSystem [4]. The evaluation used a cluster-randomized design at 6 government hospitals (3 intervention, 3 control) and the designated central laboratories where study hospitals send their EID samples for processing. Hospitals were matched on hospital level (provincial, county, or district), geographic region, resource level, and patient volume. Intervention sites began using the HITSystem in February 2014. Clinicians at intervention hospitals and laboratory technicians at the central laboratories received a full day training on how to use the HITSystem, with periodic refresher training provided as needed by the site coordinator. Site coordinators were stationed at intervention hospitals to support HITSystem implementation. While providers from control hospitals and laboratories had no experience using the HITSystem, they were aware of the intervention and its functions. A total of 690 HIV-exposed infants were enrolled during the study period (392 at the intervention hospitals and 298 at the control hospitals).

Study Participants and Procedures

Between February 2015 and January 2016, we conducted semistructured individual interviews with all key EID providers or HITSystem users at each of the study sites (total of 17 people). Control site clinicians and laboratory technicians were included to contextualize standard EID services during the time period of study implementation, allowing for better comparison to HITSystem-supported EID. The distribution of providers by site designation (intervention or control), facility type (hospital or laboratory), and participant role can be found in Table 1.

Interview guides were developed collaboratively by the Kenyan and US primary investigators, piloted among Kenyan-based site coordinators, and then refined based on feedback. Guides for control hospitals and laboratories assessed the perceived importance of EID, strengths and challenges associated with standard EID services, and hospital-laboratory communication under standard EID conditions. Guides for intervention hospitals and laboratories assessed differences in EID services since HITSystem introduction, challenges with HITSystem implementation, adequacy of HITSystem training, and mothers' responses to the HITSystem.

Table 1. Description of participants.

Participant ID	Site designation and facility type	Facility ID	Infants enrolled (n)	Provider role
1	Control hospital	CH_A	115	Mentor mother[a]
2	Control hospital	CH_A	115	Mentor mother
3	Control hospital	CH_B	84	Nurse
4	Control hospital	CH_B	84	Mentor mother
5	Control hospital	CH_B	84	Nurse
6	Control hospital	CH_C	99	Mentor mother
7	Control hospital	CH_C	99	Mentor mother
8	Control laboratory	CL_D	—	EID[b] data clerk[c]
9	Control laboratory	CL_D	—	EID data clerk
10	Control laboratory	CL_E	—	EID data clerk
11	Intervention hospital	IH_F	109	Mentor mother
12	Intervention hospital	IH_F	109	Nurse
13	Intervention hospital	IH_G	226	Nurse
14	Intervention hospital	IH_H	57	Mentor mother
15	Intervention laboratory	IL_I	—	Laboratory technician[c]
16	Intervention laboratory	IL_I	—	Laboratory technician
17	Intervention laboratory	IL_J	—	Laboratory technician

[a]Mentor mothers are HIV-positive mothers who have been through early infant diagnosis (EID) and provide a range of services including case finding and referral; defaulter tracing; case management; facilitation of support groups; health education; and support for enrollment, retention, and adherence.

[b]EID: early infant diagnosis.

[c]We interviewed laboratory personnel involved with EID-related documentation and hospital communication. At control laboratories, EID data clerks were responsible for manual EID documentation, and at intervention laboratories, laboratory technicians were responsible for HITSystem use (documentation and alert tracking).

All interviews were conducted by the study manager, who was trained in qualitative methods and human subject research. Written informed consent was obtained from participants prior to each interview. Interviews lasted approximately 45 minutes, were conducted in English, and occurred in a private setting. All study procedures were approved by the institutional review boards at the Kenya Medical Research Institute and University of Kansas Medical Center.

Analysis Strategy

All interviews were audiorecorded, transcribed, and analyzed using Dedoose analysis software (SocioCultural Research Consultants). During the first round of coding, transcripts were coded independently by 3 study team members based on a priori and emergent themes [22]. These initial thematic codes were then combined into axial codes through group consensus [23,24]. In consultation with literature on facilitators and barriers related to provider adoption of mHeath interventions [18-21], we identified our axial codes closely related to the concepts of perceived usefulness and ease of use. To present the themes of our data, we discuss how the perceived usefulness and ease of use of the HITSystem serve as facilitators and barriers to HITSystem use.

Results

Facilitators to HIV Infant Tracking System Use

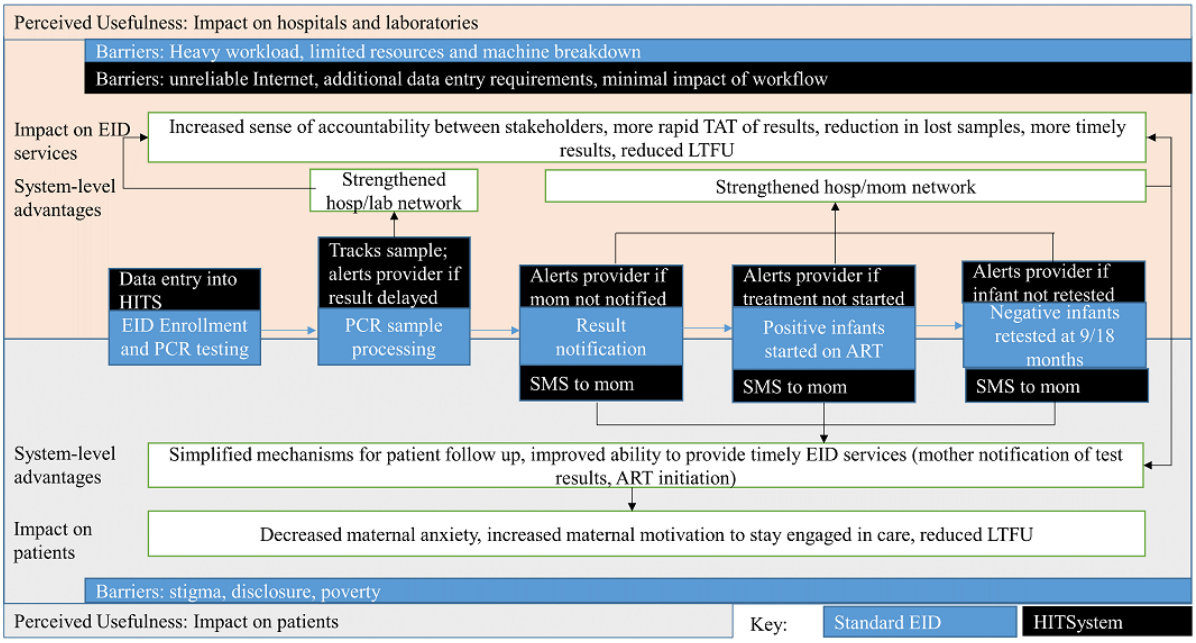
Perceived Usefulness

The perceived usefulness of the HITSystem was a strong theme among intervention respondents, who saw it as providing several benefits over standard EID care (Figure 1). Users described the primary uses of the HITSystem as (1) improving communication between mothers, clinicians, and laboratories and (2) simplifying mechanisms of patient follow-up. Together, these increased provider ability to deliver timely and efficient EID to their patients.

Improved Mother-Clinician and Clinician-Laboratory Communications

Clinicians emphasized the necessity of communication with mothers throughout the EID cascade: when laboratory results are ready to be picked up, follow-up services are required, or scheduled services are missed.

Figure 1. Perceived usefulness of the HIV Infant Tracking System (HITSystem). ART: antiretroviral therapy; EID: early infant diagnosis; LTFU: loss to follow up; PCR: polymerase chain reaction; SMS: short message service; TAT: turnaround time.



Clinicians found the HITSystem-driven automation of communication to mothers when results were ready useful for providing timely EID services to patients because:

> *...immediately when the results enter the HITSystem, the same system communicates to the mother. So the results can come in today, and the mother comes tomorrow. So there is a lot of improvement.* [Participant 13]

Clinicians noted the benefit to mothers, and as one remarked, "[mothers] are happy about being reminded" (Participant 13). While clinicians indicated that the HITSystem's automated messages helped facilitate timely service provision, they still used existing methods of communication (phone calls or physical patient tracing) when patients did not return for services after receiving a text message, mothers did not have phones, or an incorrect phone number had been recorded.

Respondents also felt that the HITSystem was useful in facilitating communication between clinicians and laboratory technicians. In the absence of the HITSystem, provider-initiated phone calls were the most common method of communication between hospitals and laboratories, and clinicians expressed frustration with lack of clarity regarding lost or delayed sample processing in the laboratory. Control site providers expressed desires for improved systems of sample tracking in order "to assist us with follow-up and PCR results so we get them and the mothers can know the result" (Participant 6). Likewise, laboratory technicians from control sites described repeated communication regarding improper sample collection and shipping procedures which contributed to delayed turnaround time. One control site technician, for example, requested a Web-based system similar to the HITSystem to help address some of these challenges.

> *Introduce a system where the communication between us and them, it doesn't need for them to pick up the phone call and start calling... If it was possible for them to actually have a Web-based system where they can get back to us, we can get back to them on and off, continuously because Web-based is real time...* [Participant 9]

Respondents also noted increased efficiency in hospital-laboratory communication with the HITSystem's electronic messaging. The HITSystem's sample tracking allowed clinicians to know when sample processing was delayed so that:

> *...we are not relying on them [laboratory personnel] much but on HITSystem. Unless there is a sample that was rejected, or was not sent, then we know faster through the HITSystem.* [Participant 12]

Providers also reported that the number of unreturned results had decreased because "even when the hard copy gets lost, the soft copy has been reported on" (Participant 14). The improved flow of information along with the HITSystem's sample tracking led to an increased sense of accountability among laboratory technicians. This increased follow-up appeared to motivate increased prioritization and more efficient processing of EID samples.

> *But after the HITSystem, I personally realized there are some people who are concerned with this [turnaround time of EID results]. So it gave us a challenge to attend to this much faster. To me, this is like supervision, because things like seeing things are not going well, my colleague asks what is [taking] long. That is part of supervision. But previously you were just left to work, things go awry, and nobody asks.* [Participant 16]

With increased engagement facilitated by the HITSystem, providers described more options for hospital-laboratory communication and increased responsiveness to queries.

> *[Communication between hospital and laboratory] is better than before. My colleague just writes an email, it reaches the other colleague on the other side and we receive the results the same day. Before I would call with the only available contact, and find the staff is away on leave, or they request you call another day. So it was a problem.* [Participant 13]

These noted improvements contributed to a reduction in the frequency of phone calls required between the hospital and laboratory, for example, from "in a week, even more than 10 times" (Participant 12) to "maybe it's one [call] a month, depending on what you're following" (Participant 13).

Simplified Mechanisms for Patient Tracking

Clinicians from intervention sites discussed how the HITSystem simplified patient tracking. Clinicians from both intervention and control hospitals identified patient loss to follow-up as a barrier to providing comprehensive EID services, noting that in some instances, "you can meet with the mother, but she won't bring the baby back to EID" (Participant 2). Clinicians from control sites described a manual tracking system that involved paper record review and required coordination between the maternal and child health departments (where mother-infant pairs present for care), internal hospital laboratories (where samples are drawn and shipped and results are received), and comprehensive care centers (where positive infants receive HIV care including ART initiation) for identifying and initiating follow-up with mothers whose infants had missed a critical service.

> *Should there be any defaulter, we have a diary ... and actually it is very, very full. She takes the contacts of all those babies who are exposed. She has the contact for the mothers so we are able to track until 18 months to 2 years ... and there is somewhere that she writes those who have defaulted and then been found.* [Participant 4]

Clinicians from intervention hospitals appreciated both the HITSystem-generated alerts for faster and easier identification of patients who missed services and the HITSystem's facilitation of text messages for patient follow-up; clinicians attributed reduced rates of loss-to-follow-up to these advantages.

> *If we said today we stop this system, it would be bad, because we would see defaulters. When my colleague notices someone has missed their appointment, we find their contact and reach out to them to come for their appointment.* [Participant 14]

Improved Ability to Provide Timely and Efficient Early Infant Diagnosis Services

The benefits the HITSystem offered in sample tracking and result distribution allowed clinicians to provide more timely results for their patients. In the absence of the HITSystem, clinicians from control sites expressed frustration with long turnaround times for EID results and emphasized how these delays caused maternal anxiety and discouragement, impacted patient management and, for positive infants, delayed initiation of life-saving ART.

> *If they return and the results are not available, the mother is anxious to know the result which is not there. So convincing her, and telling her when the exact day the results will be available is a challenge, because she might lose hope.* [Participant 2]

> *You find that the result stays, and when the mother returns the next visit, results are not yet back, so the third time she returns then the results might be back. And sometimes the baby is weak, we suspect the baby is positive but you cannot start him on the medication until the [dried blood spot] is out.* [Participant 5]

The HITSystem was seen as an effective way of minimizing long turnaround time, reducing maternal anxiety, and increasing mothers' motivation to stay engaged in EID:

> *...because once they get results early they are encouraged to come. When they come at 9 months, they complete 18 months without missing an appointment.* [Participant 12]

With more timely results, clinicians:

> *...noticed that [mothers] are happier that their baby's sample is collected fast, results are back faster, and they know the results quickly.* [Participant 11]

Many clinicians also noted that HITSystem-driven improvements in turnaround time and return of results contributed to earlier initiation of ART among infants with a confirmed positive diagnosis.

> *Since HITSystem came, compared to the past, we get results faster, they are ready. When the mother [brings baby for testing], samples go, and she receives a message after 2 weeks or 3 weeks. Results are back and she gets results for the baby. Not like the past it would take 2 months, the mother will get discouraged and might be out there with a positive diagnosis and get lost. But HITSystem has helped a lot, even if the baby is positive it helps to initiate treatment early to prevent the baby from falling ill.* [Participant 12]

Ease of Use

Themes related to ease of use fell into 2 primary categories: complexity of the intervention and compatibility with existing workflow and patient needs.

Complexity

According to respondents, the HITSystem had a low level of complexity. Despite varied comfort levels with computers, most providers considered the HITSystem to be "straightforward, it is not something complicated" (Participant 16) and indicated that "if you're trained, it [HITSystem] is easy" (Participant 12).

Compatibility

The HITSystem was largely perceived as compatible with current EID service delivery systems, with about half of intervention site clinicians stating that the HITSystem either improved or did not interfere with workflow, "because it is a touch of a button. I see that it will reduce our work load" (Participant 11). Likewise, laboratory technicians recognized

that improved efficiencies offset any additional time expended on HITSystem-specific data entry, saying that:

> *...it takes time, but that is part of the work. And I know that when this comes, when all sites are there, it makes my work easier. So I do not take it as extra work.* [Participant 16]

Providers felt that the intervention was sensitive to and compatible with patients' right to confidentiality throughout the EID process. They indicated that the automated HITSystem messages were informative enough to signal action without compromising the woman's confidentiality or putting her at risk of unintentional disclosure.

> *Those messages are good; they don't have any details about health. Just "bring your baby to the clinic." Not about medication, so there is that confidentiality...Even the spouse is surprised, and she can tell him, "it's immunization." So he would not know anything, but if the message mentioned testing for HIV, it would arise suspicion.* [Participant 14]

Barriers to HIV Infant Tracking System Use

Perceived Usefulness

While, overall, participants felt that the HITSystem was useful, many suggested adaptations to allow the HITSystem to better support their needs. These included suggestions to (1) "begin with the mother, since [antenatal care]..." (Participant 11) and support provision of prenatal care and HIV services throughout pregnancy, (2) increase the HITSystem's capacity to "generate reports, depending on what the government wants" (Participant 17), and (3) integrate the HITSystem "with the [electronic medical record], with the [laboratory systems], so once the results have been posted, it will communicated with HITS so you don't have to do double work" (Participant 17).

Ease of Use

HITSystem compatibility was strained by limited staffing and space for confidential enrollment.

> *For example, today, I had 2 clients, 1 old case, 1 new case. So you can't take too much time, because you have 1 room, and sister needs to use it. So it becomes a challenge. Even one of them ran away because [there is no privacy].* [Participant 12]

Half of the clinicians indicated that entering data into the HITSystem during the patient encounter was:

> *...slightly difficult because you are entering this and that. There's also another one waiting for counseling, another one wants something about adherence, so you find it taking a bit longer.* [Participant 14]

Therefore, some clinicians stated that on busy days:

> *...sometimes you find yourself pushing the HITSystem to another day, depending on the workload...maybe I will do it another day when I don't have a heavy workload.* [Participant 13]

HITSystem use was also dependent on reliable internet connectivity and adequate internet and phone credit, which both clinicians and laboratory technicians identified as barriers to consistent use:

> *We are not connected to the network. We use the modems. Yes? Well if we run out of credit that is the end of the story.* [Participant 15]

While providers from intervention hospitals and laboratories appreciated the continuous on-the-job training they received from study staff, most felt that additional, off-site training would be beneficial to minimize distractions, enhance skills, and ensure continued implementation, especially as updates were made to the HITSystem.

> *It's good also to have a repeat of the same [training] because...as time goes by, I think you people are improving on the system and maybe some new ideas have also been included up to now because people keep on growing. And I believe it's growing.* [Participant 15]

Furthermore, there were challenges impacting standard HIV services that continued to hinder EID service provision that the HITSystem was unable to address. Lack of consistent resources was cited as a key challenge to providing timely and efficient EID services at both intervention and control sites. Laboratory technicians' ability to achieve quick turnaround time, even with HITSystem tracking and prompts, was dependent on working machines and availability of laboratory supplies. Laboratory technicians recognized that:

> *...once in a while we have delays and mostly it is because of lack of reagents or breakdown of equipment.* [Participant 17]

Likewise, for hospitals, stock outs for sample collection materials were a challenge:

> *...because you find the mother will come and be asked to return next week or the following day because the kits are finished.* [Participant 2]

Clinicians from intervention and control hospitals also discussed nondisclosure of HIV status and poverty as barriers to providing EID services. Providers described how adhering to medication and appointment schedules, breastfeeding, and family planning recommendations may be difficult for undisclosed mothers. They indicated that hospital transport expenses were challenging for women and that women may arouse suspicion if they ask partners or family members for transport money. Respondents indicated that, in some cases, women may be forced to choose between using money for transport to the hospital or other essentials. One intervention clinician indicated that mothers were sometimes concerned about receiving a message asking them to return to the hospital when they didn't have money for transport. In these situations, clinicians would:

> *...assure them that the SMS is just to prepare you, and once you get fare you can come to the clinic expecting the results to be ready.* [Participant 13]

Discussion

Principal Findings

Previous research on implementation of new technological interventions in health care has identified perceived usefulness and ease of use as 2 of the most important factors impacting provider adoption [25]. Our findings suggest that providers see both of these factors as prominent features of the HITSystem, suggesting perceived usefulness and ease of use may have facilitated the high adoption at the intervention sites. Strengthened networks between key stakeholders through improved mechanisms for patient tracing, sample tracking, and result distribution and automated communication between stakeholders allowed providers to provide more efficient EID services. The intervention's compatibility with existing workflows further facilitated HITSystem adoption by providers. Providers indicated that these advantages contributed to noticed improvements in EID services including shortened turnaround time of HIV DNA PCR sample processing, reductions in lost samples, reduced maternal anxiety, lower rates of loss to follow-up, more rapid initiation of ART among infants identified as positive, and improved communication between stakeholders.

Barriers to intervention implementation included shortages of HITSystem-specific resources including reliable internet and phone credit and the time associated with additional data entry requirements in light of heavy workloads. Providers described how they were able to overcome these barriers and integrate the HITSystem with minimal disruptions to their daily working routines by delaying data entry until their workload was lighter or until the internet was more reliable. Overall, interviews indicated that intervention providers felt that HITSystem-driven improvements in EID service provision outweighed the challenges associated with HITSystem use. Even after HITSystem implementation, however, barriers at the system level (supply stock outs and machine breakdowns) and patient level (maternal poverty and fear of disclosure) remained beyond the scope of the HITSystem intervention and continued to hinder timely and complete EID services.

Responsiveness to feedback generated during these interviews will improve the utility of the HITSystem within implementing hospitals and laboratories and can generate additional provider buy-in, facilitate greater HITSystem implementation, and support sustainability. After providers' suggestions, a new module of the HITSystem that tracks women throughout their pregnancy and then automatically links the infant to the EID was developed and rolled out to all facilities implementing the HITSystem [26]. Linkage of the HITSystem with other national systems, including the Laboratory Information Management System, and development of enhanced reporting features to generate customized data reports are actively underway. These linkages are expected to decrease data entry requirements for clinicians and laboratory technicians, further enhancing compatibility of the HITSystem. Additional training will be provided to clinical and laboratory staff using the HITSystem to ensure they are familiar with and comfortable using these additional features.

Limitations

Our study had several limitations that should be noted. First, while we interviewed the primary EID providers and HITSystem users at control and intervention hospitals, our sample of only a few facilities is relatively small and limited our ability to achieve saturation on all emergent themes of interest. Second, as part of the study, each intervention site had a designated study coordinator to support HITSystem implementation. Thus, these data may not reflect the range of provider experiences in programmatic settings. Third, interviews were conducted around the time study participants were returning for their 9-month services. Since the intervention lasts through completion of EID at approximately 18 months, these data do not capture the full cycle of implementation through the EID cascade. Lastly, other factors outside of the scope of providers likely impact eHealth adoption. For example, other studies have shown that cost to the institution or other stakeholders [25,27], stakeholder collaboration, and government involvement can also impact eHealth adoption [25,28]. Our study was limited in that we interviewed only providers and thus were unable to assess factors at different levels that may facilitate or impede adoption, sustainability, and scalability.

Conclusions

Despite these limitations, this study provides a comprehensive qualitative evaluation of provider experiences using an eHealth intervention in the context of an RCT, illustrating how implementation research can complement RCTs. The noted advantages that the HITSystem offered over standard EID services, allowing providers to better meet patient needs, were a strong theme across site and provider type and served as a facilitator to HITSystem uptake. Workload and resource constraints were barriers to use. Provider experiences with the HITSystem indicate that the usefulness of the HITSystem, along with the ease with which it can be incorporated into hospital workflows, contribute to its sustained adoption and use in Kenyan hospitals. Their perspective suggests that other eHealth interventions in similar settings may maximize the potential for implementation success by assuring end users see clear advantages of the new technology and can easily integrate it into their workflow. Care should be taken in intervention design to account for variations in workflows, patient populations, and resource levels by allowing for flexibility in implementation to suit varying workflow and user needs. However, a larger sample of stakeholders (patients, hospital administrators, policy makers, government representatives, etc) is needed to more comprehensively describe the multilevel factors that may influence adoption and sustainability.

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Conflicts of Interest

None declared.

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Abbreviations

ART: antiretroviral therapy
EID: early infant diagnosis
HITSystem: HIV Infant Tracking System
PCR: polymerase chain reaction
RCT: randomized controlled trial
SMS: short message service

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Original Paper

Supportive Care in Radiotherapy Based on a Mobile App: Prospective Multicenter Survey

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Abstract

Background: Consumer electronics and Web-enabled mobile devices are playing an increasing role in patient care, and their use in the oncologic sector opens up promising possibilities in the fields of supportive cancer care and systematic patient follow-up.

Objective: The objective of our study was to assess the acceptance and possible benefits of a mobile app–based concept for supportive care of cancer patients undergoing radiotherapy.

Methods: In total, 975 patients presenting for radiotherapy due to breast or prostate cancer were screened; of them, 200 owned a smartphone and consented to participate in the survey. Patients were requested to complete a questionnaire at 2 time points: prior to the initiation (T0) and after the completion (T1) of radiotherapy. The questionnaire included questions about the habits of smartphone usage, technical knowledge and abilities of the participants, readiness to use a mobile app within the context of radiotherapy, possible features of the mobile app, and general attitude toward the different aspects of oncologic treatments. For quantitative analysis, sum scores were calculated for all areas of interest, and results were correlated with patient characteristics. Additionally, answers were quantitatively compared between time points T0 and T1.

Results: Median patient age was 57 (range 27-78) years. Of the 200 participants, 131 (66.2%) reported having the ability to use their smartphones with minimal to no help and 75.8% (150/200) had not used their smartphones in a medical context before. However, 73.3% (146/200) and 83.4% (166/200) of patients showed a strong interest in using a mobile app for supportive care during radiotherapy and as part of the clinical follow-up, respectively. Patients most commonly requested functionalities regarding appointment scheduling in the clinic (176/200, 88.0%) and the collection of patient-reported outcome data regarding their illness, therapy, and general well-being (130/200, 65.0%). Age was identified as the most influential factor regarding patient attitude, with patients aged <55 years being significantly more inclined toward and versed in smartphone use (P<.001). The acceptance of mobile apps was significantly higher in patients exhibiting a Karnofsky performance index <80% (P=.01). Support in the context of therapy-related side effects was judged most important by patients with poor clinical performance (P=.006). The overall acceptance of mobile apps in the context of radiotherapy surveillance was high at a median item sum score of 71.4/100 and was not significantly influenced by tumor stage, age, gender, treatment setting, or previous radiotherapies.

Conclusions: The acceptance of mobile apps for the surveillance and follow-up of cancer patients undergoing radiotherapy is high; this high acceptance level will serve as a basis for future clinical trials investigating the clinical benefits of mobile app–based

treatment support. Introduction of mobile apps into the clinical routine should be considered as an opportunity to improve and intensify supportive treatment for cancer patients.

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KEYWORDS

mHealth; radiotherapy; mobile app; quality of life; surveillance; patient-reported outcome; acceptance; smartphone; mobile phone

Introduction

The usage of consumer electronics and Web-enabled mobile devices is steadily increasing in the medical sector. Mobile health care apps are summarized by the World Health Organization under the term "mHealth" (mobile health) and have recently shown a significant rise in availability and market share [1,2]. Far from being but a response to the increased availability of smartphones and similar devices, the increased role of mHealth can be interpreted as a reaction to structural and demographic challenges faced by health care providers in today's society. As patient empowerment and shared decision making become increasingly valued in health care, mHealth can provide the means of incorporating those values into modern treatments, for example, facilitating the collection of patient-reported outcomes or providing information about disease management and prevention [3]. The main arguments that favor mHealth approaches include the possibility to overcome geographic distances and language barriers or selectively address special needs of patient subgroups, such as children or ethnic minorities [4,5].

Mobile apps have been well implemented for the management of highly prevalent conditions such as diabetes, obesity, or cardiovascular diseases [4,6,7]. Cancer, with generally improved long-term survival rates, is developing into a chronic illness with similar requirements such as close patient monitoring and extensive and long-term supportive care [3]. Few mobile apps have been established for supportive cancer care, and the areas of use are still limited [8]. Furthermore, cancer-related mHealth apps and online resources often lack clinical validation. Several reviews examining the clinical benefits of available mobile apps have shown that the overall accuracy, actuality, and systematic validity of the provided information have rarely been confirmed in clinical studies [9-11]. To date, there are no validated mobile apps specifically for the management of patients receiving radiotherapy, a treatment modality with its very own subset of possible side effects and requirements regarding surveillance and supportive care [12].

The acceptance of mobile apps and Web-based medical resources by cancer patients remains largely unclear, especially because patient satisfaction in this context is rarely assessed systematically [11]. This is even more critical as this patient cohort is extremely heterogeneous regarding patient age, technological affinity and skills, income status, and individual burden and distress attributable to this often severe illness.

This prospective study aimed to systematically examine the acceptance of mobile apps by cancer patients undergoing radiotherapy by conducting a systematic survey at the Departments of Radiation Oncology of the National Center for Tumor Diseases, Heidelberg University Hospital and the German Cancer Research Center in Heidelberg. It specifically addresses the patients' readiness and inclination toward the usage of a mHealth-based approach for additional supportive care in the context of radiotherapy. Furthermore, patient-side infrastructure, such as technical skills, reachability, or mobile data availability, was assessed. The possible functionalities and features of a supportive mobile app were systematically evaluated, and the potential influences of radiotherapy and other predictive and clinical factors on patients' attitude were investigated.

Methods

Patient Characteristics

A total of 975 cancer patients presenting for radiotherapy at the above-mentioned institutions for breast or prostate cancer were screened for participation in this survey. Of them, 200 patients owned a smartphone and consented to participate. All the participants were asked to complete a survey prior to the initiation of radiotherapy (T0) and again upon the completion of the treatment (T1). Patient characteristics are presented in Table 1, and a flowchart of the recruitment workflow is illustrated in Figure 1. This prospective survey was approved by the Heidelberg University Independent Ethics Committee on February 15, 2017 (approval #S-007/2017).

Survey Methods

The survey form consisted of a standardized paper questionnaire containing 27 items (Q1-Q27) about smartphone use. The questionnaire was developed by experienced radiation oncologists with the help of a biomedical informatist and biostatistician and was tested on a small group of patients to allow room for clarifications and corrections before its distribution within this survey. The types of questions included multiple-choice questions, requiring the patients to choose one or several answers out of 2, 4, or 5 provided options. Two were polar questions, requiring the patients to choose either "yes" or "no." Five questions prompted the patients to additionally fill in optional free text. Items assessed the habits of smartphone usage (Q3, Q7, and Q8), assessed technical knowledge and abilities in smartphone usage (Q4-Q6), assessed readiness to use a smartphone app within the context of cancer and radiotherapy (Q9, Q14, Q20-22, and Q27), suggested features for a potential radiotherapy-related mobile app (Q10-Q13), suggested the timeframe of reachability for smartphone notifications (Q23-Q25), and assessed the general attitude toward the different aspects of radiotherapy (Q15-Q19 and Q26). Additionally, patient- and disease-related information was collected. An English version of the survey questionnaire is provided in Multimedia Appendix 1.

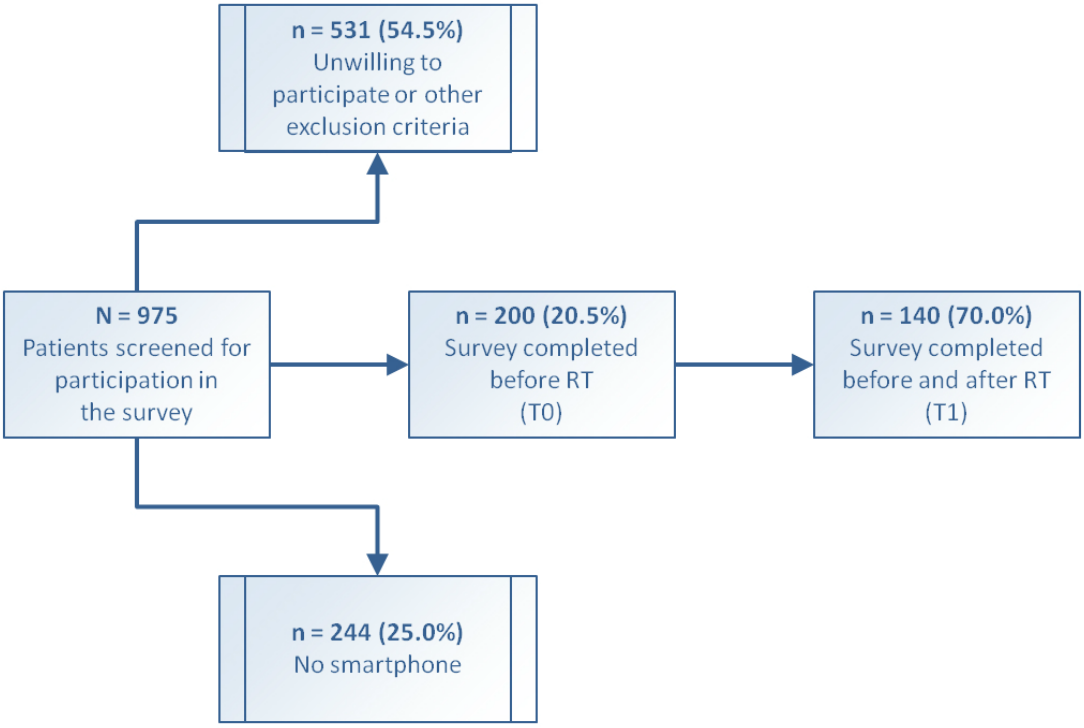
Table 1. Patient characteristics before radiotherapy (N=200).

Characteristics	Value
Age (years)	
Mean (SD)	57.2 (11.08)
Median (range)	57 (27-78)
Q1-Q3	50-65
Gender, n (%)	
Male	85 (42.5)
Female	115 (57.5)
Diagnosis, n (%)	
Breast cancer	115 (57.5)
Prostate cancer	85 (42.5)
Treatment setting, n (%)	
Curative	169 (84.5)
Palliative	31 (15.5)
T status, n (%)	
is	4 (2.0)
1	88 (44.0)
2	65 (32.5)
3	36 (18.0)
4	4 (2.0)
X	1 (0.5)
Unknown	2 (1.0)
N status, n (%)	
0	132 (66.0)
+	19 (9.5)
1	38 (19.0)
2	4 (2.0)
3	4 (2.0)
X	3 (1.5)
M status, n (%)	
0	159 (79.5)
1	34 (17.0)
X	7 (3.5)
Initial Karnofsky performance index, n (%)	
60	3 (1.5)
70	19 (9.5)
80	43 (21.5)
90	68 (34.0)
100	67 (33.5)
Previous radiotherapy, n (%)	
No	144 (72.0)
Yes	56 (28.0)
Tumor stage[a], n (%)	

Characteristics	Value
Early	102 (51.0)
Advanced	98 (49.0)

[a]Early tumor stage: Tis/1/2, N0, M0; advanced tumor stage: T3 or above, N1 or above, M1.

Figure 1. Flowchart illustrating patient screening and recruitment workflow. RT: radiotherapy.



Statistical Analysis

To allow for quantitative comparison, a simple scoring method was devised in which the aforementioned areas of interest (AOI) were considered as the subscales of the questionnaire. Within each subscale, every question was weighted by the number of possible answers, and the points were divided equally between the provided answers. Questions Q5, Q10, and Q13 were taken out of the score because they only provided qualitative information. The sum for every subscale was calculated and used for the comparison. Detailed information about the scoring system is provided in Multimedia Appendix 2.

For descriptive analyses, continuous variables were presented as mean (SD) and median (IQR and min and max) and categorical variables as absolute and relative frequencies. Group comparisons were made according to tumor stage, age (below and above 55 years), Karnofsky performance scale index (KPI), previous courses of radiotherapy, treatment setting, and gender [13]. Wilcoxon rank sum test for ordinal scaled variables and chi-square test for categorical variables were used to evaluate potential differences between patients in the mentioned groups. Group differences were assessed for all subscales and, additionally, for all questions included in the calculation for one of the subscales. To evaluate the differences at time points T0 and T1, Wilcoxon signed-rank test for paired ordinal scaled data and McNemar test for categorical variables were used. All statistical analyses were performed using R software (version 3.4.3, The R Foundation for Statistical Computing, Vienna, Austria).

Results

Descriptive Analysis

Of all patients, 73.2% (146/200) indicated that they were using mobile data on their smartphones, and the common usage included social media apps (45/200, 22.5%), picture taking and Web browsing (86/200, 43.0%), or further apps (48/200, 24.0%); 10.5% (21/200) of the patients used their smartphones for voice calls and instant messaging. Only 24.2% (48/200) of the patients indicated having used their smartphones in a health-related context before; 66.2% (131/200) of the patients stated that they never or rarely required assistance in using their smartphones and 63.9% (124/200) estimated their technical skills in this regard to be solid or advanced.

Patients showed a high overall readiness to use a mobile app in the context of radiotherapy: 73.3% (146/200) of all patients judged using a dedicated mobile app for additional supportive care during their treatment as helpful or very helpful. Mobile apps usage was judged especially helpful in providing support for the occurrences of treatment-associated toxicities (163/200, 81.8%, helpful or very helpful). The favored frequencies at which patients would be willing to answer short app-based queries regarding their well-being or general symptoms were weekly (98/100, 50.8%) and as required (37/200, 19.2%).

Thirty-two out of 200 patients (16.6%) wished to do this only at the beginning and end of therapy. Concerns regarding data security were voiced by 12.2% (24/200) of patients. These concerns were somewhat more frequent in patients older than 55 years, although the difference was not significant compared with patients younger than 55 years (13.7% vs 10.0%, *P*=.16).

The most requested feature of a mobile app was assistance in appointment making for radiotherapy and consultations (176/200, 88.0%), followed by general or specific questions regarding patient well-being during radiotherapy (130/200, 65%). Additionally, patients requested the option to receive answers to questions and information material about diagnosis and therapy. Of all patients, 83.4% (166/200) welcomed the idea of continually using the app during follow-up to stay in touch with the treating physicians, describing this option as helpful or very helpful. The same was true for being contacted by the treating physician if medical warning signs were detected (182/200, 91.6%, helpful or very helpful). A reminder feature for scheduled follow-up examinations was favored by 81.5% (163/200) of patients.

Of the 200 patients, 21.8% (43/200) indicated their timeframe for reachability via smartphone between 7 am and 11 pm to be at least 12 hours; 40.1% (79/200) of patients indicated it to be between 2 and 12 hours. Regarding smartphone notifications about missed calls, instant messages, or push notifications, 75.4% (147/200) of patients stated that they would review those within a maximum timeframe of 2 hours or shorter; 21.5% (42/200) of patients answered “within 12 hours,” and only 3.1% (6/200) would need “2 days or longer.” The same was true for app-specific notifications regarding radiotherapy: the percentages were 67.8% (132/200) for 2 hours or less, 26.2% (51/200) for 12 hours, and 6.2% (12/200) for 2 days or longer.

In addition to the above-mentioned aspects of smartphone and app usage, the survey enquired about the general and organizational aspects of radiotherapy that could be improved using a smartphone app. Regarding the desired frequency of consultations with a supervising physician during radiotherapy, 34.4% (67/200) of patients favored weekly appointments, followed by 29.2% (57/200) favoring appointments “only as required.” Regarding consultations, a waiting period of up to 30 minutes was considered acceptable by 53.4% (106/200) of patients. However, regarding daily radiotherapy, the acceptable waiting period was shorter: 25.7% (50/200) of patients opted for 15 minutes or less and 6.2% (12/200) for even 10 minutes or less. Detailed information about the answers provided to all survey items is illustrated in Figures 2 and 3 and in Multimedia Appendices 3 and 4.

In Figure 2, Q9 corresponds to “Use of a dedicated smartphone app for support during radiotherapy”; Q11 to “Staying in touch via smartphone app during follow-up”; Q12 to “Being contacted about medical warning signs via a smartphone app”; Q20 to “App collecting relevant medical information prior to consultation”; and Q27 to “App-based supportive care in the context of treatment side effects.”

Areas of Interest

For quantitative evaluation, the items in the questionnaire were grouped according to subject to calculate the scores for AOI, as described above. The scores were transformed to represent a value between 0 and 100, where a higher score represents a higher inclination or acceptance toward the use of a smartphone app [14-16]. The scores for AOI as calculated from the analysis of all returned questionnaires filled out at T0 are indicated in Table 2 and Figure 4. The highest scores were achieved for AOI 3 (“readiness to use a dedicated app within the context of radiotherapy”) and AOI 4 (“suggested features of a mobile app”), achieving median values of 71.4 (Q1-Q3=61.9-76.2) and 75.0 (Q1-Q3=75.0-87.5), respectively. AOI 3 and 4 translate most directly into a high acceptance for the presented app-based model of therapy support. A similar median value of 71.4 (Q1-Q3=42.9-85.7) was calculated for AOI 2 (“technical knowledge and abilities”). AOI 5 (“timeframe of reachability”) and 6 (“general attitude”) provided mostly qualitative information regarding reachability and the setting and frequency of medical consultations during treatment. The median score of 58.3 (Q1-Q3=41.7-66.7) for AOI 5 translates into an average reachability within 2 hours during a daily timeframe of 2 to 12 hours for the majority of patients. The score of 33.3 (Q1-Q3=25.0-50.0) for AOI 6 shows a general acceptance for waiting periods of up to 30 minutes for a medical consultation.

Influence of Radiotherapy

For 140 patients, survey data before (T0) as well as after the completion (T1) of radiotherapy were available and were compared to evaluate whether having undergone radiotherapy influenced the attitude of patients. A small but statistically significant decrease of 4.7 points in the median transformed score for readiness to use an app within the context of radiotherapy (AOI 3) was detected at T1 (mean 68.6 vs 65.5, *P*<.001, Wilcoxon signed-rank test). The question within AOI 3 leading to this difference addressed the favored frequency of answering symptom-related questions posed by the app (Q14). At T1, patients selected “at therapy start and completion” and “only as required” more frequently instead of “weekly” and “every other day.” The helpfulness of app-based support in the context of toxicity was judged slightly lower at T1 (mean 4.04 before radiotherapy vs 3.88 after radiotherapy, *P*=.03). Regarding the median score for Q12, addressing the helpfulness of being contacted by a physician in case of medical warning signs, the mean/median score was 4.29/4 at T0 and 4.11/4 at T1 (*P*=.03). This question translated into a small but significant difference of 4.4 points in the transformed score for AOI 4 (mean 79.4 before radiotherapy vs 75.0 after radiotherapy, *P*=.04, Wilcoxon signed-rank test). For the other AOIs (AOI 1, 2 and 5, 6), as well as for individual questions, no significant difference was observed between the time points T0 and T1. A comparison of AOI scores between the time points T0 and T1 is illustrated in Figure 5. Detailed information regarding the quantitative comparison between answers provided at T0 and T1 for different survey items is provided in Table 3.

Figure 2. Distribution of the answers provided to selected questions regarding the helpfulness of mobile app–based therapy support in different situations.

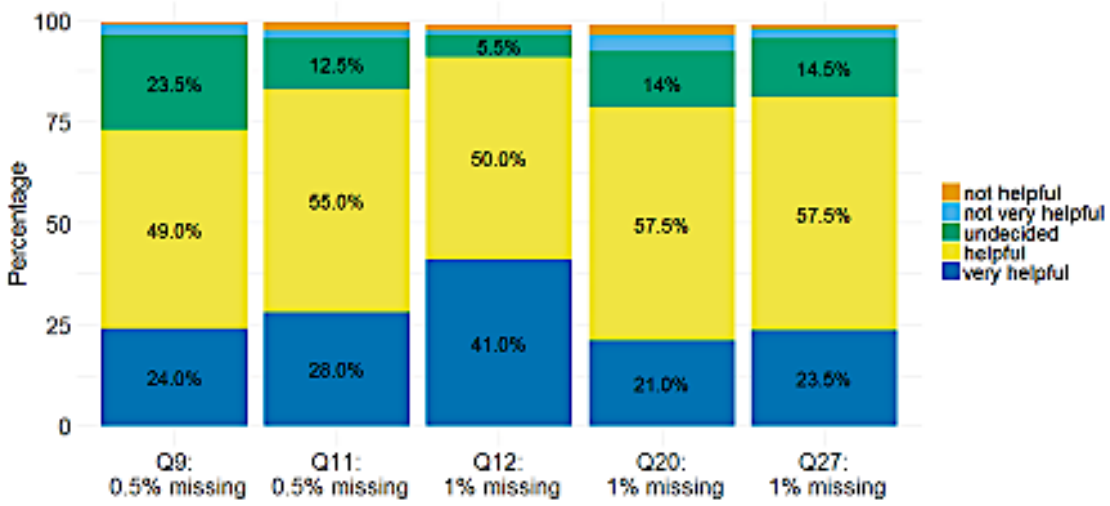


Figure 3. Distribution of the answers provided to selected questions regarding the favored frequencies of consulting a physician (Q14) or answering app-based health-related queries (Q15) as well as maximum acceptable waiting times for daily radiotherapy (Q16) or for a spontaneous medical consultation, if required (Q17).

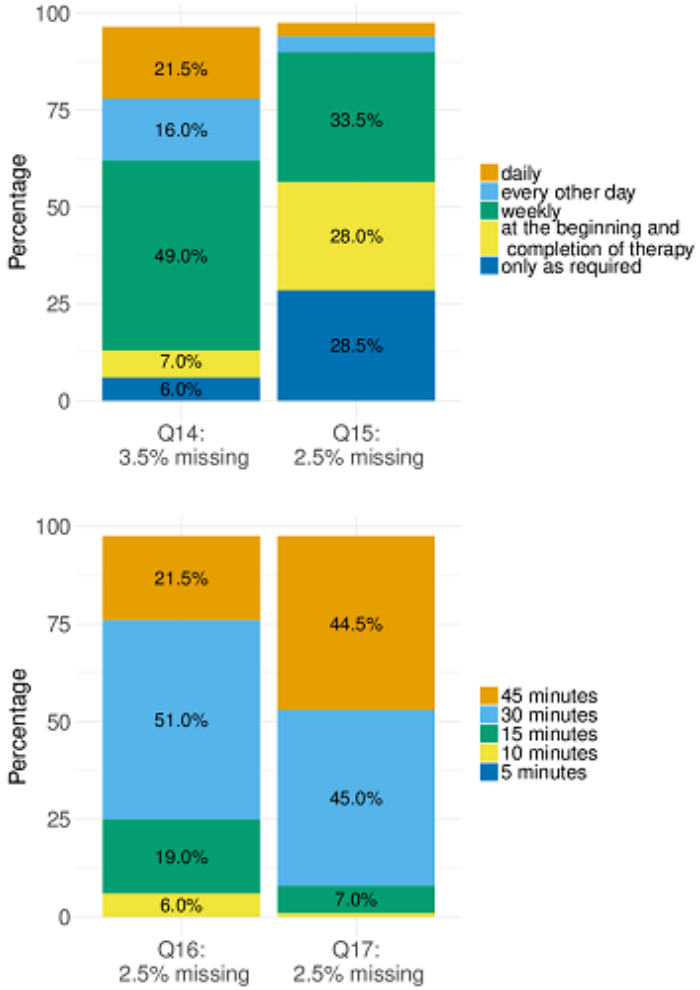


Table 2. Scores for the areas of interest (AOI) as calculated from the analysis of all returned questionnaires filled out at T0.

Scale	Description	Items	Mean (SD)	Median	Q1	Q3	Min	Max
AOI 1	Habits of smartphone use	Q3 + Q7 + Q8	52.2 (27.22)	50	40	80	0	100
AOI 2	Technical knowledge and abilities	Q4 + Q6	66.2 (21.39)	71.4	42.9	85.7	0	100
AOI 3	Readiness to use an app	Q9 + Q14 + Q20 + Q21 + Q22+ Q27	68.6 (14.44)	71.4	61.9	76.2	19	95.2
AOI 4	Possible features of a mobile app	Q11 + Q12	79.4 (17.01)	75	75	87.5	0	100
AOI 5	Timeframe of reachability	Q23 + Q24 + Q25	58.8 (18.58)	58.3	41.7	66.7	16.7	100
AOI 6	General attitude	Q15 + Q16 + Q17	37.5 (13.47)	33.3	25	50	0	75

Figure 4. Scores for the different areas of interest (AOI) covered by the questionnaires. The asterisks indicate the mean value of the corresponding AOI.

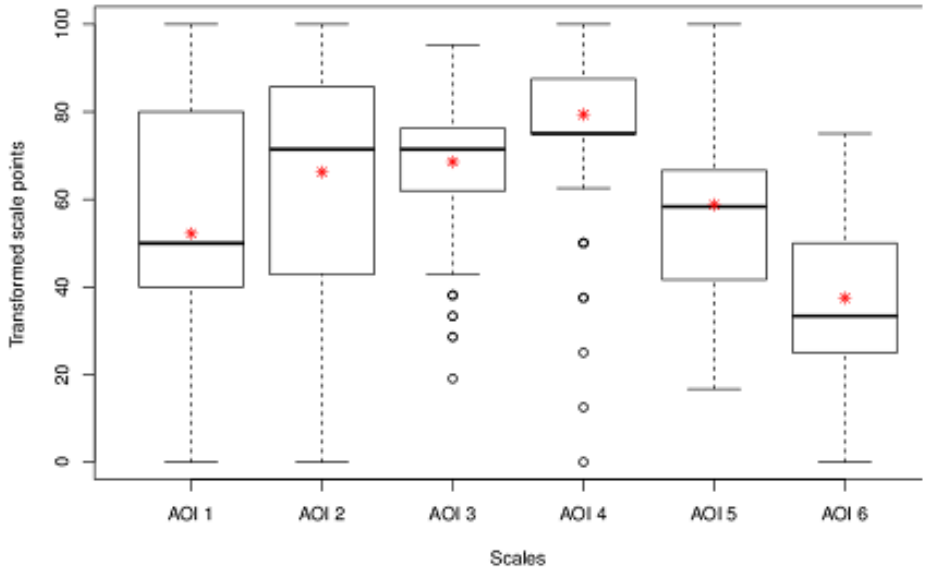


Figure 5. Comparison between the area of interest (AOI) scores of 140 patients who answered the survey at time points T0 and T1.

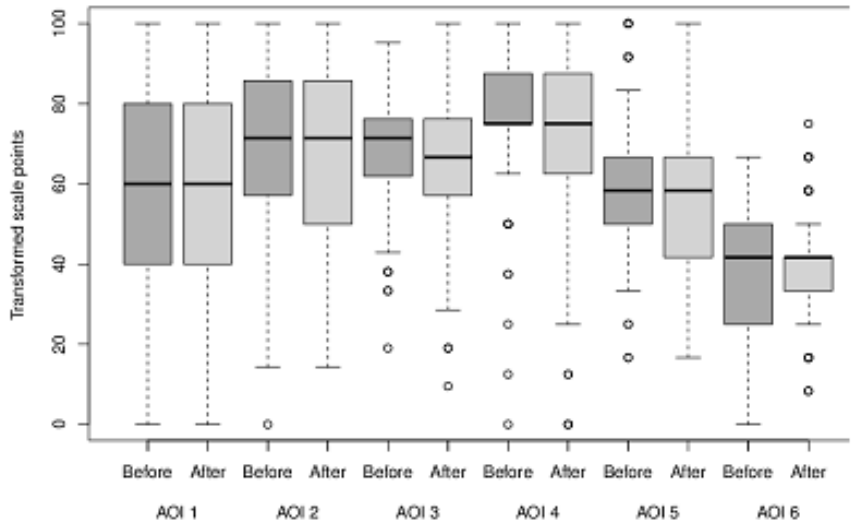


Table 3. Quantitative comparison between answers provided at time points T0 and T1 for different survey items for 140 patients who filled out the survey questionnaire twice.

Area of interest (AOI)	*P* value
AOI 1	.27
Q3	.81
Q7	.94
Q8	.005
AOI 2	.497
Q4	.98
Q6	.23
AOI 3	.001[a,b]
Q9	.17
Q14	<.001[a,b]
Q20	.23
Q21	.98
Q22	<.001
Q27	.03[b]
AOI 4	.04[a]
Q11	.09
Q12	.03[a,b]
AOI5	.76
Q23	.68
Q24	.14
Q25	.88
AOI 6	.21
Q15	.45
Q16	.39
Q17	.13
Q18	.56
Q19	.81
Q26	.77

[a]Lower score after the completion of radiotherapy.

[b]Significant *P* values.

Table 4. *P* values for the influence of tumor stage, age, gender, initial Karnofsky performance scale index (KPI), treatment setting (curative vs palliative), and previous radiotherapy on the answers provided to the survey items and area of interest (AOI) scores.

AOI	Tumor stage	Age 55 years	Gender	KPI	Treatment setting	Previous radiotherapy
AOI 1	.45	.005[a,b]	.78	.51	.006[a,c]	.26
Q3	.63	.19	.57	.56	.16	.09
Q7	.74	.01[a,b]	.64	.81	.002[a,c]	.48
Q8	.047[a,d]	.004[a,b]	.12	.83	>.99	.73
AOI 2	.66	.001[a,b]	.72	.24	.495	.93
Q4	.73	.003[a,b]	.64	.35	.25	.88
Q6	.70	.004[a,b]	.92	.28	.88	.74
AOI 3	.08	.26	.67	.01[a,e]	.32	.89
Q9	.45	.58	.17	.58	.12	.35
Q14	.09	.12	.26	.06	.003[a,f]	.22
Q20	.20	.75	.39	.04[a,e]	.94	.77
Q21	.29	.16	.67	.15	.91	.84
Q22	.67	.88	>.99	.64	.76	.83
Q27	.18	.67	.13	.006[a,e]	.63	.99
AOI 4	.09	.86	.203	.12	.92	.90
Q11	.19	.74	.146	.20	.95	.99
Q12	.07	.68	.542	.18	.72	.99
AOI 5	.07	.003[a,b]	.058	.54	.55	.29
Q23	.94	.06	.106	.30	.77	.19
Q24	.07	.002[a,b]	.484	.87	.41	.30
Q25	.26	.12	.641	.84	.75	.98
AOI 6	.96	.05	.041[a,g]	.67	.99	.84
Q15	.71	.009[a,h]	.091	.78	.82	.58
Q16	.50	.53	.186	.17	.87	.87
Q17	.78	.20	.116	.49	.63	.36

[a]Significant *P* values.

[b]Higher score for age <55 years.

[c]Higher score for curative treatment setting.

[d]Higher score for advanced tumor stage.

[e]Higher score for KPI <80%.

[f]Higher score for palliative treatment setting.

[g]Higher score for gender (male).

[h]Higher score for age ≥55 years.

Predictive Factors

To determine possible factors that influenced patients' attitude toward the usage of a mobile app, we tested several patient characteristics for their impact on survey results. The tested factors were age (<55 years vs ≥55 years), tumor stage (early [defined as tumor stage ≤T2, N0, M0/X] vs advanced), gender, previous radiotherapies, treatment setting (curative vs palliative), and initial KPI (<80% vs ≥80%). Age appeared to have the most sizable impact on the answers provided in the questionnaire, leading to significant differences in usage habits and technical skills as well as reachability. In all cases, younger patients were found to be more inclined toward and versed in more intensive smartphone use (AOI 2, *P*<.001). Interestingly, the favored frequency of seeing a physician during therapy was higher in patients younger than 55 years (*P*=.009). An overview of the survey items significantly impacted by the analyzed patient characteristics is displayed in Table 4.

Discussion

Interpretation of Survey Results

We conducted a prospective and systematic survey regarding the habits and skills in smartphone usage, readiness to use a supportive mobile app during and after radiotherapy, and opinions on suggested functionality for such an app among cancer patients undergoing radiotherapy. Our results showed high overall acceptance levels for the usage of mobile technology in the context of radiotherapy, and the proposed functionality and features were considered as helpful by a large majority of patients.

Moreover, our survey showed that the ability to use a dedicated mobile app for additional supportive care (eg, mobile data on smartphone, reachability, and technical skills) on the patient side were present in almost three quarters of the survey population, and the obtained numbers were consistent across the different subareas of this survey. These results suggest a promising potential for an mHealth approach in the field of radiotherapy, although they also outline the need for careful patient selection to avoid the unnecessary burdening of subgroups that are either not willing or not capable and, thus, will likely not benefit. As the ownership of a smartphone and informed consent were prerequisites to participating in the survey, 975 patients were screened, and a total of 200 patients participated. The possible selection bias introduced by this approach has to be considered when generalizing the survey results to all patients undergoing radiotherapy. On the other hand, the results can be valuable in identifying and describing patient subgroups that are most likely to benefit from additional mobile app–based support.

The quantitative analysis of the survey data allowed us to identify age as the most influential factor for patient willingness with younger patients being considerably more inclined toward the use of mobile technology in the context of radiotherapy. Oncological diagnoses are typically associated with certain age groups (eg, prostate cancer, lung cancer, and different subgroups of head and neck cancer). Thus, a degree of patient selection based on age and age-associated diagnosis seams feasible when offering mHealth-based support. On the other hand, prospective clinical evidence exists, showing that patients with unfavorable characteristics regarding age and diagnosis, such as lung cancer patients, can also benefit. This especially holds true if the design of the electronic health (eHealth) or mHealth app integrates the patient's next of kin to assist in the usage [17,18].

Several studies have shown that patient compliance plays a special role in the successful implementation of mHealth initiatives [19]. Clinical experience in oncology shows patient compliance to be worse in subgroups with lifestyle-related risk factors (eg, heavy smoking and alcohol abuse), potentially making such patients less eligible for mHealth-based support [20,21]. However, evidence exists that offering mHealth support in addition to close clinical surveillance may improve patient compliance, particularly in the abovementioned subgroups, by providing regular prompts and reminders and facilitating adherence to prescribed exercises or supportive regimens [22-24].

The perceived needs of cancer patients for supportive measures are manifold; they may strongly vary depending on culture, diagnosis, prognosis, and associated symptoms and may, hence, influence the acceptance of such measures [25-27]. Our survey showed that, disregarding few minor points, the acceptance of the proposed mobile app approach was high among patients, irrespective of tumor stage, treatment setting, potential previous radiotherapies, and initial clinical performance. Regarding toxicity-related surveillance, acceptance was significantly higher in patients with a reduced performance status. Nevertheless, as poor-performing patients require a different form of intensified personal care, the use of a mobile app alone may show limitations, particularly in the palliative setting [28].

It can be argued that by limiting the present survey to include only prostate and breast cancer patients, a selection bias in favor of patients with favorable prognosis and good clinical performance is introduced, and the generalizability of the results for other cancer patients undergoing radiotherapy could be limited. This potential limitation was accepted to achieve a more homogeneous dataset and ensure timely and systematic survey completion and analysis. However, it should be noted that we included 49.0% of patients with advanced tumor stages, 17.0% of patients with a metastatic disease, and 28.0% of patients who had undergone previous radiotherapy. These patient subgroups feature a different clinical profile characterized by unfavorable prognosis, usually a rapid decline in clinical performance, and a high need for supportive care [29]. The described clinical profile is shared by a majority of patients undergoing radiotherapy for different diagnoses, and the survey results regarding the acceptance of mobile app–-based support did not differ significantly in this subgroup [30-32]. Furthermore, it is of interest that irrespective of age, no further diagnosis-specific influencing factors regarding mobile app acceptance were identified for either breast or prostate cancer patients. This finding, in turn, supports the approach of cautiously extrapolating our results to patients with differing diagnoses.

The helpfulness of app-based supportive care in the context of monitoring potential radiotherapy-induced side effects was judged minimally higher by patients before the beginning of therapy, as was the favored frequency of interaction with the app. These results highlight the importance of providing sufficient information and support before and during the early stages of radiotherapy to address potential fears and worries. Such fears and worries and, thus, the need for additional support are less likely to be observed when the therapy is successfully completed, and the results of our survey accurately mirror this constellation.

Review of the Literature

The management of cancer patients is an area of special interest for the development of new eHealth and mHealth initiatives because they show promising potential, particularly in the context of supportive care and follow-up [7].

Only one other survey focusing on the acceptance of a dedicated mobile app among cancer patients has been published [33]. Overall results showed convincing similarity in both surveys. However, good or very good technical skills and the willingness to send data to the treating clinic via an app were slightly less

frequent in the previous survey than in our survey (54.1% vs 63.9% and 48.5% vs 71.1%, respectively). Moreover, younger patients were generally more willing to use mobile technology in a disease-related context. In comparison, our survey described a more homogeneous and precisely selected cohort, focusing exclusively on patients receiving radiotherapy. Consequently, the specific requirements and circumstances related to this course of treatment are more comprehensively examined.

Ruland and colleagues have reported results similar to those of our survey, testing the usefulness and acceptance of a Web-based, multicomponent eHealth app with special focus on patient self-management among breast and prostate cancer patients [34]. The tested app did not focus exclusively on radiotherapy, and it provided supportive care in a more general manner, featuring message boards and general information sections, among other functionalities. Active usage among the regarded cohort was 64%, which is close to the results of our survey, and in this context, age and diagnosis were reported to significantly impact patient usage [34].

The value of an eHealth or mHealth resource is particularly high when tailored to fit the needs of the target patient cohort because patients are more likely to appreciate the immediately relevant and personalized support [34]. Depending on the diagnosis and therapy regimen, the wide heterogeneity among cancer patients and the very specific needs of different subgroups make them a challenging collective to address as a whole. Consequently, existing mHealth projects have typically been addressing either a specific question or a specific subgroup of cancer patients.

A recent randomized controlled trial by Denis and colleagues has shown a significant median overall survival benefit of 5 months for lung cancer patients who were systematically telemonitored using a mobile app based on patient-reported data and using the dynamics of patients' clinical symptoms for risk stratification and individualized follow-up [18,35]. Similar approaches have successfully been used in the management of toxicities related to head and neck cancer treatment: computerized screening could facilitate the identification of treatment-related toxicities, and telepractice apps or videoconferencing could assist in the delivery of intensive home-based dysphagia therapy [24,36]. Regarding general supportive care, considerable advances have been made in the development of mHealth interventions to address the common issue of fatigue among cancer survivors. A recent meta-analysis identified 9 completed eHealth studies that revealed a significant beneficial effect of eHealth interventions on fatigued patients with improvements in health-related quality of life and depression [37].

Patients undergoing radiotherapy represent a distinct subgroup of cancer patients with special requirements in terms of supportive care. The nature of radiotherapy results in a specific set of therapy-related side effects and medical issues that require surveillance and potential support. Of the symptoms, the most common are dermatitis, nausea, fatigue, and localized toxicities within the respective treatment region [12]. Furthermore, depending on the diagnosis, patients undergoing radiotherapy vary in terms of age and characteristic profiles regarding individual risk constellations and comorbidities. Based on the data reported here, the usefulness and clinical implementation of a mobile app will be evaluated in a prospective trial (OPTIMISE-1; ClinicalTrials.gov identifier #NCT03168048) for which the dedicated mobile app has been designed according to the requirements of the patients who were assessed [38].

Conclusion

To the best of our knowledge, this study is the first to prospectively evaluate and demonstrate a high acceptance of and distinct patient requirements for the use of a supportive mobile app in a large homogeneous cohort of cancer patients undergoing radiotherapy. The reported patient acceptance will serve as a basis for future clinical trials that prospectively investigate the benefits of mobile app–based treatment support in routine clinical settings. The introduction of mobile apps into the clinical routine should be regarded as an opportunity to improve and intensify supportive treatment for cancer patients.

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Authors' Contributions

RAES, JD, and NHN developed and planned this survey. NB and DO helped devising survey items for the usage of mobile app and electronic data management. DW is the trial biostatistician, and she performed data analysis. RAES and TS performed patient recruitment and data collection. RAES and NHN drafted the manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey questionnaire.

[PDF File (Adobe PDF File), 42KB - mhealth_v6i8e10916_app1.pdf]

Multimedia Appendix 2

Scoring system.

[PDF File (Adobe PDF File), 38KB - mhealth_v6i8e10916_app2.pdf]

Multimedia Appendix 3

Descriptive statistics before radiotherapy.

[PDF File (Adobe PDF File), 33KB - mhealth_v6i8e10916_app3.pdf]

Multimedia Appendix 4

Descriptive statistics after radiotherapy.

[PDF File (Adobe PDF File), 33KB - mhealth_v6i8e10916_app4.pdf]

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Abbreviations

AOI: area of interest
eHealth: electronic health
KPI: Karnofsky performance scale index
mHealth: mobile health

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Original Paper

An mHealth Management Platform for Patients with Chronic Obstructive Pulmonary Disease (efil breath): Randomized Controlled Trial

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) is one of the major morbidities in public health, and the use of mHealth technology for rehabilitation of patients with COPD can help increase physical activity and ameliorate respiratory symptoms.

Objective: This study aimed to develop a comprehensive rehabilitation management platform to improve physical activity and quality of life in patients with COPD.

Methods: The study comprised the following 2 stages: (1) a pilot stage in which a prototype app was developed; and (2) a fully-fledged platform development stage in which 2 apps and 1 COPD patient monitoring website were developed. We conducted a randomized clinical trial to investigate the efficacy of the apps developed in the second stage of the study. In addition, two 12-week exercise regimens (fixed and fixed-interactive) were tested for the trial. The clinical parameters of the respiratory function and patient global assessment (PGA) of the app were obtained and analyzed. Notably, Android was the chosen operating system for apps.

Results: We developed 2 COPD rehabilitation apps and 1 patient monitoring website. For the clinical trial, 85 patients were randomized into the following 3 groups: 57 were allocated to the 2 intervention groups and 28 to the control group. After 6 weeks, the COPD assessment test scores were significantly reduced in the fixed group (P=.01), and signs of improvement were witnessed in the fixed-interactive group. In addition, the PGA score was moderate or high in all aspects of the user experience of the apps in both intervention groups.

Conclusions: A well-designed mobile rehabilitation app for monitoring and managing patients with COPD can supplement or replace traditional center-based rehabilitation programs and achieve improved patient health outcomes.

Trial Registration: ClinicalTrials.gov NCT03432117; https://clinicaltrials.gov/ct2/show/NCT03432117 (Archived by WebCite at http://www.webcitation.org/71Yp0P64a)

(JMIR Mhealth Uhealth 2018;6(8):e10502) doi:10.2196/10502

KEYWORDS

chronic obstructive pulmonary disease; mHealth; mobile phone; physical activity; rehabilitation; quality of life

Introduction

Chronic obstructive pulmonary disease (COPD) is recognized as a major public health problem and might become a considerable burden worldwide in the near future [1]. The same phenomenon has been witnessed in Korea, where COPD has become the sixth leading cause of death, and its prevalence has reached close to 13% among individuals aged ≥40 years (19.4% of males and 7.9% of females) [2,3]. Pulmonary rehabilitation (PR) is a comprehensive intervention through which patient assessment, exercise training, education, nutritional intervention, and psychosocial support [4,5] are administered to meet the goals of improved physical and psychological condition, for example, exercise capacity and quality of life (QoL), and reduced health care utilization [6]. However, it is challenging to ensure that patients with COPD do conform to the recommended and agreed-upon quantity and quality of rehabilitation programs as part of their disease management plan [7], and patients with severe or extreme disease activity tend to exhibit fewer and shorter bouts of physical activity [8,9]. Furthermore, the factors affecting low uptake and incompletion of PR include the low degree of perceived benefits and the lack of support for transport in these patients [7].

According to a 2016 survey of 7 tertiary hospitals in Korea that provided PR programs, only 5 hospitals had established protocols for PR programs, while 2 hospitals had only conventional rehabilitation programs. Inpatients were admitted to a 1- to 2-week PR program with an average of 3-5 sessions a week, and each session ran 10-60 minutes. Only 1 hospital had a 12-week PR program with exercise programs and patient education sessions focusing on the muscular endurance, cardiorespiratory fitness, and breathing training. Though most of the hospitals' survey acknowledged the need for an extended PR program, the hardships included a lack of funding or certified facilities, and low national health insurance coverage. An alternative model that assists in overcoming these barriers is home-based rehabilitation (HBR) [10,11]. A well-structured HBR has the potential to surpass center-based rehabilitation by promoting exercise capacity and health-related QoL [12-14]. Many established HBR programs yet require qualified health care professionals, such as physiotherapists or home-care nurses, who periodically pay a visit to patients [10,12]. Without tracking physical activity automatically [15], the burden of manual entry of the vast amount of data, such as exercise duration and walked distance [13], lies on health care professionals and patients. The burden of data recording, for both patients and health care professionals, could be solved by accessible, user-friendly mHealth technology [16,17]. Equipped with mobile apps and monitoring platforms that can manage COPD patients' PR, health care professionals are better positioned to monitor patients' compliance and activities and provide accurate feedback.

A significant body of studies exists proving that HBR using mobile technology is as effective as center-based rehabilitation programs [15,18]. Specifically, home-based COPD rehabilitation programs have been an optimal alternative to center-based rehabilitation; improved exercise capacity and QoL resulted in increased physical activity and reduced respiratory-related hospitalizations [10,13,19-23]. Mobile technology assists automatic data recording of exercise activities, and certain apps send data to a central server, where health care professionals with proper clearance use the data for patient monitoring and feedback.

There are, however, only a few available HBR mobile apps that incorporate evidence-based health recommendations [24]. To achieve better health outcomes in patients with COPD, the following requirements for mobile HBR programs should be met: (1) exercise programs must conform to evidence, such as public health recommendations (ie, the Consensus Document on Pulmonary Rehabilitation in Korea) [24]; (2) a baseline assessment of exercise capacity, such as the 6-minute walk test (6MWT), must be provided prior to the onset and end of the exercise [25]; (3) exercise regimens should be adequately flexible to be adjusted according to the patient status [4]; and (4) a patient management and monitoring platform should be present [26].

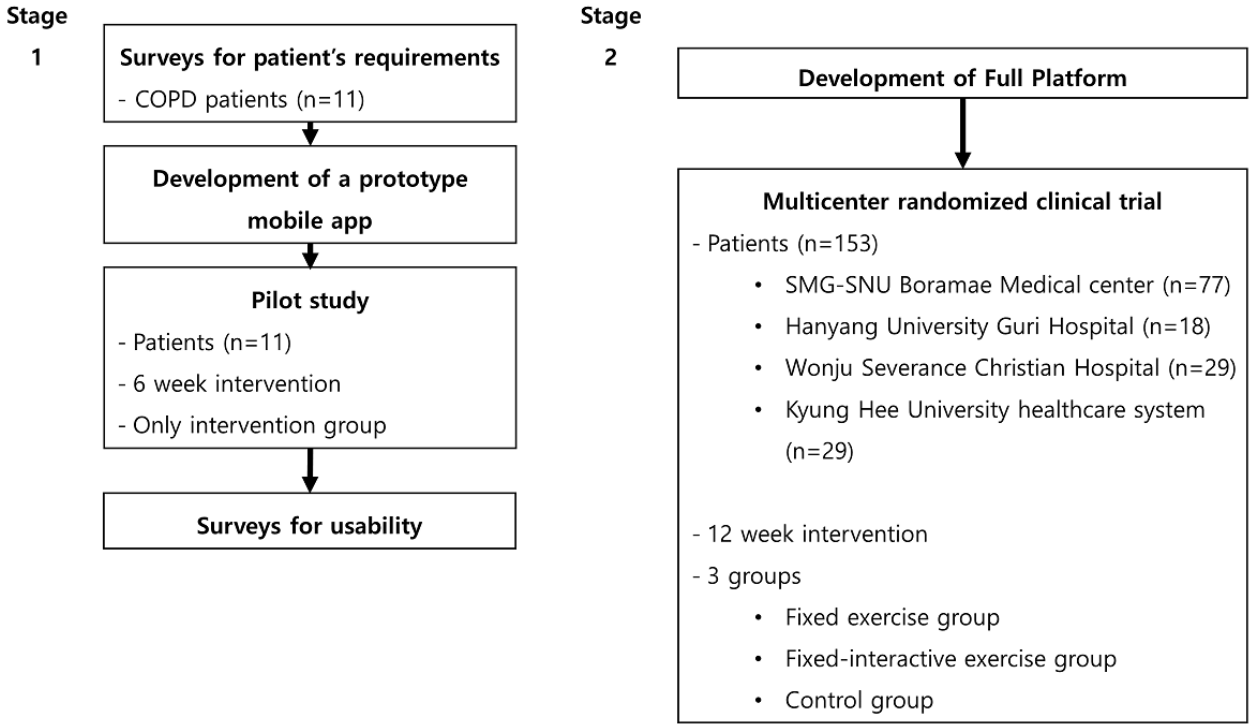
This study aimed to develop a home-based mHealth PR for patients with COPD to improve their daily physical capacity and QoL. To achieve this goal, we developed *efil breath*, which combines a mobile PR app platform, including a wearable device, a personalized app, and a website for monitoring patients by health care professionals. Furthermore, a randomized clinical trial was conducted to investigate the effectiveness of the platform. Notably, the study is the first multicenter-based clinical trial of a home-based mobile PR program for Korean patients with COPD.

Methods

Study Design

The study was divided into the following 2 stages (Figure 1): a pilot study (Stage 1), and the full development of a platform, followed by a clinical trial (Stage 2). Stage 1 consisted of the following 4 steps: (1) collection of user requirements using survey results from patients with COPD (n=11), who used the home-based PR, and in-person consultations obtained from qualified health care professionals; (2) development of a prototype mobile app; (3) a 6-week pilot study testing the app (no control group) to assess the study feasibility; and (4) a usability survey. Stage 2 consisted of (1) the development of 2 types of mobile apps (one with a fixed exercise regimen, and another with an interactive exercise regimen) and a patient management or monitoring website; and (2) a 12-week, multicenter-based randomized clinical trial. The trial participants in the intervention groups were instructed to use the app with a fixed or interactive exercise regimen, and those in the control group went on with their daily lives without using the app.

Figure 1. Study design. COPD: Chronic obstructive pulmonary disease; SMG-SNU: Seoul Metropolitan Government-Seoul National University.



Participants of the Clinical Trial

The study participants of Stage 2 were recruited from outpatient clinics of 4 secondary or tertiary hospitals in Korea. Patients with COPD were selected according to the following inclusion criteria: (1) age>20 years; (2) a postbronchodilator forced expiratory volume in 1 second of <80% compared with the reference range; (3) ability to walk >150 m in a 6MWT; and (4) an Android smartphone owner. Of note, patients who were unable to follow the exercise regimen were excluded from the screening process. All study participants were to sign a written informed consent.

Clinical Trial Protocol

The study participants were randomized into 3 groups as follows: fixed exercise, fixed-interactive exercise, and control group. The fixed-interactive exercise group initiated a fixed exercise regimen for the first 6 weeks, followed by an interactive exercise protocol for 6 weeks. A random allocation (1:1:1) within each center was moderated by an independent coordinator; patients were stratified by the baseline forced expiratory volume in 1 second and COPD assessment test (CAT) scores. The 6MWT, self-perceived dyspnea assessment in relation to a physical disability (modified Medical Research Council, mMRC), and CAT were acquired at the baseline (V1), 6 weeks (V2), and 12 weeks (V3). Patient global assessment (PGA) by a 5-point Likert scale (1=strongly disagree, 2=disagree, 3=neither disagree nor agree, 4=agree, 5=strongly agree) was measured at V3. Participants in both intervention groups were provided with a wearable pulse oximeter (Checkme O2, Viatom, China). The trial commenced in May 2017 and ended in December 2017 and was approved by the Institutional Review Board of each participating hospital. In this study, the primary endpoint was the change of respiratory function parameters (6MWT, CAT, and mMRC) at V3 compared with the baseline.

Statistical Analysis

All statistical analyses were performed using SPSS, version 18.0 (IBM, Armonk, New York, United States). One-way analysis of variance was used to compare the baseline characteristics of the 3 groups. In addition, one-way analysis of variance with repeated measures was performed to analyze changes between visits. We considered $P<.05$ as a statistically significant difference. Based on previous studies showing 6MWT improvement in clinical trials, we hypothesized a mean difference of 6WMT to be >50 m in the intervention group versus 0 m in the control group after 12 weeks [27,28]. Assuming an SD of 60, a two-sided test of an alpha level of.05, a power of 80%, and a participant dropout rate of 20%, a sample size of 84 patients (28 per group) was required for the primary analysis.

Results

Pilot Study (Stage 1)

User Requirements for Mobile App and Wearable Device

To collect user requirements for the home-based COPD rehabilitation app and wearable devices, we recruited 11 patients (7 males and 4 females) for the interview. Textbox 1 describes the final user requirements.

In tandem with patient interviews, a comprehensive literature review and in-person consultations were obtained from health care professionals regarding the requirements for the app, wearable devices, and the patient monitoring website. In addition, patients were asked to perform a 30-minute walk every

day, and blood oxygen saturation (SpO_2) and heart rate were measured and displayed to users during exercise.

Usability Evaluation

After 6 weeks of use, a simple usability test was performed. Of initial 12 participants, 11 participants completed a 5-item usability questionnaire using a 5-point Likert scale. The results showed that the "Exercise Diary" was the highest and "Exercise Method" the lowest (Figure 2). The average score was 3.56.

Stage 2

Figure 3 shows the main components of our platform, *efil breath*, developed in Stage 2; it includes 1 wearable pulse oximeter, 2 mobile apps, and 1 patient monitoring website. The apps access time, distance and frequency of the exercise, heart rate, and SpO_2. The website collects patients' health data from the apps, which are used during future hospital visits.

Textbox 1. User requirements for the mobile app and wearable device.

User requirements for the mobile app

- App configuration should be easy to understand and use for all age groups.
- All menus pertinent to the current task should be displayed on the screen, and the menu structure should not be overly complicated.
- It should seamlessly integrate to wearable devices with smartphones.
- Biometric parameters of the patient heart rate, blood oxygen saturation (SpO_2), and calorie consumption should be locally and securely stored in the smartphone.
- Step-by-step exercise guidance should be provided that reflect patients' exercise capacity.
- Simple feedback of breathing difficulty during exercise should be included.
- Patient exercise history should be presented both graphically and numerically for easy peruse.
- Alarm function should be provided to alert the patient of critical health status (SpO_2 and heart rate) during exercise.

User requirements for wearable device

- It should be easy to wear.
- It should display patient's health status on the device screen.
- It should be easy to store and view measurements.

Figure 2. Usability evaluation results (Stage 1).

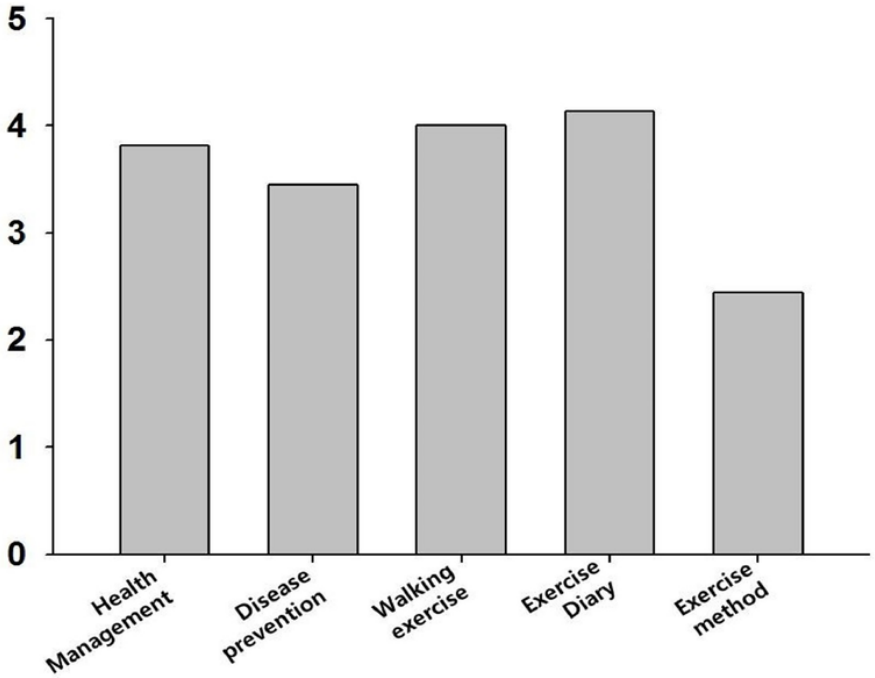
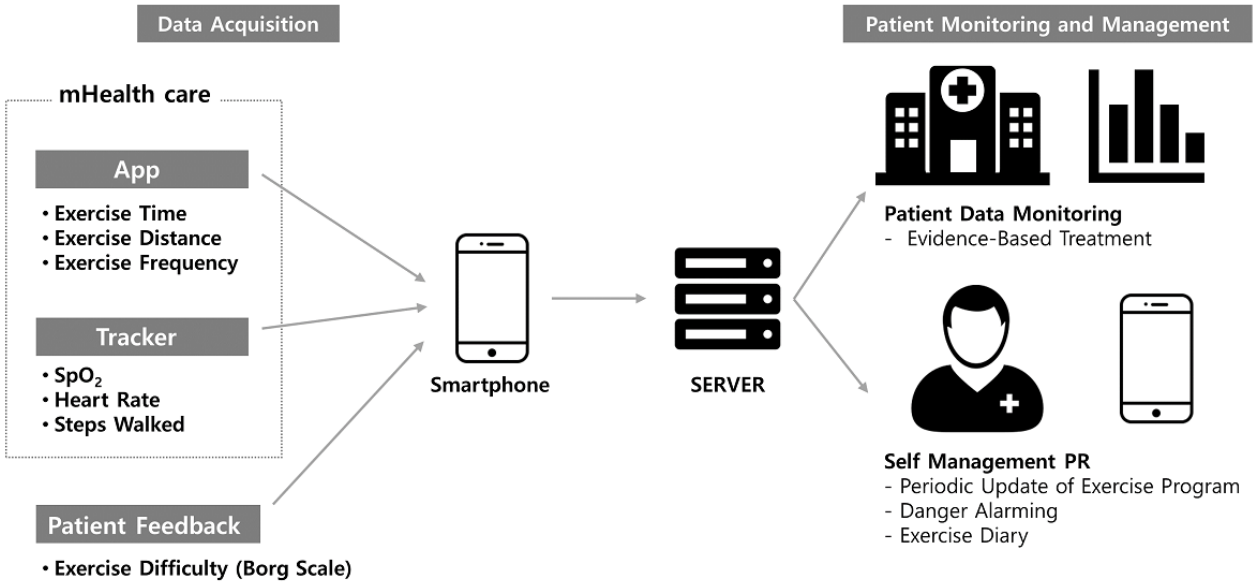


Figure 3. Architecture of the home-based mobile COPD care service. PR: pulmonary rehabilitation; SpO2: blood oxygen saturation.



Apps

The goal of Stage 1 was to enable patients with COPD to maintain, at least, a minimum level of exercise per day (30 minutes). However, the feedback at the end of the pilot study expressed the desire that the app should offer longer exercise regimens with varying intensity; this was confirmed by the fact that 45% (5/11) of participants after 2 weeks and 55% (6/11) after 4 weeks stated that the exercise target was set too low (which might give the opportunity to set new targets as the PR continued). Therefore, at Stage 2, we developed 2 apps, one with a fixed exercise regimen, and the other with an interactive regimen for mobile phones running on the Android operating system (version 4.4.4 or above), as shown in Figure 4. Android was chosen as it was the most commonly used operating system in Korea.

The apps were linked to a wearable pulse oximeter via Bluetooth (version 4.0), and activity-related data (exercise compliance rate, heart rate, and SpO_2) were sent to the monitoring website. Furthermore, a 6MWT was performed using the apps before initiating the exercise regimen.

Figure 5 shows the 2 exercise regimens used in the apps. The fixed regimen uses 6 levels of walking distance—600 m, 1200 m, 1800 m, 2400 m, 3000 m, and 3600 m. When the user achieves a fixed walking distance within a day and 14 times in total, the app increases the walking distance to the next level. The interactive regimen conforms to the exercise recommendations of the Consensus Document on Pulmonary Rehabilitation in Korea 2015 [29] and uses 12 levels [30]. The initial walking intensity is set to 80% of the maximum walking speed recorded in the 6MWT. Once initiated, a metronome in the app is used to help guide the walking speed of the patient. The level of exercise is then adjusted according to the modified Borg scale (0-10) [31] in the following manner. After the user has completed a walking session, the app with the interactive regimen asks to record the degree of breathing difficulty during exercise using the modified Borg scale. When a scale of ≤3 is recorded for 3 consecutive days, the exercise level goes up by 1, and when the scale persists ≥7, the level goes down by 1. In addition, when the final 12th level is reached, the patient is asked to perform a 6MWT, and the walking intensity is readjusted to an initial level of 7. The mobile phone vibrates when SpO_2 falls <90% in both apps, prompting the patient to pause.

Furthermore, the apps provide guided resistance exercises that can be used at leisure by patients. The exercises feature audioguides and clickable links to external videos for further guidance. A simple exercise diary is available for both apps to help summarize daily exercise results such as calories burned, duration of exercise, distance walked, etc.

Central Patient Monitoring Website

The patient monitoring website acts as a central storage of records and history of the PR activities of patients. The secure database ensures that each participating hospital can only access its patient data. The patient health status is sent from the apps to the website in which the health care professionals view patient records such as patient PR compliance, heart rate, and SpO_2 during exercise, and the 6MWT results.

The website provides a summary of the patient PR compliance of individual patients after enrollment. Figure 6 shows the PR records of a patient, such as their progress, heart rate, and distress. In addition, the website also enables health care professionals to view a list of patients with low SpO_2 (<90%) and those experiencing breathing difficulties (Borg scale score ≥7) who need closer monitoring during the use of the app.

Figure 4. Fixed and interactive exercise regimens.

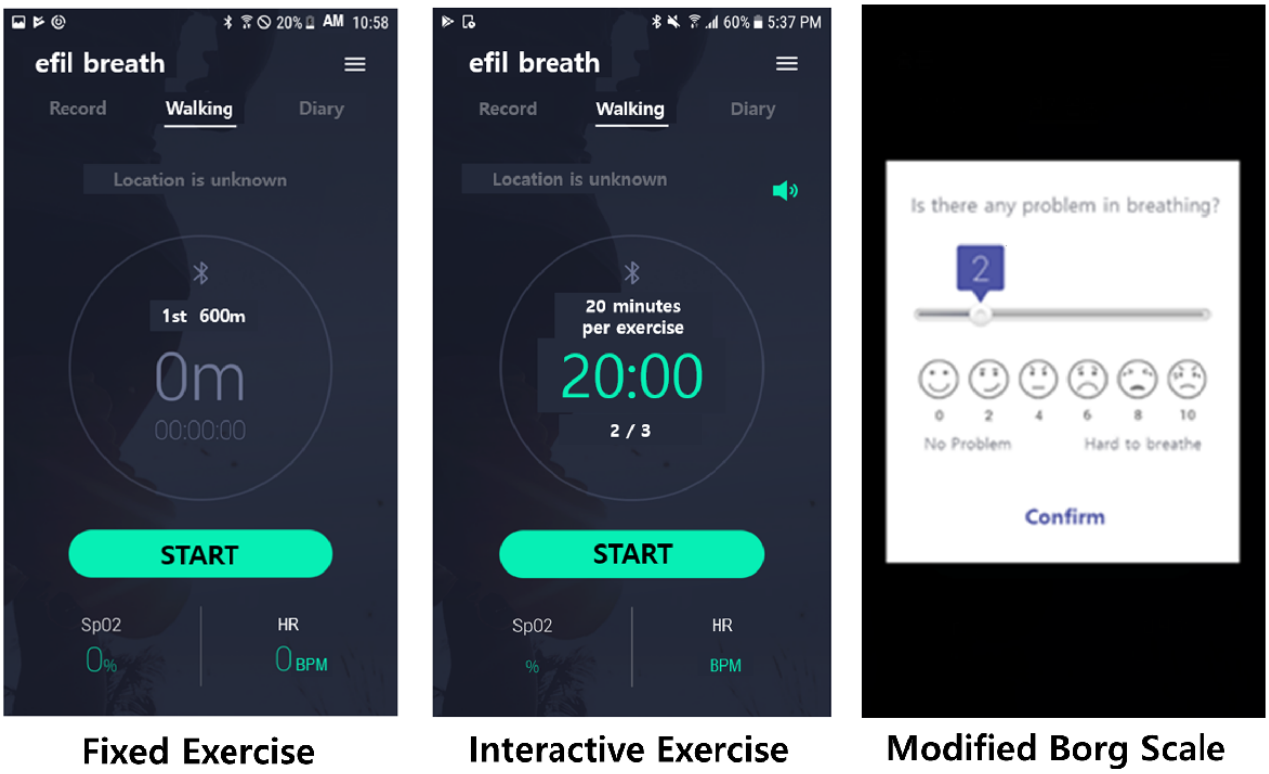


Figure 5. Walking exercise regimens: (1) fixed regimen and (2) interactive regimen.

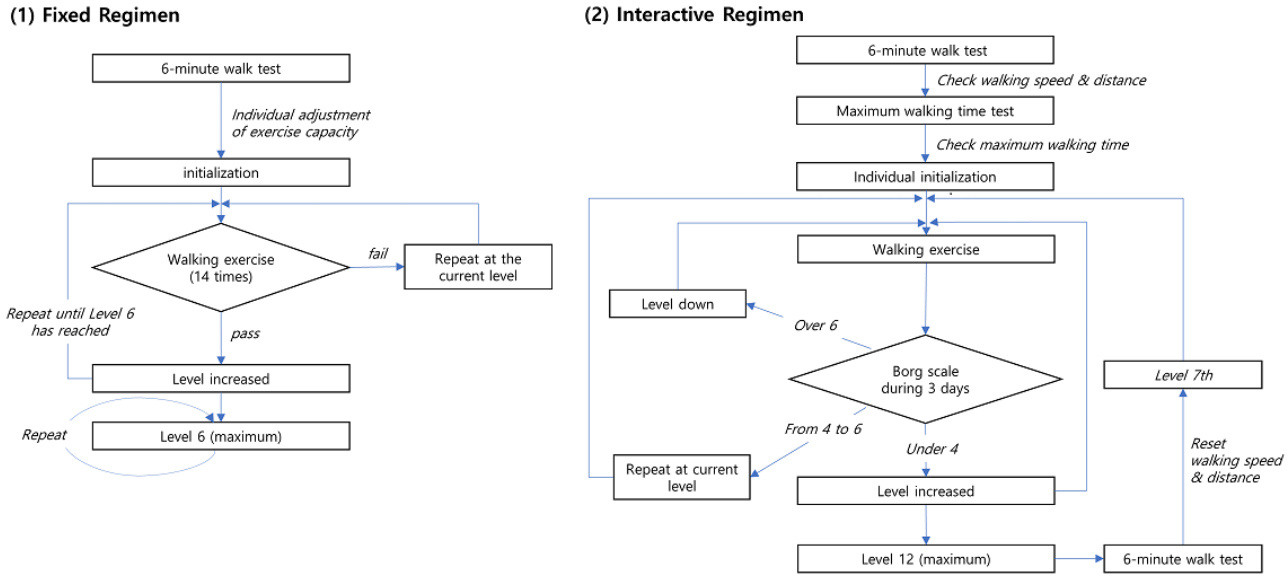


Figure 6. Patient pulmonary rehabilitation record.

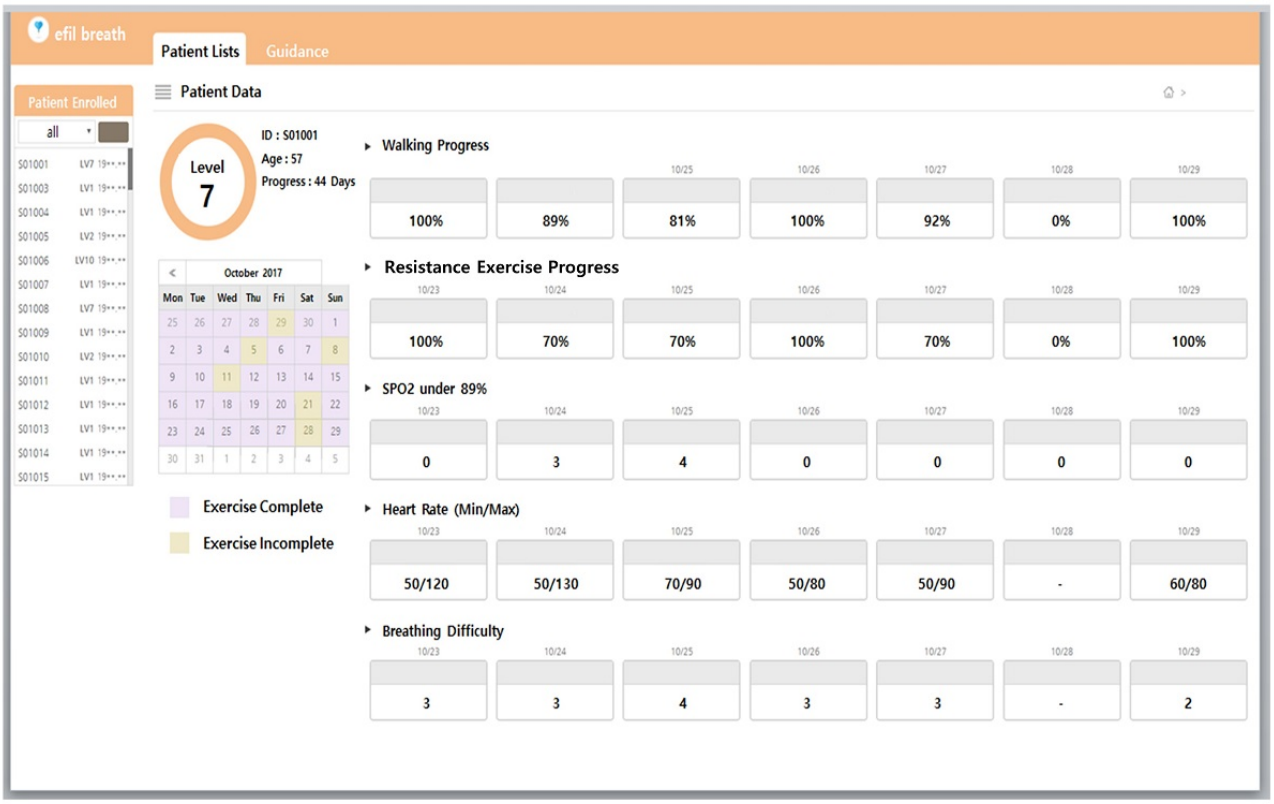
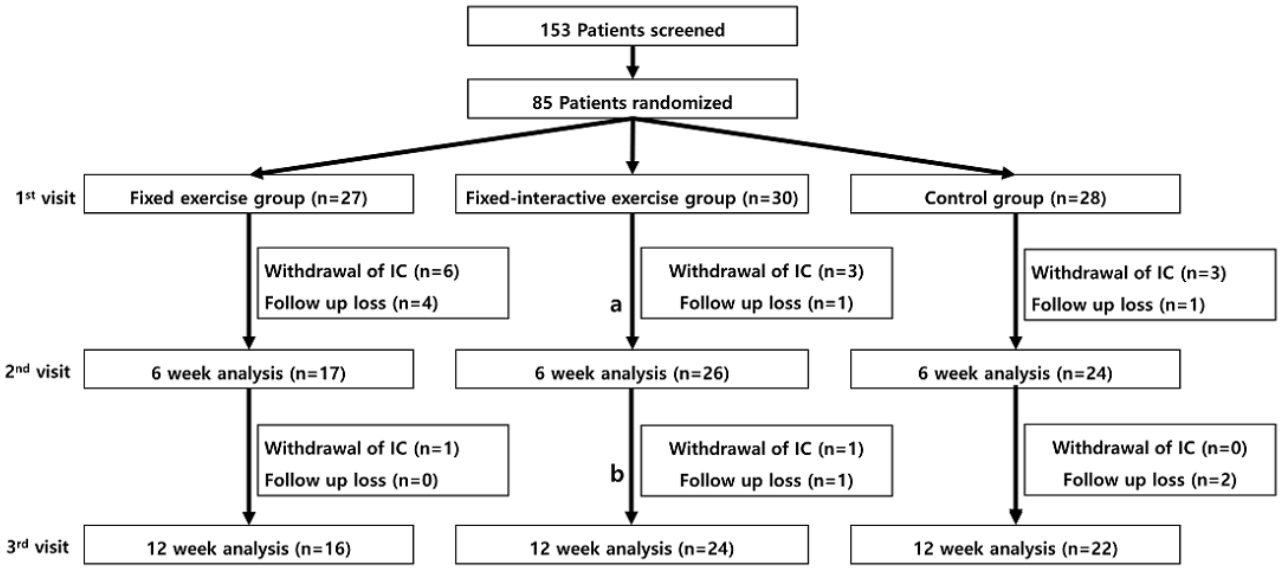


Figure 7. Study groups. IC: informed consent; a: Participants used fixed-regimen app; b: Participants used interactive-regimen app.



Participants' Characteristics in the Clinical Trial

A total of 153 patients were screened, and 85 participants were randomized into 3 groups (Figure 7). Of these, 40 participants in the intervention groups and 22 in the control group completed the 12-week clinical trial. Table 1 presents the baseline characteristics. Overall, 82% of participants were males, and 29.4% were current smokers who smoked for 39 pack-years on average. Around 80% of participants were in Global Initiative for Chronic Obstructive Lung Disease Stage I or II. Notably, no significant difference was observed between the groups at the baseline such as age, exercise capacity, and lung function (Table 1).

Table 1. Participant characteristics (N=85).

Characteristics	Fixed group (n=27)	Fixed-Interactive group (n=30)	Control group (n=28)	*P* value
Age (years), mean (SD)	64 (8)	65 (7)	64 (8)	.86
Age (years), range	47-79	47-76	45-80	N/A[a]
Gender, n (%)				
Male	23 (85)	26 (86)	21 (75)	.46
Female	4 (15)	4 (13)	7 (25)	.46
Body mass index (kg/m^2), mean (SD)	23.6 (3.7)	22.6 (3.0)	24.3 (3.9)	.19
Current smoker, n (%)	9 (33)	8 (27)	4 (29)	.85
Pack-year (years), mean (SD)	43 (25)	37 (19)	37 (17)	.57
6-min walking distance (m), mean (SD)	356 (98)	392 (84)	356 (84)	.21
FVC[b] (L), mean (SD)	2.80 (0.87)	2.83 (0.84)	2.88 (0.66)	.95
FEV1[c] (L), mean (SD)	1.52 (0.47)	1.52 (0.51)	1.43 (0.39)	.70
FEV1 (% predicted), mean (SD)	58.59 (15.75)	57.13 (16.74)	55.79 (15.48)	.81
FEV1/FVC (%), mean (SD)	55.04 (13.17)	56.73 (15.34)	52.67 (16.71)	.64
COPD assessment test score, mean (SD)	15.59 (7.84)	14.97 (8.48)	16.18 (16.71)	.87
Modified Medical Research Council, n (%)				
0	0 (0)	0 (0)	1 (4)	.23
1	11 (41)	16 (53)	6 (21))	.23
2	12 (44)	11 (37)	15 (54)	.23
3	3 (11)	3 (10)	6 (21)	.23
4	1 (4)	0 (0)	0 (0)	.23
Comorbidities, n (%)				
Yes	25 (93)	27 (90)	24 (89)	.91
No	2 (7)	3(10)	3 (11)	.91
Global Initiative for Chronic Obstructive Lung Disease stage, n (%)				
1	8 (31)	5 (17)	7 (28)	.93
2	14 (54)	18 (62)	13 (52)	.93
3	3 (12)	4 (14)	4 (16)	.93
4	1 (4)	2 (7)	1 (4)	.93

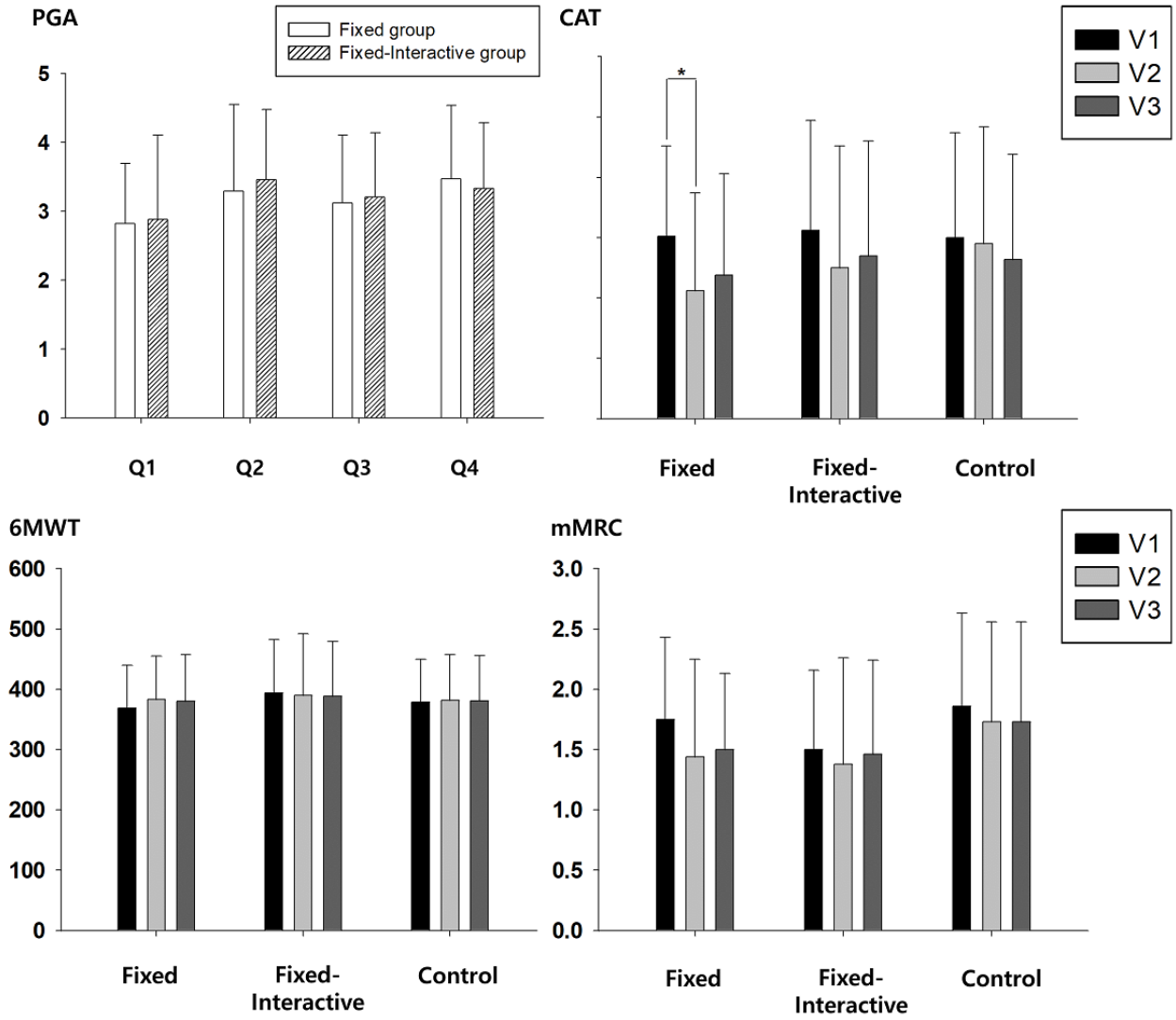
[a]N/A: not applicable.

[b]FVC: forced vital capacity.

[c]FEV1: forced expiratory volume in one second.

Regarding primary endpoints (Figure 8), CAT scores showed significant changes in the fixed group (*P*=.01) at V2, and some improvement was also observed in the fixed-interactive group (*P*=.06). The CAT scores at V3, however, did not show further improvement in both intervention groups. No significant change was observed in CAT scores in the control group throughout the trial. In addition, 6MWT and mMRC did not show statistically significant changes at V2 or V3 in all groups. PGA was measured at V3 for both fixed and fixed-interactive regimens, which showed a moderate level of satisfaction (min-max, 2.8-3.5) regarding the rehabilitation education content (Q2), helpfulness of content toward physical activity (Q3), and management of exercise and physical strength (Q4). The overall satisfaction of the apps (Q1) received an average of 2.8 points for both regimens.

Figure 8. Respiratory function parameter changes and the patient global assessment of trial participants. PGA: patient global assessment; CAT: COPD assessment test; 6MWT: 6-minute walk test; mMRC: modified Medical Research Council; V1: baseline; V2: 6 weeks; V3: 12 weeks.



Discussion

Principal Findings

Mobile PR for use by patients with COPD has great potential in improving health outcomes for patients, especially when it incorporates standardized guidelines for PR, and malleable exercise programs that can accommodate the diverse physical capacity of patients. Therefore, this study aimed to develop a mobile PR platform for COPD patients that offers an opportunity to observe the improvement or maintenance of daily physical capacity and QoL. The final technological aspects of this study consisted of (1) 2 mobile apps, one with a fixed exercise regimen and the other with flexible exercise regimen in accordance with the level of physical capacity; (2) a secure COPD patient management and monitoring server with a database used for better patient care. Moreover, our first randomized multicenter-based clinical trial in Korea demonstrated the benefits of applying mobile technology to the HBR of COPD patients.

Among respiratory function parameters, CAT scores showed significant improvement after 6 weeks in the fixed exercise group. As a matter of fact, both intervention groups underwent a fixed exercise regimen for the first 6 weeks. The statistical significance of improvement of CAT scores was high (P=.002) in the sum of patients in both groups after 6 weeks. Meanwhile, the majority (80%) of study participants in all groups had mild or moderate disease severity (Global Initiative for Chronic Obstructive Lung Disease stages I and II), and their 6MWT ranged 350-400 m at the baseline; this might explain why the 6MWT did not show significant improvement at V2 or V3. In addition, mMRC, a change-resistant outcome measure, did not show meaningful improvement in our trial, yet correlations between the measured CAT and mMRC changes were present in this study. Useful as it may, mMRC is more of a subjective value ranging from 0 to 4. Considering our patient population, the baseline respiratory function, exercise regimen, and study period, CAT may be the better outcome measure than mMRC in this type of study or even future trials [32].

Regarding the demographics of participants, we first speculated that the interactive regimen or app may present some difficulty in its use, owing to a relatively more complex interface. However, the difference in outcomes between the fixed and fixed-interactive regimens was interestingly largely insignificant.

Despite the results, further refinement of the user interface would be necessary to assist users of our platform.

Limitations

There are several limitations in the trial. First, study subjects were aware to which group they were allocated to during the study. We attempted to minimize further bias by blinding the person who obtained the primary endpoints or analyzed the data. The dropout rate in the intervention groups was noted to be slightly higher than expected, indicating that ongoing patient education and feedback would be required to maximize the benefits of adherence and better secure the merits of mobile PR. Hence, more studies are needed to direct the suitable outcome measure to assess the effectiveness of the utilization of appropriate mobile PR platforms, especially in use for patients with COPD.

Conclusions

mHealth technology is on the verge of being sufficiently robust to be incorporated as an ancillary component of chronic disease management and rehabilitation. Its efficacy and relevance as an alternative or supplemental means for COPD rehabilitation can be strengthened by accumulating evidence in mobile rehabilitation programs and services; this will enable the prescription of flexible exercise regimens and commensurate with patients' physical capacities. Moreover, a well-designed rehabilitation monitoring and management of patients with COPD will fill the gap left open by traditional center-based rehabilitation programs. Our *efil breath* is the first attempt in Korea at developing a comprehensive mHealth management platform for the rehabilitation of patients with COPD. Further research is required to study the long-term benefits of compatible mobile COPD rehabilitation services and to investigate the benefit of mobile-only COPD rehabilitation services for patients without access to local or regional clinical health care centers or health care providers.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 500KB - mhealth_v6i8e10502_app1.pdf]

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Abbreviations

CAT: COPD assessment test
COPD: chronic obstructive pulmonary disease
PGA: patient global assessment
PR: pulmonary rehabilitation
QoL: quality of life
HBR: home-based rehabilitation

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Original Paper

A Smartphone Game-Based Intervention (Tumaini) to Prevent HIV Among Young Africans: Pilot Randomized Controlled Trial

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Abstract

Background: There is a pressing need to ensure that youth in high HIV prevalence settings are prepared for a safer sexual debut. Smartphone ownership is increasing dramatically in low-income and middle-income countries. Smartphone games that are appropriately grounded in behavioral theory and evidence-based practice have the potential to become valuable tools in youth HIV prevention efforts in Sub-Saharan Africa.

Objective: To pilot-test a theory-based, empirically grounded smartphone game for young Kenyans designed to increase age and condom use at first sex, aiming to establish directionality of effects on behavior change.

Methods: Tumaini ("hope for the future" in Swahili) is an interactive, narrative-based game grounded in social cognitive theory. A randomized controlled pilot study was conducted in Kisumu, Western Kenya, from April to June 2017 with 60 participants aged 11-14 (mean 12.7) years. Intervention arm participants (n=30) were provided with an Android smartphone with Tumaini installed on it and were instructed to play the game for at least 1 hour a day for 16 days; control arm participants (n=30) received no intervention. All participants completed a survey on behavioral mediators, delivered via an audio computer-assisted self-interview system at baseline (T1), post intervention (T2), and at 6 weeks postintervention (T3). The postintervention survey for intervention arm participants included questions eliciting feedback on the game. Intervention arm participants and their parents participated in 8 postintervention focus group discussions. Game log files were analyzed to calculate the length of exposure to the game. Behavioral survey data were analyzed using two-sample *t* tests to compare mean change from T1 to T2 and to T3 for intervention versus control arm participants. Descriptive statistics on game feedback questions were computed. Focus group transcripts were uploaded to MAXQDA software, where they were labeled with deductive and inductive codes. Data were analyzed thematically and compared across demographics.

Results: Intervention arm participants played Tumaini for a mean of approximately 27 hours. The intervention arm showed significant gains in sexual health-related knowledge and self-efficacy (both $P<.001$), behavioral intention for risk-avoidance strategies and sexual risk communication ($P=.006$), and overall survey scores ($P<.001$) compared with the control arm at T3. The postintervention survey revealed high subjective measures of the game's value, relevance, and appeal. Focus groups identified a wide range of knowledge and skills the participants had gained, including setting goals and planning how to achieve them, which was perceived as a key motivator for avoiding or reducing risk.

Conclusions: The study supports the need for further research to assess the efficacy of the game-based intervention. If proven efficacious, smartphone games have the potential to dramatically increase the reach of culturally adapted behavioral interventions while ensuring fidelity to intervention design.

Trial Registration: ClinicalTrials.gov NCT03054051; http://clinicaltrials.gov/ct2/show/NCT03054051 (Archived by WebCite at http://www.webcitation.org/70U2gCNtW)

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KEYWORDS

HIV; youth; Sub-Saharan Africa; Kenya; serious game; narrative; smartphone; pilot study; randomized controlled trial; mhealth; prevention

Introduction

A third of all new adult HIV infections occur in young people aged 15-24 years [1]. In African countries most affected by HIV, demographic change is increasing the size of adolescent cohorts, thereby increasing their contribution to HIV incidence [2]. In addition, this age group suffers disproportionately high levels of HIV-related morbidity and mortality [3]. Reaching preadolescents with prerisk prevention interventions may help establish lifelong patterns of safer sexual behavior and avert high-risk behaviors in the future [4,5]; for example, those who use condoms at first sex are more likely to use them consistently in the future [6,7].

Electronic games have the potential to be a valuable tool in youth HIV prevention in Sub-Saharan Africa if they are appropriately grounded in behavioral and instructional theory [8,9], informed by existing evidence-based interventions [10], and contextually appropriate. Smartphone ownership is increasing dramatically in emerging and developing nations [11], opening up new possibilities for delivering highly interactive, culturally relevant mHealth interventions at scale and low cost. Serious digital games [12] have high entertainment and motivational appeal for young people. They also have distinctive advantages from the perspective of pedagogy and behavioral theory. By allowing players to experience real agency in a virtual and safe environment, well-designed games provide a level of experiential learning unparalleled by many other interventions. They are particularly well aligned with key constructs of social cognitive theory [13], allowing for both cognitive and behavioral rehearsal through role-play and simulation. Although a relatively limited number of games to date have been designed with solid theoretical grounding and rigorously evaluated [14-20], there is evidence of their effectiveness for health, including clinical, outcomes [21-28].

In addition to their appeal, mobile games for sexual health have further distinctive advantages over common group-based, evidence-based interventions [29]. They have considerable potential for scalability, low cost per person reached, and cultural adaptability. Exposure to the intervention can be reliably measured through automated data collection, which can also help pinpoint "active ingredients," contributing to the building of behavioral, pedagogical, and game design theory. Fidelity to intervention design is much more likely as the intervention is no longer dependent on a skilled cadre of facilitators. Electronic delivery offers potential for remote updates, while portability via mobile handsets can allow the intervention to link into people's everyday lives, offering more sustained intervention exposure.

There is a pressing need to assess the feasibility of using game technologies for HIV prevention in low-resource settings and their potential for efficacy. In this study, we pilot-tested an interactive narrative-based smartphone game to prevent HIV among preadolescents in Kisumu Town, Western Kenya, where adult HIV prevalence (19.9%) is over three times the national average [30,31]. We describe here results from this pilot study of the game's potential to influence behavioral mediators of increased age and condom use at sexual debut.

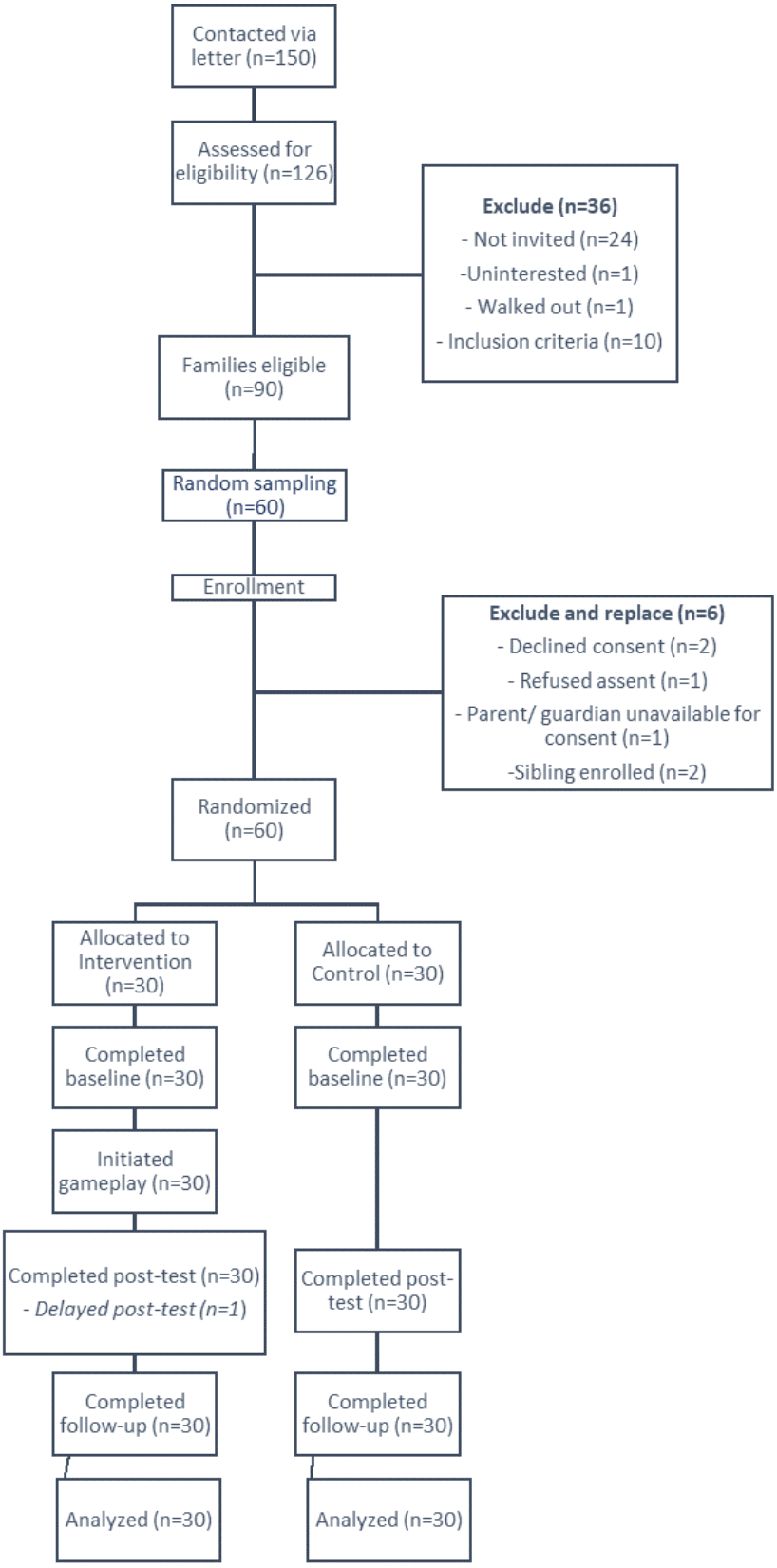
Methods

Study Design

We conducted an individually randomized pilot study of the game *Tumaini* ("hope for the future" in Swahili) in a sample of 60 male and female preadolescents aged 11-14 years in periurban and urban Kisumu, Kenya, between April and June 2017. The intervention was carried out over 16 days during the 3-week school holiday in April 2017 (Figure 1). Assessment was performed via a survey at baseline (T1), immediately postintervention (T2), and at 6 weeks postintervention (T3). Intervention arm participants also took part in focus group discussions (FGDs) after the intervention to provide additional data on the game experience. The study was approved by the Emory University and Kenya Medical Research Institute (KEMRI) Institutional Review Boards and was registered with ClinicalTrials.gov (NCT03054051).

The eligibility criteria for participation were as follows: age 11-14 years, grade 3-4 English proficiency on the Flesch-Kincaid Reading Scale, residence in Kisumu Town, and willingness to complete all study activities. Letters were distributed through schools to parents of age-eligible children inviting them to attend informational meetings. Consent and assent were secured at the home of the participants, following an explanation of the study. Parents consented to participate in the postintervention focus groups if their child was randomized to the intervention arm. No incentives were provided.

Figure 1. CONSORT flow diagram.



Participants

Randomization

Participants (n=60) were randomized 1:1 to the control arm (n=30) or the intervention (game) arm (n=30) of the study. Randomization, stratified by the school attended by the participant, gender, and age, was undertaken using a coin flip by a blinded research team member. Within each school, gender, and age block of participants, coin flips were repeated until participants were equally distributed between the two study

arms. Assignments were revealed to participants after they had completed the baseline assessment.

Intervention

Participants assigned to the intervention arm played *Tumaini* (Multimedia Appendix 1), a theoretically grounded, narrative-based game for inexpensive Android smartphones developed in collaboration with a US commercial game developer, Realtime Associates, and with input from US-based and Kenyan specialists in adolescent sexual health and Kenyan preadolescents and their parents.

Tumaini is designed to increase age and condom use at first sex by increasing knowledge about sexual health and HIV; building risk-avoidance and risk-reduction skills and related self-efficacy; challenging HIV stigma and harmful gender norms and attitudes; fostering future orientation, goal setting, and planning; and promoting dialogue with adult mentors.

The game's design draws on social behavioral theory, including social cognitive theory [13] and the theory of possible selves [32]; existing evidence-based interventions for youth HIV prevention [33,34-36]; and games for health [8,12,17,37] and entertainment-education [38] literature. It is grounded in research on HIV-themed narratives written by young Africans [39-41]. *Tumaini* uses interactive narrative to promote observational learning, cognitive and behavioral rehearsal, problem-solving, and immersion.

The game is made up of 3 intersecting components. First, the role-playing narrative (Multimedia Appendix 2) uses a "choose-your-own-adventure" format that allows the player to make decisions for 6 diverse characters and observe the consequences of those choices in the characters' lives. At the start of the game, the characters are 3 boys and 3 girls aged 11-14 years. Players role-play each of the 6 young characters as they pass into or through adolescence and face real-life challenges that the players are likely to face at some stage in their own lives. These include peer pressure, puberty, violence, and decisions about smoking, alcohol, drugs, and sex. The story takes place over 18 chapters, distributed over 3 levels (Multimedia Appendix 3). For example, in the second level, the player chooses whether to have a male character, Juma, drink alcohol at a party. Later in the chapter, this decision affects Juma, his sexual decision-making, his ability to recognize the risks associated with failing to use a condom, and his options regarding, and successful negotiation of, condom use. These choices regarding sex and condom use have consequences on his sexual health in a subsequent chapter. Second, the mini-games are designed to reinforce knowledge and skills relating to puberty; HIV and other sexually transmitted infections (STIs); pregnancy and avoiding pregnancy; identifying, avoiding, and responding to risk situations; and resisting peer pressure. Mini-games take various forms, including quizzes, jigsaws, and role-playing scenarios with feedback. The topics of the mini-games coordinate with the topics in the role-playing narrative. The third component, *My Story*, incorporates a customizable avatar and invites players to connect the knowledge and skills they learn in the game with their own lives, including through setting goals and how they will achieve them. As with the mini-games, the topics for this part of the game coordinate with the main role-playing narrative.

Tumaini comprises approximately 12 hours of discrete gameplay and is designed to be replayed so that players can observe the outcomes of different decisions. Each chapter is accompanied by either a mini-game or a *My Story* component. The player is rewarded with prizes (furniture and other items for the player's virtual home) upon successful completion of game components. There are 40 possible endings in the role-playing game across the 6 characters. Once the player finishes the last chapter and observes the long-term outcomes for the characters, he or she can replay and collect the remaining prizes by making different choices and observing different outcomes. This rewards system thus encourages players to explore the game and experience the consequences of both health-protective and harmful choices.

Intervention arm participants completed a 45-minute informational onboarding session, including instructions on the interface, technology, and game content. They were instructed to play at least 1 hour per day for the 16 days of the study and asked not to share their own gameplay profile with others. The game interface allows for 5 additional players' profiles so that others may play without compromising the enrolled player's data. Intervention participants were provided with a phone with the game preloaded and used it at their own pace for the duration of the intervention. Control participants received standard of care, namely no additional intervention beyond any existing sex education from family, school, and peers. No specific data on the content or source of this education were collected from participants. All study smartphones were returned by the participants at the end of the intervention period.

Survey Measures

All participants completed a self-administered behavioral survey at T1, T2, and T3. The English language survey was completed at the KEMRI offices, using the audio computer-assisted self-interview (ACASI) system with headphones to protect privacy. It took approximately 1 hour to complete. Surveys were the same for participants in the control and intervention arms for T1 and T3: participants in the intervention arm completed additional survey items at T2, providing subjective assessments of the game itself, including its appeal, value, and relevance.

The behavioral survey assessed mediators associated with age at onset of sexual activity and condom use at sexual debut, including knowledge, self-efficacy, risk assessment, perceived social norms, attitudes, and behavioral intentions. Thematic areas included puberty, sex, relationships, peer pressure, condom use, HIV, STIs, pregnancy, and alcohol and drugs. Table 1 provides examples of the questions and response options by theoretical construct.

Table 1. Behavioral survey measures: sample questions and response options by theoretical construct.

Theoretical construct	Sample questions	Response options	Thematic area
Knowledge	*Can a girl get pregnant the first time she has sex?*	1. Yes 2. No	Pregnancy
Attitudes	*There are times when it is ok to force someone to have sex.* Do you think this is true?	1. Yes 2. Maybe 3. No	Sex
Self-efficacy	*If you have a question about puberty, how sure are you that you could ask someone you trust for advice?*	1. Very sure 2. A little sure 3. Not sure	Puberty
Intention	*Imagine that in several years you are in a couple.* Would you talk with your partner about preventing HIV?	1. Yes 2. No	Condoms
Perceived social norms	"*Most young people like me would not want to be friends with someone who has HIV.*" Do you think this is true?	1. Yes 2. Maybe 3. No	HIV
Sources of advice	*If you have a question about sex, who will you talk to?*	1. Mother 2. Father 3. Brother/sister 4. Grandmother/grandfather 5. Aunt /uncle 6. Friend 7. Religious leader 8. Teacher 9. Doctor or nurse 10. A peer educator 11. Someone else 12. No one	Sex

Where possible, items were drawn from existing surveys with a focus on instruments that had been validated in Sub-Saharan African youth populations [33,42-52]. Source literature for these measures included the tool used as part of the evaluation of the Families Matter! Program (FMP) with a similar Nyanza youth population [52]; measures validated with adolescents in Botswana as part of a randomized controlled trial (RCT) of Project AIM [33] conducted by CDC's Division of Global HIV and TB; the questionnaire from the Guttmacher Institute's Protecting the Next Generation Project, used with adolescents in Uganda [42]; Kalichman et al's brief HIV stigma scale, validated in South Africa [43]; IMB subscales (including, eg, the Perceived Effectiveness of AIDS Preventive Behavior sub-scale) [44], used with adolescents in South Africa; the Gender Equitable Men (GEM) Scale [47]; and CARE's Gender Equity Index (GEI; modeled after the GEM scale for 10-14 year olds and tested and implemented in Kenya) [45]. Items were adapted, where necessary, to be culturally, linguistically, and age-appropriate and consistent in formatting. A draft instrument was presented to parents for acceptability, then cognitively tested in 3 rounds with preadolescents to ensure acceptability, consistent interpretation, and face validity of the questions. This resulted in, for example, our abandoning 5-point scales as too complex for very young adolescents with limited English proficiency. Also in the interests of age-appropriateness, we included three hypothetical risk scenarios presented as vignettes [53] that contextualized situational risk assessment, behavioral intention, and self-efficacy (see Table 2). The final draft of the instrument was pilot-tested with preadolescents.

Table 2. Behavioral survey measures: example of scenario-based question. The Vignette: *Imagine that a boy/girl you like invites you to his/her house after school. He/She tells you that the two of you will be alone.*

Theoretical construct	Questions	Response options
Risk assessment	*How safe is this situation?*	1. Safe 2. A little unsafe 3. Very unsafe
Intention to avoid risk	*Would you go with him/her?*	1. Yes 2. No
Self-efficacy for risk avoidance	*If you did not want to go, how sure are you that you could say no firmly?*	1. Very sure 2. A little sure 3. Not sure

Knowledge questions (15 items) focused on puberty, pregnancy, HIV and STIs, alcohol and drugs, and condoms, including procedural knowledge for condom use. These items drew on measures from Save the Children's Adolescent Puberty Workbook assessment questionnaire [51], the Guttmacher Institute's Protecting the Next Generation Project survey [42], Kalichman et al's brief HIV stigma scale [43], and Catania et al's instrument from an assessment of the prevalence of AIDS-related risk factors [48]. The *self-efficacy* domain (9 items) drew from the measures used in the evaluation of the Families Matter! Program (FMP) [52], Save the Children's questionnaire [51], Johnson-Mallard's assessment of women's self-efficacy [50], and Fisher et al's IMB subscales [44]. This domain included questions about seeking advice about puberty, refusing to engage in risky situations, using a condom, and discussing HIV and pregnancy prevention with a partner; some questions linked to the hypothetical scenarios were presented as short vignettes, which also included measures of behavioral intention and risk assessment. In addition to the scenario-based questions, *behavioral intention* items (6 items) included measures of intention to communicate with a partner about preventing HIV or pregnancy. *Risk assessment* (4 items) also included an item about unprotected sex. Participants were asked to identify whom they would talk to about puberty, relationships, or sex from a list of individuals they might identify as trusted *sources of advice.* This drew on similar questions used for the evaluation of FMP [52]. *Attitude* questions (15 items) were related to control over one's future, sex, condom use, HIV, and gender. These items were drawn from Kalichman et al's scales [43], Catania et al's measures [48], the GEM scale [47], CARE's GEI [45], the evaluation of FMP [52], Norris et al's Sexual Abstinence Behavior Scale [49], and the questionnaire used in the evaluation of Project AIM by CDC's Division of Global HIV and TB [33]. The thematic areas addressed by the *perceived social norms* (6 items) questions were sex, condom use, HIV, and gender. These measures were adapted from items in Norris et al's [49] and Kalichman et al's [43] scales, and the GEM [47] and GEI [45] scales.

Where necessary, definitions of certain terms (including "condom" and "sex") were included for clarity. The survey also collected demographic information at baseline: age, religion, living situation, school grade, access to computers and smartphones, and proxies for economic status (materials from which home was constructed and number of rooms in the house). ACASI survey data were downloaded as comma-separated values files and compiled into an Excel file for cleaning and analysis.

Additional Measures

The game software automatically generates a user log file that records all in-app activity. Each user interaction is time-stamped, allowing for calculation of time spent on specific components of the game, as well as total exposure time.

Intervention arm participants (n=27) and their parents (n=22) took part in FGDs (n=8) between T2 and T3. The four adolescent focus groups were stratified by age (11-12 and 13-14 years) and gender of the study child; the four parent focus groups were stratified by the age of the study child. Questions in postintervention discussions with participants included what they had learned from the game. Parental focus group questions also included how their children had played the game and communicated about it and with whom.

Data Analysis

Preliminary cleaning of survey data was conducted in MS Excel, with additional cleaning and all analyses completed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). All control arm participants were included in analyses. One participant from the intervention arm was removed from analyses of effect at T2 due to delayed completion of the T2 survey. His data were retained for T1-T3 analyses, as he completed all other study activities on time. Descriptive statistics on demographic questions and game feedback questions were computed.

Changes in behavioral mediators of sexual behavior from baseline (T1) were compared between the two study arms at T2 and T3 in an intent-to-treat analysis, using two-tailed two-sample *t* tests on individual survey items, as well as domain-level composite scores. This approach was used to identify both which theoretical mediators and which thematic areas were influenced by the intervention. Composite scores (eg, knowledge) were calculated as the equally weighted sum of the individual items within that domain (or thematic area) for which there were objectively correct or incorrect answers. In composite scores, each correct answer was worth 1 point. Analyses were conducted across the whole sample, as well as stratified by age and gender of the participants.

Data from the phone log files were downloaded as .txt files and converted into Excel files, and exposure time was calculated from time stamps. Focus group transcripts were translated into English and uploaded to MAXQDA 2018 (VERBI Software, Berlin, Germany), where they were labeled with inductive and deductive codes by two coders. The data were analyzed thematically and compared across demographics.

Results

Description of Study Sample

We recruited and enrolled 60 adolescent participants. Half of the participants were allocated to the intervention arm. All adolescents who were recruited completed all 3 study visits, and all intervention arm participants initiated gameplay. Participant demographics are presented in Table 3. There were no significant demographic differences between the two arms. Preliminary calculations of exposure indicate that the intervention arm played *Tumaini* a mean of approximately 27 hours over the 16 days of the intervention.

Table 3. Participant demographics.

Characteristics	Intervention (n=30)	Control (n=30)	Total (N=60)
Gender, n (%)			
Female	14 (47)	16 (53)	30 (50)
Male	16 (53)	14 (47)	30 (50)
Age (years), mean (SD)	12.8 (1)	12.6 (1)	12.7 (1)
Religion, n (%)			
Catholic	14 (47)	14 (47)	28 (47)
Protestant/Anglican	8 (27)	2 (7)	10 (17)
Muslim	2 (7)	4 (13)	6 (10)
Seventh Day Adventist	4 (13)	4 (13)	8 (13)
Other	2 (7)	6 (20)	8 (13)
Living with both parents, n (%)	22 (73)	20 (67)	42 (70)
Housing type, n (%)			
Permanent	8 (27)	13 (43)	21 (35)
Semi-permanent	11 (37)	6 (20)	17 (28)
Temporary	9 (30)	6 (20)	15 (25)
Iron sheets	2 (7)	4 (13)	6 (10)
Smartphone ownership, n (%); check all that apply			
Parent	21 (70)	15 (50)	36 (60)
Self	2 (7)	1 (3)	3 (5)
Sibling	11 (37)	5 (17)	16 (27)
Other adult	4 (13)	1 (3)	5 (8)
No one	3 (10)	8 (27)	11 (18)
Have used a smartphone before baseline, n (%)	22 (73)	19 (63)	41 (68)

Behavioral Survey Outcomes

Analyses of changes in survey scores between T1 and T2 and between T1 and T3 showed a significant effect of the intervention on individual survey items and on composite scores for certain theoretical domains. Results from the two-sample *t* tests comparing changes in scores from T1 to T3 across the two study arms are reported in the following format: mean score change and SD for each study arm, t-statistic with associated degrees of freedom, and *P* value.

There was no significant difference in the overall baseline scores between the two arms: intervention arm, mean 30.73 (SD 5.32) and control arm, mean 31.13 (SD 4.74); for baseline difference, t_{58}=0.30, *P*=.76 (see Table 4). The intervention arm saw significantly greater gains in the overall survey scores (mean 8.03, SD 4.46) than the control arm (mean 2.23, SD 3.88) at T3 (t_{58}=−5.38, *P*<.001). At T3, the intervention arm showed significant gains in knowledge (mean 3.80, SD 2.37) compared with the control arm (mean 0.80, SD 2.14) (t_{58}=−5.14, *P*<.001).

At T3, the intervention arm participants also showed significant sustained increases in self-efficacy scores (mean 2.03, SD 1.83) compared with the control arm (mean 0.63, SD 1.20) (t_{58}=−3.50, *P*=<.001).

At baseline, participants reported having 7-8 trusted individuals they could turn to for advice. By T3, players had identified a mean of 3.10 additional sources of advice compared with 1.53 for the control arm (t_{58}=−1.19, *P*=.24).

At T3, the intervention arm participants' score gains for behavioral intentions for risk avoidance and reduction showed significant increases compared with those of the control arm (t_{58}=−2.87, *P*=.006), although they had not been significant at T2. No significant change was seen in the intervention arm participants' assessment of risk, attitudinal measures, or perceived social norms compared with the control arm.

The intervention arm showed significant increases in survey scores across constructs (eg, knowledge, attitudes, risk assessment, self-efficacy, and behavioral intentions) in the thematic areas of puberty (t_{58}=−3.46, *P*=.001), HIV (t_{58}=−3.25, *P*=.002), condoms (t_{58}=−4.06, *P*=.001), and pressure from adults and peers (t_{58}=−2.41, *P*=0.02) compared with the control arm (Table 5).

Table 4. Baseline scores and changes in knowledge, attitudes, intentions, risk assessment, self-efficacy, perception of social norms, sources of advice, and overall score on the behavioral survey between baseline (T1) and postintervention (T2) and between baseline and 6 weeks postintervention (T3) by study condition.

Behavioral mediator (mean change from baseline)	Number of items, maximum possible score	Intervention (n=30)	Control (n=30)	*P* value
Knowledge, mean (SD)	15			
Baseline score[a]		7.33 (2.12)	7.93 (1.74)	
T1-T2[b]		4.76[c] (2.96)	0.27 (2.07)	<.001
T1-T3		3.80 (2.37)	0.80 (2.14)	<.001
Self-efficacy, mean (SD)	9			
Baseline score[a]		5.87 (2.03)	6.22 (2.41)	
T1-T2[b]		1.95 (1.57)	0.47 (1.07)	<.001
T1-T3		2.03 (1.83)	0.63 (1.20)	<.001
Sources of advice, mean (SD)	33			
Baseline score[a]		7.57 (5.79)	7.07 (6.59)	
T1-T2[b]		2.24 (4.09)	1.13 (4.19)	.31
T1-T3		3.00 (4.79)	1.53 (4.73)	.24
Risk assessment, mean (SD)	4			
Baseline score[a]		2.67 (1.25)	2.45 (1.50)	
T1-T2[b]		0.41 (1.17)	0.00 (1.23)	.19
T1-T3		0.52 (0.99)	0.07 (1.03)	.09
Behavioral intention, mean (SD)	6			
Baseline score[a]		4.43 (0.77)	4.83 (0.70)	
T1-T2[b]		0.28 (0.86)	−0.12 (0.76)	.07
T1-T3		0.43 (0.75)	−0.15 (0.82)	.006
Attitudes, mean (SD)	15			
Baseline score[a]		9.95 (2.30)	9.22 (2.07)	
T1-T2[b]		0.74 (2.13)	0.82 (1.95)	.89
T1-T3		1.18 (1.82)	0.80 (2.25)	.47
Perceived social norms, mean (SD)	6			
Baseline score[a]		3.72 (1.12)	3.67 (1.24)	
T1-T2[b]		0.47 (1.26)	−0.07 (1.30)	.12
T1-T3		0.37 (0.37)	−0.15 (1.35)	.14
Total score, mean (SD)	49[d]			
Baseline score[a]		30.73 (5.32)	31.13 (4.74)	
T1-T2[b]		8.09 (5.78)	1.58 (3.45)	<.001
T1-T3		8.03 (4.46)	2.23 (3.88)	<.001

[a]Mean domain score at baseline for participants in each study arm.

[b]T1-T2 calculations based on n=59.

[c]Positive values indicate a desirable change in scores.

[d]Total survey score does not include questions where there is no objectively correct or incorrect answer (sources of advice and perceived social norms).

Table 5. Changes in thematic domain scores (combined knowledge, attitudes, intentions, risk perception, and self-efficacy scores) on the behavioral survey between baseline (T1) and postintervention (T2) and between baseline and 6 weeks postintervention (T3) by study condition.

Thematic domains (mean change from baseline)	Number of items, maximum possible score	Intervention (n=30)	Control (n=30)	*P* value
Future, mean (SD)	1			
Baseline score[a]		0.86 (0.30)	0.90 (0.24)	
T1-T2[b]		0.05[c] (0.34)	0.10 (0.34)	.55
T1-T3		0.04 (0.31)	0.08 (0.27)	.54
Puberty, mean (SD)	4			
Baseline score[a]		2.27 (0.98)	2.84 (0.79)	
T1-T2[b]		0.83 (0.99)	0.18 (0.17)	.01
T1-T3		0.86 (1.10)	−0.03 (0.94)	.002
Alcohol or drugs, mean (SD)	1			
Baseline score[a]		0.77 (0.43)	0.87 (0.35)	
T1-T2[b]		0.21 (0.41)	−0.03 (0.21)	.03
T1-T3		0.20 (0.39)	0.03 (0.41)	.11
Peer pressure, mean (SD)	10			
Baseline score[a]		7.03 (1.40)	7.02 (1.53)	
T1-T2[b]		0.69 (1.60)	0.15 (1.35)	.17
T1-T3		0.90 (1.26)	0.07 (1.39)	.02
Pregnancy, mean (SD)	2			
Baseline score[a]		1.07 (0.78)	1.17 (0.75)	
T1-T2[b]		0.72 (0.80)	0.03 (0.72)	<.001
T1-T3		0.59 (1.02)	0.17 (0.87)	.09
HIV, mean (SD)	8			
Baseline score[a]		4.02 (1.42)	3.83 (0.86)	
T1-T2[b]		1.66 (1.74)	0.22 (1.45)	.001
T1-T3		1.24 (1.44)	0.15 (1.23)	.003
Condoms, mean (SD)	11			
Baseline score[a]		5.70 (2.05)	6.02 (1.83)	
T1-T2[b]		3.17 (2.49)	0.20 (1.47)	<.001
T1-T3		2.88 (2.20)	0.80 (1.67)	<.001
Sex, mean (SD)	10			
Baseline score[a]		7.32 (1.84)	6.87 (1.45)	
T1-T2[b]		0.66 (1.64)	0.62 (1.44)	.92
T1-T3		1.05 (1.57)	0.95 (1.75)	.82
Gender, mean (SD)	3			
Baseline score[a]		1.73 (0.73)	1.62 (0.77)	
T1-T2[b]		0.09 (0.86)	0.12 (0.81)	.89
T1-T3		0.14 (0.85)	0.00 (0.68)	.50

[a]Mean domain score at baseline for participants in each study arm.

[b]T1-T2 calculations based on n=59.

[c]Positive values indicate a desirable change in scores.

Analyses stratified by gender and age (11-12 year olds vs 13-14 year olds) showed similar patterns in score increases. In particular, knowledge, self-efficacy, and the thematic domain of condoms showed significant gains in all four subgroups of participants.

Quantitative Game Experience Data

The postintervention survey eliciting participant feedback on the game revealed high subjective measures of the value, relevance, and appeal of the game, as well as participants' perceived gains in self-efficacy to address risk situations. All participants (n=30) indicated that they had learned "a lot" and that the information would be "very useful for the future" (see Table 6). Of these participants, 29 found the information presented to be immediately useful. The overwhelming majority further responded that, after playing, they felt more prepared to handle difficult situations (n=28) and to say no firmly in situations of pressure (n=29). Ratings of the game's appeal were very positive, with most players rating it as "very fun" (n=27) and indicating that they would like to play "much more" (n=28) and would tell their friends to play (n=29).

Qualitative Game Experience Data

Participants' comments and those of their parents during postintervention FGDs provided context for the gains observed in behavioral survey scores. Participants identified a wide range of knowledge and skills they had gained through playing *Tumaini*. Puberty, the reproductive systems, HIV, STIs, and condom use were mentioned repeatedly. Skills commonly mentioned were saying a strong no, how to use condoms, recognizing and avoiding bad influences, and setting and achieving goals. One female player reported, "It taught me how I can abstain from sex and how I can say a firm no to those who are persuading me to have unprotected sex and how I can keep myself away from them" (FGD for females, aged 13-14 years).

Participants reported sharing—or intending to share—what they had learned with their peers. A younger female participant said the game was useful: "If we are under pressure or forced to have sex with someone, I found that very educative and I even teach others" (FGD for females, aged 11-12 years). An older male participant felt confident he could now teach others about condom use: "*Tumaini* also teaches how to use a condom well and if [my friends] do not know how to use it I would go with them and teach them how to use a condom" (FGD for males, aged 13-14 years).

Many participants described attitudinal learning related to gender, consent, delaying sex, condom use, puberty, and people living with HIV. When asked what he thought of *Tumaini*, one older male participant responded saying, "the game taught me I do not have to force girls to do something if they do not want to" (FGD for males, aged 13-14 years). Another male participant described *Tumaini* as "the game that shows girls are as important as the boys are" (FGD for males, aged 13-14 years).

A common theme among both parent and child focus groups was the value of the game in helping children set goals and plan how to achieve them, including when faced with challenges. Parents reported that their children's newly identified or reinforced goals were encouraging them to study hard and make good choices in order to be successful. In one child's words, "It helps you plan your future and not make bad choices so that when you grow up you may have a smooth future and a happy family" (FGD for females, aged 11-12 years). This future orientation was presented by parents and children as a key motivator for risk avoidance or risk reduction.

Parents also described how the game had facilitated discussion about HIV and related subjects with their children. Parents reported that participants had sought out adults—parents, older siblings, and teachers—to discuss or validate the information presented in the game. One parent recalled his daughter asking, "Father, so it is true that when out there if a boy calls you to go to where he is you can refuse?" (FGD2 for parents of 13-14 year olds). Another reported, "You know at this stage men may also be interested in this young girl, and if such a thing happens right now I know she would tell me" (FGD1 for parents of 13-14 year olds).

Table 6. Game experience survey responses.

Variables	Male (n=16)	Female (n=14)	All (N=30)
Value and Relevance, n (%)			
Learned a lot	16 (100)	14 (100)	30 (100)
Information very useful now	15 (94)	14 (100)	29 (97)
Information very useful for future	16 (100)	14 (100)	30 (100)
Since playing Tumaini, I feel more prepared for difficult situations I might face in the future	16 (100)	12 (86)	28 (93)
Since playing Tumaini, I feel more sure I can say no firmly when people are trying to pressure me	16 (100)	13 (93)	29 (97)
Appeal, n (%)			
In general playing was very fun	13 (81)	14 (100)	27 (90)
Would like to play much more	15 (94)	13 (93)	28 (93)
Would tell friends to play	15 (94)	14 (100)	29 (97)

Discussion

Principal Findings

In this pilot study, we found evidence of significant effects of exposure to a game-based intervention on mediators of sexual risk avoidance and risk reduction, including related knowledge, self-efficacy, and behavioral intentions, in addition to overall survey scores at 6 weeks postintervention. This is notable and encouraging, given that this pilot study was intended only to establish the directionality of effects on behavior change and was not powered to detect changes in any behavioral mediators. Additionally, the duration of the intervention (16 days) was very brief, which may have limited its potential effects on mediators of sexual risk. Should the game prove efficacious and be available for download to parents', older siblings', or adolescents' own phones, no external time limit would be placed on gameplay, thereby allowing adolescents to make use of the intervention at will, potentially maximizing its effects. Once the game is downloaded, full functionality of the game would be available without data or internet access.

FGDs with youth and parents contextualized these quantitative findings within participants' reports of gains in knowledge and skills, increased reflection on and planning for their future, and increased dialogue with parents. The increase in the number of trusted adults identified by participants as sources of information in the surveys was also validated by parents' focus group comments.

In the behavioral surveys, no significant effect was seen on risk assessment, attitudes, or perceived social norms. However, participants in FGDs mentioned attitudinal learning around themes including gender, consent, delaying sex, and puberty. In a systematic review and meta-analysis of sexual health interventions involving serious digital games, DeSmet et al found that changes in attitudes have not been observed [54]. However, Fiellin et al reported attitudinal changes in boys and younger participants in their recent RCT of a tablet-based HIV prevention game among US minority youth of a similar age to our study participants [55]. Narrative, which forms the central component of *Tumaini*, is considered a particularly promising way to influence attitudes [54]. While it has been argued that the effects of computer-based interventions may be stronger when nonmixed gender groups are targeted [56], *Tumaini* requires players to play characters of both sexes (and one HIV-positive character) with the aim of using empathetic identification through role-play to challenge harmful norms. A larger study, powered to detect these effects, is needed in order to better understand whether our narrative-based approach influences attitudes and norms.

High levels of intrinsic motivation among adolescents and of acceptability to parents are critical for the feasibility of a remotely delivered intervention for this age group. Several sources of evidence triangulate to support *Tumaini* 's high appeal to participants. An objective indicator of participants' liking of the game is mean exposure, which was over 50% higher than instructed. Enthusiasm for the game in subjective feedback provided immediately postintervention was also reflected in FGDs with participants and with parents.

Comparison with Other Studies

HIV prevention interventions that seek to reach children before they engage in sexual risk show particular promise in improving sexual health [4,5]. In Sub-Saharan Africa, an HIV prevention intervention for 11-14 year olds found significant reductions in self-reported sexual risk behaviors compared with a control intervention 54 months postintervention [57-59]. This theoretically and contextually grounded group-based intervention, conducted in schools in South Africa, had some similarities to our intervention. It used cartoon workbooks to incorporate narrative and prepare for role-play, and activities including games, along with take-home assignments to increase parent-child communication. While *Tumaini* does not incorporate group-based activities, it is clear from the levels of discussion with parents, siblings, and peers reported in focus groups that it provoked considerable family and interpersonal interaction. In addition, as a smartphone-based intervention, *Tumaini* has certain advantages over a group-based intervention, namely the potential for sustained and on-demand exposure, increased fidelity to intervention design (because not reliant on a cadre of facilitators), low cost of implementation per participant, scalability, ease of cultural adaptability, and remotely delivered updates.

In their meta-analysis, DeSmet et al [54] found that sexual health games had positive effects, albeit small in size. However, they noted that most games in their study did not use immersive game features, relying instead on gamification features such as reward and feedback. They identify features believed to facilitate behavior change, namely tailoring, personalization, personal goal setting, narrative, scaffolding levels, challenges of increasing difficulty, interactivity, rewards, feedback, and real-life transfer. *Tumaini* incorporates all of these components, with tailoring determined by the player through the decisions made in the choose-your-own-adventure game. *Tumaini* places particularly strong emphasis on role-playing and simulation, which are believed to be especially well-suited to influencing behavioral determinants like knowledge, attitudes, skills, and self-efficacy. In the context of a larger, longer study, a mediation analysis, drawing on the game log files, will allow us to better identify the active ingredients of this game design. Results from analyses of thematic domains suggest that the game mechanics and platform are versatile and can lead to gains across a range of thematic priorities, in addition to gains across theoretical mediators.

The limitations of this study include the small sample size and limited exposure and follow-up time. A future efficacy study should track behaviors in addition to behavioral mediators and ideally include biomarkers for sexual activity to validate self-report data.

Conclusion

To the best of our knowledge, this is the first randomized controlled study to demonstrate the influence on behavioral mediators of a smartphone game for HIV prevention in Sub-Saharan Africa. We are aware of only one other RCT of a serious sexual health game in Sub-Saharan Africa that is currently underway: this is of a mobile game designed to

increase HIV risk perception among an adult population in Swaziland [60].

Our findings support the need for a rigorous study of the efficacy of *Tumaini* and similar game-based mobile interventions, with long-term follow-up and measures of behavior and not merely their determinants, ideally validated by biomarkers. Such a study could incorporate mediation analyses to pinpoint active ingredients. If appropriately grounded in behavioral theory, evidence-based practice, and contextually relevant scenarios, electronic games delivered via smartphones have the potential to become valuable tools in HIV prevention efforts in low-resource and high-prevalence settings.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Tumaini homescreen.

[PNG File, 257KB - mhealth_v6i8e10482_app1.png]

Multimedia Appendix 2

Sample graphic from narrative.

[PNG File, 280KB - mhealth_v6i8e10482_app2.png]

Multimedia Appendix 3

Level 1 opening screen.

[PNG File, 199KB - mhealth_v6i8e10482_app3.png]

Multimedia Appendix 4

CONSORT-EHEALTH checklist (V 1.6.1.).

[PDF File (Adobe PDF File), 117KB - mhealth_v6i8e10482_app4.pdf]

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Abbreviations

ACASI: audio computer-assisted self-interview
CDC: US Centers for Disease Control and Prevention
FGD: focus group discussion
GEI: Gender Equity Index
GEM Scale: Gender Equitable Men Scale
KEMRI: Kenya Medical Research Institute
RCT: randomized controlled trial
STI: sexually transmitted infection

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Original Paper

mHealth Approaches in Managing Skin Cancer: Systematic Review of Evidence-Based Research Using Integrative Mapping

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Abstract

Background: mHealth, which encompasses mobile health technologies and interventions, is rapidly evolving in various medical specialties, and its impact is evident in oncology. In particular, mHealth has established itself as a prominent part of dermatology for cancer screening. Intensified research to seek its use and effectiveness in each phase of the skin cancer continuum is needed in this fast-growing field of teledermatology.

Objective: The purpose of this review was to describe current trends in research addressing the integration of mHealth and its contributions across the skin cancer continuum.

Methods: A systematic review framework was applied to the search using three electronic databases: PubMed, Web of Science, and Embase. We extensively reviewed appropriate studies regarding skin cancer and mobile technology published between 2007 and 2017. Studies of the role and impact of mobile technology in the prevention and management of skin cancer were included. We selected 18 studies adhering to the inclusion and exclusion criteria for analysis.

Results: Of the 18 studies, 5 (28%) evaluated prevention interventions, 6 (33%) assessed diagnostic accuracy, and 7 (39%) pertained to feasibility in the context of mHealth approaches for skin cancer care. These studies portray the potential of mobile teledermatology in the prevention and management of skin cancer. However, not all phases of skin cancer involve mHealth, and not all have been addressed by research.

Conclusions: This review extends our knowledge not only on the contributions of mHealth technologies, but also on their integration in different phases of skin cancer care. To optimize the effectiveness of mHealth in dermatology, larger numbers of robust, evidence-based studies on teledermatology implementations, distributed evenly across the care continuum, should be conducted so that research can be expanded to systematic reviews.

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KEYWORDS

skin cancer; mHealth; e-Health; mobile technology; teledermatology; melanoma

Introduction

As mHealth, which includes mobile health technologies and interventions, has become more common in various medical fields, the concept has begun to receive more attention in cancer care [1]. In the last few years, mobile technologies have contributed to prevention, diagnosis, treatment, and follow-up in the field of skin cancer [2-4]. Skin cancer is a major health problem as it is one of the most common malignancies associated with significant morbidity. Despite the burgeoning interest in mHealth in the context of dermatological care, the outcomes of existing research on mobile technology in skin cancer care have been inconsistent [5,6].

The primary objective of this systematic review was to investigate recent research trends related to the use of mobile technology in the prevention and management of skin cancer,

focusing on how such technology is evaluated and what impact it has in each phase across the cancer continuum. The review aims to answer the following key question: In what phase of the skin cancer continuum has mHealth technology been used and been effective among the adult population? We offer a holistic view and lessons for a roadmap of how mHealth technology has been engaged and its degree of success in the delivery of skin cancer care, setting the direction for future research.

Methods

A systematic review was performed and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist. The detailed protocol was registered with PROSPERO (CRD 42018094442), an international prospective register of systematic reviews.

Search Strategy and Information Sources

We searched PubMed, Web of Science, and Embase for articles published between January 1, 2007, and December 31, 2017. Appropriate studies addressing skin cancer and mobile technology were extensively reviewed. A list of relevant search terms was created around two domains: “skin cancer” and “mHealth.” The keywords—skin cancer, mHealth, e-Health, mobile technology, teledermatology, and melanoma—listed in no particular order, were included in the advanced search process using the conjunction “AND” and the disjunction “OR” as logical operators. An example of PubMed search strings is as follow: skin cancer and mHealth {“skin neoplasms”[MeSH Terms] OR (“skin”[All Fields] AND “neoplasms”[All Fields]) OR “skin neoplasms”[All Fields] OR (“skin”[All Fields] AND “cancer”[All Fields]) OR “skin cancer”[All Fields]} AND (“telemedicine”[MeSH Terms] OR “telemedicine”[All Fields] OR “mhealth”[All Fields]). Some of the equivocal terms were re-sorted into medical subject headings (MeSH), which brought forth more specific and relevant results. Upon obtaining various results according to the search criteria, we examined titles, abstracts, and keywords (MeSH terms) for further screening. Reference lists of selected studies were also checked for other potentially relevant studies.

Eligibility Criteria

To be eligible for inclusion, records had to be official publications written in English and peer- reviewed articles in the scientific literature that constituted original research exclusive of systematic reviews. All publication dates had to be between 2007 and 2017, given that the use of mobile phones evolved and became widespread in the late 2000s, and more importantly, because the review intended to explore recent research trends. Records included in the review had to discuss the role and assess the effectiveness of mobile technology in all aspects of skin cancer interventions, ranging from prevention, feasibility and acceptability, and diagnostic accuracy to follow-up care. The population of interest was targeted to adults (aged 18 years or older). Excluded from the review were articles that were not original research, such as systematic reviews, correspondence letters, editorials, book chapters, briefing reports, articles that pertained to economic or cost analyses of teledermatology or app analyses, and articles describing studies in which no intervention had been performed. When the main theme of the intervention was not skin cancer, melanoma, or suspicious malignant lesions with a high likelihood of being cancerous, the study was excluded. Reports about dermatologic care pertaining to esthetics were also disregarded.

Study Selection Process

The first task was to systematically search the three databases: PubMed, Web of Science, and Embase. When selecting the studies, we first performed a review of the titles and abstracts of all publications that were identified as relevant to this systematic review. Subsequently, duplicate citations across the databases were identified and removed using Endnote, and additional manual revision was performed for verification. Third, the remaining abstracts were meticulously checked for eligibility. Following this process, the full papers of the included abstracts were screened according to the inclusion and exclusion criteria. On the basis of the selection process, we were able to categorize the articles by the purpose of their interventions (ie, prevention, feasibility, diagnostic accuracy, and follow-up care) and the type of mobile technology used in the interventions.

Data Collection and Extraction

Two authors (JC and YC) independently screened the titles and abstracts of all identified studies. Potentially relevant studies were retrieved in full text and further examined for eligibility by both authors. Disagreements were discussed and resolved with the corresponding author (HW). The first author (JC) extracted the following information into a synthesis table from the final set of relevant studies: author and publication date, setting/country, mHealth technology used in the intervention, description of target population (sample size, age, and comparison group), study objectives, study design and intervention content, outcome measures, and results.

Quality Assessment for Risk of Bias

Quality assessments were performed to assess the methodological quality of included studies. Because this was a review of studies pertaining to more than one type of study design concerning different phases of the cancer continuum, the authors applied separate quality assessments accordingly. The authors used the Cochrane Collaboration tool [7-9] to make judgments about the extent of bias in each of the randomized controlled trial studies and to rate the information in each component of the paper. For diagnostic accuracy studies, the authors followed the revised version of Quality Assessment of Diagnostic Accuracy Studies [10,11] for quality assessment. As with the Cochrane Collaboration tool, the component ratings were scored as low risk, high risk, or unclear. Finally, the Newcastle-Ottawa Quality Assessment Form [12,13] was used for evaluating bias in cohort studies. The risk of bias for each of the studies was assessed by 2 authors (JC and YC). Any discrepancies between the authors were discussed with the corresponding author (HW) to reach consensus. The report of the risk of bias assessment is mentioned in the Results section, and a full presentation is included in Multimedia Appendix 1.

Study Characteristics

Among the 18 articles selected for analysis, a considerable rise was observed in interest regarding mobile technology and skin

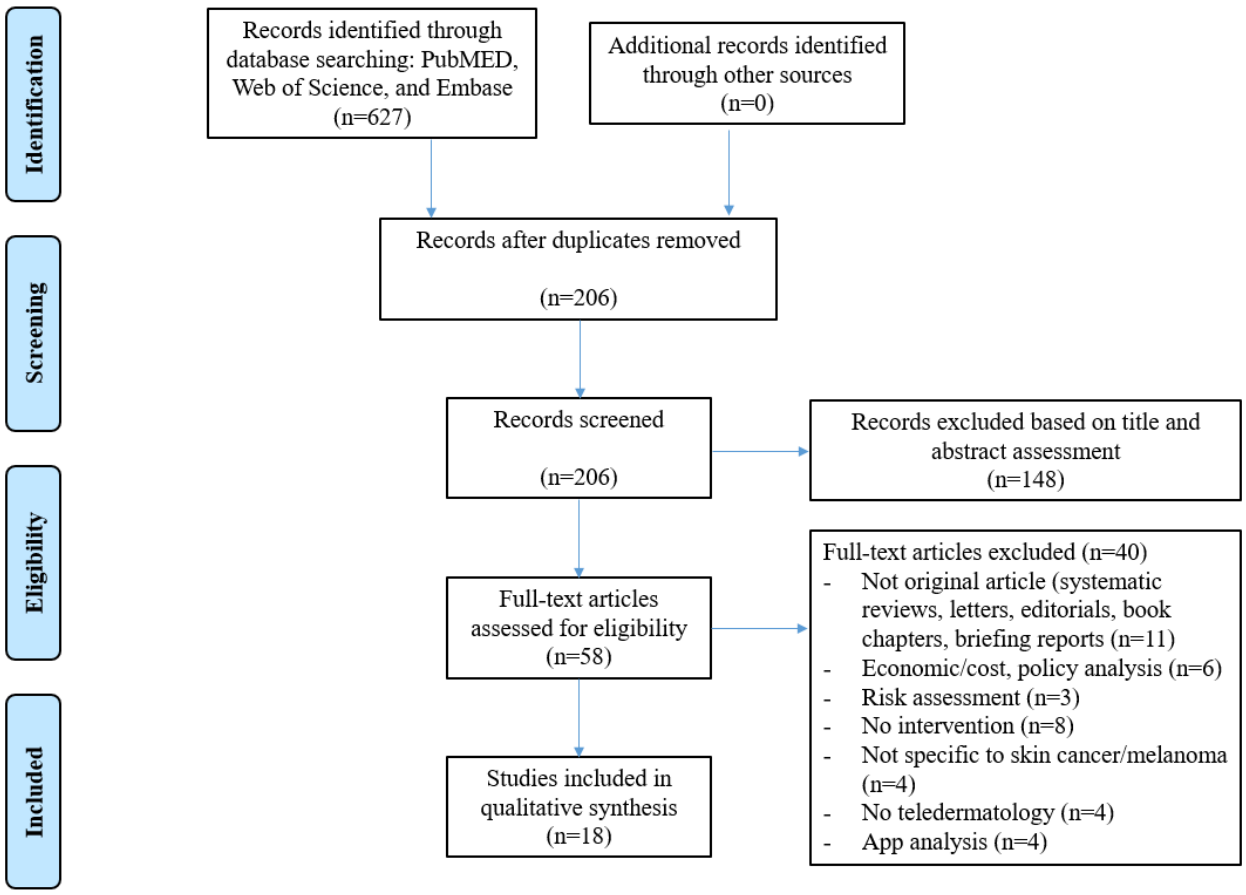
cancer during the second half of the time period under consideration. Between 2007 and 2011, only five articles (28%) were published, whereas 13 articles (72%) were published between 2012 and 2017. The majority of the selected articles (14/18, 78%) were published in clinical dermatology journals and the remainder (4/18, 22%) in journals specializing in mHealth, medicine, preventive medicine, or photochemistry. Selected studies represented various geographical settings: Europe (9/18, 50%), the United States (4/18, 22%), Australia (3/18, 17%), Egypt (1/18, 6%), and Brazil (1/18, 6%). As for content, six studies (33%) assessed the accuracy of mobile technology in detecting and diagnosing skin cancer, seven studies (39%) examined the feasibility and acceptability of adopting mobile technology as well as its reported advantages in skin cancer management, and five studies (28%) concerned skin cancer prevention through mHealth interventions. A discussion of skin cancer follow-up via teledermatology was critically lacking among these articles. The findings are summarized in Multimedia Appendix 2.

Results

Search Results

Figure 1 summarizes the literature search and review process. The foremost task was to systematically search PubMed, Web of Science, and Embase. A total of 627 records were retrieved, and duplicates within and among databases were removed, leaving a total of 206 records published between 2007 and 2017. These records were further screened by assessing whether the title or abstract contained the exact key terms (skin cancer, mHealth, e-Health, mobile technology, teledermatology, melanoma) and whether the content was in accordance with the established inclusion criteria. Following a detailed scrutiny of full-text articles for eligibility and exclusion of those that were inadequate for the analysis listed in the flowchart, the final set of records for the review comprised 18 studies. Regarding quality assessment, randomized controlled trial studies were assessed adhering to the Cochrane Collaboration tool. Of five potential biases (selection, performance, detection, attrition, and reporting), the most frequently occurring biases were performance and detection, whereas there was low risk of selection and attrition bias. Risk of bias for diagnostic accuracy studies that was assessed following Quality Assessment of Diagnostic Accuracy Studies was generally low with the exception of a few studies in which patients were not randomly or consecutively selected, index and reference tests were not blindly conducted, or loss to follow-up was observed. Finally, risk of bias was also generally low among the studies that were evaluated according to the Newcastle-Ottawa Quality Assessment Form, while risk of bias for some components could not be fully appraised due to insufficient report. An expanded report of the risk of bias assessment for each study can be found in Multimedia Appendix 1.

Figure 1. Flowchart of the systematic review process.



Prevention

Skin cancer prevention efforts that entail mHealth approaches are often carried out via short message service (text messaging) and mobile apps as tools to facilitate sun practices [14-18]. In a study that used cellular text messaging as a reminder strategy to improve adherence to wearing sunscreen, participants who received text-message reminders were nearly twice as adherent to a regimen of daily sunscreen application compared with control participants not receiving reminders [14]. Another study showed that personalized educational emails and mobile messages can engender greater motivation and adherence to sunscreen use because these personalized messages conveyed knowledge about the advantages to the people targeted, in comparison to their counterparts who did not receive messages [15]. Positive changes in sun protection habits were seen when text messages addressed increasing self-efficacy, building behavioral capacity, or guiding outcome expectations. Persuasive messages with encouraging reminders about using skin protection from the sun and reducing any risk of skin cancer showed substantial compliance and improved skin self-examination among the recipients [16].

While significant improvement in behavior change was commonly observed in skin cancer prevention interventions via personalized, narrative text messages and emails, the success of a mobile phone app through which sun safety information was disseminated to promote sun protection practices has been insignificant and inconsistent [17,18]. Users of the app reported less time spent in the sun indicating some sun protection from the use of the app but no reduction in number of sunburns since the app was used, raising questions about the true effectiveness of the app [17]. Likewise, in a sequel study, although the app users reported a relatively higher mean percentage of time practicing all sun protection behaviors than in the previous study, the app appeared to confer weak improvement of sun protection, and the interventions were again unrelated to actual sunburn prevalence [18]. In these studies, individuals were generally inclined to download the mobile app, but once it was installed, the willingness of participants to continue using the app varied [17,18].

Feasibility

The value of mHealth interventions in skin cancer management depends on successful transmission of medical data and dermatologic photographs without any technical issues and concerns being experienced by patients or health professionals [19,20]. The acceptance and feasibility of mobile teledermoscopy in the home environment were measured based on the ease of use, compatibility, and overall satisfaction perceived by melanoma patients [19]. While mobile teledermoscopy was well received and regarded as an easy process to conduct, concerns included trust in the telediagnosis and difficulty capturing some of the lesions, thereby indicating the need for more training to remedy competence issues among individuals, or for optimization of the technology [19]. Another study that investigated the feasibility of teleconsultation using a new generation of mobile phones with suspicious pigmented lesions demonstrated that mobile teledermatology has the potential become a flexible tool for enhanced self-monitoring for skin cancer screening [20].

Another prominent determinant of the feasibility of teledermatology was the attainment of high-quality images for all suspicious lesions likely to develop into cancerous lesions [21]. Transmission of images directly through mobile phone technology without the need to load them onto a computer enabled immediate analysis, making the process faster and more efficient [21]. Timeliness was an important criterion for determining the acceptance and feasibility of mHealth technology for the improved management of skin cancer. The expeditious analysis of high-quality dermoscopic images from patients referred by mobile phone teledermoscopy facilitated prioritization (faster response time from the designated dermatologist) and shorter waiting times prior to surgical treatment in comparison with the delayed arrival of paper referrals [22]. The feasibility of teledermatology for skin cancer was valid, particularly in the avoidance of unnecessary referrals for face-to-face consultations; that is, selecting only patients truly in need of dermatological intervention, in which case a definitive management decision was also established. This finding again aligns with those of other studies of the cost and time effectiveness of teledermatology [23]. The Breslow thickness, a measure that determines the stage of cancer, was on average significantly lower among patients managed by teledermatology than among their counterparts, and this clear difference between groups indicated the feasibility of teledermatology and its favorable impact in the initial prognosis of patients with melanoma [24]. In the case of Egyptian melanoma patients, the software-enabled mobile telephone with wireless connectivity was successful in both transmission and retrieval of diagnoses between onsite physicians and teleconsultants, demonstrating technical feasibility of using mobile teledermatology to expand access to dermatologic expertise and teaching where computers and Internet are absent [25].

Diagnostic Accuracy

The diagnostic accuracy of mHealth technology or tele-evaluation for skin cancer remains a common theme to be substantiated in the discourse of teledermatology for skin [26]. Studies of the diagnostic accuracy of teledermatology have compared diagnoses made through teledermatology with those of in-person dermatologists or made by histology, which serve as the gold standard in current treatment. Four studies [26-29] reported a high accuracy of teledermatology in the primary diagnosis of skin cancer or lesions suspicious for malignancy. Diagnosis by the teledermatologist based on mobile phone-transmitted images was also in close agreement with that of the in-person dermatologist or histopathology used as the reference standard [27,28]. Likewise, equally high concordance was observed between photographs of lesions taken with a digital camera and the gold standard treatment, whether it was skin biopsy or evaluation by an in-person dermatologist [29]. The diagnoses of oncologists based on the direct visual inspection of electronically sent images were in close agreement (85.8% and 93.5%, respectively) with clinical descriptions and attached information, from which they were blinded [29].

In contrast, two studies [30,31] indicated that face-to-face diagnoses made by dermatologists were not in any way less accurate than diagnoses made by teledermatologists and that teledermatology was inferior to face-to-face dermatology. Borvë et al reported that primary face-to-face diagnoses made by dermatologists showed higher or similar, but not lower, accuracy than those made by teledermatologists who assessed incoming images from the mobile phone app used in the intervention. Accuracy then increased for all dermatologists when it came to distinguishing lesions as benign or malignant. Interobserver concordances between face-to-face dermatologists and teledermatologists, and among teledermatologists were virtually identical for all levels of diagnosis, with no particular overriding success among teledermatologists [30]. For clinical diagnosis, interobserver concordance of telediagnosis was lower than that of face-to-face diagnosis and the number of discordant telediagnoses increased with the progression of dermoscopic steps; clinical evaluation was superior for detailed diagnoses [31]. Occasional disagreement also occurred between the teledermatologist and the in-person dermatologist in the diagnosis of older patients after controlling for other variables [27].

Discussion

Principal Findings

We aimed to systematically review recent research trends in the integration of mHealth into the prevention and management of skin cancer by examining 18 studies found to be appropriate for a qualitative analysis. Teledermatology has gained popularity in the oncology community [32]. The emerging interest in the subject has called for intense scrutiny of mHealth interventions for skin cancer. With regard to skin cancer prevention, personalized text messaging as a reminder and informative tool successfully persuaded those at risk of skin cancer to practice sun protection behavior more conscientiously, which indicated that interventions incorporating text messages might be an effective innovative preventive health measure against the development of skin cancer [33]. The consensus has been that teledermatology targeting high-risk skin cancer patients is feasible and promising based on the positive responses and general willingness of the at-risk population to accept teledermatology, which is likely to persist given the continuing advancement of technological resources [34]. By contrast, opposing views exist about teledermatology in the diagnosis of skin cancer. Concerns and skepticism about underdiagnosis are evident due to previous failures to distinguish malignant tumors from benign ones and a high rate of discordance between teleconsultations and histological examinations [35]. The unprecedented merger of mobile technology and skin cancer management may still be in a nascent stage [36,37]. Continued research and numerous trials will be required to realize the potential for the expansion of interdisciplinary work in mHealth and skin cancer. Mobile teledermatology at this stage is perhaps best seen as a complementary diagnostic tool that aids clinicians, rather than as one that completely supplants in-person examinations causing omission of communication between doctor and patient [38].

Although mHealth technologies may not supersede conventional clinical procedures or human decision making, efforts have been made to establish mHealth as an overarching infrastructure to advance the process of skin cancer care [39]. The key mHealth technologies can be categorized as follows: mobile phone apps, text messaging, digital hand-held devices, and Web-based systems [40]. Each type of technology was proposed to target at least one phase in cancer care delivery to assist patients and medical professionals. However, differences in the role of mHealth technology between earlier and later phases of the cancer care continuum are noteworthy. Based on the categories mentioned above, the selected articles were regrouped according to how mHealth technologies were used to intervene in a specific phase of cancer care continuum. Table 1 shows that the application of mHealth technologies in skin cancer care continuum, and consequently the focus of current research, tend to be skewed toward store-and-forward diagnosis, with a few in the prevention and treatment phases. In particular, mobile phones with digital cameras or teledermascopes attached, along with the concomitant network-based communication system for relaying images, were the most frequently used technologies in the diagnosis phase of skin cancer management. We speculate that this is because mHealth has been largely used to support data collection and structured activities, such as automatic measurement and monitoring of patients' vital signs during the progression of a disease [41].

In contrast, the treatment and follow-up phases of skin cancer care were least often addressed in the literature on teledermatology; no intervention was observed in the follow-up care of the continuum among the studies reviewed. The effectiveness of skin self-examination and the reduction of waiting times before surgery were discussed as part of the treatment phase [40], but evaluation of actual treatment procedures, including remote surgery with mobile technology intervention, has yet to occur. Although skin self-examination using mobile teledermatology is thought to effectively decrease unnecessary follow-up exams [41], its shortcomings should not go unremarked. For instance, skin self-examination using mobile teledermoscopy may be possible but may require assistance to photograph hard-to-see body areas [19,42].

Another distinct weakness of incorporating mobile technology in skin cancer management is that, given the nature of the store-and-forward technique, instantaneous feedback is limited because image analysis is essentially a human-executed, highly intricate task [43]. This process entails more than merely transmitting and processing numerical medical data; images need to be of high quality and punctiliously inspected by dermatology specialists [44]. Very few studies have attempted complete real-time decision making in teledermatology, probably due to the challenges and complexity in immediate image analysis relative to the current store-and-forward methodology [22]. These aforementioned limitations are often disregarded, perhaps due to a proclivity to highlight only the advantages of mHealth.

Table 1. Organization of studies: mHealth technologies used in the skin cancer care continuum.

mHealth Technology and study name	Cancer continuum			
	Prevention	Diagnosis/early detection		Treatment (primary management)/wait times
		Store and forward	Real-time	
Text messaging				
Armstrong et al [14]	X			
Szabó et al, 2015 [15]	X			
Youl et al, 2015 [16]	X			
Borvë et al, 2015 [22]				X
Ferrándiz et al, 2012 [24]				X
Mobile phone apps				
Buller et al, 2015 [17]	X			
Buller et al, 2015 [18]	X			
Horsham et al, 2016 [19]		X		
Borvë et al, 2015 [22]		X		X
Lamel et al, 2011 [27]				X
Borvë et al, 2013 [30]				X
Hand-held digital devices (digital cameras attached to mobile phones, mobile dermascopes)				
Horsham et al, 2016 [19]		X		
Massone et al, 2007 [20]		X		
Hue et al, 2016 [21]	X		X	
Borvë et al, 2015 [22]		X		X
Massone et al, 2014 [23]		X		
Ferrándiz et al, 2012 [24]		X		X
Tran et al, 2010 [25]		X		
Kroemer et al, 2011 [26]		X		
Lamel et al, 2011 [27]		X		X
Markun et al, 2017 [28]	X	X		X
Silveira et al, 2014 [29]		X		
Borvë et al, 2013 [30]		X		
de Giorgi et al, 2016 [31]		X		
Web-based (social networking sites, Skype, electronic referral system, virtual network)				
Massone et al, 2007 [20]		X		
Hue et al, 2016 [21]	X		X	
Borvë et al, 2015 [22]		X		
Massone et al, 2014 [23]		X		
Ferrándiz et al, 2012 [24]		X		X
Tran et al, 2010 [25]		X		
Kroemer et al, 2011 [26]		X		
Silveira et al, 2014 [29]		X		
Borvë et al, 2013 [30]		X		X
de Giorgi et al, 2016 [31]		X		

Whether it is through mobile phone apps, text messaging, or digital photography functions attached to mobile phones, the potential is assumed to exist for mHealth technology to benefit cancer survivors based on various attested interventions that target the earlier phases of skin cancer. However, relevant literature on mHealth in follow-up care is scant, even for cancer in general, let alone skin cancer specifically [45,46]. The lack of studies on this subject casts doubt on the thoroughness and robustness of mHealth research in dermatology.

Therefore, we can be less sure of how mHealth technologies can influence the equally important posttreatment and recovery phases for cancer patients, who are at risk of recurrence at any point [47]. Unfortunately, the absence of research on follow-up care does not adhere to the intended aim of mHealth strategies for continuous health monitoring, leaving considerable doubt regarding the sustainability of mobile technology in skin cancer management [48,49].

The transition from acute cancer treatment to survivorship is often poorly managed, and skin cancer is no exception [50]. When designing and implementing mHealth-driven interventions targeting skin cancer survivors, the following key elements should be considered: tailored information and constant feedback from dermatology specialists, assistance with self-monitoring of suspicious lesions, and communication with other survivors through participation in social networks to sustain their well-being [51-53]. Mobile phone apps germane to health are the only mode of mHealth technology to have become recently available, although not always specifically for a given cancer type [54]. For the increasing population of cancer survivors with differing medical, psychosocial, and practical needs for daily living, mHealth apps could empower them by providing opportunities to engage in follow-up interventions that are informative, easily accessible, affordable, and personalized to their specific circumstances [55]. However, information on survivors is sparse, and very few apps have been formally tested. Doing so could be a tremendous step forward in widening the scope of effective melanoma follow-up care [56].

Strengths and Limitations

This review extends our knowledge on the contributions and integration of mHealth in all phases of skin cancer care in order to gain a broad perspective on its uses and efficacy. Due to the number of available articles, this literature search was restricted to published articles from a limited number of selected sources. This may have led to selection and reporting bias in our review. Nevertheless, it serves as a good entry point from which readers can gain an overview of what mHealth technology has to offer in skin cancer care.

Conclusion

The advent of mobile technology and its application are transforming the way health information is accessed and health care provided in various fields of medicine [57], including oncology. Accordingly, future mHealth interventions will need to be constantly revised and modernized [58]. To optimize the effectiveness of mHealth in skin cancer management, larger numbers of robust, evidence-based studies on teledermatology implementations should be conducted evenly across the cancer continuum from the mHealth perspective so that research can be expanded to systematic reviews.

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Authors' Contributions

This study was conceived and designed by HW and JC. JC carried out the review of titles and abstracts to assess eligibility, assessed full texts against inclusion criteria, conducted data extraction, quality assessment, and analysis. Review and data abstraction were completed by JC, HW, and YC. The manuscript was drafted by JC and HW, and critically reviewed by YC. All authors have critically revised the manuscript and approved the final version submitted.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Risk of bias assessment.

[PDF File (Adobe PDF File), 106KB - mhealth_v6i8e164_app1.pdf]

Multimedia Appendix 2

Summary of findings.

[PDF File (Adobe PDF File), 111KB - mhealth_v6i8e164_app2.pdf]

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Review

The Effect of Mobile App Interventions on Influencing Healthy Maternal Behavior and Improving Perinatal Health Outcomes: Systematic Review

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Abstract

Background: Perinatal morbidity and mortality are significant public health issues with an enduring impact on the health and well-being of women and their families. Millions of pregnant women now download and use mobile applications to access, store, and share health information. However, little is known about the consequences. An investigation of their impact on perinatal health outcomes is particularly topical.

Objective: To determine the effects of mobile app interventions during pregnancy on influencing healthy maternal behavior and improving perinatal health outcomes.

Methods: Searches of PubMed, Embase, the Cochrane Library, CINAHL, WHO Global Health Library, POPLINE, and CABI Global Health were conducted with no date or language restrictions. Randomized and non-randomized studies were included if they reported perinatal health outcomes of interventions targeting pregnant women, using mobile apps compared with other communication modalities or with standard care. The primary outcome measure was the change in maternal behaviors (as defined by trial authors), by intervention goals. Two reviewers independently extracted data using standardized forms.

Results: Four randomized controlled trials (RCTs) involving 456 participants were included. All studies targeted participants in early pregnancy; however, wide variation was evident in participant characteristics, intervention, and study outcomes measures. Three trials were based in hospital settings, comparing women using mobile apps with routine antenatal care. One community-based trial gave all participants a device to promote physical activity; the intervention arm was also given a mobile app. All studies reported data for the primary outcome measure, describing some benefit from the intervention compared with controls. However, few statistically significant primary or secondary outcomes were reported. Due to insufficient data, the planned meta-analysis and subgroup analyses were not performed.

Conclusions: Due to limited numbers, heterogeneity of interventions, comparators, and outcome measures, no firm conclusions can be drawn on the effects of mobile application interventions during pregnancy on maternal knowledge, behavior change, and perinatal health outcomes. As millions of women utilize mobile apps during pregnancy, rigorous studies are essential for health care and maternity care providers to optimally design, implement, and evaluate interventions.

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KEYWORDS

apps; pregnancy; perinatal; maternal; infant; mobile; systematic review; behavior change; intervention

Introduction

Adoption, practice, and maintenance of healthy behaviors during pregnancy can potentially improve maternal and child health. Adverse perinatal health outcomes such as emergency cesarean section, preterm birth, low birthweight, and stillbirth [1] are associated with maternal risk factors that may be modifiable through changes in maternal behavior [2-4]. During pregnancy and in preparation for motherhood, many women seek information and try to adopt a healthy lifestyle [5]. Pregnant women are increasingly using digital resources such as mobile apps—computer programs designed to run on mobile devices such as mobile phones and tablet computers—to access information, monitor fetal development, track individual health indicators, and provide reassurance [6-10]. Collectively, pregnancy apps have been downloaded hundreds of millions of times and are an integral source of information for many pregnant women [11]. Pregnant women may feel heightened support for informed decision-making and a sense of control by using a familiar device to access, store, and share information [9].

In 2017, over 325,000 health and fitness and medical apps were available [12]; apps directed at pregnancy constitute a major genre [13]. These apps can include health information, motivational messages, monitoring, and behavior change tools. The content of apps can be tailored by demographics such as gestational age, maternal age, language or risk factors. App developers may employ methods to engage users, such as "push communication," including notifications designed to encourage users to follow a prompt (eg, read, listen, view content or perform an activity). Pregnancy apps may also link to a device such as a camera, glucometer, fitness activity tracker, Kegel "exerciser," fetal heartbeat "listener," or other monitoring equipment. Some devices associated with an app are marketed directly to consumers and avoid regulatory scrutiny, while a woman's health care provider may provide other devices as part of clinical care.

From an institutional perspective, health systems and maternity care facilities are investigating whether and how to integrate digital patient support modalities into care and are seeking evidence to support decision making. It has been hypothesized that mobile apps may improve perinatal outcomes by encouraging access to health information, modifying demand for services, and enabling provision of targeted care [14]. This systematic review aims to determine the effects of mobile app interventions during pregnancy on influencing healthy maternal behavior and improving perinatal health outcomes, compared to interventions using other communication modalities or standard care.

Methods

Criteria for Considering Studies for this Review

Study Design

All randomized controlled trials (RCTs) and non-randomized studies including controlled before-after studies, interrupted time-series studies, and prospective comparative cohort studies were considered for inclusion. Case-control studies and cross-sectional studies were excluded due to their retrospective design. Crossover trials were also excluded as they are considered most suitable for temporary effects and chronic conditions [15]. Women at any stage of pregnancy or labor were considered for participation.

Interventions

Studies assessing the effects of mobile app-based interventions designed to influence maternal knowledge or behavior during pregnancy were considered for inclusion if they provided general information for pregnant women or focused on a specific maternal risk factor or perinatal outcome. There was no restriction on who sponsored the intervention or type of setting.

Studies were excluded if the intervention (1) did not utilize a mobile app, (2) used a mobile phone solely for telephone conversations or SMS (short message service) text messaging, (3) did not report on maternal or infant health outcomes, (4) did not target pregnant women (focus on clinicians, partners), and (5) focused on physical effects of mobile phone usage (such as radiation) during pregnancy.

Comparators

The following comparisons were planned:

1. Mobile health apps versus paper-based or SMS text messaging-based communications.
2. Mobile health apps versus interpersonal communication modes (ie, face-to-face or telephone conversation).
3. Mobile health apps versus standard care or no specified intervention.

Outcome Measures

The primary outcome measure was a change in maternal behaviors (as defined by trial authors), by intervention goals. Secondary outcomes addressed maternal and infant health outcomes, maternal experience with the intervention, and health service utilization measures (Table 1).

Search Methods for Identification of Studies

Sources

Systematic searches were performed using seven electronic bibliographic databases: PubMed, Embase, The Cochrane Library, CINAHL, World Health Organization Global Health Library, POPLINE, and CABI Global Health. Handsearching of journals and conference proceedings from the reference lists of retrieved studies were also conducted. No language or date restrictions were applied. Abstracts and full-length articles were obtained for each citation, where available.

Search Strategy

The specific search strategies were developed by the primary author (LMD) and an experienced clinical research librarian, with input from all authors. Electronic searches using subject headings and all fields for keywords were conducted to avoid missing non-indexed concepts. Search terms and returns by the database and handsearching are presented in Multimedia Appendix 1. Articles published in non-peer reviewed publications were excluded, as per the review protocol.

Remaining citations and abstracts were uploaded to the Web-based software platform Covidence [16]. Throughout the review process, authors were not blinded to journal titles, study authors or institutions. If it was unclear whether studies met inclusion criteria, study authors were contacted up to two times by email to request further information.

Study Selection

Abstracts of articles retrieved through the search strategy were independently screened by 2 review authors to determine if inclusion and exclusion criteria were met. A third author addressed any concerns about inclusion. If necessary, additional information was sought from study authors to resolve eligibility queries. For selected studies, full-text articles were obtained and read by 2 authors to confirm that they met inclusion criteria.

Bias Assessment

Studies were assessed for quality by 2 reviewers independently (LMD, VF), according to the guidelines in the Cochrane Handbook for Systematic Reviews of Interventions [17], by 6 domains: (1) selection bias, (2) performance bias, (3) detection bias, (4) attrition bias, (5) reporting bias, and (6) any other possible bias. All included studies were assessed on the risk of bias, likely magnitude, and potential impact on findings.

Data Collection and Analysis

Data Extraction and Management

Once the studies were selected, using standardized forms, 2 reviewers (LMD, VF) independently extracted data including study objective, study design, inclusion and exclusion criteria, data sources, study period, methodology, sample size, intervention details and effects, and outcomes. Due to the complexity of the interventions found, a post-hoc decision was taken to collect data on the interventions based on the Template for Intervention Description and Replication (TIDieR) checklist [18,19].

Synthesis of Results

As described in the review protocol [20], we set out to synthesize data and present measures of treatment effects including summary risk ratios for dichotomous outcomes and mean difference for continuous data and subgroup analysis. Due to the considerable heterogeneity of participant characteristics, intervention features, and reported outcomes, it was decided that meta-analysis could not be performed, and results were summarized in a narrative synthesis.

Table 1. Primary and secondary outcome measures.

Outcome	Outcome characteristics
Primary outcomes	
Maternal	• Change in maternal behaviors (as defined by trial authors), by intervention goals
Secondary outcomes	
Maternal	• Major adverse maternal outcome (composite of death, admission to intensive care unit, or near-miss mortality as defined by the World Health Organization) • Antepartum hemorrhage • Postpartum hemorrhage • Preeclampsia • Gestational diabetes mellitus • Emergency cesarean birth • Successful initiation of breastfeeding • Maternal knowledge (about the topic targeted by intervention) • Maternal general health (as defined by standardized measures such as general health questionnaires) • Maternal evaluation of the intervention (as reported by the trial) • Maternal psychosocial outcomes, such as satisfaction or anxiety (as measured by any validated, standard instrument) • Health service utilization (antenatal care attendance, maternal antenatal admission, length of hospital stays of mother or infant)
Infant	• Stillbirth • Neonatal death • Small for gestational age • Large for gestational age • Preterm birth (<32 weeks' gestation) • Gestational age at birth • Cesarean section • Major neonatal morbidities (as defined by trial authors)

Results

Description of Studies

Included Studies

The search strategy for this review has been consolidated into a Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) diagram (Figure 1), summarizing inclusion and exclusion of studies [21]. For database screening, one author (LMD) searched the databases on 15-16 February 2017, with a yield of 5,089 articles. After initial screening to remove duplicates and articles from non-peer reviewed journals, the titles and abstracts of 2,241 articles were reviewed by 2 authors independently (among LMD, VF, DH, PFM, and FMB). Title and abstract screening of 1,091 additional articles identified through handsearching was performed by 2 reviewers (LMD and VF); however, no additional studies were identified. Full-text screening of 69 articles was performed by 2 review authors (among LMD, VF, PFM, and DH). At all stages, disagreements between authors were resolved by consultation with a third reviewer. Reasons were recorded for excluding studies (Multimedia Appendix 2). Several articles had multiple reasons for exclusion, although each was allocated to a single category. A total of 4 trials met the inclusion criteria.

The characteristics of included studies are presented in Table 2. Though not specified as a requirement for inclusion, all studies that met inclusion criteria used RCT designs and involved pregnant women in high-income countries. Three trials were based in hospital settings, comparing women using mobile apps with standard antenatal care. One community-based trial gave all participants a device to promote physical activity; participants in the intervention arm were also given a mobile app.

Bias Assessment of Included Studies

Objective assessments and validated data collection tools were employed in all included studies. Studies performed generally well regarding the risk of bias in random sequence generation; 3 studies were low risk and 1 study was unclear, as it was not described. High risk of performance bias was shared across all studies. Due to the nature of mobile app interventions, blinding participants is difficult, and did not occur in any of the included studies. Blinding health care providers can also be difficult and occurred in only 1 study. Most studies had a low risk of attrition bias, with low rates of withdrawal, drop-out or loss to follow-up. Reporting biases were also low, with all studies reporting results for their respective primary outcomes. The overall risk assessment is presented in Multimedia Appendix 3.

Description of Participants

Overall, 456 pregnant women participated in the 4 included trials, with 180 women categorized as low risk in 2 trials and 276 as moderate risk in 2 trials. Of these, 1 trial included pregnant women with asthma and another recruited pregnant women classified as overweight or obese. All trials recruited women prior to 20 weeks gestation. Table 3 shows the participant characteristics reported by each study.

Description of Interventions

All interventions used mobile apps specifically designed for the study, rather than apps available through commercial "app stores." None of the included studies reported if modification of the intervention occurred during the trial or described a cost-benefit analysis or compared cost of the app to other communication modalities. To motivate users to engage with the content, 2 studies developed apps utilizing "push" communication strategies. These same interventions also included a device available through a "plug-in" [23,25]. Three studies allowed users to record and track personal data within the app and provided individualized information [22,23,25]. None of the studies reported that their apps included shared participant "chat" spaces. Intervention features are described using the TIDieR checklist [18,19] presented in Table 4. Additional information about intervention characteristics—including user experience, content, patient-provider communication, functionality, and data tracking—was also collected by one reviewer (LMD) using a customized form (Multimedia Appendix 4).

Effects of Interventions

The included trials reported different maternal and infant health outcomes such that meta-analysis or subgroup analysis was not possible.

Primary Outcomes

The primary outcome of interest was a change in maternal behaviors (as defined by trial authors), by intervention goals. All studies reported some type of behavior change and better results for the intervention group than controls for their respective primary outcomes (Table 5). Inventories and data collection tools used in the included studies are listed in Multimedia Appendix 5. The Ainscough et al study [22] concluded that a significantly higher proportion of the intervention group had transitioned to a "maintenance stage" of healthy lifestyle behaviors by 28 weeks' gestation, compared to the control group (52.8% versus 32.7%, P=.004). The primary outcome measure for the Choi et al study [23] of physical activity was weekly mean steps, and intervention participants had a greater increase in daily steps at 12 weeks with 1096 (SD 1898) steps, compared with 259 (SD 1604) steps among control participants (P=.13). The change between groups reported across the 12-week study period was not statistically significant (P=.38). The Ledford et al study [24] found that by 32 weeks' gestation, participants using a mobile app recorded information more frequently than the control group, and that they had developed greater "patient activation" than the control group (F [1127]=4.99, $P \geq .05$, n^2=.04, marginal mean of 79.88 versus 74.81). The Zairina et al study [25] reported that the intervention group had a higher proportion of participants with well-controlled asthma than the control group (82% versus 58%, P=.03) at 6 months from baseline.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analysis diagram of included and excluded studies.

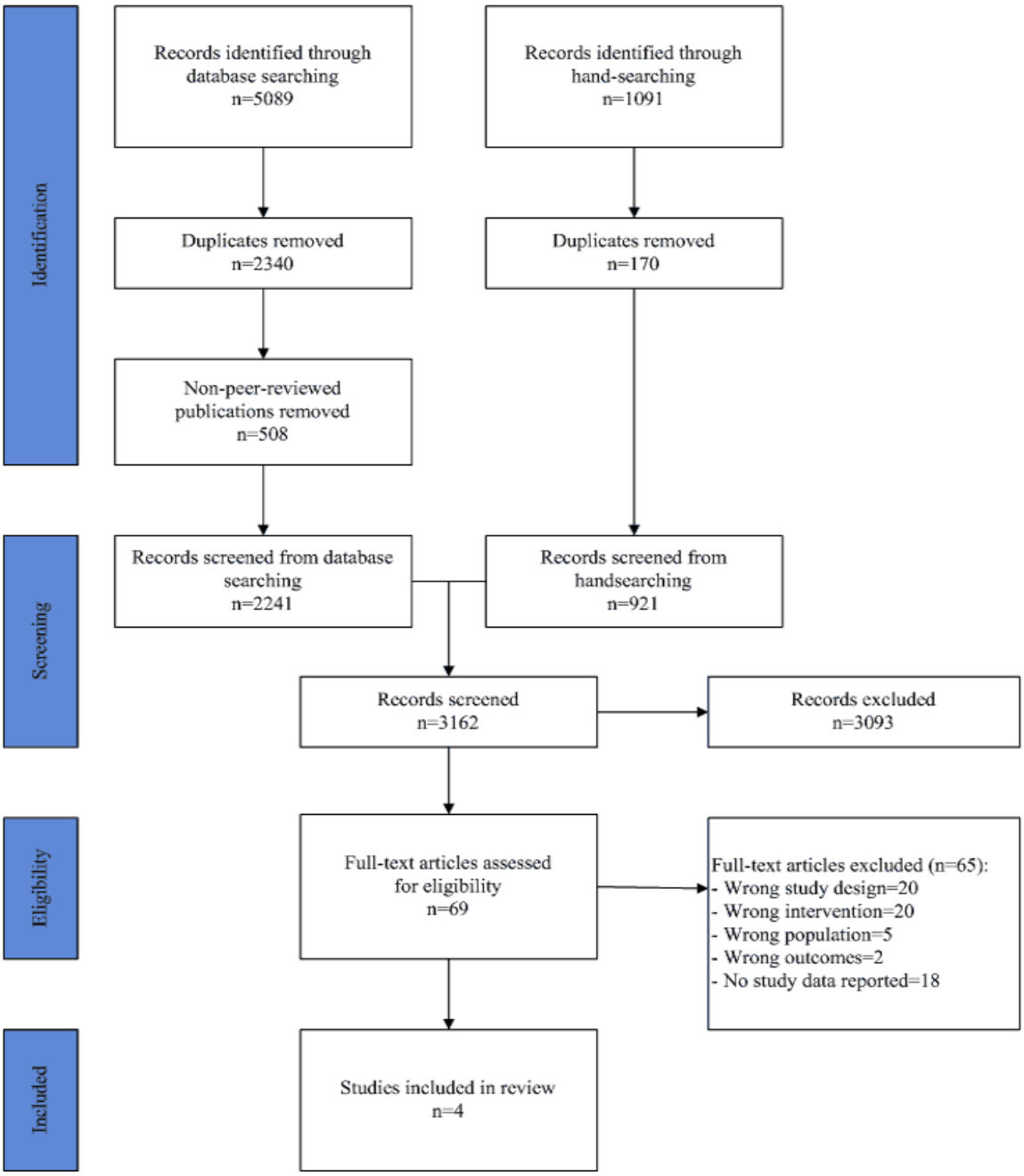

Table 2. The characteristics of included studies.

Study characteristics	Ainscough et al [22]	Choi et al [23]	Ledford et al [24]	Zairina et al [25]
Country	Ireland	United States	United States	Australia
Year	2016	2016	2016	2016
Design	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial
Aim	To investigate the influence of a mobile phone app-supported antenatal healthy lifestyle intervention on the behavioral stage of change among overweight and obese pregnant women	To examine the feasibility of subject recruitment, randomization, intervention, and efficacy of an mHealth physical activity program for physically inactive pregnant women	To compare the effectiveness of a mobile application with a spiral-notebook guide in prenatal care	To evaluate the efficacy of a telehealth program supported by a handheld respiratory device in improving asthma control during pregnancy
Participants (risk category)	204 pregnant women with body mass index≥25 and <40 kg/m^2 (Moderate)	30 pregnant women with a sedentary lifestyle and intent to be physically active (Low)	150 low-risk obstetrics participants following standard care pathway (Low)	72 pregnant women with asthma (Moderate)
Control group (n)	Standard care: no consistent diet or lifestyle advice offered (98)	Recommendations for gestational weight gain and safety instruction for promoting physical activity during pregnancy, and an accelerometer (15)	Standard care: a spiral notebook designed to educate participants about pregnancy and enable recording of pregnancy experiences (78)	Standard care through a participant information brochure (36)
Intervention group (n)	A “healthy lifestyle package” of individualized nutrition counseling and exercise advice, supported by a mobile phone app (106)	The same information and an accelerometer as women in the control group plus a mobile phone application, a daily message, activity diary, and feedback graphs of personal data (15)	The standard care spiral notebook replaced with a mobile app with identical content. (72)	In addition to standard care, participants were given a mobile app to record data, a proprietary medical device intended for measuring lung function (COPD-6) and a written asthma action plan (36)

Table 3. Participant characteristics.

Study characteristics	Ainscough et al [22]	Choi et al [23]	Ledford et al [24]	Zairina et al [25]
Participant risk category	Moderate	Low	Low	Moderate
Total number of participants, N	204	30	150	72
Control, n	98	15	78	36
Intervention, n	106	15	72	36
Inclusion characteristic among pregnant women	Body mass index≥25 and <40 kg/m^2	Desire to increase physical activity	Low-risk	Asthma
Group differences	No	No	No	No
Age (years), mean (SD)	—[a]	33.7 (2.6)	28.91 (5.03)	31.45 (4.5)
Gestation age at recruitment (weeks); mean (SD)	15[b]	17.2 (3.4)	10-12[b]	16.35 (2.9)
Married[c], n (%)	—	29 (97)	133 (92.4)	56 (78)
Body mass index (kg/m^2)[d], mean (SD)	—	27.7 (3.7)	—	28.5 (5.7)
Race/ethnicity[e] n (%)				
White	—	13 (43)	100 (69.4)	60 (83)
Asian	—	12 (40)	8 (5.6)	6 (8)
Black/African-American	—	2 (7)	14 (9.7)	—
Hispanic/Latina	—	3 (10)	15 (10.4)	—
Other	—	—	7 (4.7)	6 (8)
Education, n (%)				
High school graduate	—	6 (20)	51 (34.0)	9 (13)
University graduate	—	24 (80)	92 (61.3)	45 (63)
Ability to communicate in English	—	Yes	—	Yes

[a]Dashes indicate unreported values.

[b]Standard deviation was not reported.

[c]Studies reporting data used the term “married,” except the Choi et al study, with response category “married/cohabitating.”

[d]Choi et al reported prepregnancy body mass index. Zairina et al reported study baseline.

[e]Response categories as described by study authors.

Table 4. Intervention features by the Template for Intervention Description and Replication (TIDieR) checklist.

Study characteristics	Ainscough et al [22]	Choi et al [23]	Ledford et al [24]	Zairina et al [25]
Brief name (trial registration)	*Pears* (Pregnancy, exercise, and nutrition research study with mobile phone app support) study (ICTRN29316280)	*MOTHER* (Mobile Technologies to Help Enhancing Regular Physical Activity) Trial for Pregnant Women (NCT 01461707)	Mobile app as a prenatal education and engagement tool (No registration provided)	*MASTERY* (Management of Asthma with Supportive Telehealth of Respiratory function in Pregnancy Telehealth to improve asthma control in pregnancy) study (ACTRN 12613000800729)
Why	Investigate the influence of mobile app-supported antenatal healthy lifestyle intervention on the behavioral stage of change	Examine the feasibility of an mHealth physical activity program	Compare the effectiveness of a mobile app with a spiral-notebook guide in prenatal care	Evaluate the efficacy of a telehealth program supported by a handheld respiratory device in improving asthma control during pregnancy
What (materials)	Mobile app	Mobile app, accelerometer	Mobile app	Mobile app, a proprietary medical device intended for measuring lung function (COPD-6), individualized written asthma action plan (WAAP)
What (procedures)	Participants received individualized nutrition counseling and exercise advice, and mobile app. Behavioral stage-of-change score measured at baseline and late pregnancy	Participants provided with a mobile app, accelerometer, and goal-setting session at baseline. Data remotely monitored and extracted	Participants provided with a mobile app. Paper-based surveys completed at each prenatal appointment. App use assessed. Outcomes reported from health record at delivery	Participants received a COPD-6, mobile app, and individualized WAAP. Data transmitted automatically to a server accessed by researchers, participants, and clinicians. Data collected at 3 and 6 months from baseline, and after delivery
Who provided	Not described	Research staff	Antenatal care providers, researchers	Antenatal care providers, researchers
How	Mobile app	Mobile app	Mobile app	Mobile app
Where	Not described. Study authors based in Dublin, Ireland	Not described. Participants recruited by obstetricians, prenatal clinics, and communities (San Francisco, United States)	Community hospital in women's health and family medicine departments (Maryland, United States)	Antenatal clinics of two large maternity hospitals (Melbourne, Australia)
When and how much	From (mean of) 15 weeks' gestation to 28 weeks' gestation	From 10-20 weeks' gestation, continuing for 12 weeks	From 8-10 weeks' gestation, continuing throughout pregnancy	From (mean of) 16.7 weeks' gestation, continuing throughout pregnancy
Tailoring	Individualized nutrition and exercise advice	Individualized prescheduled weekly step goals	Not described	Individualized WAAP and weekly feedback messages
Modification of intervention during trial	Not described	Not described	Not described	Not described
Strategies to improve or maintain intervention fidelity	Not described	Feedback offered on user progress, based on uploaded activity diaries	Not described	Feedback based on individualized WAAP, lung function and asthma symptoms
Extent of intervention fidelity	Retention and adherence rates not reported	97% (29/30) participants retained during the intervention. Adherence by intervention group waned over the study period	73% (127/173) participants retained during the intervention. Change mainly due to miscarriage and elevation to high-risk care	96% (69/72) participants retained during the intervention

Table 5. Primary maternal outcomes: change in maternal behaviors by intervention goals.

Study	Study results	
	Primary maternal outcome	Results
Ainscough et al [22]	• Shift in the stage-of-change score (transitioning from contemplation/preparation to maintenance stage of healthy lifestyle behaviors in pregnancy): baseline to 28 weeks. • Study participants at Maintenance stage (stage 5).	• Mean score showing a shift in stage-of-change score distribution observed for both groups. Change reported as more significant for the intervention group (P<.001 versus P=.03). The proportion in each group achieving change not reported. • At 28 weeks, a higher proportion of intervention group at stage 5 (52.8%) compared with the control group (32.7%), (χ^2=8.4, P=.004).
Choi et al [23]	• Physical activity: change in mean steps per day.	• Intervention participants had a greater increase in daily steps at 12 weeks with 1096 (SD 1898) steps, compared with 259 (SD 1604) steps among control participants (P=.13).
Ledford et al [24]	• Patient use of a tool to find information about pregnancy (information-seeking). • Patient use of tool to record information about pregnancy (information-recording). • Patient activation at 32 weeks' gestation (use of a tool).	• No significant difference detected between the 2 groups (data not provided). • Across all time points, intervention group recorded more frequent use of information source than the control group (F [1118]=4.10, $P \geq .05$, ^{2}=.03). • The intervention group activation score was greater than controls (patient activation score marginal mean 79.88 versus 74.81 (F [1127]=4.99, $P \geq .05$, ^{2}=.04).
Zairina et al [25]	• Asthma control (ACQ) 6 months from baseline.	• Mean difference between groups was significant (–0.36 [SD 0.15], P=.02). The intervention group had higher proportion of participants with well-controlled asthma than the control group (82% versus 58%, P=.03).

Secondary Outcomes

Of the 4 studies in this review, 2 studies [23,25] report maternal secondary outcomes relevant to this review, as further detailed in Multimedia Appendix 6. One study of asthma control reports a clinically significant improvement in the asthma-related quality of life among the intervention group compared with usual care at 6 months from baseline, but the mean change was not statistically significant [25]. Another study of physical activity during pregnancy reported reduced barriers such as lack of energy, time, and willpower among the intervention group, and decreased severity of pregnancy symptoms [23]. No studies reported data on major adverse maternal outcome, maternal knowledge about the targeted health topic, maternal evaluation of the intervention, or successful initiation of breastfeeding. Furthermore, none of the trials report statistically significant differences in neonatal outcomes between intervention and control groups.

Discussion

Principal Findings

Despite the broad search criteria used, this systematic review identified only 4 studies for inclusion. This was an unexpected outcome of the review given the expanding use of mobile applications in maternity care. All studies included in the review reported on the primary outcome, "change in maternal behaviors by intervention goals," but the specific outcomes reported varied by intervention. None of the studies included in this review reported statistically significant differences between intervention and control groups for neonatal outcomes, delivery or pregnancy complications. As advocated through the *Core Outcomes in Women's and Newborn Health* initiative, a standard set of perinatal outcome measures, reported alongside those appropriate to specific health conditions or interventions, would enhance comparability [26-27]. A standardized approach using reliable and valid methods to analyze participant usage, navigation, adherence, and satisfaction would also improve comparability further and inform the design of future interventions.

Further areas for research include investigation of which intervention features yield the desired results, for example, to establish if it is an individualised clinical care plan or the advice supported by a mobile app that makes a difference. Future studies could also explore how technology can support individualized patient care plans, and if technology can be used for data tracking or streamlined reporting of symptoms to automatically prompt closer clinical scrutiny. A more in-depth exploration of the theories of behavior change underpinning study results could also add an important dimension to understand how mobile interventions influence behavior and improved perinatal outcomes.

None of the studies were designed to gauge the longitudinal benefit of mobile app interventions commenced during the perinatal period. This would be another important avenue to understand longer-term benefits, potential diminishing effects, data tracking and patient engagement opportunities offered by

interventions commenced during pregnancy. Qualitative research or follow-up surveys of interventions could provide insight into users' experiences of these interventions, including how such apps are used, and if they augment or affect perceptions of care.

Hundreds of pregnancy apps are available to the public, yet all the studies in this review developed their own mobile apps. Researchers may find it easier to guide content, facilitate communication, track data and assure user privacy with their own apps. The potential commercialization of successful interventions that could generate income for research programs could also be a consideration. However, bespoke models are likely to require more investment in development, testing, maintenance, and marketing than existing apps.

Despite creating their own apps, reviewed studies did not report extensively on their development, testing or architecture, or whether modifications were required, which would assist replication efforts. Further, none of the included studies reported an economic analysis, comparing the cost of the intervention with standard care or comparators. Policymakers and those guiding educational or clinical interventions during pregnancy would likely require such information to gauge investment alongside projected perinatal health benefits.

Strengths and Limitations

There are several important strengths and limitations in our review. To the best of our knowledge, this systematic review is the first to assess the effects of mobile app interventions during pregnancy on influencing healthy maternal behavior and improving perinatal outcomes. This review followed an established methodology for the conduct of systematic reviews [17,19] and used a highly sensitive search strategy with no language or date restrictions to identify as many relevant studies as possible. Two authors completed the review process and extracted data independently at all stages based on prespecified criteria, and a third author participated when required to achieve consensus. Included studies were limited to those which provided comparators between mobile applications and any other intervention, including standard care, so that the role of the communication modality on intervention effects could be analyzed.

This review may have some methodological limitations. Findings are limited by the few studies that met inclusion criteria, and the small sample sizes involved in each study. Although search criteria and the databases searched were comprehensive, it is possible that relevant articles were missed. Only articles published in peer-reviewed journals were included, which may have left out some studies. Over 3,000 published study abstracts were assessed, and it was unexpected that only 4 studies would meet inclusion criteria. The heterogeneity of outcome measures further hampered the ability to meta-analyse data as originally intended, or to explore impact. Future updates of this review could search additional databases and expand the inclusion criteria to enable the analyses originally intended by the authors.

Conclusions

As an increasing number of pregnant women use mobile apps, further research on intervention components, usage, and associated perinatal health outcomes should influence content, features, and quality of interventions. The effect of mobile app interventions on maternal knowledge, behaviour, and perinatal outcomes is still largely underreported, as evidenced by the few studies that met inclusion criteria for this review, and the minimal significant impact reported on perinatal health outcomes. Results of this systematic review may contribute to decision making by health systems, hospitals, and clinicians about the integration of mobile applications into clinical care. Emerging evidence from future trials should help to make firmer conclusions about the effectiveness of mobile app interventions during pregnancy on primary and secondary outcomes, compared to other communication modes.

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Conflicts of Interest

None declared

Authors' Contributions

LMD and VF conceptualized the review in consultation with the coreviewers. LMD performed the literature search with a clinical librarian. All authors (LMD, FMB, DH, PFM, VF) screened studies to determine inclusion. LMD and VF performed data collection, data extraction, and bias assessment. LMD wrote the manuscript, with review and input from all authors. The corresponding author is the guarantor of this review.

Multimedia Appendix 1

Search terms and returns.

[PDF File (Adobe PDF File), 89KB - mhealth_v6i8e10012_app1.pdf]

Multimedia Appendix 2

Excluded studies.

[PDF File (Adobe PDF File), 61KB - mhealth_v6i8e10012_app2.pdf]

Multimedia Appendix 3

Bias assessment.

[PDF File (Adobe PDF File), 103KB - mhealth_v6i8e10012_app3.pdf]

Multimedia Appendix 4

Intervention characteristics.

[PDF File (Adobe PDF File), 79KB - mhealth_v6i8e10012_app4.pdf]

Multimedia Appendix 5

Inventories used in included studies.

[PDF File (Adobe PDF File), 92KB - mhealth_v6i8e10012_app5.pdf]

Multimedia Appendix 6

Secondary outcomes.

[PDF File (Adobe PDF File), 181KB - mhealth_v6i8e10012_app6.pdf]

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Abbreviations

COPD-6: a proprietary medical device intended for measuring lung function
RCT: randomized controlled trial
SMS: short message service
TIDieR: Template for Intervention Description and Replication
WAAP: written asthma action plan

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Original Paper

mHealth Self-Report Monitoring in Competitive Middle- and Long-Distance Runners: Qualitative Study of Long-Term Use Intentions Using the Technology Acceptance Model

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Abstract

Background: International middle- and long-distance running competitions attract millions of spectators in association with city races, world championships, and Olympic Games. It is therefore a major concern that ill health and pain, as a result of sports overuse, lead to numerous hours of lost training and decreased performance in competitive runners. Despite its potential for sustenance of performance, approval of mHealth self-report monitoring (mHSM) in this group of athletes has not been investigated.

Objective: The objective of our study was to explore individual and situational factors associated with the acceptance of long-term mHSM in competitive runners.

Methods: The study used qualitative research methods with the Technology Acceptance Model as the theoretical foundation. The study population included 20 middle- and long-distance runners competing at national and international levels. Two mHSM apps asking for health and training data from track and marathon runners were created on a platform for web survey development (Briteback AB). Data collection for the technology acceptance analysis was performed via personal interviews before and after a 6-week monitoring period. Preuse interviews investigated experience and knowledge of mHealth monitoring and thoughts on benefits and possible side effects. The postuse interviews addressed usability and usefulness, attitudes toward nonfunctional issues, and intentions to adhere to long-term monitoring. In addition, the runners' trustworthiness when providing mHSM data was discussed. The interview data were investigated using a deductive thematic analysis.

Results: The mHSM apps were considered technically easy to use. Although the runners read the instructions and entered data effortlessly, some still perceived mHSM as problematic. Concerns were raised about the selection of items for monitoring (eg, recording training load as running distance or time) and about interpretation of concepts (eg, whether subjective well-being should encompass only the running context or daily living on the whole). Usefulness of specific mHSM apps was consequently not appraised on the same bases in different subcategories of runners. Regarding nonfunctional issues, the runners competing at the international level requested detailed control over who in their sports club and national federation should be allowed access to their data; the less competitive runners had no such issues. Notwithstanding, the runners were willing to adhere to long-term mHSM, provided the technology was adjusted to their personal routines and the output was perceived as contributing to running performance.

Conclusions: Adoption of mHSM by competitive runners requires clear definitions of monitoring purpose and populations, repeated in practice tests of monitoring items and terminology, and meticulousness regarding data-sharing routines. Further

naturalistic studies of mHSM use in routine sports practice settings are needed with nonfunctional ethical and legal issues included in the evaluation designs.

(JMIR Mhealth Uhealth 2018;6(8):e10270) doi:10.2196/10270

KEYWORDS

running; mHealth; health technology; diagnostic self-evaluation; remote sensing technology; self-evaluation programs; qualitative research

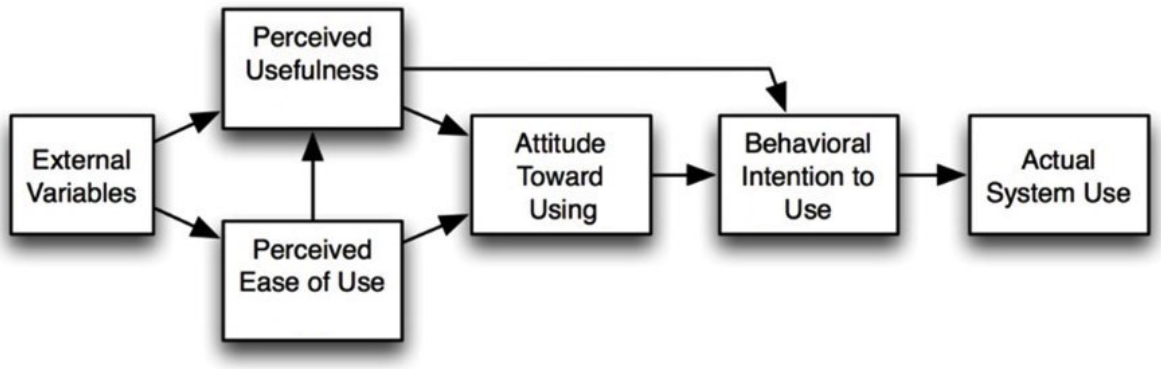
Introduction

Middle- and long-distance running is one of the most popular forms of physical exercise worldwide, and running competitions attract millions of spectators in association with city races, world championships, and Olympic Games [1]. It is therefore a major concern that ill health and pain, as a result of sports overuse, are common causes of lost training and decreased performance among long-distance runners [2-4]. Recent research suggests that early detection of overuse syndromes may be achieved through observation of indicators at levels other than tissue damage. One way to identify early indications of decreased performance among runners is to continuously record external loads and then evaluate how the runners are affected by these loads [5]. However, such passive monitoring requires extensive technical resources, and it is also challenging to analyze data monitoring from different individuals in a meaningful way. As an alternative, self-report measures have been described as adequately reliable and sensitive compared with other ways of measuring athletes' responses to training load [6]. Athlete self-reporting on training and health status, using the World Wide Web, is simple to administer and inexpensive [7,8]. Despite its potential, research on implementation of mHealth self-report monitoring (mHSM) among runners is sparse [9].

In any setting where novel technology is incorporated with established practices, knowledge of user acceptance is important [10]. The Technology Acceptance Model (TAM) was developed to help analyze, explain, and modify computer usage behaviors in a framework based on the Theory of Reasoned Action, as seen in Figure 1 [11,12]. In this model, it is assumed that a person's willingness to use a technical system or device is mediated by attitudes toward system use that are founded on the system's perceived usability and usefulness. Usability is defined as the level at which a person finds using the system to be free of effort, whereas usefulness is the extent to which the person finds that using the system enhances his or her performance of important tasks. The attitude concept in TAM involves a person's beliefs about the consequences of adopting the novel technology and whether these consequences are regarded to be positive or negative. These beliefs influence the reasoning that determines the person's inclination to use or not to use technology [11]. According to TAM, perceived ease of use, perceived usefulness, and attitudes toward the consequences of using the technology thus shape use intentions that guide use behaviors. TAM also recognizes that usability and usefulness perceptions are influenced by preexisting contextual factors. More recent versions of TAM explicitly include concepts denoting external barriers to technology use, such as costs and maintenance [13].

In theory, monitoring by self-report measures has the potential to provide useful information for competitive runners exposed to high training intensities and large training volumes, predisposing them to running-related health problems [14,15]. However, the usability and usefulness of mHealth monitoring systems, based on such measures, have not been assessed among middle- and long-distance runners. The aim of this study was to explore individual and situational factors associated with mHSM acceptance and long-term use in competitive runners.

Figure 1. The original version of the Technology Acceptance Model used in the present study [12].



Methods

Study Design and Setting

This study was based on a pre-post intervention design and qualitative research methods [16]. The setting was an initiative by the Swedish Athletics Federation to monitor the performance and health of runners competing at middle, marathon, and ultramarathon distances. Following a development and test period, the ambition is to introduce mHealth monitoring and feedback as a regular component of coaching and medical support. The purpose of mHSM in this research was defined as follows: "to collect longitudinal training and health data to be used for individual-level feedback among coach- and self-directed runners." Before data collection, a web survey design tool was used to develop specific mHSM apps for longitudinal data collection. Semistructured interviews were used for collection of data before and after use of the prototype apps. The qualitative interview data were structured, interpreted, and categorized using a thematic analysis and have been reported according to the consolidated criteria for reporting qualitative research criteria for reporting qualitative research based on interview data [17].

Ethical Considerations

In accordance with the Swedish legislation, this study was subject to review by research ethics committees [18]. The project was planned and conducted in accordance with the ethical principles of the Declaration of Helsinki. Before inclusion in the study, oral and written information about the purpose of the study was provided and each participant gave his or her written informed consent. Participation in the study was voluntary. All study data were handled without breaching the integrity of individual athletes.

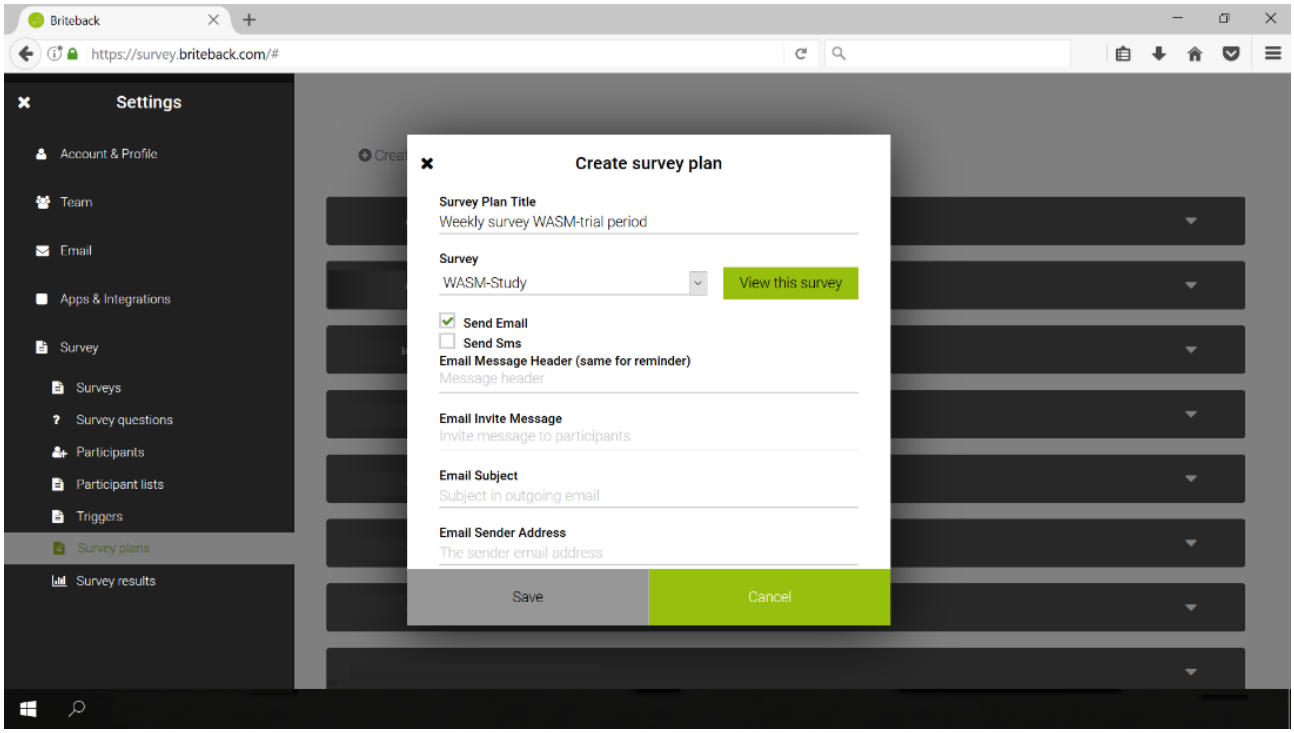
Study Population

The study population was defined to include adult runners (>18 years) competing at the national level, in middle or longer distances, in elite or veteran categories. Purposive sampling was used to ensure variation in gender, age, and running events. For recruitment of participants, 3 running clubs in Sweden were contacted through their head coaches. After discussions with their runners, all clubs accepted, at the group level, to participate in the study. The clubs offered runners support both by individual coach-directed schemes and through group-level coaching for self-directed runners. Individual invitations were then sent by email. According to the saturation principle, the recruitment of participants for individual interviews continued as long as new aspects appeared in the data.

mHealth Self-Report Monitoring Software

The mHSM software used in this study was developed on a Web platform , Briteback AB, Norrköping, Sweden) where Web survey apps can be created and handled. For this study, 2 surveys asking for health and training data were developed and adapted for track and marathon runners. Both surveys included questions about the runners' training and if they had experienced health issues. The surveys distributed to the marathon runners were slightly more detailed regarding training load, and the surveys provided to track runners were more detailed regarding health issues. After the survey items had been compiled for the monitoring events, the distribution of the events was sequenced in a monitoring plan, as seen in Figure 2, where the timing of repeated longitudinal monitoring was scheduled. The runners who did not complete the survey in 3 days received an automatic reminder by email with a new link to the survey.Automated system-generated statistics were provided for the researchers immediately after reporting of data.

Figure 2. Display from the Web platform (Briteback) used to create and schedule weekly monitoring (Source: Sara Rönnby, Athletics Research Center, Linköping University).



Textbox 1. The 6-step method used for thematic analysis of the interview data [19].

Thematic analysis

1. Familiarization with data
2. Initial code generation
3. Searching for themes
4. Reviewing themes
5. Naming themes and categorizing them according to Technology Acceptance Model
6. Producing report

Data Collection

The first set of semistructured interviews were conducted by two authors (OL and SR) before mHSM was initiated. An interview guide with open-ended questions that covered the main aspects of TAM was used. The interviews lasted for about 30 minutes and were audio recorded. The preuse interviews investigated the experience and knowledge of mHealth monitoring, followed by the runners' thoughts on possible benefits and side effects. The postuse interviews investigated perceived usability and usefulness, attitudes toward nonfunctional issues, and intentions to adhere to longitudinal monitoring. In addition, the runners' trustworthiness when using the system was questioned, and thoughts on improvements and what they would want to change to optimize the system for their training were investigated. After the interviews, the pre- and posttrial interviews were transcribed verbatim.

Data Analysis

A deductive thematic analysis [19] was performed using TAM as the theoretical foundation, as seen in Textbox 1.

To familiarize themselves with the data, the transcribed interviews were read through repeatedly by three authors (SR, OL, and TT). With the study aims in mind, the most relevant parts of the data were identified, and key parts were extracted from the individual responses, from which meaning units were identified regarding their content and context. The meaning units were interpreted at a semantic level rather than a latent level. Codes were produced consisting of keywords that captured the essence of the meaning units. The codes were used to gain understanding and to compare meaning units. The coded meaning units were then grouped into categories. After reviewing the categories and adjusting some of them, the categories were grouped into themes named using a short sentence. These themes were finally contextualized and classified according to TAM (Textbox 1) in a process that included all authors.

Results

Data were collected from 20 runners (9 males and 11 females) aged between 20 and 64 years (Table 1). Most runners reported previous monitoring experience, mainly the use of training diaries for communication with their coach. Also, some self-directed runners without a personal coach stated that they had practiced data collection during their training. More often than not, the coach-directed runners planned their training down to exact exercises, whereas the self-directed runners scheduled their training in a less detailed way (eg, a rough weekly plan of the amount of training).

The runners' previous mHSM experience was scarce. None of them had used more complex documentation and analysis tools than an mHealth training diary. A male runner's description of his experiences was typical for the runners.

> *I have looked at some online tools, I may well say. Online coaches, those kind of automated, for instance. But it's nothing that I have followed regularly. It is mostly really training diaries that I have used.*

During the mHSM trial period, 19 participants provided monitoring data every week; one runner failed to provide data for the final week because of technical issues (Table 2). Most participants responded in the first couple of days for most of the weeks in the trial period. However, 15 of 20 runners received a first reminder (sent out 3 days after the initial weekly survey).

Predispositions and External Factors

To be motivated for participation in mHSM, the runners explained that they needed to expect a positive balance between immediate burden and future reward. A long-distance runner explained:

> *It depends on how much data I should report, that is, how many questions I have to answer. The more questions, the less keen I am to report.*

Regarding rewards, the runners envisioned new services that could be provided through mHSM, such as ubiquitous availability of support to interpret trends and long-term planning of running schedules. Integrated graphical displays of training patterns and competition performances were asked for by a middle-distance runner:

> *I would like to more easily be able to see trends and patterns over time. Such as 'Oh, here I trained so and so, and then I got these results.' It would provide a better overview of how I've trained and what it provides in terms of consequences, both regarding results but also injuries and other things.*

Table 1. Characteristics of participating runners.

Participants	Sex	Age (years)	Event(s)	Coach directed	Detailed schedule	Monitoring experience	mHealth self-report monitoring experience
1	Male	27	10-21 km	Yes	Yes	Yes	No
2	Female	20	5-21 km	Yes	Yes	No	No
3	Male	24	1500 m to 5 km	Yes	Yes	Yes	No
4	Male	24	5-21 km	No	No	Yes	No
5	Male	21	5 km	No	Yes	Yes	Yes
6	Female	25	Middle distance	Yes	Yes	No	No
7	Male	27	3-5 km, cross country	No	No	Yes	Yes
8	Male	24	10-21 km	No	No	No	No
9	Female	34	5-10 km	Yes	Yes	Yes	No
10	Male	24	10-42 km	No	No	No	Yes
11	Female	55	Marathon	No	No	No	No
12	Male	57	Marathon	No	No	Yes	No
13	Female	56	Marathon	No	Yes	No	No
14	Female	64	Ultramarathon	No	Yes	Yes	No
15	Male	40	Marathon	No	Yes	Yes	No
16	Female	45	Ultramarathon	No	No	Yes	No
17	Female	55	Ultramarathon	No	No	Yes	No
18	Female	48	Ultramarathon	No	Yes	Yes	No
19	Male	46	Marathon	No	No	Yes	No
20	Male	31	Marathon	No	No	Yes	No

Nonetheless, in parallel to the visions of new services and uses, concerns were also expressed that the playful aspect of participating in the sport might disappear. One runner clarified:

> *Somehow, the more you record about your training and the keener you are on structure and control, the greater is the risk that the spontaneity and joy will diminish or disappear. I'm running and working out mainly because I think it is so nice and fun. Yes, in some way you can feel a little limited or controlled [by mHSM], and, if you take this too far, there is a risk that the feeling of freedom and joy of running disappears in part I think.*

A related concern was that mHSM could introduce unnecessary stress. In particular self-directed runners, who less often discuss their training and competition schedules with a coach, were seen to be at risk. A self-directed long-distance runner explained:

> *Some people may become slaves under the system, and get anxious. 'I was to have a 150 km week' and then you find that you just reached 139 km and then you feel bad because of that.*

Other runners envisioned that mHSM, in the future, would allow large quantities of data to be collected from many runners. Access to these large datasets would be interesting also for parties outside the traditional athlete-coach setting. The runners were clear that the new external uses of their data should not be allowed without their permission, highlighting the "market value" of the data collected:

> *Well, if [the data] can be linked to me as a person, I think no one should have access to [my data] without my knowledge, but it may be okay with my consent. I would lett physicians and coaches and others use these data. However, not just anyone, it should be based on my consent.*

Perceived Ease of Use

The mHSM apps were considered easy to use and understand, and most runners did not experience technical difficulties during the test period. They stated that use was easier and less demanding than expected. One of the middle-distance runners expressed a typical opinion:

> *The survey itself was not as long as I had feared it would be. It went a lot faster than I expected, but that's of course linked to my expectations. I experienced it as quick and easy to fill in.*

However, although the monitoring items were understandable, they still could be perceived as problematic. For example, one runner had difficulties differentiating between well-being with regard to running achievements and well-being in general:

> *It is hard to know how to report some features. They are kind of subjective, for example, 'How you do feel today?'*

Table 2. Overview of runners' monitoring behaviors.

Participants	Monitoring compliance	Response lag (days)	Reminders issued	Device used	Human-computer interface concerns[a]
1	Yes	1-3	1	Mobile phone	No
2	Yes	1-2	1	Mobile phone	No
3	No[b]	1-3	2	Computer	Yes
4	Yes	1-2	0	Computer	No
5	Yes	1-2	0	Mobile phone	No
6	Yes	1-2	1	Computer	No
7	Yes	1-2	1	Mobile phone or tablet	Yes
8	Yes	1-4	3	Mobile phone	No
9	Yes	1-3	1	Computer	No
10	Yes	1-2	1	Computer	No
11	Yes	1-5	2	Computer	No
12	Yes	1-2	0	Computer	Yes
13	Yes	1-3	1	Computer	No
14	Yes	1-3	1	Mobile phone	Yes
15	Yes	1-2	0	Mobile phone	No
16	Yes	1-3	1	Mobile phone or tablet	No
17	Yes	1-2	0	Computer	No
18	Yes	1-2	0	Mobile phone or tablet	No
19	Yes	1-3	1	Mobile phone	No
20	Yes	1-2	0	Computer	No

[a]Problems with the human-computer interface for data entry.

[b]Technical problems in the final week.

The timing of survey distribution was found to be important when responding to the weekly questions in the midst of everyday chores. The runners tried to find a situation where they could routinely respond to the survey without being disturbed:

> *I replied probably almostright away. It was sent out just before Iwere going to sleepso then I did it before I went to bed.*

Despite the mHSM apps being perceived as easy to use, responding could still be complicated by the fact that safe access to the internet was unnecessarily difficult. One of the runners explained:

> *Web developers [sigh]… They are going to complicate everything. The purely IT-related parts have to be both safe and easy. Best would be if you could log in via a social network or email, so you do not have 3 billion passwords everywhere.*

Perceived Usefulness

The runners expressed that mHSM was useful in general but emphasized that the items being monitored had to be formulated so that they were relevant to improving their running. A certain level of detail in the training data was needed to offer this usefulness, although the effort had to stay as low as possible. One middle-distance runner's view summarized the general perception of the monitoring scope:

> *The length of the survey was really good. Comprehensive, but not too extensive. It cannot be too long if you're going to fill it in frequently...Multiple choice questions, ratings, and such are good. It becomes fairly accurate and time efficient.*

Opinions varied on the useful levels of sports load recording, but the runners agreed that the balance between information detail and the recording burden was important. Another runner explained:

> *I would probably want it more detailed; the survey was a little too brief for it to be really useful. But more detail would be more demanding. However, as long as you can feel motivation and purpose, there is no problem with more extent.*

However, in some circumstances, there were differing opinions about what data to report (eg, recording training volume as running distance or time) and difficulties with the interpretation of concepts (eg, whether subjective well-being should encompass daily living as a whole or only the running context). The runners also pointed out questions and functions that were

not included in the monitoring. For example, one runner asked for more open reporting formats:

> *The survey questions were very specific. Yes, running is what it was about, so that was no problem [to report]. But then using skiing and swimming as alternative forms of exercise [were also asked for]. There may well be many other relevant alternative forms of exercise that runners use.*

Attitudes Toward Using

Based on that, the runners found mHSM easy to use and potentially useful, their reasoning about adoption consequences came to focus on concerns about nonfunctional issues, mainly privacy and integrity. Regarding access to monitoring data, individuals directly supporting the runners and researchers were generally tolerated. However, the attitudes associated with access privileges differed between training and health data; data on personal health and mental well-being were considered more sensitive. One runner explained:

> *I thought about the questions regarding personal health, which are quite private. I had that in mind when I answered the surveys. A running diary can be really personal. Then I found that integrity is very important. Everybody may not want to show how they train or how they feel.*

However, the perceptions of integrity breaches were contextual and relatively specific. A middle-distance runner clarified:

> *It could have been [sensitive for runners] if anything about mental health aspects was included, but it was not. There were questions only about general well-being and nothing about 'Have you visited a psychologist?' No, it would only be [sensitive] if deeper issues such as performance anxiety and depression were asked about. But such questions were not included.*

A few of the runners suggested that if the information was made anonymous, access could be completely open. Regarding training data access, there were notable differences between different groups of runners. The typical standpoint among the runners was that training data could be shared relatively freely. A veteran marathon runner summarized her views after having used the mHSM system.

> *I feel that it does not matter if anyone knows that I've gone to the gym 2 days a week for 5 weeks, which I actually did, and ran 20 km one week and 100 km next week. I do not think that would be an invasion of privacy for me.*

The deviating opinions regarding data sharing and integrity were related to team selections. The most competitive runners requested detailed control over who in the sports organizations they belonged to, from clubs to federations, should be allowed access to their data. One of these runners stated:

> *No, I believe that selections and so on should be based on performance and other ways [than monitoring]. It is difficult, I think, to associate competition results with this type of statistics and data. No, no I do not think it would be reasonable.*

A typical argument for objecting to sharing data with team managers was that the runner was concerned that it would lead to untruthful self-reporting, that is, competitors for team selections would overstate training and downplay injuries.

> *I would not like it to influence selection to competitions and national teams. There should not be any reason not to be honest in your training diary or such. But all in your personal team should have access, if relevant. Otherwise I prefer it not spread.*

Nonetheless, the runners also stated that they were truthful when providing data, as is shown in the following examples:

> *I tried to be very honest, there's no reason to lie, it's not a competition that way.*
>
> *Since I keep a paper backup [for myself] as well, I know that [the data I provide] are honest [and accurate].*

Behavioral Intention to Use

The runners were willing to use mHSM for extended periods of time, provided that the monitoring was adjusted to their personal settings and feedback needs. Reporting on a weekly basis was preferred. One runner explained:

> *At least once a week. Otherwise, you start to forget. Above all, you forget how it felt. It would be most favorable to report each session but then it can be difficult to get it done.*

mHSM technology in the runners was regarded as potentially beneficial for their personal development as athletes, for example, for performance improvement through injury prevention. Even so, the runners highlighted the balance between cost and benefit when considering use over extended periods of time:

> *If you think it is meaningful, it is time well invested considering what you can get out of it, as long as the system is easy to use.*

The perfect balance between usefulness and burden was not the same for different categories of runners. However, overall, the runners found that acceptable reporting habits could be achieved.

Discussion

Principal Findings

In this qualitative study based on TAM, we found that variations in intentions to adopt mHSM among competitive middle- and long-distance runners could be explained by the perceived usefulness of the technology rather than its usability. The overall system design and the monitoring content were regarded as more important for adoption than specific utilities of the human-computer interface. Moreover, contextual nonfunctional issues, such as control of access to the collected data, influenced use intentions among the most competitive runners. These finding imply that acceptance of mHSM in routine settings in competitive runners will require clear definitions of purpose and user populations, meticulousness regarding data-sharing

routines, and formative evaluations of the monitoring content in each specific app.

Usefulness of mHealth Self-Report Monitoring

We found that the competitive runners needed to see a positive balance between immediate burden and future reward to be motivated for mHSM. Among self-directed runners, the burden of analyzing the data and using the results for their own health maintenance and performance improvement may be overwhelming. However, these athletes also need to gain a positive balance from a monitoring process to be sufficiently motivated to record data [20]. Consequently, being able to effortlessly generate interesting output from mHSM data analyses, such as graphical displays of performance and health trends, is particularly important for self-directed athletes. In comparison, for coach-supported runners, the burden of supplying mHSM data is more likely to be balanced by factors such as improved coordination of training management [21]. The perceptions of the members of the support team, in particular, the coach, are therefore important to consider when assessing the usefulness of mHSM for this category of runners.

The accuracy of the self-reported data is a related concern. Although the runners generally stated that they supplied accurate data, some athletes indicated that they occasionally guessed or made estimations. Acquiescent responding or indiscriminate agreement irrespective of survey content [7,22] may thus affect the quality of mHSM data among runners. In addition, conscious bias may occur. For instance, coach-supported athletes may report favorable data and underreport unfavorable data to gain selection, that is, “faking good” [23]. However, the validity of objective recording of physical loads, such as accelerometer data, has recently been questioned [24], and self-reporting has been shown to be the favored monitoring method regarding well-being and health influencing athletes’ performance [21,25]. This study did not analyze the validity of the reported training load data or that of the well-being and health data. The quality of self-reported data for these parameters should be further assessed among both self- and coach-directed athletes.

Nonfunctional Issues

The finding that the most competitive runners were more concerned about access to their data can be compared with that of a recent study [8] that reported that coach-supported athletes were less concerned than self-directed athletes about data being secure and not misused. This lack of concern among coach-supported athletes was interpreted to reflect either a lower subjective importance of data sharing compared with the other factors or a particularly positive social environment in the study setting. However, other studies involving coach-supported athletes have reported concerns about athletes reporting their injury data to coaches [23]. In individual sports such as middle- and long-distance running, athlete selection for major competitions and teams usually takes place above the personal coaching level. The critical circumstance influencing attitudes toward data sharing in this setting thus appears to be athlete ranking and selection and not the coaching relationship per se. From these observations, we infer that ethical issues associated with mHSM in competitive runners cannot be evaluated without first defining the exact purpose of the monitoring and describing the individuals and groups that will have access to the data. Therefore, we suggest that future studies of mHSM usefulness are performed in routine sports practice settings. This implies that nonfunctional ethical and legal issues also need to be included in evaluations and that their solutions are allowed to influence the results.

Usability Issues

The finding that mHSM usability was associated with the structure of the survey items can be compared with experiences from electronic data collection on preparticipation health in association with athletics championships [26] and mHSM among Paralympic athletes [27]. In both these contexts, the athletes encountered few usability problems but expressed concerns about medical terminology and formulation of the survey items. In sports settings, where standardized questionnaires have been used for data collection from athletes, differences have been observed regarding the ability to interpret concepts and respond as intended [28]. We infer that adequate adaption of monitoring items with regard to the characteristics and heterogeneity of the monitored population is key to be able to attain meaningful and useful data from long-term mHSM. However, before addressing the items, decisions need to be made on what proportions of standardized questionnaires, specific variables of interest, and pragmatic measures should be included in the monitoring. Therefore, we recommend that when developing an mHSM tool for long-term use, sufficient time and effort is allocated to define the specific purposes and goals of the data collection, the design of the tool is adjusted to whether it is to be used by self-directed or coach-directed runners, and the individuals and groups that will have access to the data are carefully considered. Thereafter, instruments need to be chosen or customized monitoring items need to be formulated such that the intended users understand and are motivated to use them. The runners in this study were not directly (hands on) involved in the creation of the mHSM items. We agree with the recommendations from a recent Dutch study that providing athletes with a tangible take away benefit from mHSM is essential [29] but add that inclusion of runners early in the design process of the app is strongly desirable. Before wide dissemination of an mHSM app for long-term use, several test periods, when intended users try out both the technical system and the monitoring items, should be completed. At the end of each period, experiences should be collected and the app design updated. Availability of a flexible software environment, where survey items can be changed easily during pilot trial processes, is a necessity.

Future mHealth Self-Report Monitoring Apps

Preintervention, the participating runners reported having routinely recorded and analyzed training load data but had almost no mHSM experience. Accordingly, several novel uses of mHSM technology were suggested after the trial period. Alternative ways of using mHSM than those addressed in this study have been reported in the scientific literature, for instance, rather than using mHSM data for self-direction or traditional coaching support, data analysis can be performed cooperatively in peer-to-peer learning processes. For professional runners, their sport is their main source of income. By including mHSM data in structured peer-to-peer communication, self-employed

runners can share information about training conducted as well as planned training programs, competition calendars, and competition venues. Groups of runners can thereby establish a contextualized learning process based on cooperative discovery. Web technology and devices are then used as facilitators and mHSM data as references for learning by comparison. Evaluations have highlighted that professional runners find discussions and sharing of experiences with peers in chat forums stimulating [30]. Self-esteem and self-reliance were found to improve as a consequence of receiving feedback, analyzing that feedback, and using the results to make adjustments and increase performance. Peer-to-peer communication supported by mHSM can thus predispose athletes toward a learning process where runners access education at low cost and are simultaneously empowered through integration into a wider community of sporting peers [31]. Sharing of training and health data thereby becomes the basis for a highly contextualized performance enhancement program.

Strengths and Limitations

This study has strengths and weaknesses that need to be taken into consideration when interpreting the results. A strength is that the study used a pre-post design, which allowed analysis of attitude stability over time. An important limitation is that the mHSM system used in the trial only covered the initial mHSM phases (to record and review data) [32]. Inclusion of the remaining aspects (to contextualize and act) would have required involvement of coaches and other staff supporting the runners. Such an extended evaluation should be performed using more recent versions of TAM that include aspects such as costs, maintenance, integrity, and privacy [33,34]. Another weakness is that in this study, as in many other qualitative studies, the study group was relatively small (N=20). Nonetheless, recruitment of participants continued until saturation of the data was reached. Also, every runner category has unique features and needs. Therefore, extrapolating experiences of using mHSM from one category of runners to other running contexts should be done with caution. This study addressed usability and issues that might occur when attempting to create an mHSM app for the long-term surveillance of competitive middle- and long-distance runners, and the results do not provide complete information for the design of such a system for other runner categories. However, this study still highlights important aspects that should be considered when designing mHSM tools in other areas of sports epidemiology.

Conclusions

Adoption of long-term mHSM by competitive runners requires clear definitions of purpose and populations, extensive in practice tests of survey items and terminology, and meticulousness regarding data-sharing routines. We suggest that further naturalistic studies of mHSM should be performed in routine sports practice settings. This implies that nonfunctional ethical and legal issues need to be included in the evaluation designs and that the solutions to these challenges are allowed to influence the results.

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Conflicts of Interest

None declared

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Abbreviations

mHSM: mHealth self-report monitoring
TAM: Technology Acceptance Model

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Original Paper

A Mobile App (WhiteTeeth) to Promote Good Oral Health Behavior Among Dutch Adolescents with Fixed Orthodontic Appliances: Intervention Mapping Approach

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Abstract

Background: The insertion of fixed orthodontic appliances increases the risk of dental caries, particularly in adolescents. Caries can be prevented through good oral health behavior. To support adolescents with fixed orthodontic appliances and for promoting oral health behavior, we developed a theory- and evidence-based mHealth program, the WhiteTeeth app.

Objective: The objective of our paper was to describe the systematic development and content of the WhiteTeeth app.

Methods: For systematic development of the program, we used the intervention mapping (IM) approach. In this paper, we present the results of applying the first 5 steps of IM to the design of an mHealth program: (1) identifying target behaviors and determinants through problem analysis, including a literature search, a survey study, and semistructured interviews, to explore adolescent oral health behavior during orthodontic therapy; (2) defining program outcomes and objectives; (3) selecting theoretical methods and translating them into practical strategies for the program design; (4) producing the program, including a pilot test with 28 adolescents testing the acceptability and usability of the WhiteTeeth app; and (5) planning implementation and adoption.

Results: On the basis of our literature search, we identified fluoride use and control of dental plaque levels (eg, tooth brushing and proxy brush usage) as target behaviors for preventing caries. Next, we identified important and changeable determinants of oral health behavior that fitted the theoretical concepts of the Health Action Process Approach (HAPA) theory. The HAPA theory, the self-regulation theory, and the results of the semistructured interviews were used to define the program objectives, that is, the performance and change objectives. After defining the objectives, we identified multiple behavior change techniques that could be used to achieve these objectives, such as providing oral health information and feedback, prompting self-monitoring, coaching of set actions and coping plans, and sending reminders. We translated these methods into practical strategies, such as videos and a brushing timer. Next, we combined these strategies into a single program resulting in the WhiteTeeth app (which is available on both iTunes and Google Play stores as “Witgebit”). Adolescents with fixed orthodontic appliances and dental professionals were included in the development process to increase the success of implementation. The pilot test revealed that the app users appreciated and liked the app. The WhiteTeeth app can be integrated into current orthodontic care.

Conclusions: IM allowed us to identify multiple techniques that have been shown to be the most effective in initiating behavior change, but have not yet been incorporated into existing orthodontic apps. The WhiteTeeth app contains all these techniques, which makes it a unique and promising home-based app for promoting oral health in adolescents with fixed orthodontic appliances.

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KEYWORDS

health behavior; mHealth; oral health; oral hygiene; dental caries; adolescent; dental plaque; prevention; intervention mapping

Original Paper

Introduction

Dental caries remains a major public health problem that affects young people and adults [1]. Worldwide, nearly 60%-90% of young people and the majority of adults have dental caries, which often leads to pain and discomfort [2-4]. In several industrialized countries, oral diseases are the fourth most expensive disease to treat [2]. Furthermore, 5%-10% of public health expenditure is devoted to oral health treatment [5-6]. Adolescents with fixed orthodontic appliances are at high risk of developing dental caries [7], as fixed orthodontic appliances (eg, brackets) impede oral hygiene procedures, restrict salivary and mucosal self-cleaning capacity, unfavorably altering the balance of oral bacteria and increasing the retention of dental plaque [8-10]. Prolonged dental plaque accumulation can lead to enamel demineralization, which is an early stage of dental caries. Due to their white appearance, these demineralizations are named as *white spot lesions*, which are a common complication in orthodontics [11]. The incidence of patients who develop at least one new white spot lesion during orthodontic treatment ranges from 68% to 95% [12-14]. White spot lesions may develop around the bracket, thus seriously compromising aesthetics [15,16]. After the removal of fixed orthodontic appliances, white spot lesions often remain permanently visible; along with being unaesthetic, they increase the risk of lesion progression [15,16]. Oral health education is essential for the prevention of dental caries in patients with fixed orthodontic appliances. A central role in such education—which is given both before and during orthodontic treatment [17]—involves oral health behavior that targets dental plaque control, dietary behaviors, and fluoride administration [18-21]. However, it is not always easy to achieve regular patient compliance with such oral health behavior [22]. A recent study among Dutch adolescents with fixed orthodontic appliances showed that they had poor overall oral hygiene and poor compliance with the use of fluoride mouth rinse [23]. This emphasizes the need for interventions that focus on changing the oral health behavior in this age group. As growing numbers of young people now have mobile phones, mobile phone apps may be effective means of promoting oral health behavior in orthodontics [24-26]. As a delivery method, apps have many advantages: they are constantly accessible, can be adjusted to the needs of the user, can provide tailored feedback, are more anonymous than face-to-face contact, can send cues to action (ie, reminders), and have a wide reach and interactive features such as animations [27-29]. To promote good oral health behavior among adolescents with fixed orthodontic appliances, we decided to develop a mobile phone app, the WhiteTeeth app (Dutch name: WitGebit app). To ensure that this app would be both theory- and evidence-based and also be feasible for use in orthodontic clinics, we used the IM protocol [30] for its systematic development. This paper provides a detailed description of the development and content of the WhiteTeeth app.

Methods

Intervention Mapping Protocol

IM is a protocol for planning and developing theory- and evidence-based health promotion programs [30]. The IM process comprises 6 steps: Step 1, identifying target behaviors and determinants through problem analysis; Step 2, specifying program outcomes and objectives; Step 3, selecting theoretical methods and practical strategies for the program design; Step 4, producing the program; Step 5, planning the implementation and adoption; and Step 6, planning for evaluation [30]. Each step has a defined end product and consists of various tasks that are required for the systematic integration of theoretical and empirical information. The product of a preceding task or tasks guides the developmental activities for the subsequent step or steps.

To guide the developmental process for this intervention, we established a multidisciplinary planning group consisting of an orthodontist, a dental hygienist, two dentists, a mobile phone app developer, a health psychologist, two health scientists, and a child psychologist with communication expertise.

Step 1: Problem Analysis

The first step of the IM process was to conduct a problem analysis, which included the identification of determinants related to the problem and specific health-related behaviors. The IM process is based on the assumption that health outcomes can be improved by targeting health behaviors and their determinants [30].

To explore the oral health behavior of adolescents during treatment with fixed orthodontic appliances, we conducted semistructured interviews with adolescents with orthodontic fixed appliances (n=20), asking them about their oral health behavior. These semistructured interviews were performed after a regular orthodontic check-up in a private room at the Academic Centre for Dentistry Amsterdam (ACTA).

Adolescents with fixed orthodontic appliances were purposively sampled to ensure that the patient group exhibited a range of sexes, educational levels, ethnicities, and dental hygiene levels. The clinicians told adolescents about the aim of the study and the voluntary nature of participation. Their parents or legal representative were given written information about the study.

Informed consent was obtained from both adolescents and their parents.

During the interview, we asked the adolescents about their beliefs and motivations concerning the performance of oral health behavior during fixed orthodontic treatment. Interview topics relevant to the adolescents' oral health behavior consisted of (1) oral hygiene practices; (2) reasons or motives for performing oral health behavior; (3) awareness and knowledge of dental health and recommendations on oral health (see Textbox 1); (4) personal strategies and reported barriers; (4) role of the social environment; and (5) facilities (accessibility). The adolescents were individually interviewed using open-ended questions to guide the interview. The audiotaped interviews were anonymously transcribed verbatim and transported to a software program "NVivo" to analyze the transcripts. After 20 interviews, saturation was attained, that is, no new relevant information emerged in subsequent interviews. The Medical Ethics Committee of the University of Amsterdam approved this qualitative study (VUMC - 2014-577).

After exploring adolescent oral health behavior during orthodontic treatment through these semistructured interviews, we searched the literature to identify behavioral determinants and theoretical constructs to explain this behavior. We therefore conducted a systematic literature review with a meta-analysis [33]. Since the findings of this review applied to young people in general, not specifically those with fixed orthodontic appliances, we conducted a survey among adolescents undergoing fixed orthodontic therapy (n=116) [23]. This survey study aimed to explain oral health behavior and the presence of dental plaque during orthodontic treatment. A sample of 116 adolescents (12-15 years) with fixed orthodontic appliances was recruited from an orthodontic clinic situated in Almere (Netherlands), and the respondents completed a questionnaire to map their oral health behavior. In addition, a dental hygienist measured their dental plaque levels. Linear regression analyses were performed to examine the factors associated with dental plaque and specific oral health behavior [23].

Next, the planning group selected important and changeable determinants of oral health behavior. According to IM, the importance of determinants is related to their relationships with oral health behavior. The changeability of the determinants that can be achieved by an intervention and the importance of the determinants were established by the development group on the basis of the available scientific literature [23,30,33-40] and consensus judgments.

Step 2: Identification of Program Outcomes and Objectives

Step 2 involved a detailed specification of program outcomes and objectives indicating those behaviors that needed to change to achieve the overall goal of the program, that is, to prevent dental caries in adolescents during orthodontic treatment, and to prevent existing dental caries from getting worse. The performance objectives formalized the behavioral changes that adolescents with fixed orthodontic appliances needed to make to achieve the behavioral goals of the program (the program outcomes). Per program outcome, two researchers (JS and PvE) defined performance objectives on the basis of the following question: "To perform the desired behavior, what, in concrete terms, do participants in this program need to do?" Next, the same two researchers identified specific determinants that would be deemed useful in changing each performance objective. For example, if a performance objective was "to decide to prevent dental diseases and to change their tooth brushing behavior," appropriate behavioral determinants may be "risk perception," "knowledge," "outcome expectancies," and "self-efficacy." Subsequently, we formulated change objectives that stated what determinants needed to change to achieve the performance objectives. The change objectives were the result of combining performance objectives with the changeable determinants of oral health behavior. Thus, to give an example, the determinant was adolescents' "self-efficacy," and the performance objective was "adolescents decide to prevent dental diseases and to change their tooth brushing behavior." In this example, the change objective would be for "adolescents with fixed orthodontic appliances (to) feel able to prevent dental diseases and (to) gain confidence in their ability to brush their teeth twice daily according to the 5-step method." The first author constructed a matrix, as explained by IM [30], specifying performance objectives, behavioral determinants, and change objectives, which were subsequently validated by the planning group.

Step 3: Selecting Theoretical Methods and Practical Strategies for Program Design

The third step of IM comprised two phases. In the first phase, we identified and selected theoretical methods. Theoretical methods or behavior change techniques are general techniques or processes that have been shown to enable change in one or more behavioral determinants and which have their origins in behavioral and social sciences theories. One example of a theoretical method is modeling, which is frequently used to facilitate behavior change [30].

Textbox 1. Oral health recommendations for patients with fixed orthodontic appliances from the Academic Centre for Dentistry Amsterdam.

- To control dental plaque levels, it is recommended to brush teeth at least twice a day according to the "5-step method" and to use dental aids (such as a proxy brush to clean the tooth surfaces around the brackets and to maintain gingival health). The "5-step method" consists of brushing (1) the gingival sites, (2) mesial and distal sites, and (3) incisal sites of the teeth in relation to the position of the bracket on the buccal sites of the teeth; (4) the occlusal sites (chewing surfaces); and (5) the lingual or palatal sites of the teeth. This 5-step procedure takes approximately 3 minutes to fulfill [31].
- Daily use of fluoride mouth rinse and toothpaste during orthodontic treatment is strongly advised for the prevention of dental caries [20,31] .
- Consumption of sugars, refined carbohydrates, and acid or soft drinks should be limited [32].

For each behavioral determinant and in conjunction with the change objective, two researchers (JS and PvE) selected theoretical methods on the basis of the literature on existing dental and orthodontic health promotion interventions [36-52] and behavior change techniques [30,53,54]. For example, to reach the change objective "adolescents monitor their tooth brushing behavior and dental plaque levels," we selected the methods "self-monitoring of behavior" and "self-monitoring of the outcome of behavior" for changing the determinant "action control."

In the second phase, we assessed the conditions under which the methods were shown to be effective and translated the selected methods into practical strategies. A practical strategy is "a specific application of a theoretical method, adjusted to the intervention setting, tailored to the target population, and applied considering parameters for effective use of the methods" [30]. For example, the selected method "self-monitoring of behavior" was translated into the practical strategy "adolescents enter into the app whether or not they accomplish their daily oral health tasks." The planning group decided if the methods and strategies were suitable for the target population and appropriate for designing a mobile phone app. When necessary, small changes were made, resulting in strategies that were easier to implement.

Step 4: Program Production

In the fourth step, we combined the chosen strategies into a coherent program leading to the development of the WhiteTeeth app. First, the strategies were clustered to create a program plan, which described the intervention components and presented the wireframe drafts. To ensure that the program met the users' needs and expectations, we organized meetings with the target audience to obtain feedback on the program plan. Helen Parkhurst, a high school in Almere, The Netherlands, allowed us to organize 2 meetings with 30 adolescents (most had current or previous orthodontic appliances) attending preuniversity technology classes.

The first author showed the wireframe drafts and offered a brief demonstration of the main functionalities of the app. As an assignment for a technology class, adolescents were asked to give feedback on the program plan and to design an app. During the second meeting, adolescents presented their app design. New ideas or suggestions for improvements to optimize the program plan were discussed with the planning group. Based on the adjusted version of the program plan, the first author created an adapted version of the app wireframes to increase the app's acceptability and usability. These adapted wireframes were then improved by a user experience designer. The WhiteTeeth app was developed by ACTA in collaboration with Inholland University of Applied Sciences and TNO Research group. A programmer at ACTA programmed the WhiteTeeth app using Ionic software (Ionicframework.com), which enabled the app to function on two operating systems: IOS≥7 and Android ≥4.1.

To identify aspects of the program that could be improved, the WhiteTeeth app 1.0 was pilot tested. It was first tested for bugs (ie, system errors) by the planning group (resulting in WhiteTeeth 1.1). Second, to increase the app's acceptability and usability, it was pilot tested for 2 weeks by 28 adolescents with fixed orthodontic appliances, who then provided feedback on its acceptability and usability in an online survey containing 49 questions. The survey measured perceived usefulness, attractiveness, and ease of use and included the System Usability Scale (SUS) for measuring the app's usability [55]. The SUS scale ranged from 0 to 100 with response ranges from strongly agree to strongly disagree. A SUS score of >68 would be considered above average. This questionnaire has been published elsewhere [56]. The results of the pilot test were used to refine the WhiteTeeth app (resulting in WhiteTeeth 1.2).

Step 5: Program Implementation Plan

The previous IM steps focused on ensuring the effectiveness of the program. The purpose of the penultimate step of IM is to ensure that the program reaches the intended population by preparing for the adoption and implementation [30]. The planning began by identifying who would use the program, who would adopt it, who would implement it, and who would be responsible for sustaining the program over time. The best way to increase the chances for successful implementation is collaborating with future program implementers from the start of the planning process, thereby linking program developers with program implementers. Dental health professionals were therefore involved throughout the entire process. The planning group discussed the adoption and implementation of the app.

Step 6: Evaluation Plan

In the final step of IM, an evaluation plan was created. As this final IM step is not within the scope of this paper, it is reported in detail elsewhere [56].

Results

Step 1: Problem Analysis

Semistructured interviews with adolescents with fixed orthodontic appliances provided insight into their oral health behavior. These interviews revealed that recommended dental aids, such as proxy brushes, were used only occasionally. Although most respondents stated that they brushed their teeth twice a day as a matter of routine, they often failed to brush for as long as recommended. These respondents had little awareness of the benefit of fluoride, and fluoride mouth rinses were not a preventive measure they chose consciously. The dietary recommendations were familiar to most respondents, but many of them did not fully adhere to these recommendations. The main reasons for performing desired or undesired oral health behavior are listed in Table 1. Respondents felt their parents (especially mothers) were helpful with dental care since they influenced the availability of dental aids and supported the adolescents by reminding them to clean their teeth.

Table 1. Main reasons or motives for performing desired or undesired oral health behavior during fixed orthodontic therapy.

Oral health behavior	Reasons for performing or not performing the oral health behavior
Brushing as recommended	• Personal appearance and attractiveness (white teeth without discoloration and bad breath)
Not brushing as recommended	• Lack of time, forgetfulness, no prioritization, and tiredness
Using dental aids	• The necessity they perceived for removing food residues between the brackets
Not using dental aids	• They believed that it was unnecessary to follow recommendations with respect to use of these aids: in their view, some dental aids had the same function as the toothbrush. • Forgetfulness and uncertainty about their ability to use them correctly.
Rinsing with fluoride mouth rinse	• Freshness of breath, better oral health, perceived attractiveness to others due to fresh breath and cleanliness
Not using fluoride mouth rinse	• Forgetfulness, not being familiar with the guidelines, or unavailability of mouth rinse at home
Following dietary recommendations	• Oral health reasons
Ignoring dietary recommendations	• Dietary habits among young people, and social pressure from friends • Misperceptions about the recommendations—eg, perceptions regarding the negative effects of soft drinks

The relevant literature was systematically reviewed to identify those behavioral determinants and theoretical constructs that best explained adolescent oral health behavior. The results of this systematic literature review with meta-analysis revealed that the psychosocial factors most strongly correlated with oral health behavior were “self-efficacy,” “intention,” “social influences,” “coping planning,” and “action planning.” These factors are part of the Health Action Process Approach (HAPA) theory [33]. The findings of this review applied to the oral health behavior of young people in general.

Our survey study (n=116) revealed that the HAPA theory could be applied to explain the differences in oral health behaviors in adolescents with fixed orthodontic appliances [23]. According to this theory, behaviors are established in two subsequent phases: (1) a motivational, intention-forming phase and (2) a volitional phase in which intention is translated into action [57]. Regarding the motivational phase, the motivation (ie, intention) to adopt health behaviors is formed by a growing “risk perception,” “outcome expectancies,” and “action self-efficacy.” A minimum level of threat must exist (“risk perception”) before people start considering the benefits of possible actions (“outcome expectancies”) and think about their competence to actually perform these actions (“action self-efficacy”) [57]. Once intentions are formed, the volitional phase starts. The behavioral intention has to be transformed into specific planning of when, where, and how to perform the desired action (“action planning”) and planning of anticipated barriers and ways to overcome them (“coping planning”). Planning is strongly influenced by self-efficacy because self-efficacious individuals achieve mastery through planning, and they visualize successful scenarios that may guide goal attainment (“maintenance or coping self-efficacy”). Persons with confidence in their ability to cope with setbacks will quickly recover when running into unforeseen difficulties (“recovery self-efficacy”). When the behavior has been initiated, self-regulatory cognitions to control and maintain the behavior must be activated (“action control”) [57]. Next, the planning group selected important and changeable determinants of oral health behavior, which are presented in Table 2.

Step 2: Identification of Program Outcomes and Objectives

The results of the problem analysis were used to specify the program outcomes, performance objectives, and change objectives, which are described below. The program outcomes were specified as follows: (1) Adolescents control their dental plaque levels by improving: (a) their tooth brushing frequency and duration, that is, by brushing their teeth consistently and correctly (5-step method, see Textbox 1) at least twice daily and (b) cleaning around the brackets with a dental aid (eg, a proxy brush). (2): Adolescents increase their exposure to fluoride (ie, a fluoride mouth rinse).

The next stage was to stipulate the performance and change objectives for each of the specific program outcomes. The results of the semistructured interviews (see Step 1), in combination with the frameworks of the HAPA [57] and self-regulatory theory [58] were used to define the performance objectives. Self-regulation theory provides an understanding of the behavioral processes needed for adequate self-management in order to obtain a behavioral goal. As such, it is very useful to define subsets of behaviors. Once the performance objectives had been specified, we created a matrix of change objectives by linking performance objectives to behavioral determinants. In order to design the program, 21 performance objectives and 69 accompanying change objectives were defined. Due to the similarities between the performance objectives for all program outcomes, a selection is presented in Table 3. Table 3 presents 7 performance objectives (PO1-PO7) and 23 change objectives (CO1-CO23) pertaining to program outcome 1a “Adolescents control their dental plaque levels by improving tooth brushing.”

Step 3: Selecting Theoretical Methods and Practical Strategies for Program Design

After careful consideration of parameters for use, theoretical methods and practical strategies addressing the determinants were selected to achieve the change objectives. The determinants and change objectives, their linked theoretical methods and practical strategies for program outcome 1, "Adolescents control their dental plaque levels by improving their tooth brushing frequency and duration," are presented in Multimedia Appendix 1. The following paragraphs present the selected theoretical methods and their translation into practical strategies for the same 7 performance objectives (PO; Step 2).

Performance Objective 1—Providing Health Risk Information, Personal Advice, and Instructions

Suitable methods for supporting decision-making on oral health behavior include providing health risk information on oral health behavior and giving personal advice and instructions (targeting determinants: "risk perception," "outcome expectancies," and "knowledge") [53]. To personalize dental advice and instructions, the app collects information on adolescents' oral health behavior and dental plaque levels. Adolescents were asked to answer questions covering their tooth brushing frequency, their use of fluoride mouth rinse and dental cleaning aids, the duration of their brushing sessions, and the type of toothbrush they used. Next, they were asked to use disclosing tablets in order to visualize their dental plaque. The app then showed an example of a selfie, asked them to take a selfie of the teeth where plaque was visualized, and also asked them to indicate the plaque by clicking on the selfie (the app is installed in the orthodontic clinic, where a dental hygienist provided instructions on using the disclosing tablets and using the mobile phone to take a selfie of the teeth). Based on the number of clicks (ie, the amount of plaque) and answers to the questions, the app provided personal advice on oral health behavior (see Table 4 for the algorithm). If an adolescent did not adequately control his or her plaque levels or if his or her oral health behavior was poor, health risk information was offered via a short animated movie, which depicted the likely development of white spot lesions. This and an image of beautiful white teeth were shown as outcomes resulting from complying with oral health recommendations and thus provided adolescents with motivation for performing the desired oral health behavior.

Table 2. Selection of significant determinants of oral health behavior[a].

Determinants	Importance[b]	Changeability[c]	Evidence for importance
Personal			
Knowledge and awareness	+[d]	+++	r=0.20; *P*<.001
Risk perception	+	+	Precondition for personal relevance
Attitude and expectancies	++[e]	+	r=0.20; *P*<.001
Subjective norm	++	+	r=0.26; *P*<.001
Self-efficacy	+++[f]	+	r=0.37; *P*<.001
Intention	+++	+	r=0.40; *P*<.001
Planning (action and coping)	+++	+	r=0.52; *P*<.001
Self-regulatory skills, such as action control and goal commitment	+++	+	Maintaining behavior
Motor skills	++	+	Precondition for improvement in self-efficacy
Habit	+++	+	Making a certain behavior automatic
External			
Social influences			
Parental behavior	+++	+	r=0.4; *P*<.001
Dental professional	+	+	Based on consensus judgments of the development group
Cues	+++	+	Most direct environmental influence
Access or Availability	+++	+	Making healthy behavior easier

[a]Correlation and significant levels are based on results from previous studies on oral health and behavior change [23,30,33-40].

[b]Importance: the strength of the evidence for the relationship between the determinant and oral health behavior we want to change.

[c]Changeability: the strength of the evidence that the proposed change can be realized by a program.

[d]+: not very important, not easy to change.

[e]++: important, changeable.

[f]+++: very important or easy to change.

Table 3. Seven performance objectives (PO1-PO7) and 23 change objectives (CO1-CO23) pertaining to program outcome 1a "Adolescents control their dental plaque levels by improving tooth brushing."

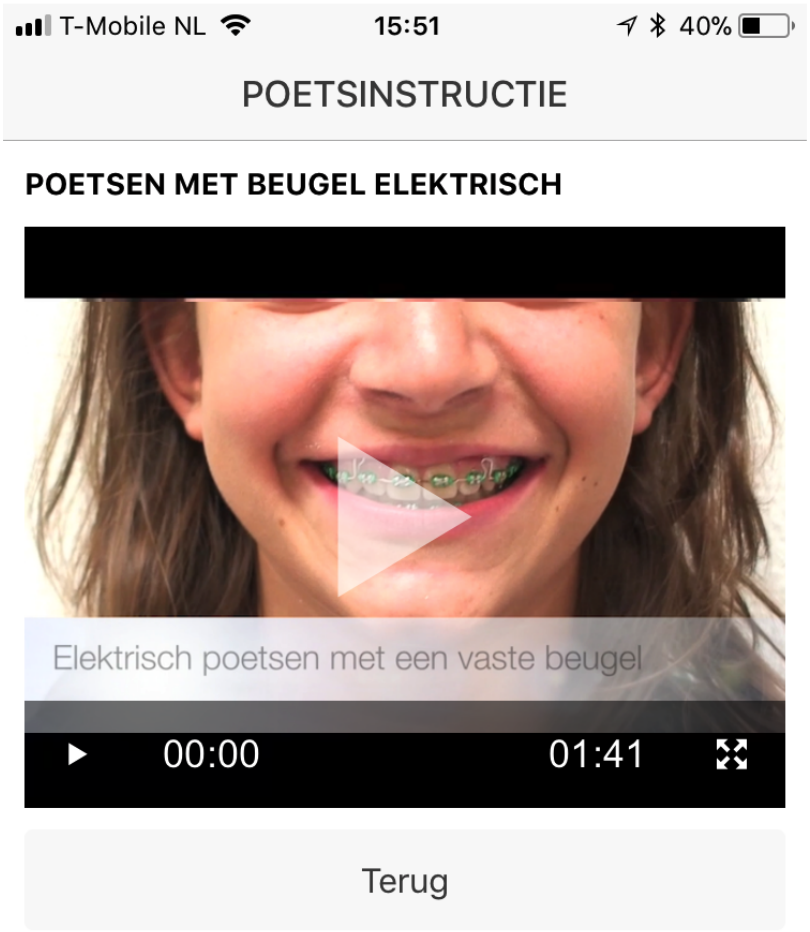
Performance objective and determinant	Change objectives
PO1: Adolescents decide to prevent dental diseases and to change their tooth brushing behavior	
Risk perception	CO1: Are aware of their susceptibility to dental diseases
Awareness	CO2: Are able to describe their tooth brushing behavior
Knowledge	CO3: Know what good oral health is and its association with dental plaque
Risk perception, Expectancies	CO4: Acknowledge the risk of not brushing teeth as recommended and its consequences
Expectancies	CO5: Know the benefits of maintaining good oral health
Knowledge	CO6: Know how to brush teeth according to the 5-step method
Self-efficacy	CO7: Feel able to prevent dental diseases and gain confidence in ability to brush teeth twice daily according to the 5-step method
Skills	CO8: Develop tooth brushing skills (5-step method) to remove all dental plaque
PO2: Adolescents choose or plan how to improve their tooth brushing behavior	
Goal commitment, Self-efficacy	CO9: Choose a change about which they feel self-efficacious
Skills	CO10: State a clear tooth brushing or oral hygiene goal
PO3: Adolescents prepare strategies to establish how they will change their tooth brushing behavior.	
Action planning	CO11: Plan in terms of when and where to brush their teeth
Attitude	CO12: Show commitment to their goals
PO4: Adolescents change their tooth brushing behavior	
Support	CO13: Receive support during brushing on where and for how long to brush teeth
Cues to action	CO14: Receive cues to tooth brushing
PO5: Adolescents evaluate their tooth brushing behavior, their dental plaque levels, and the effect of brushing on these levels	
Self-regulatory skills—action control	CO15: Monitor their tooth brushing behavior and dental plaque levels
Self-regulatory skills, Awareness	CO16-17: Examine how well their performance corresponds to agreed goals, and consider modifying goals accordingly
PO6: If adolescents have difficulty attaining their tooth brushing or dental plaque goal, adolescents identify possible solutions	
Coping planning, Action control	CO18: Identify and anticipate barriers and ways to overcome them
Self-efficacy	CO19: Gain confidence to deal with possible barriers
Social influences	CO20: Enlist others to help overcome barriers
PO7: Adolescents maintain the desired tooth brushing behavior	
Self-efficacy	CO21: Gain confidence in maintaining tooth brushing behavior
Expectancies	CO22: Feel positive about tooth brushing
Attitude	CO23: Believe that long-term benefits can be achieved by maintaining tooth brushing over time

Our semistructured interviews showed that doubts about personal oral hygiene skills and the perceived complexity of the techniques were important barriers to the use of dental cleaning aids. To target adolescents' self-efficacy, movies of a peer model were shown (adolescent with fixed orthodontic appliances), demonstrating how to clean teeth correctly (according the 5-step method—see Textbox 1) that have fixed orthodontic appliances (Figure 1) [59]. This demonstration was tailored to the kinds of toothbrushes the adolescents used.

Performance Objective 2—Goal Setting

Goal setting can help adolescents to choose how to improve their oral health behavior (targeting the determinant: "skills") [34]. Important conditions for the success of goal setting are the adolescent's commitment to the goal and the fact that the goals are challenging, but lie within the adolescent's abilities to achieve them. To ensure their commitment, adolescents chose a health behavior goal that best matched their preferences and abilities. In a series of questions, the app guided them through the process of defining one or more oral health goals. The adolescents then selected an oral health behavior he or she would like to change, for example, improving the frequency and duration of tooth brushing and the use of a proxy brush or a fluoridated mouth rinse. The answers were presented as clear goals on the main page of the app.

Figure 1. Screenshot of a movie of the WhiteTeeth app. Taken on an iPhone, this movie shows users a peer model who demonstrates how to use an electric toothbrush to brush teeth fitted with fixed orthodontic appliances.



Performance Objective 3— Planning and Behavioral Contracting

Planning (ie, formulating action plans) and contracting were identified as methods for preparing oral health behavior change (targeting determinants: "action planning" and "attitude") [37-39,44-46]. The app asked questions, which guided the adolescents in the creation of action plans by specifying goals, in terms of when and where they should act. The answers were presented as their action plan, which would state where and when they would brush their teeth. This action plan was formulated as an implementation intention ("If situation X arises, then I'll do Y"). When one or more goals were formulated, the adolescent agreed to the overall action plan by signing a contract in the app. This was saved on its main page. The action plan was linked to the option for setting reminders.

Performance Objective 4—Practical Support (the Brushing Timer)

To establish oral health behavior change, practical support was identified as a useful method [53]. To provide practical support, the app incorporated a brushing timer, which users could turn on when they decided to brush (targeting determinants: "support"). The timer showed how much time had elapsed. Throughout brushing, it also supported good brushing, according to the 5-step method, by showing where to brush (location in the mouth). Figure 2 shows a screenshot of the brushing timer. When brushing with the brushing timer was completed, the app congratulated the user on fulfilling the task.

Table 4. The algorithm for personal recommendations that were provided based on plaque assessment and answers to the registration questions.

Flow	Answer options (the answer)	Interpretation of the answers and personal recommendations
1.1	• Question A: Tooth brushing frequency <2 times/day (0/1), OR • Question B: Tooth brushing duration <3 min/day (0/1/2), OR • Dental plaque is visible on the selfie.	• The user does not follow the tooth brushing recommendations and dental plaque is present. • The app provides information on health risk plus recommendations and instructions. It helps to set goals for increasing brushing frequency and duration. It advises users to use the brushing timer and to monitor their tooth brushing frequency daily.
1.2	• Question A: Tooth brushing frequency >2 times/day (2/3 or more often), AND • Question B: Tooth brushing duration ≥3 min/day (3/4 min or longer), AND • Dental plaque is or is not visible on the selfie.	• The user follows the tooth brushing recommendations and dental plaque is absent or present. • Continue to question C—flow 2.
2.1	• Question C: Proxy brush usage <1 time/day (0), OR • Dental plaque is or is not visible on the selfie.	• The user does not follow the proxy brush recommendations or dental plaque is present. • The app provides information on health risk plus recommendations and instructions. It helps to set goals for increasing the use of a proxy brush and for increasing tooth brushing frequency and duration. It advises users to use the brushing timer and to monitor their tooth brushing frequency and proxy brush usage.
2.2	• Question C: Proxy brush usage 1 time/day (1/2 or more often), AND • Dental plaque is visible on the selfie.	• The user follows the proxy brush recommendations, but dental plaque is present. • Idem as flow 2.1.
2.3	• Question C: Proxy brush usage 1 time/day (1/2 or more often), AND • Dental plaque is not visible on the selfie.	• The user follows the proxy brush recommendations and dental plaque is absent. • Continue to question D—flow 3

3.1	• The user does not have 3 fluoride moments per day:
	  • Question A: Tooth brushing frequency <3 times/day (0/1/2), OR
	  • Question D: Fluoride mouth rinse usage <1 time/per day.
		• The user does not follow the fluoride recommendations.
		• The app provides information on health risk plus recommendations and instructions. It helps to set goals for increasing the use of fluoride mouth rinse. It advises users to monitor their fluoride mouth rinse usage.

3.2	• The user has 3 fluoride moments per day:
	  • Question A: Tooth brushing frequency ≥3 times/day (3 or more often), OR
	  • Question D: Daily fluoride mouth rinse usage.
		• The user follows all recommendations.
		• Positive reinforcement.

Performance Objective 4— Prompt Cues (Reminders)

Since numerous studies have shown that sending short message service (SMS) text messages as prompt cues is an effective way for establishing behavior changes and improving oral hygiene during fixed orthodontic treatment [48-50], the app also provided an option for setting reminders for oral health behavior tasks (including monitoring of behavior and dental plaque) and the use of the brushing timer (targeting determinants: “cues to action or habit formation”). The reminders were sent as push notifications.

Performance Objective 5—Prompt Self-Monitoring

We identified prompt self-monitoring as a suitable method for evaluating tooth brushing behaviors and dental plaque levels (targeting determinants: “self-regulatory skills or action control” and “awareness”) [36,40,51,52,60]. The use of disclosing agents provided a suitable method of monitoring plaque levels and thereby improved oral hygiene [60]. When the app was installed in the orthodontic clinic, a dental hygienist explained how oral health behavior and plaque levels should be monitored. The next day, the app sent a push notification that urged the adolescents to monitor their oral health behavior daily by entering into the app whether they accomplished their daily dental activities. If they failed to complete the monitoring, a push notification was sent the next day. Each week, adolescents were asked, via the app, to evaluate their dental plaque levels and review their behavioral goals. For this purpose, they were asked to use a disclosing tablet to visualize the dental plaque, to take a selfie of the result, and to indicate the visualized dental plaque. On the basis of the information on the selfie and the activities performed that week, the app concluded whether the adolescent’s goals had been attained. It then congratulated the adolescent for using the app, and if necessary, guided him or her in setting goals or adapting existing ones and in creating coping plans.

Figure 2. Screenshot of the brushing timer. Taken on an iPhone, it shows how adolescents can use the brushing timer (poetstimer) to see how much time has elapsed and also where to brush; in this case, the inside (binnenkant) of the maxilla (bovenkaak).

Performance Objective 6— Prompt Barrier Identification to Establish Coping Plans (Volitional Sheets)

We identified prompt barrier identification and the creation of coping plans as suitable methods for helping adolescents to identify possible ways of achieving their oral health goal if they encountered difficulties (targeting determinants: "self-regulatory skills or action control," "coping self-efficacy," and "coping planning") [40,61,62]. If adolescents failed to attain their goals, coping plans could be formulated [57]. These plans use "if-then" formulations to specify how they would deal with difficult situations. However, although adults realized positive effects for if-then planning (ie, implementation intentions [61-62] on oral health behavior were undertaken with adults [40]), it is possible that planning interventions would be less suitable for adolescents, who may be less familiar with creating behavioral coping plans. To mitigate this, the app therefore incorporated volitional help sheets [63]—a tool for constructing effective (if-then) coping plans—by asking participants to link difficult situations (where "if" indicates barriers against performing the desirable behavior) with a behavioral response (where "then" indicates solutions) [47]. For example, "If I often forget to brush my teeth, then I ask someone at home to remind me to brush my teeth." Table 5 shows the content of a volitional help sheet intended to establish coping plans for tooth brushing behavior. The content of the volitional help sheets was informed by the results of the semistructured interviews (performed in Step 1). To remind the adolescents of their coping plans, the plans were saved on the main page of the app, and thus were visible when the app was opened.

Table 5. An example of the content of the volitional help sheet used to establish coping plans for tooth brushing behavior.

Difficult situations (Think about difficult situations that hinder tooth brushing and possible solutions to them. Please select the difficult situations and solutions that fit you best)	Possible solutions
☐ (If) I am too tired to brush my teeth	☐ Then I think of the dentist who has to fill all the cavities
☐ (If) I don't feel like tooth brushing	☐ Then I think of the brown spots and cavities I might get if I don't brush my teeth
☐ (If) I want to skip tooth brushing because I'm in a hurry	☐ Then I think about how fresh and clean my teeth will feel after brushing
☐ (If) want to skip tooth brushing because I've got something much more fun to do	☐Then I ask someone at home to remind me to brush my teeth
☐ (If) I often forget to brush my teeth	☐ Then I think about what the orthodontist or assistant told me about brushing my teeth
☐ (If) I'm so busy that I don't have time for tooth brushing	☐ Then I think about the bad breath I can get if I don't brush my teeth
☐ (If) I prefer not to brush my teeth because they're sensitive or painful	☐ Then I set a reminder
☐ (If) I don't want to brush my teeth because it's too difficult	☐ Then I think of tooth brushing giving me fresh breath and white teeth
☐ (If) I prefer not to brush my teeth because my gums are bleeding	☐ Then I look in the mirror and say to myself: "I can do it! Every day!"
☐ (If) I'm too tired to brush my teeth in the evening	☐ Then I watch the movie about tooth brushing in the app
☐ (If) I… (option to fill in)	☐ Then I'll brush my teeth right after dinner
	☐ Then… (option to fill in)

Performance Objective 7—Providing Positive Reinforcement (Coaching Short Message Service Text Messages)

Maintaining oral health behavior requires long-term commitment. Providing reinforcement by sending coaching SMS text messages was identified as a suitable method of motivating adolescents to maintain the desired behavior (targeting determinants: "attitude" and "maintenance self-efficacy") [53]. To personalize coaching SMS text messages, adolescents were asked what outcomes motivated them to maintain good oral health. They could select from pre-established motives such as "keeping my gums healthy," "getting fresh breath," or "white teeth." If desired, these notifications could be switched off.

Step 4: Program Production

The practical strategies were clustered into 4 main program components: (1) Registration to help adolescents to decide to change their oral health behavior, to choose how to change it, and to plan appropriate actions; (2) behavior change to help adolescents to actually change their behavior with respect to their daily oral health routines; (3) evaluation to help adolescents to evaluate their behavior change over the past week and to adapt goals weekly; and (4) maintenance to help adolescents to maintain their behavior. Textbox 2 shows an overview of the flow of the program.

The Final Program: the Whiteteeth App

The app was listed on both iTunes and Google Play stores as the "WitGebit" app. The WhiteTeeth ("WitGebit") app was made available free of charge for IOS≥7 and Android≥4.1 operating systems.

Pilot Test of the WhiteTeeth App

The most important finding of the pilot test was that adolescents with fixed orthodontic appliances liked and appreciated the WhiteTeeth app, particularly the movies with instructions on how to use proxy brushes. The mean SUS score was 77, indicating an acceptable score for usability. Since the app users suggested changing the amount of storage of the WhiteTeeth app, we compressed the movies to reduce the storage of the app to 52.8MB. The app users also suggested improving the instructions for the brushing timer and the statistics for evaluating their behavior. Even though the users requested gamification, this could not be included due to financial limitations. The program was adapted using their feedback.

Step 5: Program Implementation Plan

The planning group agreed to deliver the intervention through dental professionals that already had regular contact with adolescents receiving orthodontic therapies, thereby allowing the app to be implemented within existing oral health care processes. One of the barriers to implementation perceived by the dental professionals was the limited time they had during appointments. They therefore recommended that we created an app that could operate as a stand-alone program. To encourage adolescents to use the WhiteTeeth app, several practical strategies were planned. For example, if the adolescents did not use the app for 3 days, the app used the registration information to send personalized SMS text messages reminding them to use the app, such as "Brushing your teeth will help to keep them healthy and beautiful."

Textbox 2. An overview of the flow of the WhiteTeeth app: targeted performance objectives (POs).

1. Registration—First day (PO1- PO3)
   - Users are required to respond to registration questions and provide some personal information.
   - The app asks users to visualize dental plaque using disclosing tablets and to indicate the plaque on the selfie.
   - On the basis of the information collected on their oral health behavior and dental plaque, the app then provides health risk information, personal advice and instructions in short videos.
   - Next, it helps the users to customize their personal oral health goals, creating action plans and setting reminders.
   - At the end of installation, it encourages them to use the brushing timer and monitor their oral health behavior every day.
2. Behavior change—Every day (PO4)
   - When they decide to brush, they have the option of turning on the timer. Afterward, the app provides positive reinforcement.
   - Users receive a push notification on a daily basis to monitor their behavior.
3. Evaluation—Every week (PO5, PO6)
   - Users are asked by the app to evaluate their dental plaque levels, to review their behavioral goals, and to create coping plans if needed.
4. Maintenance—Every 3 days (PO7)
   - Users receive coaching short message service text messages.

Discussion

Principal Findings

This paper describes the development process and content of the WhiteTeeth app. The WhiteTeeth app was developed to promote oral health behavior among adolescents with fixed orthodontic appliances who were at high risk of developing dental caries. We used an IM protocol as a tool for the systematic development of the app [30]. IM linked the phases of intervention development to theory and empirical evidence and made the process of program development transparent. IM was proven to be a suitable method for developing health promotion programs for various health issues [64-66]. In the field of orthodontics, authors did not describe the process of program development explicitly in their publications [41,42,48-50,67-71]. This limited opportunities for comparison. Mapping the development and contents of an intervention, as in this study, is useful because it allows researchers to faithfully replicate effective programs or design programs that are even more effective [72]. In contrast to other studies, our study used theory to inform the program design. The use of theory was necessary to ensure that the factors related to achieving change were addressed [73,30]. When reviewing the few available orthodontic apps promoting oral health, we concluded that the integration of behavior change techniques was limited in these apps [25,70-71,74-75]. However, a meta-analysis revealed that programs with a larger differentiation of behavior change techniques tended to have larger effects on behavior than programs that incorporated fewer techniques, which may be a consequence of the fact that different techniques target different aspects of the behavior change process [73]. In addition to this matter, behavior change techniques that were most effective for initiating behavior change, such as creating action and coping plans, were not incorporated into these apps [73,76]. Our app contains multiple proven techniques that focus on the motivation and initiation of oral health behavior changes. We believe this makes it a unique and promising mHealth program for oral health promotion. Our work represents a major contribution to the field of oral health care, as it is the first study to systematically develop an mHealth program based on sound evidence and theory. The involvement of dental professionals and adolescents enabled us to develop a feasible program, which offered ample opportunities for effective implementation in the future. To increase the likelihood that the app would meet the preferences of the target group, we invited a user experience designer to participate in the app development and also included future users through semistructured interviews and a pilot test. Interaction with the adolescents enabled us to create program materials, such as volitional sheets that listed barriers and solutions, suited to the individual situations of target group members. Our problem analysis helped us to identify important determinants that were not addressed by the existing oral health programs, such as volitional factors that are outlined in the HAPA theory [57]. Using the IM protocol ensured that all important program objectives were addressed in the WhiteTeeth app, based on the theoretical insights and methods, empirical findings, and practical strategies.

Limitations

However, there were some limitations that should be highlighted. Despite the value of this robust development process, IM is very time-consuming. Our experience in this regard was similar to that of other researchers who used the IM protocol [77-81]. Our development process required more time than expected because we had to carry out additional research to gain insights into oral health behavior and its determinants during orthodontic treatment (Step 1), as there was little information available on these topics. Another challenge regarding IM, as others have acknowledged [79-82], was the complexity of detailing the performance and change objectives. Program developers and researchers recognized that targeting

multiple complex behaviors may create a high degree of complexity since data obtained during the development process can become cumbersome and overwhelming [80,82]. In our study, the creation of matrices of change objectives was particularly time-consuming and resulted in an overwhelming amount of information about what should be targeted by the program. During our development process, we excluded an important target behavior, intake of sugar-sweetened beverages, in order to manage the data of our study and the complexity of our program [83].

Conclusions

and promising mHealth intervention for adolescents with fixed orthodontic appliances. This app incorporated several behavior change techniques, such as self-monitoring, goal setting, and volitional sheets. The app simultaneously targeted important determinants of oral health behavior change. The lessons learned from using the IM process have relevance for researchers and practitioners, especially considering the current paucity of evidence-based oral health promotion programs for orthodontic patients and their failure to incorporate important behavior change techniques addressing meaningful behavioral determinants. Our future randomized controlled trial will indicate whether the app is effective in improving adolescent oral health.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Performance objectives, selected change objectives, theoretical methods, and practical strategies for program outcome 1 "adolescents control their dental plaque levels by improving their tooth-brushing frequency and duration."

[PDF File (Adobe PDF File), 51KB - mhealth_v6i8e163_app1.pdf]

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Abbreviations

ACTA: Academic Centre for Dentistry Amsterdam
CO: change objective
HAPA: Health Action Process Approach
IM: intervention mapping
PO: performance objective
SUS: System Usability Scale

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Original Paper

Effect and Process Evaluation of a Smartphone App to Promote an Active Lifestyle in Lower Educated Working Young Adults: Cluster Randomized Controlled Trial

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Abstract

Background: Mobile technologies have great potential to promote an active lifestyle in lower educated working young adults, an underresearched target group at a high risk of low activity levels.

Objective: The objective of our study was to examine the effect and process evaluation of the newly developed evidence- and theory-based smartphone app "Active Coach" on the objectively measured total daily physical activity; self-reported, context-specific physical activity; and self-reported psychosocial variables among lower educated working young adults.

Methods: We recruited 130 lower educated working young adults in this 2-group cluster randomized controlled trial and assessed outcomes at baseline, posttest (baseline+9 weeks), and follow-up (posttest+3 months). Intervention participants (n=60) used the Active Coach app (for 9 weeks) combined with a Fitbit activity tracker. Personal goals, practical tips, and educational facts were provided to encourage physical activity. The control group received print-based generic physical activity information. Both groups wore accelerometers for objective measurement of physical activity, and individual interviews were conducted to assess the psychosocial variables and context-specific physical activity. Furthermore, intervention participants were asked process evaluation questions and generalized linear mixed models and descriptive statistics were applied.

Results: No significant intervention effects were found for objectively measured physical activity, self-reported physical activity, and self-reported psychosocial variables (all $P>.05$). Intervention participants evaluated the Active Coach app and the combined use with the Fitbit wearable as self-explanatory (36/51, 70.6%), user friendly (40/51, 78.4%), and interesting (34/51, 66.7%). Throughout the intervention, we observed a decrease in the frequency of viewing graphical displays in the app ($P<.001$); reading the tips, facts, and goals ($P<.05$); and wearing the Fitbit wearable ($P<.001$). Few intervention participants found the tips and facts motivating (10/41, 24.4%), used them to be physically active (8/41, 19.6%), and thought they were tailored to their lifestyle (7/41, 17.1%).

Conclusions: The lack of significant intervention effects might be due to low continuous user engagement. Advice or feedback that was not perceived as adequately tailored and the difficulty to compete with many popular commercial apps on young people's smartphones may be responsible for a decrease in the engagement. A stand-alone app does not seem sufficient to promote an

active lifestyle among lower educated working young adults; therefore, multicomponent interventions (using both technological and human support), as well as context-specific sensing to provide tailored advice, might be needed in this population.

Trial Registration: ClinicalTrials.gov NCT02948803; https://clinicaltrials.gov/ct2/show/results/NCT02948803 (Archived by WebCite at http://www.webcitation.org/71OPFwaoA)

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KEYWORDS

mHealth; mobile apps; active transport; Fitbit; accelerometers; mobile phone; emerging adulthood; physical activity intervention; health promotion

Introduction

Insufficient physical activity has been estimated to cause 6%-10% of the major noncommunicable diseases such as coronary heart disease, type 2 diabetes, and breast and colon cancers and 9% of premature mortality [1]. Globally, up to 38% of young adults (aged 15-29 years) are physically inactive [2]. In Belgium, approximately 50% of 15- to 24-year-old individuals do not reach the recommended levels of physical activity [3], which is estimated to increase the all-cause mortality risk by 11.4% [1]. Young adulthood comprises many life changes (ie, changes in education, employment, and place of residence) [4,5], which have been shown to be associated with decreases in overall physical activity as well as in different types of physical activity, such as active transport [6-9]. Active transport represents an opportunity to include physical activity in the busy daily lives of young adults [2]. There is a need to improve overall physical activity during young adulthood as young adults' behaviors are likely to track into adulthood [10,11]. Intervening during this life stage may facilitate positive behavior changes and improved health beyond young adulthood [12]. A large US cohort study has showed that a healthy lifestyle (ie, high physical activity levels and healthy weight) in young adulthood is strongly associated with a low risk of cardiovascular disease in middle-aged adults [13]. Young adults who do not complete higher education (college or university) and who start employment around the age of 18 years have an even higher risk for inactive lifestyle because of their lower educational attainment [14]. Among adults of all ages, lower levels of education have been associated with lower levels of overall physical activity [5,15], less active transport [16,17], higher levels of overweight or obesity, and the prevalence of common chronic diseases [18]. Specific research on young adults is scarce and mostly focused on students as they are easier to recruit through university and college settings [4]. Therefore, there is a need to promote an active lifestyle in the underresearched target group of lower educated working young adults.

Among all strategies to promote physical activity, the use of mHealth approaches is promising, especially among young adults. mHealth includes mobile technologies such as phones, tablets, and tracking devices that can be used to support and improve public health practice [19]. Mobile Smartphones are immensely popular worldwide and are most frequently used by young adults compared with other age groups [20-23]. In the United States [20] and Belgium [24], respectively, 85% and 80% of young adults own a smartphone. Moreover, in Belgium in 2015, 96% of 16-to-34-year-old individuals and 87% of adults with a low educational level used a mobile phone or smartphone [25]. Smartphone apps can measure health behaviors such as physical activity 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 [26]. In two systematic reviews and a meta-analysis, it was concluded that smartphones and health and fitness apps have great potential as a tool for assessing and promoting physical activity in all age groups [27-29]. However, a recent review and meta-analysis of randomized controlled trials (RCTs) using mHealth technologies to influence physical activity (also in all age groups) concluded that current mHealth interventions have only small effects on physical activity [30] as differences between mHealth intervention groups and comparators did not reach the statistical significance. However, most of these interventions were based on short message service text messages, while apps could enable more comprehensive, interactive, and responsive intervention delivery [30]. Nevertheless, there is still considerable scope to improve the efficacy of app-based interventions. In addition, process evaluations are necessary to identify factors that influence user engagement and retention and ultimately intervention efficacy [29]. Nevertheless, few mHealth interventions have conducted process evaluations [29,31,32].

Promoting an active lifestyle in the underresearched target group of lower educated working young adults is important, and mobile technologies have great potential to assist. Therefore, we developed a new evidence- and theory-based smartphone app called "Active Coach," which aims to promote an active lifestyle to lower educated working young adults [33]. Therefore, in this study, we aimed to examine the effect and process evaluation of the Active Coach app on objectively measured total daily physical activity; self-reported, context-specific physical activity; and self-reported psychosocial variables among lower educated working young adults.

Methods

Study Design, Recruitment, and Sample

This cluster RCT included the baseline (T0), posttest (T1, 9 weeks after the baseline), and follow-up measurements (T2, 3 months after posttest) in 2 different study conditions (intervention and control). The intervention group received a smartphone-based intervention to promote an active lifestyle using a newly developed Android app called Active Coach in combination with a wearable activity tracker. Conversely, the

control group received a printed brochure with generic information and tips about a physically active lifestyle. This study was approved by the Ethics Committee of the University Hospital of Ghent University (B670201525362). The trial registration number is NCT02948803 (Clinicaltrials.gov).

We identified, via an internet search, suitable workplaces in Flanders (northern, Dutch-speaking part of Belgium) based on the presence of lower educated (no university or college degree) employees aged 18-30 years. To recruit participants with various educational levels and various types of jobs, a range of workplace types (shops, retail stores, catering industry, social employment businesses, factories, etc) were contacted. Of the workplaces contacted by us in June and July 2016 via email and phone with information about the study, 51% (36/70) replied positively. After providing more details during a second contact, 14% (5/36) workplaces were excluded because of a lack of lower educated young employees and 6% (2/36) eventually disagreed to participate (eg, practical issues, no time). The required sample size was based on previous research, a statistical program (GPower [34]), and additional calculations to account for clustering. An effect size of 0.18 was determined based on a meta-analysis of internet-delivered interventions to increase physical activity levels [32]. In this meta-analysis, an overall mean effect size of 0.14 was found. However, after specifying the intervention based on the study design, participant characteristics, and intervention features, a mean effect size of 0.18 was determined [32]. Without accounting for clustering, the total sample size was calculated at 82 (80% power at a significance level of .05 with 2 groups [intervention group and control group] and 3 repeated measurements). This result was in line with a previously conducted RCT to test the effectiveness of a smartphone app to promote physical activity (step count) in primary care [35,36]. To account for clustering, an intraclass correlation coefficient (ICC) of .025 was assumed, based on previous worksite intervention studies with health-related outcomes [37-40]. Research states that sample size estimates need to be inflated by a factor $1 + (n - 1)r$ (where n is the cluster size and r is the ICC) to appropriately account for the clustering in the data [41]. As we did not know the number of clusters beforehand, we performed the calculation with 10, 20, 30, 40, and 50 clusters; this resulted in sample sizes of 100, 121, 141, 162, and 182, respectively. Therefore, we aimed to achieve a sample size of at least 120. Eventually, we included 130 participants (intervention group, 60; control group, 70) from 29 clusters (workplaces) in this study. Eligible employees were recruited through a contact person (eg, human resources manager), if available. At many smaller workplaces, as no contact person was available, the employees were directly contacted by the researchers. The recruitment process was conducted by DS, assisted by master students and research colleagues.

Eligible clusters (workplaces) needed to employ lower educated working young adults (aged 18-30 years). Allocation was based on clusters (workplaces), which were randomly assigned following block randomization (restricted randomization) to the intervention or the control group. Block sizes varied randomly (2, 4, or 6), and for each block of clusters, half (1, 2, or 3) would be allocated to each arm of the study (intervention or control group). Eligible participants needed to be employed, between 18 and 30 years of age, lower educated (no university or college degree), currently not meeting the physical activity guidelines of 150 minutes of moderate-to-vigorous physical activity (MVPA) a week [42], and not using an activity tracker or not participating in a sports program (via a website, an app, or a sports center). Furthermore, they needed to be in possession of an Android smartphone.

Procedures

In September 2016, baseline measurements were performed (Figure 1). During the first visit to the workplaces, researchers and accompanying research assistants met every participant separately. The study details were explained to the participants based on an information letter. After agreeing to participate using a written informed consent, participants completed a brief questionnaire assessing sociodemographic data. Next, a face-to-face interview was conducted (mean duration: 30 minutes) to assess physical activity and psychosocial variables. In addition, participants were provided with an accelerometer (Actigraph GT3X+) for 1 week (7 days) and with explanations on how to wear it. One week later, the research team returned to the workplaces to collect the accelerometers. During that second visit, participants in the intervention group were asked to download the Active Coach app on their smartphone, and they received a wearable activity tracker (ie, Fitbit Charge). They were asked to use the Active Coach app and the wearable activity tracker for the next 9 weeks. However, participants in the control group only received a printed brochure with generic information and tips on a physically active lifestyle and did not use an activity tracker.

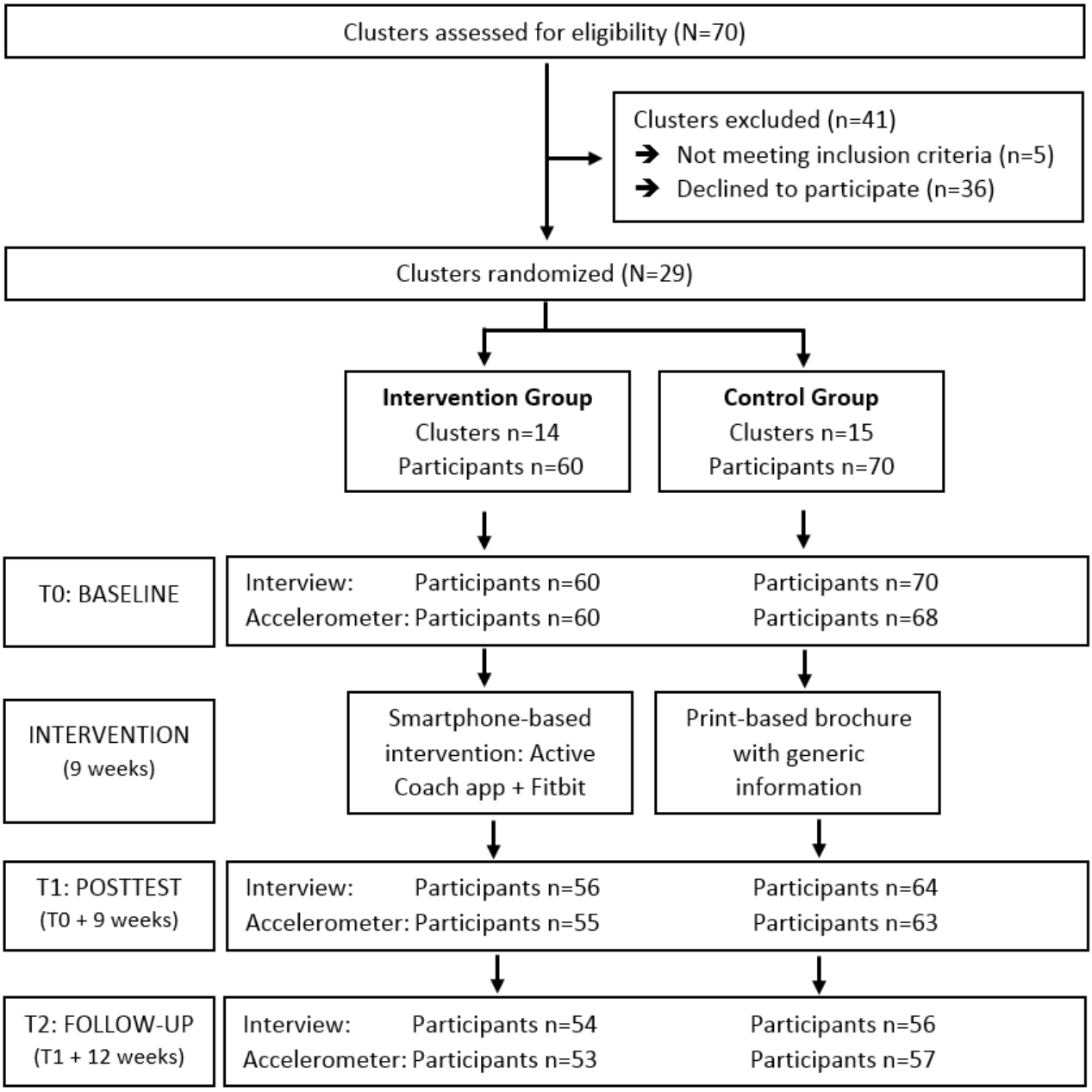
In November 2016, posttest measurements were performed. During this third visit to the workplaces (8 weeks after baseline), all participants were instructed again to wear an accelerometer. One week later (9 weeks after baseline, fourth visit to the workplace), the accelerometers were collected and a face-to-face interview (~30 minutes) was conducted to assess physical activity and psychosocial variables in both groups and process evaluation questions in the intervention group only. Notably, participants from the intervention group returned their Fitbit activity tracker.

In February 2017, follow-up measurements were performed. During this fifth visit to the workplaces (19 weeks after baseline, 11 weeks after posttest), all participants were instructed again to wear an accelerometer. One week later (12 weeks after posttest), the accelerometers were collected and a face-to-face interview (~30 minutes) was conducted to assess physical activity and psychosocial variables.

Intervention

The development of the evidence- and theory-based app Active Coach has been described in detail elsewhere [33]. Briefly, a native Android app Active Coach was purposefully developed for lower educated working young adults using a stepwise approach, consisting of 4 steps, based on the Intervention Mapping Approach and the developmental steps for mHealth interventions [43,44].

Figure 1. Flowchart of the smartphone-based intervention.



In step 1, knowledge, attitude (perceived benefits and barriers), social support, and self-efficacy were selected as determinants important to promote an active lifestyle among lower educated working young adults. The selection was based on the existing literature, previous studies from our research group, the attitude-social influence-self-efficacy (ASE) model [45], and an exploratory qualitative study among the target group [33]. In step 2, self-regulation techniques (eg, goal setting and self-monitoring) were selected as evidence-based Behavior Change Techniques (BCTs) to convert the determinants into practical applications [46].

BCTs are the active component of an intervention designed to change behavior [47]. BCTs were selected on the basis of their previously demonstrated effectiveness and an exploratory qualitative study among the target group [33]. In step 3, the Active Coach app was developed. In step 4, the app was tested on errors; acceptability (is the target group willing to receive the strategies?); and feasibility (is it realistic to consider implementing the proposed strategies?) via (think aloud) interviews, a questionnaire, and Google Analytics. The app was accordingly adapted for the final version.

The app consists of a 9-week program with personal goals, practical tips, and scientific facts to encourage an active lifestyle. Users of the app receive tailored information about their goal, tips, and facts through notifications on their smartphone and messages in the Active Coach app. To ensure all-day and automatic self-monitoring of physical activity, the app works in combination with a wearable activity tracker, the Fitbit Charge. The Fitbit Charge is a wrist-worn activity tracker [48] that has been found to be valid and reliable for measuring step counts in healthy young adults [49]. The only measure tracked by the Fitbit Charge that was used in the Active Coach app was the number of steps.

During the registration in the Active Coach app, participants were provided with a choice on how to make their lifestyle more active: through overall physical activity or through active transport. Recreational physical activity was not added as a separate choice based on previous research and the results of the exploratory qualitative study during the development of the app stating that active transport can be integrated more easily into emerging adults' busy lives compared with finding additional time to spend on recreational physical activity. After the registration, the app consists of a 9-week program. During those 9 weeks, participants' physical activity (step count) was tracked by the Fitbit Charge and their active transport was tracked by inbuilt smartphone sensors (global positioning system and accelerometer). Regardless of the activity choice (overall physical activity or active transport), both behaviors were tracked automatically and were visible for the user in the app via graphical displays. However, other information and goals they received differed according to the chosen behavior. The first week of the 9-week program was a "monitoring week" during which the baseline activity level of users was assessed by the app. At the end of this week, a personal goal dependent on the baseline level of the chosen behavior (overall physical activity or active transport) was set by the app for the following week (eg, *Your goal for the next week is to try and walk 6000 steps each day*). Every day during the following 8 weeks, users received a notification on whether or not they had achieved their daily goal. Besides, their daily and weekly goal progression could also be viewed on the graphs in the app. In addition, users received feedback on their goal achievement at the end of each week. If they achieved their goal, they could increase it or maintain the same goal for the next week. If they did not achieve their goal, they could choose to decrease it or maintain the same goal for the next week. Additionally, users were asked why they did not achieve their goal to determine their perceived barriers. Different response options were shown for those who chose overall physical activity or active transport. This information was used to give users more personal feedback. Furthermore, every Monday and Friday during the 8 weeks after the baseline week, users received a notification with a practical tip, and every Wednesday, they received a notification with a scientific or educational fact to help and motivate them to reach their goal. The content of the tips and facts was tailored based on the information from the registration process (gender, type of job, overall physical activity or active transport, perceived benefits), goal achievement, and the selected barriers.

Measures

Objective Measures

physical activity was assessed objectively using Actigraph GT3X+ accelerometers. Both reliability and validity of Actigraph accelerometers have been documented extensively [50-52]. Accelerometers were distributed in person, and participants were asked to wear the accelerometers on the right hip for 7 consecutive days during waking hours and remove it only for water activities (eg, swimming and showering). Uniaxial accelerometer data were collected in 15-second epochs and analyzed in 1-minute epochs. Nonwear time was defined as ≥60 minutes of consecutive zero counts. Only data of participants with at least 10 wearing hours for at least 3 days (as recommended to reliably predict physical activity behavior in young adults) were included in the analyses [53-55]. Furthermore, counts per minute were converted into minutes of light- (100-1951 counts/min), moderate- (1952-5724 counts/min), and vigorous-intensity physical activity (5725+ counts/min) according to the Freedson cut points for adults (based on uniaxial data) [50,56].

Self-Reported Measures

Sociodemographic variables were assessed using a paper-and-pencil questionnaire (only at baseline). Gender (male, female), age (open-ended), nationality (Belgian, other), workplace (open-ended), type of job (open-ended), employment duration (open-ended), and educational level (elementary, special secondary, vocational secondary, arts secondary, technical secondary, and general secondary education) were assessed. At all 3 time-points (T0, T1, and T2), participants reported their height (m) and weight (kg), which were used to calculate body mass index (BMI; weight/height^2).

At all 3 time-points (T0, T1, and T2), a face-to-face interview was conducted. The interview consisted of the International Physical Activity Questionnaire (IPAQ) to assess context-specific physical activity. The Dutch IPAQ (long version, last 7 days interview version) has been validated in Flemish adults [57] and assesses the frequency (number of days in the last 7 days) and duration (hours and minutes per day) of physical activity in 4 different contexts (occupational physical activity, active transport, household physical activity, and recreational physical activity).

In addition, psychosocial variables were assessed during the interview. All questions on psychosocial variables were derived from previous studies [58-62]. The following psychosocial variables in relation to both physical activity and active transport were included because the Active Coach app focused on the following variables: social support, attitude (perceived benefits and perceived barriers), self-efficacy, and knowledge. A summary of the measures of psychosocial variables (ie, questions and scales) and Cronbach alpha for internal consistency is shown in Table 1. Averages of item scores were calculated. In addition, the intention to be physically active was also assessed. Participants could choose between "being physically active for more than 6 months or in the last 6 months" and "not being physically active but intend to start this month or but intend to start in the next 6 months or do not intend to begin."

During the interview at baseline (T0), general smartphone usage was assessed by asking how many apps the participants (intervention and control group) had on their smartphone and how often they used these apps.

Table 1. Summary of psychosocial measures and Cronbach alpha values.

Scale (composition)	Question	Cronbach alpha		
		Pre	Post	Follow-up
Social support (1 item)[a]	How often do you have a physically active partner (someone to play sports with, to be physically active with, or to walk or cycle together with)?	N/A[b]	N/A	N/A
Perceived benefits (12 items)[c]	A benefit of being physically active (playing sports or walking or cycling somewhere) for me is (1) weight control; (2) less stress; (3) improved fitness; (4) improved health; (5) becoming more productive at work; (6) sleeping well; (7) social interaction; (8) fun; (9) low costs of active transport; (10) flexibility of active transport; (11) no traffic jams; (12) active transport is environment friendly	.78	.80	.84
Perceived barriers (13 items)[c]	Following reasons hinder me from being physically active (playing sports or walking or cycling somewhere): (1) no discipline; (2) no time; (3) no energy; (4) no company; (5) sweating; (6) no equipment; (7) no showers at work; (8) bad weather; (9) family demands; (10) too much work; (11) carrying luggage during active transport; (12) unsafe traffic; (13) no sports facilities	.76	.77	.75
Self-efficacy (8 items)[d]	How confident are you to be physically active (playing sports or walking or cycling somewhere) in the following situations: (1) bad weather; (2) busy for work; (3) darkness; (4) after a tiring day at work; (5) sweating; (6) friends or family demanding time; (7) stress; (8) no time	.78	.81	.82
Knowledge (1 item)	What do you think the recommended amount of moderate physical activity is? (1) 60 min on 1 d/wk; (2) 30 min on 3 d/wk; (3) 30 min on 7 d/wk; (4) 60 min on 7 d/wk; (5) I do not know	N/A	N/A	N/A

[a]5-point scale from 1 (never) to 5 (very often).

[b]N/A: Not applicable.

[c]5-point scale from 1 (strongly disagree) to 5 (strongly agree).

[d]5-point scale from 1 (know I cannot do it) to 5 (know I can do it).

Intervention group participants were asked process evaluation questions during the individual interview at posttest (T1). The use of the Fitbit Charge wearable (bracelet) was assessed by asking the participants whether (1) it was easy to use, (2) it was annoying to wear, (3) it was interesting to see the steps taken, (4) they would like to keep using it, and (5) they had technical issues (5-point scale from 1 [strongly disagree] to 5 [strongly agree]). In addition, the number of days (0-7) wearing the Fitbit wearable during the first 2 weeks, middle 4 weeks, and final 2 weeks of the intervention period was assessed, including the reasons why the participants did not wear it (open-ended question). Next, the use of the Active Coach app was assessed by asking the participants whether the app was (1) self-explanatory, (2) boring, (3) fun, (4) interesting, (5) complicated, (6) easy to use, and (7) motivating and (8) whether they encountered technical issues (5-point scale from 1 [strongly disagree] to 5 [strongly agree]). We also assessed which component of the app the participants liked best or least (open-ended question). Participants were asked how often (never, less than once a week, once a week, 2-4 times a week, every day, multiple times a day) and why or why not (open-ended question) they viewed the graphs during the first 3 weeks and the last 3 weeks of the intervention.

Similarly, participants were asked how often and why or why not they read the notifications on their smartphone and the app messages regarding tips, facts, and their goal. Furthermore, 4 statements about goal achievement and 7 statements about the tips and facts were assessed on a 5-point scale from 1 (strongly disagree) to 5 (strongly agree). Finally, participants were asked how often (5-point scale from 1 [never] to 5 [very often]) they used the official Fitbit app (which is needed to activate the wearable) and why they used it (open-ended question).

During the individual interview at the follow-up test (T2), participants (intervention and control groups) were asked whether they purchased or were planning on purchasing a consumer wearable activity tracker and why or why not (open-ended question).

Website Usage Statistics

Google Analytics [63] was used to obtain the 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. We evaluated the number of users, number and duration of app visits, and number and duration of screen views and events (ie, user interactions with content that can be tracked independently from a screen load, such as clicks on a notification or other element in the app).

Analyses

Data were analyzed using IBM SPSS Statistics version 23 (Armonk, NY, United States). To check for differences between the control and intervention groups at baseline, independent-samples *t* tests and chi-square tests were conducted. We performed generalized linear mixed models analyses with a negative binomial distribution (log link) to assess the effectiveness of the intervention on the dependent variables of self-reported physical activity (minutes per week of occupational physical activity, active transport, household physical activity, recreational physical activity, and total physical activity [occupational physical activity + active transport + household physical activity + recreational physical activity]). The negative

binomial distribution was used because the self-reported physical activity variables were positively skewed and contained a large number of zero values [64,65]. In addition, linear mixed models were performed to assess the effectiveness of the intervention on the following dependent variables: objective physical activity (minutes per day [not bouts] of light physical activity, moderate physical activity, vigorous physical activity, MVPA, total physical activity [light physical activity + moderate physical activity + vigorous physical activity], and steps per day) and self-reported psychosocial determinants (benefits, barriers, self-efficacy, intention, knowledge, and social support). In addition, the intervention group was split into participants who chose to focus on active transport and those who chose to focus on the overall physical activity in the Active Coach app to assess the effectiveness of the intervention in the corresponding types of self-reported physical activity (active transport among those who chose active transport and total physical activity among those who chose the overall physical activity). All models were controlled for gender (because of a significant baseline gender difference between the intervention and control groups) and included 3 hierarchically ordered levels: workplace, participant, and time. Intercepts were allowed to vary randomly at the workplace and participant level, and all slopes were assumed to be fixed. Generalized linear mixed models analyses allowed us to include all available measurements, even if participants completed only 1 or 2 measurements. Mixed models have advantages over fixed effects models in the treatment of missing values of the dependent variable. Mixed models are capable of handling the imbalance caused by missing observations and yield valid inferences if the missing observations are missing at random [66]. Furthermore, linear mixed models can handle correlated data such as responses of participants from the same workplace. To analyze the process evaluation measures, linear mixed models and descriptive statistics were calculated. *P* values<.05 were considered statistically significant.

Results

Study Sample

Table 2 shows the descriptive statistics of the total sample and group differences at the baseline. The total sample consisted of 130 participants with a mean age of 25 years, of which 48.5% (63/130) were males. The mean BMI was 24.5 kg/m², with 25% (32/130) participants being overweight and 11% (14/130) being obese. Of all participants, 31.2% (39/130) had very low educational attainment (elementary and special secondary education), and the mean employment duration was almost 5 years. Of all participants, 45% (59/130) had a blue-collar job (eg, production line worker, warehouse manager, cleaner, and welder), 33% (43/130) had a pink-collar job (eg, sales, childcare worker, health care worker), and 21% (28/130) had a white-collar job (eg, administrative assistant). There was a gender difference between the 2 groups, with more males in the intervention group than in the control group. Participants in both groups had on average 10-20 apps on their smartphone and 85.4% (111/130) used these apps every day or multiple times a day. Dropout throughout the study period was rather limited (see Figure 1); it was mostly caused by changing jobs (participants were no longer available via the recruited workplace), being ill for a long period, and resistance toward wearing the Actigraph accelerometer. In the intervention group, 98% (59/60) participants had valid accelerometer data at baseline, 87% (48/60) at posttest, and 77% (41/60) at follow-up. In the control group, 93% (63/70) participants had valid data at baseline, 86% (54/70) at posttest, and 75% (43/70) at follow-up. The mean valid wear days were 5.7 (SD 2.3) days at baseline, 4.5 (SD 2.4) days at posttest, and 4.2 (SD 2.2) days at follow-up. The mean valid wear time was 13.5 (SD 1.4) hours/day at baseline, 13.1 (SD 1.5) hours/day at posttest, and 13.1 (SD 1.5) hours/day at follow-up.

Effect Evaluation

Table 3 shows that there were no significant intervention effects for the objective physical activity data (light physical activity, moderate physical activity, vigorous physical activity, MVPA, total physical activity, and steps), for the self-reported physical activity data (occupational physical activity, active transport, household physical activity, recreational physical activity, and total physical activity), and for the self-reported psychosocial variables. However, significant time effects showed a decrease in self-reported total physical activity from baseline to follow-up and a decrease in the objective light intensity physical activity, total physical activity, and number of steps from baseline to posttest (the latter also showing a decrease in steps to follow-up).

Table 2. Descriptive statistics and group differences at baseline.

Characteristics	Total (n=130)	Intervention group (n=60)	Control group (n=70)	Group comparisons	*P* value
Males, n (%)	63 (48.5)	35 (58.3)	28 (40.0)	$\chi^2_1=4.4$	.04
Age (years), mean (SD)	25.0 (3.0)	24.8 (3.1)	25.1 (3.0)	$t_{128}=-0.73$	.47
Body mass index (kg/m²), mean (SD)	24.5 (4.5)	24.9 (4.5)	24.1 (4.4)	$t_{124}=0.94$	.35
Elementary and special secondary education, n (%)	39 (31.2)	18 (30.5)	21 (31.8)	$\chi^2_2=0.03$	.98
Employment duration (years), mean (SD)	4.8 (3.0)	4.8 (2.9)	4.8 (3.1)	$t_{127}=-0.05$	.96

Table 3. Intervention and time effects of the objective physical activity, self-reported physical activity, and self-reported psychosocial variables.

Measures and groups	Baseline, mean (SE)	Posttest, mean (SE)	Follow-up, mean (SE)	*P* value	
				Time	Time × Group
Objective					
Light physical activity (min/d)				.03[a]	.31
Intervention group	320.8 (16.7)	291.7 (16.7)	296.7 (16.7)		
Control group	338.9 (16.6)	329.7 (16.6)	333.4 (16.6)		
Moderate physical activity (min/d)				.12	.56
Intervention group	30.8 (3.4)	25.9 (3.4)	31.4 (3.4)		
Control group	31.9 (3.8)	29.4 (3.8)	30.6 (3.8)		
Vigorous physical activity (min/d)				.66	.26
Intervention group	0.9 (0.5)	1.2 (0.5)	1.2 (0.5)		
Control group	1.5 (0.5)	0.8 (0.6)	1.2 (0.6)		
Moderate-to-vigorous physical activity (min/d)				.09	.66
Intervention group	32.1 (3.6)	27.3 (3.6)	32.6 (3.6)		
Control group	33.5 (4.0)	30.1 (3.9)	31.8 (3.9)		
Total physical activity (min/d)				.01[a]	.36
Intervention group	351.0 (18.2)	317.0 (18.2)	326.9 (18.2)		
Control group	372.0 (18.4)	359.5 (18.4)	364.8 (18.4)		
Steps per day				.003[a]	.64
Intervention group	8619 (614)	7741 (614)	7767 (614)		
Control group	8982 (644)	8061 (644)	8543 (644)		
Self-reported					
Occupational physical activity (min/wk)				.28	.88
Intervention group	530.8 (177.5)	484.4 (165.6)	377.5 (131.2)		
Control group	619.0 (188.5)	517.2 (164.5)	322.0 (109.3)		
Active transport (min/wk)				.91	.98
Intervention group	68.4 (19.3)	74.2 (21.5)	73.7 (21.8)		
Control group	81.3 (21.3)	86.9 (23.8)	96.0 (28.2)		
Household physical activity (min/wk)				.10	.52
Intervention group	109.9 (29.9)	116.5 (32.3)	92.9 (26.1)		
Control group	162.3 (39.5)	158.6 (40.1)	85.7 (22.9)		
Recreational physical activity (min/wk)				.59	.84
Intervention group	189.5 (48.6)	139.2 (36.7)	130.1 (34.9)		
Control group	179.7 (42.8)	158.9 (39.9)	165.3 (44.1)		
Total physical activity (min/wk)				.02[a]	.81
Intervention group	942.1 (153.6)	877.8 (145.1)	726.1 (121.5)		
Control group	975.9 (141.8)	862.8 (130.8)	639.1 (101.5)		
Benefits[b]				<.001[a]	.75
Intervention group	3.7 (0.1)	3.4 (0.1)	3.4 (0.1)		
Control group	3.7 (0.1)	3.5 (0.1)	3.4 (0.1)		
Barriers[b]				.84	.82
Intervention group	2.5 (0.1)	2.5 (0.1)	2.4 (0.1)		

Measures and groups	Baseline, mean (SE)	Posttest, mean (SE)	Follow-up, mean (SE)	*P* value	
				Time	Time × Group
Control group	2.5 (0.1)	2.5 (0.1)	2.5 (0.1)		
Self-efficacy[c]				.85	.41
Intervention group	3.6 (0.1)	3.6 (0.1)	3.6 (0.1)		
Control group	3.6 (0.1)	3.6 (0.1)	3.6 (0.1)		
Intention				.55	.566
Intervention group	3.3 (0.2)	3.1 (0.2)	3.1 (0.2)		
Control group	3.4 (0.2)	3.3 (0.2)	3.3 (0.2)		
Knowledge (% correct answer)				.002[a]	.514
Intervention group	45.0%	51.7%	58.3%		
Control group	42.9%	57.1%	50.0%		
Social Support[d]				.94	.247
Intervention group	2.6 (0.2)	2.5 (0.2)	2.7 (0.2)		
Control group	2.8 (0.2)	2.9 (0.2)	2.7 (0.2)		

[a]*P*<.05 considered statistically significant.

[b]5-point scale from 1 (strongly disagree) to 5 (strongly agree).

[c]5-point scale from 1 (know I cannot do it) to 5 (know I can do it).

[d]5-point scale from 1 (never) to 5 (very often).

Table 4. Opinions about the use of the Fitbit Charge wearable and the Active Coach app in the intervention group.

Opinions	Strongly disagree, n (%)	Disagree, n (%)	Sometimes (dis)agree, n (%)	Agree, n (%)	Strongly agree, n (%)	Mean (SD)
Fitbit wearable						
Easy	1 (1.8)	3 (5.5)	1 (1.8)	20 (36.4)	30 (54.5)	4.36 (0.91)
Annoying	30 (54.5)	12 (21.8)	6 (10.9)	5 (9.1)	2 (3.6)	1.85 (1.16)
Keep using	6 (10.9)	10 (18.2)	7 (12.7)	15 (27.3)	17 (30.9)	3.49 (1.39)
Interesting	0 (0.0)	3 (5.5)	6 (10.9)	13 (23.6)	33 (60.0)	4.38 (0.89)
Problems	27 (50.0)	8 (14.8)	6 (11.1)	7 (13.0)	6 (11.1)	2.20 (1.46)
Active Coach app						
Self-explanatory	5 (9.8)	3 (5.9)	7 (13.7)	26 (51.0)	10 (19.6)	3.65 (1.16)
Boring	20 (39.2)	15 (29.4)	8 (15.7)	6 (11.8)	2 (3.9)	2.12 (1.18)
Fun	2 (3.9)	8 (15.7)	12 (23.5)	22 (43.1)	7 (13.7)	3.47 (1.05)
Interesting	3 (5.9)	2 (3.9)	12 (23.5)	20 (39.2)	14 (27.5)	3.78 (1.08)
Complicated	18 (36.0)	17 (34.0)	3 (6.0)	6 (12.0)	6 (12.0)	2.30 (1.39)
Easy	1 (2.0)	4 (7.8)	6 (11.8)	22 (43.1)	18 (35.3)	4.02 (0.99)
Motivating	7 (14.3)	12 (24.5)	4 (8.2)	16 (32.7)	10 (20.4)	3.20 (1.40)
Problems	13 (26.5)	9 (18.4)	11 (22.4)	3 (6.1)	13 (26.5)	2.88 (1.55)

In addition, in both groups, perceived benefits significantly decreased from baseline to posttest and to follow-up, while knowledge regarding the physical activity recommendations significantly increased from baseline to posttest and to follow-up. After splitting the intervention group (data not shown) into participants who chose to focus on active transport and those who chose to focus on overall physical activity in the Active Coach app, no significant intervention effects were found in the corresponding types of self-reported physical activity (active transport among those who chose active transport and total physical activity among those who chose overall physical activity).

Process Evaluation

At posttest (Table 4), 70%-90% of the intervention group indicated (agree + strongly agree) that the Fitbit wearable was easy to use (50/55) and not annoying to wear (42/55) and that it was interesting to look at the number of steps walked (46/55). In addition, more than half (32/55) of the intervention group participants indicated that they would like to keep using it. Technical problems when using the Fitbit wearable were encountered by 24% (13/55) of participants.

The frequency of wearing the Fitbit wearable decreased significantly (P<.001) from the first 2 weeks (mean 6.6 [SE 0.3] days/week) to the final 2 weeks (mean 4.6 [SE 0.3] days/week) of the intervention period. Participants indicated that they did not wear the Fitbit wearable because they forget to put it on (18/55, 32.7%) or forgot to recharge it (7/55, 12.7%), they found it annoying or unattractive to wear (5/55, 9.1%), they were not planning on being physically active ("what's the point?"; 4/55, 7.3%), or they encountered technical problems (9/55, 16.4%).

Regarding the use of the Active Coach app (see Table 4), >70% of the intervention group participants found the app self-explanatory (36/51) and easy to use (40/51; agree + strongly agree). In addition, >60% of the participants found the app interesting (34/51), and approximately half of the intervention group found it fun (29/51) and motivating (26/51). The app was found boring by 15% (8/51) and complicated by 24% (12/51) of participants, and 32% (16/51) of participants had encountered technical issues when using the app. The high battery use (depending on smartphone type) due to Bluetooth connection with the Fitbit wearable was the most frequently mentioned technical issue.

Several participants indicated the graphs (graphical display of steps and minutes active transport) as the best feature of the app. The frequency of viewing the graphs decreased significantly (P<.001) from the first 3 weeks (mean 3.4 [SD 0.2] days/week) to the final 3 weeks (mean 2.7 [SD 0.2] days/week) of the intervention period. Participants indicated viewing the graphs less frequently toward the end of the intervention period because of decreased interest (n=12), they forgot about it (n=4), and the data were not up-to-date as they wore their Fitbit wearable less frequently (n=8).

During the intervention period, there was also a significant decrease in the frequency of reading the push notifications on the smartphone and messages (in the app) regarding participants' goal, tips, and facts (Table 5). Participants indicated not reading the notifications or messages from the Active Coach app because they were getting lost among all other notifications (n=12; they did not see or read them, they swiped them [ie, moving a finger across the notification on the smartphone screen to quickly remove it]). Participants already received many notifications from others apps (eg, Facebook, Snapchat, and WhatsApp), and they did not want any extra notifications. In addition, they indicated that there was too much repetition among the notifications about their goal (n=5), and they mentioned a lack of interest in the notifications and messages (n=7).

Table 6 shows that >50% (25/45) of the intervention group participants tried to achieve their daily goal (agree + strongly agree) and >60% (30/45) found it motivating to have a goal. In addition, 40% (18/45) of participants found it helpful to receive daily feedback on their goal and 35% (15/45) found it helpful to receive weekly feedback on their weekly goal. The tips and facts were self-explanatory for 73% (30/41) of the intervention group participants, useful for 63% (26/41), and boring for 14% (6/41) of them. Half (20/41) of the intervention group participants thought the tips and facts were interesting, but only 24% (10/41) thought the tips and facts were motivating. Furthermore, the tips and facts were used to be physically active by only 20% (8/41) of the participants and only 17% (7/41) thought they were tailored and adapted to their life.

The official Fitbit app (this is the accompanying app with the Fitbit wearable) was sometimes used by 27.3% (15/55) and regularly used by 27.3% (15/55) of intervention group participants. The additional features within the Fitbit app that do not exist in the Active Coach app (eg, calories burned and sleep overview) were mentioned as reasons for using the Fitbit app. Furthermore, some participants found the Fitbit app more self-explanatory or opened the Fitbit app to enhance the syncing process with the Active Coach app.

At follow-up, 9 intervention group participants (3 in the control group) purchased a wearable activity tracker, and 14 intervention group participants (8 in the control group) were planning on purchasing it. Participants indicated that they found the wearable interesting, motivating, and useful when being physically active. Those who did not want to purchase it mentioned the high costs (n=13) and a lack of interest (n=12) as the reasons.

Table 5. Frequency of reading notifications and messages regarding goals, tips, and facts from the Active Coach app. 6-point scale: 1=never; 2=less than once a week; 3=once a week; 4=2-4 times a week; 5=every day; 6=multiple times a day.

Item	First 3 weeks, mean (SE)	Final 3 weeks, mean (SE)	P value (time)
Notification goal	2.95 (0.29)	2.57 (0.29)	<.001
Notification tips and facts	2.38 (0.22)	2.13 (0.22)	.004
Message goal	2.14 (0.21)	1.96 (0.21)	.005
Message tips and facts	2.39 (0.26)	1.99 (0.26)	.049

Table 6. Statements about goals, tips, and facts of the Active Coach app in the intervention group.

Statements	Strongly disagree, n (%)	Disagree, n (%)	Sometimes (dis)agree, n (%)	Agree, n (%)	Strongly agree, n (%)	Mean (SD)
I tried to achieve my daily goal.	3 (6.7)	8 (17.8)	9 (20.0)	15 (33.3)	10 (22.2)	3.47 (1.22)
I found it motivating to have a goal.	2 (4.4)	8 (17.8)	5 (11.1)	19 (42.2)	11 (24.4)	3.64 (1.17)
It was helpful that I received daily feedback about my daily goal.	8 (18.2)	9 (20.5)	8 (18.2)	12 (27.3)	6 (13.6)	2.91 (1.41)
It was helpful that I received weekly feedback about my weekly goal.	12 (27.9)	10 (23.3)	6 (14.0)	9 (20.9)	6 (14.0)	2.70 (1.44)
The tips and facts were interesting.	7 (17.1)	5 (12.2)	9 (22.0)	11 (26.8)	9 (22.0)	3.24 (1.39)
The tips and facts were clear, and I understood them.	7 (17.1)	1 (2.4)	3 (7.3)	16 (39.0)	14 (34.1)	3.71 (1.42)
I found the tips and facts motivating to be physically active.	10 (24.4)	12 (29.3)	9 (22.0)	7 (17.1)	3 (7.3)	2.54 (1.25)
The tips and facts were boring.	16 (39.0)	14 (34.1)	5 (12.2)	3 (7.3)	3 (7.3)	2.10 (1.22)
The tips and facts were tailored and adapted to my life.	12 (29.3)	12 (29.3)	10 (24.4)	5 (12.2)	2 (4.9)	2.34 (1.18)
The tips and facts were useful.	3 (7.3)	6 (14.6)	6 (14.6)	11 (26.8)	15 (36.6)	2.29 (1.31)
I used the info from the tips and facts to be physically active.	14 (34.1)	10 (24.4)	9 (22.0)	4 (9.8)	4 (9.8)	2.37 (1.32)

Results from Google Analytics showed that the Active Coach app did not crash a single time during the intervention period. In total, 59 people visited the app, with 59 people visiting the app in the first 3 weeks and 37 visitors in the last 3 weeks. The number of visits halved from 824 visits in the first 3 weeks to 403 visits in the last 3 weeks. The average duration of visiting the app was 1 minute 5 seconds (1 minute 19 seconds in the first 3 weeks vs 53 seconds in the last 3 weeks), and the average time users spent on a screen was 13 seconds (constant throughout the intervention period). Users viewed on average 5.3 screens per visit (repeated views of a single screen were counted). When examining events (user interactions which are not screen loads such as clicks on a notification or other element in the app), the event “daily goal not reached” occurred more often (242 times) compared with “daily goal reached or almost reached” (169 and 15 times, respectively). In addition, the event “weekly goal not reached” occurred more (39 times) compared with “weekly goal reached or almost reached” (35 and 26 times, respectively). The events of the tips (on Monday 77 times, on Friday 78 times) and facts (79 times) all occurred in similar amounts.

Discussion

Principal Findings

In this study, we investigated the effects and process evaluation of the Active Coach app, in combination with the Fitbit wearable activity tracker, in lower educated working young adults. The evidence- and theory-based Active Coach app was developed using a stepwise, user-centered approach to develop an app that is optimally suited to the needs and preferences of lower educated working young adults [33]. Nevertheless, results showed no significant intervention effects on the objective (light physical activity, moderate physical activity, vigorous physical activity, MVPA, total physical activity, and steps) and self-reported (occupational physical activity, active transport, household physical activity, recreational physical activity, and total physical activity) physical activity. Moreover, no significant intervention effects were found on the psychosocial variables.

Although no significant intervention results were found, intervention participants found the Active Coach app easy to use, self-explanatory, not complicated, and not boring. However, user engagement with the app showed significant decreases in the frequency of viewing the graphs and reading the messages and notifications throughout the intervention period. App engagement has previously been demonstrated to be positively associated with the intervention effectiveness and health behavior change [67-69]. Nevertheless, user engagement typically declines after the first few weeks in most eHealth and mHealth interventions [32,69-71]. This might be particularly true for lower educated working young adults as a qualitative study showed that young adults often lack commitment to using any particular app and they only tend to engage in transient and casual app use [22]. In addition, engagement with health interventions in general has typically been lower among those with lower levels of education [71].

Interactive app features such as notifications have been found to be essential for app engagement [72,73]; they are important as prompts for reuse of the app [74-76], and qualitative data also indicate that young adults want apps that include positively framed alerts or reminders (but not too frequently) [22,77]. In our study, participants mentioned that the notifications were getting lost among all the notifications from other apps on their smartphone. All young adults received many notifications from different apps such as communication apps (eg, WhatsApp) or social media apps (eg, Facebook and Snapchat), which were often perceived as more urgent and interesting compared with

Active Coach app notifications. The app (particularly its notifications) was competing with many very popular and high-end commercial apps. Although young people have demonstrated high usage and adoption of app technology [22,29,78], this does not assure high engagement with health behavior apps. On the contrary, the abundance of popular commercial apps on smartphones might make it difficult for health behavior apps to cut through all the distractions and excitement created by other apps. All this makes young populations harder to reach using mHealth interventions.

Another explanation for the lack of intervention effects may be the fact that few intervention participants found the tips and facts motivating, used them to be physically active, and thought they were tailored and well suited to their life. Providing individually tailored feedback and advice (ie, based on users' own characteristics [79]) has shown to be important for the engagement with and effectiveness of health behavioral change interventions [80-82]. However, this requires a knowledge of participants' characteristics, which is typically gathered by manual data entry (eg, answers to a questionnaire). However, research has demonstrated that young adults want apps that require low effort, and this indicates the difficult balance between manual data entry burden and providing app users with personally tailored advice [22,73,83]. To limit the data entry burden, the personal advice in the Active Coach app was only tailored to a small extent [33]; unfortunately, this resulted in advice that was not perceived as motivational or useful. Therefore, advanced context sensing (using mobile or environmental sensors to automatically detect features of the person's current behavior and circumstances) could be a solution for providing tailored advice with very low manual data entry burden in future studies, although the development of such apps is complex and costly [22,84-86].

A final explanation for the fact that the Active Coach app combined with a Fitbit wearable was not sufficient to encourage an active lifestyle among lower educated working young adults may be the lack of using additional intervention strategies in combination with the app and tracker. A recent review of mHealth interventions showed that multicomponent interventions yielded stronger intervention effects than stand-alone app interventions [29]. The use of multiple intervention strategies has been previously recommended to achieve long-term health behavior changes [87,88]. Integrating the Active Coach app into a multicomponent intervention in which digital and human support are combined might be necessary to increase the engagement in this particular target group. Especially, lower educated individuals may need an (expert) human coach who could reassure, guide, emotionally support them, or hold them accountable [69].

Notably, intervention participants were rather positive about the use of the Fitbit wearable. They found the wearable easy, user friendly, and interesting. In addition, many participants purchased or were planning on purchasing a wearable activity tracker at the end of the study. Previous research has also found positive evaluations of Fitbit use among both young and middle-aged adults [89-91]. Nevertheless, this did not influence physical activity levels; this might be because the frequency of wearing the Fitbit wearable during the intervention period decreased significantly. Participants mentioned not wearing it because, among other reasons, they forgot to put it on or forgot to recharge it. Although the use of the Fitbit wearable was included to ensure automated tracking of physical activity, which is important for user engagement with the app, it seemed that continuous engagement with the Fitbit wearable itself was also a problem. Similarly, previous studies on Fitbit use in young people found low engagement over time [92,93]. In addition, some participants did not see the need to wear the Fitbit wearable on days or moments when they were not planning on being physically active. They seemed to use the wearable to track planned sports activities, instead of monitoring everyday lifestyle physical activity at work, at home, or while traveling.

Lower educated working young adults are often employed within different occupational types, such as blue-collar work (ie, nonagricultural manual labor). Blue-collar jobs typically include more occupational physical activity compared with white-collar jobs. It could be suggested that lower educated working young adults do not benefit from an intervention to promote an active lifestyle because of their higher levels of occupational physical activity. However, occupational physical activity often includes activity patterns (heavy lifting, prolonged standing, repetitive work, and twisting or bending the back) that create opposing effects on health compared with other types of physical activity [94-96]. Moreover, high occupational physical activity has been associated with an increased risk of cardiovascular disease [97] and all-cause mortality, especially among employees with low physical fitness levels [95,96]. These contrasting health effects have been termed the physical activity health paradox [94,98], highlighting the importance of a good balance between physical fitness and physical work demands [96]. Encouraging an active lifestyle in lower educated working young adults could be beneficial for this balance.

We found decreases in both objective physical activity (light physical activity, total physical activity, and steps) and self-reported physical activity (total physical activity) in both the intervention and control groups; weather influences might have caused these physical activity declines. During baseline measurements (September 2016), the weather was unusually warm and dry for that time of year in Belgium (abnormally high mean temperature, 17.5°C, and sunshine duration and abnormally low total precipitation and wind speed), while it was normal during posttest (November 2016) and follow-up (February 2017) measurements and, therefore, markedly colder and wetter than that during baseline measurements [99]. Additional analyses (data not shown) support this hypothesis as we found a significant increase from baseline to posttest in the barrier related to bad weather and a significant decrease (all $P<.05$) in 4 benefits related to active transport. Weather has been shown to be a very important determinant for active transport [60,100,101] (see Table 1).

Limitations and Strengths

A limitation of this study includes the relatively small sample size as multiple comparisons were not considered during sample size calculations. A larger sample size would have increased power and would have allowed for secondary outcome analyses such as gender differences in intervention effects. In addition,

because the Active Coach app was specifically developed for Flemish lower educated working young adults, the generalizability of the evaluation results is limited. Furthermore, recall bias might have occurred as the IPAQ was conducted 3 times in 5 months. Participants might have become familiar with the questions and might have answered more accurately at posttest or follow-up (learning effect). In addition, participants may have been more physically active at baseline when wearing the accelerometer for the first time. It is possible that these 2 measurement effects contributed to the decreases in the objective physical activity and self-reported physical activity in both the intervention and control groups after the intervention.

Strengths of this study include the stepwise development of the Active Coach app, which was evidence and theory based and which was developed with frequent consultations with the target group. Nevertheless, we found no significant intervention effects. Due to the repetitive design of the pretesting study and the frequent contact with the researchers during the development, participants may have come to know what they had to do (use the app, read the notifications, give feedback, etc); they were more involved with the app and, therefore, provided a more positive reaction. The inclusion of both objective and self-reported measures to assess physical activityA is also a strength of this study. The elaborate process evaluation with both quantitative (eg, 5-point scales) and qualitative (open-ended questions) measures allowed for detailed insights into participants' perceptions and experiences regarding using the Active Coach app [69]. This mHealth intervention study is unique as, to the best of our knowledge, it is the first to focus on the underresearched target group of lower educated working young adults.

Conclusions

In this study, lower educated working young adults perceived the Active Coach app and its combined use with the Fitbit wearable as self-explanatory, easy, user friendly, and interesting. However, no significant intervention effects were found due to low continuous user engagement. The difficulty to compete with popular commercial apps on young people's smartphones and the lack of highly tailored advice may have caused low engagement toward the end of the intervention. As a stand-alone app does not seem sufficient to promote an active lifestyle among lower educated working young adults, combining digital and human support in a multicomponent intervention and increased use of context sensing to provide tailored advice might be needed.

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Authors' Contributions

All authors were involved in the study design. DS led the data collection, performed the data analyses, and drafted the manuscript. All other authors critically reviewed and revised versions of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V.1.6.1).

[PDF File (Adobe PDF File), 135KB - mhealth_v6i8e10003_app1.pdf]

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Abbreviations

ASE: attitude-social influence-self-efficacy
BCT: Behavior Change Technique
BMI: body mass index
ICC: intraclass correlation coefficient
IPAQ: International Physical Activity Questionnaire
MVPA: moderate-to-vigorous physical activity
RCT: randomized controlled trial

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Original Paper

Assessing the Cross-Cultural Adaptation and Translation of a Text-Based Mobile Smoking Cessation Program in Samoa (TXTTaofiTapaa): Pilot Study

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Abstract

Background: Samoa faces a persistently high prevalence of adult tobacco use and few existing cessation support services. Mobile phones are ubiquitous and generally affordable.

Objective: This study aimed to adopt a text message (short message service, SMS) smoking cessation program designed in New Zealand (stop smoking with mobile phones, STOMP) for use in Samoa to assist national objectives in reducing the tobacco use.

Methods: Using focus groups with smokers and ex-smokers, we explored the context for tobacco use and preferences for SMS text messages. Postintervention focus groups were held after participants received SMS text messages for 1 week. Frequent face-to-face meetings with the primary partner (Ministry of Health Samoa) and key stakeholders contributed to the adaptation process. Participatory feedback and collaboration from stakeholders became an integral part of the cultural adaptation and translation of the program. Furthermore, detailed document analyses were included as part of the formal evaluation of the initiative to explore the core determinants of success in adapting the program to the Samoan cultural context.

Results: The SMS text messages evolved remarkably following an iterative process of consultation, in situ testing, revision, and retesting to arrive at an acceptable country-specific version of the mobile smoking cessation program. The SMS text messages retained in the final set were consistent with the theory of behavioral change but reflected both linguistic and cultural nuances appropriate for Samoa. Adapting messages required simultaneous multilevel processes, including complex high-level engagement, between the team and the stakeholders, along with crafting the precise content for (character limited) messages.

Conclusions: Receiving cessation support messages through a mobile phone is promising and appears to be an acceptable and accessible mode of delivery for tobacco cessation, particularly in the absence of alternative support. Adapting a text-based program in Samoa requires fastidious attention to the nuances of culture, language, and sociopolitical structures in the country.

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KEYWORDS

mHealth; mobile phone; Pacific; Samoa; tobacco cessation; text messages

Introduction

Mobile phones can deliver programs to support behavioral change [1,2], data management or surveillance [3,4], and other essential public health activities. The use of mobile phones could potentially promote health and gender equity [5,6] and enhance community empowerment [7,8]. Short message service (SMS) text messaging, in particular, has been shown to be a simple and effective intervention for improving health service delivery in pregnant women [9,10], infectious disease cases [11,12], weight loss cases [13], and diabetes cases [14] and increasingly for smoking cessation support [15-18]. SMS text messages can present timely cues, behavioral reinforcement, and social support [19] all through an inexpensive delivery medium.

The increasing use of mobile phones in health care delivery, combined with its accessibility and relative affordability, underpins the growth of mobile-based programs in low- and middle-income countries (LMICs). The advantages of using mobile phones are especially emphasized when access to health services is limited to the lack of resources [20,21]. Innovative solutions requiring minimal resource and promising great impact are an attractive option driving the burgeoning number of mobile phone-based pilot studies in LMICs [22]. At present, there is a plethora of programs and lessons learned from pilot programs that many countries can leverage from to understand what works to minimize risks, provide savings, and increase impact [23]. However, adapting mobile phone-based programs for use in another context is complex and challenging because of the varied cultural contexts of countries where the intervention is being adapted [24-26]. The adaptation may transcend linguistic translation and extend to cultural themes and values that affect the interpretation and reception of people receiving the messages [24,27].

To ensure that mHealth interventions are effective and reflect both changing technology and users' needs, it is critical to consider the pathways for adapting mHealth interventions to different populations and settings. This paper describes the processes involved in the adaptation of a successful mobile phone-based smoking cessation program from New Zealand for the Pacific country of Samoa. We reflect on the process of adapting an intervention to a cultural environment with technical and resource limitations. Given the near ubiquitous use of mobile technologies in the Pacific region [28], mobile health (mHealth) and mobile smoking cessation (mCessation) specifically, could be an innovative technology-based alternative to the existing initiatives or occupy a void where there are little options [23]. Previous studies on the use of mHealth interventions in LMICs have identified success in improving the uptake of behavioral change (for example, reducing tobacco use and improving diet) [29]. Yet, the arguments in favor of increasing the technology potential, including apps and wearables, are emerging but with caveats regarding cost and access [30]. Low-resource settings, such as Samoa, may have an impressive mobile penetration rate, but preferences for and levels of mobile use for personal behavior change are not well understood. Furthermore, the issue of equity is important to consider in the context of LMICS—who has access to smartphones is influenced by age, gender, and affordability. We specifically opted to explore the use of text messages as a vehicle for the delivery of smoking cessation support because of the opportunity to engage wide participation and potential scale-up. To this end, we adapted a New Zealand-designed program, which was relatively affordable and potentially modifiable in terms of message content, timing of delivery, and other key cultural distinctions.

Samoa, having reached one of the highest rates of mobile phone coverage in the Pacific region in recent years [28], is well placed to initiate mobile phone-based health interventions. With increased government support, Samoa has made progress toward reducing the percentage of adult smokers from 34.6% in 2002 [31] to 25.6% in 2013 [32,33]. However, as environmental and social risk factors for the early uptake still present a significant challenge [34], mCessation presents an attractive, cost-effective option to deliver health messages. Several factors suggest that mCessation may be a viable motivator to quit smoking in Samoa: the high acceptability of the mCessation program among Pacific populations in New Zealand [30], the empirical evidence of its efficacy [15,35], and increasing mobile phone coverage in Samoa [28].

In this study, we adapted a text-based smoking cessation support program called STOMP (stop smoking with mobile phones) for pilot-testing in Samoa. STOMP was designed in New Zealand to deliver targeted, theoretically sound SMS text messages to people who wanted to quit smoking; this original program demonstrated success in a randomized controlled trial by doubling quit rates after 6 weeks compared with unassisted quit attempts, that is 239 (28%) versus 109 (13%), respectively, (P<.001) [15].

STOMP has been adapted and used in the United Kingdom and Argentina [35,36]. In the United Kingdom, the adaptation process of STOMP included reviews by smoking cessation counselors and focus group among potential participants (ie, smokers, ex-smokers, and smokers trying to quit) [37]. In a large randomized controlled trial, the adapted and modified SMS text messaging program (txt2stop) doubled biochemically verified continuous abstinence in 6 months compared with unassisted quit attempts, that is, 268/2911 (9%) versus 124/2911 (4%), respectively, (P<.001) [16]. The adaptation in Buenos Aires, which included translation and back-translation, expert review, and discussions among potential users, emphasized that nuances in tone and translations may negatively affect the acceptability. Hence, conducting a formal cross-cultural adaptation is a necessary step in the adoption of smoking cessation interventions [36].

The original STOMP design was based on effective brief intervention methods and social cognitive theory, particularly around enhancing self-efficacy for quitting [15] and was retrospectively referenced against the Michie's Behaviour Change Technique Taxonomy [38]. The suite of messages was tailored to recognize the iterative phases that are typical, but not universal, in the process of behavior change: contemplation (prep for quit date), action (quit day), and maintenance (relapse support) [39].

In Samoa, this project aimed to adapt and pilot a text-based smoking cessation program called TXTTaofiTapaa (TxtStopSmoke); the process involved identifying the nuances within Samoan cultural context and values important for adaptation of the tool with the overarching intention of increasing smoking cessation attempts among participants. This paper aimed to present insights and lessons learned from the adaptation and implementation of the TxtStopSmoke program.

Methods

Adaptation Design

The adaptation process included the following three major steps: (1) preliminary translation and adaptation design; (2) adaptation test and formative evaluation by users; and (3) linguistic and cultural adaptation and refinement. The design process of the adaptation was dynamic, taking into consideration the user experience as an essential part of the adaptation outcome. As such, the adaptation was responsive to the sociocultural context of Samoa and Samoan smokers. Researchers from the University of Auckland collaborated closely with the Samoa Ministry of Health and the National University of Samoa to provide feedback and finalize the translation to the local language. Ethical approval for this study was granted by the University of Auckland Ethics Committee and the Samoa Ministry of Health Research Committee (reference 016631).

Step 1: Preliminary Translation and Adaptation Design

Initially, 14 SMS text messages from the STOMP program were selected for pretesting. SMS text messages were extracted from each of the STOMP mCessation program phases, based on the Theory of Behavior Change model [39]; these included messages based on the countdown to quit, quit day, intensive phase, and relapse prevention phase [15]. The messages included a combination of motivational messages to persevere with the quit attempt, reminders of the benefits of quitting smoking, and provided information about the consequences of smoking, how to quit and stay quit. These messages were translated verbatim to Samoan. Following the translation, SMS text messages that exceeded the 160-character limit were paraphrased, but the overall content and tone were retained.

Step 2: Preliminary Adaptation Test and Formative Evaluation by Potential Users

The recruitment of focus group participants was conducted in the capital of Samoa, Apia. Participants, including smokers and ex-smokers, were recruited through posters placed in high people-traffic areas. The participant inclusion criteria were as follows: being a smoker or an ex-smoker (defined as having quit in the last ≥6 months), being aged ≥16 years, having access to a mobile phone, being able to receive SMS text messages for 1 week, being able to provide written informed consent, and participating in two 1-hour group interviews (before and after receiving the SMS text messages). Although >40 people expressed interest in participating, several were excluded because of the lack of mobile phone access or because they did not arrive at the focus group venue. Others were unable to be available to receive the messages for the 1 week required for participation. Notably, 36 people directly contacted the research assistant to participate in the study and fulfilled the eligibility to participate. Participants were grouped according to the demographic homogeneity (age and gender) [40] and smoking status (Table 1). This strategy was used in recognition of traditional Samoan-speaking customs [41] and to leverage on participants shared experiences.

All 6 focus groups were moderated by a Samoan researcher (HT). Participants completed a brief demographic and tobacco use questionnaire at the beginning of each focus group. During the focus groups, the following topics were included in the discussion: beliefs about tobacco use, mobile phone use and preferences, including phone sharing, typical daily use, perceived benefits, and problems with mobile for messages to support quitting. All participants received 20 tala (approximately US $8) following their participation in the interviews.

Following the in-depth discussion on the participants' views of tobacco use, smoking initiation, and quitting strategies awareness [42], 36 participants agreed to received SMS text messages for 1 week (2 SMS text messages per day) on their mobile phones. A sample of 14 SMS text messages was sent to participants by the research assistant on a prepaid mobile phone. This process aimed to provide qualitative information on the potential users' attitude toward the mobile phone use and explore their views on the mCessation program within their local context.

After 1 week, participants reconvened for a follow-up group discussion to provide feedback. The follow-up interviews aimed to draw participants' general feedback on the SMS text messages they received, with particular attention to the content, tone, comprehension, and acceptability. The follow-up interviews covered the following topics: preferences for the program, technical issues, phone and message sharing, preferences for the timing of messages, message engagement, and suggestions for improvements in the messages and the timing of delivery.

The focus groups were digitally recorded, transcribed, and subsequently translated into English for non-Samoan researchers. The results were analyzed using a general inductive thematic analysis method [43]. Two researchers (HT and EU) independently performed an initial coding, which was later categorized and organized into themes by the research team.

Step 3: Linguistic and Cultural Adaptation

An initial linguistic translation process required all messages to be translated to create a full suite of messages. The translation process was iterative, drawing upon both the content of interviews and consultation with participants regarding the message content and tone. Rigorous consultations with stakeholders were undertaken to ensure the appropriateness and suitability of messages to local setting or preferences.

Messages were delivered at various transition and maintenance stages of the program—countdown to quit day, quit day, 4-week intensive phase, and relapse prevention. Table 2 presents examples of messages created for each of the 4 stages of behavioral change. The SMS text messages were available in both English and Samoan and were then developed into a single, predefined quit day for the pilot.

Table 1. Demographics, smoking status, and mobile phone use (N=36).

Characteristics	n (%)
Demographics	
Gender	
Male	22 (61)
Female	14 (22)
Age (years)	
16-25	19 (53)
>25	17 (47)
Smoking status	
Smoker	27 (75)
Ex-smoker	9 (25)
Mobile phone use	
Sharing a mobile phone	
Yes	14 (39)
No	22 (61)
Smartphone ownership	
Yes	19 (53)
No	11 (31)
No answer	6 (17)
SMS[a] text message use	
Everyday	21 (58)
Most days	11 (4)
Few times a week	6 (17)
Few times a month or less	1 (3)
No answer	1 (3)

[a]SMS: short message service.

Table 2. Example of short message service text messages translation and adaptation for each stage of the program.

Stage in mCessation[a]	English message example	Samoan message example
Countdown to quit day—2 messages per day for 1 week. 15 messages in total including welcome messages.	Talofa lava! Welcome to the TXTTaofiTapaa programme. We will send you texts to help you stop smoking. Seven days to go until you quit!	Talofa lava! O le polokalame lenei o le “TXTTaofiTapaa” o le a lafo atu ni feau tusitusia e fesoasoani i le tuu o lou ulaula tapa'a. Toe 7 aso tuu loa le tapaa!
Quit day—3 messages.	TXTTaofiTapaa: This is it, (name)! QUIT DAY. Mark it! Throw away all your smokes, today is the start of a new beginning. Be strong.	TXTTaofiTapaa: (Name), o le aso lenei e TUU AI LOA LOU ULAULA TAPAA. Tiai loa lau pepa sikareti o se amataga fou lenei moo e. Faamalosi.
4-week program.	TXTTaofiTapaa: Your withdrawal symptoms are probably high right now. Avoid old smoking places.	TXTTaofiTapaa: Masalo ua faateleina lagona o le fia ula i se tapaa. Faaauau pea le tuu o le ulaula tapa'a. Alo ese mai nofoaga e masani ona e ulaula ai.
Relapse prevention—6 weeks of 3 messages per week. 18 messages in total.	TXTTaofiTapaa: (Name), some old smoking situations will keep coming up again and again. You know how to deal with cravings & temptations.	TXTTaofiTapaa: O lagona o le fia ula i se tapa'a e tupu i nisi taimi. Ua e iloa le gaioiga e fai pe a lagona le fia ula i se tapaa. Tetee i le tapaa.

[a]mCessation: mobile smoking cessation.

Results

Themes

The themes that informed the development of the adaptation design were described accordingly: (1) initial program perception; (2) message tone and content; (3) message delivery; and (4) perception of the value of mCessation program in general. The results below reflect participants' perceptions of the messages after receiving them for a week.

Initial Program Perception

Before receiving an actual program of SMS text messages, participants were shown examples of 3 SMS text messages that they were to receive and then asked about their thoughts regarding the concept of a SMS text messaging program to help them quit smoking. Overall, participants were generally positive toward the idea of receiving supportive messages and concurred the program would offer support to Samoans who smoke.

> *Good thing to try and see how and would it work. To inform me of the harms that smoking can do and will see how it works. Reading just one of these messages just makes me think about my smoking.* [Female smoker, aged >25 years]

However, a few expressed doubts about the SMS text messages' effects, comparing them with antismoking advertisements previously viewed on television or billboards.

> *Some of those billboards about smoking don't affect me at all. They shouldn't follow overseas things, because they just cut and paste it and add a Samoan face but they should do their own.* [Female smoker, aged >25 years]

These participants suggested that messages should be personalized and tailored to Samoans for greater impact on users.

Message Tone and Content

During the follow-up focus group discussions, many participants preferred a positive tone of the SMS text messages—encouraging messages that reflected the physiological challenges when quitting were perceived to be helpful. Practical suggestions on what to do to avoid smoking were appreciated (eg, "Get lots of rest to keep your energy up to fight the cravings. If you get tired, it's easy to have cravings for a smoke."), as well as those that highlight the benefits of quitting smoking to their family.

> *The texts that are most helpful were the ones that showed me how to do things…like don't be around people who smoke. Practical advices were helpful.* [Female smoker, aged >25 years]
>
> *I can remember also the one where if you stop smoking, you have more time with you family, and it saves money.* [Female smoker, aged >16 years]

Some participants preferred SMS text messages that contained information about the negative effects of smoking—the shock effect perceived to be a necessary motivator for attracting attention and potentially nudging behavioral change. Some requested photo evidence to be included with the SMS text message. Notably, these suggestions were more likely to come from older males in groups. Furthermore, visual representations of the message were considered important, partly for validation; seeing is believing.

> *But for me, our country if it comes like that [funny], then they won't take it seriously. What is important is to scare people and [to say] that it will affect them so that they take it seriously. Even the young ones that have just started smoking, if they get this message, then they'll know how important it is to stop smoking.* [Male smoker, aged >25 years]

Some SMS text messages stood out among participants and elicited discussion. For instance, many participants disagreed with the SMS text message that encouraged going to public places to avoid smoking, saying that public places are where smokers congregate and many start smoking.

> *The text about going to public places where there are no smoking, well, there are laws now to not smoke in public places, but it is still going on, like smoking on buses and so on. So, that text might not be appropriate.* [Male smoker, aged >16 years]

Another message aroused humor and curiosity; that cigarettes contain chemicals found in toilet cleaner. Although some questioned the validity of that specific message, others suggested that these were the most impactful—clear linkages between smoking, the chemicals, and the risk to body organs.

> *There was one that I got, and I read it to my family, and they thought it was funny and didn't believe it. The one about the chemicals that are in smoking are also used to clean toilets, and they didn't believe me. And they said they're all lies.* [Ex-smoker, aged >16 years]

Participants preferred SMS text messages that did not use abbreviated slang language, with some commenting that these SMS text messages will be difficult to understand among older smokers. Furthermore, some participants suggested providing the option for smokers to choose between receiving English and Samoan SMS text messages.

Message Delivery

The timing of message delivery was also carefully considered within the groups. When asked about the time of the day they prefer to receive the SMS text message, participants broadly agreed that sending messages at midday (after a meal, which is a trigger to smoke) and in the evening (when family is around and after dinner) were the most beneficial times.

> *Time that is appropriate is times of meal times, like the morning, lunch and dinner. Then I can read and change my mind about smoking.* [Male smoker, aged >16 years]
>
> *It's good at the beginning in the morning and then at the end of the day when people are unwinding, and people are wanting a break and craving a smoke.* [Female smoker, aged >25 years]

Generally, participants suggested avoiding times when the messages would be disruptive to important events (Bingo night, church services) or rituals (during a meal). Most participants reported being satisfied with the timing of messages and the frequency. Some even suggested they would like to receive more messages to assist them to quit smoking.

Perception of the Value of Short Message Service Text Messages

After 1 week of receiving messages, many participants reported that they had reduced the number of cigarettes they smoked. A few said nothing changed, but expressed that the SMS text messages increased their intention to quit.

> *A lot of use of the program for me especially for my family and my relationship with my wife. Because it has given me good thoughts and saving money…I feel better now…I have reduced smoking because it is cheaper, and better for my family. It is important for all Samoans to stop smoking.* [Male smoker, aged >25 years]

The majority of participants who received the messages were positive about the potential of the program in assisting them to quit smoking. Many felt that, in the absence of any alternative tobacco cessation support (eg, nicotine replacement therapy), messages were likely to be helpful in prompting thoughts about quitting.

> *Samoans take a while to change because of the way they feel, and it will take a long time to change, but the program is there and helps straight away, and so the program is quicker in helping quit attempts, when they get text messages.* [Male smoker, aged >16 years]

Phone sharing in Samoa and the close connectivity with family was believed to help in spreading the message. A number of participants reported that they shared the SMS text messages with family or friends, through either actual forwarding the SMS text message or relaying the content of the SMS text messages to family and friends.

> *I think that this programme is good and so if it is good for me, then it is good for my family and friends. I shared it with others.* [Female smoker, aged >25 years]

Discussion

Principal Findings

The cultural translation and adaptation of the STOMP program was a necessary first step to implementing an mCessation program in Samoa. The value of undertaking a cultural translation cannot be underestimated, with strong evidence of its marked contribution to the acceptability and effectiveness of mHealth interventions [24,44,45]. The current literature provides some guidance on how to adapt mobile phone-based interventions (for use in countries wherein it was not specifically designed), acknowledging the essential role of the end user in this process [24,46,47].

A sample of Samoan smokers and ex-smokers were involved in the process of cultural translation and adaptation of a mCessation tool designed for use in Samoa. Smokers were essential as key informants on design-related decisions such as which messages to include or revise and the timing of message and themes highlighted in the SMS text messages (eg, benefits to the family, negative effects of smoking, practical suggestions to avoid smoking). Previous qualitative analyses affirm the critical role of the social environment, familial connections, including smokers, and perceived barriers and motivations for quitting; this led to minor revisions of the original STOMP messages to include more reference to family (eg, messages about the benefits of quitting smoking to family), and changes to suggested activities and snacks (reduce craving to smoke). Participants identified when cravings to smoke were the highest and when SMS text messages were most useful in providing timely encouragement. The positive response of participants to the program, including the increased focus on quitting or reducing the consumption of tobacco products, was consistent and provided modest evidence that Samoans smokers are likely to use the mCessation program if the program is scaled up and made available as an option for smoking cessation.

One challenge during the initial translation was to retain the integrity of the message while ensuring that the messages were kept within 160 characters. As Samoan words are typically lengthier than their English equivalent, alternative words were selected.

The involvement of key stakeholders and potential implementers of the mCessation program was critical for the formative linguistic translation and subsequent refinement of the SMS text messages. Colantonio et al [36] conducted similar consultations, mostly with tobacco cessation experts, to validate their translated messages for suitability and relevance to the local setting. The process of translation required considerable time and effort, a step that could potentially be underestimated. Our consultations with experts improved the suitability of messages to the local setting, as well as the accuracy and integrity of translation and language use. The translation quality was determined according to the integrity of the translator, with the primary challenge being the identification of the definitive authority in translation [48]. In our experience, New Zealand-based Samoan translators were the least preferred over local officially appointed translators.

Strengths and Limitations

An important aspect of our cultural adaptation process and one of the strengths of this study is integrating both a “bottom-up” and a “top-down” approach; this process underscores the vital role of the end user of mHealth tools, in this case smokers, to provide inputs about the shape and design of the adapted program. It also recognizes the involvement of key stakeholders who can determine the local acceptability and appropriateness of the intervention. Another strength of this study is partnership with the Ministry of Health Samoa to undertake the process of adaptation and the fact that this work reflects the reality of adapting an SMS text message program for a limited-resource environment.

A local coinvestigator, fluent in Samoan, conducted the interviews. Although this adds strength to the integrity of the data collection, it might have introduced a social desirability

response, owing to the tendency to offer affirmative opinions when researching within socially connected group settings.

The aim of this study reflects an appreciation that culturally adapted messages will increase engagement, a predictor of the positive impact of SMS text message programs on health [45,49]. Similarly, engagement with SMS text message interventions is recognized as important to uptake and behavioral change [27]. Behavioral change is a complex process, which despite efforts to define a predictable, universal model remains largely elusive. However, what our work has shown is that careful attention to the nuances of the content and delivery timing of SMS text messages for behavioral change is important.

Conclusions

The current provision under the Samoa Tobacco Control Act (2013) covers smoke-free environments, tobacco advertising, and plain packaging [50]. However, most tobacco control initiatives in Samoa have been focused primarily on regulating the sale and distribution of tobacco products and tobacco marketing, with some enforcement at the local level [51]. New Zealand, under its bilateral agreement with Samoa, offers support to Samoa to achieve its health goals and targets [52]. Within this scope, we worked with the Samoa Ministry of Health to adapt a mobile phone-based smoking cessation intervention to support Samoan smokers to quit. Lessons learned and observations made throughout the process of adapting the intervention provide value for others attempting similar efforts. Adapting mobile phone-based interventions requires considerable time and resource and keen attention to the nuances of language and meaning—as well as partnerships. Hence, this study suggests that this investment is essential for meaningful improvements to the integrity of technology-based health interventions.

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Conflicts of Interest

None declared.

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Abbreviations

LMICs: low- and middle-income countries

mCessation: mobile smoking cessation
mHealth: mobile health
SMS: short message service
STOMP: stop smoking with mobile phones

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Original Paper

Veterans' Attitudes Toward Smartphone App Use for Mental Health Care: Qualitative Study of Rurality and Age Differences

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Abstract

Background: Mental health smartphone apps provide support, skills, and symptom tracking on demand and come at minimal to no additional cost to patients. Although the Department of Veterans Affairs has established itself as a national leader in the creation of mental health apps, veterans' attitudes regarding the use of these innovations are largely unknown, particularly among rural and aging populations who may benefit from increased access to care.

Objective: The objective of our study was to examine veterans' attitudes toward smartphone apps and to assess whether openness toward this technology varies by age or rurality.

Methods: We conducted semistructured qualitative interviews with 66 veterans from rural and urban areas in Maine, Arkansas, and California. Eligible veterans aged 18 to 70 years had screened positive for postraumatic stress disorder (PTSD), alcohol use disorder, or major depressive disorder, but a history of mental health service utilization was not required. Interviews were digitally recorded, professionally transcribed, and coded by a research team using an established codebook. We then conducted a thematic analysis of segments pertaining to smartphone use, informed by existing theories of technology adoption.

Results: Interviews revealed a marked division regarding openness to mental health smartphone apps, such that veterans either expressed strongly positive or negative views about their usage, with few participants sharing ambivalent or neutral opinions. Differences emerged between rural and urban veterans' attitudes, with rural veterans tending to oppose app usage, describe smartphones as hard to navigate, and cite barriers such as financial limitations and connectivity issues, more so than urban populations. Moreover, rural veterans more often described smartphones as being opposed to their values. Differences did not emerge between younger and older (≥50) veterans regarding beliefs that apps could be effective or compatible with their culture and identity. However, compared with younger veterans, older veterans more often reported not owning a smartphone and described this technology as being difficult to use.

Conclusions: Openness toward the use of smartphone apps in mental health treatment may vary based on rurality, and further exploration of the barriers cited by rural veterans is needed to improve access to care. In addition, findings indicate that older patients may be more open to integrating technology into their mental health care than providers might assume, although such patients may have more trouble navigating these devices and may benefit from simplified app designs or smartphone training. Given the strong opinions expressed either for or against smartphone apps, our findings suggest that apps may not be an ideal

adjunctive treatment for all patients, but it is important to identify those who are open to and may greatly benefit from this technology.

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KEYWORDS

smartphone apps; mobile phone; mhealth; mental health; qualitative analysis; rurality; age; veterans; depression; anxiety disorders; posttraumatic stress disorder; PTSD; alcohol abuse

Introduction

Smartphone apps are a fast-growing mode of mental health treatment delivery with the ability to provide support, skills, and symptom tracking on demand at minimal to no additional cost to patients. Recent efforts have attempted to formally evaluate these tools, and a developing body of evidence suggests that apps can be effective in the treatment of mental health disorders [1-3]. The Department of Veterans Health Affairs (VA) has established itself as a leader in the creation of mental health apps addressing conditions ranging from depression to insomnia and posttraumatic stress disorder (PTSD). The PTSD Coach app, made available to the general public, has been downloaded over 340,000 times and has demonstrated effectiveness in multiple rigorous studies [4-7]. The rate of smartphone ownership reported by veterans ranges from 47% to 76% [8,9], and roughly 17% of veterans with PTSD have reported ever having used a health-related app [8,10], suggesting relatively low levels of current engagement.

Gaining a better understanding of veterans' attitudes toward mental health apps may help explain their current rates of use. Survey data have provided conflicting results regarding veterans' openness to smartphone interventions, with veterans who are currently receiving mental health treatment, perhaps, being more favorable toward this modality as opposed to those with mental health diagnoses who are not in care [8,11]. Findings from a small focus group of veterans with PTSD revealed that they were generally less comfortable navigating smartphone apps as opposed to personal computers, the internet, or email. However, several veterans reported using mental health apps, and the PTSD Coach app was found to be particularly helpful in managing symptoms and directing veterans to additional resources, such as a suicide crisis line [10].

It is particularly important to examine attitudes toward mental health app use among rural veterans, a population with lower mental health–related quality of life, greater risk of suicide, less health care service utilization, fewer specialty care services, longer travel times to clinics and hospitals, and poorer overall access to care [12-15]. This group may particularly stand to benefit from receiving mental health coping skills and support remotely via mental health apps. Smartphone ownership among rural populations, while lower on average than urban and suburban populations, continues to increase, with approximately 65% of the rural population reporting having a smartphone in 2018 [16]. While rural and urban patients were demonstrated to be equally open to integrating technology, such as telehealth appointments, into their care in one study [17], another study found rural patients to be less likely to utilize technological interventions citing attitudinal differences or network connectivity difficulties as potential explanatory factors [18]. To the best of our knowledge, openness toward the use of mental health smartphone apps and potential barriers to use have not yet been comprehensively examined among rural veterans.

Differences in attitudes toward mental health apps may also exist between older and younger veterans. Compared with their younger counterparts, older adults are often perceived as being uninterested, unwilling, or physically unable to engage with new technologies, and providers may hesitate to recommend such treatments, despite evidence demonstrating a wide range of abilities and attitudes within the aging population [19]. mental health apps could serve as an important tool within the growing population of older adults who seek health care services by increasing their sense of independence and self-management of chronic conditions [20,21]. A study of current mental health treatment seekers found older veterans to have a strong interest in mental health apps and reported a trend toward current users of PTSD apps being older, despite findings that older veterans were, on the whole, less likely to own a smartphone [8]. Similarly, large national surveys have found smartphone ownership to decline with age, although the rates of ownership continue to increase across all age groups over time [16]. Another study found that while many older adults were digitally literate, this population more often perceived technology as replacing in-person care, to which they reacted negatively [18]. Visual, motor, or cognitive impairments may make smartphone use more difficult within older populations and may decrease their confidence in navigating new technologies; these physical changes have been shown to take effect beginning at the age of 50 [19,21]. Given these varied findings, it is critical to conduct a focused examination of attitudes toward mental health app usage among younger and older veterans to better characterize the population that may benefit the most from these tools.

This qualitative study, therefore, aimed to examine attitudes toward mental health app usage among a diverse sample of rural and urban veterans who varied in age and screened positive for at least one mental health diagnosis. Semistructured interviews and qualitative analyses were conducted with the goals of examining (1) veterans' attitudes toward smartphone apps; (2) facilitators and barriers to mental health app usage; and (3) potential differences in attitudes between rural or urban and older or younger veterans.

Methods

Participants

This manuscript presents a secondary analysis from a larger study examining veterans' access to mental health care [22]. To meet the eligibility criteria, participants were required to be

US military veterans ranging in age from 18 to 70 years who screened positive for PTSD, alcohol use disorder, or major depressive disorder at a VA health care appointment during the previous year, as documented in their medical record. Participants were not required to have received VA mental health services. However, veterans were excluded if they denied any distress related to the condition(s) for which they screened positive as they were deemed unlikely to require mental health treatment. In addition, veterans with psychosis or dementia diagnoses were excluded as these conditions may have limited their ability to provide informed consent and adequately complete study protocols.

Recruitment

Participants were recruited from 9 VA community-based outpatient clinics located in Maine, Arkansas, and Northern California. To further achieve geographic diversity, at least one metropolitan facility and at least one rural facility were included within the 3 clinics sampled per state. We used a stratified purposeful sampling strategy for variability regarding age, sex, race, mental health diagnoses, and history of mental health care. Recruitment packets were mailed to 585 eligible veterans who had received health care services at any of the 9 identified VA clinics. Packets contained a letter introducing the study and explaining that the veteran could be contacted by the research team unless he or she declined participation by either calling the research office or returning a preaddressed and stamped opt-out letter. Veterans who did not opt out within 2 weeks of notification (n=496) were called by trained research staff to review study participation and confirm eligibility. Within this group, 258 veterans were reached, and 72 of them were included in the study after accounting for those who declined or were deemed ineligible. These 72 veterans, plus 8 additional veterans recruited onsite, constituted the study sample (n=80). Notably, 14 veteran transcripts contained no codes pertaining to smartphones or mobile apps (see Data Analysis section for additional information regarding coding and transcript inclusion criteria), resulting in a final sample of 66. Additional information regarding the study's opt-out design and recruitment procedures can be found elsewhere [23].

Procedure

Most interviews were conducted in person, and 6 interviews were completed by telephone. Participants who completed in-person interviews provided written informed consent, whereas those who participated by phone provided verbal consent. Participants then completed a battery of self-reported quantitative questionnaires followed by a semistructured qualitative interview. Interviews were conducted by a team of 4 experienced qualitative researchers, including 1 communication scientist, 1 applied anthropologist, 1 nurse scientist, and 1 clinical psychologist. Interviews lasted approximately 1.5-2 hours, and veterans received financial compensation for their participation. All research procedures were approved by the VA Central Institutional Review Board (Study #13-29).

Measures

At the start of each interview, participants first completed a series of self-reported questionnaires related to descriptive demographics and physical and mental health histories and then completed a semistructured qualitative interview informed by the State of the Art (SOTA) Access Model [24] (Multimedia Appendix 1). The SOTA Access Model consists of 5 domains that may influence access to health care: geographical (eg, distance to a clinic), temporal (eg, appointment wait time), financial (eg, cost of care), cultural (eg, stigma surrounding mental health care), and digital (eg, ownership of a smartphone or personal computer). The semistructured qualitative interview guide was developed and pilot-tested by the study team, and it contained questions tailored to each of the 5 SOTA domains. The interviewers asked additional open-ended questions throughout to explore veterans' experiences with access to VA health care more broadly.

Data Analysis

We performed qualitative data analysis in 2 phases. In Phase I, the qualitative team uploaded interview transcripts into ATLAS.ti (ATLAS.ti Scientific Software Development GmbH; Berlin, Germany) for data management and analysis [25]. The team used a modified form of directed content analysis [26] to develop an original analytic codebook capturing factors related to veterans' overall access to mental health care, including digital access such as smartphone and app use. Conducted between 2015 and 2017, this phase resulted in a large dataset of coded interviews for domains related to the SOTA Access Model and new domains described in more detail elsewhere [27,28].

In Phase 2, we examined responses within the digital domain of the SOTA Access Model and specifically focused on veterans' discussions of and perceptions of smartphone apps as they pertain to mental health care. We used thematic analysis [29,30] to systematically identify meaningful patterns regarding veterans' attitudes toward apps from a critical realist standpoint, meaning that participants' statements were taken at face value, acknowledging that these interpretations are influenced by the researchers' individual beliefs and expectations [31,32]. Analyses were informed by existing theories of technology adoption that consider the influence of multiple factors on individuals' openness toward a novel intervention, including its perceived effectiveness, accessibility, and compatibility with ones' values (Unified Theory of Acceptance and Use of Technology; UTAUT [33,34]). The UTAUT served as a sensitizing concept, which helped guide pattern identification and data analysis but did not prescribe the interpretation of findings [35].

To develop this secondary analysis, the lead author first read all transcripts in their entirety, noting when and how veterans discussed smartphones and mobile app use. Next, segments to which "Smartphone" and "Mobile Apps" codes within the SOTA digital domain had been applied in the overall Phase 1 dataset were identified and reread. All relevant segments were read and annotated multiple times. Then, the lead author generated and assigned subcodes to the data; the subcodes were modified and consolidated to ensure consistency and uniformity

across segments. Next, patterns and relationships were identified between subcodes, resulting in the development of key themes and subthemes representing broader concepts within the data, which were subsequently reviewed by a larger team and streamlined to provide a refined summary of findings. Finally, participants' age and urban or rural status were introduced into the analysis to assess potential patterns within themes and subthemes based on these demographic characteristics. The first author developed an analytical summary of study findings that was first discussed with the second and third authors and was then presented to the full research team for review. All revisions to the analytical summary were determined through consensus, resulting in a final model that adequately captured meaningful patterns and themes within the data.

To explore potential age-related patterns within the data, the sample was divided into older (≥50, n=25) versus younger (<50, n=41) age groups based on the literature demonstrating that cognitive and physical changes influencing technology use can begin by the age of 50 [19,21,36,37]. Rural status was determined using Rural Urban Commuting Area (RUCA) codes [38], a classification system that uses the Bureau of Census urbanized area and urban cluster definitions as well as commuting patterns to classify census tracts into 33 distinct subdivisions, which typically are consolidated into 4 categories (1) Urban areas with metropolitan cores of at least 50,000 residents and substantial commuting flow patterns to urbanized areas; (2) Large rural towns with micropolitan cores with a population of 10,000-49,999 and substantial commuting patterns to urban clusters; (3) Small rural towns with primary commuting flows to or within population centers of between 2500 and 9999 residents; and (4) Isolated rural towns, defined as less populated rural areas with no commuting flows to urbanized areas or urban clusters. We further aggregated these data based on the established RUCA recommendations to differentiate between urban and rural status (categorization method C), such that veterans falling into category 1 were designated as urban, while those in categories 2-4 were deemed rural [39].

For reporting between-group differences, we calculated the percentage of veterans within a given group (rural or urban, young or old) who made statements coded within a particular theme. Findings of group differences were reported when the percentage of respondents within a given theme was at least 1.5 times greater for the dominant group (eg, rural veterans) than that for the comparison group (eg, urban veterans).

Results

Descriptive Statistics

Participants within the final sample (N=66) ranged in age from 20 to 69 (mean 44.61 [SD 13.39]) years. Overall, 26% (17/66) of the sample was female and 42% (28/66) resided in rural areas. The sample was racially and ethnically diverse (47/66, 71% white; 14/66, 21% black; 7/66, 11% Hispanic; 5/66, 8% Native American or Pacific Islander; and 3/66, 5% Asian), and participants had a range of educational backgrounds, employment statuses, and incomes (Table 1). There were no significant differences between rural and urban veterans regarding age (t_{64}=−0.50, P=.62) or race (χ^2_1<2.3, where P values for all categories were >.13), although it should be noted that all Asian respondents belonged to urban locations. Rural and urban veterans also did not differ in sex, income, employment status, or level of education (χ^2_1-χ^2_9<8.7, where P values for all categories were >.22). Regarding site-level differences, there were more black and fewer white participants in the Arkansas sample than in the Maine or California sample (χ^2_2>7.5, where P values for all categories were <.03), and all Asian participants in this study were from California (χ^2_2=8.7, P=.01). There were no other site-level differences regarding any demographic measures (χ^2_1-χ^2_9<3.1, where P values for all categories were >.21).

Veterans' statements regarding mental health smartphone apps tended to be either strongly positive or negative in nature. We examined positive and negative attitudes within the 5 primary themes identified within the data: Treatment effectiveness, Ease of use, Culture and identity, Facilitators, and Barriers. Furthermore, we explored the potential differences in responses between rural and urban veterans, as well as between older and younger age groups; exemplar quotes as well as rurality and age differences across themes have been presented in Table 2.

Treatment Effectiveness

Positive Attitudes

Overall, urban veterans made more positive statements regarding mental health app effectiveness compared with their rural counterparts. However, beliefs that mental health apps could be effective did not vary based on age. Multiple veterans who had not yet used an mental health app stated a willingness to try this new intervention and felt that apps could become an effective part of their care by serving multiple distinct functions. Some discussed how a smartphone app could act as a guide providing strategies to address or track symptoms, distract them from strong emotions at the moment, or direct them to additional resources if they are in crisis, such as a suicide hotline. Others noted the role of an app as a journal to log thoughts and feelings:

> *It's also a diary of sorts. Because whatever [patients] are feeling at that time, they can just pick up their phone and put it in there, and then the therapist can go back and look at it, and be like, "This is how you were feeling this day." It's a nice communication tool between the two.* [ID #1042, 30-year-old urban female]

This participant described the potential for collaboration between the provider and patient, a concept echoed by several other veterans.

In addition to these positive statements from veterans without mental health app experience, multiple veterans reported finding apps helpful for managing mental health problems and associated symptoms. For example, several veterans noted that PTSD Coach provided effective real-time support around managing anger symptoms:

> *I have the PTSD app on my phone, which is really cool. It actually goes over your breathing exercises, it gives you little reminders of how to get around*

> *being angry, what to do if you find yourself in a situation where you're going to hurt someone, it's really helpful.* [ID #2009, 44-year-old urban female]

Another veteran described how quickly he was able to find relief in the moment using PTSD Coach:

> *I like the focusing on other stuff...you're in an anger situation and you focus on something else and it really does work. Because it takes you out of the moment for a second and it doesn't take long...I like how quick it works.* [ID #3012, 53-year-old rural male]

Although PTSD apps were most commonly mentioned, other veterans reported using sleep, relaxation, and mindful eating apps.

Some veterans noted that mental health apps could serve as a good adjunctive therapy tool, but they would not want them to replace in-person contact with their therapist:

> *I mean, [apps] would be helpful, but I don't think [I would want] to have all my services done that way, versus talking to someone face to face...that would be still important when it comes to getting mental health [treatment].* [ID #1037, 37-year-old urban female]

Table 1. Sample demographics.

Characteristics	Total sample (N=66)	Urban subset (n=38)	Rural subset (n=28)
Age (years), mean (SD); range	44.61 (13.39); 20-69	43.89 (12.46); 20-69	45.57 (14.74); 26-69
Rurality (rural), n (%)	28 (42)	N/A[a]	N/A
Sex (female), n (%)	17 (26)	11 (29)	6 (21)
Race and ethnicity, n (%)			
White	47 (71)	25 (66)	22 (79)
Black	14 (21)	10 (26)	4 (14)
Hispanic	7 (11)	6 (16)	1 (4)
Asian	3 (5)	3 (8)	0 (0)
Native American or Pacific Islander	5 (8)	4 (11)	1 (4)
Multiracial	2 (3)	2 (5)	0 (0)
Other	2 (3)	1 (3)	1 (4)
Education, n (%)			
High school graduate or general equivalency diploma	12 (18)	7 (18)	5 (18)
Technical school	1 (2)	1 (3)	0 (0)
Some college	28 (42)	17 (45)	11 (39)
Bachelor's degree	15 (23)	6 (16)	9 (32)
Master's degree	4 (6)	4 (11)	0 (0)
Employment status, n (%)			
Employed (full- or part-time)	25 (38)	15 (39)	10 (36)
Disabled	18 (27)	12 (32)	6 (21)
Retired	6 (9)	3 (8)	3 (11)
Unemployed	3 (5)	2 (5)	1 (4)
Student	5 (8)	1 (3)	4 (14)
Other	3 (5)	1 (3)	2 (7)
Income (US $), n (%)			
<10,000	9 (14)	5 (13)	4 (14)
10,000-25,000	18 (27)	10 (26)	8 (29)
25,001-50,000	15 (23)	9 (24)	6 (21)
50,001-75,000	14 (21)	8 (21)	6 (21)
≥75,001	3 (5)	2 (5)	1 (4)

[a]N/A: not applicable.

Table 2. Primary themes: exemplar quotes and rurality and age differences.

Theme and attitude	Exemplar quotes	Greater % of statements[a]
Treatment effectiveness		

Positive	*[A mental health app] would be fantastic...whenever I have one of those outbursts and frustration, I can just open it up, say "Okay, what's my first step?" I'm sure there's some pamphlet or publication out there that I could use, but carrying around a pamphlet everywhere you go [is cumbersome]*...[ID #1023, 26-year-old rural male]	• Urban veterans:
		  • 68% (26/38) urban
		  • 36% (10/28) rural
		• No age differences observed

Negative	*[Using a mental health app] sounds crazy...I don't think I've got the patience to be sitting down reading about what can help me, I've pretty much heard it all...it just don't seem like it would do anything.* [ID #1004, 33-year-old rural male]	• Rural veterans:
		  • 24% (9/38) urban
		  • 60% (17/28) rural
		• No age differences observed

Ease of use		

Positive	*Everything's really simplified with the apps. It's easy. From my experience on the smartphone, you search almost anything, you find the one you want, you hit download. When it's downloaded, you open it.* [ID #2002, 39-year-old urban male]	• Urban, younger veterans:
		  • 45% (17/38) urban
		  • 18% (5/28) rural
		  • 39% (16/41) young
		  • 24% (6/25) old

Negative	*I haven't gotten acclimated to a smartphone yet...the technology is kind of difficult to navigate through.* [ID #2023, 66-year-old rural male]	• Rural, older veterans:
		  • 13% (5/38) urban
		  • 39% (11/28) rural
		  • 15% (6/41) young
		  • 40% (10/25) old

Culture and identity		

Positive	*I mean my generation, [we] don't have that much difficulty using technology as a means of communication or seeking help, but I can imagine older veterans...they're just not used to using technology...it might be too much change.* [ID #3003, 27-year-old urban female]	• Urban veterans:
		  • 13% (5/38) urban
		  • 4% (1/28) rural
		• No age differences observed

Negative	*Now I see people standing there just looking at their phone, and they're all in a group but nobody's talking to each otherI mean what kind of society is this...I don't understand it, there's no interaction with other human beings.* [ID #3019, 55-year-old urban male]	• Rural veterans:
		  • 11% (4/38) urban
		  • 29% (8/28) rural
		• No age differences observed

Facilitators	*I went to a computer class you can sign up for while you're inpatient [to learn] the basics, how to get on a computer. I haven't used smartphones but...I believe I could probably use that, just pushing with your finger and all.* [ID #1005, 56-year-old urban male]	• Greater % of veterans reporting mobile phone ownership were younger:
		  • 56% (23/41) young
		  • 32% (8/25) old
		• No rurality differences observed

Barriers	*I've got these [sleep] apps...but I haven't been doing quite as much [because] for the first month [my phone] worked and then all of a sudden it did like my old phone and won't connect to the Wi-Fi. So [I don't] use it that much because you use up your minutes.* [ID #1006, 54-year-old urban female]	• Greater % of veterans reporting not owning a mobile phone and having financial or connectivity barriers were rural and older:
		  • 16% (6/38) urban
		  • 32% (9/28) rural
		  • 12% (5/41) young
		  • 40% (10/25) old

[a]Values indicate the raw count and percentage of veterans per group (urban or rural, young or old) who made statements within a given theme. Findings are reported as a difference between groups if there is at least a ×1.5 difference between percentages.

Several veterans expressed similar sentiments, mentioning that they were open to using apps for mood tracking or skills practice but were not interested in sharing the more personal information that they disclose in the context of in-person therapy.

Negative Attitudes

A considerable number of veteran statements described apps as being ineffective and unhelpful in addressing mental health concerns. These statements were more often made by rural veterans, but no clear differences emerged between age groups.

One veteran noted the risk of potentially stirring up strong emotions on an app when alone:

> *I don't think it would be beneficial to me to read about [my PTSD] on my smartphone. And bring up bad memories of my own and then I'm stuck right there trying to figure out how to deal with this. What do you do then?* [ID #1013, 40-year-old urban male]

Another younger rural veteran explained that he tends to get angry while driving and felt that it would not be feasible to turn to a smartphone app for support while behind the wheel. Some veterans described being satisfied with their current strategies for managing their mental health, including researching their condition on the internet, and, therefore, did not see an added value of using apps. Others felt that game apps or podcasts were ultimately more effective at distracting them from their negative thoughts.

Several veterans who had utilized mental health smartphone apps discussed burdensome components of these interventions. One veteran described how previously useful components of the PTSD Coach app became irritating over time as his functioning declined:

> *I put the PTSD app on my phone and I used it quite regularly for probably two years. And then lately I deleted it because it just got annoying. It has the constant reminders and at first it was great because it was like, aha, I can track my ups and downs...then as things progressively got worse over the past couple of years, it became a reminder of, "Hey, you do have issues...*" [ID #2003, 35-year-old urban male]

He went on to say that apps would be more effective if data were directly shared with clinicians as a part of his medical record so that they can be informed of changes in patient functioning and follow up during sessions.

Ease of Use

Positive Attitudes

Some veterans mentioned that apps and smartphones are specifically designed to be user friendly and simple. These veterans were more often from urban versus rural locations, and younger veterans tended to discuss apps and smartphones as being easy to use more so than older veterans. Several veterans noted that having information on their phone was more streamlined and organized than using a physical journal or worksheets that could be misplaced or forgotten. One veteran described the convenience of receiving support when he needed it without having to travel and the discreetness of using an app versus having to explain why he had to leave work for an appointment. Another noted that patients may feel less anxious opening up to a device compared to a therapist:

> *I think it's easier for some people to go to a computer because they may not feel judgment; the computer can't say, "You're doing this wrong. And you should never come and see me," you know? So I think it's a benefit...they may not feel as pressured and may be willing to give more information.* [ID #1042, 30-year-old urban female]

Negative Attitudes

Smartphone technologies were often characterized as being unwieldy, complicated, and mentally taxing to learn how to use. These statements were overwhelmingly made by rural versus urban veterans and by those in the older age group. Some veterans noted how technology is changing too quickly to keep up with, and others mentioned that the smartphone touchscreen was difficult to navigate. One veteran experiencing neurological symptoms described the difficulty of attempting to use a smartphone:

> *They can't figure out why my hands shake so bad...so trying to use a smartphone [is frustrating]...I don't have a whole lot of feeling in my hands...so knowing, ok I'm actually touching this thing, why is it not working? I started listening for my finger tapping the phone to see if I'm actually touching it because otherwise I can't feel it.* [ID #1013, 40-year-old urban male]

Some older veterans described having trouble interacting with the small smartphone interface due to vision decline and others cited the overall burden of the aging process, as this veteran exemplified:

> *No can do...I don't want to tax my brain with something like that...I'll be 70 next year you know...my brain is just kind of wore out.* [ID #3021, 69-year-old rural male]

One older rural veteran with experience using the PTSD Coach app explained that it requires patients to upload their own photos and songs; he noted that this added an additional step and that he would prefer that the app was ready to use as soon as it was downloaded.

Culture and Identity

Positive Attitudes

Several veterans described the compatibility of new technologies with aspects of their culture and identity. These veterans tended to be from urban locations but were distributed across age groups. One veteran noted:

> *I love the idea...I like carrying an iPhone...I'm a geek in some sense, I think. I kind of like messing with some of those things.* [ID #2025, 65-year-old rural male]

mental health apps were viewed as complementary to their lifestyle and preferences for care. Some relatively younger veterans perceived themselves as being part of a "technological generation" who are expected to embrace new innovations and were, therefore, open to the integration of smartphone technology into their health care. A considerable number of older veterans expressed either a working knowledge of smartphone technologies or an interest in honing those skills and did not cite their age as a barrier to technology adoption. One middle-aged veteran spoke about the ability of his generation to adjust to changing times:

> *We weren't born into [smartphone technology].but we adapted pretty well.* [ID #2005, 43-year-old urban male]

Negative Attitudes

A theme emerged within a subset of veterans' statements in which new technologies were found to be in broad opposition to their personal values and were viewed as a destructive force within society. More of these statements were made by rural veterans, but no patterns were observed in chronological age. Several mentioned "hating" technology and feeling forced into using it by their health care system. Some went on to say that the advent of new technologies was intended primarily for companies to make a profit at the expense of its users. A considerable number of veterans spoke of the impersonal nature of smartphone apps, as one veteran exemplified:

> *I really hate the times that we're in where everything is electronic...you send somebody a text message, there's no voice inflection, there's nothing...there's no feelings behind it at all, so we're just numbing our society.* [ID #2020, 28-year-old rural male]

Multiple veterans expressed beliefs that technology is harming society by weakening face-to-face communication skills and limiting opportunities for human connection. Some interpreted the introduction of mental health apps as signaling the reduction or replacement of in-person therapy visits. As one veteran explained:

> *It's pretty hard to make a relationship with a phone as opposed to having a face-to-face relationship with someone.* [ID #2005, 43-year-old urban male]

Multiple statements described the low salience of new technologies within veterans' lives and, therefore, their low level of interest in spending time on a smartphone and utilizing its more advanced functions:

> *I have a little phone, a little forty-dollar phone. And phones are to talk on...and computers are to compute...now [my son] has one of those crazy little phones that you can do everything with. I just don't have an interest.* [ID #1007, 57-year-old rural female]

This overall indifference toward smartphones, therefore, precluded any interest in using mental health apps.

Regarding identity, a greater number of urban versus rural veterans described being "old fashioned" or "old school" when explaining why they were not proponents of mental health apps. While most of these veterans were older than 50 years, multiple relatively younger veterans echoed this preference for older technologies. As this 27-year-old rural male explained:

> *I'm an old school guy, I don't mind writing in a journal [versus using an app]...I mean I like video games like the next guy and I have a computer, but I'm not that tech savvy to be honest with you. I'm still living in dial-up. That's where I'm at.* [ID #3009]

Many veterans cited generational differences when explaining who is and is not open to smartphone technologies. These statements tended to make generalizations regarding the capabilities of older cohorts of veterans:

> *Anybody younger than 50 has got a smartphone in their pocket, but some of these older guys don't have a clue in life about some of that stuff...Vietnam era guys...they're not ready for smartphone time.* [ID #2025, 65-year-old rural male]

In these cases, veterans inferred causal relationships between chronological age and the ability to utilize new technologies.

Facilitators

Many veterans reported owning a smartphone or a tablet; these veterans tended to be younger in age. Those who noted prior experience using an app were overwhelmingly urban but varied in chronological age. Some reported having Wi-Fi network connectivity in their homes, which facilitated app usage by eliminating cellular data fees. Veterans often described feeling comfortable utilizing new technologies; several reported having completed degrees in computer science or related fields, and others noted frequently using smartphones as part of their job. Some veterans who were less experienced reported an interest in obtaining a device if they did not already have one or increasing their technological skills by enrolling in classes or trainings. In addition, social influence was discussed as a facilitator of app usage. One urban veteran noted that his doctor recommended apps to manage stress and monitor his heart health, while another discussed the impact of observing others utilizing health apps:

> *I've seen a lot of people, including my wife, who use iPhones. And I tried to hike the other day with a neighbor and that person has how many miles you walk and all this stuff...so many different applications. I've seen somebody try to lose weight with an iPhone...I think it can really be useful.* [ID #3024, 53-year-old urban male]

Barriers

Some veterans reported barriers including not owning a smartphone or tablet, limited finances, or wireless connectivity difficulties; the majority of these respondents were older and from rural locations. Many veterans reported having little experience or familiarity with new technologies and had never downloaded a smartphone app. For some, the multiple steps involved in adopting smartphone technologies appeared to be more trouble than it was worth, as this veteran explained:

> *Don't have the tools, don't have the equipment, don't have the money, don't have the knowledge, don't want the knowledge, don't want to pay for that—I'd just as soon fix the house up before something goes to something else.* [ID #2027, 57-year-old rural male]

Several veterans reported having experience using computers or smartphones at work but noted wanting a break from technology outside of the office. They, therefore, were not interested in using apps as a component of their mental health care.

A relatively small number of veterans discussed privacy concerns as being a barrier to using mental health smartphone apps:

> *Smartphones are smart but we as users are not. There's a lot of features on there that allow all these different apps and sites access to your pictures and*

> *cameras and microphone and I don't know.* [ID #3002, 35-year-old rural male]

These veterans ranged in age and were predominantly from urban locations. While one veteran felt more confidence in information being protected by the VA versus outside companies, another reported mistrusting the government and was worried that the VA may expose his mental health data. One veteran noted that information relayed digitally is inherently not confidential, and another explained that it is easy and common for a mobile phone to be hacked into, which thereby limited them from sharing any personal health information on their devices.

An additional barrier to use was a lack of awareness of app availability. Multiple veterans were surprised to hear from their interviewer that the VA has developed publicly accessible smartphone apps for mental health concerns. They denied having received this information from VA providers during treatment. Several veterans stated that they planned to research these apps after the interview was complete and were curious what might be available to help their symptoms:

> *I never knew there was apps out there that could help with what I'm dealing with...* [ID #1018, 25-year-old urban male]

These veterans varied in age and were distributed between urban and rural locations.

Discussion

Principal Findings

We conducted a qualitative study of attitudes toward mental health app use among a diverse sample of veterans varying in age and rural status who screened positive for at least one mental health diagnosis. Veterans tended to express either a strong positive or negative stance regarding apps, and we, therefore, examined positive and negative attitudes within 5 central themes within the data: Treatment effectiveness, Ease of use, Culture and identity, Facilitators, and Barriers. We found more prominent attitudinal differences regarding rural status compared with those regarding age, such that rural veterans expressed more negative opinions regarding mental health apps than their urban counterparts, while fewer differences emerged between older and younger veterans.

Rural veterans more often expressed beliefs that mental health apps would be ineffective, difficult to use, and in opposition to their values and identity. They also reported barriers to usage more often than urban veterans, including not owning a smartphone, not having experience using apps, lacking wireless connectivity, and having financial limitations. It remains unclear to what extent rural veterans' negativity is primarily the result of financial or infrastructural barriers versus an overall unwillingness to use mental health apps, a question that has been posed in previous research reporting similar findings [18]. Gaining a better understanding of the respective contributions of these factors will help identify points of intervention, such as offering internet or smartphone subsidies; increasing network connectivity; or providing digital literacy training to increase comfort, confidence, and openness toward new technologies [40]. As a growing number of initiatives introduce technology-based interventions into rural communities in efforts to improve access, including within the VA [41], it will be of particular importance to acknowledge and address these barriers to uptake.

Regarding age differences, the majority of those reporting not owning a smartphone were 50 years and older, and this group more often described apps and smartphones as difficult to use compared with younger veterans. However, no age differences were observed regarding beliefs that mental health apps could be effective and congruent with one's lifestyle and values. This finding of older adults having less access to smartphones but being open to their use mirrors results within a sample of PTSD-diagnosed veterans [8] and complements findings that many older adults are digitally literate and accepting of technology-based interventions [18]. Our results oppose widely held notions that older adults are not interested in new technologies [19]; interestingly, a trend emerged within the data such that veterans made assumptions regarding older generations' purported lack of interest in new technologies that did not prove to be true within this sample. Collectively, these misconceptions underline the need for providers to resist assuming that older patients are not interested in incorporating mental health apps into their care [8]. However, findings also emphasize that smartphones may be less accessible within older populations and that certain aspects of their design, such as their smaller typeface and touchscreen format, may prove challenging or prohibitive due to declining vision and dexterity, which may begin by the age of 50 [19,21]. Increasing the default font size, choosing apps with simpler interfaces, using tablet devices with larger screens, and bolstering confidence through smartphone training may be particularly helpful within older populations, who may lack experience successfully navigating smartphones and apps.

A central theme emerged such that mental health apps were thought to be an impersonal replacement to face-to-face time with a therapist, a perception that has been reported in prior work examining opinions toward technology-based care [18]. This finding emphasizes the need to clarify that mental health apps can serve as an adjunctive tool intended to supplement and not replace in-person psychotherapy [42]. Apps can serve as platforms to log thoughts, track symptoms, or receive psychoeducation between sessions versus the more "personal" role of a therapist. However, it is worth noting that many mental health apps are not contingent on users receiving concurrent psychotherapy services and can also serve as a helpful tool for those not receiving face-to-face mental health care.

An additional theme within the data indicated a lack of awareness about VA mental health apps among some veterans, several of whom requested additional information about this resource. Limited knowledge about app options, both among patients and providers, may be a major contributor to low observed rates of mental health app usage within veteran populations. Given that providers are typically the gatekeepers for the dissemination of new interventions, there is a need for increased provider education and training regarding mental health apps to ensure that patients are aware of available treatment options that are well-aligned with their goals and

preferences [8,43,44]. As mental health apps can be useful tools regardless of whether a veteran is currently in care, information regarding app availability should also be distributed directly to veterans to further increase engagement. Furthermore, it is essential for patients to be fully informed regarding the extent of privacy provided by apps and the potential risks of logging personal information in an electronic format prior to deciding to use these tools [42]. Overall, given the strong opinions expressed either for or against smartphone apps, findings suggest that apps may not be an ideal adjunctive treatment for all veterans, but it is important to (1) identify those who are open to and may greatly benefit from this technology, (2) provide these patients with comprehensive information regarding the availability and functionality of mental health apps, and (3) tailor care to individuals' needs, recognizing that mental health apps are one of the many treatment options available and that they may not be appropriate for every patient [9,18,19].

Strengths and Limitations

Strengths of this study include its use of a relatively large and diverse sample regarding age, sex, race, rurality, education, and socioeconomic status. Veterans were interviewed at 9 distinct VA clinics distributed across Maine, Arkansas, and California, and the study's qualitative analysis of in-depth interviews allowed for a thorough examination of factors that may influence openness toward mental health app use, which may ultimately help tailor interventions and improve overall access to care. Importantly, eligible veterans were not required to be seeking mental health care, which distinguishes the current findings from previous studies of exclusively treatment-seeking populations [8] or samples with experience integrating technology into their health care [10]. This allowed for a broader range of attitudes to be gathered, as the sample was not limited to those who have already demonstrated openness toward receiving mental health treatment or utilizing novel technologies.

No veterans in the sample were older than 69 years, which represents a limitation of the work. We, therefore, are unable to draw conclusions regarding more elderly populations, which would be an important extension of this study as they may demonstrate a unique set of barriers and attitudes toward mental health app use. This study also did not examine attitudinal differences based on additional demographic factors such as sex, race, income, or education. For example, previous research has found that veterans with higher levels of education are more interested in integrating technology into mental health care [11] and that women may be more likely to download a health-related smartphone app [45]. While a thorough qualitative examination of all of these factors was beyond the scope of this work, they warrant additional investigation in future research. In addition, while a strength of the sample includes its distribution across 3 distinct regions of the country, it must still be acknowledged that this represents a subset of the population and national generalizability may be limited. Moreover, the study comprised a veteran-only sample, which limits generalizability; future research should assess whether similar patterns emerge within nonveteran populations. To assess for group differences, veterans were dichotomized into old and young age groups. While this allowed for qualitative comparisons based on age, it is possible that additional information could have been gained by operationalizing age as a continuous variable. Finally, this work does not assess mental health providers' knowledge or attitudes regarding the integration of apps into care. This is an important avenue to explore, as providers play a crucial role in disseminating information about these novel interventions and a lack of awareness on their part may have a strong influence on rates of mental health app usage.

Conclusions

This qualitative analysis examined attitudes toward mental health app use among a diverse sample of veterans varying in age and rural status. Rural veterans expressed more negative attitudes toward apps compared with their urban counterparts. A greater number of older adults reported not owning a smartphone and found these devices more difficult to use than younger veterans, but age-related differences were not observed regarding beliefs that apps could be effective or congruent with one's values. Our findings highlight potential areas of intervention to increase the use of mental health apps within these populations, such as by addressing financial and wireless access, digital literacy, accessibility for those with physical impairments, and dissemination of information to both patients and providers. Although mental health apps may not be an ideal treatment modality for all patients, it is important to identify the populations that may benefit from integrating these novel tools into their care.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Semistructured qualitative interview guide.

[PDF File (Adobe PDF File), 41KB - mhealth_v6i8e10748_app1.pdf]

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Abbreviations

PTSD: posttraumatic stress disorder
RUCA: Rural Urban Commuting Area
SOTA: State of the Art
UTAUT: Unified Theory of Acceptance and Use of Technology
VA: Department of Veterans Health Affairs

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Original Paper

What Predicts Patients' Adoption Intention Toward mHealth Services in China: Empirical Study

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Abstract

Background: With the increasing concerns about the health of individuals in China and the development of information technology, mHealth enables patients to access health information and interact with doctors anytime and anywhere. Examining patients' willingness to use mHealth is considered critical because its success depends on the adoption of patients.

Objective: The objective of our study was to explore the determinants of mHealth service adoption among Chinese patients using an extended technology acceptance model (TAM) with trust and perceived risks.

Methods: We conducted a questionnaire-based survey in 3 large hospitals in China and analyzed the data using structural equation modeling.

Results: The results corroborated that the proposed model fits well. Trust, perceived usefulness, and perceived ease of use positively correlated with mHealth service adoption. Privacy and performance risks negatively correlated with the patients' trust and adoption intention toward mHealth services. In addition, patients' age and chronic diseases can help predict their trust level and adoption intention toward mHealth, respectively.

Conclusions: We concluded that the TAM generally works in the context of mHealth adoption, although its significance has declined. In addition to technical factors, trust and perceived risks are critical for explaining mHealth service adoption among Chinese patients.

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KEYWORDS

mHealth service; perceived risk; trust; TAM; Chinese patients; mobile phone

Introduction

Background

Since Professor Robert Istepanian first proposed the concept of *mHealth* in 2005, it has become a new type of medical service mode combining medical services with the internet, medical sensors, mobile equipment, and information communication technology [1]. Compared with traditional medical services, mHealth offers clear advantages, such as portability, mobility, personalization, and ubiquity [2]. The users of mHealth services are diverse, ranging from general public, physicians, and nurses to patients with or without chronic diseases. mHealth services generally consist of Web-based appointments with physicians; Web-based health consultations; health information seeking; and medical examination result checking via wearable, portable devices; and smart devices or smartphone-based apps [3]. Enabled with the mobile devices, health services are available without the constraints of time and space [4,5]. mHealth services cost much less than the traditional ones [6]. In addition, the Chinese government has been implementing the "Health China" strategy since 2016, and the primary objective of this strategy is to solve the problem of "difficulty and expense of seeing a doctor." Thus, the development and success of mHealth services are important in implementing this national strategy.

mHealth services have garnered extensive attention worldwide [7]. A report released by the World Health Organization in 2011 affirmed that many countries had implemented mHealth care schemes [8]. Moreover, the global telemedicine market was expected to reach 27.3 billion dollars in 2016 [9]. For instance, more than 40,000 health care apps were available in the Apple iTunes Store in 2013 [10,11]. To protect the rights of users, the US Food and Drug Administration has implemented certain laws for mHealth, such as approval, denial, and licensing of medical equipment [11]. mHealth service has flourished in China as well. According to Wang, China's market of mHealth services will have reached 12.53 billion in 2017 [12]. Enabled by the internet, users can easily communicate their sensitive personal information, such as private diseases or emotions, to others. However, the risk of information leakage can hinder users from utilizing mHealth services [11,13]. Risks incurred by legal concerns may also emerge because no specific law enforcement regulates mHealth services in China.

Although mHealth services can reduce health care costs, improve health care quality, and promote health education, some problems may arouse individual risk perception. Considering the co-existence of technical advantages and potential risks of the mHealth service, we added perceived risk into the classic technology acceptance model (TAM) to analyze the users' adoption of mHealth services. The TAM represents the positive factors, whereas the perceived risk represents the negative factors associated with mHealth service adoption. In addition, we introduced trust as a middle variable to further explore the beneficial effects of and the risk factors associated with the adoption of mHealth services.

Literature Review and Hypothesis

Literature Review

Studies about mHealth services can be divided into four categories: (1) The current situation of services, which primarily focuses on the status quo of mobile medical services; the development of the services; and the existing defects, problems, or challenges; (2) the technical part of the services, which mainly explores the design and implementation of mHealth service platforms and system terminals; (3) the analysis and evaluation of application effects, which compares the effectiveness of certain mobile medical services and evaluates the effects; and (4) the acceptance of services, which empirically analyzes the factors influencing the consumers' willingness to adopt mHealth services. For instance, Marzano et al have studied the application of mHealth care in the field of mental health and discussed the associated risks [14]. Liang et al designed an emergency call service, which helped users to quickly and accurately transfer their emergency data to nearby search and rescue personnel through mobile medical social networks [15]. Lv et al used randomized controlled trials to examine the impact of mHealth services that send health messages to patients with asthma on patients' perceived control [16]. Deng et al also compared the adoption of mHealth services between middle-aged and older users in China [17].

From the perspective of acceptance, Lim et al used the TAM as a theoretical basis to explore the adoption behavior in using mobile phones to search for health information [18]. The results showed that perceived usefulness, perceived ease of use, and self-efficacy significantly affected the adoption. Another research showed that technical anxiety has no significant effect on the willingness to adopt [19]. Wu et al combined TAM and theory of planned behavior to explore the adoption intentions of medical staff toward mobile medical services; the results confirmed that attitude, perceived usefulness, perceived behavioral control, and subjective norms significantly influence the willingness to adopt [20]. Alaiad and Zhou built a model based on the unified theory of acceptance and use of technology (UTAUT) and investigated the willingness to adopt home medical robots for all types of personnel in the organization; the results validated that performance expectations and social effect convenience and conditions significantly affect users' adoption of home medical robots and that privacy and ethical concerns negatively affect users' adoption intentions [21].

Technology Acceptance Model

Proposed by Davis in 1989, the TAM is a classical theory used in predicting and interpreting users' adoption of and behavior toward information technology [22]. Similar to the theory of rational behavior and the theory of planned behavior, TAM theory follows the idea of *Faith-Intention-Behavior.* For an individual, one's faith, for example, attitude and beliefs, affects his or her intention to act in the first place, and then, the actual behavior will change accordingly [23]. The TAM mainly consists of five variables: perceived usefulness, perceived ease of use, attitude, behavioral intention, and actual behavior. According to the TAM, whether an individual performs a certain goal behavior depends on his or her behavioral intention to perform the behavior. Behavioral intention is determined by one's attitude and perceived usefulness toward a certain behavior or technology, which can also be called adoption intention. In addition, perceived usefulness and perceived ease of use can influence one's attitude toward a certain behavior or technology [24]. Later studies have proposed new theories based on the TAM, such as the TAM2 and UTAUT [25,26]. Compared with the TAM, TAM2 incorporates the antecedents of perceived usefulness; TAM 3 adds external factors influencing the perceived ease of use; and the UTAUT model combines exploratory factors, performance expectancy, effort expectancy, social influence, facilitating conditions, and four moderators (gender, age, experience, and voluntariness of use). mHealth service involves patients' health issue, which is irreversible and cannot be returned. If patients use wrong health information, then the body will be greatly affected. Thus, patients' risks should be considered. In this study, we combined the TAM and patients' perceived risk concerns to examine their adoption of mHealth services.

Perceived Risk

Raymond A. Bauer, a Harvard University scholar in the field of psychology, introduced the concept of perceived risk. Bauer believed that any act of an individual can lead to unforeseen consequences. The undesirable or unexpected aspect of these consequences is that individuals cannot control them and that they may cause some loss to the individual, which is called the risk of an individual's actions [27]. Many scholars have further defined perceived risk in their research. Cunningham showed

that if the final outcome of one's behavior is unpleasant or perceived detrimental to him or her, the potential loss of this outcome will be perceived risks [28]. Peter and Ryan believed that perceived risk is one's subjective perception of the expected loss of a target behavior [29]. Mitchell regarded perceived risk as one's subjective assessment and perception where behavior may cause a loss [30].

When introduced into the field of behavior research, Bauer emphasized the subjectivity of perceived risks rather than focusing on objective risks [27]. Although objective risks persist, only subjective risks perceived by an individual might affect his or her behavior. On the basis of Bauer's work, several scholars have explored the dimensions of perceived risks. Jacoby and Kaplan classified the perceived risk into 5 types: financial, performance, physical, psychological, and social [31]. Stone and Grønhaug added the time risk into the previous research and proved that the 6 types can interpret the perceived risk at a rate of 88.8% [32]. Of all the classification methods, the 6 types of perceived risk have been generally recognized by the academic community. However, the specific variables of the perceived risk are not limited to the 6 types. Scholars usually group them into different risk variables according to their research context. For instance, Lee studied individuals' adoption of Web-based banking services from the perspectives of function, time, financial, social, and security risks [33]. Kim et al examined the effect of perceived risks on individuals' e-commerce purchasing decisions based on 3 dimensions: privacy protection, security protection, and information quality [34]. Although perceived risks are mainly adopted in the context of business, they are being gradually applied to the health care fields, for example, wearable devices and electronic medical records [35,36].

Theoretical Foundation and Hypothesis

Trust

Trust is an essential factor for attracting new users and maintaining the loyalty of old users [34]. If one trusts the services provided by mHealth, he or she is likely to adopt the service [37]. In this study, we utilized the definition of trust by Doney et al and Yang et al [38,39]. Trust lies on users' willingness to believe and implement the advices or information acquired through mHealth services; thus, users prefer to believe that mHealth services can fulfill their health needs [38,39]. As a belief variable, trust is an individual's positive expectation toward another party's future behaviors [40]. According to the TAM, individuals' beliefs can influence their attitudes and adoption intentions. If one trusts mHealth and has a positive attitude toward mHealth services, he or she is likely to adopt these services. Therefore, we propose the following hypothesis:

> H1: One's trust toward mHealth services is positively associated with his or her intention to adopt the services.

Perceived Usefulness

According to Holden and Karsh, perceived usefulness refers to one's subjective perception that the use of new technologies or services will improve his or her work efficiency [24]. In this study, perceived usefulness is one's belief that the use of mHealth services can enhance or improve his or her health condition, which suggests that mHealth services might be useful for individuals to obtain low-cost health information easily and fast, thereby eventually improving the overall health care quality [41]. In the TAM theory, perceived usefulness may exert an influence on one's attitude and adoption intention [42]. For instance, Lim et al. confirmed that perceived usefulness significantly affected women's adoption intention of health information seeking using mobile phones [18]. Wu et al proved that medical staff are likely to adopt mHealth services if they perceive it as useful in their daily work [20]. Similar to attitudes, trust is a classic belief variable. According to the TAM theory, perceived usefulness can significantly influence people's attitudes toward a certain service or technology. If one perceives a service as useful, he or she turns to evaluate it as highly positive [24]. Therefore, we argue that an individual is likely to trust mHealth services if he or she perceives these services as useful. Moreover, an individual is likely to adopt mHealth services if he or she perceives them as useful. Therefore, we propose the following hypotheses:

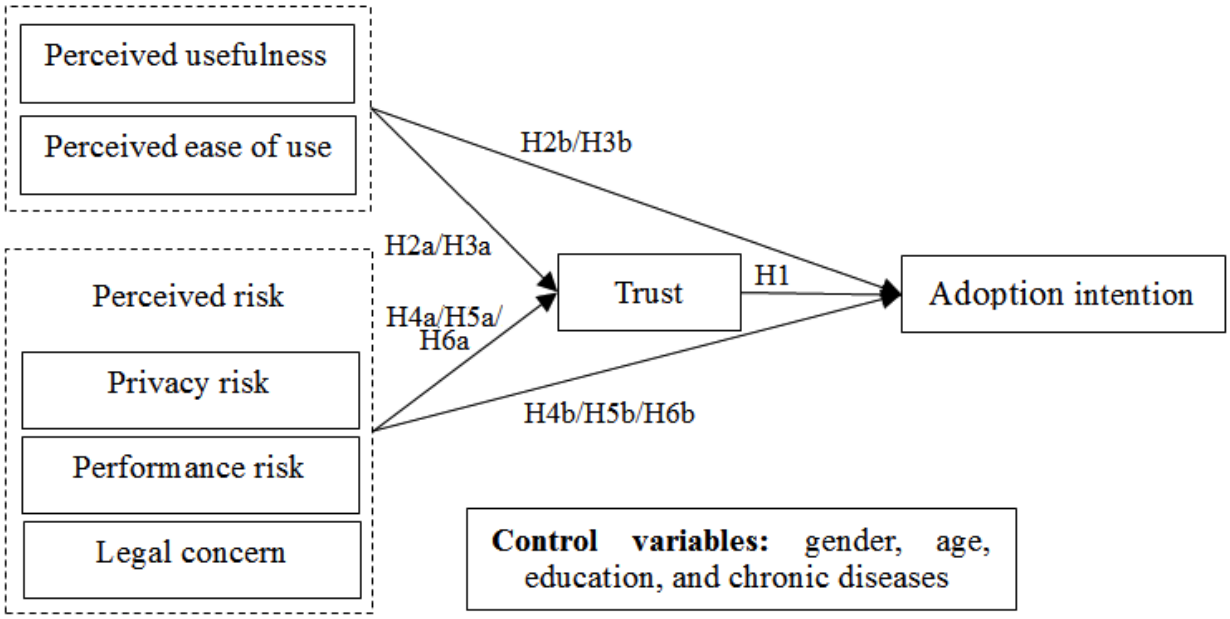
> H2a: Perceived usefulness is positively associated with one's trust toward mHealth services.
>
> H2b: Perceived usefulness is positively associated with one's adoption intention toward mHealth services.

Perceived Ease of Use

Another commonly used variable in the study on technology adoption behavior is *perceived ease of use*, which has been defined as the perception that using a particular technology will be free from physical or mental efforts [24]. In the mHealth context, perceived ease of use refers to the degree of difficulty experienced during the use of mHealth services. Different from the traditional health services, mHealth is based on the internet and mobile devices that provide health services [43]. Compared with elderly individuals, young individuals are more open to new things and are more likely to perceive mHealth services as easy to use. In the TAM, perceived ease of use has a direct influence on perceived usefulness and attitude [42]. Perceived usefulness is important for one's adoption intention. An individual will not use mHealth services if he or she perceives them as difficult to use regardless of the provision of usefulness [44]. Therefore, we propose the following hypotheses:

> H3a: Perceived ease of use is positively associated with one's trust toward mHealth services.
>
> H3b: Perceived ease of use is positively associated with one's adoption intention toward mHealth services.

Figure 1. Proposed research model. H: hypothesis.



Perceived Risk

Perceived risk refers to one's perception of uncertainty in the use of mHealth services and its severity in terms of consequences [45]. The mHealth service in China is still in its infancy stage, promising but also problematic [24]. Potential problems, such as privacy invasion, may pose a certain risk to users. mHealth services might not work well in terms of desired performance. Meanwhile, legal concern is also highlighted in China's context, where no specific law enforcement regulates the interest of parties in mHealth services. In this study, we measured the perceived risks through the following 3 variables: privacy risk, performance risk, and legal concern. The measurement of legal concern was shown by Alaiad and Zhou. In their research, they explored the effect of privacy, ethical, and legal concerns on the adoption intention toward home medical robots [21]. In the mHealth context, privacy risk refers to the possibility of information abuse due to the use of mHealth services, such as information theft and leakage [46]. Performance risk refers to the possibility of a match between the desired outcomes and actual use of mHealth services. Legal concern refers to the possibility of users' worry due to lack of law enforcement [21]. Previous research has also shown that perceived risk and privacy can effectively predict users' adoption intention and trust [21,34]. We argue that the greater the perceived risk, the lesser the trust and adoption intention toward mHealth services. Therefore, we propose the following hypotheses:

H4a: Privacy risk is negatively associated with one's trust toward mHealth services.

H4b: Privacy risk is negatively associated with one's adoption intention toward mHealth services.

H5a: Performance risk is negatively associated with one's trust toward mHealth services.

H5b: Performance risk is negatively associated with one's adoption intention toward mHealth services.

H6a: Legal concern is negatively associated with one's trust toward mHealth services.

H6b: Legal concern is negatively associated with one's adoption intention toward mHealth services.

Control Variables

Adding control variables will increase the explanatory power [47]. The control variables include gender, age, education, and chronic diseases. Patients with chronic diseases, who suffer throughout their lifetime, are more aware of their health condition and need constant health care compared with patients with acute diseases. Thus, we propose that chronic diseases may lead patients to significant mHealth service usage because of the associated convenience. Long-term monitoring of chronic diseases is very important for the treatment and transformation of diseases. We argue that whether users suffer from chronic diseases may affect the adoption intention toward mHealth services to some extent. On the basis of the abovementioned reasons, in this study, we used *chronic diseases* as the control variable.

Considering all the above mentioned hypotheses, we propose a new research model as shown in Figure 1.

Methods

Development of the Study Questionnaire

We developed a survey questionnaire for the proposed research model. The measurement items were either directly obtained from extant studies or slightly modified to fit in China's context. Items for perceived usefulness are from Mun and Hwang and Parkes, and those for perceived ease of use are from Burton-Jones and Hubona [48-50]. Items for privacy risk, performance risk, and legal concern are from Featherman and Pavlou, Nepomuceno et al, and Alaiad and Zhou, respectively [21,51,52]. Items for trust are from Mun et al and Martin et al [53,54] and those for adoption intention are from Wu et al [55].

Table 1. Demographic characteristics of the participants (N=388).

Characteristic	Number of participants, n (%)
Gender	
Male	203 (52.3)
Female	185 (47.7)
Age (years)	
≤20	21 (5.4)
21-30	116 (29.9)
31-40	123 (31.7)
41-50	85 (21.9)
51-60	32 (8.2)
≥60	11 (2.8)
Education level	
Junior high school and below	32 (8.2)
High school	54 (13.9)
Specialist college	82 (21.1)
Undergraduate degree	180 (46.4)
Master's degree	35 (9.0)
Doctoral degree and higher	5 (1.3)
Marital status	
Unmarried	64 (16.5)
Married	288 (74.2)
Divorced	28 (7.2)
Widowed	8 (2.1)
Career	
Enterprises (state-owned or foreign or private)	54 (13.9)
Civil servants	101 (26.0)
Medical workers	35 (9.0)
Freelancers	46 (11.9)
Self-employed	34 (8.8)
Students	47 (12.1)
Other	71 (18.3)
Personal monthly income (Chinese yuan)	
≤1000	43 (11.1)
1001-3000	64 (16.5)
3001-5000	142 (36.6)
5001-7000	94 (24.2)
≥7000	45 (11.6)
Suffering from chronic diseases	
Yes	138 (35.6)
No	250 (64.4)

To ensure the quality of the designed questionnaire, we performed a pretest among 30 postgraduates and 30 undergraduates in the Tongji Medical College. We assumed that the medical students were young and familiar with mHealth services in general, and they may have had considerable opinions regarding these services. The final questionnaire was

developed on the basis of the modifications of the pretest. The questionnaire consists of 34 questions with two sections: (1) 7 questions about demographic information (eg, age, gender, educational level, and chronic diseases) and (2) 27 questions to measure perceived usefulness, perceived ease of use, privacy risk, performance risk, legal concern, trust, and adoption intention. All the items in section 2 were measured using a 5-point Likert scale, with scores ranging from 1 (strongly disagree) to 5 (strongly agree). The details of the questionnaire can be found in Multimedia Appendix 1.

Data Collection

To test the proposed research model, we conducted an on-site survey in 3 large hospitals in China from September 20 to October 20, 2016. Among them, one is a medical college hospital, where patients comprise the students or faculty members studying or working in the university campus and the other two are famous hospitals in central China, where patients come from all over China, particularly the central region. Both are affiliated with this medical college. The target population included patients and their caregivers, who may be highly interested in mHealth services. We first asked them politely whether they would give 5-10 minutes to participate in our survey. If they answered yes, the survey was conducted accordingly. Small gifts were provided as incentives to those who completed the questionnaire. To avoid disturbing patients, we asked patients and their caregivers either waiting for a doctor or chatting with each other in the hospital waiting and resting areas to fill in our questionnaires; a total of 450 questionnaires were distributed and collected. After discarding the questionnaires with incomplete answers and those with the same answers, we obtained a total of 388 usable responses; the effective response rate was 86.2%. Approximately, 52.3% (203/388) of the respondents were male, and the age of the respondents ranged from 20 to 60 years. Approximately 67.0% (260/388) of the respondents were younger than 40 years and 2.8% (11/388) were older than 60 years. Approximately half of the respondents had a bachelor's degree or higher, and 35.6% (138/388) of the respondents had at least one chronic disease. Table 1 shows the detailed information of the respondents.

Results

Structural Equation Model

The structural equation model includes the measurement and structural models. We analyzed the research model using a two-step approach with an exploratory factor analysis and a confirmatory factor analysis to test the measurement and structural models, respectively [56].

Results of the Measurement Model Testing

We performed a confirmatory factor analysis to test the measurement equation, including reliability and validity tests. Reliability refers to the degree of reliability of each construct. Composite reliability and Cronbach alpha were used to measure the reliability. Validity is a measure of the validity of a measurement scale, usually based on discriminant validity and convergent validity. Discriminant validity refers to the degree of difference between the items with different latent variables, which can be tested using the average variance extracted of each latent variable and the standard load of each item. Table 2 shows the confirmatory factor analysis results of the measurement model. The composite reliability, Cronbach alpha, and average variance extracted of each construct and all the standard loadings are greater than the recommended values, indicating a good reliability and discriminant validity [56].

Convergent validity refers to a higher level of correlation between the measurement items of the same variable, which can be tested using the square root of the average variance extracted of each construct and its correlation coefficients with other constructs. The correlation coefficients between any two variables are smaller than the square root of the corresponding average variance extracted, thereby indicating a high discriminant validity [57]. Table 3 shows the specific results.

The fitting degree of a model is an evaluation of the research model. The commonly used goodness-of-fit indices are the ratio of χ^2 and degrees of freedom (df), Root Mean Square Error of Approximation (RMSEA), goodness of fit index (GFI), adjusted goodness of fit index (AGFI), comparative fit index (CFI), mormed fit index (NFI), and incremental fit index (IFI). The confirmatory factor analysis results are presented in Table 2 and Table 4 (χ^2_{388}=840.0, χ^2/df=2.165<3, RMSEA=0.055<0.08, and AGFI=0.863>0.80). The values of GFI, CFI, NFI, and IFI are all greater than 0.90. All the fitting indices of the research model are above the normal average acceptance level, which shows that the research model agrees well with the acquisition data [58].

Results of the Structural Model Testing

We used a regression method to test structural equations. The proposed research model includes seven latent constructs and several control constructs. The seven latent constructs are the primary factors, including perceived usefulness, perceived ease of use, privacy risk, performance risk, legal concern, trust, and adoption intention, and they were analyzed in Model 1. The control constructs such as gender, age, education, and chronic diseases were added into Model 2 to test the control effects.

Table 4 summarizes the results of multiple linear regression analysis. Table 5, Table 6, and Table 7 show the specific results of the hypothesis testing. The results showed that trust, perceived usefulness, and perceived ease of use positively correlated with the adoption intention in the context of mHealth services. Meanwhile, privacy and performance risks negatively correlated with trust and adoption intention. We did not observe a significant correlation between legal concern and trust or adoption intention. For the control constructs, education and chronic diseases can be effective predictors for individual adoption intention toward mHealth services. The variations in age lead to different levels of trust toward mHealth services. However, gender has no significant effect either on trust or adoption behavior.

Table 2. Confirmatory factor analysis results of the measurement model.

Constructs and items	Standard loadings	Average variance extracted of each latent variable	Composite reliability	Cronbach alpha
Perceived usefulness		0.625	0.833	.747
1	0.76			
2	0.78			
3	0.83			
Perceived ease of use		0.585	0.875	.765
1	0.72			
2	0.76			
3	0.74			
4	0.77			
6	0.83			
Privacy risk		0.720	0.911	.909
1	0.81			
2	0.86			
3	0.91			
4	0.81			
Performance risk		0.584	0.848	.846
1	0.68			
2	0.79			
3	0.84			
4	0.74			
Legal concern		0.672	0.857	.843
1	0.63			
2	0.89			
3	0.91			
Trust		0.612	0.887	.877
1	0.75			
2	0.80			
3	0.81			
4	0.80			
5	0.75			
Adoption intention		0.657	0.851	.853
1	0.85			
2	0.80			
3	0.78			

Table 3. Correlation coefficient matrix and square root of average variance extracted of latent variables.

Constructs	Perceived usefulness	Perceived ease of use	Privacy risk	Performance risk	Legal concern	Trust	Adoption intention
Perceived usefulness	0.790[a]	—[b]	—	—	—	—	—
Perceived ease of use	0.401	0.765[a]	—	—	—	—	—
Privacy risk	−0.121	−0.058	0.848[a]	—	—	—	—
Performance risk	−0.086	−0.212	0.155	0.764[a]	—	—	—
Legal concern	−0.069	−0.144	0.316	0.412	0.819[a]	—	—
Trust	0.310	0.321	−0.288	−0.227	−0.245	0.782[a]	—
Adoption intention	0.440	0.233	−0.247	−0.185	−0.119	0.438	0.810[a]

[a]Square root of average variance extracted.

[b]Not applicable.

Table 4. Fit index of the research model.

Fit	χ^2/df[a]	RMSEA[b]	GFI[c]	AGFI[d]	CFI[e]	NFI[f]	IFI[g]
Recommended value	<3	<0.08	>0.90	>0.80	>0.90	>0.90	>0.90
Research model	2.165	0.055	0.909	0.863	0.925	0.905	0.935

[a]χ^2/df: chi-square divided by degrees of freedom.

[b]RMSEA: Root Mean Square Error of Approximation.

[c]GFI: goodness of fit index.

[d]AGFI: adjusted goodness of fit index.

[e]CFI: comparative fit index.

[f]NFI: normed fit index.

[g]IFI: incremental fit index.

Table 5. Results of multiple linear regression analysis for independent variable Trust. R^2: coefficient of determination, ΔR^2: change in the coefficient of determination, ΔF: change in the F-statistic.

Independent variable	Trust			
	Model 1 (95% CI)	*P* value	Model 2 (95% CI)	*P* value
Independent variable				
Perceived usefulness	0.046 (−0.085 to 0.178)	.65	0.042 (−0.090 to 0.174)	.42
Perceived ease of use	0.027 (−0.116 to 0.170)	.45	0.026 (−0.117 to 0.169)	.60
Privacy risk	−0.153 (−0.269 to −0.037)	.005	−0.148 (−0.267 to −0.032)	.03
Performance risk	−0.147 (−0.264 to −0.030)	.002	−0.121 (−0.239 to −0.004)	.01
Legal concern	−0.033 (−0.061 to 0.156)	.52	−0.033 (−0.096 to 0.121)	.40
Control variables				
Gender	—[a]	—	0.044 (−0.073 to 0.191)	.38
Age	—	—	0.150 (0.084 to 0.216)	.008
Education	—	—	0.092 (−0.002 to 0.152)	.12
Chronic diseases	—	—	0.082 (−0.037 to 0.236)	.81
R^2	0.280	—	0.313	—
ΔR^2	—	—	0.033	—
ΔF	—	—	32.447	0.03

[a]Not applicable.

Table 6. Results of multiple linear regression analysis for dependent variable Adoption Intention. R^2: coefficient of determination, ΔR^2: change in the coefficient of determination, ΔF: change in the F-statistic.

Dependent variable	Adoption intention			
	Model 1 (95% CI)	*P* value	Model 2 (95% CI)	*P* value
Independent variables				
Trust	0.427 (0.327 to 0.527)	<.001	0.371 (0.270 to 0.472)	<.001
Perceived usefulness	0.125 (0.05 to 0.20)	.02	0.120 (0.008 to 0.232)	.02
Perceived ease of use	0.107 (0.035 to 0.179)	.01	0.107 (0.012 to 0.202)	.02
Privacy risk	−0.134 (−0.24 to −0.028)	.004	−0.132 (−0.238 to −0.026)	.002
Performance risk	−0.252 (−0.369 to −0.135)	.003	−0.221 (−0.339 to −0.103)	.001
Legal concern	−0.033 (−0.061 to 0.156)	.52	−0.033 (−0.096 to 0.121)	.40
Control variables				
Gender	—[a]	—	0.066 (−0.066 to 0.197)	.08
Age	—	—	0.027 (−0.039 to 0.093)	.36
Education	—	—	0.104 (0.044 to 0.164)	.04
Chronic diseases	—	—	0.112 (0.04 to 0.220)	.05
R^2	0.460	—	0.512	—
ΔR^2	—	—	0.052	—
ΔF	—	—	27.593	<.001

[a]Not applicable.

Table 7. Results of the hypothesis testing.

Hypothesis	Path	Path coefficient	*P* value	Supported
H1	Trust → Adoption intention	0.427	<.001	Yes
H2a	Perceived usefulness → Trust	0.046	.27	No
H2b	Perceived usefulness → Adoption intention	0.125	.04	Yes
H3a	Perceived ease of use → Trust	0.027	.07	No
H3b	Perceived ease of use → Adoption intention	0.107	.11	Yes
H4a	Privacy risk → Trust	−0.153	.004	Yes
H4b	Privacy risk → Adoption intention	−0.134	.002	Yes
H5a	Performance risk → Trust	−0.147	.003	Yes
H5b	Performance risk → Adoption intention	−0.252	.002	Yes
H6a	Legal concerns → Trust	−0.033	.54	No
H6b	Legal concerns → Adoption intention	−0.065	.08	No

Discussion

Principal Findings

With the introduction of perceived risks in the classic TAM theory, this study aimed to explore the factors influencing an individual's trust and adoption intention toward mHealth services. Furthermore, we analyzed the effects of gender, age, and chronic diseases as control variables. We proposed 11 hypotheses, of which 7 are supported. The primary findings are summarized as follows.

First, trust, perceived usefulness, and perceived ease of use are strong predictors for the adoption intention toward mHealth services, whereas the influence of perceived usefulness and perceived ease of use on trust is not significant. Trust, perceived usefulness, and perceived ease of use are important positive and technical factors explaining a user's adoption intention toward mHealth services. Among them, trust exerts the greatest influence, followed by perceived usefulness and perceived ease of use. In sum, this result is consistent with those of previous studies by Gu et al and Huang et al [44,59]. It reveals that if individuals think that mHealth services are trustworthy, they are more willing to adopt them. For mHealth service operators,

building trust is crucial. Corroborating the results of a study by Zhang et al [60], we also validated that although perceived usefulness and perceived ease of use are still influential in explaining the adoption of mHealth services, their significance seems to decline. In our study, trust significantly correlated with mHealth adoption intention with a *P* value of <.001, whereas perceived usefulness and perceived ease of use significantly correlated with mHealth adoption intention with a *P* value between .05 and .01. This may have been caused by the evolution of the technology itself [61]. People are generally more technology savvier than their counterparts 10 years ago, and they can easily adjust with using modern mHealth services. However, for the mHealth service operators, strategies such as improving service quality and simplifying user process can still result in more individuals adopting the services.

Second, the 3 dimensions of perceived risk, privacy risk, and performance risk negatively correlated with the trust and adoption intention, whereas legal concern showed no significant effect. When people perceive a potential risk associated with using mHealth services, for example, privacy or information leakage issues, they are less likely to trust and adopt these services. This result is similar to that of other studies. For example, Guo et al concluded that privacy concerns significantly influence a user's trust toward mHealth [13]. Zhang et al also found that privacy concern can affect adoption intention via attitude [62]. Meanwhile, the influence of privacy risk and performance risk on trust and adoption intention differs. Compared with performance risk (−0.147), privacy risk (−0.153) has a more remarkable effect on trust. Compared with privacy risk (−0.134), performance risk (−0.252) has a more remarkable effect on adoption intention. This may be caused by the differentiations of specific risk. For example, performance risk features the perception of the possible risks of specific service functions and quality, and adoption intention centers on people's willingness to use a certain service. According to previous studies, the function and quality of mHealth services are more likely to affect people's willingness to adopt these services [18,20]. Privacy risk concerns personal health-related information during the use of mHealth services. Privacy risk is not directly correlated with the functions of the mHealth services and is aroused by psychological factors. Hence, compared with performance risk, privacy risk may likely exert more effect on trust. For mHealth service operators, the major tasks include the following: (1) improving overall quality and (2) building a reliable information security system that protects a user's privacy [63,64]. These strategies will enhance the trust level of users and will ultimately encourage the adoption of the services. In addition, legal concern is seldom discussed because the primary function of mHealth services in China is Web-based health consultation, and patients still need to obtain medical treatment in hospitals. This may also help us understand the result showing no significant effect of legal concern on trust and adoption.

Third, control variables, such as age and chronic diseases, correlated with trust and adoption intention toward mHealth services. In terms of age, older individuals are more likely to trust mHealth services compared with the young individuals. This result is in accordance with that of several studies. For example, Guo et al found that the influence of personalization and privacy concerns on trust toward mHealth was different between old and young individuals [13]. Morris and Venkatesh also concluded that young individual's attitudes had a greater influence on their decisions regarding the use of technology, whereas the individuals were more easily influenced by subjective norms and perceived adoption control [65]. In terms of chronic diseases, patients with chronic disease were more likely to adopt mHealth services compared with those without them. A possible explanation is that chronic condition usually requires patients to monitor their health instantly, and mHealth services perform well in addressing this problem. This finding is also consistent with that of an earlier study, which showed that a respondent's health status can moderate the relationship between trust and an individual's intention of using mHealth [37].

Implications and Limitations

On the basis of the TAM and perceived risks, we built an mHealth service adoption model and further tested the model via a cross-sectional study on patients from 3 large hospitals in China. This study has several implications. First, we empirically tested the effects of perceived usefulness, perceived ease of use, privacy risk, performance risk, and legal concern on trust and adoption intention toward mHealth services. The findings supported the effect of perceived risk, trust, and adoption intention on the use of mHealth services. Second, we added several control variables to the research model, which include gender, age, and chronic diseases, and results showed that age and chronic diseases affect an individual's trust and adoption intention. Although the influence of age and gender on people's technology adoption behavior has been extensively studied, only few studies have focused on the effects of chronic diseases. This study may serve as a valuable reference for future studies on the effect of chronic diseases on the adoption of mHealth services in China. Third, the empirical results highlight the significant effect of perceived usefulness and perceived ease of use on an individual's adoption intention and the significant influence of privacy risk and performance risk on trust and adoption intention. These findings may offer practical suggestions for the developers of mHealth services as well as the enterprises working in the mHealth industry. For example, the flow of the mHealth services can be simplified or specific tutorials or videos can be provided. Regarding the risk concerns, the security issue is always the focus of reducing the potential risk perceived by the users.

The study has its own limitations. First, this research was conducted in the context of China's mHealth services. Thus, the results may not be generalized to other countries and regions. Second, the proposed research model was based on the TAM and perceived risk, and the variance rate explained in the model was 48.9%. Other important factors that are associated with the adoption intention toward mHealth may have been overlooked in this study. Future research can incorporate relevant variables to increase the explanatory power of the research model. Another limitation of this study is its small sample size. We might not have a representative sample of patients who intended to use mHealth services in China. Researchers should exercise caution when citing our results.

Conclusions

This study proposed an extended TAM research model using the concept of perceived risk to study the determinants of trust and adoption intention toward mHealth. The results corroborated that trust, perceived usefulness, and perceived ease of use positively correlated with adoption intention. Privacy and performance risks negatively correlated with trust and adoption intention toward mHealth services. In terms of the control variables, we confirmed that age has a significant influence on an individual's trust and that chronic diseases can be an important predictor for mHealth service adoption. These findings are conducive to future research on mHealth service adoption.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire: Measurement of the major constructs.

[PDF File (Adobe PDF File), 29KB - mhealth_v6i8e172_app1.pdf]

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Abbreviations

AGFI: adjusted goodness of fit index
CFI: comparative fit index
GFI: goodness of fit index
IFI: incremental fit index
NFI: normed incremental fit index
RMSEA: Root Mean Square Error of Approximation
TAM: technology acceptance model
UTAUT: unified theory of acceptance and use of technology

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Original Paper

A Web-Based Survey Assessing the Attitudes of Health Care Professionals in Germany Toward the Use of Telemedicine in Pregnancy Monitoring: Cross-Sectional Study

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Abstract

Background: The demand for fetal monitoring and constant reassurance is high in pregnant women. Consequently, pregnant women use various health apps and are more likely to visit emergency departments due to subjective but nonurgent complaints. However, electronic health (eHealth) and mobile health (mHealth) solutions are rarely used to prevent nonurgent emergency consultations. To implement modern care solutions, a better understanding of the attitudes, fears, and hopes of health care professionals toward eHealth and mHealth is needed.

Objective: The aim of this study was to investigate the attitudes of health care professionals in obstetrics toward telemedicine.

Methods: A quantitative Web-based survey on health care professionals in obstetrics in Germany was conducted. The participants included nurses, midwives, and physicians of all age groups and job positions working in hospitals that provide various levels of health care. The questionnaire comprised 24 questions about the characteristics of the study population, views about emergency consultations in obstetrics, attitude toward telemedicine, job satisfaction, and sleeping behavior.

Results: In total, 244 health care professionals participated in the Web-based survey. In general, health care professionals were skeptical (170/233, 72.9%) about the use of telemedicine in obstetrics; however, 55.8% (130/233) recognized its potential. Moreover, 72% (62/86) of physicians were optimistic in using apps for pregnancy monitoring, whereas 36.1% (47/130) of nonphysicians (P<.001) were not. Significantly, more nonphysicians rejected such developments (75/130, 57.7% rejected) compared with physicians (24/86, 28%; P<.001). We also found that obstetricians with more than 10 years of work-experience are more skeptical; however, approximately 49% (18/37) of them believed that telemedicine could reduce nonurgent emergency consultations, whereas 73.2% (106/145) of obstetricians with less than 5 years of experience (P=.01) thought otherwise. Our survey revealed a high job satisfaction and a prevalence of regular sleeping problems of 45.9% (91/198) among health care professionals in obstetrics. Surprisingly, both job satisfaction and sleeping problems were independent from the number of night shifts per month (P=.77 and P=.99, respectively). Yet, 56.6% (112/198) of the survey participants thought they would be happier with their job if they had to work fewer night shifts per month.

Conclusions: Our study reveals an ambivalent attitude toward the use of telemedicine among health care professionals in obstetrics in Germany at the moment. Efforts to promote the use of telemedicine should focus on nurses and midwives because these groups are the most skeptical. By contrast, particularly young physicians recognize the potential of apps in patient care and would like to use such technology in pregnancy monitoring.

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KEYWORDS

telemedicine; obstetrics; eHealth; pregnancy monitoring; job satisfaction; sleeping problems; night shift; emergency consultation

Introduction

Physician-Patient Interaction in the Digital Age

Information technology is transforming our world and will inevitably change the way physicians monitor their patients' health. Consequently, the World Health Organization stresses the importance of utilizing information and communication technology opportunities in their global strategy on human resources for health [1]. For telemedicine to reach its full potential, however, it is important to know and understand the attitudes of patients and health care professionals toward such technology.

The general public is open-minded about monitoring their well-being electronically, as illustrated by the fact that 65% of mobile phone users have downloaded at least one health or fitness app and that new devices are being developed to monitor and improve patients´ compliance [2,3]. This does not only apply to a healthy population but also to patients with chronic diseases, for example, kidney transplant recipients [4,5]. However, physicians seem less positive and more reluctant to use electronic health care records and linked Web messaging during patient interaction [6,7]. This partly explains why telemedicine and smart wearable body sensors have not been widely adopted. Instead, their use is limited and oftentimes part of pilot projects [8-11]. At the same time, it also raises the question about the factors that can be used to determine physicians' attitudes toward telemedicine. Kim et al have found that the intention of physicians to use electronic medical record systems was influenced by performance expectancy and attitude [12]. Therefore, a detailed knowledge about the attitudes and performance expectancies of health care providers toward telemedicine may be essential for a more widespread use of such technologies.

Telemedicine in Obstetrics

A study on US adults investigating acceptance found that females are more likely to engage in different electronic health (eHealth) behaviors than males [13]. At the same time, younger patient groups tend to be more technophile [14,15], rendering pregnant women extremely fit for the use of telemedicine. Pregnancy requires intense monitoring, especially in the case of high-risk pregnancies. Therefore, the potential of maternal self-monitoring has been recognized for years [16]. Telemonitoring is more cost-effective than traditional patient-physician interaction in high-risk pregnancies [17]. Consequently, a variety of eHealth tools have been developed, ranging from smart wearable sensors for fetal electrocardiography [18,19], health platforms for nutrition and lifestyle during pregnancy [20], to pregnancy-specific mobile phone apps [21]. Pregnant women have a positive attitude toward the use of apps for pregnancy monitoring and improvements in patient empowerment [22].

Study Aims

These findings raise the question whether the attitude of health care professionals toward the use of such technologies in pregnant women is equally positive. We therefore conducted a Web-based survey among obstetric health care providers investigating their perspective on telemedicine in pregnancy. The questions had a broad scope and covered topics that are related to the introduction of telemedicine, particularly from a health care professional's perspective, such as perception of emergency consultations, number of night shifts per month, job satisfaction, and sleeping behavior.

Research Questions

The primary research questions in this survey were as follows:

- What is the attitude of health care professionals toward the surveillance of pregnant women using telemedicine?
- How do physicians and other health care providers differ in terms of attitudes toward telemedicine?
- How is the overall job satisfaction among health care professionals working in labor and delivery?
- How is the sleeping behavior of health care professionals affected by frequent emergency consultations of pregnant women?

Methods

Survey Design and Questionnaire

A Web-based open survey addressing health care professionals in obstetrics in Germany investigated their attitudes toward telemedicine. The study population included midwives, nurses, and doctors in training who had completed their specialization in obstetrics and gynecology. We aimed to assess the views of all types of health care professionals in obstetrics and to obtain at least 200 representative responses. The number of responses targeted to achieve sufficient statistical power for subgroup comparison. The study was advertised via email newsletters at the University of Heidelberg, social networks of midwives and doctors in training, and direct distribution of the survey link. Data were collected for 2 months in the spring of 2017 using the survey platform SurveyMonkey. All study participants consented prior to the start of the survey. Furthermore, they agreed that the collected data would be stored for analysis and publication. If no online consent was provided, the potential participants could not access the online questions. The participants did not receive any rewards for participation in this study. One item was displayed per screen, and a completeness check was not implemented. Moreover, the participants could review their answers. The estimated response rate based on the number of health care providers reached by our advertisement was 40%, and the completeness ratio was 80%.

The questionnaire covered four main topics in succession: characteristics of the population, emergency consultations, attitudes toward the use of telemedicine, and sleeping behavior. The questions were made by two experienced obstetricians following literature studies and an interdisciplinary discussion

with staff members working in the labor and delivery department of the University of Heidelberg, as well as by a psychologist and a sleep coach. The questions were self-developed and subsequently tested independently by 10 health care professionals from our intended survey population. Their feedback was used to test the questions and prove the reliability of the questionnaire. These test participants were excluded from the final study. This study was approved by the ethics committee of the medical faculty of the University of Heidelberg (S-525/2016).

Survey Questions

The questionnaire consisted of 22 close-ended questions to appropriately conduct the statistical analysis of the responses. The remaining two questions were open-ended questions, which asked the participants to state their opinion on the use of telemedicine in obstetrics and to provide opinions about the topic in general. The open-ended questions were used as a qualitative account of their attitude toward telemedicine to formulate a hypothesis for the subgroup analyses.

Questions 1-10 consisted of the study population characteristics, such as age, sex, employment, number of years since the completion of training and experience in obstetrics, number of night shifts per month, funding structure of the employing institution, level of care, and number of deliveries per year. Questions 11 and 12 focused on emergency consultations during pregnancy. Questions 13-15 explored the attitudes of health care professionals on the use of telemedicine in general and toward preventing emergency consultations in obstetrics in particular. Questions 14 and 15 referred to a specific scenario: Doctors were asked to imagine that an app that could be used by pregnant women at home to assess for fetal well-being was available. This scenario was developed during an interdisciplinary discussion on health care professionals in the labor and delivery department of the University of Heidelberg to address future care strategies. Questions 15 and 16 examined job satisfaction as well as working conditions of the health care professionals. Finally, questions 18-22 were about sleeping problems as indicators of work-related stress and measures to improve sleeping behavior.

Statistical Analysis

Statistical analyses were performed using Microsoft Excel version 15.31 and SAS 9.1 Documentation (SAS, Cary, NC). All responses were analyzed even if the 24 questions were not answered completely. The close-ended questions were analyzed by determining the relative frequencies and presented as the percentage of the total number of responses. In some questions, the participants were asked to rank their agreement to a statement on a scale from 1 to 6, in which 1 expressed a strong agreement and 6 a strong disagreement. We analyzed these questions by stating the exact percentages of the responses and by calculating the weighted mean. The hypotheses of the subgroup analyses were formulated based on the responses to the qualitative questions. The medical students were counted as physicians in the comparisons of physicians and nonphysicians. The stated *P* values were determined using chi-square test for categorical data, and the common threshold for a significance level of .05 was used. In cases of questions with rankings from 1 to 6, the weighted means were compared and the *P* values were determined using two-sided *t* tests.

Results

Study Population

The characteristics of the study population are presented in Table 1. In brief, 244 health care professionals working in the field of obstetrics in Germany completed the survey. The participants included senior and junior physicians, midwives, nurses, physician assistants, and medical students. Hence, health care professionals from all age groups were represented. Yet, a slight skew toward younger participants was observed, with 60.7% (139/229) of the respondents aged less than 30 years. In accordance with the strong proportion of women among the residents, midwives, and nurses in obstetrics and gynecology, four-fifths of the study population were female (183/229, 79.9%). The majority of physicians were residents (43/78, 55%), which is representative for most hospitals in Germany.

The majority of respondents had several years of experience in obstetrics, of which 28.8% (66/229) had more than 5 years of practice. Furthermore, the median number of births at their workplace was between 2001 and 2500 deliveries/year, and 61.5% (134/218) of the survey participants worked in perinatal centers level I. Perinatal centers of this level offer the most comprehensive treatment, taking care of pregnant women at any gestational age, those with high-risk pregnancy, or those with twin pregnancies [23]. Quite in line with this, slightly more than half of the respondents worked at university hospitals, followed by almost a quarter working in other forms of public hospitals. More than four-fifths (185/228, 81.1%) of the participants worked during night time, mostly between 1 and 4 shifts per month.

Current Job Situation and Physician Well-Being

This study aimed to explore the working conditions of health care professionals in obstetrics and gynecology and how telemedicine might be able to affect or even improve these working conditions. Table 2 shows the record of obstetricians' well-being and satisfaction. In summary, the majority of study participants was satisfied with their current working situation and enjoyed working in the obstetrics department. Yet, a minority believed that their work-life balance was good. Surprisingly, however, only one-third of the respondents were in favor of reducing their work load or the number of night shifts. Meanwhile, 56.6% (112/198) of the participants agreed that they would be happier and more satisfied if they had to work fewer night shifts per month.

Sleeping Behavior

Many health care professionals in obstetrics complained of sleeping problems. Only 16.0% (32/200) of the respondents denied having any sleeping problems. The most common symptoms were tiredness after waking up and tiredness during the day. Approximately 40.1% (77/192) of the respondents experienced these symptoms several times a week.

Table 1. Characteristics of the study population (N=229).

Characteristics	n (%)
Age (years)	
<30	139 (60.7)
30-35	43 (19.0)
36-40	19 (8.0)
41-50	17 (7.0)
>50	11 (5.0)
Gender	
Female	183 (79.9)
Male	46 (20.0)
Job position	
Resident in the obstetrics/gynecology department	43 (19.0)
Consultant	11 (5.0)
Senior physician	20 (9.0)
Chief physician	4 (2.0)
Midwife	36 (16.0)
Student midwife	66 (29.0)
Nurse	11 (5.0)
Student nurse	5 (2.0)
Physician’s assistant	3 (1.0)
Medical student	19 (8.0)
Number of years since the completion of residency	
<2	10 (13.0)
2-5	6 (8.0)
5-10	6 (8.0)
>10	9 (12.0)
Not completed	47 (60.0)
Years of experience in obstetrics care	
<1	58 (25.0)
1–5	86 (38.0)
5-10	31 (13.0)
>10	35 (15.0)
No experience (students)	19 (8.0)
Type of employment	
Full-time	175 (76.4)
Part-time	35 (15.0)
Currently not employed	19 (8.0)
Night shifts per month	
1-4	111 (48.5)
>5	74 (32.0)
None	43 (19.0)
Funding body	
University hospital	114 (52.3)

Characteristics	n (%)
Public, not a university hospital	51 (23)
Nonprofit carrier hospital	36 (17.0)
Private hospital	4 (2.0)
Others	13 (4.0)
Care level	
Perinatal center level I	134 (61.5)
Perinatal center level II	20 (9.0)
Institution that specializes in perinatal care	8 (4.0)
Basic	23 (11.0)
Others	33 (15.0)
Number of births in hospitals per year	
500-1000	9 (4.0)
1001-1500	23 (11.0)
1501-2000	23 (11.0)
2001-2500	107 (49.0)
2501-3000	27 (12.0)
>3000	10 (5.0)
Others	19 (9.0)

Table 2. Attitude toward their current job situation (N=200).

Statements	Scale[a], n (%)						Weighted mean (SD)
	1	2	3	4	5	6	
I am happy with my working situation.	18 (9.0)	75 (37.5)	65 (32.5)	26 (13.0)	10 (5.0)	6 (3.0)	2.8 (1.1)
I would be happier in my job if I had to work fewer night shifts.	50 (25.0)	32 (16.0)	30 (15.0)	13 (6.5)	27 (13.5)	46 (23.0)	3.4 (1.9)
I would like to reduce my average working hours.	36 (18.0)	28 (14.0)	39 (19.5)	39 (19.5)	24 (12.0)	32 (16.0)	3.4 (1.7)
I enjoy working in obstetrics.	101 (50.5)	65 (32.5)	20 (10.0)	8 (4.0)	2 (1.0)	3 (1.5)	1.8 (1.0)
I would like to work fewer night shifts.	40 (20.0)	23 (11.5)	31 (15.5)	48 (24.0)	16 (8.0)	37 (18.5)	3.5 (1.7)
My work life balance is good.	11 (5.5)	30 (15.0)	50 (25.0)	67 (33.5)	24 (12.0)	16 (8.0)	3.6 (1.3)

[a]The participants were asked to indicate their agreement on a scale from 1 to 6, where 1 indicates strong agreement and 6 a strong disagreement.

Only few participants had difficulty falling asleep, which was defined as requiring more than 30 minutes to fall asleep and having trouble staying asleep. By contrast, only few participants regularly presented with muscle cramps or nocturia. The complaints that the study participants experienced as most bothersome were tiredness after waking up (46/200, 23.0%) and extreme tiredness during daytime (40/200, 20.0%), followed by trouble falling asleep (36/200, 18.0%) and staying asleep (30/200, 15.0%).

Consequently, more than half of the study participants (106/196, 54.1%) had already tried to improve their sleeping habits. The most common and most successful attempt to improve sleeping habits was engaging in sports. This improved sleep of two-thirds of those who tried (21/51, 41%). Other, less successful attempts included a change in activities before going to bed (tried by 102/196, 52.0%) and during the day (tried by 93/196, 47.4%), stress and anxiety reduction techniques (tried by 97/196; 49.4%), changes in sleeping time (tired by 99/196, 50.5%), changes in the sleeping environment (tried by 63/196, 32.1%), and the use of medications (tried by 31/196, 15.8%).

Job Satisfaction in Different Subgroups

We also found that overall job satisfaction of the participants was good and significantly higher in physicians than in nonphysicians (2.9 vs 2.6, P=.026). Yet, the physicians were extremely in favor of reducing the number of night shifts and believed that this would increase their job satisfaction. Meanwhile, most nonphysicians did not have the same view (2.4 vs 4.2, P<.001). These differences could not be explained by the varying prevalence of sleeping problems between these two groups (51% of nonphysicians vs 54% of physicians, P=.77). Our data did not suggest that a reduction of night shifts

indeed increased job satisfaction. Health care professionals working 5 or more night shifts per month did not significantly differ in terms of job satisfaction compared with their colleagues who were working at most 4 night shifts per month (2.8 vs 2.7, *P*=.70). Similarly, job satisfaction did not significantly differ between health care professionals working full-time compared with those working part-time (2.9 vs 2.7, *P*=.47). Older study participants (over 40 years) did not have more significant sleeping problems than the younger participants (less than 40 years; 53% vs 46%, *P*=.99). Also, our data did not indicate a correlation between the number of night shifts per month and the prevalence of sleeping problems. Regardless of whether the participants worked night shifts, 46.0% (92/200) regularly experienced sleeping problems (*P*=.99).

Emergency Consultations and Telemedicine

More than two-thirds of the participants agreed that most emergency consultations were unnecessary. Yet, approximately 72.8% (153/210) still considered such consultations as valid if the patients were worried and insecure about a medically harmless condition. We also asked the study participants to specify the most common reasons for emergency consultations based on their experience (naming multiple reasons was allowed). Besides pain (174/210, 82.8%), bleeding (151/210, 71.9%), labor (153/210, 72.8%), and rupture of membranes (141/210, 67.1%), uncertainty about the well-being of their pregnancy (141/210, 67.1%), negative feelings (84/210, 40.0%), and anxiety or concerns for the baby (78/210, 37.1%) were highly prevalent. By contrast, emergency visits due to reduced fetal movements (80/210, 38%), cervical insufficiency (34/210, 16.2%), acute hypertension (19/210, 9.0%), or trauma (34/210, 16.2%) were less prevalent. In the light of these results, the perspectives of health care professionals on telemedicine may seem particularly relevant because telemedicine promises to prevent some patients from consulting doctors or emergency departments unnecessarily. A majority (143/210, 68.1%) of the study participants agreed that telemedicine would affect unnecessary medical consultations or over consultation.

Attitudes Toward the Use of Apps in Pregnancy Monitoring

To investigate the attitude of health care professionals toward the use of telemedicine in obstetrics in more detail, we focused on one particular implementation. Namely, we described the scenario in which pregnant women should consult an app when feeling unwell or experiencing unspecific symptoms. This app would then execute a series of measurements and obtain a conclusion from the joint evaluation of the indicated symptoms and measurements. This conclusion could provide either an advice to consult a physician or to give an all-clear without the need to see a doctor.

The attitudes of health care professionals toward this form of telemedicine are listed in Table 3. Surprisingly, 23.9% (56/234) of the respondents reported that they did not understand the concept. Several of them categorically rejected the use of telemedicine in obstetrics. Approximately 72.6% (170/234) had doubts about these new developments, whereas more than half believed in the potential of telemedicine. Few study participants would recommend this form of telemedicine to their patients, and only 37.6% (88/234) were enthusiastic about these developments and were willing to put them into practice as soon as possible.

More Experienced Participants are Less Confident in Using Telemedicine

In the second step, we analyzed how the attitudes of the health care professionals differed between the subgroups. First, we compared the difference between health care professionals with more than 10 years of experience from those with less than 5 years of experience. The more experienced professionals were significantly less confident in using telemedicine, which could have had an influence on unnecessary night shift consultations, than their less experienced colleagues (49% vs 73.2%, *P*=.01). This difference in terms of attitude might in part be explained by age. We found that only 54% (15/28) of the participants aged greater than 40 years believed that the use of telemedicine results in a change in night shift consultations compared with approximately 76.1% (105/138) of participants aged below 30 years who believed otherwise (*P*=.02). However, the evaluation of the necessity of most night shift consultations was similar across all age groups and level of experience.

Table 3. Attitude toward the surveillance of pregnant women using telemedicine (N=234).

Statements	Scale[a], n (%)						Weighted mean (SD)
	1	2	3	4	5	6	
I do not understand the concept.	28 (12.0)	28 (12.0)	57 (24.3)	40 (17.1)	51 (21.8)	30 (12.8)	3.6 (1.6)
I reject such developments categorically.	26 (11.1)	33 (14.1)	40 (17.1)	47 (20.0)	40 (17.1)	47 (20.0)	3.8 (1.6)
I have my doubts about these developments.	49 (20.9)	53 (22.6)	68 (29.0)	30 (12.8)	16 (6.8)	17 (7.3)	2.8 (1.5)
I see potential in these developments.	26 (11.1)	44 (18.8)	60 (25.6)	60 (25.6)	25 (10.7)	18 (7.7)	3.3 (1.4)
I would recommend such developments to my patients.	18 (7.7)	49 (20.9)	42 (17.9)	56 (23.9)	34 (14.5)	34 (14.5)	3.6 (1.5)
I find such developments excellent and would like to put them into practice as soon as possible	18 (7.7)	26 (11.1)	44 (18.8)	56 (23.9)	33 (14.1)	56 (23.9)	3.5 (1.6)

[a]The participants were asked to indicate their agreement on a scale from 1 to 6, where 1 indicates a strong agreement and 6 a strong disagreement.

Table 4. Differences in the attitudes between physicians and nonphysicians (N=218).

Statements	Physicians (n=89)	Nonphysicians (n=129)	Statistics		*P* value
			χ^2_2	*t* test[a]	
I consider the use of apps for pregnancy monitoring reasonable, n (%)	62 (69.7)	47 (36.4)	15	—	<.001
I reject such developments categorically, n (%)	24 (27.0)	75 (58.1)	21	—	<.001
How satisfied are you in your job[b], mean (SD)	2.6 (1.1)	2.9 (1.0)	—	2.2	.03
Would you be happier in your job if you had to work fewer night shifts[b], mean (SD)	2.4 (1.2)	4.2 (1.2)	—	11	<.001
Do you experience sleeping problems, n (%)	47 (52.8)	66 (51.2)	0.09	—	.77

[a]Two-sided *t* test.

[b]1=very; 6=not at all.

Physicians are More Open and Optimistic Toward Telemedicine Than Nonphysicians

The attitudes toward the use of apps for pregnancy monitoring diverged substantially between physicians and nonphysicians, such as midwives and nurses (Table 4). Moreover, 72% (64/89) of physicians believed that the development of such apps is reasonable, whereas only 36.1% (47/130) of nonphysicians thought the same way (*P*<.001).

Consequently, 57.7% (75/130) of nonphysician health care professionals categorically rejected such developments compared with just 27% (24/89) of physicians who did not (*P*<.001). The following reasons were frequently associated with rejection: fear that actual emergencies are detected too late, lack of personal care for worried patients, and fear of replacement of human workforce by machines. On the contrary, those in favor of such technologies hoped that this form of telemedicine would reduce unnecessary emergency consultations and allow health care professionals to focus on actual emergencies. No significant differences were observed in the regression analysis of demographic variables, such as sex, job position among physicians, sleeping behavior, and job satisfaction.

Discussion

Principal Findings

This is the largest survey on the attitudes of health care professionals in obstetrics in Germany toward telemedicine. Our study showed that the majority of health care professionals in obstetrics perceived most emergency consultations as unnecessary, indicating the need for new strategies to overcome this added workload. The study participants with several years of experience were skeptical about the use of telemedicine to avoid unnecessary consultations, whereas younger, less experienced colleagues were more optimistic in this regard. Interestingly, we found a significant difference in the attitudes toward telemedicine between physicians and nonphysicians. Physicians were more open and optimistic about the potential of telemedicine than other health care providers. Furthermore, despite the limited use of telemedicine and the fact that approximately 40% of the study participants (n=77) presented with sleeping disorders, the overall job satisfaction was high, regardless of age and the number of night shifts per month.

Comparison With Prior Work

These results are in accordance with those of other previous studies, showing that doctors are satisfied with their profession in general [24]. However, this is usually affected by organizational issues both in Germany [25] and other countries worldwide [26]. Recent studies have indicated that the workload of most doctors in Germany increased within the last couple of years [27] and that most health care professionals are aware of the health risks associated with night shifts, such as sleeping problems and hypertension [28-30], and this result is in accordance with the responses in our survey. A recent study has found that faculty members are dissatisfied with working night shifts compared with residents and emergency medicine nurses [31]. Furthermore, they abstained more often from pharmacological sleeping aids and had a higher rate of accidents while driving home [31].

Although there is no evidence that flexibility in duty hours has an impact on patient outcomes, education quality or resident satisfaction [32], a relevant proportion of physicians in Germany considers that personal consequences are associated with increased workload and the high pace in patient care [33]. These indicators are alarming considering the demographic development and existing shortage of physicians in Germany. Consequently, innovative solutions are crucial to meet these challenges and maintain high-quality health care. Telemedicine promises home-based pre-evaluation of patients and may substantially decrease the workload in a variety of medical specialties. Our study suggests that this potential is increasingly recognized by physicians.

Outlook Toward Telemedicine in Obstetrics

Emergency departments are increasingly used for nonurgent visits in general and in pregnancy-related concerns in particular, both in the United States and Germany [34,35] (Schramm et al under review). This is unsatisfactory given that addressing nonurgent problems in outpatient settings is more cost-effective and that it leads to a higher quality of life for patients [35]. Our study highlighted that health care professionals in obstetrics in Germany are well aware of this problem. Yet, despite the potential of telemedicine to alleviate this problem, it has not

been widely adopted in obstetrics [8,30,32-34]. This is contrasted by a growing demand for Web-based pregnancy apps among patients [22] and a general interest in health care apps [5,15,36]. It is also surprising because other countries and specialties, such as internal medicine or neurology, have already adopted telemedicine in patient care [37-39].

Our survey suggests that especially nonphysicians are still not convinced of the benefits and potential of telemedicine for pregnancy monitoring. The regression analysis of other demographic characteristics did not obtain significant results, probably due to insufficient statistical power in the respective subgroups. Hence, larger scaled studies are needed to evaluate possible differences between these subgroups.

The majority of nurses and midwives seemed to reject telemedicine partly because they were skeptical about the replacement of human labor by machines or intelligent algorithms. Therefore, health care professionals must be reassured that telemedicine is not a threat to their work and that it could help in allowing them to focus on patients who urgently need help. This is of particular importance given the increasing shortage of midwives in obstetrics care [40]. One should also bear in mind that our study included only 33 (16%) midwives. Hence, studies including more professionals are needed to support these preliminary results. However, the number of participants in this study was in concordance with other studies in this field [25,41].

The use of silver bullet in establishing wider acceptance of telemedicine in obstetrics care aimed to develop smart wearable devices that offer practical and reliable monitoring services for pregnant women. These technologies could facilitate the empowerment of mothers to autonomously assess fetal well-being to some degree at home. Ideally, this implementation could help reduce the burden in emergency departments and could improve the standard of care through closer pregnancy observation at the same time. The willingness of expectant mothers to engage in these forms of pregnancy monitoring is well established [22]. At the same time, self-monitoring of blood pressure in individuals with hypertension significantly reduces blood pressure in conjunction with cointerventions [42]. Similarly, self-care in individuals with heart failure via telemonitoring improves their quality of life [43]. The eHealth literacy among women of reproductive age is more favorable than that among other patients who usually use telemedicine [44-47]. Consequently, the development and application of telemonitoring in obstetrics care should be implemented more vigorously and decisively.

Conclusions

Our study reveals that an ambivalent attitude toward the use of telemedicine in pregnancy monitoring prevails among the health care professionals working in obstetrics in Germany. Frequent health education must be provided to improve skepticism and insecurity among health care professionals, especially among midwives and nurses. Given the enthusiasm we found among young doctors and the openness of patients who are pregnant toward telemedicine, the use of telemedicine in Germany must be increased. This opens new perspectives for structurally weak regions and could help in reducing the burden in emergency departments.

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Authors' Contributions

SS, KS, TCS, CS, JS, and JN designed the project. SS, TCS, and KS designed the questionnaire and conducted the survey. NG and SS interpreted the data and wrote the manuscript. All authors edited and approved the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

eHealth: electronic health
mHealth: mobile health

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Review

Correlations Between Objective Behavioral Features Collected From Mobile and Wearable Devices and Depressive Mood Symptoms in Patients With Affective Disorders: Systematic Review

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Abstract

Background: Several studies have recently reported on the correlation between objective behavioral features collected via mobile and wearable devices and depressive mood symptoms in patients with affective disorders (unipolar and bipolar disorders). However, individual studies have reported on different and sometimes contradicting results, and no quantitative systematic review of the correlation between objective behavioral features and depressive mood symptoms has been published.

Objective: The objectives of this systematic review were to (1) provide an overview of the correlations between objective behavioral features and depressive mood symptoms reported in the literature and (2) investigate the strength and statistical significance of these correlations across studies. The answers to these questions could potentially help identify which objective features have shown most promising results across studies.

Methods: We conducted a systematic review of the scientific literature, reported according to the preferred reporting items for systematic reviews and meta-analyses guidelines. IEEE Xplore, ACM Digital Library, Web of Sciences, PsychINFO, PubMed, DBLP computer science bibliography, HTA, DARE, Scopus, and Science Direct were searched and supplemented by hand examination of reference lists. The search ended on April 27, 2017, and was limited to studies published between 2007 and 2017.

Results: A total of 46 studies were eligible for the review. These studies identified and investigated 85 unique objective behavioral features, covering 17 various sensor data inputs. These features were divided into 7 categories. Several features were found to have statistically significant and consistent correlation directionality with mood assessment (eg, the amount of home stay, sleep duration, and vigorous activity), while others showed directionality discrepancies across the studies (eg, amount of text messages [short message service] sent, time spent between locations, and frequency of mobile phone screen activity).

Conclusions: Several studies showed consistent and statistically significant correlations between objective behavioral features collected via mobile and wearable devices and depressive mood symptoms. Hence, continuous and everyday monitoring of behavioral aspects in affective disorders could be a promising supplementary objective measure for estimating depressive mood symptoms. However, the evidence is limited by methodological issues in individual studies and by a lack of standardization of (1) the collected objective features, (2) the mood assessment methodology, and (3) the statistical methods applied. Therefore, consistency in data collection and analysis in future studies is needed, making replication studies as well as meta-analyses possible.

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KEYWORDS

mood disorder; affective disorder; depression; depressive mood symptoms; bipolar disorder; objective features; correlation; behavior; sensor data; mobile phone; wearable devices; systematic review

Introduction

Recently, there has been an increasing body of research investigating the use of mobile and wearable devices as a treatment intervention for depression [1]. Several mobile solutions have been proposed to utilize a self-monitoring and intervention-based treatment of depression [2-5]. One particular research approach adopted by many research groups has been to investigate how objectively measured behavioral features such as "location" and "social interaction" correlate with depression; using this approach, they have tried to differentiate euthymic and depressed states [6-11]. For example, using a mobile phone app passively recording information from sensors in the phone, Saeb et al [7] could show a statistically significant correlation between 6 different objective features, including mobile phone usage frequency and self-assessed mood using the Patient Health Questionnaire-9 (PHQ-9) scale [12] in nonclinical samples. Similarly, Faurholt-Jepsen et al [6] found 5 different objective features, including the number of outgoing short message service (SMS) text messages, which had a statistically significant positive correlation with depression severity as assessed using the Hamilton Depression Rating Scale (HDRS) in patients with bipolar disorder (BD).

The diagnostic process, as well as the process of symptom severity assessment in affective disorder, is based upon a combination of clinical evaluations and patient information, and there is a lack of objective markers of, for example, trait and state.

Digital behavioral markers have been defined as higher-level features reflecting behaviors, cognitions, and emotions, which are measured using low-level features and sensor data collected from digital technology, including mobile and wearable computing devices [13]. Many studies have found statistically significant correlations between objective behavioral features collected from mobile and wearable devices and mood symptoms in nonclinical samples of participants without psychiatric illnesses [14-17] as well as in clinical samples of patients diagnosed with psychiatric disorders [11,18-20].

The discovery of such significant correlations between objective features and depressive mood symptoms has raised great enthusiasm regarding using mobile and wearable devices in the treatment and monitoring of depression and other affective disorders. It has been argued that such an approach may provide an easy and objective way to monitor illness activity and could serve as a digital marker of mood symptoms in affective disorders [13,18]. Thus, if there is a well-established correlation between a specific digital marker—such as the number of steps taken and depressive mood symptoms—it would, in practice, be possible to develop an entirely automatic monitoring system. When, for example, the measured objective feature deviates from healthy behavior, an alarm or trigger could be raised in the clinic, which then could contact the patient [21].

However, when looking across individual studies, it is not easy to identify which objective features consistently correlate with depressive mood symptoms and in what way. Some studies have shown similar results, while others have shown contradicting results. For example, Beiwinkel et al [22] found a statistically significant negative correlation between the number of outgoing SMS text messages and the HDRS, whereas Faurholt-Jepsen et al [6] found a statistically significant positive correlation. Asselberg et al [15] found a negative correlation with mobile phone usage frequency and depressive symptoms, while Saeb et al [7] found the opposite.

No prior work has presented a comprehensive quantitative overview of objectively collected mobile features and how they relate to depressive mood symptoms. A more qualitative overview has recently been provided by Dogan et al [5], which highlights different mobile systems that have been developed to record subjective and objective features of individuals with affective disorders. They describe the findings of 29 different studies divided into different feature categories, such as physical activity, location, and phone usage, in a study-by-study evaluation.

Hence, a relevant question arises: to what degree studies show similar or different correlations between objective features and depressive mood symptoms, and how strong these correlations are? The purpose of this paper is to provide a systematic review of the available studies investigating the correlation between objectively collected features from mobile and wearable devices and depressive mood symptoms measured using various methods. Our systematic review aims to answer the following questions: (1) Which objective features have been collected? (2) What is the correlation between objective features and depressive mood symptoms? (3) Are the correlations similar across studies collecting the same features? Answering these questions could help us identify which objective features have shown most consistency across multiple studies and assist in designing future studies using technologies for objective assessment of depressive mood symptoms.

Methods

Systematic Review Process

We initiated the systematic review by following the PICO (Patient problem Intervention, Comparison, and Outcome) worksheet guidelines [23]. Then, we conducted and reported the systematic review according to the preferred reporting items for systematic reviews and meta-analyses statement [24].

Inclusion and Exclusion Criteria

The following inclusion criteria were met with the included original papers: (1) The study involved any type of objectively measured features; (2) the data were collected via a mobile phone or other nonintrusive consumer-based mobile or wearable device; (3) participants were assessed on a mood scale, which included self-reported scales (eg, PHQ-9) or clinical diagnostic

scales (eg, HDRS) used within psychiatry to quantify abnormal depressed mood either prior, during, or within the poststudy period; (4) comparisons of the objective features and the assessed depression scales between or within subjects were available or provided upon request from the respective corresponding author; (5) and as per the PICO Search Strategy, the following publication types were included: Meta-Analysis, Cohort study, Systematic Review, Case-Control Study, Randomized Controlled Trial, and Case series or report.

To ensure a broad inclusion of studies investigating the relationship between objective features and mood symptoms, the third statement was deliberately chosen to reflect a broad selection of clinical and nonclinical participants rated on different mood scales. This included both commonly used and clinically verified rating scales, such as the HDRS and PHQ-9, as well as nonstandard scales designed for a specific usage or technology, such as the 7-point (−3 to 3) scale used in the MONARCA (MONitoring, treAtment and pRediCtion of bipolAr Disorder Episodes) project [25,26].

We excluded original papers on the following premises: (1) nonquantitative studies or studies where only subjective features were collected; (2) if no English version of the paper was available; (3) studies that included participants with disorders other than mood disorders; (4) studies with nonhuman participants; (5) studies within social media since this topic has been thoroughly investigated elsewhere [27]; (6) studies with participants <18 years of age [28], to keep the focus on behavioral objective features collected on adults; (7) studies conducted before January 1, 2007; (8) studies that have not been published through peer review; and (9) the following publication types: trial protocols, in vitro or lab research, animal research, and editorials or letters or opinions.

Search Strategy

The corresponding author (DAR) searched the following databases on November 25, 2016 to target both clinical and technical scientific literature: IEEE Xplore, ACM Digital Library, Web of Sciences, PsychINFO, PubMed, DBLP computer science bibliography, HTA, DARE, Scopus, and Science Direct. Systematic reviews and meta-analysis publications were included in the search for a subsequent cited reference search, which was conducted on April 27, 2017.

A broad database-specific search string was designed to target all studies that investigated mood disorders within a mobile setting. The specific search string for PubMed was as follows:

(smartphone OR mobile OR wearable OR "smart phone" OR app OR apps) AND (depression OR bipolar OR unipolar OR "affective disorder" OR "mental health" OR "mood disorder") AND ("2007/01/01"[Date–Publication]: "2017/01/01"[Date–Publication]) AND English[Language]

The search strings for the other databases can be found in Multimedia Appendix 1.

The resulting publications were combined to one large spreadsheet, using an in-house Matlab script, with header information: database, title, author, publication year, publication type, and publisher.

Study Selection

After removal of duplicates, studies were screened for eligibility in two phases. In phase 1, one author (DAR) excluded the studies based on the title. The title revealed several exclusion criteria, including different disorders (Alzheimer, schizophrenia, diabetes, chronic pain, autism, Parkinson, PTSD, or anorexia nervosa); nonhuman experiments; mobile phone addiction topics; focuses on diary methods, which only involve subjective data; use of internet-based interventions; and nonmedical-related topics such as bipolar electricity. In phase 2, one author (DAR) went through the abstract. If eligible, the full text was retrieved and reviewed. We excluded studies in which no objective features were collected, studies that only used self-assessment, and studies concerning emotion.

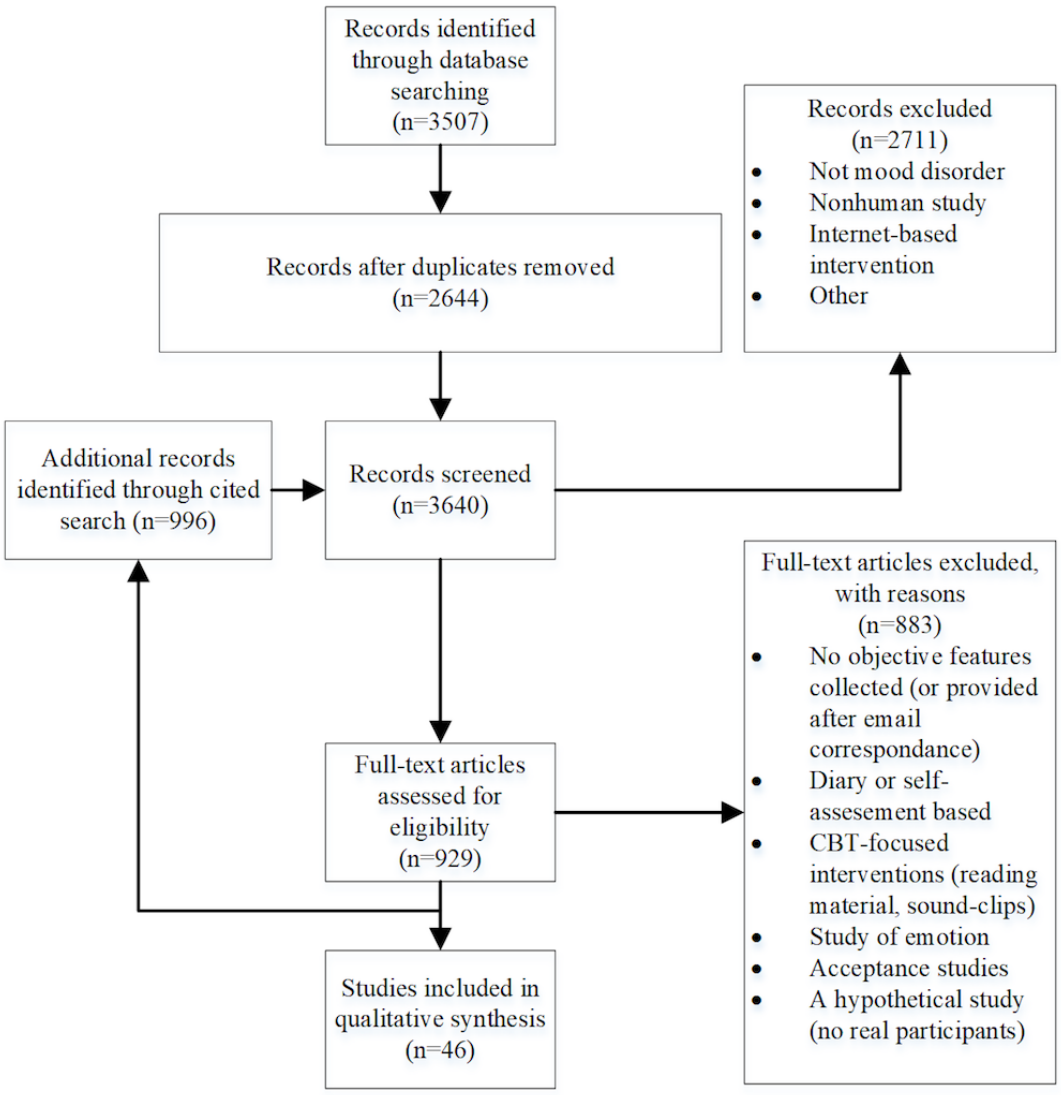
The resulting list, together with review papers from phase 1, were then used in a cited reference search by two authors (DAR, JEB) to produce the final list. The final list was critically investigated by all authors, which led to the exclusion of 16 papers due to outcome measures that did not represent mood assessment (eg, happiness scales [29-31], Quality of Life [32], or Satisfaction With Life Scale [33], as these do not reflect abnormal depressed mood) or wearables that were not consumer based (eg, a Holter monitor [34] or multisensory clothing [35-37]).

Several studies only reported correlation strengths or did not include correlation results between the objective features and the outcome assessment [9,14,31,38]. For these studies, we contacted the corresponding author via email and acquired the relevant data in all cases. The results of the study selection process are outlined in Figure 1.

Data Extraction

Data were extracted from the final list by one author (DAR) in a predetermined format validated by a second author (JEB). The data were extracted into 2 separate tables; one for nonclinical samples of participants without psychiatric illnesses (Table 1) and one for clinical samples of patients diagnosed with Unipolar Disorder (UD) or BD (Table 2). The division into 2 tables was reviewed by all authors. Both tables listed the following data for each study; first author, year of publication, the specification of the mobile device, number of participants, participant age, days of the study, and the outcome depression scale. Table 2 included a diagnosis column. The supplementary material contains expanded versions of Tables 1 and 2 (found in Multimedia Appendices 2 and 4 respectively), which also include information about the method of recruitment and the method of assessing the relation between objective features and mood symptoms (eg, Pearson correlation, two-sample *t* test). The tables in Multimedia Appendices 3 and 5 provide a detailed overview of the different features for each study, classified into a feature category, the sensor used, a small description, and the results with respect to the mood assessment.

Figure 1. Flowchart illustrating the number of reviewed studies through the different phases. An exhaustive cited search was performed on the eligible studies, as represented by the "Additional records identified through cited search" box. CBT: cognitive behavioral therapy.



Data Analysis

We were interested in investigating the correlation between behavioral objective features and depressive mood symptoms across all the included individual studies. To do this, we first identified all types of objective features, which have been applied in the eligible studies. The features were presented in a nomenclature list to create a standardized definition across all studies. Second, we investigated the strength of the correlation between objective features and depressive mood symptoms (ie, the *correlation coefficient*) across the included studies.

The investigation was performed by combining the directionality of the correlation values for identical objective features, weighted by the respective sample size and visualized as the x-axis and total sample size (log-transformed) on the y-axis. This was done in two separate graphs: one presenting nonclinical samples of participants (Figure 2 presents data from Table 1) and the other presenting clinical samples of patients diagnosed with either UD or BD (Figure 3 presents data from Table 2; Multimedia Appendix 6 shows patients with BD only). The two groups would most likely display different behaviors, and the separation was done on this premise. However, a combined result is displayed in Multimedia Appendix 7 for the convenience of the reader.

A positive directionality indicates that a larger quantity of the respective feature tends to give a higher depression score (eg, lower mood score, indicating a positive correlation with the depression score), while a negative directionality indicates that a larger quantity of the feature value tends to give a lower depression score (eg, a larger mood score, indicating a negative correlation with the depression score). All correlation values with outcome measures that represented larger values with better mood outcomes were multiplied by −1 to achieve the same weighted correlation directionality across studies.

Table 1. Summary of the included studies with nonclinical samples of participants.

Reference	Technology used	Participants (N=1189), n		Participant age (years), mean (SD)	Study duration (days)	Mood scale
		Male	Female			
Asselbergs et al, 2016 [15]	Android; Funf	5	22	21.1 (2.2)	36	10p mood
Baras et al, 2016 [40]	Android; EmotionStore	9	1	N/A[a]	14	BRUMS[b]
Becker et al, 2016 [41]	Android; Funf	5	22	N/A	42	Mood
Ben-Zeev et al, 2015 [42]	Android	37	10	22.5	70	PHQ-9[c]
Berke et al, 2011 [43]	Multisensor (waist)	4	4	85.3 (4.1)	10	CES-D[d]
Canzian and Musolesi, 2015 [9]	Android; MoodTraces	15	13	31	71	PHQ-8[e]
Cho et al, 2016 [44]	Phone records	234	298	57	N/A	BDI-21[f]
Chow et al, 2017 [45]	Android	35	37	19.8 (2.4)	17	DASS-21[g]
DeMasi et al, 2016 [46]	Android	17	27	N/A	56	BDI-21
Edwards and Loprinzi, 2016 [47]	Digi-Walker Pedometer	16	23	21.82	7	PHQ-9
Farhan et al, 2016 [17]	Android or iOS; LifeRhythm	21	58	18-25[h]	N/A	PHQ-9
Mark et al, 2016 [48]	Fitbit flex	20	20	N/A	12	Affect balance
Matic et al, 2011 [16]	Windows M. 6.5; MyExperience	6	3	28.4 (2.8)	7	rPOMS[i]
Mehrotra et al, 2016 [49]	Android	25[j]	N/A	N/A	30	PHQ-8
Mestry et al, 2015 [14]	Android	1	1	22	34	DASS21
Pillai et al, 2014 [50]	Actigraph	10	29	19.55 (3.2)	7	BDI-21
Saeb et al, 2015 [7]	Android; Purple robot	8	20	28.9 (10.1)	14	PHQ-9
Saeb et al, 2016 [39]	Android; Studentlife	38	10	N/A	70	PHQ-9
Wang et al, 2014 [51]	Android; Studentlife	38	10	N/A	70	PHQ-9
Wang et al, 2015 [52]	Android; Studentlife	37[j]	N/A	N/A	70	PHQ-9

[a]N/A: not applicable.

[b]Depression subscale of Brunel Mood Scale.

[c]PHQ-9: Patient Health Questionnaire-9

[d]CES-D: The Center for Epidemiological Studies Depression Scale.

[e]PHQ-8: Patient Health Questionnaire-8

[f]BDI-21: Becks depression inventory.

[g]DASS-21: Depression Anxiety Stress Scales.

[h]Study reported participant age as a range, rather than mean.

[i]rPOMS: reduced Profile of Mood States.

[j]Total number of participants; number of male and female participants not specified.

Table 2. Summary of the included studies with clinical samples of participants diagnosed with unipolar (UD) or bipolar (BD) disorder.

Reference	Technology used	Participants (N=3094), n		Clinical diagnosis	Participant age (years), mean (SD)	Study duration (days)	Mood scale
		Male	Female				
Abdullah et al, 2016 [53]	Android; MoodRhythm	2	5	BD	25-64[a]	28	SRM II-5[b]
Alvarez-Lozano et al, 2014 [11]	Android; Monarca	18[c]	N/A[d]	BD	N/A	150	7p mood
Beiwinkel et al, 2016 [22]	Android; SIMBA	8	5	BD	47.2 (3.8)	365	HDRS[e]
Berle et al, 2010 [54]	Actigraph	10	13	UD	42.8 (11)	14	Group difference
Dickerson et al, 2011 [55]	iOS; Empath	0	1	UD	83	14	10p mood
Doryab et al, 2016 [18]	Android	3	3	UD	>18[f]	20	CES-D[g]
Faurholt-Jepsen et al, 2012 [56]	Actiheart	8	12	UD	45.2 (12)	3	Group difference
Faurholt-Jepsen et al, 2015 [57]	Actiheart	7	11	UD	45.6 (11.1)	3	HDRS-17
Faurholt-Jepsen et al, 2016 [58]	Android; Monarca	9	19	BD	30.3 (9.3)	84	HDRS-17
Faurholt-Jepsen et al 2014 [10]	Android; Monarca	5	12	BD	33.4 (9.5)	90	HDRS-17
Faurholt-Jepsen et al, 2015 [26]	Android; Monarca	20	41	BD	29.3 (8.4)	182	HDRS-17
Faurholt-Jepsen et al, 2016 [6]	Android; Monarca	11	18	BD	30.2 (8.8)	84	HDRS-17
Gershon et al, 2016 [59]	Actigraph	14	23	BD	34.4 (10.4)	46	Group difference
Gonzales et al, 2014 [60]	Actigraph	15	27	BD	41.0 (11.2)	7	IDS-C-30[h]
Grünerbl; 2015 [61]	Android	2	8	BD	33-48	84	7p mood
Guidi et al, 2015 [20]	Android	0	1	BD	36	98	mood state
Hauge et al, 2011 [62]	Actigraph	14	11	UD	42.9 (10.7)	14	Group difference
Krane-Gartiser et al, 2014 [63]	Actigraph	5	7	BD	39.9 (15.6)	1	Group difference
Loprinzi and Mahoney, 2014 [64]	Actigraph (hip)	1261	1313	UD	46.3	7	Group difference
Miwa et al, 2007 [65]	Armband; SenseWear Pro	5	0	UD	35.1	87	Group difference
Muaremi et al, 2014 [66]	Android	6[c]	N/A	BD	18-65	76	7p mood
O'Brien et al, 2016 [8]	Actigraph	16	43	UD	74 (6)	7	MADRS[i]
Osmani et al, 2013 [19]	Android	0	5	BD	N/A	90	−3:3 mood[j]
Palmius et al, 2016 [67]	Android; AMoSS	9	27	BD	44 (14)	60	QIDS-SR16[k]
St-Amand et al, 2013 [68]	Actigraph	7	7	BD	44.6 (11)	14	Group difference
Todder et al, 2009 [69]	Actigraph	14	13	UD	49 (13)	7	Group difference

[a]Study reported participant age as a range, rather than mean.

[b]SRM II-5: Social Rhythm Metric II-5.

[c]Total number of participants; number of male and female participants not specified.

[d]N/A: not applicable.

[e]HDRS: Hamilton Depression Rating Scale.

[f]All participants in study above 18 years of age.

[g]CES-D: The Center for Epidemiological Studies Depression Scale.

[h]IDS-C-30: Inventory for Depressive Symptomatology, Clinical-rated.

[i]MADRS: Montgomery-Åsberg Depression Rating Scale.

[j]−3:3 mood: 7-point mood scale ranging from −3 to 3.

[k]QIDS-SR16: Quick Inventory of Depressive Symptomatology-Self Reported.

Figure 2. Features collected from at least two studies using nonclinical samples of participants. The x-axis (*wD*; weighted directionality) represents a weighted directionality of the correlation between the feature and mood symptoms. Positive values represent a larger depressive score and vice versa. The y-axis represents the logarithm of the total number of participants across all studies for this feature. The size of each pie chart represents the number of studies that recorded the feature, while the green, red, and gray areas represent statistically significant, statistically nonsignificant correlations, and missing statistical significance, respectively.

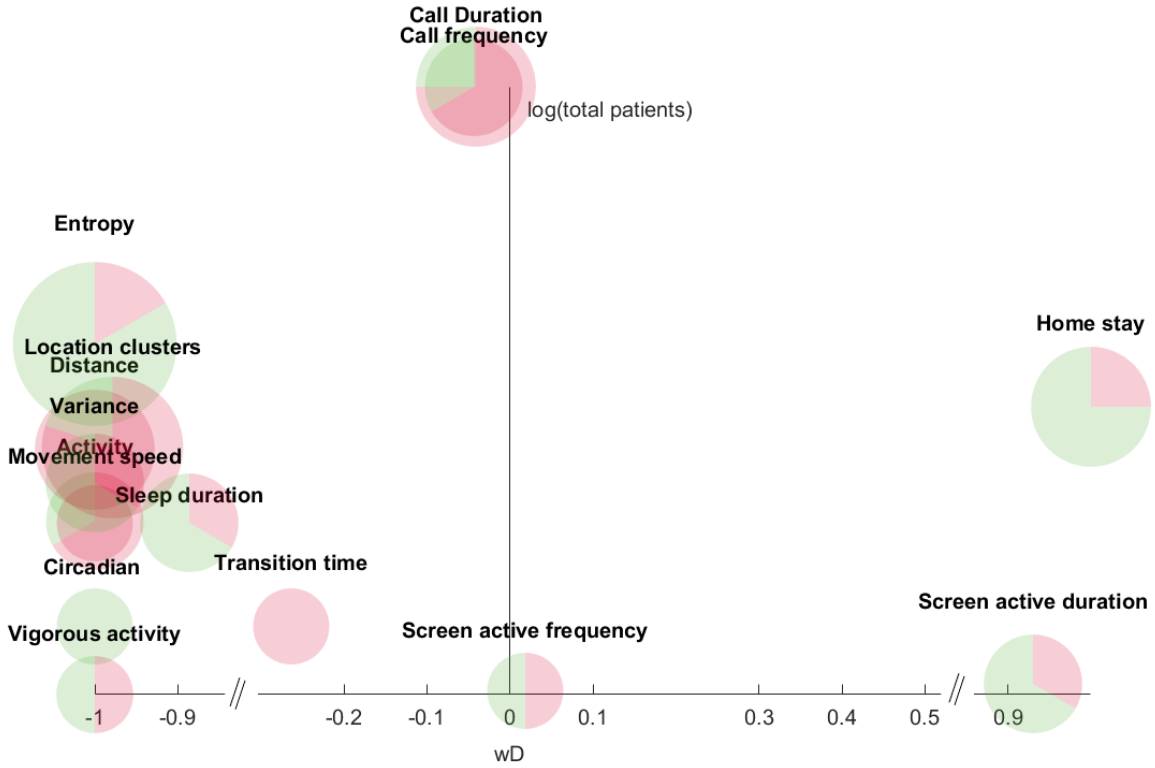
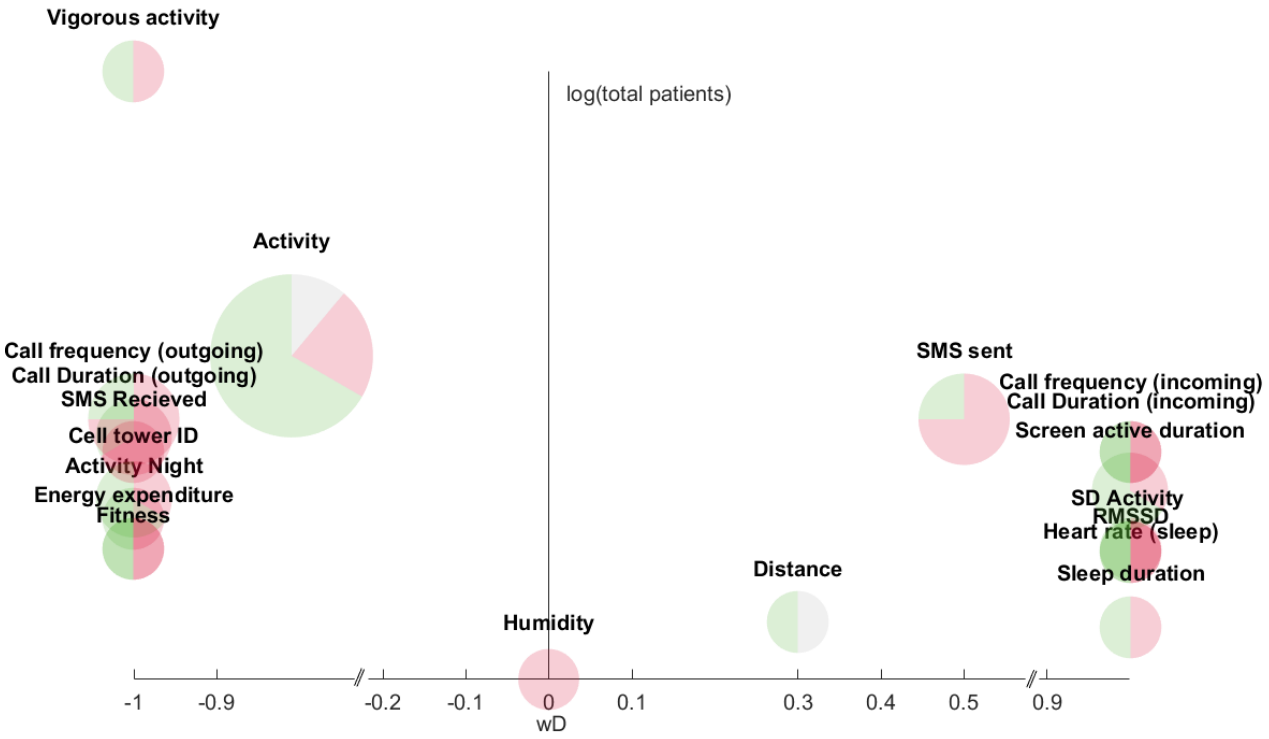


Figure 3. Features collected from at least two studies using nonclinical samples of participants. The x-axis (*wD*; weighted directionality) represents a weighted directionality of the correlation between the feature and mood symptoms. Positive values represent a larger depressive score and vice versa. The y-axis represents the logarithm of the total number of participants across all studies for this feature. The size of each pie chart represents the number of studies that recorded the feature, while the green, red, and gray areas represent statistically significant, statistically nonsignificant correlations, and missing statistical significance, respectively.



A meta-analysis of the specific correlation values was not considered for this systematic review. The heterogeneity across the studies was too substantial to perform any valid meta-analysis of correlations.

Not only were different analytical methods applied (eg, some using within-subject correlation others between subjects, some using day-averaged others week-averaged data) but also different apparatus and mood assessments were used. However, there is a clear correlation directionality invariance shown by studies comparing different analysis methods [6,22] and studies replicating same analysis methods on different datasets [7,39], which puts forth the argument that the directionality is a stable metric. Regarding the specific correlation values, we still encourage the reader to look at the results across studies using Multimedia Appendices 2,3,4, and 5 as a reference.

Results

Of 3507 potentially eligible studies, 46 met the criteria of the review. A flowchart of the screening process is shown in Figure 1. Characteristics of the included studies are summarized in Tables 1 and 2.

Table 1 lists studies including nonclinical samples of participants (n=20), and Table 2 lists studies including clinical samples of patients diagnosed with either UD or BD (n=26). A more detailed overview of the included studies is listed in Multimedia Appendices 2,3,4, and 5.

We identified 7 overall behavioral feature categories, which we denoted as "Feature Categories." These categories used 17 unique data inputs to analyze 85 different objective features. The same features were used across studies, yielding 176 investigated features, with information about directionality with respect to the mood score on 155/176 (88%) of the cases. The other cases (n=21) report on accuracy and weightings by combining objective features into single evaluations, which was mostly observed in research papers with classification models [53,61,66,67].

The 7 feature categories are defined and described in Table 3. An overview of the studies that contributed to each of the categories is provided in Multimedia Appendix 8. The supplementary files also include a graph illustration of the data inputs and how they contributed to the different category (Multimedia Appendix 9).

An in-depth analysis of each feature occurring in more than 2 studies is shown in Figures 2 and 3 for nonclinical and clinical samples of participants, respectively. Figures 2 and 3 were constructed as follows.

The x-axis is a weighted directionality of the correlation between the feature and mood symptoms. Positive values represent a larger depressive score and vice versa.(*wD*) is defined as:

F_x is the correlation value of a unique feature such as *SMS text message sent*. M is the total number of F_x across all studies where N is the combined total number of participants. "*sgn*" denotes the sign operation which is −1 for values below zero, and 1 for values above zero. As an example, when considering the correlation between *screen active frequency* and mood symptoms, according to the table in Multimedia Appendix 3, this is analyzed in 2 studies; one study with N=28 shows a positive correlation, whereas one study with N=27 shows a negative correlation. This yields a *wD* as follows:

A *wD* value of 1 would indicate that all studies have a positive correlation between the measured feature and the mood assessment. This means that consistency across studies would place the feature on either +1 (consistent positive) or −1 (consistent negative) on the x-axis.

The y-axis is log-transformed values, to accommodate the large diversity, of the total number of participants on which the feature is measured. Nonclinical samples of participant studies measuring *call frequency* (n=370) had the highest average study participants, while clinical samples of participants measuring *humidity* (n=6) had the lowest.

The size of the feature pie chart represents *M*, which is the total number of studies of that particular feature. Similarly, the pie charts are divided into statistically significant (green), statistically nonsignificant (or lack of reporting; red) correlations, and missing information on statistical significance (gray).

In total, Figures 2 and 3 provide an overview of the correlation between statistically significant features and depressive mood symptoms. Each feature is followed by the result reported in the figure, which is the *wD* value, the number of studies that included the feature (n), the percentage of statistically significant cases (s), and the mean (SD) of the participants included in the "n" studies.

For nonclinical samples of participants (Figure 2), we observed the following:

Most studies, excluding *call duration* (*wD*=−0.04, n=4, s=25%, mean 278.50 [SD 293.32]), *call frequency* (*wD*=−0.04, n=3, s=33.33%, mean 370.67 [SD 279.44]), *screen active frequency* (*wD*=0.02, n=2, s=50%, mean 27.5 [SD 0.71]), and *transition time* (*wD*=−0.26, n=2, s=0%, mean 38.00 [SD 14.14]), agree on the correlation direction because most features are either at −1 or +1. *Home stay* (*wD*=1, n=4, s=75.00%, mean 56.75 [SD 23.32]), *circadian rhythm* (*wD*=−1, n=2, s=100%, mean 38.00 [SD 14.14]), and *entropy* (*wD*=−1, n=6, s=83.33%, mean 51.67 [SD 22.98]) have the largest number of statistically significant studies, whereas *distance* (*wD*=−1, n=4, s=0%, mean 45.75 [SD 24.10]), *movement speed* (*wD*=−1, n=2, s=0%, mean 63.50 [SD 21.92]), and *transition time* have no statistically significant studies.

Table 3. An overview of the included features together with the data input name separated into 7 distinct categories.

Feature Category	Feature
Social (n=38), with statistically significant correlation reported for 26% (10/38) results and statistical evaluation missing for 16% (6/38) results. Features describing social behavior, including activity related to phone calls, texting, social network size, and other people in the user's context.	• Call duration (incoming or outgoing)-Call log • Call frequency (incoming or outgoing)-Call log • Calls missed-Call log • Maximum call duration-Call log • Number of conversations-Call log • SMS[a] text messages received (characters)-SMS text message log • Characters in SMS text message (sent or received)-SMS text message log • SMS text message (sent or received)-SMS text message log • Speak duration-Call log • Devices seen-Bluetooth
Physical activity (n=48), with statistically significant correlation reported for 46% (22/48) results and statistical evaluation missing for 6% (3/48) results. Features describing physical activity, including movement and step count.	• Activity (afternoon, day, evening, morning, night)-Accelerometer • Autocorrelation-Accelerometer • Vigorous activity-Accelerometer • Distance-Accelerometer, GPS[b] • Energy expenditure-Multiple sensors • Fourier analysis-Accelerometer • Inactivity duration-Accelerometer • Jerk-Accelerometer • Movement duration-GPS • Movement speed-Accelerometer, GPS • Movement speed variance-GPS • RMSSD-Accelerometer • Sample Entropy-Accelerometer • SD of stillness-Accelerometer • Steps-Accelerometer, Pedometer
Location (n=38), with statistically significant correlation reported for 50% (19/38) results and statistical evaluation missing for 8% (3/38) results. Features describing mobility, including GPS tracking, clustering of location (eg, home stay), and transition time.	• Cell tower ID-GSM[c] • Home stay-GPS • Location clusters-GPS • Break duration-FM radio signal • Circadian rhythm-GPS • Entropy-GPS • Home to location cluster-GPS • Maximum distance between clusters-GPS • Raw entropy-GPS • Routine index-GPS • Transition time-GPS • Location variance-GPS • Coverage area-GPS
Device (n=24), with statistically significant correlation reported for 54% (13/24) results and statistical evaluation missing for 0% (0/24) results. Features describing device (mobile phone or wearable) usage, including app usage, lock or unlock events, and classification of app usage.	• Communication or social usage-App • Duration-App • Browser usage-App • Images taken-Camera • Number of running apps-App • Response time-Notification • Screen active duration or frequency-Screen • Screen clicks-Screen • Time from arrival till seen-Notification • Time from seen till acted-Notification • Data transmitted-Wi-Fi

Feature Category	Feature
Subject (n=24), with statistically significant correlation reported for 50% (12/24) results and statistical evaluation missing for 21% (5/24) results. Features capturing the subject's physical state, including sleep and voice.	• Deep sleep or total sleep-Accelerometer • Deviation of F0-Microphone • Envelope-Microphone • Fitness-ECG[d] • Fundamental frequency-Microphone • Harmonics-to-noise ratio-Microphone • Pauses in recording-Microphone • Short turns during conversation-Microphone • Sleep (duration, efficiency, onset latency)-Accelerometer • SD pitch frequency-Microphone • Laying down-Camera • SD sleep-Accelerometer
Environment (n=2), with statistically significant correlation reported for 0% (0/2) results and statistical evaluation missing for 0% (0/2) results. Features collected from the physical surroundings of the user.	• Intensity level-Light sensor • Humidity-Internet
Bio (n=2), with statistically significant correlation reported for 50% (1/2) results and statistical evaluation missing for 0% (0/2) results. Biometric features related to the subjects body.	• Heart rate (sleep, day)-LED[e] light sensor, ECG • Skin conductance-EDA[f]

[a]SMS: short message service.

[b]GPS: global positioning system.

[c]GSM: Global System for Mobile communication.

[d]ECG: electrocardiography.

[e]LED: light-emitting diode.

[f]EDA: electrodermal activity.

Similarly, for the clinical sample of patients (Figure 3), we observed the following:

Most studies, excluding *distance* (*wD*=0.30, n=2, s=0%, mean 10.00 [SD 4.24]), *humidity* (*wD*=0, n=2, s=0%, mean 6.00 [SD 0.00]), *SMS text message sent* (*wD*=−0.50, n=4, s=25%, mean 30.00 [SD 21.76]), and *activity* (*wD*=−0.81, n=9, s=66.67%, m 23.33 [SD 16.10]), agree on the correlation direction because they are at either −1 or +1 on the *wD* axis. *Cell tower ID* (*wD*=−1, n=3, s=66.67%, mean 19.67 [SD 8.33]), *screen active duration* (*wD*=1, n=3, s=66.67%, mean 21.33 [SD 6.66]), and *activity* have the largest statistically significant percentage, whereas *distance*, *SMS text message received* (*wD*=−1, n=2, s=0%, mean 45.00 [SD 22.63]), and *humidity* have the lowest.

Several objective features were only included in a single study. Therefore, their relationship to a depressive mood scale cannot be compared across studies as done in Figures 2 and 3. Some of these features are quite creative and worth mentioning. The most promising results for the nonclinical samples include the time spent in break rooms (ρ=−0.21, nonsignificant) [16], and less SD of stillness amount, which can be interpreted as a more uniform activity pattern (beta=−3.3, *P*<.001) [46]. For the clinical samples, it includes the increased amount of time with no sound detection (*speech pauses*; beta=0.34, *P*=.004) [55], increased number of *calls missed* (beta=0.05, *P*=.006) [6], and fewer incidences of quick or sudden movements (*jerk*; *t*=4.06, *P*<.001).

Data and Methods Reporting

In the 46 eligible studies, 19 different mood assessment methods were used. The most common assessment method was the PHQ (n=9), whereas assessment methods like the Montgomery-Åsberg Depression Rating Scale and the Brunel Mood Scale [40], which are patient-reported outcome measures, were only used in a single study.

Seven different technologies were used for collecting the objective features. The most frequent one was mobile phone (n=30); mostly Android phones were used (n=27), with iOS (n=2) and Windows (n=1) phones also being used. Wearable devices were reported to be located on various areas on the body, including the upper arm [65], wrist (nondominant hand [69], right hand [62]), waist [43], hip [64], and chest [57].

When analyzing the relation between the objective features and depressive mood assessments, we identified several regression-, machine learning–, correlation-, and group-difference methods. In total, across the 46 eligible studies, 12 different methods were used, with Pearson correlation being the most used (n=17).

Details on the analysis method were, in general, not well documented. This especially applied to studies where correlation analysis was secondary to the main hypothesis [70,71]. Important details that were mentioned in few of the studies included possible confounding variables such as age, sex, and body mass index (BMI) [18,53]; data sampling methods such as global positioning system (GPS) polling strategies [30]; the window-length in days or averaging methods of objective data that were correlated with the outcome [7,51]; and within-subject or between-subject analysis [22,42]. Full transparency, by providing the data, was seen in only 2 of the studies [15,51], with 5 studies using existing public data [39,64,70-72].

Discussion

Principal Findings

In this paper, we present the results of the first systematic review on the correlation between objective behavioral features collected via mobile and wearable devices and the assessment of depressive mood symptoms as measured by different rating scales and questionnaires. This was possible due to the increased research on mobile and wearable computing devices in the context of mental health [4,73,74], yielding 46 included studies in this review. We found that 57% (26/46) studies (a small majority) were performed on clinical samples of participants. However, when analyzing the number of participants included in these studies, they constituted a majority (3094/4283, 72%). We separated these two groups since nonclinical samples of participants are, by definition, healthy and, most likely, will display different behaviors than clinical samples of patients diagnosed with UD or BD.

We want to emphasize, for the subsequent discussions, that correlation assessments do not imply causality, but rather simple associations. The correlation between two measures could also be mediated through one or several covariates, which were not explored in any of the included studies [75]. For instance, Disabato et al were able to validate a correlation by including a statistical mediation model [76]. They concluded that the presence of positive life events mediated the correlation between gratitude and depression. A simple correlation assessment also does not provide knowledge on the clinical utility of these data in the classification of affective episodes in UD or BD because sensitivity, specificity, positive predictive values, and negative predictive values were not investigated in most studies. However, discovering and understanding the relationships between objective features and their relation to mood symptoms may be relevant in a clinical setting because it may provide an easy and objective way to monitor illness activity outside the clinical settings and could serve as a digital marker for mood symptoms [18].

Feature Categories

The *social* category had the lowest percentage of statistically significant correlations, by vote counting, across studies (10/38, 26%). *Social* included features such as *call duration* and *number of conversations*, which can be accessed on Android phones, contrary to iPhones [77]. We did not find any research article that explains how social patterns change with depression, but the review article by Baker et al [27] on online social networks suggests a complex relation involving factors that mediate or moderate the correlation and increase the variability in the findings. Furthermore, Cho et al [44] found a direct opposite correlation between genders (male negative, female positive) in the *call duration* and *call frequency* features. This suggests that social-based features should be treated as a highly personalized feature that should be assessed in a within-subject analysis.

The feature category with the highest percentage of statistically significant correlation features across studies was *device* (13/24, 54%). As an example, using data provided by the corresponding author [14], we observed statistically significant results in *communication app usage* (r=−0.33, P=.007) calculated using a within-subjects analysis of covariance. The low variability with device-based features could indicate that there is a general tendency for participants to use their phones more, but at the same time, withdraw from the social context by lowering the *communication app usage*.

The feature category *subject* is similar to *Device*, investigated less but with a high percentage of statistically significant correlations across studies (12/24, 50%). This includes features within sleep and voice. In particular, *sleep duration* was the most investigated feature (n=6), with statistically significant correlations in 4 studies Furthermore, *subject* was one of the less included categories, which could be due to the second-level processing required to achieve features of voice [66] or sleep durations through multiple sensors [51].

Objective Features

Nonclinical Samples of Participants

As seen in Figure 2, we found two features that have a strong positive (ie, close to 1 *wD*) correlation with depression: *home stay* and *screen active duration*; both of these showed a large proportion of statistically significant correlations across studies. Moreover, all 4 studies with a positive correlation between *home stay* and depression level also had a large average participant number. Individual studies have shown that the degree to which a person stays at home is associated with depression [45], and it is a general hypothesis that this relation is positive. We were able to verify this hypothesis by combining the results across the included studies in this review.

On the other hand, no prior hypothesis has been formulated regarding the relationship between general phone usage and depressive mood symptoms. However, studies have shown a statistically significant positive correlation between depressive symptoms and the feature *screen active duration* [78]. Similarly, subjective-based mobile phone use has been studied in relation to depression, where Thomée et al found that high mobile phone use was associated with symptoms of depression [79]. These findings were replicated in this review, with only a single statistically nonsignificant contradictive result from a two-sample study by Mestry et al [14] (r=−0.03, P=.79).

On the left side in Figure 2, we see several features that have a strong negative correlation to depression, including *location clusters*, *entropy*, and *sleep duration*. A majority of these features indicates that enhanced physical activity and more movement outside of the house are observed when participants score lower on the depression scale. This is consistent with the Actigraph systematic review papers by Scott et al [80], who revealed a consensus of lower mean activity levels associated with bipolar depression, and Burton et al [81], who revealed a pattern of lower daytime activity but higher nighttime activity in depression.

Entropy is the most prominent feature in the figure with many studies (n=6), all yielding a negative correlation and a high statistically significant proportion. The only case of nonsignificance was reported by Saeb et al [7] (r=−0.42, P=.082), who, however, did show a high negative correlation. *Entropy* is a measure that captures the distribution of time spent

at the different location clusters registered. Thus, a high *entropy* would indicate that the participant spends time more uniformly across different location clusters. Because all studies consistently showed a negative correlation, this implies that a higher *entropy* correlates with a better mood. If a participant stays home for a longer time than usual, the *entropy* will drop. Hence, there is a dependency between *entropy* and *home stay*, which is also evident in the figure where they are almost mirrored, both with a large proportion of statistically significant findings. Both features can be collected via the location Application Programming Interface, which uses the GPS sensor typically embedded in all mobile phones or wearables.

Features with less consistent findings across studies regarding positive or negative correlations are located closer to 0 *wD*; these include features such as *screen active frequency*, *call duration*, *call frequency*, and *transition time*. At first look, it seems that these features are not related to mood symptoms and, hence, exhibit random correlation values. However, another explanation could be gender or cultural differences. In a cross-cultural study with people from Switzerland and Turkey, Hernández et al [29] found different correlation directions between the two groups in *screen active frequency* and *number of running apps*. Furthermore, several device-based features such as *browser app usage* and *reading app usage* have different correlation directions between genders (male positive, female negative) [33], and the two social features *call duration* and *call frequency* also exhibit different correlation directions between genders (male negative, female positive) [44].

Transition time has been currently only investigated by the research group of Saeb et al [7,39], who conducted a study to replicate previous findings of the same features. The first study showed a positive correlation (r=0.21, P=.40), while a second study showed negative correlation (r=−0.32, nonsignificant). The feature then yields a low negative *wD* due to the latter including more participants and placed more centrally due to the contradictive results.

Clinical Samples of Patients Diagnosed With Unipolar or Bipolar Disorder

The feature *screen active duration* is similar to the nonclinical samples, with a high proportion of statistically significant studies and a consensus on positive correlation among the studies. Note, however, that this feature was the only one within the *Device* category that was investigated for both nonclinical and clinical samples of participants.

The features of *sleep duration* and *distance* have switched to a positive *wD* in Figure 3 compared with Figure 2. Only 2 studies have investigated *distance* for clinical samples of patients. Beiwinkel et al [22] reported a negative correlation in a between-subject analysis, but the within-subject analysis that we reported had almost zero correlation (r=0.03, P=.66). In contrast, Abdullah et al [53] showed a negative correlation direction by the negative weighting coefficient (w=-1.56×10^{-2}) using the Support Vector Machine analysis. However, with a small number of total participants, only 2 studies, both nonsignificant, *distance* was found to be weakly represented in the literature. *Sleep duration*, on the other hand, had statistically significant findings in both groups. This feature is a good example of the reasoning in analyzing depressed symptoms in clinical samples separately from the nonclinical sample. In clinical samples of nonseasonal depression, patients often suffer from abnormal sleep patterns with problems falling asleep, interrupted sleep, and early morning waking, while such a sleep pattern not is seen among healthy subjects.

Social-based features were more extensively investigated with clinical samples of patients. The two features *incoming call duration* and *incoming call frequency* reveal a strong tendency that participants tended to receive more calls and talk longer during these calls when depressed. On the other hand, the features *outgoing call duration* and *outgoing call frequency* tend to suggest that patients make more and longer calls when they are less depressed. This difference between incoming and outgoing calls highlights that these features should be kept separate, and it raises concerns with some of the results on *Call duration* with nonclinical samples of participants as in a study by Wang et al [51], who measured *call duration* and *frequency* across incoming and outgoing calls.

The feature *SMS text messages sent* was found to have a lower *wD*, showing inconsistencies across the 4 studies. We did not find any results in the literature that could explain the lower *wD* on *SMS text messages sent*, although the use of internet- and app-based chat and video communication platforms has been increasing, while SMS text message communication has fallen drastically. In Denmark, there has been a drop of 19.6% in SMS text messages sent from 2015 to 2016 [82]. This suggests that SMS text message logging should be used with caution and should be extended to include other relevant messaging technologies.

The clinical sample consisted of both unipolar and bipolar patients. Optimally we would have liked to analyze data separately for these two patient groups due to findings that show psychomotor activity and sleep discrepancies between unipolar and bipolar depression [80]. However, the focus here is on the level of depressive mood symptoms as a function of objective features, where bipolar and unipolar patients show same directionality compared with healthy controls [56]. Nevertheless, we repeated the analysis of correlation directionalities, including patients with BD only, and the results remained unchanged. See Multimedia Appendix 6.

Limitations

Data Collection and Analysis Method

When combining the studies investigating objective features and their relation to mood symptoms, it became apparent that a meta-study on the exact correlation values would be misleading. The lack of detailed reporting on analysis methods was clearly demonstrated in a study by Beiwinkel et al [22], where a between-subject (cross-sectional analysis) relationship yielded a statistically nonsignificant (P=.82) regression coefficient of −0.04, while a within-subject (longitudinal analysis) relationship yielded a statistically significant (P=.03) regression coefficient of −0.11, on the feature of *cell tower ID*. Data aggregation length was also a concern because the duration of studies included in this review spans from 7 days [16,47] to

12 months [22]. Canzian & Musolesi [9] presented results on the correlation between PHQ-8 and different mobility features for 1 to 14 days of aggregation. The absolute correlation value increased from .152 (−.016 not absolute) to .432 on the feature *maximum distance*. The change was most likely due to a larger data pool, which lowered the variance toward "outlier" days or even noise in the data stream. It might also be related to the day of the week. For instance, Saeb et al [39] found variations in the objective feature *home stay* between work days and weekends. Furthermore, the lack of reporting confounding variables in the analysis was a concern. Faurholt-Jepsen et al [6] have demonstrated the effect of adding confounding variables to the analysis, where an unadjusted model without confounding variables on, for example, *screen active duration* (beta=194.8, *P*=.06) becomes statistically significant when controlling for age and sex (beta=209.6, *P*=.04).

To investigate depressive severity, many studies measured mood pre-, during, and poststudy, and there were correlation differences depending on when the mood assessment was done [51]. In a more detailed study [39], we saw a gradual lowering in correlation between various objective features and prestudy PHQ-9, which was not that surprising because the PHQ-9 questionnaire captures symptoms of the last 2 weeks and not future behavior. However, interestingly, the correlation was stable in the 8 weeks when the features were assessed using the poststudy questionnaire. Ben-Zeev et al [42] looked even closer on a day-based sample resolution. Here we see a directionality switch with some of the objective features. Sleep duration was modeled with a positive regression coefficient with pre-post change PHQ-9 (eg, higher sleep duration modeled a worse PHQ-9 change score) almost throughout the study period, but during the last quarter, it changed to a negative regression coefficient, which is consistent with the literature, as depicted in Figure 2 [48,51]. These findings highlight the importance of transparency regarding the analysis methods. The implications regarding the results presented in this systematic review are minimal because the induced correlation differences remain invariant to the correlation directionality, which is the focus here.

Limitations are also associated with the different technologies, including hardware and software, used to collect objective features from mobile phones and wearables. Studies have shown statistically significant differences that need to be accommodated within the study design [83]. For example, Farhan et al [17] developed a mobile phone-based sensing app with the PHQ-9 assessment on both iOS and Android. The study showed that the feature *movement duration* changed from a correlation of *r*=0.06 (*P*=.43) on Android to *r*=−0.13 (*P*=.07) on iOS. They argued that the difference was due to technical details regarding whether data was pooled or sent from the sensor. This example demonstrates a change in correlation directionality, which could have had an impact on our results if more studies were reporting on movement duration. Even though we reported the Android results, to be consistent with the other mobile phone-based studies, there was no impact on our results because the directionality of the remaining features was identical.

The result on weighted directionality in Figure 3 includes 9 studies that reported on group differences between clinical subjects and healthy controls. They compared the mean value of the feature between the two groups to understand what directionality the feature has concerning the disorder. If the study reported longer sleep duration in the clinical group than in healthy controls, it indicates that the directionality is positive. This could be problematic in nonlinear cases, such as the observation by McKercher et al [84]. They found that male participants with depression were taking 7500-9999 steps per day, contrary to healthy controls who were in the lower or upper levels of respectively <7500 or >9999 steps per day.

Mood Assessment

The included studies used different ways of measuring mood symptoms, which undoubtedly had an impact on the correlation value, while the directionality of the correlation stayed intact. Several studies have shown a high correlation between different mood assessment methods. Simple mood scales for self-assessment, such as a 7-point selection from −3 till 3, have shown statistically significant correlations with clinically validated rating scales such as the HDRS [26]. For example, there is a high correlation between the commonly used assessments methods of depression; PHQ-9, Becks depression inventory (BDI), and HDRS (lowest PHQ-9 vs HDRS: *r*=0.73; Table 3) [85]. The Center for Epidemiological Studies Depression Scale and BDI have also been shown to be highly correlated (*r*=0.84, *P*<.001) [86]. Patient-based outcome measures such as PHQ-9 and BDI have the benefit of being conducted outside the clinic, target very specific symptoms, exclude clinician bias, and facilitate the doctor-patient communication. However, they have some drawbacks such as a biased response depending on the recipient and a lack of meaningful interpretation of the changes to the outcome value [87].

As previously mentioned, we have chosen to include a broad definition of mood-based assessments in this review. However, a limitation is that some of them are questionable in the assessment of mood and depression. For instance, studies assessing "happiness," "well-being," and "quality of life" have been excluded in this review [29-33], even though it has been shown that happiness scores correlated moderately with depression, measured using BDI (*r*=−0.57, *P*<.001) [88].

The heterogeneity of the included studies also limits implementations in future studies. Faurholt-Jepsen et al [6] presented a new feature *calls missed*, which is statistically significantly correlated with HDRS-17 (beta=0.05, *P*=.006). The result was presented in 2016, but not replicated in any of the later studies, such as the comprehensive study on phone records with 532 subjects [44].

Absolute Valued Correlations

Several research groups chose to present their correlation results in absolute values [9,49,89]. This is a problem because the directionality of the correlation is lost, and the only information left is a measure of the strength of the relation. Canzian & Musolesi [9] clearly visualized this problem in several histogram plots representing each subject correlation values; these plots almost resemble a normal distribution around zero, but with a tail toward one of the directions. Raw correlation values were

provided when requested from 1 of 3 studies [9]. The other 2 commented on their choice of reporting absolute values of the correlation:

> *We observed very different behaviors among users, having in some cases positive correlations, in others, negative ones and in others no correlation at all [89].*

However, as Figures 2 and 3 show, there are several consistent correlations between features and mood assessments. Therefore, because this systematic review has revealed several features with common correlations across multiple studies, we hope to encourage future studies to present raw correlation values. This will make cross-study comparisons more valid. Further discussion on the use of absolute correlation values can be found elsewhere [90].

Future Directions

The analysis provided in this paper has shown that it is time consuming and difficult to compare and analyze data across studies due to a high level of heterogeneity. To provide more systematic and automatic analyses, a significant degree of standardization is needed in three areas:

1. Standardized data collection and feature extraction. The way that physical activity, social activity, and mobility features based on accelerometer and GPS data are extracted should be standardized across studies. For example, the feature *location entropy* seems like a promising feature and could be collected and calculated consistently across studies.
2. Standardized mood assessment tools. The review revealed that a wide range of clinical (n=11) and nonclinical (n=9) mood rating scales were used. This makes it hard to compare correlations across studies when such different scales are used. We suggest that future studies include a clinician-based rating scale of severity of depression such as the HDRS as well as a self-reported questionnaire of depression such as the PHQ-9 or the BDI-21.
3. Standardized statistical correlation methodology. The reviewed papers applied more than 11 different methods for correlation values, with different time windows. We suggest that raw correlation values are presented in addition to associations adjusted for relevant demographic variables, including sex and age, and clinical variables, such as BMI.

We also invite future systematic reviews to focus on classification models. They include accuracy measures and weightings that assist in the understanding of the individual objective features to classify mood and can investigate nonlinear interactions between multiple features and mood scores. As an example, Muaremi et al [66] used microphone features to classify mood; they achieved an F1 accuracy of 82% and discovered *speaking time* as the best-performing feature. By expanding to include GPS and accelerometer-related features, Abdullah et al [53] achieved an F1 accuracy of 85.5%, with the GPS feature *distance* achieving largest weighting. A Naïve Bayes Classifier, to predict mood based on a combination of location features, achieved an accuracy of 81.7% [61].

In our search, we came across several studies with sensor systems that are not currently fully mobile. This includes electroencephalogram (EEG) systems [91-93]. For instance, Li et al [93] achieved a 99.1% accuracy discriminating depressed and nondepressed participants based on EEG. Other systems monitoring body temperature [94], saliva [95], autonomic nerve balance [96], and facial muscle activities [97] could also be relevant. However, because these sensor modalities are not mobile or wearable to any great extent, they were excluded. These sensor modalities could, however, potentially be included in a ubiquitous mobile system for mood disorders in the future.

Conclusions

Mobile and wearable devices provide a unique platform for continuous collection of behavioral data from patients in real-time and within naturalistic settings. Many researchers have used this to investigate the relationship between behavior and mood disorder symptoms, as recorded by mobile or other wearable devices. In this systematic review, we identified a total of 46 eligible papers of such studies, of which 26 involved clinical samples.

We found 7 feature categories (Table 3) that were investigated across the studies. Subject-based and device interaction features represented the largest percentage of statistically significant relationships. In a detailed analysis of the 85 objective features that were identified, we were able to find strong consistencies between several behavioral features across the studies. For example, in the nonclinical sample, there was a consistent positive correlation between the features *home stay* and mobile phone *screen active duration* with mood symptoms (eg, more time at home and longer phone usage indicated a more depressed mood). Furthermore, several behavioral features had a coherent negative correlation with mood symptoms, including amount of *vigorous activity*, *location variance*, and *distance* moved. In the clinical samples, mobile phone *screen active duration* was replicated as a constant positive correlating feature together with *incoming call frequency* and *duration*. Similarly, a coherent negative correlation was found, including the amount of visible *GSM cell towers* (reflecting mobility), *SMS text messages received*, and *outgoing call frequency* and *duration*.

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Conflicts of Interest

LVK has within the preceding 3 years been a consultant for Sunovion. JEB is a shareholder in Monsenso ApS and has been a consultant for Lundbeck A/S. Other authors report no financial activities.

Multimedia Appendix 1

Search string used in all the database searches.

[PDF File (Adobe PDF File), 48KB - mhealth_v6i8e165_app1.pdf]

Multimedia Appendix 2

Extended information of the included study for the nonclinical samples.

[PDF File (Adobe PDF File), 57KB - mhealth_v6i8e165_app2.pdf]

Multimedia Appendix 3

The reported results between the measured objective feature and the outcome measure for the nonclinical sample.

[PDF File (Adobe PDF File), 66KB - mhealth_v6i8e165_app3.pdf]

Multimedia Appendix 4

Extended information of the included study for the clinical sample.

[PDF File (Adobe PDF File), 61KB - mhealth_v6i8e165_app4.pdf]

Multimedia Appendix 5

The reported results between the measured objective feature and the outcome measure for studies with a medical diagnose of either Unipolar Disorder (UD) or Bipolar Disorder (BD).

[PDF File (Adobe PDF File), 72KB - mhealth_v6i8e165_app5.pdf]

Multimedia Appendix 6

Features collected from at least two studies using clinical samples with Bipolar disorder only. The x-axis (wD) represents a weighted directionality of the correlation between the feature and mood symptoms. Positive values represent a larger depressive score and vice versa. The y-axis represents the logarithm of the total number of participants across all studies for this feature. The size of each pie chart represents the number of studies that recorded the feature, while the green, red, and grey areas represent statistically significant, statistically nonsignificant correlations, and missing statistical significance respectively.

[PNG File, 62KB - mhealth_v6i8e165_app6.png]

Multimedia Appendix 7

Features collected from at least two studies using clinical and nonclinical samples of participants. The x-axis (wD) represents a weighted directionality of the correlation between the feature and mood symptoms. Positive values represent a larger depressive score and vice versa. The y-axis represents the logarithm of the total number of participants across all studies for this feature. The size of each pie chart represents the number of studies that recorded the feature, while the green, red, and grey areas represent statistically significant, statistically nonsignificant correlations, and missing statistical significance respectively.

[PNG File, 128KB - mhealth_v6i8e165_app7.png]

Multimedia Appendix 8

Table of the 46 included studies showing the feature category that they report on.

[PDF File (Adobe PDF File), 56KB - mhealth_v6i8e165_app8.pdf]

Multimedia Appendix 9

Graphical linkage showing which sensor types are used within the seven feature categories.

[PNG File, 47KB - mhealth_v6i8e165_app9.png]

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Abbreviations

BD: bipolar disorder
BDI: Becks depression inventory
BMI: body mass index
CBT: cognitive behavioral therapy
EEG: electroencephalogram
GPS: global positioning system
HDRS: Hamilton Depression Rating Scale
MONARCA: MONitoring, treAtment and pRediCtion of bipolAr Disorder Episodes
PHQ: Patient Health Questionnaire
PICO: Patient problem Intervention, Comparison, and Outcome
SMS: short message service
UD: unipolar disorder

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Original Paper

Comparing the Data Quality of Global Positioning System Devices and Mobile Phones for Assessing Relationships Between Place, Mobility, and Health: Field Study

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Abstract

Background: Mobile devices are increasingly used to collect location-based information from individuals about their physical activities, dietary intake, environmental exposures, and mental well-being. Such research, which typically uses wearable devices or mobile phones to track location, benefits from the growing availability of fine-grained data regarding human mobility. However, little is known about the comparative geospatial accuracy of such devices.

Objective: In this study, we compared the data quality of location information collected from two mobile devices that determine location in different ways—a global positioning system (GPS) watch and a mobile phone with Google's Location History feature enabled.

Methods: A total of 21 chronically ill participants carried both devices, which generated digital traces of locations, for 28 days. A mobile phone–based brief ecological momentary assessment (EMA) survey asked participants to manually report their location at 4 random times throughout each day. Participants also took part in qualitative interviews and completed surveys twice during the study period in which they reviewed recent mobile phone and watch trace data to compare the devices' trace data with their memory of their activities on those days. Trace data from the devices were compared on the basis of (1) missing data days, (2) reasons for missing data, (3) distance between the route data collected for matching day and the associated EMA survey locations, and (4) activity space total area and density surfaces.

Results: The watch resulted in a much higher proportion of missing data days (P<.001), with missing data explained by technical differences between the devices as well as participant behaviors. The mobile phone was significantly more accurate in detecting home locations (P=.004) and marginally more accurate (P=.07) for all types of locations combined. The watch data resulted in a smaller activity space area and more accurately recorded outdoor travel and recreation.

Conclusions: The most suitable mobile device for location-based health research depends on the particular study objectives. Furthermore, data generated from mobile devices, such as GPS phones and smartwatches, require careful analysis to ensure quality and completeness. Studies that seek precise measurement of outdoor activity and travel, such as measuring outdoor physical activity or exposure to localized environmental hazards, would benefit from the use of GPS devices. Conversely, studies that aim

to account for time within buildings at home or work, or those that document visits to particular places (such as supermarkets, medical facilities, or fast food restaurants), would benefit from the greater precision demonstrated by the mobile phone in recording indoor activities.

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KEYWORDS

urban population; spatial behavior; mobile phone; environment and public health; data accuracy

Introduction

Background

Significant relationships between health and the places in which we live and work are now widely acknowledged, with associations having been found for health behaviors ranging from diet to physical activity to the use of health care services [1,2]. In addition, location-based data acquired from mobile devices can be used to assess physical activity [3], exposures to hazardous substances [4], and symptoms of mental health conditions such as depression [5-8]. Accordingly, there is growing interest in the use of location-tracking devices as a data collection tool for health research.

Researchers investigating relationships between health, place, and mobility require location-tracking devices, which are both acceptable to users and accurate. To date, a variety of pilot and feasibility studies have examined user acceptance of devices such as wearable activity trackers [9,10], dedicated global positioning system (GPS) devices [11], and GPS-enabled mobile phones [12,13]. Although this research generally shows reasonable acceptance among varied user groups, there remain gaps in understanding the spatial accuracy of each of these devices, particularly those that are available on the consumer market and thus could facilitate population-level research. Therefore, building on prior health informatics research examining the accuracy of other types of devices used in research [14,15], we compared the accuracy of two widely available location-tracking devices that determine location using two different technical approaches (described further below).

One of the key approaches adopted in health research that uses location-tracking data focuses on characterizing the spaces in which participants typically spend their time; this is typically used to overcome the limitations of determining participant location solely based on the place of residence [16]. This is important as recent research has shown that environmental characteristics of such nonresidential places are associated with health-related outcomes, such as self-rated health [17] and dietary intake [18-20]. Therefore, a growing number of studies on health, place, and mobility are using an analytical approach that involves constructing an *activity space* for each participant (eg, [21-24]). This concept, proposed by space-time geographers, describes the portion of the environment actually used by an individual to fulfill activities and travel between locations [25-27].

Activity space construction requires detailed spatial information from participants, ideally records of travel through the environment collected in real time. Accordingly, researchers have used GPS devices to study the relationship between the environment and physical activity [28] and food environments and eating [29]. However, GPS devices pose a set of well-known research challenges: commercially available devices can have limited battery life and nonintuitive interfaces, are often physically bulky, and lose satellite signals indoors or in dense urban environments [30-32]. Mobile phones offer one potential alternative to dedicated GPS devices; they provide integrated location services through a combination of GPS, cellular tower triangulation, and geolocation of Wi-Fi networks. As mobile phone location information is acquired through multiple methods, these devices work in a variety of physical contexts and may result in more accurate data about activities taking place within and close to buildings. In addition, mobile phones may have other benefits such as greater acceptability by study participants which, in turn, may reduce data loss [13]. Although dedicated apps can collect location data, Android devices can record location information automatically via the integrated Google Location History feature, making the collection and analysis of mobility data feasible at the population level. Tracking studies such as this one raise important ethical concerns, such as those around the privacy of the data collected [33]. As described further below, we took typical steps to obtain informed consent and protect the privacy of the data collected. Although privacy is not the primary focus of this study, we briefly comment on this issue in the Discussion.

Objectives

In this study, we evaluated the quality of location data generated from mobile phones and a wearable GPS device, providing a novel direct comparison. The three specific comparative aspects of the mobile devices that we examined in this study were (1) data loss experienced, (2) accuracy of the gathered data, and (3) activity spaces generated using the data. We focused on people with diabetes, hypertension, and chronic kidney disease as spatially sensitive health behaviors such as physical activity, diet, medication, and health care appointment adherence are important drivers of outcomes in people with these conditions (eg, [34-36]).

Methods

Participant Recruitment

This study was conducted as part of a larger research project focused on *big data* methods for characterizing the relationship between place of residence and health, with a focus on new data sources such as social media [37,38] and location tracking using mobile devices. This study focused on diabetes, hypertension, and kidney disease, as these conditions often co-occur [39] and have outcomes that are influenced by health behaviors such as eating, physical activity, and treatment adherence [40-42].

Moreover, prior research has shown that these behaviors are related to neighborhood contextual features such as the food environment, physical activity resources, and local health care services [43-47]. Accordingly, location-tracking devices hold particular promise for studying the relationship between place, health behavior, and health outcomes in this patient group. Participants were recruited through a university portal for research participants at the University of Michigan. Eligible participants were 18 years or older and self-reported at least one of these conditions.

Device Deployment

Participants were provided with two consumer-oriented location-tracking mobile devices to carry for 28 days, although some kept the devices for longer based on our ability to schedule a final interview with them. We selected two mobile devices for this study—a GPS-enabled device and a mobile phone with location tracking enabled. The GPS device used was a Garmin fēnix 2 GPS Watch (henceforth referred to as the watch), whereas the mobile phone was a Samsung Galaxy S5 (henceforth referred to as the phone). As the phone is an Android device, it has an integrated Google Location History feature that was enabled to track locations as part of the study. These devices were chosen to represent consumer-oriented technologies that are widely available at reasonable price-points (US $399 for the watch and US $650 for the mobile phone without a contract) and that use the two prevalent methods of determining user location: GPS satellites as opposed to mobile phones' use of a combination of cellular towers, Wi-Fi networks, and GPS triangulation.

Participants were asked to keep the devices switched on for at least 8 hours daily, ideally from the time they awoke until they went to bed. Each device was enabled to capture digital traces of participant location. The watch was set to the *Smart* default-sampling rate, which records data every 4 to 7 seconds. According to product forums, the sampling rate for Location History is variable and depends on factors such as the strength of available signals, battery strength, and whether the Google Maps app is running in the foreground or background. They were asked to keep the devices charged and synchronize data from the watch to the mobile phone every day. Participants were trained in the use of the devices and were given instruction cards as a follow-up reminder. They were also given a phone number for the technical support provided by the research team, and the devices were returned at the end of the study. Participants earned US $3.57 for each day of data they uploaded, up to a maximum of US $100 for the full 28 days. The study received ethical approval from the Health Sciences and Behavioral Sciences Institutional Review Board at the University of Michigan (HUM00098270).

Data Collection Methods

In addition to the spatial information, a brief ecological momentary assessment (EMA) survey configured using the Personal Analytics Companion (PACO) software for Android phones presented two free-text survey questions to participants at 4 random times in a given day: "where are you?" and "what are you doing?" and prompted participants to take a photograph of their location using the mobile phone. Participants also took part in qualitative interviews and completed surveys twice during the study period—once after the first 14 days and then at the end of the 28-day period. In these two interviews, participants were asked about their experience using the devices and to review the phone and watch trace data on Web-based platforms designed for this purpose (Google Maps and the online website, Garmin Connect) for the 2-4 most recent days (the range depended on whether data were missing for recent days) and to compare the data with their memory of their activities on those days. Data were collected from summer to fall of 2015.

Analysis Methods

The analyses presented here rely on three data sources: (1) digital location information logged by each device, (2) results of the brief EMA survey that inquired about participants' locations and activities, and (3) interview results concerning reasons for data loss. The phone data resulted in a line representing travel routes, with selected points recorded along the route corresponding to destinations. On the other hand, the watch data consisted of a route and regular waypoints. Due to this difference, only the route (or trace) information from each device was used in this analysis. Points contained in the Keyhole Markup Language files that are exported from the Google Location History service are named according to the assumed mode of travel (eg, "Walking," "Driving") or specific destination (eg, "Olson Park") assigned to the user by Google's software. In addition, additional information such as raw data can be viewed, but not downloaded, on the Location History website. Either may be useful for researchers. Without waypoints for the phone data, standard smoothing techniques could not be applied to the phone data.

Missing Data Analysis

Although participants were asked to carry both devices for 28 days, the number of days in which they acquired 8 hours of data varied. Data completeness was evaluated by calculating the proportion of missing data days, defined as the number of days in which the participant did not collect 8 hours of data divided by the participant's number of days in the study. As an additional measure of the amount of data collected, the number of days where any spatial information was collected was also reported.

The interview data containing user evaluations of the accuracy of the data contained user reflections on reasons for missing or incorrect data, which were coded using structural coding [48]. These coded data were compared with trace data for each participant for whom there was missing data, to identify the reasons for the specific missing data episodes. These reasons were then grouped into descriptive categories [48].

Geographic Information System Data Procedures

As described, the EMA surveys included a free-text field for the participants' current location. Among the survey responses, 30.4% could be converted into a street address, including the terms "home" and "work," or another identifiable location. Other locations included a park or campsite, business, theater, home of friend, health care organization, library, church, and gym. In other cases, respondents either provided no response to the other surveys or responses which could not be mapped.

This resulted in 1375 geocoded destination points. Among these, 461 were collected on days in which spatial information was available from both the devices. The distance between the route data collected for that day and the associated survey locations was then computed using the spatial join tool in ArcGIS Desktop 10.3.1. The spatial join function was run using the "closest" option, which records the nearest location feature from either the phone or watch data to the point mapped from the PACO survey responses. The mean distances were then computed for each location category and for all locations combined.

Activity Space Analysis

Multiple methods have been proposed for converting raw spatial information into a representation of an activity space [22], such as the use of Census Tracts [23,49], the characteristics of known destinations [24], or constructing standard deviational ellipses from location information [50,51]. Tailored approaches include *travel time polygons* describing an area of potential travel, *road network buffers* of routes to regular destinations, or daily path areas constructed from actual routes taken [18,52]. We selected the daily path method because it utilizes the detailed route information collected from the devices and results in a representation of actual (vs potential) travel during the study period.

Therefore, an activity space was constructed using the daily path area method, which buffers digital location traces with buffer distance depending on the geographic context and study aims [18,22]. The activity space analysis was conducted for comparison days only, where data were available from both devices. The average number of days per participant was 19.2, with a range of 5 to 33. A buffer was applied to the data for those days. We used 400 m as the buffer distance because it can be considered as the minimum walking distance to reach a destination in an urban environment [53,54]. The buffer was then clipped to the participant's home county to exclude nonroutine activities such as vacation travel. The total area of the resulting polygon was then computed. No changes or corrections to either data sources were made for this analysis, except for the removal of one obviously errant line from participant 14's phone data, described further below.

In the activity space analyses, a *kernel density* function can be used to calculate a continuous surface from a set of known locations [55]. In a geographic information system, a kernel density function calculates a magnitude-per-unit area from a point or line feature using a kernel function to fit a smoothly tapered surface. The surface resulting from this analysis can be interpreted as a probability surface similar to that presented in the study by Downs et al [56]. We used this approach because unlike the buffering method, a kernel density function takes into account multiple traces in the same area, weighing them differently depending on the shape of the density function employed and the kernel density function bandwidth. In addition, unlike the buffer that delineates a specific area, the kernel density results in a continuous representation. As our purpose was to compare the data obtained from the 2 devices, the output of this analysis shows the difference between the density maps for each device. The method included the following steps: (1) clip the trace data to the participant's home county, (2) compute the kernel density with a search radius of 400 m, (3) rescale the values in the density surface resulting from the phone and watch data so that they total to 1, and (4) compute the difference between the density surfaces.

Results

Characteristics of Participants

As shown in Table 1 below, 57% (12/21) of participants were women, and the mean participant age was 52.4 (SD 11.36) years, with a range of 33 to 74. Majority of the participants (17/21, 81%) had a bachelor's degree or higher and just over half were employed. Two-thirds of the population were white and about one-third had another racial or ethnic identity. In this sample of chronically ill participants, 76% (16/21) had hypertension, 62% (13/21) had diabetes, and 19% (4/21) had chronic kidney disease.

Missing Data Analysis

As shown in Table 2, the watch resulted in a much higher proportion of missing data days, primarily because of a large number of days on which data were collected for less than 8 hours (Z=3.920, $P<.001$). However, considering all days with any amount of valid trace data, the phone resulted in only slightly more data than the watch ($t_{20}=0.460$, $P=.65$).

Interviews with the study participants revealed that the differences in missing data were explained by technical differences between the devices as well as participant behaviors. Explanations for these differences revealed in the interviews included the following: participants forgetting to initiate data collection at the beginning of the day on their GPS watch, the GPS watch not being able to locate satellites in certain buildings, removing the watch during activities participants perceived to be unsafe for the watch (eg, sports and kitchen work), and troubles syncing the watch data to the mobile phone so that it could be recorded.

Spatial Accuracy Analysis

The mean distance from the points obtained from self-reported participant location based on the EMA survey data and the spatial data from each device was lower for the phone than for the watch overall and for each of the four categories considered (Table 3). The destination category with the smallest distance was home, followed by business. The two devices yielded marginally significantly different mean distances for all points ($P=.07$). When stratified by specific categories, the only statistically significant difference between the two devices has been found for home locations ($P=.004$).

Activity Space Analysis

The resulting daily path area from the buffer analysis from both devices was much larger for the phone than for the watch. As shown in Table 4, the average activity space for the phone was 18,084.74 ha, whereas it was 10,494.57 ha for the watch. A two-sample *t* test with unequal variances found the difference is statistically significant at the 99% level ($t_{20}=3.164$, $P=.003$). On average, the watch showed 42.0% fewer hectares in participants' activity spaces.

Table 1. Participant demographics and technology ownership (N=21).

Characteristics	n (%)
Gender	
Female	12 (57)
Male	9 (43)
Race[a]	
Black or African American	5 (24)
White or European American	17 (81)
Native American or Native Hawaiian or Pacific Islander	1 (5)
Other	1 (5)
Ethnicity	
Hispanic or Latino	3 (14)
Non-Hispanic or Latino	18 (86)
Education	
Some college	3 (14)
Associate's degree	1 (5)
Bachelor's degree	6 (29)
Master's degree or PhD	8 (38)
Professional degree (eg, JD and MD)	3 (14)
Employment[a]	
Full-time employment (30+ hours per week)	8 (38)
Part-time employment (<30 hours per week)	3 (14)
Student	2 (9)
Unemployed	4 (19)
Disabled	3 (14)
Retired	4 (19)
Health conditions[a]	
Hypertension	16 (76)
Diabetes	13 (62)
Chronic kidney disease	4 (19)

[a]More than one response possible.

Table 2. Missing data analysis results.

Measure	Phone	Watch	Z value	*t* value (*df*)	*P* value
Proportion of missing data days (<8 hours)	0.03	0.54	3.920	N/A[a]	<.001
Mean valid data days	23.5	22.2	N/A	0.460 (20)	.65

[a]N/A: not applicable.

Table 3. Spatial accuracy analysis.

Categories	Phone distance (m), mean (SD)	Watch distance (m), mean (SD)	Comparison		
			N	*t* value (*df*)	*P* value
Home	24.6 (38.6)	106.2 (576.9)	352	−2.649 (351)	.004
Work	2318.0 (2982.1)	2831.9 (3821.7)	81	−0.954 (80)	.17
Business	694.3 (1484.5)	804.2 (1549.4)	19	−0.315 (18)	.38
Other	360.4 (493.4)	1240.7 (2778.8)	9	−0.936 (8)	.19
All	461.7 (1547.1)	636.0 (2023.5)	461	−1.470 (460)	.07

Table 4. Activity space comparison from travel route buffer.

Participant ID	Comparison days	Phone area (ha[a])	Watch area (ha)	Difference (ha)	Difference (%)
S11[b]	20	26,472	5576	20,895.61	−78.9
S14	12	32,454	9426	23,027.38	−71.0
S7	11	9583	3780	5803.16	−60.6
S25	24	28,341	12,192	16,148.12	−57.0
S6	4	8153	3570	4582.34	−56.2
S18	32	29,253	14,054	15,199.08	−52.0
S15	18	30,310	16,236	14,073.42	−46.4
S4	11	19,971	10,858	9113.31	−45.6
S23	21	26,855	15,256	11,598.97	−43.2
S3	14	10,811	6644	4166.75	−38.5
S22	33	17,990	11,106	6883.89	−38.3
S5	17	15,652	10,105	5547.28	−35.4
S13	21	9239	5974	3264.86	−35.3
S12	29	29,726	22,346	7379.34	−24.8
S2	20	14,959	11,341	3618.06	−24.2
S21	17	5937	4922	1014.76	−17.1
S26	29	23,364	19,414	3949.83	−16.9
S24	32	11,154	9820	1334.41	−12.0
S17	6	20,494	19,035	1458.29	−7.1
S27	7	3472	3245	227.60	−6.6
S9	13	5592	5485	107.14	−1.9
Mean	—	18,084.74	10,494.57	7590.17	−42.0

[a]1 ha=10,000 m^2.

[b]S: subject.

Illustrative examples of this analysis are shown in the first two columns of Figure 1 for participants with extreme (S14 and S23) and minor differences (S26 and S9) in daily paths. To facilitate visual comparison at the same map extent, the 3 participants from outside of Washtenaw County are excluded. This figure illustrates that the watch traces produced activity surfaces with travel closely following highway and street routes. The greater buffer areas produced by the phone are explained by two primary issues: the inclusion of activities in the phone data, which are missing from the watch data, and the phone's inaccurate representation of highway travel, which resulted in straight lines that artificially inflated the activity space size. The kernel density analysis was conducted to create a more nuanced representation of the differences between the patterns, which can better account for the many overlapping features. The result is shown in the third column of Figure 1, and areas where the phone data resulted in greater density than the watch are shown in green and the reverse pattern in purple. The map can be interpreted as visualizing areas where the participant is more likely to be only because of the choice of device.

Figure 1. Illustrative activity space data for 4 participants residing in Washtenaw County. The third column shows the difference between the density surfaces computed for the watch and phone data; higher watch density is shown in purple and higher phone density in green. Base map source: Esri [57].

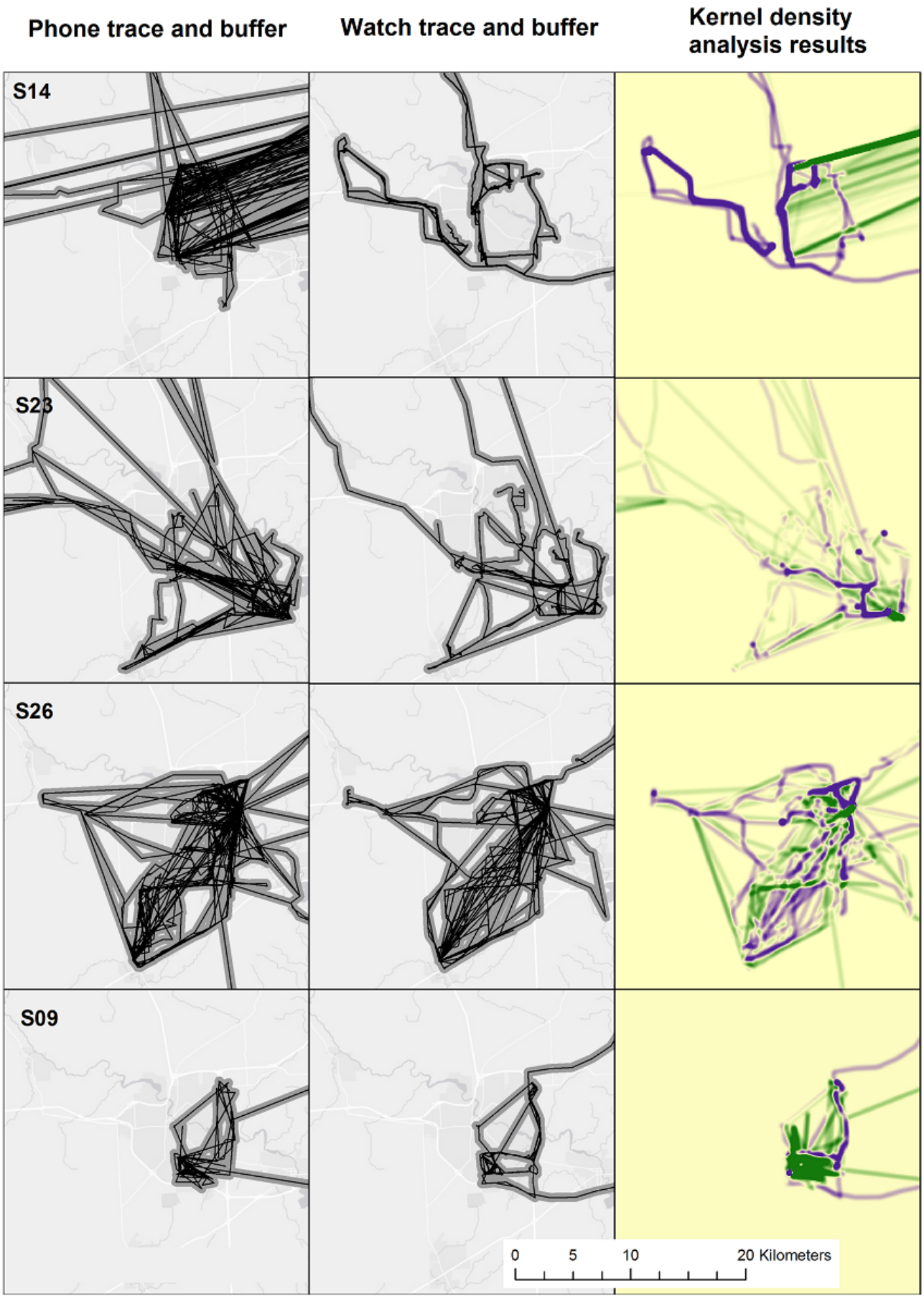
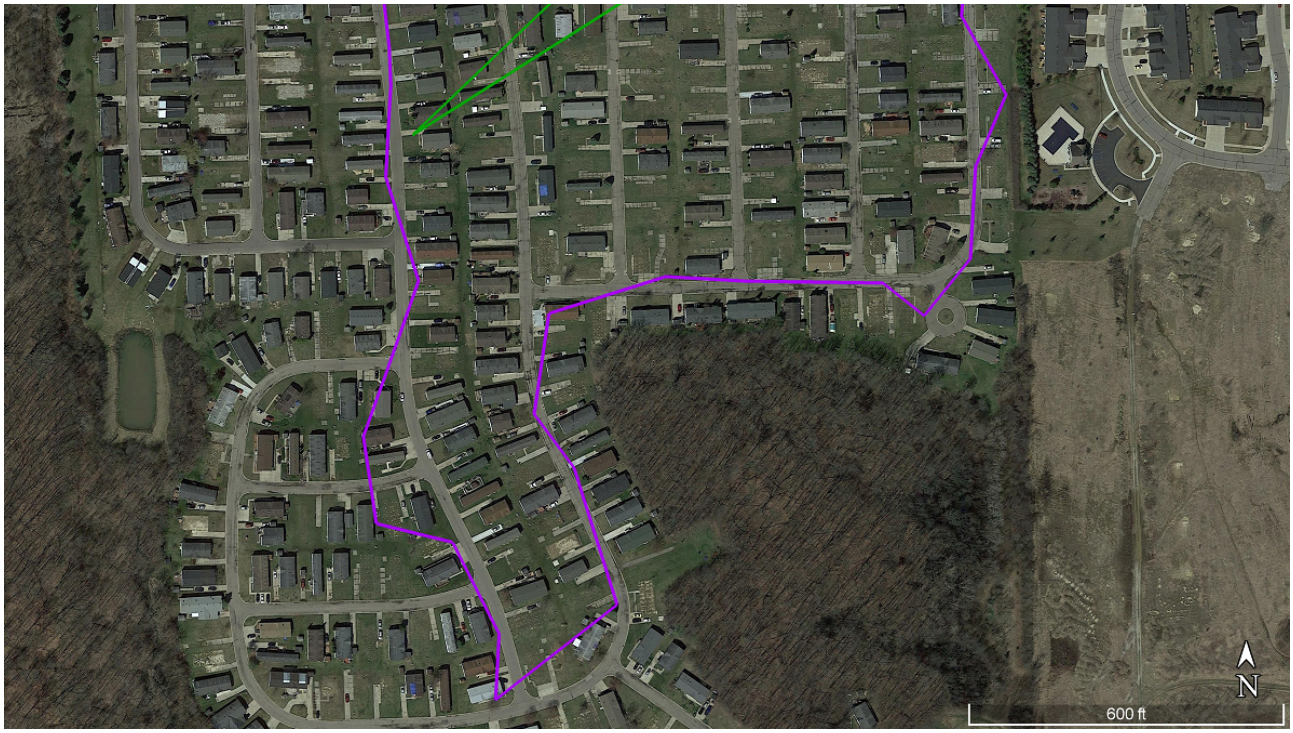


Figure 2. Trace data collected for participant S12 on one study day, illustrating greater spatial detail in watch data (purple) compared with phone data (green) for outdoor exercise (neighborhood walk). Source: Google Earth [58].



The spatial quality of information about outdoor activities, in particular, was higher for the watch than for the phone. For example, as shown in Figure 2, participant S12 described engaging in evening walks near his home, at least one of which was clearly recorded in the watch but not in the phone data.

Discussion

Principal Findings

Overall, the phone resulted in a lower proportion of missing data days. In addition, the phone data had a lower mean distance to the known location points and for each of the categories examined, although only the differences in distance to home was statistically significant. The activity space analysis reveals that the phone generated larger activity spaces than the watch. This was because of higher missing data for the watch and inaccurate recording of travel by the phone, which erroneously enlarged the activity space. The watch data resulted in much more accurate data when traveling outdoors, such as riding in an automobile or walking.

Comparisons With Prior Work

Our research showed that there were activities that were reflected in the phone data but not recorded by the GPS watch. As described in our related work [13], one factor contributing to this difference was user acceptance; as the phone is less obtrusive and it provided other benefits to the participants, they were more likely to carry it. In addition, the participants had difficulty in using the watch, particularly when syncing the device to store data for the study. Unlike the watch that must be synced daily, phone data were logged to a remote server automatically. Although using an alternative GPS device may reduce or eliminate some of these issues, other factors related to the GPS infrastructure, such as the delay in obtaining a satellite signal, would still hinder the widespread use of GPS devices for location tracking. Prior feasibility studies with GPS devices for location tracking in health have surfaced similar issues in use of such devices [32,59]. Moreover, previous work shows that GPS devices typically only function outdoors, where they can connect with multiple satellites, and perform best in places away from dense buildings [10,11].

The spatial accuracy analysis highlights one strength of the phone, which is the improved quality of the collected spatial information about locations in buildings, probably because of the phone's use of Wi-Fi signals to determine location. Future research could further investigate this issue for specific location categories. Although previous work has shown that a mobile phone–based app can generate accurate spatial data [21], this is the first study, to our knowledge, to empirically compare such devices with other prevailing technologies. Moreover, this study focused on a technology that is available on many mobile phones without requiring the downloading of additional software (Google Location History). The widespread adoption of this technology means that it holds special promise for population-level monitoring and surveillance.

Previous research on the accuracy of location-tracking devices has focused on comparing different types of GPS devices [30,31,60]. This is the first study, to our knowledge, that compares GPS technology with the now-ubiquitous forms of location tracking available in mobile phones. This permitted the identification of sources of error in mobile phone data, which are likely to be increasingly used in research because of their ubiquity.

Implications for Researchers

The main conclusion we draw from the study is that there are important trade-offs between the use of these two types of

devices in health research. Participants successfully collected more data with the phone, with less data loss. In addition, our analysis showed that the phone traces were closer to known destination points than the watch data. However, these benefits came with a significant trade-off, namely, the straight lines and inaccuracies for outdoor activities, described earlier for the phone data. As described earlier, a combination of user behaviors and technical issues explain these results.

Therefore, the suitability of each category of a device depends on the specific research question of a study. Studies that seek precise measurement of outdoor activity and travel, such as measuring outdoor physical activity, characterizing mental health symptoms, or exposure to localized environmental hazards, would benefit from the use of GPS devices. Conversely, studies in which the aim is to account for time within buildings at home or work, or document visits to particular places (such as supermarkets, medical facilities, or fast food restaurants), would benefit from the phone's demonstrated greater precision in recording indoor activities. For studies that only require the general location and duration of indoor activities, mobile phones may be a more practical data collection device than others that are available to collect this type of information [3]. Furthermore, the weaknesses of each device suggest steps that researchers should take in their research protocols to minimize the associated errors. Given the difficulty of syncing, alternative GPS devices that do not require this step may reduce data losses, if available.

As described, the phone data often included straight-line features that appear to connect points for which detailed locations were obtained by the device. We speculate these lines may be produced through a low data collection rate compared with GPS watches at those times. Consequently, the trace data sometimes included implausible travel routes, which leads us to conclude that the device may have less accurate data for outdoor activities, particularly those that involve travel. Researchers using similar phone data in the future should develop procedures for identifying and removing the straight lines from their datasets. Alternatively, researchers could benefit from the development of a tailored mobile phone app to log location data automatically; this would allow researchers greater control over the nature of the spatial data (such as specifying the desired data collection rate) and allow survey responses to be linked with locations. At the same time, this comes with trade-offs, as these apps will not be adopted at a population level like Google Location History, which could be used to gain new insights into mobility patterns at a large scale.

Locational Privacy

Although our participants did not express concerns about the privacy of their data, this was primarily because of the use of the data for research purposes, accompanied by our use of ID numbers [13]. Furthermore, in this paper, we included only large-scale maps of the results to minimize the risk of identification [61]. Nevertheless, in general, location tracking has important privacy implications [61]. We acknowledge that studies such as ours raise a variety of issues that, although did not arise here, deserve greater attention from researchers engaging in location tracking in health research studies [33]. These include special considerations for vulnerable populations and what should be done if evidence of harm or illegal activities is observed in participant data [33]. Finally, the paper provides the opportunity to comment on broader privacy issues, as we demonstrate the usefulness of the Google Location History data, which are passively collected for many millions of users. Although Google provides users with the ability to deactivate and delete location history, the sensitivity of the information raises important questions about how this information should be managed in ways that minimize the risk of harm to participants and protect their anonymity and confidentiality.

Study Limitations

Several limitations of this study should be kept in mind. First, the difficulties that participants faced in using the GPS watch may not persist with newer generations of wearable GPS technology; this may reduce discrepancies in missing data. Second, the straight-line errors concerning travel routes had a differential impact based on the method of characterizing activity space. The buffer methodology, which does not account for the frequency of trips in any particular area, was particularly sensitive to this issue. However, the kernel density analysis somewhat reduced the effect of these features, particularly for participants who collected the most data. Finally, this study was also conducted with a small sample of relatively educated adults in an urban environment, who were recruited through online means. Therefore, user-related data accuracy difficulties may be even greater in populations with less education and technology experience. The generalizability of these results to areas with lower Wi-Fi or cellular tower density (eg, rural areas) is therefore unclear. Finally, although we are unaware of major changes to the technologies here, future improvements to GPS receivers or mobile phone location services may affect the future generalizability of these results.

Conclusions

Health research increasingly uses fine-grained spatial data gathered from mobile devices to evaluate relationships between health, place, and mobility. Such research, which may be conducted with wearable GPS devices or mobile phones, requires accurate spatial data for analysis. This study reports a direct comparison of the spatial information collected from each of such devices during a field study involving 21 participants. Mobile phones resulted in less missing data, spatial data closer to known destination points, and larger activity spaces. In contrast, the mobile phone data resulted in the recording of outdoor travel inaccurately, including physical activities such as walking. Therefore, the best device for health research depends on the particular study objectives, and data generated from both devices require careful analysis to ensure quality and completeness.

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Authors' Contributions

TV, XY, and JH coordinated the administration of the field trial. XY, TV, and RG processed the collected data. JH and TV conducted interviews. RG and TV conducted the missing data analysis, RG and Russell Pildes conducted spatial accuracy analysis, and RG conducted the activity space analysis. RG led writing the manuscript, with major contributions from TV, VGVV, and JH. VJB, DMR, PC, and ING-L provided input on the study methods and provided substantive revisions to the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

EMA: ecological momentary assessment
GPS: global positioning system
PACO: Personal Analysis Companion

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Review

Accuracy of Fitbit Devices: Systematic Review and Narrative Syntheses of Quantitative Data

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Abstract

Background: Although designed as a consumer product to help motivate individuals to be physically active, Fitbit activity trackers are becoming increasingly popular as measurement tools in physical activity and health promotion research and are also commonly used to inform health care decisions.

Objective: The objective of this review was to systematically evaluate and report measurement accuracy for Fitbit activity trackers in controlled and free-living settings.

Methods: We conducted electronic searches using PubMed, EMBASE, CINAHL, and SPORTDiscus databases with a supplementary Google Scholar search. We considered original research published in English comparing Fitbit versus a reference- or research-standard criterion in healthy adults and those living with any health condition or disability. We assessed risk of bias using a modification of the Consensus-Based Standards for the Selection of Health Status Measurement Instruments. We explored measurement accuracy for steps, energy expenditure, sleep, time in activity, and distance using group percentage differences as the common rubric for error comparisons. We conducted descriptive analyses for frequency of accuracy comparisons within a ±3% error in controlled and ±10% error in free-living settings and assessed for potential bias of over- or underestimation. We secondarily explored how variations in body placement, ambulation speed, or type of activity influenced accuracy.

Results: We included 67 studies. Consistent evidence indicated that Fitbit devices were likely to meet acceptable accuracy for step count approximately half the time, with a tendency to underestimate steps in controlled testing and overestimate steps in free-living settings. Findings also suggested a greater tendency to provide accurate measures for steps during normal or self-paced walking with torso placement, during jogging with wrist placement, and during slow or very slow walking with ankle placement in adults with no mobility limitations. Consistent evidence indicated that Fitbit devices were unlikely to provide accurate measures for energy expenditure in any testing condition. Evidence from a few studies also suggested that, compared with research-grade accelerometers, Fitbit devices may provide similar measures for time in bed and time sleeping, while likely markedly overestimating time spent in higher-intensity activities and underestimating distance during faster-paced ambulation. However, further accuracy studies are warranted. Our point estimations for mean or median percentage error gave equal weighting to all accuracy comparisons, possibly misrepresenting the true point estimate for measurement bias for some of the testing conditions we examined.

Conclusions: Other than for measures of steps in adults with no limitations in mobility, discretion should be used when considering the use of Fitbit devices as an outcome measurement tool in research or to inform health care decisions, as there are seemingly a limited number of situations where the device is likely to provide accurate measurement.

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KEYWORDS

wearable activity tracker; accuracy; Fitbit; steps; sleep; energy expenditure; distance; time in activity; systematic review; fitness trackers; data accuracy; energy metabolism; review

Introduction

Commercially available wearable activity trackers have grown rapidly in popularity since their introduction just over a decade ago [1]. While the technologies behind them are quickly and continuously changing, in general they are small devices that are commonly worn on the wrist or attached to clothing. They aim to provide the user with real-time feedback on various aspects of daily activities, such as number of steps taken, energy expenditure, time spent asleep, and time spent in different levels of activity. They also typically provide personal goal-setting options, summary data, and visualizations through synchronization with interactive mobile- and computer-based apps, as well as opportunities to connect to social media and other health and fitness apps. These devices are aimed primarily at health- and fitness-conscious consumers and are designed to motivate and offer support to individuals to self-monitor and increase their daily physical activity.

Fitbit (Fitbit Inc, San Francisco, CA, USA), one of the most popular commercial wearable activity trackers, holds approximately 20% of the market share for wearable tracking devices, with more than 63 million devices sold worldwide in the last 10 years [2]. In 2017, the company sold 15 million devices and had 25 million active users [2]. The Classic model was introduced in 2009 as a clip-on device to be worn on the torso; new models of clip-on devices became commercially available in 2011 with the introduction of the Ultra, Zip, and One models. In 2013, Fitbit introduced a line of wristband activity trackers: Force, Flex (2), Charge (2, HR), and Alta (HR).

Fitbit devices use a microelectronic triaxial accelerometer to capture body motion in 3-dimensional space, with these motion data analyzed using proprietary algorithms to identify patterns of motion to identify daily steps taken, energy expenditure, sleep, distance covered, and time spent in different intensity of activities. Although designed as a consumer product to help motivate individuals to be physically active, Fitbit devices are becoming increasingly popular as measurement tools in physical activity and health promotion research and are also commonly used to inform patient–health professional interactions [3-7]. Between 2011 and 2017, a total of 171 clinical trials registered at ClinicalTrials.gov used Fitbit as an outcome measurement tool; 97 of those were registered in the last 3 years [8]. Most of the registered trials identified number of steps taken as the outcome of interest, followed, in order, by time in activity, sleep, energy expenditure, and distance covered.

Fitbit devices, and particularly the wrist-worn devices, have demonstrated dependability, durability, and acceptability [9,10]. A 2015 systematic review by Evenson et al examined the "validity and reliability of...[Fitbit devices] and their ability to estimate steps, distance, physical activity, energy expenditure, and sleep" [11]. They concluded that Fitbit devices were moderately associated with criterion reference devices for measures of steps, sleep, and distance, with associations varying from poor to moderate with criterion reference devices for measures of energy expenditure and time in activity [11]. They also found that Fitbit had a high interdevice reliability for all outcome measures. In addition, the review provided some data for measurement accuracy; however, it did not comprehensively examine device measurement accuracy or study quality. Measurement accuracy, or how close to "true" the measured value is, is an important consideration, as Fitbit devices are being used as an outcome measurement tool in research and to inform health care decisions [12,13]. Therefore, the purpose of this review was to systematically examine and report the accuracy of measures derived from the triaxial accelerometry data in Fitbit devices—that is, measures of steps, energy expenditure, sleep, distance, and time in activity—when used by adults in controlled and free-living settings.

Methods

Search Strategy

We conducted an electronic literature search of the PubMed, EMBASE, CINAHL, and SPORTDiscus databases, with an additional supplementary search conducted via Google Scholar. Keywords within each database search included variations on the terms Fitbit AND Accuracy (accura*) OR Validity / Validation (valid*) OR Comparison / Comparative (compar*) OR Relationship (relation*) OR Association (associa*) Or Equivalence (equival*) OR Agreement (Multimedia Appendix 1). We applied a language filter to limit results to English and a date limitation from January 1, 2011 (Fitbit devices were not commercially available prior to this date) to October 31, 2017 (the end date for our search). We applied no further search limits or filters. We also hand searched reference lists of the included studies for potentially eligible studies.

Study Selection and Eligibility Criteria

We screened all citations, removed duplicates, and assessed the remaining titles and abstracts for potential eligibility. All potentially eligible citations were retrieved for full-text review by 2 independent reviewers (JYY, JG) with disagreements resolved through consensus. Initial inclusion criteria were original research studies, published in a full, short, or letter format in English in peer-reviewed journals. We verified journal peer-review status using a Web-based serial directory database search (ULRICHSWEB, ProQuest LLC, Ann Arbor, MI, USA). The studies also had to include or separately report data for adults (≥18 years old) and examine measurement accuracy for one or more of the following outcome domains: steps, energy expenditure, time in activity, distance, or sleep. Studies could be conducted in any controlled-testing (ie, using a standardized testing protocol) or free-living (ie, during usual daily activity)

setting and could include individuals living with any health, disease, or mobility or functional status. Studies examining accuracy in controlled settings had to compare a Fitbit measure against a predefined reference-standard criterion measure, whereas studies conducted in free-living settings had to compare the Fitbit measure against a predefined research-standard criterion measure (Multimedia Appendix 2). To be included in the final review, studies had to have extractable data for one or more of the following accuracy analyses: group mean or percentage differences, mean or median absolute percentage error (MAPE), or level-of-agreement analyses [14]. We did not contact authors if these data were not reported in the publication. We excluded studies (or comparisons) if the accuracy evaluations were conducted on 10 or fewer participants. We also excluded studies (or comparisons) if they examined heart rate accuracy, as heart rate measurement is not derived from accelerometry data.

Data Extraction

Data were extracted and checked for accuracy by a second independent reviewer (JYY, JG, AME, LMF) with discrepancies resolved through discussion and consensus. Data extracted included study, participant, and Fitbit device characteristics, as well as details about the study setting, outcomes examined, and reference criterion used (Multimedia Appendix 2). Group mean or percentage difference values for the Fitbit device and criterion groups were extracted for all accuracy comparisons reported in each study. If group percentage difference was not reported, we calculated group percentage error ([$Fitbit_{mean}$–$Criterion_{mean}$] / $Criterion_{mean}$×100) to allow for a common unit of measure (rubric) for comparison of accuracy measures within and across outcome domains (Multimedia Appendix 3). We also extracted reported MAPE or level-of-agreement accuracy data when available.

Risk-of-Bias Assessment

All articles were independently assessed for risk of bias by 2 independent reviewers (JG, CP) using a modification of the validation subscale from the checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments (Consensus-Based Standards for the Selection of Health Status Measurement Instruments [COSMIN]) [15]. All discrepancies were resolved by discussion and consensus, or by a third independent reviewer (LMF). Quality evaluation included 5 design or methodology components (percentage missing data, missing data management, adequate sample size, acceptable criterion comparison, design or methodological flaws) and one analysis component (acceptable accuracy analyses). We rated each dimension as excellent, good, fair, or poor quality based on a priori modifications to the COSMIN validation subscale scoring criteria appropriate for accuracy studies (Multimedia Appendix 4) [16].

Data Handling

We sorted each accuracy comparison into one of the following outcome domains: (1) steps, (2) energy expenditure, (3) sleep, (4) time in activity, or (5) distance. Within each domain, we coded individual accuracy comparisons to identify testing parameters that may influence measurement accuracy, such as variations in the testing environment(s), placement of device(s), or variations in the type of ambulation or activity or task examined (Multimedia Appendix 5). All coding was independently reviewed by a second reviewer with discrepancies resolved through discussion and consensus (LMF, JG).

Syntheses

Given the diversity of outcomes reported and the variety of testing conditions under which accuracy measures were examined and reported across and within different studies, we were unable to conduct meta-analyses. As an alternative, and as recommended by the UK Economic and Social Research Council guidelines for conducting and reporting narrative syntheses, we conducted a narrative synthesis of quantitative data, where we explored measurement accuracy within each outcome domain (ie, steps, energy expenditure, sleep, time in activity, and distance) using group percentage difference as the common rubric for measurement error comparisons [17,18]. We performed descriptive analyses for frequency (number and percentage) of percentage error comparisons that were within and outside predefined cutoff points for measurement accuracy in controlled or free-living settings. We also explored potential trends for direction of measurement error (ie, potential measurement bias) by defining a point estimation for both mean and median percentage error, with negative values indicating a trend for Fitbit device underestimation compared with the criterion device. In addition, we explored measurement error dispersion by defining the range (maximum–minimum) for percentage error measures. Given the diversity of testing conditions, we conducted further secondary exploratory analyses for comparisons of steps and energy expenditure accuracy in controlled settings to examine the potential influence of different testing parameters such as variations in body placement, ambulation speed, or variations in the type of activity on measurement accuracy. We completed these secondary exploratory analyses only when there were 10 or more accuracy comparisons within each subgroup.

We provide summaries for all descriptive analyses in tabular formats. For selected secondary subanalyses, we also provide modified scatter plots depicting the distribution of accuracy comparisons for group percentage error, color coded by variations in testing parameters, to allow for visual interpretation of how measurement error may be influenced by variations in testing parameters.

We focused our interpretation of measurement accuracy based on predefined acceptable limits for measurement accuracy in controlled settings as a percentage difference of ±3% and acceptable limits for relative accuracy in free-living settings as a percentage difference of ±10% [19-22]. We completed all descriptive analyses and plots using SAS version 9.4 software (SAS Institute Inc).

In the review, we included accuracy studies not reporting data to allow for the examination of group percentage measurement error if they reported MAPE or level-of-agreement data. These studies were included in the syntheses of study characteristics and the risk-of-bias assessment. As well, we provide narrative summaries for how the reported accuracy from these studies

may or may not be consistent with our evaluation of percentage measurement error.

Results

Study Selection

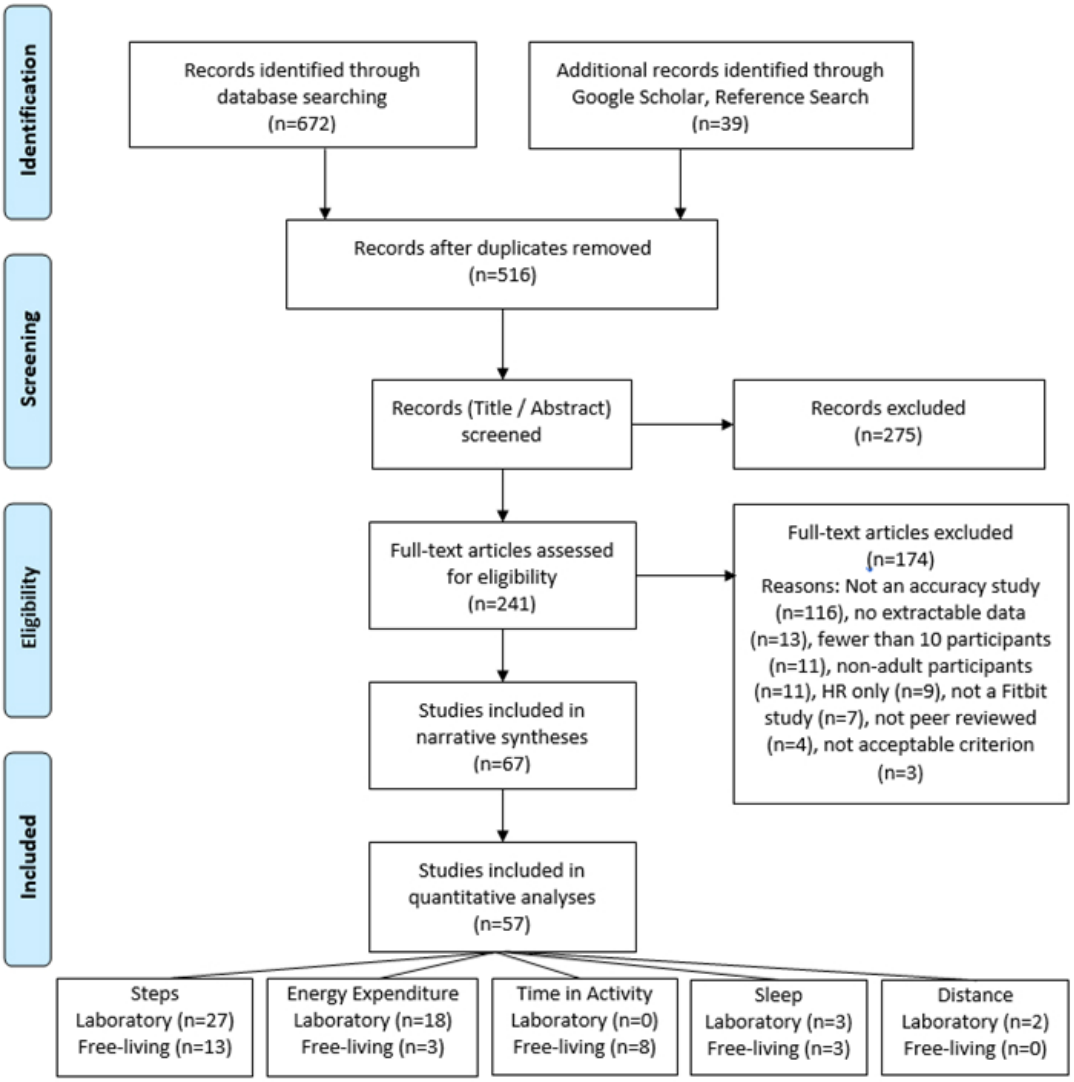
We identified 711 citations, of which we screened 516 titles and abstracts for potential eligibility after removing duplicates. Following screening, we excluded 275 titles, with the remaining 241 full-text reviewed. After full-text review, we subsequently excluded 174 articles. A total of 67 studies met the final inclusion criteria, with 57 providing adequate data for inclusion in the quantitative analyses. Of these, 40 studies investigated step count (laboratory: n=27; free-living settings: n=13), 21 addressed energy expenditure (laboratory: n=18; free-living settings: n=3), 8 examined time spent in different intensities of activity in free-living settings, 6 examined sleep measurements (laboratory: n=3; free-living settings: n=3), and 2 examined distance walked in a controlled testing environment (Figure 1) [23].

Study and Participant Characteristics

Publication dates varied from 1 publication in each of 2012 and in 2013, to 8 publications in each of 2014 and in 2015, with 49 studies published in or after 2016. Publications were from 11 countries across North America, Western Europe, South Asia, and Australia. The largest number of publications were from the United States (n=39), followed by Australia (n=9) and Canada (n=5). Of the 67 publications, 61 were full research articles, 5 were short reports, and 1 was a letter to the editor (Multimedia Appendix 6).

The 67 studies comprised a total of 2441 participants, with the mean number being 36 (SD 25), varying from 12 to 166. Of the 61 studies reporting age, the mean age of participants was 37 (SD 18) years, varying from 21 to 84 years. Of the 65 studies reporting sex, 53.95% (1251/2319) of the participants were female. A total of 55 studies included only healthy participants, with the remaining 12 including participants living with a variety of chronic diseases or mobility limitations, or both (Multimedia Appendix 6). Studies used several models of Fitbit devices, including the Ultra, Classic, Zip, or One worn on the torso (waist, hip, or chest), the Flex, Charge HR, Force, or Surge worn on the wrist, and the One worn on the ankle.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart.



Risk of Bias

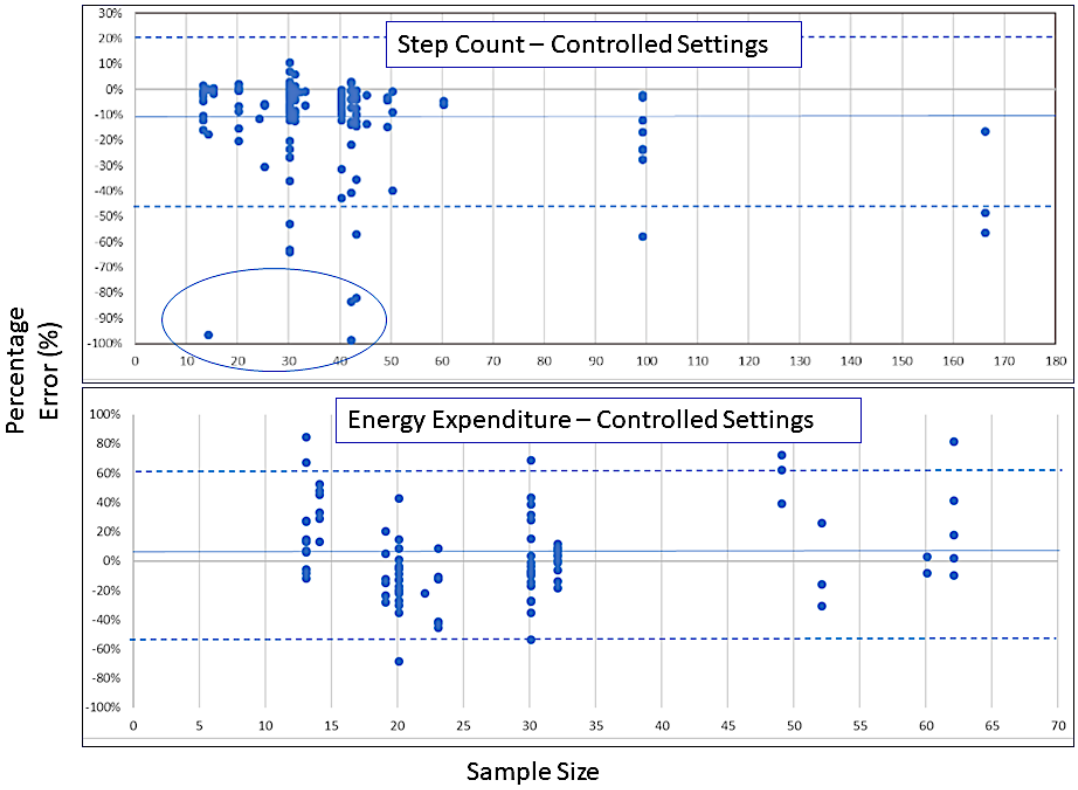
We rated the vast majority of the 67 studies as excellent or good for study design, reporting of missing data, and use of an acceptable reference criterion measure (Multimedia Appendix 7). For 34 studies (43 accuracy comparisons), it was unclear how missing data were handled in the analyses (Multimedia Appendix 7). We did not exclude these accuracy comparisons from the descriptive analyses of percentage measurement error based on this criterion. However, we did exclude 21 accuracy comparisons in the descriptive analyses, as the Fitbit versus criterion group mean or percentage differences were not reported (Multimedia Appendix 7). Rather than excluding these accuracy comparisons (or studies) completely from the review, we provide a narrative summary for how the reported MAPE or level-of-agreement accuracy data may or may not be consistent with our exploration of percentage measurement error.

We also did not exclude 55 studies (85 accuracy comparisons) rated fair or poor for sample size (<50 participants), as there were only 2 studies with 100 or more participants (excellent rating) and 10 with 50 to 99 participants (good rating) (Multimedia Appendix 7). Rather, we excluded studies (or accuracy comparisons) with 10 or fewer participants. As well, for step count and energy expenditure in controlled settings, we explored the potential for bias based on sample size by exploring the dispersion of group percentage error across different sample sizes using modified scatter plots (Figure 2). In these exploratory analyses, we saw no apparent systematic bias for measurement error, other than a slight tendency for extreme underestimation of steps in 4 comparisons from 2 studies with fewer than 50 participants. However, when we explored these extreme outliers further, we determined that they were likely true reflections of a greater tendency for underestimation of step count during very slow walking activities when the device was worn on the torso, rather than due to small sample size. Therefore, we included all percentage error accuracy comparisons, independent of sample size, in our descriptive analyses.

Step Count

A total of 27 studies (191 accuracy comparisons) examined Fitbit device step measurements compared with a reference-standard criterion of direct observation and counting of steps in a controlled setting (Multimedia Appendix 3) [12,24-49]. Of these, 21 studies recruited healthy adults with a mean age of 37.2 (SD 18.3) years; the remaining 6 recruited adults living with limited mobility or chronic disease with a mean age of 64.8 (SD 14.8) years. Fitbit devices were worn on the torso, wrist, or ankle. Across the 191 accuracy comparisons examining step count in controlled settings, 46% (n=88) were within a ±3% measurement error, 51% (n=97) were below a –3% measurement error, and 3% (n=6) were above a 3% measurement error, with an overall tendency for Fitbit devices to underestimate steps (estimated mean [median] difference of –9% [–3%]) (Multimedia Appendix 8 and Figure 2).

Figure 2. Percentage error distribution by sample size. Top: Step count in controlled settings. The blue oval indicates extreme outliers (n=4 comparisons). Bottom: Energy expenditure in controlled settings. Solid blue lines indicate mean error estimation. Dotted blue lines indicate 95% CI.



When we further explored factors potentially influencing step count accuracy, we observed that accuracy of step count in controlled settings seemed to vary with speed of ambulation (jog, normal, self-paced, slow, or very slow) [50,51], with body placement (torso, wrist, or ankle), and with variations in how the body moved during the activity (normal, constrained, variable, or exaggerated) (Multimedia Appendix 8). Constrained body motion throughout the task or activity could be due to, for example, a disease-related mobility limitation, walking with a walking aide, or pushing a stroller while walking. Levels of body motion could have varied while performing a series of different simulated household tasks or doing simulated agility-dependent sporting activities. Exaggerated motions could have occurred when the device was worn on the wrist during simulated household or sporting activities that involved exaggerated arm motions.

Within the different speeds of ambulation, measurement error was within ±3% more than 50% of the time for jogging (14/24) or normal (25/48) ambulation speeds. More than 50% of the time, measurement error was below –3% for self-paced (35/70), slow (12/23), and very slow (19/26) ambulation speeds. Within each ambulation speed, Fitbit tended to underestimate step counts (mean [median] error estimations varying from –24% [–12%] to –4% [–2%]) (Multimedia Appendix 8 and Figure 3).

Within the different body placements for the device, measurement error was within ±3% more than 50% of the time for comparisons with torso (65/114) or ankle (8/16) placement, whereas 70% (43/61) of the time measurement error was below –3% for wrist placement. Within each body placement, Fitbit tended to underestimate steps (estimated mean [median] errors varying from a –11% [–2%] to –3% [–1%]) (Multimedia Appendix 8 and Figure 4).

Within the variations of body motion during the activity, measurement error was within ±3% more than 50% (82/154) of the time during activities with normal body motion. Measurement error was below –3% more than 90% of the time for activities that involved constrained (19/24) or variable (10/10) body motion during the activity, with Fitbit tending to underestimate steps during these activities (estimated mean [median] errors varying from –35% [–26%] up to –21% [–12%]). Conversely, when the Fitbit device was worn on the wrist during exaggerated arm motion, 2 of the 3 comparisons were above 3% (Multimedia Appendix 8 and Figure 5).

We also observed that, within the different speeds of ambulation, step count accuracy appeared to be influenced further by the placement of the device on the body (Figures 3 and 4). For torso placement, measurement accuracy was within ±3% more than 60% of the time for normal (24/30), self-paced (28/44), and slow (7/11) ambulation speeds. Torso placement was lower than –3% more than 60% of the time for jogging (9/14) and more than 90% of the time for very slow (14/15) walking speeds. In addition, we observed that the underestimation of steps was largest during very slow walking when the device was worn on the torso, with 7 of these 15 comparisons having a measurement error lower than –25%. For ankle placement, 70% (11/16) of the accuracy comparisons were within ±3% measurement error for slow or very slow walking speeds. There were no accuracy comparisons for ankle placement at normal or jogging speeds and only 1 comparison for ankle placement during self-paced ambulation. For wrist placement, 90% (9/10) of time measurement error was within ±3% for jogging speeds and 75% (38/51) of the time it was lower than –3% for all other speeds.

Figure 3. Step count percentage error in controlled settings. Speed (jog, normal, self-paced, slow, very slow) by body placement (torso, wrist, ankle) of the Fitbit device. Dark lines indicate mean (horizontal). Dashed lines indicate median (horizontal). Gray shading indicates ±3% measurement error.

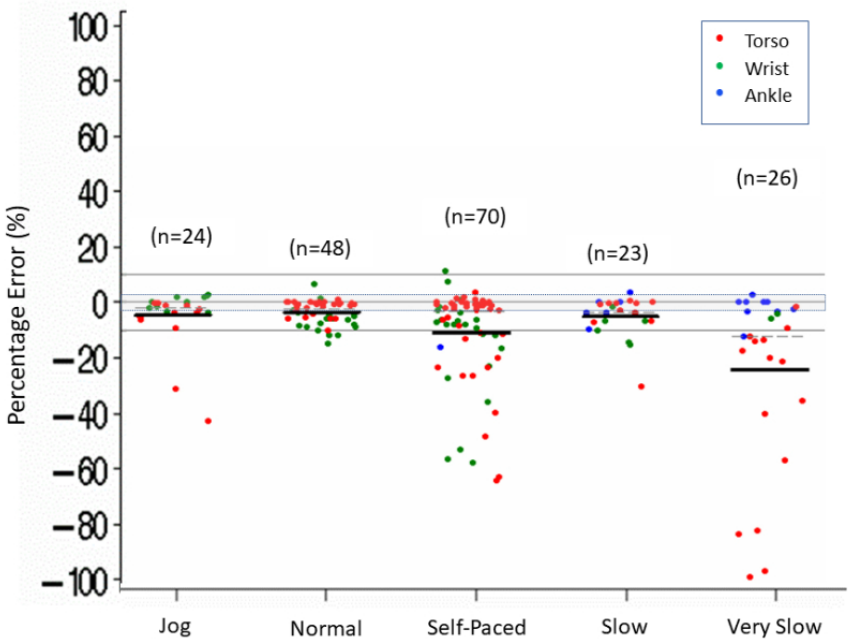


Figure 4. Step count percentage error in controlled settings. Body placement (torso, wrist, ankle) of the Fitbit device by speed (jog, normal, self-paced, slow, very slow). Dark lines indicate mean (horizontal). Dashed lines indicate median (horizontal). Gray shading indicates ±3% measurement error.

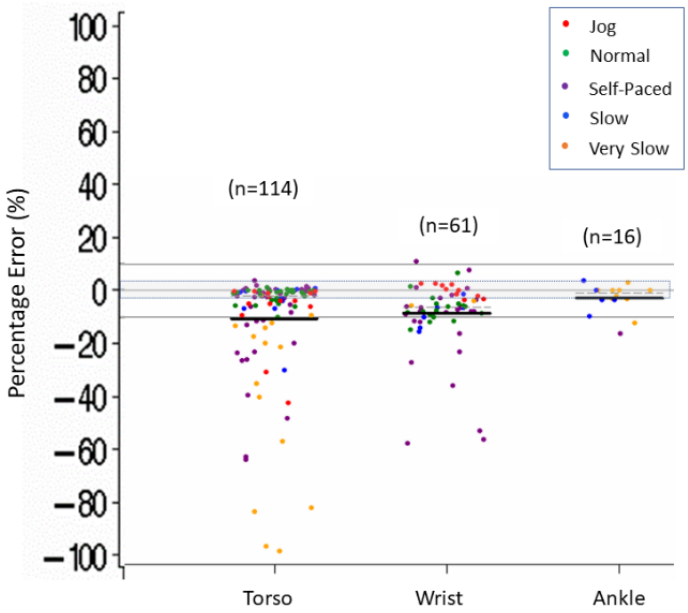
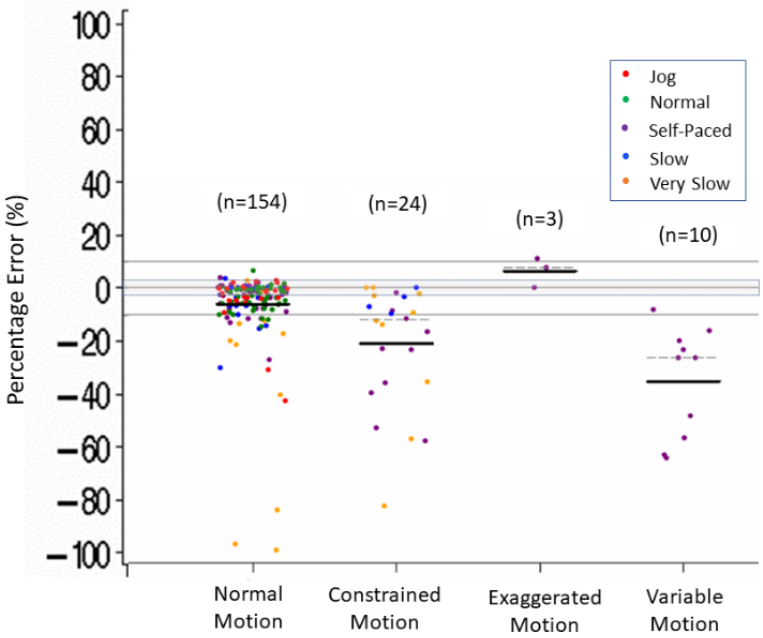


Figure 5. Step count percentage error in controlled settings. Body motion (normal, constrained, exaggerated, variable) by speed (jog, normal, self-paced, slow, very slow). Dark lines indicate mean (horizontal). Dashed lines indicate median (horizontal).



A total of 13 studies examined Fitbit accuracy for step count in free-living conditions (20 accuracy comparisons; Multimedia Appendix 3) [36,52-63]. Of these, 8 studies were conducted in healthy young adults; 5 were conducted on older adults, of whom 3 were healthy, active older adults and 2 had mobility limitations. Duration of wear varied from 1 to 14 days. Fitbit devices were compared with ActiGraph, activPAL, or Actical accelerometers, or an Omron or Shimmer pedometer.

Across the 20 accuracy comparisons examining step count in free-living settings, 55% (n=11) were within a ±10% measurement error, 30% (n=6) were below a –10% measurement error, and 15% (n=3) were above a 10% measurement error, with a tendency for Fitbit to overestimate steps in free-living conditions relative to a research-grade criterion. When explored further, it appeared that measurement error for step count in free-living conditions varied depending on the reference criterion used, body placement of the device, and the age and mobility status of the study participants. Compared with ActiGraph or activPAL accelerometers, Fitbit step count was within a ±10% error for 6 of 8 torso comparisons and 3 of 5 wrist comparisons in healthy young adults, and in 1 comparison when worn on the torso in older adults with no mobility limitation. In 1 comparison in older adults with no mobility limitations, a Fitbit device worn on the torso overestimated steps by more than 35% relative to an Omron pedometer worn on the ankle.

In contrast, in 2 of 3 accuracy comparisons in older adults with mobility limitations, Fitbit step count error was approximately –25% lower than that of a Shimmer pedometer or an Actical accelerometer worn on the ankle when Fitbit was worn on the torso (Multimedia Appendix 9).

Our evaluation for step count accuracy in free-living settings was consistent with those of 5 other studies examining MAPE or level-of-agreement differences in daily step measures in healthy adults for Fitbit compared with an accelerometer worn on the torso or a pedometer worn on the ankle [42,64-67]. These studies reported Fitbit overestimations of median steps per day varying from 700 to 1800 steps or MAPE values greater than 10% when compared with an ActiGraph accelerometer or Omron or New Life pedometers. In contrast, 1 study showed similar measures for median steps per day for Fitbit compared with a Yamax pedometer (–55 steps/day) [67].

Energy Expenditure

A total of 18 studies (98 accuracy comparisons) examined Fitbit device energy expenditure measurement accuracy in controlled settings compared with a reference standard of direct (2 studies) or indirect (16 studies) calorimetry (Multimedia Appendix 3) [29,34,37,39,46,68-80]. All 18 studies recruited healthy adults. Fitbit devices were worn on the torso or wrist. Of the accuracy comparisons, 88 measured energy expenditure during an activity, while 10 measured energy expenditure at rest.

Findings indicated that, across the 88 activity comparisons, measurement error was rarely within ±3% (4% [n=4] within a ±3% error, 47% [n=41] below a –3% error, and 49% [n=43] above a 3% error). Overall, Fitbit showed a tendency to overestimate energy expenditure during activity (estimated mean [median] error of 4% [2%]). Across the 10 comparisons at rest, 3 were within a ±3% measurement error, with 6 lower than –3% and 1 higher than 3%, with a tendency to underestimate energy expenditure (estimated mean [median] error of –3% [–6%]) (Multimedia Appendix 8 and Figure 6).

When we explored further by factors potentially influencing energy expenditure measurement accuracy, we observed that accuracy appeared to vary with speed of ambulation, with body placement, and with variations in body motion during the activity. In addition, energy expenditure accuracy appeared to be influenced by type of ambulation. Types of ambulation included continuous ambulation on an incline or a flat surface, as well as intermittent ambulation (stop-and-start ambulation) while performing common simulated household or sporting activities (Multimedia Appendix 8).

Within the different body placements, measurement error for energy expenditure was lower than –3% more than 60% (32/52) of the time with torso placement (estimated mean [median] error of –5% [–8%]) and greater than 3% more than 60% (24/36) of the time for wrist placement (estimated mean [median] error of 18% [9%]) (Multimedia Appendix 8 and Figure 7).

Within the different speeds of ambulation, more than 50% of jogging (8/15) and normal (17/24) speed comparisons for energy expenditure were greater than 3% (estimated mean [median] errors varying from 7% (5%) to 18% (12%]). Conversely, more than 50% (25/39) of the self-paced ambulation comparisons were below –3% (estimated mean [median] error of –6% [–9%]). There were fewer than 10 comparisons for energy expenditure at slow and very slow ambulation speeds, with no apparent trend or pattern for measurement error noted (Multimedia Appendix 8 and Figure 8).

Figure 6. Energy expenditure percentage error in controlled settings. Activity versus rest by body placement (torso, wrist). Dark lines indicate mean (horizontal). Dashed lines indicate median (horizontal). Triangles indicate measurement by direct calorimetry. Gray shading indicates ±3% measurement error.

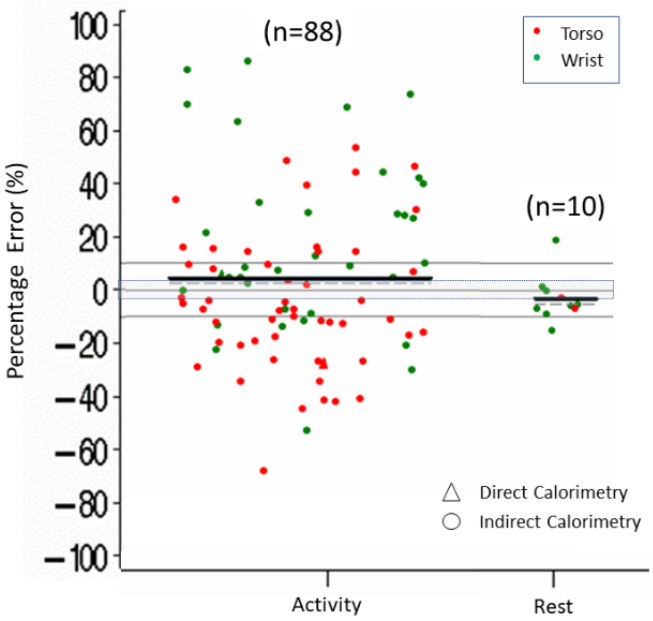


Figure 7. Energy expenditure percentage error in controlled settings. Body placement (torso, wrist) by speed (jog, normal, self-paced, slow, very slow). Dark lines indicate mean (horizontal). Dashed lines indicate median (horizontal). Triangles indicate measurement by direct calorimetry. Gray shading indicates ±3% measurement error.

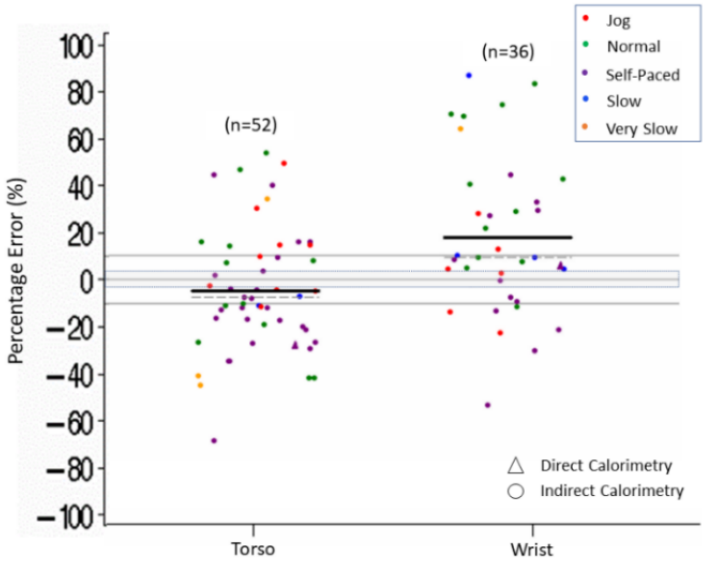
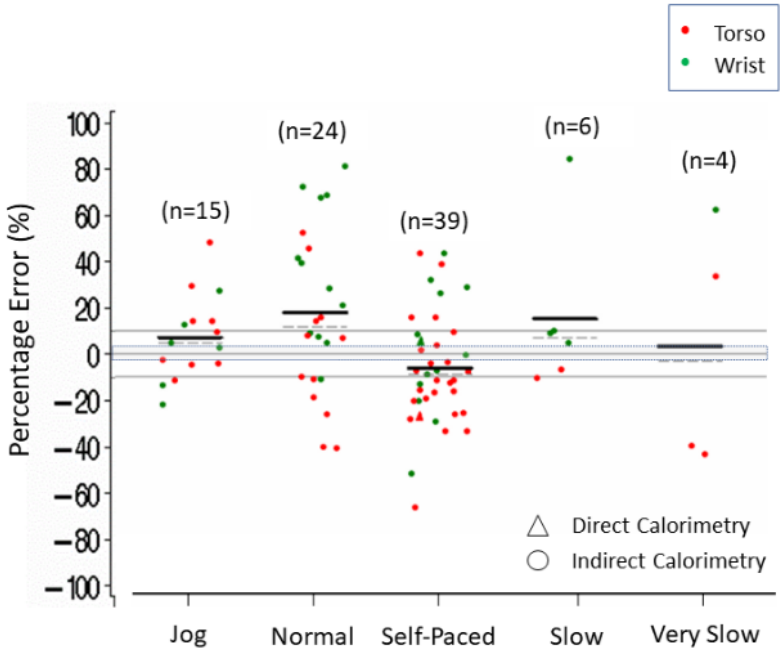


Figure 8. Energy expenditure percentage error in controlled settings. Speed (jog, normal, slow, self-paced, very slow) by body placement (torso, wrist). Dark lines indicate mean (horizontal). Dashed lines indicate median (horizontal). Triangles indicate measurement by direct calorimetry. Gray shading indicates ±3% measurement error.



Within the different body motion parameters, more than 50% (34/58) of activities with normal body motion had an energy expenditure error greater than 3% (estimated mean [median] difference of 12% [9%]). In contrast, more than 60% of the accuracy comparisons during activities with constrained (6/10) or variable (13/16) body motion activities had an energy expenditure error lower than –3% (estimated mean [median] difference varying from –14% [–15%] to –8% [–10%]). Similarly, 3 of the 4 comparisons with exaggerated motion also had a measurement error for energy expenditure lower than –3% (Multimedia Appendix 8 and Figure 9).

Within the different types of ambulation, more than 60% (35/53) of the continuous ambulation activities on flat surfaces had an error for energy expenditure greater than a 3% (estimated mean [median] difference of 17% [13%]). More than 60% of the time, the error was lower than –3% with continuous ambulation activities on an incline (7/11) or intermittent ambulation during simulated household or sporting activities (18/24) (estimated mean [median] errors varying from –19% [–21%] to –12% [–12%]) (Multimedia Appendix 8 and Figure 10).

Figure 9. Energy expenditure percentage error in controlled settings. Motion limitations (normal, constrained, exaggerated, variable) by speed (jog, normal, self-paced, slow, very slow). Dark lines indicate mean (horizontal). Dashed lines indicate median (horizontal). Triangles indicate measurement by direct calorimetry. Gray shading indicates ±3% measurement error.

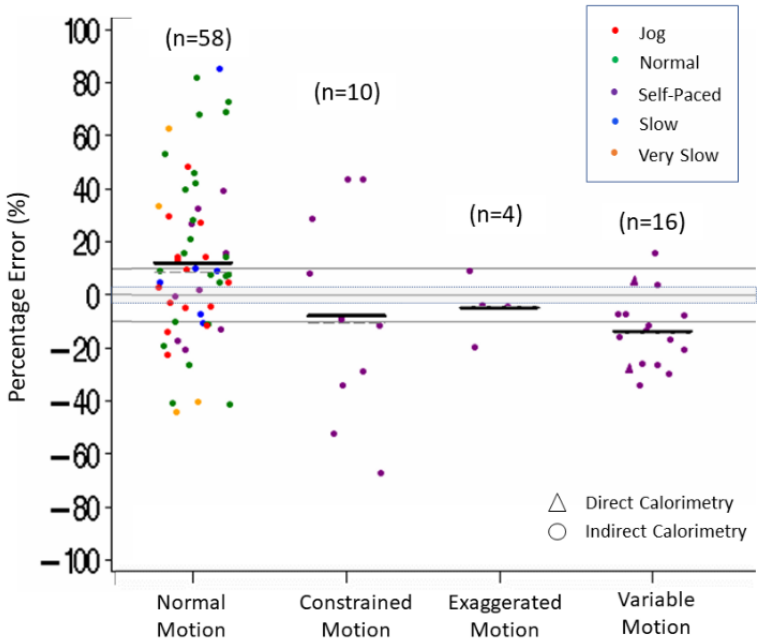
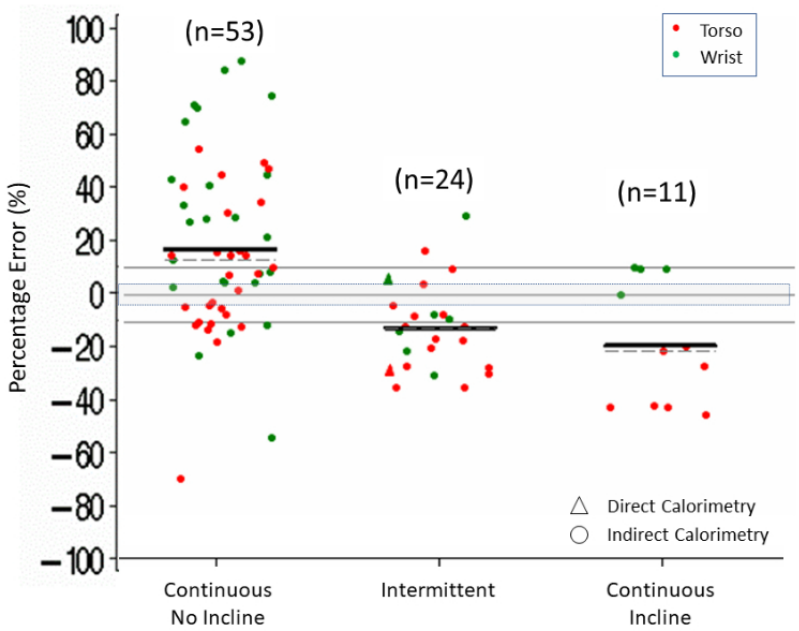


Figure 10. Energy expenditure percentage error in controlled settings. Type of ambulation (continuous no incline, continuous incline, intermittent) by body placement (torso, wrist). Dark lines indicate mean (horizontal). Dashed lines indicate median (horizontal). Triangles indicate measurement by direct calorimetry. Gray shading indicates ±3% measurement error.



A total of 3 studies examined Fitbit device accuracy for measures of energy expenditure in healthy adults in free-living conditions compared with doubly labelled water (1 accuracy comparison) or a SenseWear accelerometer (4 accuracy comparisons; Multimedia Appendix 3) [56,77,81]. Findings from 1 study showed that Fitbit worn on the wrist tended to slightly underestimate (–7%) energy expenditure over 15 days compared with doubly labelled water [77]. All 4 accuracy comparisons with a SenseWear accelerometer were lower than a –10% measurement error (estimated mean [median] difference of –15% [–15%]) (Multimedia Appendix 9). These findings are consistent with those of 2 other accuracy studies reporting Fitbit underestimations of daily energy expenditure, with MAPE values varying from 16% to 30% for Fitbit devices compared with measurements from an ActiGraph or Actiheart accelerometer [58,70].

Time in Activity

A total of 8 studies (28 accuracy comparisons) examined Fitbit device measures in free-living settings for time spent in different intensities of activity compared with measures from an ActiGraph accelerometer worn on the torso or Actical accelerometer worn on the ankle (Multimedia Appendix 3)

[52,53,56,57,59-62]. Of these studies, 5 were conducted on healthy young adults and 3 were conducted on older adults living with a variety of chronic diseases. The duration of wear varied from 2 to 9 days. Studies examined time spent in sedentary, light, moderate, vigorous, or moderate to vigorous physical activity during waking hours.

Notably, the Fitbit device and the reference criterion accelerometers across the studies used variable cutoff points for defining intensity levels of physical activity. Despite these differences, 3 of the 4 accuracy comparisons for sedentary time had an error lower than –10% when compared with ActiGraph (torso) or Actical (ankle) accelerometers. Compared with Actical (ankle) or ActiGraph (torso) accelerometers, more than 80% (21/24) of accuracy comparisons for time spent in light to vigorous activity time had a measurement error greater than 10% (estimated mean [median] difference varying from 44% [52%] to 632% [390%]) (Multimedia Appendix 9).

Our observation of marked overestimation of time spent in higher-intensity activity was consistent with those of 2 other studies reporting Fitbit overestimations of moderate to vigorous physical activity in free-living settings compared with an ActiGraph accelerometer (MAPEs >30%) [58,66]. In contrast to our finding of Fitbit underestimation of sedentary time during the day, 1 study reported Fitbit overestimation of combined night (sleep) and daytime sedentary time (MAPE ~10%) when compared with an activPAL accelerometer worn on the thigh. [66].

Sleep

A total of 3 studies examined sleep in controlled settings (12 accuracy comparisons), comparing a Fitbit worn on the wrist against reference-standard polysomnography over 1 night of sleeping in a laboratory (Multimedia Appendix 3) [82-84]. All 3 studies included young adults, 2 comprising healthy participants and 1 comprising individuals living with depression. All 3 studies examined measures of sleep in a normal-mode setting, and all reported Fitbit overestimation of total sleep time and sleep efficiency by more than 10%. On the other hand, 1 study examined total sleep time and sleep efficiency in the sensitive sleep mode, reporting Fitbit underestimation of both by more than 15% [82]. One study also examined sleep-onset latency (minutes to initial sleep) and time awake after sleep onset in normal and sensitive sleep modes and reported measurement errors varying from 12% to 180%, with an opposite tendency for either over- or underestimations of these sleep parameters depending on the sleep-mode setting (Multimedia Appendix 8).

A total of 3 studies (5 accuracy comparisons) reported sleep measurement accuracy in healthy young adults in free-living settings comparing a Fitbit device worn on the wrist with a SenseWear or Actiwatch accelerometer also worn on the wrist (Multimedia Appendix 3) [56,81,85]. Duration of wear varied from 1 to 13 nights of home sleep. There were 4 comparisons for measures of time in bed, with all 4 reporting measurement errors within ±10% compared with a SenseWear accelerometer. One study also reported very similar measures for time in bed (–0.4%) by a Fitbit device compared with an Actiwatch accelerometer. One study also reported a slight overestimate (6%) of sleeping minutes for Fitbit compared with an Actiwatch accelerometer [85] (Multimedia Appendix 9). These findings are consistent with those of 2 other studies reporting Fitbit overestimations of sleeping time compared with a portable sleep monitor (MAPE approximately 10%) or Actiwatch accelerometer (approximately 10 minutes per night) [66,86].

Distance

There were 2 studies (17 accuracy comparisons) examining Fitbit device distance measurement accuracy in a controlled setting in healthy young adults (Multimedia Appendix 3) [33,48]. Both studies reported a Fitbit tendency to overestimate distance at slower and self-paced ambulation speeds (varying from 5% [torso] to 25% [wrist]) and underestimate distance at brisk walking or jogging speeds (varying from –15% [wrist] to –5% [torso]). During normal speed ambulation, torso placement tended to overestimate distance (10%), and wrist placement tended to slightly underestimate distance (–3%). These findings are consistent with 1 additional study reporting Fitbit overestimations of distances at slower walking speeds varying from 5% to 15% and underestimations of distance by more than 10% during running activities (Multimedia Appendix 8) [87].

Discussion

Principal Findings

This review adds to the existing literature, as it is the first, to our knowledge, to systematically examine and report Fitbit device measurement accuracy in controlled and free-living settings for measures of step count, energy expenditure, sleep, time in activity, and distance in healthy adults or adults living with any health condition or disability.

Findings across many studies suggested that, approximately 50% of the time, Fitbit devices were likely to provide accurate measures (within ±3%) of steps in controlled testing conditions, with an overall tendency to underestimate steps. Findings also indicated that step count accuracy was likely to improve if the device was worn on the torso during normal or self-paced walking activities, worn on the wrist during jogging activities, and worn on the ankle during slow or very slow walking activities. Findings from several studies examining step count in free-living settings also showed that, approximately 50% of the time, Fitbit devices were likely to provide relatively accurate (within ±10%) measures of steps compared with research-grade accelerometers or pedometers when worn on the torso or wrist in healthy adults with no mobility limitations, with a tendency to overestimate steps in free-living settings.

Consistent findings across studies in controlled-testing settings indicated that Fitbit devices were also more likely to provide notable underestimations of step count during activities with very slow ambulation, particularly when worn on the torso, where body motion may be constrained by mobility limitations or walking while pushing a walker or stroller, and during activities that simulate household or sporting activities that involve stop-and-start ambulation throughout the task. Findings from a few studies in free-living conditions suggested that, compared with a research-grade accelerometer or pedometer worn at the ankle, a Fitbit device worn on the torso may

markedly overestimate steps in older adults with no mobility limitation and markedly underestimate steps in older adults with limited mobility.

There were also consistent findings from many studies examining energy expenditure in controlled settings, indicating that Fitbit devices were rarely likely to provide accurate measures of energy expenditure. Findings suggested that Fitbit was more likely to markedly overestimate energy expenditure when worn on the wrist and when walking at normal adult walking speeds on flat surfaces. On the contrary, Fitbit was more likely to underestimate energy expenditure when worn on the torso, with a tendency to markedly underestimate energy expenditure during inclined ambulation, during activities with constrained or variable body motion throughout the activity, and during simulated household or sporting activities that involve stop-and-start ambulation. Findings from 1 study for measures of energy expenditure in free-living settings suggested that Fitbit and doubly labelled water may provide similar measures of total energy expenditure over a 2-week period. However, findings from a few studies in free-living settings suggested that Fitbit devices may provide notable underestimations of daily energy expenditure compared with a SenseWear accelerometer.

A few studies examined Fitbit measurement accuracy for time spent in different intensity of activity in free-living settings. Across these studies, there was consistent evidence to suggest that, compared with research-grade accelerometers, Fitbit devices may underestimate sedentary time and progressively overestimate time in spent in activity as intensity of activity increases. Similarly, a few studies examined the accuracy for measures of sleep in controlled or free-living settings. Consistent evidence from these studies suggested that Fitbit may not provide accurate measures of sleep quality or quantity in a controlled-testing setting compared with polysomnography. However, there was some indication that Fitbit may provide relatively similar measures to SenseWear or Actiwatch accelerometers for time spent in bed and time sleeping in free-living settings. Finally, findings from 2 studies suggested that Fitbit may overestimate distance with slower walking speeds and progressively underestimate distance as walking speed increases.

Most of the studies included in this review were published in the last 2 years, with studies primarily examining measurement accuracy for models of Fitbit activity trackers introduced prior to 2015. The included studies mainly focused on step count and energy expenditure outcome measurement accuracy, with only a few of the studies examining measurement accuracy for sleep, distance, or time in activity. As well, the vast majority of studies included only healthy participants, with few including older adults, and fewer still including any adult living with disease or functional limitation. Overall, the quality of the included studies was excellent in terms of study design, reporting of missing data, and use of acceptable accuracy evaluations. However, some studies did not clearly identify how they may have handled missing data in their analyses, and few comprised more than 50 participants.

Most of the studies focused on measurement accuracy in controlled-testing environments comparing measurements from a Fitbit device against a reference-standard criterion. Standardized and controlled testing environments allow for evaluations of “true” measurement accuracy but do not necessarily reflect device measurement accuracy in uncontrolled or free-living settings, which are the intended environments for Fitbit activity tracker use. However, it is very difficult to measure true device accuracy in free-living conditions, as the reference-standard criterion measures generally cannot be used over a number of days while someone is conducting their usual daily activities. Therefore, the studies examining Fitbit device measurement accuracy in free-living conditions examined the accuracy of Fitbit device measures relative to an established research-grade criterion device measure of the same outcome when worn at the same time in free-living conditions.

For the purposes of this review, we defined satisfactory levels of measurement accuracy based on previously published standards for acceptable accuracy of step count in controlled (±3%) and free-living (±10%) settings [19-22]. Given that we were not able to identify published standards for accuracy of other outcome measures, we applied these same cutoff points for acceptable limits of measurement accuracy for all outcomes. However, we provide details of our descriptive analyses in the supplemental summary tables and offer visual representations for error estimations in the figures to allow for independent assessment of alternative definitions for acceptable limits for measurement accuracy by Fitbit devices.

Limitations

Our review has some potential limitations. These include the decision to include only data that were published in peer-reviewed journals and to exclude non-English studies. These decisions may have introduced a level of bias in our analyses and interpretation. In addition, we included all studies, independent of potential risk of bias. Moreover, the descriptive analyses and subsequent point estimations for percentage measurement error (ie, potential bias) gave equal weighting to accuracy comparisons with different sample sizes and variations in significance levels, which may misrepresent the true point estimate for measurement error for some of the testing conditions examined in this review [17,18]. Allowing for these potential limitations, and the limited number of studies examining Fitbit measurement accuracy for sleep, distance, and time spent in activity, we note that discretion should be exercised when considering our evaluations of the potential accuracy for these outcome domains. To address this gap in the literature, further high-quality research examining Fitbit measurement accuracy for sleep, time in activity, and distance is warranted.

We should identify as well that defining relative (in)accuracy of a Fitbit device in free-living settings does not define true measurement (in)accuracy, as neither the Fitbit device nor the reference device was compared to a reference-standard criterion. Rather, relative inaccuracy of a Fitbit defines only the likelihood that a Fitbit device will provide different values for measures of the same outcome when compared with a research-grade criterion in free-living conditions.

It is also important to clarify that we derived estimates of Fitbit device measurement accuracy in this review from studies that used different models of Fitbit, which might have different versions of firmware, software, and data processing algorithms. Since the design details for the devices and software are proprietary information, we were not able to determine whether and what modifications have been made by the company over time. Nonetheless, we indirectly explored the potential effect of differences in model design over time by using body placement for the device as a proxy, as the earlier models (eg, Classic, One, Zip, and Ultra) were worn on the torso, whereas the later models (eg, Flex, Charge, and Surge) were worn on the wrist. Therefore, some of the variability in error estimations with different body placement may be related in part to differences in device design or in analysis protocols over time.

Finally, our finding of potential limitations in Fitbit device measurement accuracy in a variety of testing conditions does not imply that Fitbit device measurement accuracy will remain static. Rather, it is very likely that accuracy will improve as technological advances in the firmware are implemented. As well, given the ability for Fitbit to tap into metadata from millions of users worldwide and apply advanced algorithms to better identify complex patterns of motion, it is likely that evolving software upgrades will also lead to improved measurement accuracy. Furthermore, our findings do not negate the value of using Fitbit activity trackers in the manner for which the devices were intended, which is for self-monitoring of physical activity patterns and motivating individuals to achieve their physical activity goals [88-91].

Conclusion

Fitbit devices are most likely to provide accurate measures of steps in adults with no mobility limitations, when the device is worn on the torso while walking at normal or self-paced walking speeds. However, Fitbit devices are unlikely to provide accurate measures of energy expenditure. Limited evidence suggests that Fitbit activity trackers may not provide accurate measures for sleep, distance, or time spent in activity; however, further accuracy studies are warranted.

Implications

Other than for measures of steps in adults with no limitations in mobility, discretion should be used when considering the use of Fitbit devices as an outcome measurement tool in research or to inform health care decisions, as there are seemingly a limited number of situations where the device is likely to provide accurate measurement.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy example.

[PDF File (Adobe PDF File), 83KB - mhealth_v6i8e10527_app1.pdf]

Multimedia Appendix 2

Data extraction framework.

[PDF File (Adobe PDF File), 58KB - mhealth_v6i8e10527_app2.pdf]

Multimedia Appendix 3

Master data – percentage error values (all accuracy comparisons).

[PDF File (Adobe PDF File), 72KB - mhealth_v6i8e10527_app3.pdf]

Multimedia Appendix 4

Modified Consensus-Based Standards for the Selection of Health Status Measurement Instruments (COSMIN) criteria.

[PDF File (Adobe PDF File), 117KB - mhealth_v6i8e10527_app4.pdf]

Multimedia Appendix 5

Data coding (steps and energy expenditure in controlled settings).

[PDF File (Adobe PDF File), 83KB - mhealth_v6i8e10527_app5.pdf]

Multimedia Appendix 6

Study characteristics.

[PDF File (Adobe PDF File), 242KB - mhealth_v6i8e10527_app6.pdf]

Multimedia Appendix 7

Accuracy evaluations reported and risk-of-bias assessment.

[PDF File (Adobe PDF File), 179KB - mhealth_v6i8e10527_app7.pdf]

Multimedia Appendix 8

Controlled settings: accuracy – measurement error.

[PDF File (Adobe PDF File), 164KB - mhealth_v6i8e10527_app8.pdf]

Multimedia Appendix 9

Free-living settings: relative accuracy – measurement error.

[PDF File (Adobe PDF File), 131KB - mhealth_v6i8e10527_app9.pdf]

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Abbreviations

COSMIN: Consensus-Based Standards for the Selection of Health Status Measurement Instruments
MAPE: mean or median absolute percentage error

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