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Viewpoint

Acceptance of Mobile Health in Communities Underrepresented in Biomedical Research: Barriers and Ethical Considerations for Scientists

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Abstract

Background: The rapid expansion of direct-to-consumer wearable fitness products (eg, Flex 2, Fitbit) and research-grade sensors (eg, SenseCam, Microsoft Research; activPAL, PAL Technologies) coincides with new opportunities for biomedical and behavioral researchers. Underserved communities report among the highest rates of chronic disease and could benefit from mobile technologies designed to facilitate awareness of health behaviors. However, new and nuanced ethical issues are introduced with new technologies, which are challenging both institutional review boards (IRBs) and researchers alike. Given the potential benefits of such technologies, ethical and regulatory concerns must be carefully considered.

Objective: Our aim was to understand potential barriers to using wearable sensors among members of Latino, Somali and Native Hawaiian Pacific Islander (NHPI) communities. These ethnic groups report high rates of disparate health conditions and could benefit from wearable technologies that translate the connection between physical activity and desired health outcomes. Moreover, these groups are traditionally under-represented in biomedical research.

Methods: We independently conducted formative research with individuals from southern California, who identified as Latino, Somali, or Native Hawaiian Pacific Islander (NHPI). Data collection methods included survey (NHPI), interview (Latino), and focus group (Somali) with analysis focusing on cross-cutting themes.

Results: The results pointed to gaps in informed consent, challenges to data management (ie, participant privacy, data confidentiality, and data sharing conventions), social implications (ie, unwanted attention), and legal risks (ie, potential deportation).

Conclusions: Results shed light on concerns that may escalate the digital divide. Recommendations include suggestions for researchers and IRBs to collaborate with a goal of developing meaningful and ethical practices that are responsive to diverse research participants who can benefit from technology-enabled research methods.

Trial Registration: ClinicalTrials.gov NCT02505165; https://clinicaltrials.gov/ct2/show/NCT02505165 (Archived by WebCite at http://www.Webcitation.org/6r9ZSUgoT)

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KEYWORDS

telemedicine; cultural diversity; ethics, research; ethics committees; research; privacy; informed consent

Introduction

We have rapidly entered an era where personal health data (PHD) is collected on-the-fly and in real time, which is vastly expanding our ability to design and test personalized and adaptive health interventions [1]. Direct-to-consumer fitness products (eg, Fitbit, MapMyFitness) and wearable research tools (eg, SenseCam, ActivPAL) offer great potential for tracking of PHD and may serve as catalysts for behavior change within communities where health disparities are most prevalent. There are persistent health disparities in the United States, with numerous currently underserved communities who could benefit from mobile technologies designed to facilitate awareness and change in health behaviors [2].

Despite this great opportunity, a recent study evaluating the use of health apps revealed that disparities persist among racial and ethnic minority groups who are non-native English speakers and have lower levels of educational attainment [3]. A systematic review of health-related technology use by "historically underserved health consumers" revealed little progress on the development or use of culturally-informed technologies designed to reduce health disparities [2]. If adoption of health technology is a national priority [2], we clearly have a gap to fill to address disparities in technology use. Whereas barriers to engaging diverse communities with research have been documented [4], there is little information guiding researchers on barriers specific to the use of health-related technologies across diverse populations. In addition to the issues of access and equity, research studies that collect PHD using wearable sensing technologies are raising new and nuanced ethical challenges that also require attention [5].

Researchers who are using mobile health (mHealth) methods and tools can remotely record a variety of individual level data, including the participant's location, physiology, mood, and social interactions. For example, researchers can now objectively measure sedentary behavior using a wearable accelerometer sensor [6], stimulate autobiographical memory with a wearable camera [7], monitor mental health with smartphone capabilities [8], mine social media to predict disease outbreaks [9], and track geographic location to contextualize health behaviors [10] . Although the potential is exciting, researchers and institutional review boards (IRBs) are independently questioning the new ethical challenges introduced by this research (ie, informed consent, bystander rights) [5].

According to the US Census, California is considered a minority-majority state, with no single ethnic group forming a majority of the state's population. Within southern California and, specifically San Diego County, public health research and service initiatives are actively addressing health disparities within ethnically diverse communities. To explore interest in using mobile and wearable technologies for health research purposes, three independent formative pilot studies were initiated that focused on Latino, Somali, and Native Hawaiian Pacific Islander (NHPI) communities in southern California. This commentary brings together lessons learned from these pilot studies and reports the ethical, legal, and social implications raised by a sample of culturally diverse community members; stakeholders often neglected in discussions to inform ethical research practices. We applied lessons learned in the form of recommendations for scientists interested in using digital technologies with culturally diverse communities and to IRBs charged with protecting human subjects.

Pilot Studies

To identify potential barriers and motivators to participating in mHealth studies, the authors independently queried a sample of culturally diverse community members to identify perspectives about wearable and wireless sensing technologies. These independent inquiries were not coordinated in advance and, as such, different methodologies were utilized. The samples included Latino women, Somali women, and men and women from NHPI communities, each of whom experienced health disparities and might benefit from wearable technologies that translate the connection between physical activity and desired health outcomes.

Pilot Methods

Researchers working within the Latino community (JH, EA) conducted individual interviews with 10 Latino women to learn whether they would be willing to wear a global positioning system (GPS) location-tracking device as part of a health promotion study. These individuals were recruited from a larger sample of women already participating in the *Fe en Acción* study [11] and who consented to be contacted for further studies. The interviewer was bilingual/bicultural and worked as a research assistant on the larger study. Another researcher (KM) conducted a focus group with 5 adult Somali women who participated in a pilot study of a culturally adapted physical activity program [12] where compliance with wearing an activity monitor was low. These women were part of an initial pilot of the program to be tested using a randomized controlled trial design. To gauge barriers and motivators to wearing a GPS and activity monitors among the NHPI community, researcher (CH) surveyed 39 participants. The survey was self-administered, using paper and pen, to participants who were recruited from social, civic, and other cultural organizations. Each study was conducted under an IRB-approved protocol. Table 1 provides information about each of the studies and citations for further detail, where available. The purpose of this commentary is to highlight general findings of barriers to the adoption of mHealth research tools for communities currently underrepresented in research. A summary of lessons learned follows, to promote discussion in the field and to guide future research initiatives.

Table 1. Review of three pilot study samples, methodologies, and findings.

Study population	Facilitation	Informed consent	Format (type of data)	Privacy and confidentiality	Data collection and technology assessed	Key findings
Adult Latino women [11] (n=10) mean age: 49.3 years	In Spanish by research assistant	Written and verbal consent	Interviews (qualitative)	Names replaced with IDs; transcripts kept confidential	Interviews conducted following 12-month intervention regarding barriers to wearing an accelerometer and GPS[a] device	• Unfamiliar with GPS technology • Concerns about device safety • Misconceptions about data collected
Adult Somali women [12] (n=5) mean age: 46.1 years	In Somali by bicultural researchers	Written and verbal consent	Focus groups (qualitative)	Written notes without names; group confidentiality discussed	Focus group at end of 6-week intervention trial regarding lack of compliance with wrist-worn accelerometer	• Unfamiliar with accelerometer and data gathered • Unwanted attention • Inconvenient
Adult Pacific Islanders (n=39) mean age: 38.0 years	In English by research assistant	Verbal consent only	Self-administered survey (quantitative)	Privacy and confidentiality discussed verbally; study IDs used, no names	Survey items included barriers to wearing an accelerometer and GPS device	• Concerns about privacy and data access • Concerns about being tracked

[a]GPS: global positioning system.

Pilot Findings

Researchers who interviewed Latino participants reported a lack of familiarity with the location-tracking technology, misconceptions about what would be tracked, and difficulty understanding the concept of measurement in "real time." Participants also expressed concerns about device safety and perceived an elevated risk to those lacking legal documentation to be in the United States [13]. There were examples of misconceptions about safety, with one participant stating:

> *Depending on the device, which could cause something, maybe like radiation or something.*

Other participants were concerned about potential legal risks, with statements such as:

> *They have a bit of paranoia that the government always wants to know where they are, the illegals. Some people would think that (GPS) is a way to find them.*

These concerns about safety and the use of data were significant barriers within the Latino sample.

During the planning phase of a community-based participatory research (CBPR) study conducted within the local Somali community [12], the research team reported low compliance among participants who had agreed to use a wrist-worn accelerometer. A post-pilot study focus group was convened to explore participant experiences and assess the appropriateness of the study design. Results identified that participants were unfamiliar with the wearable technology and uncertain about the type and quantity of data collected. Participants revealed that the device prompted questions from others (unwanted attention) and was inconvenient to wear, as the ritual of prayer in the Muslim community is observed five times per day and require that one wash prior to praying. This inconvenience prompted participants to ask if the accelerometer could be worn on a belt around their waist to decrease inconvenience and unwanted attention. Likewise, participants indicated that they wanted study information to share with family and friends who were curious about the device and their participation.

Those working with the local NHPI community in a CBPR focusing on physical activity and sedentariness surveyed 39 participants who were involved in formative research to inform the research plan. Specific to the wearable technologies, participants were concerned about wearing a location-tracking device, citing interference with lifestyle and worries related to privacy and data confidentiality. When asked about the accelerometer, participants questioned who would have access to their information, as well as how their information would be shared and reported. Participants repeated expressions related to privacy and surveillance such as "I like to keep my affairs private...who is tracking (me)?" and "I don't like knowing that I'm being tracked."

This was further supported by participants from the *Fe en Acción* study who stated:

> *I think that it invades privacy a bit. For some people, I think there is more danger than for others.*

The concerns around privacy and the potential risks related to such data were consistent across all groups.

Ethical Principles

These summaries introduce potential barriers that may perpetuate disparities and decrease access to prevention research targeting communities where health disparities are more prevalent. Responses from participants representing these three distinct communities point to potential challenges explaining the technology (eg, informed consent), data management (eg, participant privacy, data confidentiality, data sharing

conventions), social implications (eg, unwanted attention), and legal risks (eg, undocumented status).

These challenges also align with the guiding ethical principles of autonomy, beneficence, and justice described in the Belmont Report [14]. Specifically, steps to decrease barriers may involve leveraging the three principles in this ethical framework when designing studies using mHealth tools and/or methods. For example: (1) Autonomy or respect for persons is demonstrated by obtaining meaningful informed consent and recognizing that several approaches (eg, visual, bullet points) may be necessary when communicating complex study information with individuals who may not be technology-savvy consumers; (2) Beneficence involves weighing risk and benefit in an era of seemingly limitless data collection with increased sensitivities to privacy, data confidentiality, and culture; and, (3) Justice focuses on decreasing inequities in access to technology and research through education and stakeholder engagement. Although these challenges are not unique to culturally diverse communities, the three groups represented are currently underrepresented in research and efforts should be made to increase access.

Implications for Scientists and Research Ethics Boards

Using the principles of the Belmont Report as a framework, we lay down recommendations to reduce barriers to participate in research studies that use pervasive sensing methods and tools to collect personal health data.

Autonomy: Informed Consent

The informed consent process is a cornerstone to ensuring an individual's right to autonomy is upheld and is a key element of the principle of respect [14]. Demonstrating autonomy requires that people participate voluntarily after receiving "adequate" information about the research. In practice, communicating complex information to people who may be unfamiliar with the scientific method, the technologies utilized, and the data produced poses considerable challenges to obtaining informed consent. Numerous studies have shown that the traditional method of conveying complex concepts via a written document is not effective, even when the consent language is simplified [15].

In line with current recommendations to reduce health disparities [16], we recommend that researchers engage with community members during the research design process to learn about barriers and motivators to the use of passive wearable sensing technologies to collect PHD. Likewise, efforts should be made to educate individuals who may become research participants to improve their ability to make informed decisions in studies that employ pervasive sensing strategies. Creating a meaningful informed consent process is critical and will likely require involving participants as partners who are willing to review and modify consent language and processes to increase access and understanding. Furthermore, education about technologies used in research can reduce barriers associated with a lack of familiarity and, subsequently, increase trustworthiness of the research enterprise. We recommend formative research be carried out with representatives of underserved communities to explore, for example:

- the acceptability of current practices for obtaining informed consent,
- how best to communicate complex concepts related to technology and data,
- preferences for privacy and data security, and
- how learning styles and literacy levels influence consent comprehension.

Data from this formative research can then be used to support alternatives to the traditional informed consent content and processes. Designing a meaningful informed consent process also requires that IRBs be willing to consider alternatives to the institutional templates that do more to protect institutions than facilitating an informed participant. These alternatives may involve experimenting with (1) less complex content (ie, legalese), (2) a tiered information presentation structure beginning with straightforward bullet points, and (3) conceptualizing the consent process as an opportunity to develop a relationship with a prospective participant rather than for documenting a transaction.

Beneficence: Weighing Risk and Benefit

The principle of beneficence is demonstrated by evaluating the probability and magnitude of harm in relation to the potential benefits of the research to an individual and people to whom the results may be generalized. There is little empirical evidence to guide IRB risk assessment, including threats to participant privacy if the data are breached and proper security practices to protect the amount of data collected using these methods. Pervasive sensing methods capture vast quantities of granular private identifiable information and personal health data—much of which is not protected by regulations that cover patient electronic health records. In addition, visual, audio, and location-tracking sensors may pick up information about people who are in close proximity to a research participant. These people, whom we call a "bystander" or a "by-catch," do not meet the definition of a human subject and, therefore, their rights may not be considered by an IRB. Yet, these individuals may expect to grant permission if recorded by a research participant. This concern about "tracking" a person who is with the research participant was raised by a Latino participant who believed that a GPS may introduce a potential legal risk for undocumented individuals who travel with the participant. This sensitivity may be magnified where legal matters, such as immigrant status, are concerned.

In an era of limitless opportunities to collect information, thoughtful discussions should guide what is and what is not collected to ensure maximum benefit to participants and science. As noted, participants in these three formative pilot studies expressed concerns around device safety (ie, GPS), data management (ie, handling of confidential and personal information), and potential legal risks. We recommend that standards for securely storing the volume of PHD generated via these new methods be developed and vetted by data security experts to reduce the risk for a data breach. Likewise, if the rights of a bystander are to be considered during the ethical review process (eg, when capturing data of individuals who have not directly provided informed consent), standardized protocols are needed to guide responsible practices.

Justice: Inequities in Access and Utilization

Unequal access to research and interventions utilizing pervasive sensing technologies underscores ethical challenges to principles of justice. This principle is demonstrated by making sure people included in the research represent those who will ultimately benefit from scientific findings. As with clinical research and interventions more broadly [17,18], better tracking and accountability efforts are needed to improve recruitment and retention of diverse samples. To advance these efforts, we believe researchers and funding agencies have responsibilities and recommend more systematic tracking of critical factors such as language preference, country of origin, health literacy, and socioeconomic status at screening and enrollment to identify points at which underserved communities are selected out of trials and studies. While disparities in research participation are noted [17,18], there is currently limited data to support when and why there are biases in recruitment and retention. More systematic reporting on these factors would allow for greater understanding and direct efforts to ensure greater representation. Greater support of formative research, such as those described here, are needed to identify ways to reduce barriers at identified points of attrition and to hold studies accountable for their ability to recruit and retain samples that mirror the general population.

There are a few limitations worth considering. Because there were no majority group comparisons, we were unable to comment on how the challenges in implementing mHealth studies encountered by our participants compare to those with members of majority groups that may explain the digital divide. Furthermore, our participants were recruited using convenience sampling, which limits our ability to generalize to the target groups. In addition, the methodologies used across these studies were not the same, which makes it difficult to make direct comparisons and conduct more in-depth analyses. More nuanced studies are needed to tease apart the relative weight of cultural, linguistic, and educational differences across different communities and subgroups that may vary in acculturation and exposure to wearable sensor technologies used in mHealth research.

Conclusions and Next Steps

The growth of research using wearable and passive sensing technologies provides a tremendous opportunity to overcome linguistic and literacy barriers to engaging currently underserved communities in public health research and interventions. Thoughtful steps are needed to ensure equal access, or else there will be a significant danger of perpetuating or even escalating current disparities. Our commentary sheds light on concerns that may escalate the digital divide and provides suggestions for how scientists can mitigate barriers when working with underserved and culturally diverse communities. Moving forward, we suggest that mHealth researchers and IRBs work together to create meaningful ethical research practices that are responsive to research participants and consumers who can benefit from research in the digital age.

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Conflicts of Interest

None declared.

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Abbreviations

CBPR: community-based participatory research
GPS: global positioning system
IRBs: institutional review boards
mHealth: mobile heath
NHPI: Native Hawaiian Pacific Islander
PHD: personal health data

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Original Paper

Mobile Health in Oncology: A Patient Survey About App-Assisted Cancer Care

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Abstract

Background: In the last decade, the health care sector has been enriched by numerous innovations such as apps and connected devices that assist users in weight reduction and diabetes management. However, only a few native apps in the oncological context exist, which support patients during treatment and aftercare.

Objective: The objective of this study was to analyze patients' acceptance regarding app use and to investigate the functions of an oncological app that are most required, and the primary reasons for patients to refuse app-assisted cancer care.

Methods: We designed and conducted a survey with 23 questions, inquiring patients about their technical knowledge and equipment, as well as the possible advantages and disadvantages, data transfer, and general functionality of an app.

Results: A total of 375 patients participated; the participation rate was 60.7% (375/618). Gender distribution was about 3:4 (female:male) with a median age of 59 years (range 18-92 years). Whereas 69.6% (261/375) of patients used mobile devices, 16.3% (61/375) did not own one, and 9.1% (34/375) only used a personal computer (PC). About half of the patients rated their usability skills as very good and good (18.9% 71/375; 35.2% 132/375), 23.5% (88/375) described their skills as intermediate, and 14.4% (54/375) as bad. Of all patients, 182 (48.5%, 182/375) were willing to send data to their treating clinic via an app, that is, to a server (61.0% 111/182) or as email (33.5%, 61/182). About two-thirds (68.7%, 125/182) believed that additional and regularly sent data would be an ideal complement to the standard follow-up procedure. Additionally, 86.8% (158/182) wished to be contacted by a physician when entered data showed irregularities. Because of lack of skills (34.4%, 56/163), concerns about

the use of data (35.0%, 57/163), lack of capable devices (25.8%, 42/163), and the wish for personal contact with the treating physician (47.2%, 77/163), a total of 163 (43.5%, 163/375) patients refused to use an app. Pearson correlation showed a significant but mild relationship between age and app use (P=.03, r=−.12), favoring younger age; male gender correlated as well (P=.04; r=−.11).

Conclusions: The results show that the introduction of mobile apps needs to follow different strategies depending on the patients' attitude. Age and gender seem to be the strongest predictive factors. For oncology patients, our survey showed that about half of the patients were willing to send data via an app supporting their treatment. In the future, clinical data such as quality of life and treatment satisfaction recorded by mobile health (mHealth) devices could be used to evaluate and improve therapy workflow. Furthermore, apps could support classical visits, document adverse effects, and remind patients of treatment dates or drug intake.

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KEYWORDS

clinical oncology; surveys and questionnaires; mobile apps; mHealth; eHealth

Introduction

In the last decade, apps for mobile phones and tablets changed our life completely. Since the introduction of iOS (Apple Inc., USA) in 2008, apps are ubiquitous, and more than 5 million apps are available in the leading app stores [1]. Many of these support us in our everyday lives and ensure time savings or entertainment: the possibilities are huge and range from simple weather apps to complex three-dimensional games. Also, the health care sector has been enriched by numerous new innovations such as apps for weight reduction, depression, or diabetes [2-4]. Wearables and devices such as fitness trackers, blood pressure monitors, blood glucose meters, and personal scale gears are popular and convey the impression of high acceptance for collecting medical data. The World Health Organization (WHO) defines all these tools under the labels electronic heath (eHealth) and mobile health (mHealth) [5].

Although the IT world states that the era of apps has already passed, to date, only a few native apps in oncological context exist, which support patients during treatment and aftercare, and at the same time enable data analyses and feedback strategies. Not only in oncology, but in general, health care apps often lack standardized validation regarding benefits, acceptance, costs, and risks [6]. Brouard et al [7] evaluated 117 apps for oncological information and treatment monitoring. The validation of those apps was poor (27.4%). A work by Collado-Borrell et al [8] pointed out a lack of professional involvement during development and validation of 166 apps for cancer patients. Only 48.8% were developed by health care organizations.

Recently, a randomized clinical trial by Denis et al [9] investigated the outcome of lung cancer patients and showed a significantly better survival for patients (median overall survival 19 vs 12 months) using a Web-based tool for periodical documentation of symptoms and side effects during follow-up. Earlier works of the research group showed higher compliance, better communication, and 5-week earlier detection of relapse [10].

There is an ongoing debate on patients' and health care professionals' (HCPs) opinion on app technology and telemedicine [11]. A recent survey of 108 HCPs could show a great acceptance (84.3%) of app-assisted treatment [12]. The digital medicine is unstoppable and patient empowerment plays a new and growing role in disease management.

During the certification process of our Oncology Center (Onkologisches Zentrum [OZ] am RHCCC am MRI TU Munich [TUM]), we analyzed patients' acceptance regarding oncological apps. The aim of this study was to evaluate their concerns and requests. We investigated which functions are most required and what are the primary reasons for patients to refuse app-assisted cancer care.

Methods

We designed a patient questionnaire with 23 questions (Q1-Q23), which included sociodemographic details and patients' general opinion on oncological apps. Furthermore, inquiries were made on technical knowledge and equipment, possible advantages and disadvantages, data transfer, and general functionality. The survey was designed by experienced oncologists and medical computer scientists. Before initiation, the questionnaire was tested with 15 patients to optimize format and wording. Minor changes were made to provide a better patient-friendly understanding of the content of each question.

We used either multiple-choice questions with single (Q1, Q8-10, Q14, Q15-20) or multiple answers (Q4-6, Q9.1, Q9.2, Q12, Q13, Q21), free-text questions (Q1, Q2, Q3, Q23), or matrix/rating-scale questions (Q7, Q11, Q22). Rating scales were designed with even answers to avoid a central tendency bias. Q9 was developed as a polar question with branching logic with either answer "yes" (followed by Q9.1) or answer "no" (followed by Q9.2). Foreign words and technical terms were explained in a footnote where necessary (see Multimedia Appendices 1 and 2).

The evaluation was based primarily following the criteria of the Deutsche Krebsgesellschaft (DKG) for the certification of oncological centers in Germany. The survey was performed within the Oncology Center, Munich (Onkologisches Zentrum [OZ] am RHCCC am MRI TU Munich [TUM]) in the following units: dermatooncology (DERMA), breast center and gynecology (GYN), head-and-neck tumor center (HAN), hematooncology (HEM), neurooncology (NEURO), orthopedic surgery (ORTHO), radiation oncology (RADONC), and abdominal surgery (SUR). According to the expected average

patient cases per month, we distributed a total of 750 questionnaires (Table 1).

The survey was conducted for 3 months from May to July 2016. Participation was voluntary and anonymous; hence, no written consent was required by the patient. Inclusion criteria for participation were as follows: age older than 18 years, German-speaking, and physical and mental ability to fill out a structured questionnaire. Research assistants collected the anonymized data in the institutional database. The Ethics Committee of the Technical University of Munich (TUM) approved the nature and content of the study with the project number 18/16 S.

Statistical calculations were performed using SPSS statistics version 23 (IBM Corp) in a primarily descriptive way. Bivariate Pearson correlations (2-tailed) were calculated for the relationship between app use and variables, which included gender, age group, and technical skills. $P<.05$ was considered as statistically significant.

Results

Of all 750 distributed questionnaires, 375 were filled out and returned, whereas 132 were not used. This results in a participation rate of 60.7% (375/618). Gender distribution in the whole cohort was about 3:4 (female:male), with a median age of 59 years (range 18-92 years; Table 1; Q1, Q2).

Patients received the following therapies within the oncology center (Q4, multiple answers were possible): 44.3% (166/375) radiotherapy, 42.4% (159/375) chemotherapy, and 62.9% (236/375) surgery. Of all patients, 69.6% (261/375) owned a mobile device (mobile phone: 65.1%; tablet: 33.9%), whereas 16.3% (61/375) had no device, and 9.1% (34/375) only used a standard PC or notebook (Q5). Android (138/261, 52.9%) was the most commonly used mobile operating system (OS) (Q6), followed by iOS (97/261, 37.2%), Windows Mobile (31/261, 11.9%), and BlackBerry OS (2/261, 0.8%). About half of the patients rated their own usability skills (Q7) as very good (71/375, 18.9%) and good (132/375, 35.2%), whereas 23.5% (88/375) and 14.4% (54/375) described their usability skills as intermediate and poor, respectively.

Of all patients, 48.5% (182/375) were willing to send medical data via an app to their treating clinic (Q9). While Figure 1 shows data types that patients are willing to send, Figure 2 lists the patients' concerns and reasons to refuse sending data (43.5%, 163/375). When the health insurance offered a cashback or bonus when using the app as a supporting medical health tool (Q10), 36.3% (136/375) used it; however, 48.8% (183/375) were not influenced by that. Six patients (1.6%, 6/375) who previously stated they would not transfer data via an app changed their mind and used an app when financial compensation was offered (eg, by the health insurance).

Table 1. Patient distribution according to the participating oncological units.

Unit	Questionnaires distributed	Patients, n	Not used	Return rate	Gender				Median age (range) in years
					Female		Male		
All	750	375	132	60.7% (375/618)	169	45.1%	206	54.9%	59 (18-92)
DERMA[b]	50	36		72.0% (36/50	22	61.1%	14	38.9%	56 (18-81)
GYN[c]	50	6		12.0% (6/50)	6	100.0%	0	0.0%	59 (26-76)
HAN[d]	100	36	3	37.1% (36/97)	14	38.9%	31	86.1%	59 (38-85)
HEM[e]	50	42		84.0% (42/50)	19	45.2%	23	54.8%	63 (31-78)
NEURO[f]	150	45	77	61.6% (45/73)	20	44.4%	25	55.6%	54 (21-78)
ORTHO[g]	100	50	12	56.8% (50/88)	26	52.0%	24	48.0%	60 (18-92)
RADONC[h]	200	118	40	73.8% (118/160)	55	46.6%	63	53.4%	58 (18-81)
SUR[i]	50	42		84.0% (42/50)	16	38.1%	26	61.9%	62 (30-82)

[a]DERMA: dermatooncology.

[b]GYN: breast center/gynecology.

[c]HAN: head-and-neck tumor center.

[d]HEM: hematooncology.

[e]NEURO: neurooncology.

[f]ORTHO: orthopedic surgery.

[g]RADONC: radiation oncology.

[h]SUR: abdominal surgery.

Figure 1. Q9.1: Which data are you willing to transfer? (n=182).

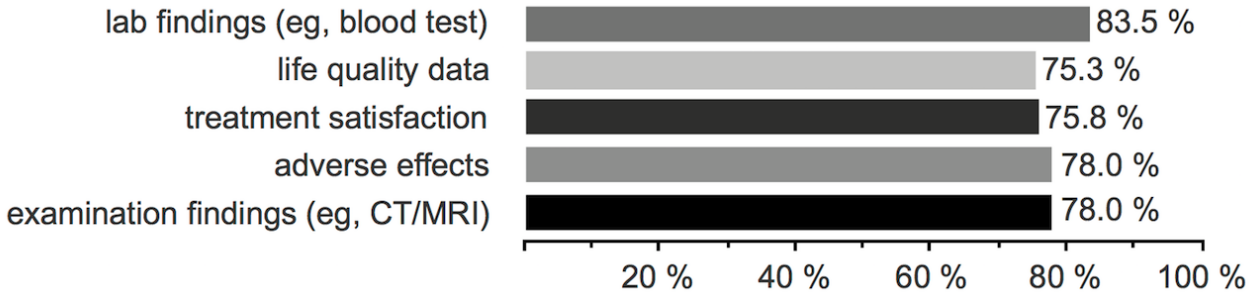
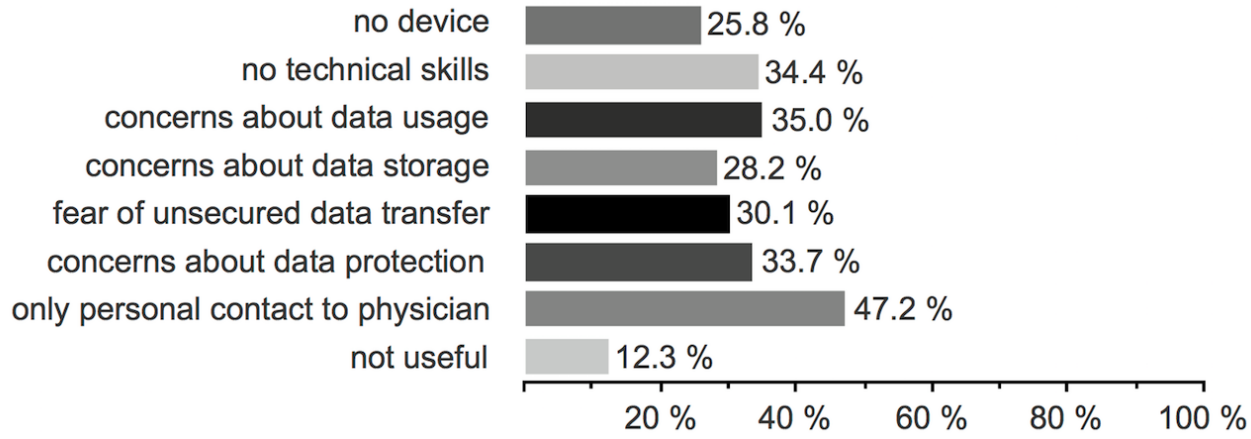


Figure 2. Q9.2: Why would you not send data via an app to your treating clinic? (n=163).



The questions Q11-Q23 were only answered by patients who indicated they would use an app with secure data transfer (48.5%, 182/375). The most important characteristics of an app should be pseudonymization, data protection, as well as feedback by a physician based on the patients' input (Figure 3, Q11). The patients agreed to the following data transfer options: data sent via the Internet to a server (61.0%, 111/182), via a cloud-based solution (11.0%, 20/182), via email (33.5%, 61/182), only on-site and locally in the clinic (19.2%, 35/182), or, for some the mode of transfer was irrelevant (10.4%, 19/182; Q12). Data entry was done at least every month (29.1%, 53/182) or every 3 months (26.4%, 48/182), in accordance to the follow-up appointments (26.4%, 48/182), and independently when necessary (17.6%, 32/182) were also favored options (Q13). The time required for data entry (eg, symptoms or current side effects) should not exceed 15 minutes (72.0%, 131/182; Q14). Additionally, 89.6% (163/182) agreed to the further use of their sent data for scientific evaluations (Q16).

About two-thirds (68.7%, 125/182) believed additional and regularly sent data would be an ideal complement to the standard follow-up procedure (Q19). About 86.8% (158/182) wished to be contacted by a physician when entered data showed irregularities (Q20).

Of all, 10.4% (19/182) also use other eHealth apps such as running apps or tracking apps for blood sugar, heart rate, or weight tracking (Q18); 10.4% (19/182) use eHealth devices such as step counters or heart rate monitors (Q17). Additional functions, apart from symptom tracking (Figure 4), were favored by 73.6% (134/182); in contrast, 15.9% (29/182) liked a simple clean app.

Furthermore, we also compared app use by age group (18-39 years; ≥40 years) and gender. Pearson correlation showed a significant but mild relationship between age and app use (P=.03, r=−.12) favoring younger age; technical skills (very good or good vs intermediate or bad) showed the same tendencies ($P \leq .001$, r=−.28). Male gender and app use correlated as well with P=.04 (r=−.11).

Figure 3. Q11: What would be important to you when considering using an app? (n=182).

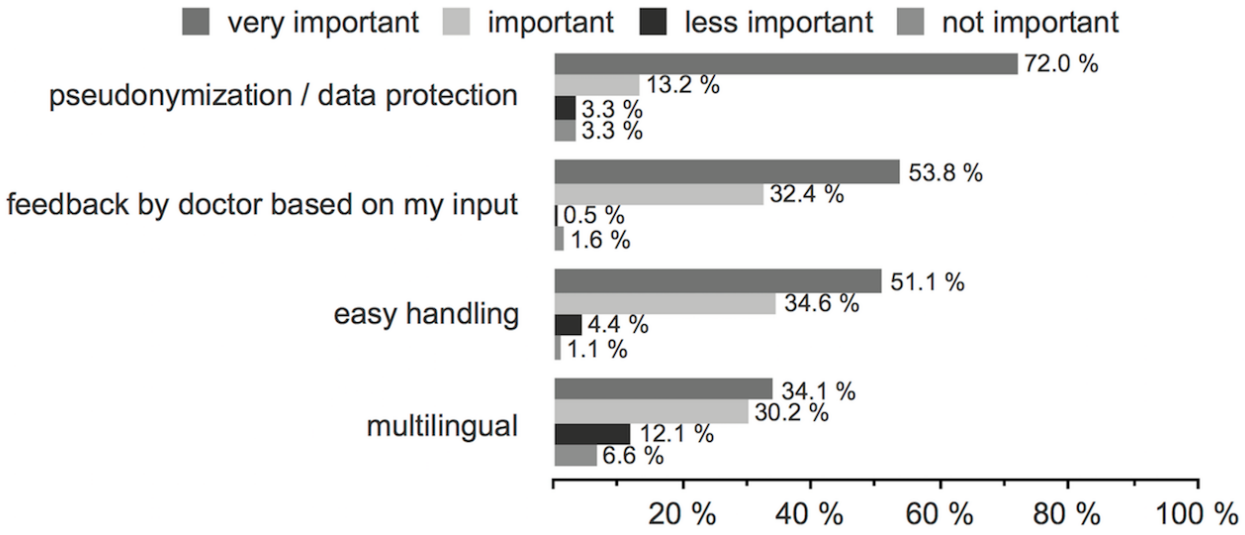
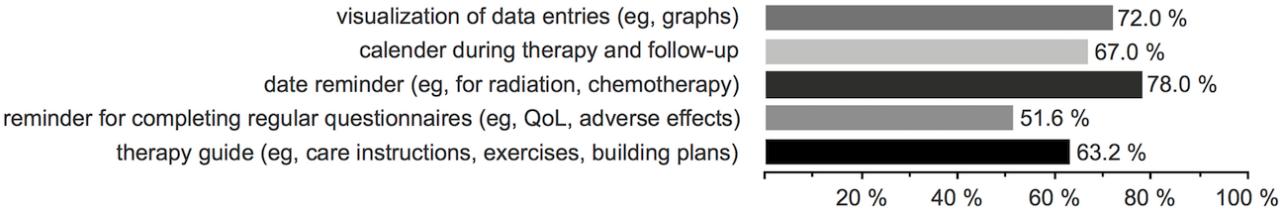


Figure 4. Q21: Figure listing desired additional functions (n=182).



Discussion

Conducted at a large, university-based oncological center, our survey revealed that about half of the patients were willing to send data via an app supporting their oncological treatment and follow-up, whereas the patients' refusal to use an app was primarily due to their fear of subsequent data use, lack of technical understanding, and data security reasons. The results showed that younger patients had a higher acceptance of these tools (P=.03 , r=−.12), as did male patients (P=.04, r=−.11). There was also a mild correlation (P ≤.001, r=−.28) between patients' technical skills and their preference for apps. Thus, the introduction of mobile apps might need to follow different strategies depending on the patients' attitude. Moreover, age and gender might be the strongest predictive factors. Younger patients show a greater inclination toward using an app. Older patients generally describe themselves as not highly skilled in the utilization of mobile phones and other mobile devices. The reluctance of female patients might be attributable to the general technical affinity of men. In contrast, a feasibility study about the use of mobile devices collecting patient-reported symptoms during radiotherapy by Falchook et al [13] showed no influence between any patient characteristic and reporting compliance; however, the cohort was relatively small with only 21 patients participating.

The possibilities for such apps are numerous. Clinical data could be used to evaluate and improve the departments' therapy workflow. The integration of quickly available digital information into daily clinical workflow seems promising. If patients are well trained, they can give input on their health status and other information by themselves without any dependence on the capacity of a physician's assistant, study nurse, or other. Moreover, information can be collected in real-time, which potentially bears high risks but also facilitates opportunities for fast response in situations of medical need. Furthermore, this type of data acquisition (eg, for blood counts and information on side effects) could be implemented in clinical studies. The limitations of our results are the relatively old patient cohort (median age 59 years) and the particular setting in oncology. The results may not apply to the general patient in other treatment situations.

However, the use of wearables and apps in the health care sector will grow strongly [2]. Chen et al [14] questioned 101 people using health care apps and 77% stated that they are willing to share their data for research. In our study on understanding the attitude of oncological patients toward app use, 48.5% (182/375) agreed to send personal and health data and make themselves available for further analyses. The expected profits in the areas of prevention, diagnostics, and therapy, as well as the increasing cost pressure for hospitals and health insurance will push mHealth innovations and drive the mobile transformation of all sorts of processes.

The compliance to use apps is high in various domains. A current health app revolution can be observed, which is exploited by many non-expert developers. Apps for oncological patients must be developed carefully by keeping in mind that the recipients are very vulnerable, as they mostly have to fight with quick relapse and bad prognosis and will use everything to

improve their outcome. Cancer patients are always interested in doing everything possible to have a positive influence on their respective disease. Oncological apps could strengthen the self-care and allow close follow-up. However, a standardized validation process must be implemented for medical apps to guarantee safety for the patient [8,15,16]. Further prospective clinical trials, such as the study by Denis et al [10] on lung cancer, which proved a positive influence of apps during follow-up on survival, would be necessary to demonstrate their respective benefit for the patient before these are deployed to the public.

Young people grow up with apps in all life situations. The constant mobile availability of information is, therefore, self-evident to them. This generation will continue to drive the development and use of mobile apps also in the medical field and ensure that they ultimately determine the digital health care. This revolution will change the way physicians work and the role of data protection and its meaning for the patient [17].

Clinical data, such as quality of life and treatment satisfaction, recorded by mHealth devices could be used to evaluate and improve therapy workflow in the future, apps could support classical visits and document side effects, or remind patients of treatment dates or drug intake. The advantages could be equally beneficial for professionals and patients. Though mobile phones and other mobile devices will certainly not replace personal contact with a physician, these will serve as a digital assistant in diagnosis, therapy, and follow-up.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Original questionnaire (German).

[PDF File (Adobe PDF File), 385KB - mhealth_v5i6e81_app1.pdf]

Multimedia Appendix 2

Translated questionnaire (English).

[PDF File (Adobe PDF File), 339KB - mhealth_v5i6e81_app2.pdf]

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Abbreviations

DKG: Deutsche Krebsgesellschaft
eHealth: electronic health
HCPs: health care professionals
mHealth: mobile health
OS: operating system
PC: personal computer
TUM: Technical University of Munich
WHO: World Health Organization

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Original Paper

A Mobile App for the Self-Management of Type 1 Diabetes Among Adolescents: A Randomized Controlled Trial

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Abstract

Background: While optimal blood glucose control is known to reduce the long-term complications associated with type 1 diabetes mellitus, adolescents often struggle to achieve their blood glucose targets. However, their strong propensity toward technology presents a unique opportunity for the delivery of novel self-management interventions. To support type 1 diabetes self-management in this population, we developed the diabetes self-management app *bant*, which included wireless blood glucose reading transfer, out-of-range blood glucose trend alerts, coaching around out-of-range trend causes and fixes, and a point-based incentive system.

Objective: The primary objective was to evaluate *bant* 's effect on hemoglobin A_{1c} (HbA_{1c}) through a randomized controlled trial (RCT). Secondary measures (eg, self-monitoring of blood glucose [SMBG]) were also collected to assess *bant* 's impact on the self-management behaviors of adolescents with type 1 diabetes.

Methods: We enrolled 92 adolescents into a 12-month RCT, with 46 receiving usual care and 46 receiving usual care plus *bant*. Clinical outcome data were collected at quarterly research visits via validated tools, electronic chart review, glucometer downloads, and semistructured interviews. App satisfaction was assessed at 6 and 12 months, and at trial end, users ranked *bant* components based on perceived usefulness. Mobile analytics captured frequency of blood glucose uploads, which were used to categorize participants into high, moderate, low, or very low engagement levels.

Results: Linear mixed models showed no changes in primary and secondary clinical outcomes. However, exploratory regression analysis demonstrated a statistically significant association between increased SMBG and improved HbA_{1c} in the intervention group. For a subgroup of *bant* users taking SMBG ≥5 daily, there was a significant improvement in HbA_{1c} of 0.58% (P=.02), while the parallel subgroup in the control arm experienced no significant change in HbA_{1c} (decrease of 0.06%, P=.84). Although

app usage did diminish over the trial, on average, 35% (16/46 participants) were classified as moderately or highly engaged (uploaded SMBG ≥3 days a week) over the 12 months.

Conclusion: Although primary analysis of clinical outcomes did not demonstrate differences between the *bant* and control groups, exploratory analysis suggested that *bant* may positively impact the use of SMBG data and glycemic control among youth. The next generation of *bant* will aim to remove barriers to use, such as deploying the app directly to personal devices instead of secondary research phones, and to explore the utility of integrating *bant* into routine clinical care to facilitate more frequent feedback. Future evaluations of mHealth apps should consider more robust research tools (eg, ResearchKit) and alternative RCT study designs to enable more rapid and iterative evaluations, better suited to the nature of rapidly evolving consumer technology.

Trial Registration: ClinicalTrials.gov NCT01899274; https://clinicaltrials.gov/ct2/show/NCT01899274 (Archived by WebCite at http://www.webcitation.org/6qWrqF1yw)

(JMIR Mhealth Uhealth 2017;5(6):e82) doi:10.2196/mhealth.7336

KEYWORDS

diabetes mellitus; mobile phone; cell phones; mobile applications; behavior change; blood glucose; self-management; self-care; adolescent; gamification

Introduction

Type 1 diabetes mellitus is among the most common chronic diseases affecting children, adolescents, and adults, with an increasing worldwide incidence of approximately 3% to 4% a year [1,2]. Optimizing blood glucose control is important for patients with type 1 diabetes, as improved control has been shown to reduce the incidence and severity of type 1 diabetes complications and diabetes-related mortality [3-6]. However, achieving optimal control requires intensive self-management, which can be challenging for patients to achieve. Adolescents, in particular, struggle with optimizing blood glucose control, with worldwide data indicating they consistently fail to meet their prescribed therapeutic targets [7,8].

Overall, advancements in the mechanism of insulin delivery (ie, insulin pump or multiple daily injections) has had a limited impact on glycemic control among youth [9,10]. Instead, research has suggested that self-care factors, such as targeted goal setting and improved self-monitoring of blood glucose (SMBG), along with educational models, may have a greater impact on health outcomes [11-13]. Given adolescents' propensity for new technology, eHealth interventions may provide a unique opportunity to communicate with and motivate youth and thereby improve their diabetes management [14,15]. Teenagers are adopting new forms of technology quicker and in a more immersive way than any other age group, with the mobile phone becoming a primary communication tool for this demographic [16,17]. In 2015, it was reported that 88% of American teens either owned or had access to a mobile phone, up from 45% in 2004 [16,17].

Recently, the use of mHealth apps as a tool for improved diabetes self-management has proliferated, as illustrated by the number of diabetes apps available for download on the iOS App Store and Google Play [18-23]. While interest in this technology continues to rise, the clinical utility of these apps remains unclear [24]. Only a limited number of diabetes apps have completed rigorous evaluation and, to date, most studies have been conducted for the adult [25] and/or type 2 diabetes mellitus population [26,27]. How effective these apps are among adolescents with type 1 diabetes remains unknown.

Furthermore, many of the existing apps require manual entry of blood glucose values and focus primarily on the display of diabetes-related data, such as blood glucose readings, carbohydrate intake, and insulin doses [24,28]. However, recent reviews have demonstrated that very few of these apps use this information to provide users with personalized feedback, education, or motivation [28-30]. With clinical guidelines emphasizing the importance of individualized feedback and targeted education, failing to provide users with these features puts current apps at risk of simply mirroring paper-based tools, instead of being a means for behavior change and comprehensive self-management [31].

Therefore, the objective of this research was to design, develop, and evaluate *bant*, an app aimed to assist adolescents with the self-management of type 1 diabetes. In 2010-2011, a pilot version of *bant* was developed and evaluated through a 12-week pilot study (n=20) among adolescents with type 1 diabetes, aged 12-16 years, with hemoglobin A_{1c} (HbA_{1c}) between 8% and 10%. Results showed an increase in daily SMBG by 50% (P=.006) and a high reported level of satisfaction, with 88% of respondents stating they would continue to use the system [32]. While use of *bant* led to improved self-management behaviors, the trial was not designed to assess effect on HbA_{1c}. This paper reports the results of a 12-month randomized controlled trial (RCT) conducted to assess the effectiveness of an updated version of *bant* as a self-management tool for adolescents with type 1 diabetes (ClinicalTrials.gov NCT01899274; Multimedia Appendix 1 [33]).

Methods

Adolescents with a diagnosis of type 1 diabetes, between the ages of 11 and 16 years, were randomly assigned to 1 of 2 groups: (1) the *bant* (intervention) group, or (2) the treatment as usual (control) group. Both groups were followed for a duration of 12 months.

Ethical Approval

Before initiating the study, protocol approval was obtained from all site-specific ethical review boards and/or committees (The

Hospital for Sick Children: #1000036524; University Health Network: #13-6237-BE; Trillium Health Partners: #619).

Enrollment

We recruited participants from August 2013 to December 2014 from 2 pediatric endocrinology centers in Toronto, Ontario, Canada. The final study visit was completed in January 2016. Patients were eligible to participate if they (1) had a diagnosis of type 1 diabetes mellitus (as defined by Canadian Diabetes Association guidelines [31]) for 1 year or more, (2) were between the ages of 11 and 16 years, inclusive, at the time of enrollment, (3) had been followed at the current clinic for at least 6 months, and (4) had 2 of their 3 most recent HbA_{1c} readings (including the day of enrollment) between 8.0% and 10.5%. We selected this HbA_{1c} range in an attempt to identify patients who were struggling with their glycemic control, and for whom the use of a smartphone app alone might be an appropriate intervention. Given that *bant* was only offered in English at the time of recruitment, participants were excluded if they did not fluently speak and understand English. All participants and parents provided written, informed consent prior to participation.

Sample Size

Sample size was determined based on a nominal 2-sided type I error rate of 5% and 80% power. Estimates of standard deviation in HbA_{1c} ranging from 0.50% to 0.75% were used to determine the minimum number of participants required to detect a clinically relevant (≥0.5%) change in HbA_{1c} levels [34-36]. Standard deviation estimations were consistent with the *bant* pilot study, which reported a baseline standard deviation of 0.55% in HbA_{1c} levels, and were also informed by longitudinal HbA_{1c} variation over 9 months in an independent sample of 13 patients. A final sample size of 92 participants (46 per intervention arm) allowed for a potential 25% dropout rate.

Random Allocation

At enrollment, participants were assigned equally to an intervention or control arm using randomly allocated block sequences of 4 to 6 participants. To ensure equal distribution between arms, we stratified random allocation for treatment modality (insulin pump vs insulin injection), as well as study center (The Hospital for Sick Children vs Trillium Health Partners). The RCT was an unblinded, open-label study, as both the participants and those delivering the intervention were aware of allocation based on whether or not the *bant* system was received. In addition, clinical outcomes were not blinded, as they are part of a participant's ongoing clinical care and diabetes monitoring regimen.

Intervention

The initial design of *bant* was informed by insights gathered through qualitative ethnographic interviews conducted with adolescents living with type 1 diabetes and their families. In addition to patient input, we held focus group sessions with clinical staff who had experience managing type 1 diabetes and chronic disease among adolescents. Feedback from these sessions, as well as input from human factors specialists, informed the development of the pilot version of *bant*, which was then evaluated among 20 adolescents for 3 months. The initial focus group sessions, user-centered design, and evaluation of *bant* have been previously reported by Cafazzo et al [32]. Upon the completion of the pilot trial, we obtained feedback from participants, leading to further refinement of *bant* (Multimedia Appendix 2). It is important to note that, while the pilot version of *bant* was designed to incentivize more frequent SMBG, the updated version of *bant* included additional tactics that could potentially further facilitate improved HbA_{1c}. Therefore, users were rewarded for taking SMBG but also for maintaining their blood glucose within their target range. Table 1 describes the key features of *bant* (for related screenshots, see Multimedia Appendix 2), and Figure 1 illustrates the system that the intervention group received.

Table 1. Key features of *bant*.

Feature	Description
Automatic Data Transfer	Blood glucose readings are wirelessly transferred from a Bluetooth-enabled blood glucose meter, using an adaptor (BluGlu), to *bant*.
Electronic Logbook	Current and past blood glucose readings categorized by context (eg, lunch) are displayed over multiple time frames (eg, 1 week, 1 month).
Trends	Percentages of readings in or out of target, per context, are displayed over various time frames (eg, over 30 days, 10% of breakfast readings were high).
Trend Wizard	Algorithm that detects and informs the user of consecutive out-of-range readings for the same context (eg, 3 consecutive high dinner readings) and prompts the user to identify the likely cause of the trend and potential fixes.
Reward System	Reward mechanism that awards points to encourage the following behaviors: (1) taking up to 5 readings per day, (2) getting readings in target range, (3) avoiding out-of-range trends, and (4) resolving any identified 3-day trends. Users can redeem their points for iTunes gift cards. *bant* also includes a leaderboard for users to see where they rank compared with their peers.
banter	A private social media community that allowed trial participants to communicate with each other.
Personal Health Record	Integration with TELUS health space, a secure personal health record that stored blood glucose data and enabled sharing with members of the care team.

Figure 1. The intervention includes an iPhone 4S loaded with *bant*, as well as a Bluetooth adapter attached to the OneTouch UltraMini blood glucose meter. Circles represent individual readings at different times of the day, with the bedtime reading having been selected to display further information; the blue region represents a particular participant's target blood glucose range. The different colors of the circles represent the different reading contexts (eg, breakfast readings are blue).

Study Protocol

Adolescents who met the inclusion criteria and provided informed consent were randomly allocated to receive either usual clinical care (control group) or usual clinical care plus *bant* (intervention group). For reference, usual clinic care was defined as the standard care all youth and adolescents with type 1 diabetes receive at their quarterly clinic visits, as dictated by Canadian Diabetes Association guidelines [31]. At baseline, those allocated to the intervention group received an iPhone 4S (Apple Inc, Cupertino, CA, USA) loaded with *bant*, a OneTouch UltraMini (Lifescan, Inc, Milpitas, CA, USA) blood glucose meter, and a Bluetooth adapter (BluGlu, a device developed by University Health Network for investigational purposes only) that allowed for wireless transmission of data from the blood glucose meter to *bant*. To facilitate independent use, all *bant* users received a standardized 1-hour tutorial at study enrollment, which included hardware setup, introduction to app features, username creation, and troubleshooting steps for potential issues. During this time, *bant* users also created a TELUS health space account (TELUS Health Solutions, Cambridge, ON, Canada), which allowed for remote and secure storage and backup of their blood glucose data. Control group participants also completed a baseline visit. However, they did not receive any study-related hardware from the research team. Both control and intervention participants received 2 movie theater passes in exchange for their effort and time during the baseline and all subsequent visits.

Baseline visits were followed by 3-, 6-, 9-, and 12-month research visits for all participants. All research visits coincided with the participant's standard quarterly clinic visit; however, these visits were conducted separate from the clinic visit by trained research staff. Qualitative and quantitative data were collected at all follow-up visits via semistructured interviews, validated instruments, downloads of blood glucose meters, and electronic chart review. Halfway between each follow-up visit, we contacted participants in the *bant* group to ensure they were not experiencing any technical issues. No advice or communication around clinical care or their diabetes regimen was discussed with participants during these calls. At study end, the *bant* system was returned to research personnel.

Primary Outcome Measures

The primary outcome of the study was change in HbA_{1c} (measured in percentage) from baseline to 12 months, between the intervention and control group. HbA_{1c} was measured during routine clinical blood work and accessed by research staff through electronic chart review. The primary research site (The Hospital for Sick Children) used a high-performance liquid chromatography assay (Bio-Rad Laboratories, Inc, Waterloo, ON, Canada) or an enzymatic assay (Abbott Laboratories, Ltd, North York, ON, Canada) to measure HbA_{1c}, with internal quality control demonstrating excellent agreement among samples assayed by both methods (r>.99). The secondary site (Trillium Health Partners) measured HbA_{1c} using a point-of-care

immunoassay (DCA 2000+, Siemens Healthcare Ltd, Oakville, ON, Canada) for all measurements.

Secondary Outcome Measures

Hypoglycemic Events

The frequency of mild and severe hypoglycemic events was assessed as secondary measures of glycemic control. A severe hypoglycemic event was defined as any episode that required the assistance of another individual and a blood glucose reading below 2.8 mmol/L and/or a subsequent reversal of clinical symptoms with intake of oral carbohydrate, glucagon injection, or intravenous glucose [37]. A mild hypoglycemia event was defined as a blood glucose reading below 3.4 mmol/L.

The frequency of severe hypoglycemic events was self-reported by participants and/or their guardians during semistructured interviews conducted at baseline and all follow-up research visits. To capture the frequency of mild hypoglycemic events, the previous 50 days of blood glucose readings were downloaded from all available (study and/or personal) blood glucose meters and/or insulin pumps during the participant's clinic appointment. All downloads were completed by trained staff using the manufacturer-provided electronic downloading programs, specific to each blood glucose meter or pump brand. In cases where not all hardware was available, participants estimated what percentage of their total blood glucose readings were on the devices they brought to clinic that day.

All individual readings below 3.4 mmol/L were recorded as an individual mild hypoglycemic event, except for low blood glucose readings taken within the same or consecutive-hour timeslots. Grouping contemporaneous readings together and counting them as a single episode ensured that a singular hypoglycemic event was not recorded multiple times.

Self-Monitoring of Blood Glucose

We measured the average number of daily SMBG using all data collected from the 50-day blood glucose meter and/or insulin pump printout(s). Each blood glucose reading was counted individually, except when taken within the same hour, in which case readings were grouped. Readings taken over a 2-hour period in apparent response to an initial low (<4.1 mmol/L) or high (>17.9 mmol/L) were also grouped together. Using the total counted readings and number of days collected, we calculated the average number of daily SMBG at baseline as well as each follow-up visit, and when warranted, corrected for the percentage of readings available as estimated by participants.

Self-Initiated Adjustments

We assessed the number of self-initiated adjustments made to a participant's type 1 diabetes insulin regimen during qualitative interviews conducted at baseline and all follow-up visits to determine whether use of *bant* led participants to attempt to adjust their insulin regimens more frequently. A self-initiated adjustment was defined as a change made to the prescribed treatment regimen that was initiated by the participant and/or their guardian(s) and implemented between clinic appointments. Changes made to the regimen by the diabetes care team during a routine clinic visit were not included. Participants self-reported who (the participant and/or their parent[s]/guardian[s]) was responsible for initiating the adjustment(s), as well as whether the diabetes team had been contacted for input on the regimen change.

Validated Questionnaires

Validated instruments were used to capture quality of life, self-care, and management data. The Diabetes Quality of Life for Youth (DQOLY) questionnaire [38,39] and the Diabetes Family Responsibility Questionnaire (DFRQ) [40] were administered at 6- and 12-month visits; the Self Care Inventory [41-43] was administered at all time points. The Readiness to Change Survey (Multimedia Appendix 3, Participant Management Questionnaire) was captured at baseline to help characterize the study population [44,45]. All surveys were given to participants to complete independently during their research visit.

Satisfaction With bant

We assessed overall satisfaction with *bant* via qualitative interviews conducted at 6- and 12-month visits. On a 7-point Likert scale, ranging from 1 (very dissatisfied) to 7 (very satisfied), users were asked to rate overall satisfaction as well as satisfaction for 5 individual *bant* components: (1) trend wizard, (2) the leaderboard, (3) automatic blood glucose transfer, (4) *banter*, and (5) iTunes rewards. In addition to collecting satisfaction scores, we conducted semistructured interviews to gather qualitative feedback from *bant* users during their 6- and 12-month research visits. Users were asked to provide feedback on app features, content, and how *bant* influenced their overall type 1 diabetes management. They were also asked to list, in a free-form text field, the 3 most and least helpful features of *bant*.

Usage Data

We collected mobile usage data through a third-party service, Flurry (Yahoo, Sunnyvale, CA, USA), which tracked (1) the number of times users accessed *bant*, (2) how often they used certain features, and (3) the number of times users wirelessly uploaded data from their blood glucose meter.

Statistical Analysis

Preliminary *t* tests and chi-square tests were used to determine if there were any statistically significant differences between the intervention and control groups for the primary and secondary outcomes and demographic characteristics at baseline. This step allowed us to ensure the comparability of both the intervention and control groups at baseline and to ensure that we did not have any chance imbalances that might have required further adjustment.

Subsequently, we used linear mixed models to determine whether there were any statistically significant differences between the treatment and control groups for the above-mentioned outcomes. As all outcomes of interest were continuous, a linear mixed-model approach provided a simple method to assess treatment efficacy while adjusting for the correlation of each participant over time (using a random effect). Moreover, this approach is more powerful than a repeated-measures analysis of variance (ANOVA), as it allows participants with missing values at 1 or more time points to

contribute some information to the analysis, while a repeated-measures ANOVA requires the availability of data at all time points for each participant [46]. We examined each outcome graphically to determine whether the data were normally distributed. All outcomes were approximately normally distributed, with the exception of the number of mild hypoglycemic events, which appeared to be somewhat skewed. However, linear mixed models have the ability to assess data that are not normally distributed and remain robust, as long as the sample size is large [47]. As a result of the large sample size and graphical appearances of normality, this assumption appeared reasonable.

Secondary analyses relied on comparison between groups at the primary end point of 12 months using 2-sample *t* tests or chi-square tests. Moreover, additional exploratory univariate regression analyses examined the impact of SMBG on clinical outcomes for those who were taking SMBG 5 or more times per day at 12 months within both the intervention (n=8) and control (n=5) groups. Although this is a very small subgroup, it provides some insight into the potential role of *bant* in controlling diabetes for those participants who are engaged and actively monitoring their blood glucose levels. Due to small sample sizes, adjusting for other confounding variables was not possible. Additionally, we used exploratory analyses, including chi-square tests, 2-sample *t* tests, and regression analyses, to evaluate the effectiveness of *bant* in subgroups based on insulin regimen (insulin pump vs insulin injections) and baseline HbA_{1c} levels (≥9.0% vs <9.0%). Finally, usage and satisfaction data were also summarized for exploratory purposes. All statistical analyses were performed using SAS software version 9.4 for Windows (SAS Institute) Results were considered statistically significant at the $P \leq .05$ level, and all reported results are 2-tailed.

Results

Study Population

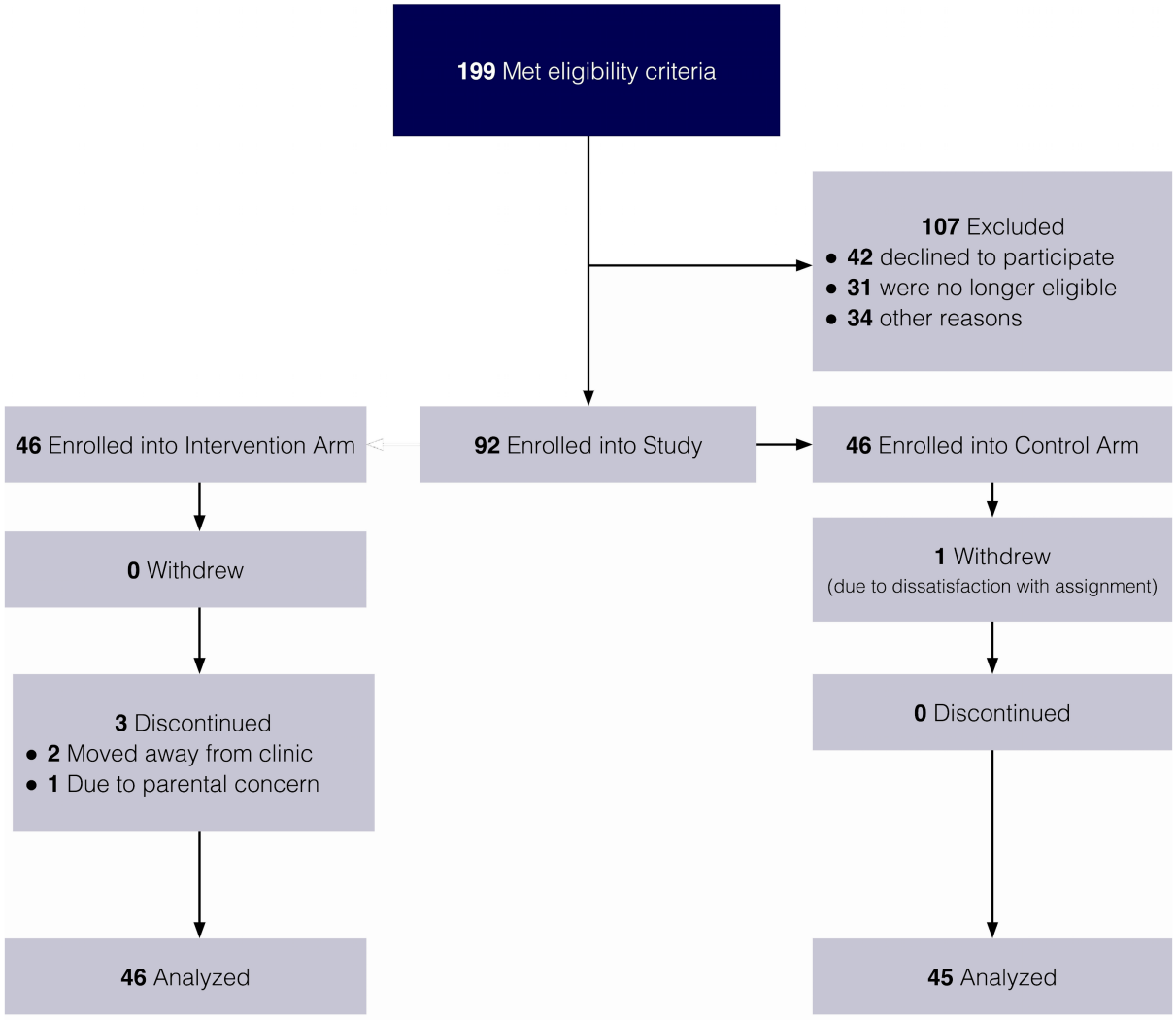
Using the study inclusion criteria, we identified eligible participants from clinical databases and enrolled them sequentially until recruitment targets were met. Through this process, 199 eligible patients were identified; 42 patients declined to participate, 31 patients no longer met eligibility criteria, and 34 patients were excluded for other reasons, including planning to change clinics within the study time frame, having recently switched insulin regimens, and participating in another study with similar outcome measures. As Figure 2 shows, a total of 92 participants were enrolled and randomly allocated into the study.

Table 2 summarizes the demographic characteristics of the participants at baseline. There were no significant differences between the 2 groups in any of the measured characteristics, nor were there significant differences between the groups with respect to the readiness to change domains.

Table 2. Baseline characteristics of intervention and control groups.

Characteristics	Treatment group (n=46)	Control group (n=46)	*P* value
Sex (male/female), n	21/25	20/26	>.99
Age at baseline in years, mean (SD)	14.1 (1.7)	13.9 (1.5)	.54
Age at diagnosis in years, mean (SD)	7.1 (3.6)	7.4 (3.3)	.71
Duration of type 1 diabetes mellitus in years, mean (SD)	7.1 (3.2)	6.6 (3.2)	.48
Insulin regimen (pump/injection), n	23/23	22/24	.84
Hemoglobin A_{1c} in %, mean (SD)	8.96 (0.7)	8.92 (0.6)	.77

Figure 2. Participant enrollment.



Clinical Outcomes

There were no significant differences in HbA_{1c} between the intervention and control groups over the duration of the 12-month trial (P=.99). Both groups demonstrated diminution in HbA_{1c} up to the 9-month time point, after which both experienced a subsequent increase to preintervention HbA_{1c} levels. This diminution speaks to study effects from the trial and demonstrates the importance of the control group. At trial conclusion, the intervention and control group displayed a mean HbA_{1c} of 8.96 (±1.3) and HbA_{1c} of 8.96 (±1.2), respectively (Figure 3).

Between group analyses also showed no significant improvements in any of the predefined secondary outcomes between the intervention and control groups (Table 3).

Table 3. Secondary outcome measures.

Outcome measures	Intervention		Control		*P* value (between-group)
	Baseline	12 months	Baseline	12 months	
Mild hypoglycemic events[a], mean (SD)	10 (8.2)	11.52 (10.7)	8.49 (9.6)	7.54 (7.7)	.047
Severe hypoglycemic events[b], mean (SD)	0.23 (0.6)	0.16 (0.4)	0.41 (1.3)	0.48 (1.2)	.13
Self-monitoring blood glucose[a], mean (SD)	3.98 (1.6)	3.49 (1.8)	3.55 (1.6)	3.39 (1.5)	.42
Number of adjustments to regimen[b], mean (SD)	1.85 (2.3)	1.77 (2.7)	2.08 (3.4)	1.10 (1.3)	.25
SCI score[c], mean (SD)	35.73 (4.6)	35.42 (5.0)	36.07 (5.4)	35.57 (6.4)	.81
DQOLY[d] subscale scores, mean (SD)					
Impact of Symptoms	3.58 (1.7)	3.33 (1.7)	3.55 (1.8)	3.16 (1.6)	.15
Impact of Treatment	2.76 (2.3)	2.53 (2.1)	2.73 (2.0)	2.28 (2.2)	.51
Impact on Activities	3.00 (2.2)	2.96 (3.0)	3.04 (2.8)	3.42 (3.0)	.72
Parental Issues	5.13 (3.3)	5.20 (3.6)	5.12 (3.1)	4.67 (3.6)	.71
Worries About Diabetes	6.83 (5.5)	6.84 (5.8)	6.51 (5.8)	4.81 (5.0)	.17
Health Perception	2.00 (0.7)	1.96 (0.7)	1.90 (0.6)	2.10 (0.6)	.50
DFRQ[e] overall and subscale scores, mean (SD)					
General Health Domain	12.76 (2.2)	13.70 (2.4)	12.53 (2.1)	13.31 (2.8)	.60
Social Presentation Domain	8.62 (1.6)	8.86 (1.5)	8.81 (1.5)	9.08 (1.4)	.38
Regimen Domain	13.90 (2.4)	14.60 (2.1)	13.61 (2.5)	14.40 (2.7)	.64
Total DFRQ score	35.29 (4.9)	37.16 (4.3)	34.94 (4.6)	36.79 (5.7)	.78

[a]Average number over 50 days prior to study clinic appointment.

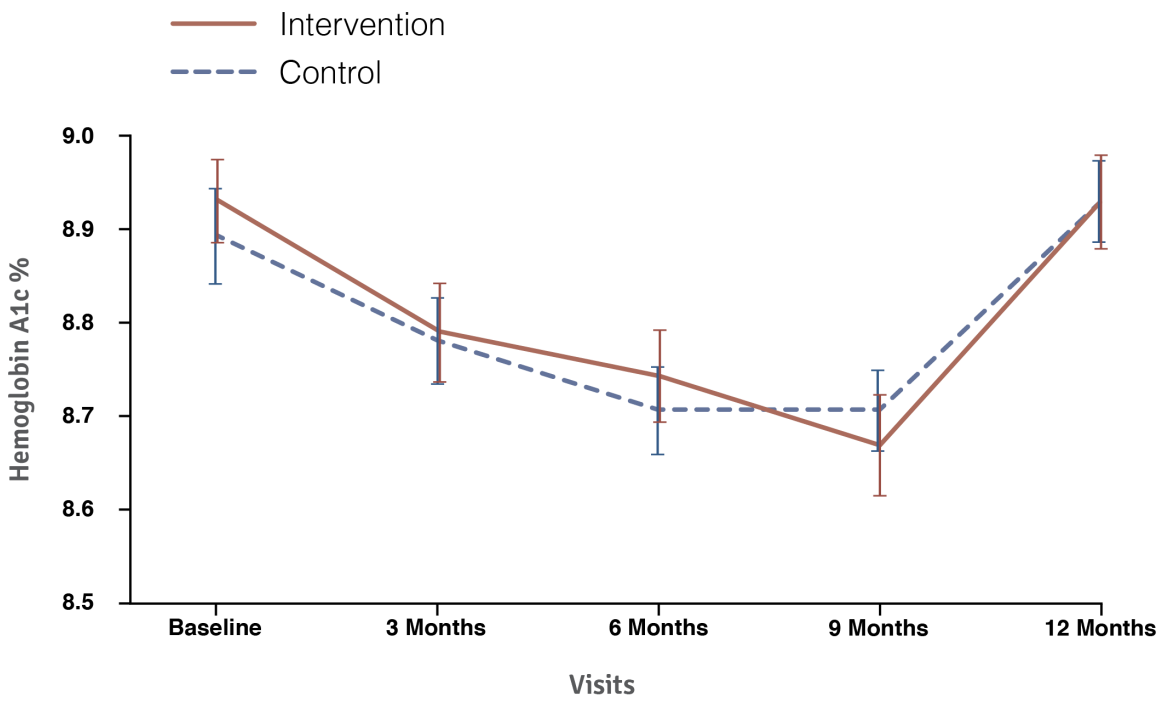
[b]Average number between study clinic appointments (typically 90 days).

[c]SCI: Self-Care Inventory, a 14-item questionnaire using 6-point scale (1 to 5, and "not applicable" option) to measure adherence to treatment recommendations. Overall score ranges from 10 to 50.

[d]DQOLY: Diabetes Quality of Life for Youth questionnaire, a 22-item questionnaire measuring quality of life, split across 6 subscales. Subscales use an inverted 5-point Likert scale (0 to 4), with the exception of the Health Perception subscale, which uses an inverted 4-point scale (1 to 4). Higher scores are associated with poorer quality of life; possible subscale scores range from 1 to 4 (Health Perception), 0 to 12 (Impact of Symptoms, Impact of Treatment, Parental Issues), 0 to 20 (Impact on Activities), and 0 to 28 (Worries About Diabetes).

[e]DFRQ: Diabetes Family Responsibility Questionnaire, a 17-item questionnaire measuring adolescent-guardian interaction around care, split across 3 subscales. All subscales use a 3-point scale (1 to 3). Higher scores are associated with increased adolescent involvement in care. Overall score ranges from 17 to 51; subscales range from 7 to 21 (General Health Domain), 4 to 12 (Social Presentation Domain), and 6 to 18 (Regimen Domain).

Figure 3. Mean hemoglobin A_{1c} values for the intervention and control groups from baseline to 12 months.



Exploratory Analyses

Using all available data at each time point, we performed additional analyses to identify potential relationships between measured clinical outcomes, both within and between the intervention and control groups. Figure 4 shows a significant relationship between increased SMBG and improved HbA_{1c} in the intervention group at baseline, which strengthened over time, specifically when comparing 9-month (*P*=.002) and 12-month visits (*P*=.008) with baseline. This relationship was not observed in the control group at any time point (n between 32 and 46 for comparison).

In further exploratory analyses, we identified a subgroup of patients with a frequency of SMBG of 5 or more per day at 12 months within both the intervention (n=8) and control (n=5) groups. This threshold was chosen because it is a commonly recommended daily SMBG target in The Hospital for Sick Children diabetes clinic, and this group represented a population of users who were actively engaged with daily SMBG at the end of the trial. No significant difference in daily SMBG was noted between the control subgroup (mean 7.02, SE 0.57) and the intervention subgroup (mean 6.32, SE 0.45) at baseline (*P*=.34). Similarly, at 12 months, there was also no significant difference in SMBG frequency between participants in the control (mean 6.24, SE 0.57) and intervention (mean 6.33, SE 0.45) subgroups (*P*=.90).

HbA_{1c} did not significantly differ between the 2 subgroups at baseline (control mean 8.84%, SE 0.27% vs intervention mean 8.40%, SE 0.21%; *P*=.21). However, as shown in Figure 5, at the 6-month time point, users in the intervention subgroup demonstrated a significantly lower HbA_{1c} when compared with the controlled subgroup (*P*<.001), a difference that persisted for the remainder of the trial (9 months, *P*<.001; 12 months, *P*=.008). Furthermore, the *bant* subgroup demonstrated an overall improvement in HbA_{1c} of 0.58% (*P*=.02), while the parallel subgroup in the control arm experienced no significant change in HbA_{1c} (decrease of 0.06%, *P*=.84).

In addition to the subset with SMBG of 5 or more per day, we also conducted subgroup analyses for insulin regimen (insulin pump vs insulin injections), as well as baseline HbA_{1c} levels (participants with baseline HbA_{1c} ≥9.0% vs <9.0%); however, no statistically significant differences were noted.

Figure 4. Regression analysis for self-monitoring of blood glucose (SMBG) and hemoglobin A_{1c}.

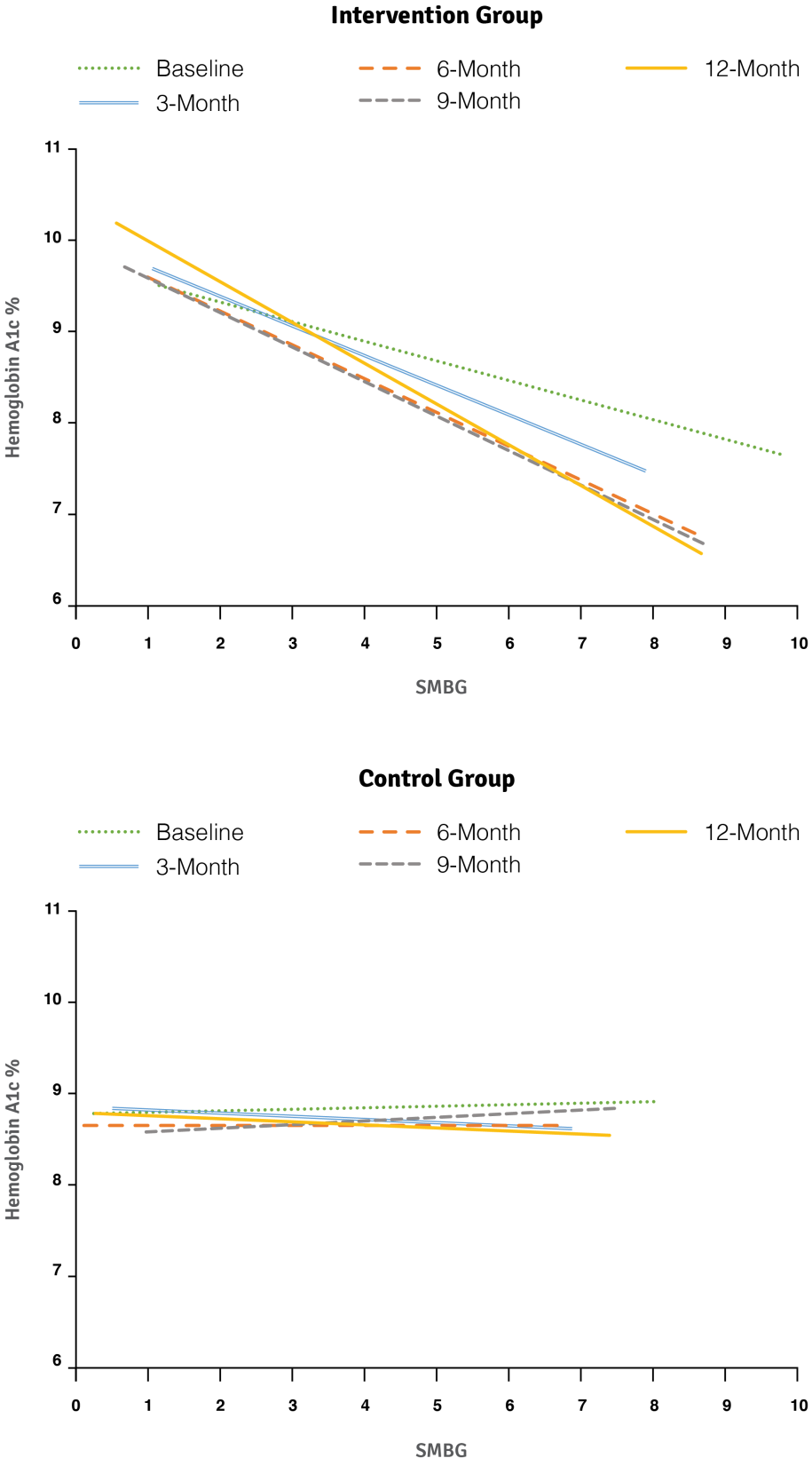
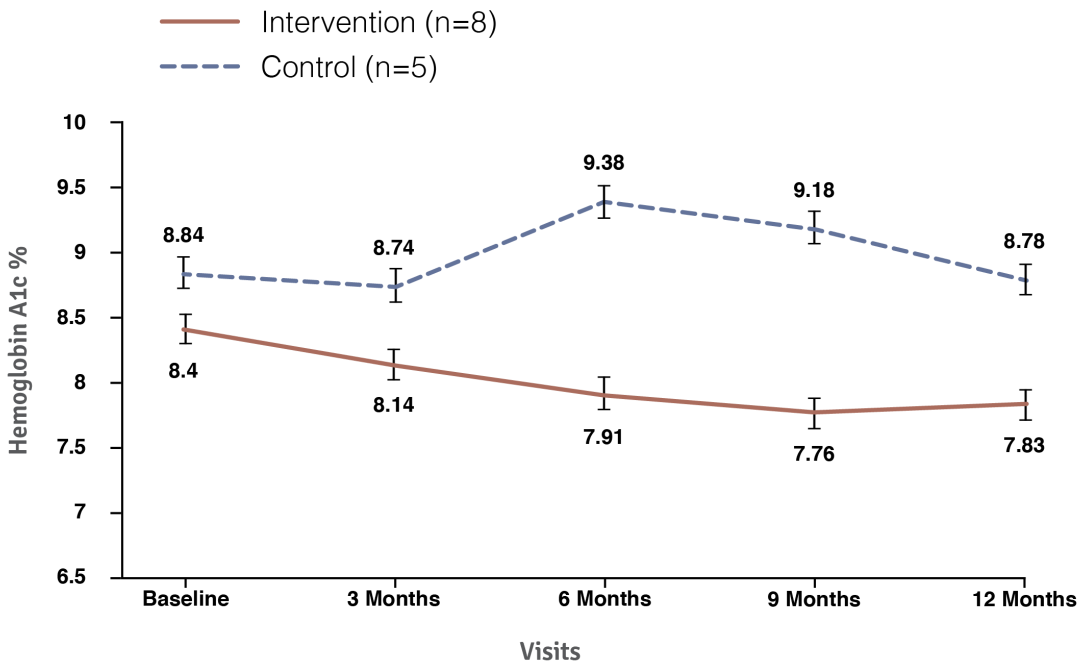


Figure 5. Longitudinal mean hemoglobin A_{1c} for intervention and control participants with 12-month self-monitoring of blood glucose of 5 or more per day.



bant Usage Data

To assess use of *bant* over the course of the study, engagement levels were established. Given that the app was designed to facilitate daily SMBG and self-management activities, the engagement threshold levels were based on the total number of days that a user wirelessly uploaded blood glucose readings to *bant* over 12 months. As Table 4 shows, 4 levels of engagement (very low, low, moderate, and high) were used, where the highest engagement level was defined by a data upload frequency greater than 3 out of 7 days.

Table 4. Engagement thresholds, determined by the frequency of reading uploads, during the 12-month trial (n=46).

Engagement levels	Definitions	Injections (n)	Insulin pump (n)	Total (n)	% of all participants within each threshold
Very low	Less than 1 of 14 days	9	8	17	37
Low	Less than 1 of 7 days	6	7	13	28
Moderate	Less than 3 of 7 days	5	7	12	26
High	3 of 7 days or more	3	1	4	9
Total		23	23	46	100

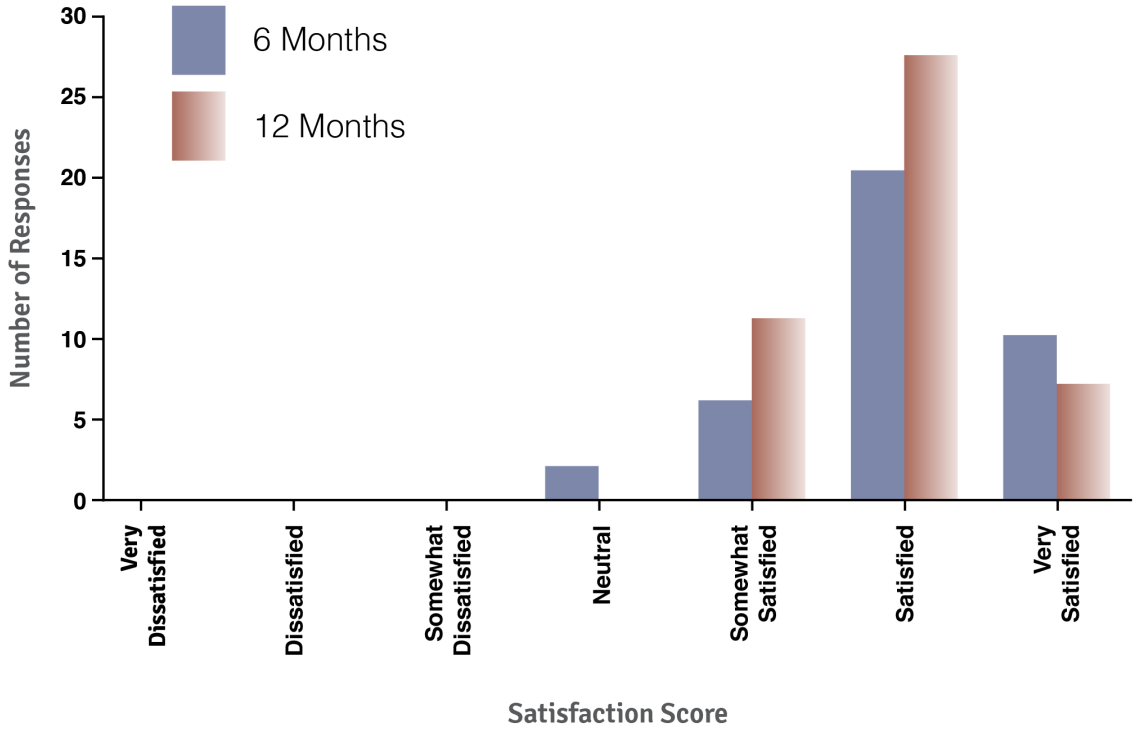
Overall, usage of *bant* showed a significant interaction with SMBG *(P*=.03), with users in the high-engagement group having a significantly higher frequency of SMBG throughout the trial than users with either low *(P*=.004) or very low engagement *(P*=.02). Further analyses demonstrated no significant association between *bant* usage and any other clinical outcomes.

Satisfaction

Participants reported high levels of satisfaction with *bant* throughout the trial (Figure 6). At 6 and 12 months, 79% (30/38) and 76% (34/45) of participants reported being "satisfied" or "very satisfied" with *bant*, respectively. In addition, 96% (43/45) of respondents reported that they would continue to use *bant* if it were available to them outside of the trial.

We also asked users to rank the features of *bant* according to their perceived usefulness in assisting with daily self-management of type 1 diabetes. Overall, the trending feature was ranked as the most useful component of *bant* by 45% (20/44) of respondents. This was followed by the logbook, which was ranked most useful by 14% (6/44), and the app home page (which displays current readings with respect to target range), which was ranked most useful by 11% (5/44).

Figure 6. Overall satisfaction with *bant* at the 6- and 12-month time points.



Discussion

Principal Findings

The aim of this 12-month RCT was to evaluate the effectiveness of *bant*, an mHealth app for the self-management of type 1 diabetes among adolescents. Although satisfaction was high across the duration of the trial, with a defined subset of users regularly accessing and using *bant*, overall we noted no significant improvements in primary or secondary outcomes.

While primary clinical outcomes remained unchanged, a post hoc exploratory analysis provided additional insights. A significant and strengthening relationship between increased SMBG and improved HbA_{1c} was observed exclusively in the intervention group (Figure 4), suggesting that *bant* users may have better used their SMBG data for the self-management of type 1 diabetes. This finding was reinforced by a subgroup analysis conducted on participants who were taking 5 or more SMBG a day at their 12-month visit. Users in this *bant* subgroup (n=8) demonstrated significant improvements in HbA_{1c} when compared with the parallel control subgroup (n=5), with a statistically and clinically significant decrease in HbA_{1c} of 0.58% over the trial duration. Thus, it is possible that, for those users who were testing frequently, *bant* enabled better self-management of diabetes, resulting in an improved HbA_{1c}, when compared with usual care.

To identify any factors that may have influenced the overall trial results, we conducted several secondary analyses, including the characteristics of the study population and potential trial design artifacts. This RCT purposefully targeted adolescents who were experiencing difficulty in managing their diabetes, as defined by sustained HbA_{1c} values between 8.0% and 10.5%, who might benefit greatly from enhanced self-management skills and motivation. However, it is possible that, by extending the HbA_{1c} inclusion range to 10.5%, patients whose poor glycemic control was caused by multiple complex factors, requiring support beyond the scope of the *bant* features, were detrimentally included in the study. While the study was not powered to look at subgroups, we conducted secondary analysis on users with a baseline HbA_{1c} of 9.0% or more and HbA_{1c} below 9.0%. The results showed no significant changes in glycemic control over the trial duration within either subgroup, suggesting that baseline HbA_{1c} was not predictive of *bant* 's effectiveness.

In addition, with equal numbers of participants on an insulin pump versus insulin injections, it was also possible that the insulin regimen may have affected clinical outcomes. However, secondary subgroup analysis was conducted, which showed no significant impact of *bant* on glycemic control, or any other clinical outcomes, in either the pump or the injector group.

We also hypothesized that a poorly motivated participant population could have resulted in the lack of improvement in clinical outcomes. However, the Readiness to Change Survey data showed that, on average, the intervention and control groups were classified in similar stages of change at baseline—including the "preparation" stage of change (for increased SMBG), associated with individuals who are ready to implement a plan of action to improve their health outcomes [45]. This observation, paired with the previously discussed subgroup results, suggests that the lack of significance found during primary analysis was likely not due to the demographics of our study population.

The *bant* usage data (Figure 7) indicated that, for many of the participants, the regular use of the app extended beyond the average 3- to 5-week engagement period reported by other mobile app industries [48,49]. This finding is in accord with the satisfaction data (Figure 6), and implies that future versions of *bant* may also be well used. However, over the 12-month trial duration, only 35% of users (n=16) wirelessly uploaded blood glucose data to *bant*, on average, once or more per week (Table 4). Given that the key self-management features of *bant* require blood glucose data, it can be inferred that usage of the app is dependent on users uploading data in the first place. There are 2 key factors that may have resulted in the low frequency of data uploads and are recognized limitations of the currently assessed system: (1) providing patients with a secondary mobile phone, and (2) the functionality of BluGlu.

First, participants in the intervention arm were given *bant* on a study-provided mobile phone, rather than installing the app directly on their own personal devices. While this was intentional, ensuring that all participants had equitable access to the iOS app, recent data indicate that many of these adolescents likely already owned a mobile phone, and therefore the addition of the study phone may have placed an unanticipated burden on the participant [16]. A key strength of mHealth is the ability to capture data and provide feedback for users via their personal devices, which are embedded into their daily routines. Providing the intervention on an additional secondary phone may have defeated the concept of embedded health interventions, as it is likely that many participants may not have wanted, or be able, to carry 2 mobile phones for 12 months.

Interestingly, in the 2011 study (n=20), *bant* elicited a significant increase in SMBG [32]. It can be hypothesized that at this time there were lower levels of mobile device penetration among adolescents, and the novelty of having an iPhone would likely compel participants to use the device as a primary phone. Future studies should deploy mHealth apps directly onto personal mobile phones in order to improve usage and facilitate seamless integration into daily life.

Second, we developed the RCT version of *bant* before the emergence of Bluetooth-enabled blood glucose meters. As such, we developed our own adapter, BluGlu, to facilitate the wireless upload of data from blood glucose meters to *bant*. However, this adapter was only compatible with the OneTouch UltraMini blood glucose meter. Throughout the study, a subset of participants continued to use additional blood glucose meters, often of a different brand. Therefore, it is possible that asking participants to use an external adapter, which only worked with one particular blood glucose meter, hindered the full integration of *bant* into their existing diabetes management routines. Over the duration of the RCT, several Bluetooth-enabled meters came onto the market, enabling a "plug and play" environment. A future consideration is to enable an open ecosystem so that users can have the option of using whichever wireless blood glucose meter suits their specific needs; this flexibility, along with no longer needing an external adapter, may improve use of mobile self-management platforms.

Another aspect that should be considered is the role of caregivers in the self-management activities adolescents perform using mobile tools. One of the key themes that emerged during the initial user-centered design of *bant* was the desire for adolescents to share their diabetes-related information with parents, peers, and clinic staff [32]. A recent literature review by Deacon et al suggested that mobile interventions that encourage data collection as well as clinician feedback may be more successful at decreasing HbA_{1c} [50]. *bant* included a feature that allowed users to store their data in TELUS health space, a secure personal health record that allowed them, if desired, to share their data with those within their circle of care. It was not possible to gather data around the use of this feature; however, based on interactions with participants, it is likely that *bant* was used as a stand-alone self-management tool. The next iteration of *bant* should explore adding features that easily enable adolescents to receive feedback from caregivers and approaches that integrate the app into routine clinical care.

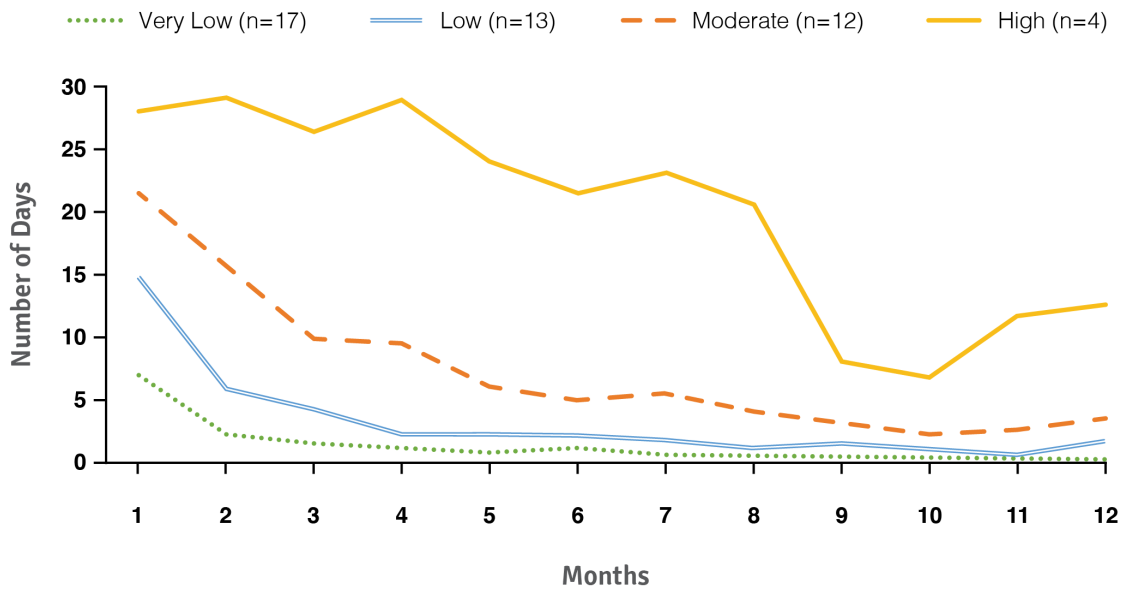
The study results illustrate the importance of rigorously evaluating mHealth apps, not only for understanding the impact on clinical outcomes and user engagement, but also for assessing the methods used to evaluate these tools. While traditional RCTs have been considered as the "gold standard" for evaluation of interventions, a recent review by Pham et al emphasized that RCTs may not be best suited for the evaluation of rapidly evolving software interventions [23]. Traditional RCTs are lengthy (average 5.5 years from enrollment to publication), expensive, and follow a rigid protocol that might not consider the sociotechnical, personal, and social components of mHealth implementation [23]. Perhaps more important, in the context of apps, they restrict the intervention to a static design and limit the ability to dynamically tailor the intervention based on unique needs of individuals. Future evaluations of *bant* and other mHealth apps should consider use of alternative research methodologies or adaptive RCT study designs [23]. For example, mPower, one of the first ResearchKit (Apple Inc) -enabled observational mHealth iOS app trials, demonstrated a completely electronic and in-app consent, enrollment, and study intervention, and 48,104 participants downloaded the app within the first 6 months of the public launch. Participants completed questionnaires at predetermined time intervals and used the native functionality of the mobile phone and its sensors to quantify symptoms of Parkinson disease (eg, tapping the screen to evaluate dexterity) [49]. Additionally, the Sequential Multiple Assignment Randomized Trial (SMART) adaptive study design enables the identification of the most effective intervention component sequencing strategy, by evaluating outcomes at predetermined time intervals. In this case, we could allocate groups to a specific combination of *bant* features and, based on the outcomes at a predetermined time point, alter the intervention according to a feature sequencing protocol, allowing us to rapidly converge on optimal intervention designs based on unique patient trajectories [51]. The Multiphase Optimization Strategy adaptive study design ensures the effectiveness of an intervention's individual components and allows for incremental optimization of an intervention, prior to a full-scale RCT [51].

Conclusions

Robust and scalable research methods, coupled with adaptive RCT study designs, have the potential to reshape mHealth research. These approaches can enable the rigorous evaluation of apps in a more timely manner, while facilitating the rapid and iterative development of an intervention, keeping pace with the rapidly and continuously evolving mHealth landscape.

While adolescents are increasingly accessing technologies to support the self-management of type 1 diabetes, the impact of these tools on clinical outcomes remains unclear. Although this RCT found no changes in primary and secondary outcomes, exploratory analysis demonstrated improved HbA_{1c} among *bant* users who tested blood glucose more frequently. This suggests that these users gained insights around their SMBG data, which may have led to positive changes in their self-management behavior. Overall satisfaction levels were high, suggesting that app users found utility in *bant*, specifically in features related to management of out-of-range blood glucose trends. The next iteration of *bant* will explore features that diminish barriers to use, enable deployment directly to personal mobile phones, are integrated into the daily clinical routine, and enable more frequent feedback from caregivers. Future evaluations of apps for diabetes self-management may also benefit from exploring methodologies that allow for more practical, scalable, and robust evaluation, given the challenges associated with rapidly evolving technology and consumer expectations.

Figure 7. Number of times (measured as days per month) users uploaded blood glucose data to *bant* across the study duration.



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Authors' Contributions

SG and CAN co-led the authorship of the manuscript; CAN led the Introduction and the synthesis of the data collected, SG led the Discussion, and both SG and CAN contributed to the Methods and Results sections. MR and ABC provided the statistical analysis content. DKK, SR, and AS provided guidance with trial development and execution, and edited the manuscript. MRP and JAC were cosupervisors.

Conflicts of Interest

The Hospital for Sick Children and University Health Network jointly own intellectual property rights to the *bant* app. Under the respective agreements with their organizations, Joseph A Cafazzo, Mark R Palmert, Debra K Katzman, and Shivani Goyal are entitled to personally benefit from any commercial use of the intellectual property.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.1.

[PDF File (Adobe PDF File), 751KB - mhealth_v5i6e82_app1.pdf]

Multimedia Appendix 2

Overview of the main pages of bant.

[PDF File (Adobe PDF File), 342KB - mhealth_v5i6e82_app2.pdf]

Multimedia Appendix 3

Participant Management Questionnaire.

[PDF File (Adobe PDF File), 235KB - mhealth_v5i6e82_app3.pdf]

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Abbreviations

ANOVA: analysis of variance
DFRQ: Diabetes Family Responsibility Questionnaire
DQOLY: Diabetes Quality of Life for Youth
HbA1c: hemoglobin A1c
RCT: randomized controlled trial
SMART: Sequential Multiple Assignment Randomized Trial
SMBG: self-monitoring of blood glucose

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Original Paper

A Mobile Phone-Based Health Coaching Intervention for Weight Loss and Blood Pressure Reduction in a National Payer Population: A Retrospective Study

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Abstract

Background: The prevalence of obesity and associated metabolic conditions continue to be challenging and costly to address for health care systems; 71% of American adults were overweight, with 35% of men and 40% of women diagnosed with obesity in 2014. Digital health coaching is an innovative approach to decreasing the barriers of cost and accessibility of receiving health coaching for the prevention and management of chronic disease in overweight or obese individuals.

Objective: To evaluate the early impact of a mobile phone-based health coaching service on weight loss and blood pressure management in a commercially insured population.

Methods: This was a retrospective study using existing registry data from a pilot commercial collaboration between Vida Health and a large national insurance provider, which enrolled adult members who were overweight (body mass index >25 kg/m2) and able to engage in a mobile phone-based coaching intervention. Participants received 4 months of intensive health coaching via live video, phone, and text message through the Vida Health app. Participants were also provided with a wireless scale, pedometer, and blood pressure cuff. Of the 1012 enrolled, 763 (75.40%) participants had an initial weight upon enrollment and final weight between 3 and 5 months from enrollment; they served as our intervention group. There were 73 participants out of the 1012 (7.21%) who had weight data 4 months prior to and after Vida coaching, who served as the matched-pair control group.

Results: Participants in the intervention group lost an average of 3.23% total body weight (TBW) at 4 months of coaching and 28.6% (218/763) intervention participants achieved a clinically significant weight loss of 5% or more of TBW, with an average of 9.46% weight loss in this cohort. In the matched-pair control group, participants gained on average 1.81% TBW in 4 months without Vida coaching and lost, on average, 2.47% TBW after 4 months of Vida coaching, demonstrating a statistically significant difference of 4.28% in mean percentage weight change (P<.001). Among 151 intervention participants with blood pressure data, 112 (74.2%) had a baseline blood pressure that was above the goal (systolic blood pressure >120 mmHg); 55 out of 112 (49.1%) participants improved their blood pressure at 4 months by an entire hypertensive stage—as defined by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.

Conclusions: Mobile phone app-based health coaching interventions can be an acceptable and effective means to promote weight loss and improve blood pressure management in overweight or obese individuals. Given the ubiquity of mobile phones,

digital health coaching may be an innovative solution to decreasing barriers of access to much-needed weight management interventions for obesity.

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KEYWORDS

digital health coaching; overweight; obesity; mobile health; weight; blood pressure

Introduction

The prevalence of obesity and associated metabolic conditions continue to be challenging and costly to address for health care systems; 71% of American adults were overweight, with 35% of men and 40% of women diagnosed with obesity in 2014 [1-5]. Being overweight and obese increases the risk of cardiometabolic disease and overall mortality, with the prevalence of hypertension and type 2 diabetes highly correlated to increasing weight [6]. Weight loss as modest as 5% total body weight in people with a body mass index (BMI) over 25 kg/m^2 can significantly improve glycosylated hemoglobin, blood pressure, and hyperlipidemia, and can reduce the progression of hypertension and diabetes [7-9]. The United States Preventive Task Force recently updated its recommendations to formally include intensive, multicomponent interventions for weight loss in patients with a BMI ≥ 30 kg/m^2, citing evidence showing its benefits in cardiovascular risk reduction [10].

With primary care clinicians in increasingly short supply and overwhelmed by burdens of the preventative and chronic care needs of their patient panel [11,12], numerous health care providers have sought to use trained health coaches to provide cost-effective, culturally sensitive behavioral counseling for weight loss and chronic disease management. There is compelling evidence that health coach-led programs can indeed significantly improve the control of metabolic risk factors [13-15]. Despite provisions in the US Affordable Care Act of mandated free obesity counseling to those who qualify and availability of robust evidence around behavior change programs for weight loss, uptake of behavioral-counseling weight loss programs has been limited. This is often due to difficulties with attending in-person sessions—offered by most programs—caused by wide-ranging issues such as transportation, childcare, work coverage, and limited availability of such programs, especially in rural settings [16].

In addition to decreasing the barriers of cost and accessibility for receiving health coaching, digital health coaching provided remotely through an Internet-connected device has been shown to be an effective approach for the prevention and management of cardiometabolic risk factors in overweight and diabetic individuals [17,18]. Given that 92% of US adults own a basic-feature mobile phone and 68% own an advanced-feature mobile phone (ie, iPhone or Android) [19], mobile devices may offer a novel continuous engagement portal for delivery of health coaching and intensive behavioral interventions for weight loss [20]. In addition to containing an array of sensors relevant to core aspects of behavior change programs (eg, pedometers to track steps, cameras to record food intake, audio and live video to communicate with a health coach), the vast majority of mobile phones are carried by users for the majority of their waking day, with users engaging with apps on their mobile devices for 3 hours and 5 minutes per day, on average [21].

While studies of Web- [17,18] and short message service (SMS) text message-based [22,23] coaching interventions have demonstrated positive results, the few number of studies examining mobile phone-based health coaching are limited either by sample size, a focus on the impact of self-monitoring rather than coaching, or a lack of clinical results beyond self-reported weight loss [24,25]. Thus, given the limited published research to date evaluating mobile phone-based coaching interventions for weight loss and cardiovascular risk reduction, the authors share here retrospective registry data from a pilot, commercial, mobile phone-based health-coaching program. The program was offered by a large national commercial insurance company to its fully insured members in the US states of Wisconsin, Georgia, and Colorado who were overweight and self-reported diagnoses of obesity, hypertension, prediabetes, dyslipidemia, or diabetes.

Methods

Overview

This was a retrospective study using existing registry data from a pilot commercial collaboration between Vida Health and a large insurance provider. Interested members under this insurance provider were enrolled starting in November 2015 in a commercial program using a mobile phone-based, digital health-coaching app, Vida Health (described below). The coaching platform was used to manage cardiometabolic conditions such as obesity, hypertension, hyperlipidemia, and prediabetes. This study has received Institutional Review Board (IRB) exemption from the University of California, San Francisco (UCSF), IRB (IRB No. 16-19903).

Participants

The registry included adults over the age of 18 years who were fully insured members in the US states of Wisconsin, Georgia, and Colorado and who were overweight—BMI >25 kg/m^2. Participants had to be English speaking and own an advanced-feature mobile phone—iPhone or Android—to ensure they were able to engage in the Vida Health coaching program. Participants were recruited from an email campaign by their insurance provider offering the free program for any current member who had a BMI >25 kg/m^2. In order not to bias the sample with individuals who would have achieved weight loss and other health goals regardless of whether or not they worked with a coach, the barrier to entry into the program was kept at a minimum—simply replying to a Web form in an email invite—with minimal exclusion criteria, including not owning

a mobile phone and having type 1 diabetes. Clinical data elements used for enrollment, including weight, height, and medical history, were based on self-reported responses. Invitations to the program were sent randomly to members in eligible geographies and the first 1000 participants were included in this pilot program.

Intervention

Enrollment for the Vida Health program started November 2015. Prior to starting the Vida Health program, accepted members were sent a package containing a Bluetooth-connected pedometer and wireless scale. Those members with known hypertension also received a Bluetooth-enabled blood pressure cuff. Participants received instructions on how to synchronize their wireless devices for passive data collection through the Vida app.

After installing the Vida app, participants were asked to complete an onboarding survey regarding their baseline health behaviors, past medical history, self-selected personality preferences (ie, if they might benefit more from a "cheerleader"- or "drill sergeant"-like coach), and general availability. Based on these attributes, participants were matched with a short list of Vida-recommended coaches from which they could select their own ongoing health coach. Health coaches were professional licensed nutritionists, physical therapists, and social workers who are certified to provide health coaching and were additionally trained by Vida once employed in the Vida network.

The first 4 months of the Vida program consisted of an intensive *active coaching* phase followed by 8 months of *maintenance* coaching. During the active coaching phase, participants had regular consults—video chats or phone calls through the Vida app—with their coaches ranging from weekly to monthly in frequency. Different coaching frequencies were recommended for each participant based on the coach's assessment of participants' needs and availability. Participants were encouraged to weigh in on a weekly basis on their wireless scales. During this time period, coaches worked with participants to set personalized health goals around healthy nutrition, physical activity, stress management, and medication adherence, carefully tailored to advance participants' weight loss goals. In between consults, coaches communicated with their clients via secure text messaging in the Vida app, providing daily accountability through quick reminders about clients' personal goals, motivation through inspirational content, and education through easily understandable pieces of content.

In addition to data passively collected by the wireless scales, pedometers, and blood pressure cuffs provided to participants, members were also asked to enter their activity (ie, steps, exercise, food intake, sleep, and stress levels). Participants who had difficulty using or synchronizing the provided devices had the option of self-entering biometric data (ie, weight and blood pressure) directly into the Vida app. For the purposes of accurate analyses, we excluded metric points that were deemed to be unrealistic outliers that fell outside of the scope of clinical weight loss or the trend of the participant. Members were not paid for their participation. Program costs, including both the coaching service and associated hardware devices, were covered by their insurance provider.

Measures

The primary outcome of the study was weight loss at 4 months as defined by percent change in total body weight (TBW) to normalize against a range of starting body weights. Participants were encouraged to weigh themselves weekly during the 4 months of the intensive coaching program. Weight data was primarily collected through the direct transmission of values via a Bluetooth scale provided as part of the intervention. Some participants chose to self-enter data due to technical difficulties setting up and using the Bluetooth scale. Change in TBW was calculated as the difference between the first weight since program enrollment and the last weight entered closest to the end of 4 months of coaching, with the caveat that the provided weight was recorded between 3 and 5 months after program enrollment.

Secondary outcomes included change in systolic blood pressure (SBP) after 4 months of intensive health coaching, as well as the change in number of participants in each hypertensive category (ie, normal, prehypertensive, type 1 hypertension, and type 2 hypertension) from the beginning of enrollment to after 4 months of coaching.

Satisfaction with the intervention was summarized using participant-reported ratings of the Vida Health app. Throughout the program, participants were asked, "How are we doing? Please help us improve your experience by taking a minute to leave feedback for your coach." Participants could input text feedback and rate their experience on a scale of 0-10, with 10 being the highest rating.

Control Group

Given that this study was based off of registry data from an existing pilot program, a designated control arm that did not receive coaching was not defined. However, there was a subset of individuals (n=73) enrolled in the program who had historic weight data from owning Bluetooth scales prior to starting the program. Using the Validic application programming interface, these historic weight data points were added to the Vida app database when individuals synchronized their devices as part of the program. These individuals' historic weight data 4 months prior to starting the Vida program were used as a proxy for a matched-pair control group, as these individuals successfully enrolled and received coaching through the program, thereby eliminating any bias toward motivation.

Analyses

Summary statistics describing the demographic characteristics are provided in Table 1, including age, gender, starting BMI, geographic state, and relevant self-reported medical history among enrolled and active participants who have recorded weight data.

Participant data were statistically analyzed using R version 3.3.3 (The R Foundation) using descriptive analysis and two-sided *t* tests to estimate the statistical difference between the preintervention and the postintervention measurements. Differences were compared in categorical and continuous data between the intervention and matched-pair control groups using chi-square and two-sample *t* tests, respectively. Absolute weight

loss and change in percent TBW were calculated at 4 months. Change in weight was calculated as the difference between the first weight since enrollment—no more than one month after enrollment—and the weight between 12 and 20 weeks that was closest to 4 months from enrollment. Paired *t* tests were used to assess significance in percent weight change at 4 months in the intervention and control groups. To assess if there was a dose-dependent relationship between engagement and weight loss, participants were stratified by engagement cohorts based on number of coaching consults and text messages sent from participant. For each cohort, mean percent weight loss was calculated. The high-engagement cohort was defined as participants who were at the top quartile of messages sent per month or number of coaching consults in the 4-month coaching period. The low-engagement cohort was defined as participants at the bottom quartile of number of messages and video consults. The medium-engagement cohort was defined as participants in the 25th-75th engagement percentiles.

Similarly, baseline blood pressure was designated as the first blood pressure reading since enrollment. Final blood pressure was designated as the blood pressure reading taken between 12 and 20 weeks that was closest to 4 months from enrollment. The mean change in SBP was calculated and assessed for significance using a two-sided *t* test. Furthermore, participants were stratified by hypertension stage—as defined by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7)—based on their baseline SBP; this stratification showed the proportion of participants whose final blood pressure placed them in a better or worse stage.

Table 1. Baseline demographic summary statistics.

Characteristics	Enrolled participants (N=1012)	Intervention group (n=763)	Matched-pair control group (n=73)	Enrolled versus intervention, P	Intervention versus control, P
Age (years), mean (SD)	44.63 (11.25)	44.78 (11.18)	42.36 (10.28)	.41[a]	.41[a]
Sex (male), n (%)	337 (33.30)	261 (34.2)	17 (23)	.73[b]	.08[b]
Starting BMI[c] (kg/m^2), mean (SE)	33.50 (0.21)	33.34 (0.24)	34.33 (0.69)	.59[a]	.19[a]
BMI distribution (kg/m^2), n (%)				.96[b]	.31[b]
25.0-29.9	368 (36.36)	283 (37.1)	19 (26)		
30.0-34.9	305 (30.14)	234 (30.7)	26 (36)		
35.0-39.9	189 (18.67)	138 (18.1)	15 (21)		
≥40.0	150 (14.82)	108 (14.2)	13 (18)		
US state, n (%)				.78[b]	.02[b]
Colorado	195 (19.27)	155 (20.3)	26 (36)		
Wisconsin	626 (61.86)	457 (59.9)	36 (49)		
Georgia	168 (16.60)	136 (17.8)	11 (15)		
Other	23 (2.27)	15 (2.0)	0 (0)		
Self-reported comorbidities, n (%)				.87[b]	.54[b]
Prediabetes	57 (5.63)	44 (5.8)	4 (5)		
Diabetes	41 (4.05)	25 (3.3)	0 (0)		
Hypertension	157 (15.51)	109 (14.3)	7 (10)		
Hyperlipidemia	124 (12.25)	93 (12.2)	7 (10)		

[a]*P* value of two-sample *t* test for intervention.

[b]*P* value of chi-square test.

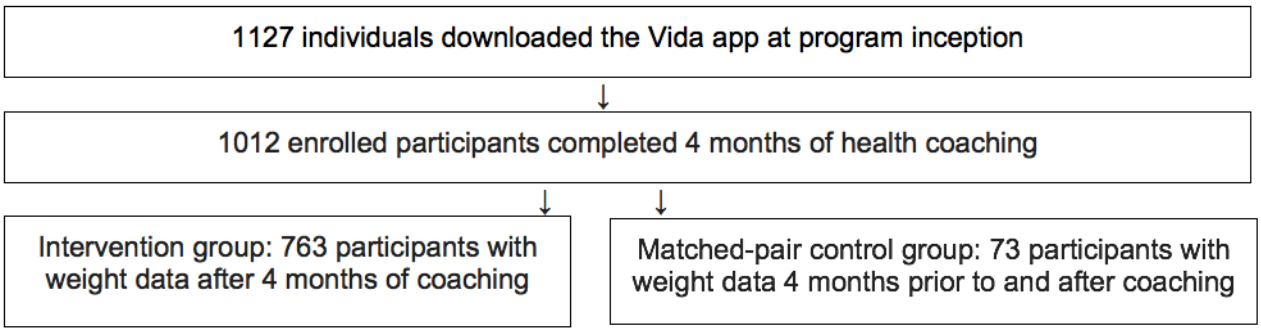
[c]BMI: body mass index.

Results

Enrollment and Demographics

Participant enrollment and retention in the program is displayed Figure 1. Among the 1127 adults who were initially enrolled in the program, 1012 (89.80%) participants completed 4 months of intensive health coaching at the time of analysis. Of the 1012 enrolled, 763 (75.40%) participants, who will now be referred to as the intervention group, had an initial weight upon enrollment and final weight between 3 and 5 months from enrollment. Of the 1012 enrolled, there were 73 (7.21%) participants who had weight data 4 months prior to and after Vida coaching, who served as the matched-pair control group.

Figure 1. Study population including enrollment and retention.



Baseline demographics and chronic disease profiles of all enrolled participants, intervention participants, and matched-pair controls with weight data are reported in Table 1. Of the 1012 total enrolled participants, 337 (33.30%) were men, 368 (36.36%) were overweight, 644 (63.64%) were obese, 98 (9.68%) were prediabetic or diabetic, and 157 (15.51%) had hypertension. These characteristics do not differ significantly between the enrolled participants and the intervention group. Compared to the intervention group, the matched-pair control group had fewer men (261/763, 34.2% intervention vs 17/73, 23% control, *P*=.08) and more obese participants (480/763, 62.9% intervention vs 54/73, 74% control, *P*=.31). These differences were not statistically significant. The only statistically significant difference between the three populations was the distribution of participants in each state between the intervention and matched-pair control groups (*P*=.02).

Changes in Weight Loss

As shown in Table 2, participants in the intervention group lost an average of 3.23% TBW at 4 months of coaching. Out of 763 participants, 218 (28.6%) achieved a clinically significant weight loss of 5% or more of TBW, with a mean of 9.46% weight loss in this cohort. In the matched-pair controls, participants gained an average of 1.81% TBW in 4 months without Vida coaching and lost an average of 2.47% TBW after 4 months of Vida coaching (see Table 3), demonstrating a statistically significant difference of 4.28% in mean percentage weight change (*P*<.001) (see Figure 2).

Figure 2 shows a box plot demonstrating the mean percentage change in weight in controls during the 4 months before Vida coaching and 4 months after Vida coaching. The mean percentage change in body weight and standard error for users before Vida and after Vida are 1.81% (SE 0.41) and -2.47% (SE 0.48), respectively. A two-sided *t* test was performed and demonstrated a statistically significant difference of 4.28% in mean percentage weight change (*P*<.001).

The level of engagement impacted the amount of weight loss among study participants. There were 306 participants in the high-engagement cohort, defined as participants who were at the top quartile of messages sent per month or number of coaching consults in the 4-month coaching period. There were 74 participants in the low-engagement cohort, defined as participants at the bottom quartile of messages and video consults. There were 383 participants in the medium-engagement cohort. The high-engagement cohort lost the most weight, followed by the medium- and then low-engagement cohorts (see Table 4).

Table 2. Percentage change from total body weight in intervention group.

Weight and TBW[a] measures	Weight, mean (SE) or % TBW change (SE)	Number of participants (n=763), n (%)
Baseline weight (kg), mean (SE)	96.23 (0.78)	763 (100)
Weight at 4 months (kg), mean (SE)	92.99 (0.76)	763 (100)
Mean weight loss at 4 months, % TBW change (SE)	-3.23 (0.22)[b]	763 (100)
≥5% weight loss at 4 months, % TBW change (SE)	-9.46 (0.41)[b]	218 (28.6)
≥2% to <5% weight loss at 4 months, % TBW change (SE)	-3.41 (0.06)[b]	210 (27.5)
≥-2% to <2% weight change at 4 months, % TBW change (SE)	-0.30 (0.07)	255 (33.4)
>2% weight gain at 4 months, % TBW change (SE)	+4.90 (0.81)[b]	80 (10.5)

[a]TBW: total body weight.

[b]*P*<.001 for two-sided *t* test.

Table 3. Percentage change from total body weight for matched-pair control group before and after Vida program.

Outcome	Weight (n=73), mean (SE) or mean % TBW[a] change (SE)
Weight 4 months before Vida program (kg), mean (SE)	95.44 (2.26)
Weight at enrollment (kg), mean (SE)	97.10 (2.29)
Weight 4 months after Vida program (kg), mean (SE)	94.65 (2.26)
4 months before Vida program compared to enrollment, mean % TBW change (SE)	1.81 (0.41)[b]
4 months after Vida program compared to enrollment, mean % TBW change (SE)	-2.47 (0.48)[b]

[a]TBW: total body weight.

[b]$P<.001$ for two-sided t test.

Table 4. Relationship between engagement and weight loss.

Level of cohort engagement	% total body weight loss, mean (SE)	Number of messages per month sent to coach, mean (SE)	Number of consults over 4 months, mean (SE)
Low (n=74)	-1.37 (0.63)	4.83 (2.73)	1.51 (0.20)
Medium (n=383)	-2.84 (0.29)	42.65 (7.14)	5.70 (0.33)
High (n=306)	-3.86 (0.34)	120.59 (12.55)	10.71 (0.26)

Change in Blood Pressure

Of 151 participants with blood pressure data in Vida, the baseline average SBP was 131 mmHg and the mean change in SBP was a 6 mmHg decrease after 4 months (see Table 5). Among these 151 participants, 112 (74.2%) had a baseline blood pressure that was above the goal, assuming a normal SBP of ≤120 mmHg; 55 out of 112 (49.1%) improved their blood pressure by an entire hypertensive stage—as defined by the JNC-7—at 4 months. Of the 76 users whose baseline SBP was in the prehypertensive range, 27 (36%) had an SBP that was normal and 8 (11%) had an SBP that was in a more severe hypertensive stage after 4 months (see Figure 3). Of the 29 participants with a baseline SBP in the type 1 hypertension range at 4 months, 22 (76%) had an SBP that was in a better stage and none had an SBP in a worse hypertensive stage. Of the 7 participants with a baseline SBP in type 2 hypertension, 6 participants (86%) had a 4-month SBP in a better stage and none had an SBP in a worse stage.

Figure 3 shows the percentage of participants from each hypertension stage at baseline that moved to a better or worse hypertension stage after 4 months of coaching.

Figure 2. Mean percentage change in weight in matched-pair controls during the 4 months before coaching and 4 months after coaching.

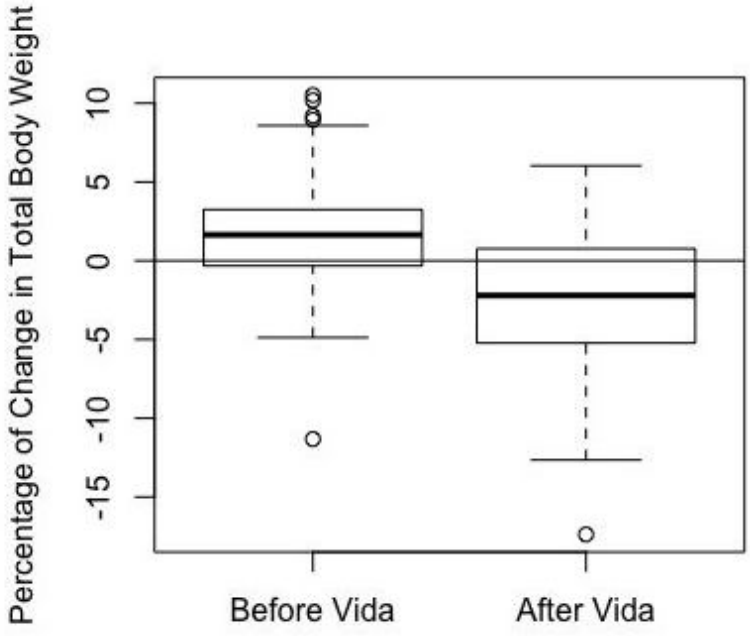


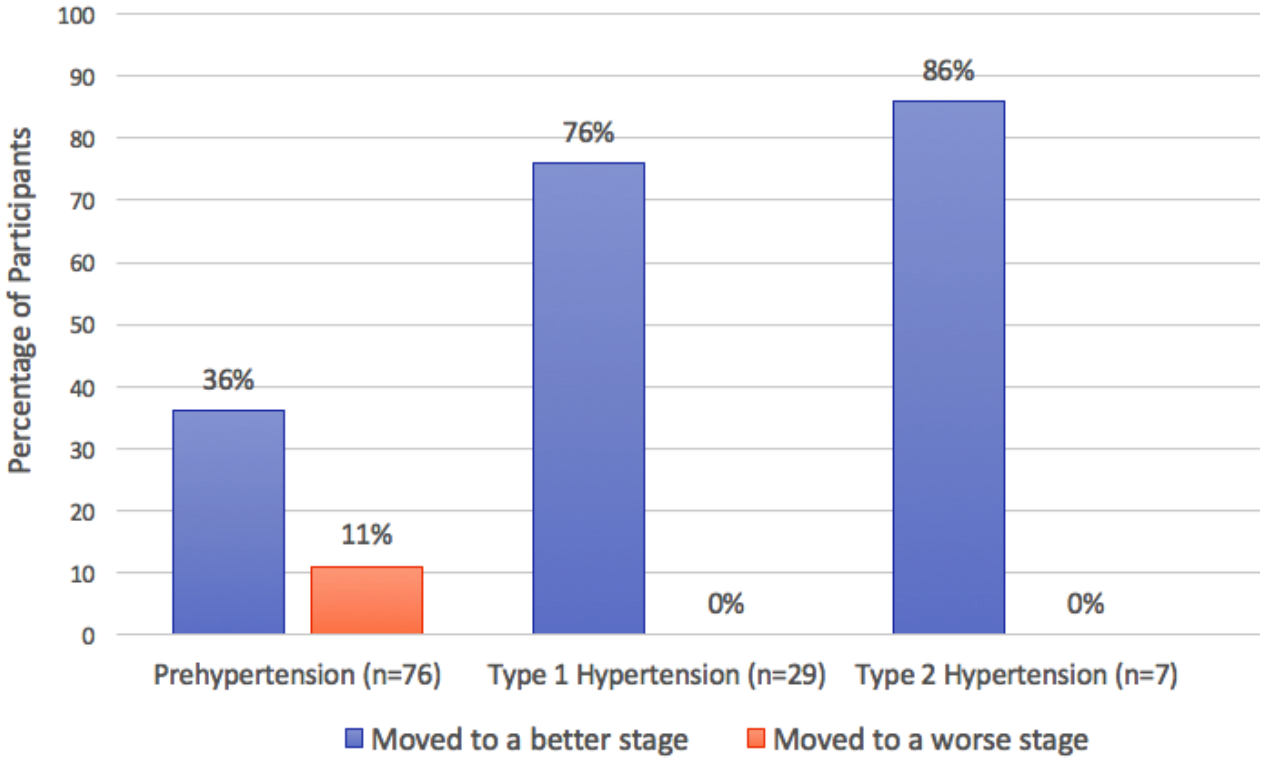
Table 5. Mean change in systolic blood pressure after 4 months of coaching (n=151).

Outcome	Blood pressure (mmHg), mean (SE)
Baseline SBP[a]	131.27 (1.52)
SBP after 4 months	125.31 (1.18)
Mean change in SBP after 4 months	-5.96 (1.64)[b]

[a]SBP: systolic blood pressure.

[b]*P*=.002 for two-sided *t* test.

Figure 3. Change in hypertensive category after 4 months of coaching.



Participant Satisfaction

Of 1012 enrolled participants, 386 (38.14%) submitted ratings of the app, with an average rating of 9.77 out of 10, with 10 being most satisfied (see Table 6). Of the 763 participants in the intervention group, 333 (43.6%) submitted ratings of the app with an average rating of 9.81 out of 10. Mean participant ratings of the app are shown for all available ratings from all enrolled participants and participants from the intervention group.

Table 6. Satisfaction data.

Participant cohort	Rating of the app (out of 10), mean (SD)	Participants who provided a rating, n (%)
All enrolled participants (N=1012)	9.77 (0.92)	386 (38.14)
Participants in intervention group (n=763)	9.81 (0.73)	333 (43.6)

Discussion

In this study, a mobile phone-based health-coaching intervention was found to be effective in reducing weight and blood pressure in overweight and obese adults over a 4-month period, with participants in the matched-pair control group demonstrating a statistically significant difference of 4.28% in mean percentage weight change.

Unlike other interventions targeting more complex conditions [17,26], this program enrolled a broad, geographically diverse, and relatively healthy population intended to mirror the general overweight population of a national commercial payer. Most participants were in their 40s, reflecting the enrollment strategy:

a commercially insured population that is, by definition, at least working age but largely younger than Medicare eligibility at 65 years. Similar to other digital health studies with weight loss interventions [17,23-25], our study cohort was predominantly female, which may suggest that women are more likely to engage in weight loss interventions.

Key aspects of the intervention included the ability for participants to self-monitor progress and be accountable for goals set with their health coach. Self-monitoring is the most common feature of mobile apps for health intervention [20,27] and has been shown to have positive effects [25,28,29]. With the ability to log health-related behaviors into the app (eg, food choices and exercise duration) and the ability to see data from wireless pedometers upload instantaneously into the app, participants are able to keep track of their progress as they progress through the intervention. However, with self-monitoring alone, engagement and retention can be a challenge, as most mobile apps have only simplistic capabilities that lack complex user needs and preferences as well as the relationship of a health care expert who can weigh in on their progress [27]. There was high engagement in the study cohort, with 90% of those who downloaded the app completing 4 months of coaching. This is highly important given that failure in clinical interventions for obesity have been primarily attributed to fluctuations in treatment adherence over time, as patients often lack sustained motivation for primary prevention compared to those with more complex conditions who face a more urgent need for behavior change [30,31]. The fact that participants were satisfied with the intervention, given their high rating of the Vida Health app, demonstrates that the mobile app is an effective platform for delivering health coaching. Participants viewed their relationship with their coach favorably, with the limitation that only 44% of those in the intervention group provided feedback.

There was notable weight loss in the intervention group at 4 months, with an average total body weight loss of 3.23%. In addition, 28.6% of participants achieved a clinically significant weight loss of 5% TBW or more, with an average of 9.5% TBW lost in this cohort. The change in weight loss is even more significant when taking into account the fact that the intervention began in late November through the winter holiday season when people have the hardest time losing weight [32]. This compares favorably to a mobile SMS text message-based weight loss program, which produced 3.16% TBW loss in its intervention arm after 4 months [33], and to a mobile phone-based, self-monitoring and health consultation program, which demonstrated 2.86% TBW loss in its intervention arm after 24 weeks [26]. Our results also corroborate findings from Chin et al who demonstrated positive weight loss benefits in their study of the mobile phone, health coach app, Noom, with 77.9% of participants reporting a decrease in body weight during app usage [25].

Unique in this analysis was the availability of 4-month pre- and postcoaching data for a subset of participants that could act as their own matched-pair controls, thereby controlling for the role of intrinsic motivation and allowing the study to isolate the impact of Vida coaching on weight loss. Given that participants in this cohort gained 1.81% TBW over the 4 months prior to using Vida and lost 2.47% TBW over the 4 months after starting Vida suggests the true impact of Vida coaching to be even greater than measured, which is due to the likely continued weight gain in the absence of additional coaching intervention. The dose-dependent relationship between engagement and weight loss further demonstrates that weight loss was driven by engagement with the coach.

In the cohort of 151 participants who had blood pressure data, Vida coaching had a positive impact in reducing average SBP by 5.96 mmHg and by moving significant numbers of participants within each blood pressure stage to a better blood pressure stage after 4 months of coaching. Overall, half of the participants with blood pressure data improved their blood pressure by an entire hypertensive stage after 4 months of coaching, with greater proportions of participants improving at higher stages of baseline hypertension. There is limited data in existing literature regarding the impact of digital health interventions on blood pressure in a comparable cohort. One meta-analysis found that digital health interventions did not have statistically significant impact on blood pressure [34]. Willey et al demonstrated a mean SBP change of 18.6 mmHg after 12 weeks of a digital health app intervention that delivered guided nutritional and physical exercise plans, albeit the sample size was limited to 10 participants [35].

There were limitations to this study. Criteria for enrollment were largely self-reported. Participants skewed toward having more female than male participants and toward being a relatively young cohort, making generalization to older individuals more difficult. While participants were geographically diverse, it is challenging to draw conclusions around the impact of the intervention on minority populations or populations of varying education and income brackets, given the lack of demographic data around ethnicity and socioeconomic status. All participants were mobile phone owners, which is associated with higher socioeconomic status and, therefore, possibly less prevalence of obesity and chronic disease [36,37]. However, mobile phone ownership has high penetrance, with the majority of people owning mobile phones even in the lowest education and income brackets [37]. Another limitation was the lack of a true control group, though this was addressed by using the closest proxy available with participants who had weight data prior to receiving coaching, albeit a small sample size. The study was also limited by data availability and attrition. A total of 15% of those enrolled completed the program but could not be included in the analysis due to lack of weight data. Technical challenges with hardware devices likely contributed to lack of weight data, given the large number of technical assistance requests from participants regarding their pedometers and scales. Further analyses of clinical results and cost-effectiveness at future time points are needed.

Despite these limitations, this study demonstrates that a mobile app-based coaching intervention can be an acceptable and effective means to achieving desired clinical results for overweight and obese individuals. As mobile phones continue to penetrate the consumer market, digital health coaching may serve as a promising model to increase access to evidence-based behavioral coaching for obesity and related cardiovascular conditions.

Acknowledgments

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Conflicts of Interest

AYM and CC were formerly employed at Vida Health, a company that provides digital health coaching, which is the subject of this study. AYM is a paid independent consultant and KCB is a current employee at Vida Health. JNO and CM have no conflicts of interest.

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Abbreviations

BMI: body mass index
IRB: Institutional Review Board
JNC-7: Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of
SBP: systolic blood pressure
SMS: short message service
TBW: total body weight
UCSF: University of California, San Francisco

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Original Paper

Beyond Basic Feedback in Mobile Brief Interventions: Designing SMS Message Content for Delivery to Young Adults During Risky Drinking Events

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Abstract

Background: Brief interventions can reduce alcohol consumption in young people through screening and delivery of personally relevant feedback. Recently, Web and mobile platforms have been harnessed to increase the reach of brief interventions. Existing literature on mobile-based alcohol brief interventions indicates mixed use of theory in developing interventions. There is no research available to guide the development of SMS text messaging (short message service, SMS) interventions delivered during risky drinking events.

Objective: The aim of this study was to develop and pilot an alcohol-related risk-reduction brief intervention delivered by SMS to Australian young adults during drinking events. This paper describes the development of intervention message content, with specific focus on the context of delivery during drinking events.

Methods: A sample of 42 young adults attended 4 workshops; these comprised focus-group style discussion on drinking habits and motivations, discussion of intervention design, analysis of existing alcohol media campaigns, and participant development of message content. Data were analyzed thematically.

Results: Participants described a focus on having fun and blocking out any incongruent negative influences during drinking episodes. For content to be acceptable, nonjudgmental and non-authoritative language was deemed essential. A preference for short, actionable messages was observed, including suggestions for reminders around drinking water, organizing transport home, checking on friends, and plans the next day. Participants were excited about the potential for messages to be tailored to individuals, as previous alcohol-related campaigns were deemed too generic and often irrelevant. Normative-based messages were also perceived as largely irrelevant as participants felt that they understood the drinking-related norms of their immediate peers already.

Conclusions: Findings from this study offer insights into young adults' drinking events and practical advice for designing alcohol-related brief interventions. During our formative development process, we demonstrated a neat correspondence between young people's preferences for alcohol harm reduction interventions and the theoretical principles of brief interventions, including acceptable topics and message style.

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KEYWORDS

alcohol drinking; young adult; mHealth; text messaging; motivational interviewing; community-based participatory research

Introduction

Alcohol consumption is a significant public health concern in Australia, particularly in relation to risky single-occasion drinking in young people [1]. Alcohol is consistently reported as a leading cause of disease and injury burden for 15-25-year olds [1,2]. Related harms include physical and sexual assault, suicide, risky sexual behavior, memory loss, blackouts, brain impairment, and cognitive deficits [1,3-5]. In the 2013 Australian National Drug Strategy Household Survey, more than 65% of 18-19-year-olds and 60% of 20-29-year-olds reported engaging in risky single-occasion drinking (defined as 4 or more Australian standard drinks in a single session, or 40 grams of alcohol) [2]. One-third of 18-24-year-olds reported drinking 11 or more standard drinks in a single episode in the past year [2]. In addition, a 2010 study found that 42% of 16-24-year olds from the state of Victoria had consumed more than 20 drinks in one session in the past year [6].

One of the few individual-level prevention strategies known to effectively reduce alcohol consumption in young people is called brief intervention. Well-designed brief interventions are a low-cost strategy to reduce alcohol consumption and harm [7-10]. Brief interventions generally involve screening and a short counseling session, which may include feedback based on screening, education on risk profile, advice for reducing consumption, and discussions around change. The FRAMES (Feedback, Responsibility, Advice, Menu Options, Empathy, and Self-Efficacy) model [7,9,11] provides more detail on evidence-based core components of brief interventions and suggests: provision of personally relevant "feedback," discussions relating to "responsibility," nonjudgmental "advice" for changing behavior, suggesting a "menu" of options to support change, expression of "empathy," and encouraging "self-efficacy."

Motivational interviewing is a key component of brief interventions [7]. Motivational interviewing is a counseling technique commonly used for health behavior change that involves a nonjudgmental and client-centered approach [11]. A motivational interviewing therapist asks a client the questions designed to elicit their own motivations for changing their behavior and engages them in personalized "change-talk" about their behavior [11]. A 5-min brief intervention that uses these principles has been found to be as effective in reducing alcohol consumption as a 20-min counseling session [12]. A key appeal of brief interventions is its effectiveness among individuals at different stages of readiness to change [7], making it applicable for use within young adults, including university students who are less likely than older adults to be specifically motivated to reduce drinking [13]. Although brief intervention approaches have been successful in changing behaviors, including alcohol consumption and other substance use [7-10,14-18], their scalability has been limited by time and the resources required to implement individualized, face-to-face (albeit brief) sessions [19].

Recently, Web and mobile phone platforms have been harnessed to increase the reach of interventions intended to change behaviors in the realms of sexual health, physical activity, chronic disease management, and alcohol consumption [20-37]. These interventions commonly involve providing health-related messages either through SMS text messaging (short message service, SMS) or mobile phone apps, allowing low-cost yet high-reach delivery of messages to target groups, with some evidence of successful behavior change [20-29,36]. However, as researchers learn to harness these technologies and translate brief interventions to mobile platforms, there has been variable emphasis placed on the theoretical basis for the intervention content [37-41]. Among studies which do publish details on the theoretical basis of interventions, there is diversity in the theoretical frameworks and behavior change techniques which have been applied [38,41,42]; as noted by Abraham and Michie, there is no standardized vocabulary for describing behavior change intervention techniques [43]. Studies of SMS interventions increasingly use the labeling of brief intervention; however, many show limited links between message content and brief intervention or motivational interviewing theory. Brief interventions that have been implemented here are commonly described in the literature as methods using basic screening and feedback components, but the other elements of FRAMES are either not described or not integrated. Though this makes for a more simple intervention, it may perpetuate the understanding that brief interventions are a homogeneous entity [44,45] and deemphasizes the importance of the rest of the brief intervention "toolbox." A recent study compared several types of brief interventions delivered to college students, including an assessment-only arm, a motivational interviewing-only arm, a feedback-only arm, and a combined motivational interviewing and feedback arm; the study found that the combined motivational interviewing and feedback intervention significantly reduced drinking, whereas none of the other interventions varied from the assessment-only arm [44]. This highlights the potential impact that different message styles might in fact have. The frequent use of feedback-only brief interventions in mobile health (mHealth) may have further implications for developing and interpreting the evidence base around effectiveness of mobile brief interventions for changing behavior such as alcohol consumption. A recent systematic review called for greater transparency in use of theory in developing mobile-based health interventions [38].

The feedback provided within mobile brief interventions has also varied considerably in terms of both content and tone. Many publications describe content developed solely by researchers or clinicians [30,42,46], with limited evidence of consultation with the target group [37,41]. Kristan and Suffoletto found that young people perceived most expert-authored messages to be only somewhat interesting or helpful [47]. Bock et al found that differences in language and construction of alcohol SMS content developed by either the researchers or students affected their interpretation and acceptability [41]. These authors, and others, have strongly advocated for participatory methods to be used in developing mHealth interventions as we continue to disentangle what components of our interventions are acceptable and effective [37,38,41]. Participatory methods are also important for the development of tailored interventions, which require understanding of the target population's culture, needs, and preferences [37,47-49]. Tailoring is thought to potentially enhance the ability of an intervention to act through personal

motivation, which theory and evidence suggest is an important feature of effective brief interventions. However, evidence is thus far limited as to how best to apply complex personalized tailoring in SMS format and further research is hence required [37].

Although other studies have examined young people's opinions of alcohol interventions [37,47,50,51], this has not previously been studied in the context of in-event intervention delivery, which could potentially be different due to mood, intoxication, attention-span, and social factors.

We developed and piloted an alcohol-related risk-reduction intervention delivered by SMS to Australian young adults during drinking events [52]. This paper describes the development of the message content for this intervention.

Methods

Sample and Recruitment

We recruited young adults to participate in the development, testing, and evaluation of the intervention [52]. Participants were recruited through advertising on social media and with hardcopy flyers pinned to bulletin boards at two major universities in Melbourne, Australia. Advertisements called for young people meeting the following eligibility criteria to participate in developing a mobile phone–based intervention aiming to help reduce risky drinking for young people. Stated inclusion criteria included those who (1) were aged 18-25 years, (2) owned a mobile phone and were willing to use it to test intervention, and (3) consumed alcohol at least weekly.

Procedure

Four development workshops were held in June 2014, with 8-12 participants in each group; each workshop lasted for 3 h. Participants were given an Aus $40 gift card and offered light refreshments. Two groups were mixed gender, one was female only, and one was male only. Participants were allocated to groups depending on preference and availability.

At the beginning of each session, we told participants that we wanted to create a mobile phone–based intervention to be delivered during nights on which they were planning to drink alcohol. We indicated that our plan included repeated reporting of alcohol consumption throughout the night and the provision of tailored messages which could correspond to surveys they filled in during the night. Participants were then engaged in a facilitated discussion relating to intervention design.

The workshops had four stages: (1) a focus-group style discussion on drinking habits and motivations, (2) discussion of the design features of the intervention, (3) analysis of existing media campaigns related to alcohol, and (4) a development component in which participants generated their own message content and gave further design feedback.

First, participants were asked to describe a "typical" night out, including usual drinking patterns and their as well as their peers' event-level behavior. They also discussed their own motivations, if any, for reducing alcohol consumption within drinking events as well as more broadly, including what intervention features they felt would motivate them, and separately, what they felt would motivate their peers and young people in general. The groups also identified the types of health promotion content they found acceptable and relevant. Message style, language, framing, and topics were discussed. Participants reflected on tailoring required for different genders and ages, as well as event-specific contexts (eg, messages which might apply when drinking at a bar but not at private venues and messages relevant to stages of the night).

Second, participants were asked questions relating to the design of the intervention including ideal platforms, frequency of data collection and message delivery, questionnaire items, and feasibility. The results of this specific component of the study are reported elsewhere [52].

Third, participants were engaged in a media content analysis of over 20 diverse alcohol-related campaigns from Australia and elsewhere. These examples were taken from previous studies and public campaigns that included short alcohol messages. We selected examples which represented different message communication approaches, with a combination of text and image-based formats. Participants were shown examples one-by-one on a projector and asked to discuss reactions, comprehension, relevance, persuasion, and attractiveness. We asked which, if any, examples would be useful and appropriate and how to modify those that they thought were potentially useful. Participants discussed how best to translate messages for mobile phone and in-moment delivery, including format, length, topic appropriateness, and language.

Finally, participants were divided into groups of 2 to 4 people and asked to develop their own content for messages to be sent at different stages of their typical night out, based on topics that they felt would be relevant to them. Participants were given activity sheets developed by the researchers on which to list content and ideas.

Analysis

The sessions were recorded digitally and the recordings transcribed verbatim. Four digital recorders were used in each session, so that any conversations which occurred during small group work could be captured. All transcripts from workshops, as well as notes written by participants, were analyzed thematically using NVivo 10 Software (QSR International Pty Ltd.) [53]. An inductive approach was used, whereby a coding framework was developed using the raw qualitative data that was iteratively refined during the analysis process. Two researchers separately coded an initial sample of transcripts and checked consistency. Only minor discrepancies emerged and were resolved by discussion; the remaining transcripts were coded by a single researcher. Data from all workshop components were combined for analysis and coded as relevant to the various codes and themes.

Results

In total, 42 people attended the development workshops—21 women and 21 men aged 18-25 years. Findings were divided into two categories: (1) the style of messages preferred for delivery during a drinking event, and (2) the topics that

participants considered were appropriate for this type of intervention.

Style of Messages

Participants were asked about the preferred style and tone of the intervention. Without prompting or leading, almost all agreed that in order for content to be acceptable, nonjudgmental and non-authoritative language was essential. Participants described getting into a different state of mind when they commenced a drinking episode. This seemed to involve a concentrated focus on having fun and blocking out any incongruent negative influences on their night. This is an important idea with respect to any intervention occurring during a social event. Participants also advocated for some messages to be framed as questions, so as to allow them to reflect on their own behavior without being told by someone else why they should change. One participant felt that this would be more effective if applied to a message sent the day following the event:

> *At the time, if you are drinking, if you are doing things, you are going to be like, "I'm so awesome, I'm doing this thing," and then the next day you go, "that was not good. Everyone is going to be remembering that. I'm going to remember that. That was awful." I think it would be more the next day because if you were regretting it at the time, you probably wouldn't maybe do it.*

Participants requested that some positive reinforcement be provided during the intervention to create a more positive interaction. One participant communicated the desire for an intervention to "tell me what I'm doing right." This sentiment was echoed across the workshops, with participants frequently mentioning the need for more encouraging messaging.

Fear-based campaigns or messages were described as likely to be ineffective as participants of both genders felt easily able to dismiss the seriousness or relevance of harms while in a social context. The following statements exemplify a common attitude among the participants:

> *I don't know anyone who got drinking-related cancer...*
>
> *...people pass out all the time...*
>
> *If you get alcohol poisoning then they just pump your stomach and you're fine the next day.*

A clear preference for short, actionable harm-reduction focused messages was observed, including suggestions for reminders around drinking water, organizing a ride home, checking on friends, eating enough, and reminders of plans the next day. One participant articulated these points as follows:

> *If you tell me I'll get sick when I'm old...What do I care? I can't change that anyway. It's the short-term stuff I can do something about.*

Both male and female participants were excited about the potential for topics to be tailored to individual preference, as they felt many of the recent public alcohol-related campaigns were too generic and often irrelevant to them and their peers. Participants were keen for the messages to provide genuinely tailored feedback based on their reported preferences and behaviors, such as reminders based on their reported plans, tracking of cumulative drinking and spending, and the reflection of their own personally reported motivations.

Message Topics

Our participants reported that messages based on drinking norms messages were largely irrelevant to them; they felt they had a strong grasp on the norms of their social circles and were not concerned about what was normal to other young people. In each group, regardless of gender, the messages provided to participants from the norms-based example campaign were contested by at least one participant who did not believe the statistics presented were accurate. This was seen to compound the preexisting idea held by many participants that researchers and practitioners were "out of touch" with young people's needs. A number of male participants touched on the idea that norms-based campaigns could have an effect opposite to that intended because of the "proud" culture around excessive drinking in Australian males:

> *Nah, and on the contrary, I reckon you would be like, "YOLO! (You Only Live Once). We do this." I reckon...Yeah, that doesn't resonate with me at all.*

Indeed, most participants from our workshops claimed that they already knew about the harms related to alcohol consumption, but they did not seem serious or relevant in a social context. This did not seem to differ by gender. Unsurprisingly, long-term harms were described as especially unmotivating, despite many of the participants not knowing about, for example, the cancer-related harms of drinking. "Wouldn't even read that—buzz killer, etc."; "I'd just ignore it. Everything gives you cancer, may as well just have fun." Instead, participants felt they would be most motivated by avoiding the consequences that they themselves had previously experienced—such as hangovers, losing possessions, vomiting, and memory loss—and therefore messages to aid the avoidance of these proximal harms were seen as useful.

Social burden was also seen as relevant: young people didn't want to let down their peers or "ruin the night." This sentiment was the same across genders, although described in a slightly different language. Participants in the male-only focus group discussed extensively the stereotype of the "shit mate," or "maggot" who would "cut loose" at the expense of others. They recounted regretful episodes where they or their friends had drunkenly started fights, passed out and been too heavy to move, had been ejected from nightclubs, or had vomited in cars. Females across both the single-gender group and mixed groups more commonly described wanting to avoid being "that messy girl" who cried, whose makeup was smudged, and who needed greater protection and supervision. Safety and protection from others was a key concern for females and for female friends, whereas protection of males was more likely to relate to stopping them from hurting themselves by engaging in a risky behavior or violence.

> *You all have that one mate that just gets agro and you're like oh god, where's he gone, what's he doing now—have to pull him away non-stop.*

One female participant described that sending messages relating to checking on friends could serve the dual purpose of encouraging them to sober up in order to be able to protect their friends, while simultaneously reminding them not to be that drunk person themselves:

> *When you drink, or when I do, and your friend is—[pause]. You all of a sudden become like this protective person that wants to help. I think a lot of people do, if you love your friends or whatever [laughter]. The protecting your friends part is important. Even, "Check on your friends, how are they going?" because it could make you look at them and be like, wait, okay, this person is acting weird. Maybe I should tone down so I can help. But also you don't want to be that weird friend either.*

Spending was seen as a key motivator, as young people reported that they often experienced financial hardship and felt inexperienced at sticking to a budget. Some participants suggested the use of diet and exercise-based messages; across all focus groups, there was a clear gender difference with females more supportive of diet-based messages and males more supportive of sporting-related messages. A suggested form of feedback was comparing calories consumed as alcohol with those as junk food: "How many cheeseburgers am I drinking?" A male participant advocating for an exercise message reported: "I have footy (football) every Saturday, so if you reminded me about that..."However not all participants were interested in diet and exercise messages, and a few females expressed concern for the unintended consequences of this message type. "If you sent me that then I probably would just skip dinner instead." Another female participant worried that it may even encourage existing disordered behavior:

> *The only thing with that is can it make people who are really insecure, anxious. It makes you not want to eat...You could get that random one person that gets it and she is like, "Oh no, I'm going to go and throw up."*

Discussion

Principal Findings

Without any prompting, young people advocated for a style very similar to motivational interviewing in approach involving four basic strategies: open-ended questions, affirmations, reflective statements and summary statements [11]. These characteristics were all raised by study participants as preferable, as were nonjudgmental framing and emphasis on personally derived motivations. These findings are in line with other relevant research [37,42,51,54], although previous studies not always described in the context of brief intervention or motivational interviewing theory [37,42]. Preferences for intervention message content do not appear to have been explored in the context of delivery during a drinking event. The findings from this development study suggest that brief intervention and motivational interviewing principles may be important considering this social context.

Our participants dismissed some previous alcohol intervention strategies and campaigns as unappealing due to their focus on health. This finding is aligned with previous studies such as that of de Visser et al who found that their young participants were generally unconcerned by health consequences and more motivated by social factors [51]. Contrary to this, Riordan et al found than both men and women preferred messages focusing on long-term health over other types of alcohol consequences [50], although social factors also rated highly. Our participants' more firm rejection of consequence-based or negative messages may reflect the social context of our intervention timing. Alternatively, it could reflect a push back from the emphasis on fear appeal which has been predominantly preferred in Australian alcohol campaigns. Although there is some evidence supporting the use of fear-based messages in specific contexts and topics, they are usually coupled with strategies that affect policy or environments [55-57]. Graphic drink-driving mass-media campaigns in Australia are often cited as successful fear-based messaging, but in reality these advertisements represent only one part of a multipronged effort that also includes policy and enforcement [56,57]. Given that there is no equivalent or relevant "enforcement" strategy with which to pair our intervention messages, fear-based messages are unlikely to be effective. Thomas et al similarly found in their formative work to develop an alcohol intervention that participants warned against the use of "scare tactics," expressing that these types of messages may induce anxiety or guilt and cause them to disengage [37]. Hospital et al described a strong consensus from participants that content for alcohol interventions should have an overly positive tone [54].

Findings relating to motivations for drinking less, such as burdening friends, have also been discussed in previous studies [50,51]. De Visser et al [51] and Riordan et al [50] both similarly found that young people were strongly motivated by wanting to avoid ruining their friends' night. Our study adds to the idea of using protection of friends to motivate young people to drink less. One previous study found that a message encouraging young people to look out for their friends was among the highest-rated of their expert-authored messages [47]. One previous study also found the same gendered differences in relation to safety and protection, with concerns for protecting females from others, and males from themselves [51]. These socially related motivations could make for a key target for in-event intervention delivery due to their broad relevance.

Diet and exercise-based messages have been used in some recent public alcohol-related campaigns, but in light of this study and other relevant findings, there is a need for caution to ensure that unintended harm is not caused. Knight [58] recently reported "drunkorexia," meaning skipping meals to allow consumption of more calories as alcohol, in young Australian women [58,59]. Our participants reporting this type of behavior, along with the high prevalence and underdiagnosis of eating disorders in Australian young people [60], was a central reason for minimizing use of diet and exercise messages in our intervention. Two exceptions were reminders early in the night to encourage eating a meal before drinking and a reminder during the night if a participant reported that they had sport or exercise planned for the following morning.

Reactions to normative-based messages were surprising, considering that these are an increasingly common feature of alcohol brief interventions [31-33,60-62]. Whereas a great deal of research shows that peer and social norms are important determinants of drinking behavior, there is less evidence for the effectiveness of social norms information being used in interventions to reduce drinking. A recent Cochrane review found only small effects on drinking in interventions which used this approach; however, authors noted that these studies were of low or moderate quality [62]. In our study, the use of norms-based feedback was seen as irrelevant when participants had contradictory real-life norms and experiences. This perception of irrelevance may be heightened in an in-moment intervention, when "contradictory behavior" is occurring during intervention delivery. It is possible that normative-based feedback needs to be context-specific or more highly tailored in order to feel relevant to the recipient and be effective. Participants also introduced the concerning idea that norms of drinking to excess were a source of pride and may be therefore ineffective even if relatable. The application of this message type for in-moment interventions requires further investigation.

Preference for short and actionable messages is well suited to the mobile platform and the in-moment delivery of messages. However, the style and tone of these short messages is important for acceptability [37,54]. Thomas et al also found that young people preferred alcohol-related text messages that were succinct, clear, and encouraging [37].

Limitations

This study used a small, nonprobability sample, but generalizability is not a focus of this qualitative research. Deep and rich insights are more important in this context, given how little is known about how to intervene during risky drinking events. Considering how new and emerging this area is, we could have chosen to employ in-depth interview methods instead, to allow deeper probing with each participant. We chose to use focus groups not only because of resource constraints but also due to the benefit of idea generation and examination of consensus which can occur in groups. At the completion of data collection, some new ideas were still emerging and some researchers may have chosen to continue collecting data. Our team decided that our main research questions had been answered with enough consistency across the four groups that we could be confident in our decision to close data collection. Acceptability might not equal behavior change. The efficacy of our intervention and the message content developed in these workshops in reducing alcohol consumption has not yet been tested; this will be the subject of future research.

Conclusions

Recent research has attempted to harness technology to deliver brief interventions via mobile phone platforms, including for alcohol harm reduction. Although this innovation offers new opportunities, there is a need for improved content development processes (such as use of theory and participatory research), as well as transparency in reporting these processes.

Findings from this study offer insights into young adults' drinking events, as well as practical advice for designing alcohol-related brief interventions. During our formative development process, we demonstrated a neat correspondence between young people's preferences for alcohol-reduction interventions and the theoretical principles of both brief interventions and motivational interviewing, including acceptable topics and message style. It is recommended that creators of future mobile brief interventions look beyond the basic "feedback" component of brief interventions and consider integrating more of the FRAMES model components in order to maximize both the acceptability and theory-base of their interventions. Delivery of interventions during risky events such as drinking alcohol also offers new opportunities, but careful consideration of the context is required when designing message content to maximize its effectiveness. In order to advance the evidence base for alcohol brief interventions delivered by SMS, further work is needed to test differences in brief intervention types, including varying approaches to messaging within interventions.

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Conflicts of Interest

Professor Dietze has received funding from Gilead Sciences Inc. and Reckitt Benckiser for work unrelated to this study. The authors declare that they have no other competing interests.

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Abbreviations

FRAMES model: Feedback, Responsibility, Advice, Menu of options, Empathy, and Self-efficacy

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Original Paper

Mobile Apps for Eye Care in Canada: An Analysis of the iTunes Store

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Abstract

Background: Mobile phone screens can facilitate stimulation to various components of the visual system and many mobile apps are accepted as a means of providing clinical assessments for the oculo-visual system. Although many of these apps are intended for use in clinical settings, there is a growing number of apps in eye care developed for self-tests and eye exercises for lay people. These and other features, however, have not yet been well described.

Objective: Our objective was to identify, describe, and categorize mobile apps related to eye care that are available to users in the Canadian iTunes market.

Methods: We conducted an extensive search of the Apple iTunes Store for apps related to eye care. We used the terms “eye,” “eye care,” “vision,” and “eye test” and included apps that are targeted at both lay people and medical professionals. We excluded apps whose primary function is not related to eye care. Eligible apps were categorized by primary purpose, based on how they were described by their developers in the iTunes Store.

Results: Our search yielded 10,657 apps, of which 427 met our inclusion criteria. After removing duplicates, 355 unique apps were subject to further review. We assigned the eligible apps to three distinct categories: 39/355 apps (11.0%) were intended for use by medical professionals, 236 apps (66.5%, 236/355) were intended for use by lay people, and 80 apps (22.5%, 80/355) were intended for marketing eye care and eye-care products. We identified 9 subcategories of apps based on the descriptions of their primary functions. Apps for medical professionals fell into three subcategories: clinical calculators (n=6), clinical diagnostic tools (n=18), and education and networking apps for professionals (n=15). Apps for lay people fell into four subcategories: self-testing (n=153), eye exercises (n=30), patient tools and low vision aids (n=35), and apps for patient education (n=18). Mixed-use apps (n=80) were placed into two subcategories: marketing of individual practitioners or eye-care products (n=72) and marketing of multiple eye-care products or professional services.

Conclusions: The most extensive subcategory pertaining to eye care consisted of apps for use by lay people, especially for conducting self-tests (n=236). This study revealed a previously uncharacterized category of apps intended for use by doctors and patients, of which the primary goal is marketing of eye-care services and products (n=80).

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KEYWORDS

mobile applications; mobile phone; ophthalmology; optometry

Introduction

In recent years, there has been growth in apps for both lay people and clinicians [1]. It is estimated that by the year 2018, half of all mobile phone users will download at least one health-related app [2]. Emerging mobile-based technologies can affect the eye-care market substantially. From the perspective of a lay person, this facilitates innovative communication channels with clinicians based on questions and images, while also empowering lay people with self-testing methods in the palms of their hands. Self-testing apps may be particularly useful for patients living in remote and low-resource areas [3]. Mobile technologies also provide a new framework for the digital connectivity of ophthalmic diagnostic devices for eye-care professionals, supporting real time decision-making, streamlining diagnostic processes, and opening new modalities for business practices and enterprise promotion.

Extensive research has evaluated mobile technologies and their readiness for clinical practice, including the evaluation of mobile color vision tests [4], visual fields tests (Amsler grid) [5], and mobile phone add-ons that convert the camera of the phone into a miniature anterior segment and retinal camera [6]. Apps for home monitoring and self-testing, including the myVision Track app, were cleared by the FDA [7].

Recent reviews on ophthalmologic apps found that they were largely clinician-oriented. It was suggested by Chhablani et al [2] that mobile apps for eye care be divided into five main categories: patient education, patient self-testing, patient visual aids, patient records and administrative tools, and programs supporting emerging hardware tools. Other studies [8] suggest that these apps be placed within five distinct categories, including patient assessment tools, patient education tools and visual aids, patient records, health care profession education, and reference. This study also suggests the addition of a broad category of "multiple function" apps. It is important to consider that in such a dynamic and volatile marketplace as that of mobile apps, technologies can change rapidly, thereby affecting how popular they may be and what their patterns of use may include.

The purpose of the study was to identify, describe, and categorize eye-care apps available to users of the Canadian Apple iTunes Store.

Methods

An extensive search of the Apple iTunes Store was performed for apps that related to eye care, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [9]. A recent study on the evaluation of app quality [10] revealed that iOS does not traditionally support older apps once a newer version of the operating system becomes available. This contrasts with Google Android, where older apps may remain available to users in the marketplace unless they are manually removed by the developer. To avoid the number of outdated apps that were no longer supported by the developer as well to reduce biases resulting from different app ranking algorithms, only the iOS market sample was included in the study.

The search hedge for this study was performed between January and February 2016 and included the terms "eye," "vision," "eye test," and "eye care."

Conventionally, eye care has been defined as the prevention or minimization of threats to the eye or to visual integrity [11]. Per the World Health Organization (WHO) [12], a "health condition" is a complex interaction with contextual factors such as body structure, functions, participation in activities (including self-care), as well as environmental and personal factors. As eye health is a component of general health, we determined it necessary to include search terms pertaining to the eye-care domain. Our assumption was that the search terms "eye," "vision," "eye test," and "eye care" are relevant and valid search terms for apps pertaining to eye care.

All apps that targeted medical professionals and patients were included in the study. We excluded apps that were not directly related to eye care, such as serious games or optical illusions. The results were screened and duplicates were removed. Eligible apps were coded based on the description provided by the developers in the iTunes Store and categorized by primary purpose based on their description. We did not apply a date range so as to include all apps that met the above described criteria.

Results

Our search identified 10,657 apps in total. Over 96.00% of the apps including those that were found using the search terms "eye," "eye care," "vision," and "eye test" were excluded after the first round of screening as they were related to optical illusions, games, and utilities and did not meet our search criteria. Our inclusion identified 427 apps related to eye care in the iTunes Store. After removing duplicates, only 355 unique apps met our inclusion criteria and were therefore included in the review (Figure 1).

Based on the descriptions of the apps in the App Store, we assigned eligible apps to three primary categories: 236/355 apps (66.5%) intended for use by patients or lay people, 39/355 apps (11.0%) for use by medical professionals (n=39), and 80/355 apps (22.5%) with a blend of potential end-users. We conducted descriptive, qualitative analyses of these apps based on the descriptions provided by their developers to assist in developing these subcategories (Figure 2).

Four subcategories were described for patient-oriented apps, including self-tests, patient education tools, eye exercises or patient utilities, as well as low vision aids. The eye-care medical professional apps category is comprised of three subcategories, including clinical calculators, clinical diagnostic tools, and clinical education and networking apps. Finally, the mixed-use category consists of two subcategories, including apps for a

single practitioner or product and those for multiple products or services.

The patient self-test subcategory consisted of apps that enabled patients to collect information pertaining to their performance after completing specific visual tasks. Apps for eye exercises included those that aimed to facilitate vision enhancement through the accomplishment of tasks. Patient education tools were those whose primary goal was providing information on eye disease prevention and maintenance as well as eye anatomy. A subcategory of patient utility tools was used for apps that provided low vision aids, magnifiers, image recognition tools, appointment reminders and apps that aimed to increase adherence to a prescribed contact lens-wearing schedule. The number of apps that fell into each of these subcategories was as follows: patient self-test (n=153), patient education apps (n=18), eye exercises (n=30), and patient utility, including low vision aids (n=35).

Apps for medical professionals (n=39) were divided into three subcategories. The first subcategory consisted of clinical calculators, including apps whose primary goal was assisting clinicians with quantitative analysis of data obtained from diagnostic instruments, such as intraocular lens calculation or vertex distance adjustment estimates used in contact lens fitting. The second subcategory consisted of clinical tools such as charts, figures, or instruments for oculo-visual assessment. The third category included medical professional education apps and apps intended to facilitate education, learning, communication, and collaboration for practitioners. Overall, there were 16 apps classified as clinical diagnostic tools for use by eye-care professionals.

Mixed use apps (n=80) were those that facilitated two-way communication between practitioners and their patients. The majority of these apps, however, were intended for the marketing of professional services or eye-care products, including appointment reminders or self-testing tools such as the Amsler grid. These apps were separated into two subcategories: 72 for marketing of single individual practitioner or eye-care products and 8 apps for lay people.

Figure 1. Systematic search for eye-care apps in the Canadian iTunes Store.

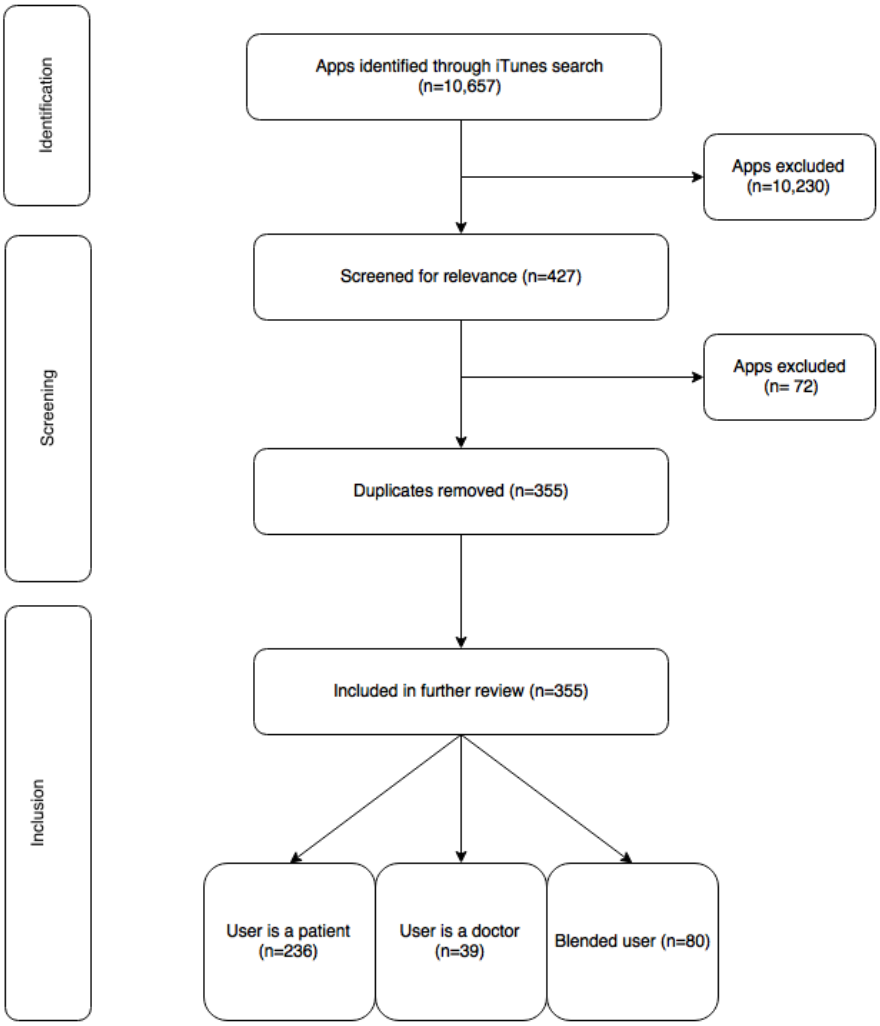

Figure 2. A classification of eye-care apps in the Canadian iTunes Store.

App user	Primary function	Description
Patient	Self-test	Apps that enable patients to collect information on their performance on completing certain visual tasks
	Education	Apps providing knowledge on eye disease prevention, management, and ocular anatomy
	Eye exercises (treatment)	Apps that aid in vision enhancement through the accomplishment of certain tasks
	Utilities (magnifiers and reminders)	Apps that provide low vision aids, magnifiers, image recognition tools, and appointment reminders and apps that increase adherence to prescribed contact lens wearing schedules
Healthcare or industry professional	Clinical calculators	Apps for estimating intraocular and contact lens power
	Vision test tools	Apps for oculo-visual assessment
	Education and networking	Apps for professional education and communication for practitioners
Mixed—users are healthcare professionals and their patients	Marketing	Apps for marketing for single service practitioners.
		Apps for marketing for more than one service

Discussion

Principal Findings

The largest group of apps in our study consisted of apps designed for patient self-testing (n=153). A literature review of studies related to the evaluation of mobile apps intended for exercises as a means of improving visual functions returned few studies. Recent studies relevant to apps available for eye care in the Apple Store [13] confirm that an estimated 37% of app developers included as a feature, consultation with a certified eye-care professional.

We conducted a supplementary PubMed search, but we were unable to identify relevant literature on the use of mobile apps for home-based vision therapy. We posit that one of the reasons for the paucity of studies in this domain is that from a Canadian medico-legal standpoint, eye exercises are considered to be vision therapy that according to the Optometry Act [14] must be administrated exclusively by health care professionals.

Patient education tools are presented in health apps for lay people as standalone applications (such as libraries, websites, and books) or as reference information materials provided to supplement other types of ocular health-related apps. We found 18 apps that were developed to be used by patients for expanding their knowledge and awareness about eye diseases, eye-health maintenance, and eye-disease prevention.

The patient utilities group consisted of 35 apps that were intended to help in the self-management of eye-care needs for visually impaired patients. In addition to magnifiers and apps that support object recognition, this category also includes apps that support adherence to a prescribed contacts lens wearing regimen. Another example includes a gesture recognition interface (currently in development), which has the potential to substantially increase engagement in users of apps who have low vision impairments [15].

A review by Meyer et al [16] posits the application of mobile technologies as visual aids; despite this, however, low vision aids remain underrepresented in studies. Authors on this topic describe the useful functionalities of mobile apps for patients with low vision, saying that they are capable of reading and communicating text fragments, recognizing products with barcodes, and enhancing spatial orientation for visually impaired patients using an integrated GPS. Overall, these functionalities of mobile phones will help visually impaired patients with spatial orientation, objects magnification, and reading a fine print [16].

Clinician-facing apps were described by Lord et al [17] and include clinical tests such as near vision cards, color vision plates, pupil gauges, pen and fluorescein lights, pediatric fixation targets, Amsler grids, Worth 4 Dot tests, accommodation targets, red desaturation tests, and an optokinetic nystagmus drum simulator. We classified 39 apps into this category in our study. Incidentally, many of these apps were assessed by eye-care professionals [16]. While one clinical study on Web-based applications for visual acuity and contrast sensitivity testing [18] included 104 participants, a strong limitation was that the

application had been developed for desktop systems for telemedicine and not as a standalone mobile app.

In addition to these categories, we were able to identify categories of apps intended for use by eye-care professionals and develop a novel category—apps designed for marketing eye-care services and products. A category of mixed-use apps indicates that two-way communication between eye-care providers and their patients as end users is typical. In addition to traditional mobile telehealth apps for doctor-patient interactions previously reviewed by Nhavoto & Grönlund [19], it was found that the primary goal of these apps was the marketing of eye-care products and services. We expect this category of mixed-use apps to further grow and evolve as new offerings, such as the Apple HealthKit, that support communication between providers and patients as well as facilitate better integration of apps continue to develop.

In addition to marketing, we found that many of these apps are multifunctional and interactive. They include patient-centered tools such as doctor finder features, which help patients find eye-care clinics in their proximity, and product finders that promote online shopping for contact lenses and other eye-care products. This subcategory might also be classified as patient tools; however, their primary goals are consumer-oriented marketing and sales. We observe that this category has yet to be well described in the scientific literature. Previous studies might exclude this category from their search results to mitigate perceived commercial biases. However, in our view, these apps should not be excluded from consideration as they reflect a burgeoning market of eye-care apps in Canada.

It is evident that the number of eye care apps available for lay people is greater than those that are intended for medical professionals. We propose two factors that might influence this proposition. First, there is increasing demand for visual testing from lay people as the number of people afflicted by conditions of the eye in Canada is projected to increase by 4% by 2032 [20]. Second, new apps intended for clinical use require a designation as a medical device and must undergo a rigorous FDA or Health Canada certification process and this testing drives the costs for development and, therefore, for the end user. Though we did locate a few free clinically evaluated apps, such as SightBook [21], we found that those apps intended for clinical eye care were largely subject to the above described review process and could be priced in the Apple iTunes Store at well over CAD $100.

Limitations

This study compiled data available in the Canadian iTunes Store in 2016 and represents only a snapshot of the very dynamic and vibrant environment of the mobile apps market. Our study design does not include apps from other app marketplaces for reasons explained in the methods section. Future research may elucidate this very important topic.

Although we attempted to categorize the apps based on their description in the App Store, the quality of the apps was not evaluated in a detailed fashion as suggested in the recent reviews on app quality assessment [22]. A longitudinal study that observes the growth and proliferation of optometric apps over time may also be similarly beneficial.

Conclusions

While mobile apps for eye conditions, monitoring, visual aids, and use by providers are growing substantially, our search for apps related to the eye and eye care in the Apple iTunes Store found that only 4.00% of the apps are, in fact, intended for use in eye care. Among these apps, self-testing represents the largest category (66.5%), yet few are properly evaluated. The wide proportion of mixed-use apps (22.5%) focused on the marketing of eye-care products and services may support the argument that the continued development of health-related apps is compelled by sustained growth in this industry.

Conflicts of Interest

Dr Alexander Rodin, Optometrist, is a consultant for CanMedApps Inc, a developer of mobile apps for health care.

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Original Paper

Users' Adoption of Mental Health Apps: Examining the Impact of Information Cues

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Abstract

Background: Numerous mental health apps have been developed and made available to users on the current app market. Users may find it difficult and overwhelming to select apps from the hundreds of choices that are available in the app marketplace. Clarifying what information cues may impact a user's selection and adoption of mental health apps is now a critical and pressing issue.

Objective: The aim of this study was to investigate the impact of information cues on users' adoption of anxiety apps using observational data from the Android app market.

Methods: A systematic search of anxiety apps was conducted on the Android app store by using keywords search. The title and metadata information of a total of 274 apps that met our criteria were collected and analyzed. Three trained researchers recorded the app rankings from the search results page on different dates and Web browsers.

Results: Our results show that ratings (r=.56, P<.001) and reviews (r=.39, P<.001) have significant positive correlations with the number of installs, and app prices have significant negative correlations with installs (r=−.36). The results also reveal that lower-priced apps have higher ratings (r=−.23, P<.001) and a greater number of app permission requests (r=.18, P=.002) from the device. For app titles, we found that apps with titles related to symptoms have significantly lower installs than apps with titles that are not related to symptoms (P<.001).

Conclusions: This study revealed a relationship between information cues and users' adoption of mental health apps by analyzing observational data. As the first of its kind, we found impactful indicators for mental health app adoptions. We also discovered a labeling effect of app titles that could hinder mental health app adoptions and which may provide insight for future designs of mental health apps and their search mechanisms.

(JMIR Mhealth Uhealth 2017;5(6):e83) doi:10.2196/mhealth.6827

KEYWORDS

user interaction design; recommendation system; mobile app search; mental health; anxiety

Introduction

Background

Mental disorders are a challenging public health issue. This is due to the high impact of these disorders on people, which limit their participation in all aspects of personal life, family life, and society. Mental disorders affect approximately one in four adults across the world at some point during their lifetime [1]. The high prevalence of mental disorders reveals a high demand for timely mental health care and intervention for people with mental disorders. However, the enormous cost of mental health care, the shortage of mental health professionals, and the barriers to accessibility make both diagnosis and treatment delayed or unavailable [1-3]. Therefore, how to provide affordable, in time,

and accessible mental health care for those in need has become a critical and urgent issue.

With the rapid development of technology, the computing capacity of mobile technologies has advanced to the point that today's mobile devices function like handheld computers and are highly integrated into our daily lives. According to surveys [4,5], over two-thirds (64%) of US adults own a mobile phone, and users, on average, check their phones 46 times a day. The prevalent ownership and use of mobile devices make mobile apps a promising venue with which to engage users into beneficial activities or therapeutic sessions in the context of mental health [6,7]. For instance, many mental health apps with self-monitoring mechanisms enable users to track their moods and emotions over time [8]. The personal use of mental health apps also provides confidentiality for users' engagement, which may further encourage their adoption by young people and users who have a high sense of autonomy for seeking self-help [9]. With the advantage of continuous and ubiquitous access, mobile apps have the potential to decrease barriers for help-seeking and make therapeutic activities more accessible and less stigmatic [6,10-12].

Although mobile apps enhance the deployment of mental health interventions, there are still significant challenges in increasing their adoption and incorporating them into users' daily lives in the real world. Thus, understanding users' adoption of mental health apps becomes an important step toward designing and utilizing them as effective intervention approaches.

Challenges in Mental Health App Adoptions

Mental health apps can encompass various functions ranging from guiding recovery for mental disorders to encouraging beneficial behaviors for improving emotional health [13,14]. For example, many mental health apps can assist clinical practice, engage real-time communication, or provide psychoeducation [15]. However, the adoption of mental health apps is rather distinctive from other types of apps because of its sensitive nature. The sensitivity of mental health issues can be attributed to the long-existing social stigma, which is the most common reason given for hindering people seeking mental health care or support [16,17]. Previous research has found that avoiding a social stigma becomes a significant reason for young people to use mental health apps [18]. Nevertheless, many available mental health apps target specific users and label them by diagnosis [14] that not only may exacerbate the stigma [6,8,14] but also affect users' adoption of mental health apps.

As there is no clear guideline, regulations (eg, Health Insurance Portability and Accountability Act [HIPPA] or Food and Drug Administration [FDA]), or recommendation for users to select mental health apps, another challenge in mental health app adoption is that users may find it difficult and overwhelming to select the appropriate app from hundreds of choices available on the app market [19]. For instance, while browsing apps on the Android app store, users can only filter apps by rating or price. The filtering mechanism on the Android app store is limited. If a user wants to find an app to help alleviate her or his anxiety, she or he may need to go through all of the apps on a search results page. Another option for users is to randomly select an app, which may not correspond to the user's needs. With more and more mental health apps available on the market, a critical and pressing issue is how to help users select and identify the "right" app for their mental health wellness. However, it is critical to understand the adoption of mental health app from the users' perspective before designing reliable mechanisms to assist users' app adoption.

App Adoption as a Heuristic Process

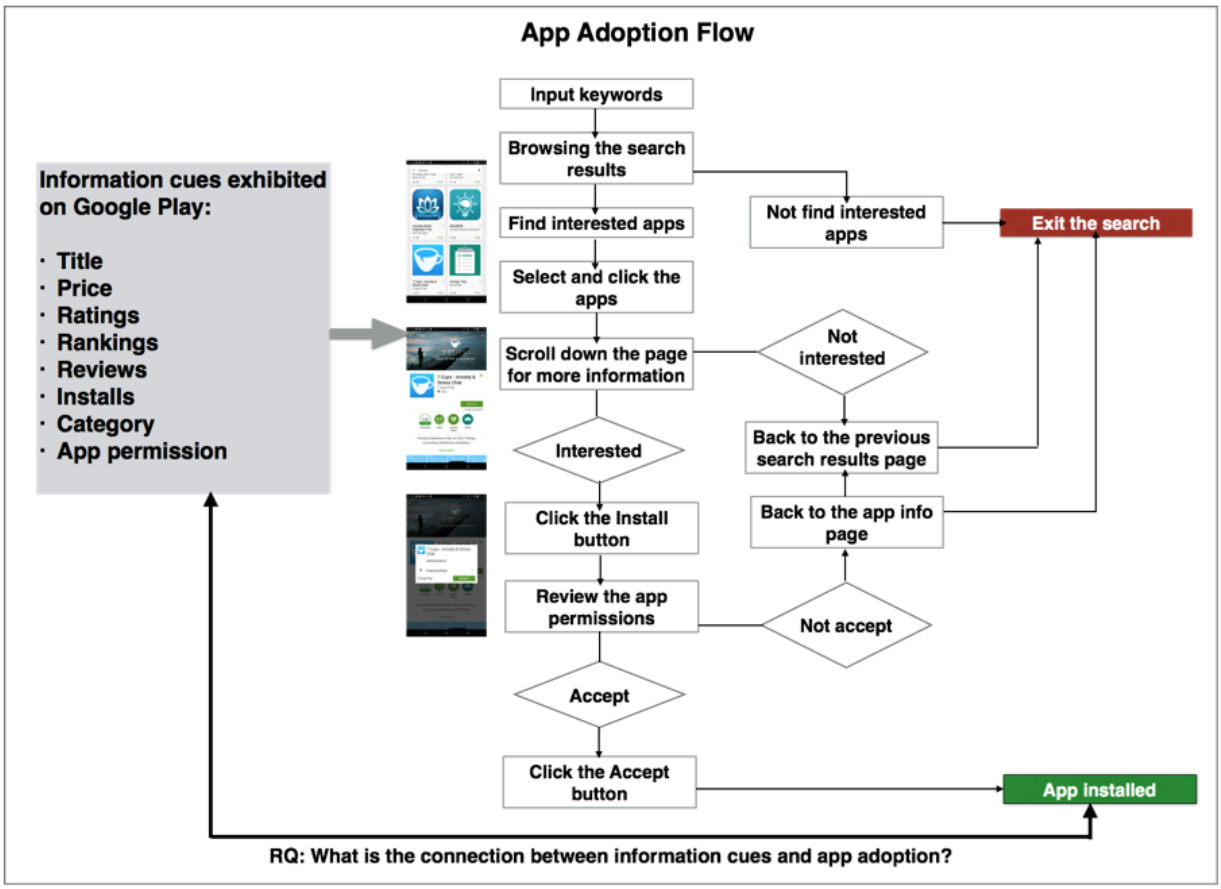
App adoption can be regarded as a selection process in a computer-mediated context where users make their decisions by relying on a variety of information cues [20,21]. While making decisions, individuals often use a heuristic approach to process information instead of a systematic approach due to the human's bounded rationality [22-24]. Heuristics are "process-oriented strategies" that allow individuals to make decisions in a faster and more frugal way by reducing cognitive efforts [24,25]. That is, when utilizing a heuristic approach, individuals are inclined to examine and integrate fewer information cues and simplify their weighing principles for cues [26].

In the selection process, heuristics comprise three stages: (1) searching, (2) stopping, and (3) deciding [23,25]. For example, when selecting an app, users may search for app titles that they recognize and stop the search once they categorize the available apps into either recognized or unrecognized titles. However, individuals may rely on multiple information cues rather than just a single cue during a heuristic process [27]. Thus, the consideration of multiple effects of information cues on users' app adoption becomes important.

Previous studies have identified a variety of information cues that can affect users' selection in app adoption, including prices, ratings, reviews, rankings, installs, titles, descriptions, functions, and privacy issues of apps [15,20,28-36]. A study by Dogruel et al [20], which is most relevant to ours, further points out that when users know what type of apps they need, they often employ the simple "take the first" heuristic approach, which is predominantly influenced by apps' titles and crowdsourcing-based cues such as ratings and rankings of apps. Users only seek additional information (eg, reviews and functions) when they are uncertain about rating and ranking cues [20].

Existing research has indicated several influential cues involved in the process of app selection and adoption. However, the literature about how users select and adopt mental health apps is still rather scarce. As users' app adoption varies by the kinds of apps, we still have no knowledge about the type of information cues that have relational impact on users' adoption of mental health apps. Considering the sensitivity of the mental health context, we are curious whether predominant cues (eg, apps titles, ratings, and rankings) indicated by previous studies remain influential in app adoption. To the best of our knowledge, this study is the first work focusing on examining the relationship between information cues and mental health app adoptions.

Figure 1. Research framework.



Research Framework

The aim of this study was to investigate how exhibited information cues in an app store are related to mental health app adoptions. As mental health is a realm too broad to investigate, we focus in particular on one mental health condition: anxiety, which is also one of the most common mental health issues among US adults [37]. In addition, the delivery of psychological intervention via mobile devices is well suited for anxiety disorders because it allows users to receive in-time treatment during their daily routine, which makes anxiety disorders an ideal research topic.

We selected Android app store, Google Play, as our research site because it is currently one of the leading app marketplaces [38]. As exhibited in Figure 1, the anxiety app adoption flow starts from the keyword search. Users input the keyword and get the first search result page that mainly displays apps' titles, ratings, and prices. If users are interested in one of the anxiety apps, they can click the app for more detail, such as the number of installs, reviews, and descriptions of the apps. After browsing the information, users can decide either to install the app or go back to their search results page for more options. If users decide to install the anxiety app, the permission consent dialogue will pop up to notify users what permissions are requested by the app. Apps will be installed if the users accept the app permission request.

As pointed out by previous studies [20,27], users' app adoption is affected by multiple information cues. However, this type of multiple effect is difficult to measure or observe directly from the users' self-report because of bounded rationality and self-bias. Therefore, we propose to use the observational data of apps for examining the multiple effects of information cues on app adoption instead of using users' self-reported data. Based on prior research, we examined 8 types of information cues exhibited on Google Play, including titles, prices, ratings, reviews, rankings, installs, category, and app permission. We conducted several statistical analyses to explore the connections between these information cues and anxiety app adoptions, which are described in the Methods section.

Methods

Anxiety App Search and Selection

To simulate the users' app search process, we used keyword search strategies to identify apps that most likely would be adopted by users seeking anxiety-related apps, which is similar to the approach employed by Ramo et al [39]. According to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) [40], we first identified 3 main keywords related to anxiety disorders, including anxiety, fear, and avoidance. Each term reported 250 results on Google Play. We decided to drop the term "avoidance" because its search results did not report anxiety-related apps. In order to identify other potential keywords, a search for the word "anxiety" was

performed at the website UrbanDictionary.com. A total of 27 commonly used terms were listed, and two of the words most compatible with anxiety and fear, “anxious” and “worry,” were selected. Four keywords were used in our final search terms on Google Play, including anxiety, anxious, fear, and worry. We used “anxiety” as our primary search term and the other three keywords for supplementary searches.

We conducted a 2-phase app search. The first app search using these keywords was conducted on Google Play from July to September 2016. Researchers collected metadata information for all of the apps and selected the anxiety-related apps based on the apps’ descriptions. After selection, a second round of app searches by keywords was conducted on October 7, 2016, by 3 researchers. Twenty-four new apps were found and 14 apps no longer existed. A total of 274 apps were selected for analysis. Figure 2 displays the search process for anxiety apps on Google Play.

Information Cues of Anxiety Apps on the Android App Store

Metadata as Information Cues

The search result of anxiety apps on Google Play provides the users different metadata information cues. According to Figure 1, we collected 8 types of metadata cues including (1) prices, (2) ratings, (3) reviews, (4) installs, (5) categories, (6) permissions, (7) ranking, and (8) title. We reassigned the number to the installs because we could only access the approximate range of installs on Google Play, instead of the exact number. Based on the range of categories, the number of installs ranges from level 1 (<10) to level 12 (>1,000,000). We want to note that installs, ratings, and reviews are represented as indicators for the adoption of apps.

App Ranking on Search Results Page

The search ranking of results has been considered as an influential factor on users’ selection [41]. Our assumption is that the more popular the app is, the higher search ranking it has. However, the app ranking of search results on Google Play is defined by algorithm, which may customize the ranking of apps based on individuals’ preferences. In order to identify the average mean ranking for each app, 3 researchers individually searched apps by keywords and recorded their rankings from October 7 to October 11, 2016. Considering that the size of a mobile screen is limited and not easy to view the ranking of all apps, we recorded the ranking on a Web browser instead of a mobile device.

In addition, to examine the stability of app ranking produced by the 3 researchers, we calculated the change of app ranking and its variability. As exhibited in Table 1, the variability of app ranking between researcher A and B is smaller than other comparisons. We also conducted paired samples *t* test to compare the mean difference of the change of app ranking among researchers. The results found no significant difference, indicating that the app ranking reported by researchers is fairly similar.

Figure 2. Systematic search of anxiety-related apps on Google Play.

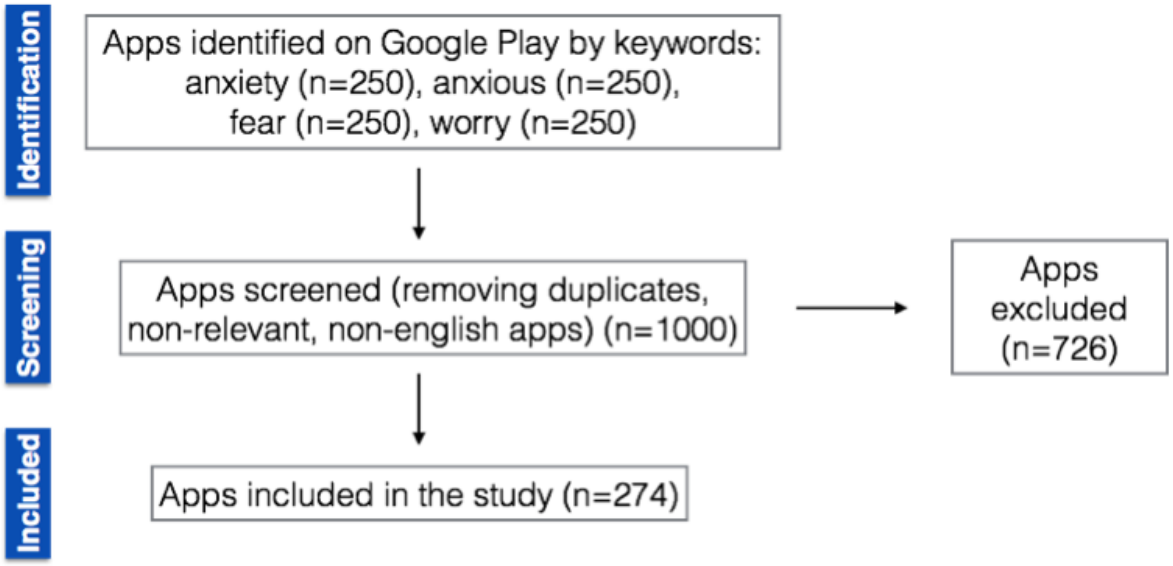


Table 1. Change of app ranking among researchers.

Statistics of app ranking change	Change 1[a]	Change 2[b]	Change 3[c]
Mean	−0.04	−1.91	−1.93
Median	0.00	0.00	0.00
Standard deviation	28.89	43.57	39.05

[a]Change 1 denotes the difference of app ranking between researcher A and B.

[b]Change 2 denotes the difference of app ranking between researcher B and C.

[c]Change 3 denotes the difference of app ranking between researcher A and C.

Classifying Titles of Anxiety Apps

The title of an app gives users their first piece of information on what the app is about, which can further influence the users' apps selection [29]. However, the functionality of apps, such as treatment, psychoeducation, and diagnosis, may not always appear in the title. Instead, they may emphasize specific disorders, symptoms, or activities. We are interested in whether anxiety apps tend to use certain terms in their titles. To classify the titles of anxiety apps, we adopted the recommendation proposed by [14] and generated six criteria from both clinical and nonclinical perspectives. The clinical criteria include anxiety disorders, symptoms, and treatments, and the nonclinical criteria are self-help approaches, mindfulness activities, and the self-tracking or management tool. We reviewed the title for each anxiety app to see if they are related to these six aspects. The details of the six criteria are exhibited in Textbox 1.

Textbox 1. Classifying criteria of anxiety app titles.

Classifying criteria

- Specific type of anxiety disorders (eg, social anxiety disorder, generalized anxiety disorders, and panic attacks)
- Symptoms (eg, fear, anxiety, and worry)
- Treatments (eg, cognitive behavioral therapy [CBT], counseling, and therapy)
- Self-help approach
- Mindfulness activities (eg, breathing, meditation, and body scan)
- Self-tracking or management tools (eg, mood tracker or monitor, diary, and stress management)

Data Analysis

To capture the connections and multiple effects of information cues on anxiety app adoptions, we employed different statistical techniques. We first examined the relationship among metadata information cues and app adoption by correlational analysis. We then tested the normality of each information cue using the Kolmogorov-Smirnov test and found that these variables were not normal distribution. Therefore, nonparametric approaches including the Kruskal-Wallis test and the Mann-Whitney test were adopted to examine the differences of app adoption by app categories and titles.

In order to test predictable effects of information cues on anxiety app adoptions, we applied a nonparametric regression technique known as generalized additive model (GAM) proposed by Hasite and Tibshirani [42]. The GAM framework assumes that the contribution of each predictor is additive, which is similar to the concept of linear regression that each variable is estimated independently. The dependent variable is an additive combination of arbitrary functions of predictors. This additive modeling technique captures the underlying predictive patterns of data by smooth functions, especially when the model has nonlinear effects [43]. In this study, the flexibility of GAM allows us to predict the nonlinear impact of each information cue on app adoption. We implemented GAM by the function gam() with regression splines in the R package "mgcv."

Results

Overview of Anxiety Apps

Descriptive Statistics of Information Cues

According to Table 2, the average price for anxiety apps on Google Play is US $0.81. The 3rd quartile price is US $0, which means that most apps are free. The median of app rating indicates that half of the apps have a rating higher than 4.1. Although the mean number of review is around 2686, the median shows that half of the apps have reviews lower than 35. The average install is 6.42, which is between 1000-5000. On average, anxiety apps request about 6 permissions from users' mobile devices. In the included categories, 52.9% (145/274)of apps are in health and fitness, 17.2% (47/274) of apps are in medical, 12.0% (33/274) are in lifestyle, 5.8% (16/274) are in books and reference, and 12.0% (33/274) are in other categories (Figure 3).

Table 2. Descriptive statistics of anxiety apps on Google Play.

Descriptive statistics of metadata	Price	Rating	Review	Install	Permission	Ranking
Mean	0.81	3.43	2686.42	6.42	6.16	112.54
Standard deviation	2.09	1.61	11475.97	2.97	4.64	64.78
Minimum	0.00	0.00	0.00	1.00	0.00	1.00
1st Quartile	0.00	3.38	2.0	4.00	3.00	57.08
Median	0.00	4.10	35.50	6.00	5.00	111.00
3rd Quartile	0.00	4.40	568.2	8.75	9.00	157.83
Maximum	16.69	5.00	151870.0	12.00	37	246.67

Observations of Anxiety App Rankings

As exhibited in Table 2, the average app ranking is 112.54. Interestingly, the minimum and maximum app ranking is 1 and 246.67, respectively. This implies that an app is always at the top of the search results, but no app is always at the bottom of the search results. We further found that 7.7% (n=21) of apps appear to have the same ranking on the search results from all 3 researchers, and 34.3% (n=94) of the apps have the same ranking on the search results from 2 researchers, although 58% (n=159) of apps appear to have different rankings on the search results from all 3 researchers. These findings suggest that the ranking orders of anxiety apps may be personalized by algorithm.

Types of Titles Used by Anxiety Apps

We found 211 app titles related to at least one of the six categories and 63 app titles not relevant to any of these 6 categories. Very few apps used clinical terms (eg, disorders and treatment) in their titles. As exhibited in Figure 4, only 10.6% of the apps associated their titles with anxiety disorders and 5.5% of the apps mentioned treatment in the titles. Over half of the apps (59.1%) used symptoms, but only 5.5% of the apps indicated a self-help approach in the title. 12% of the titles were related to mindfulness activities, and 8% were related to self-tracking or management tools.

Figure 3. Anxiety apps in different categories on Google Play.

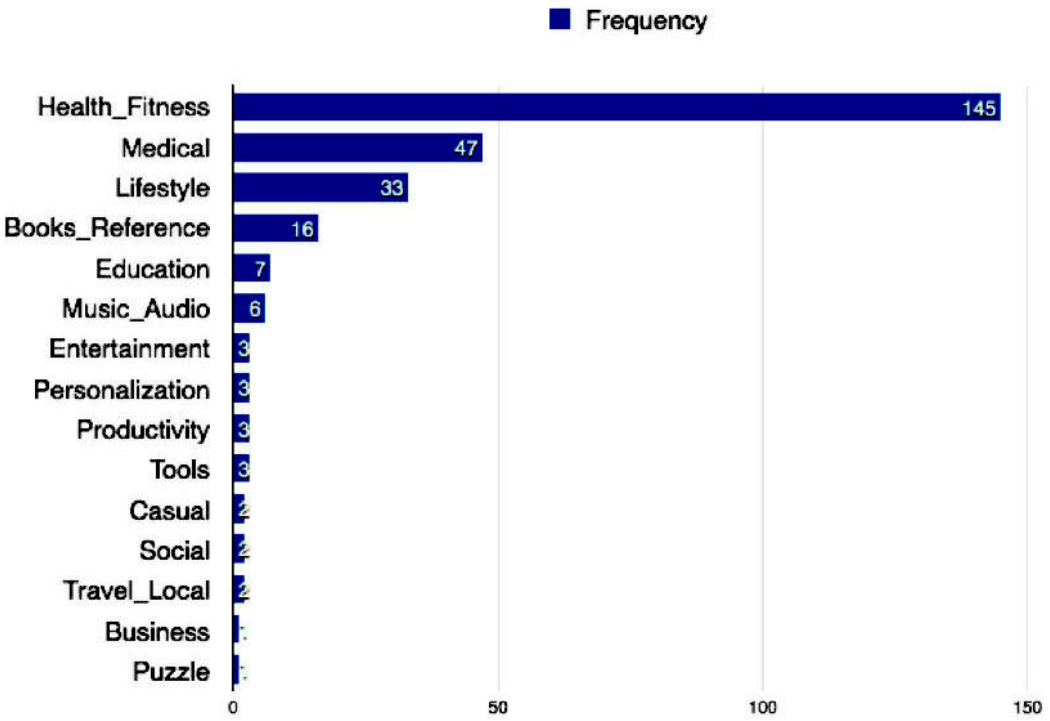
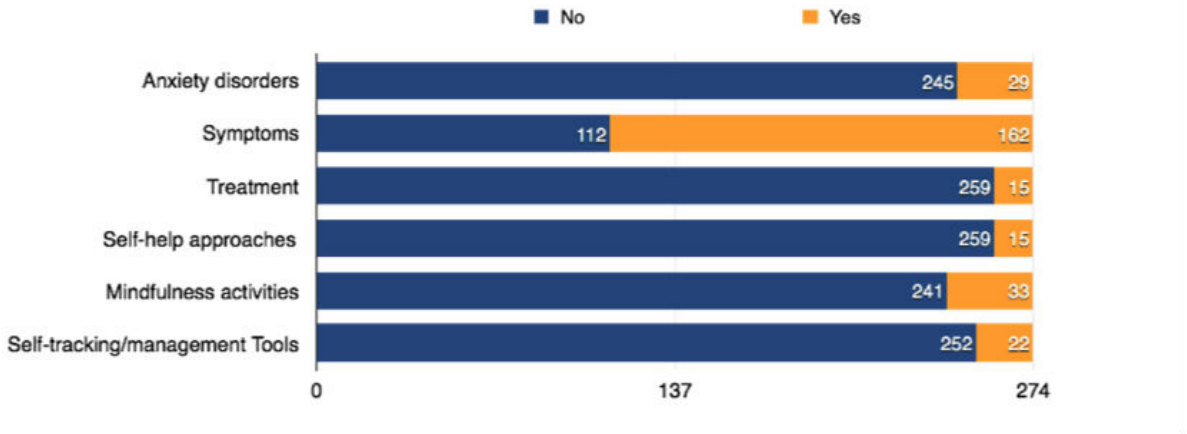


Figure 4. Number of app titles related to anxiety disorders, symptoms, treatment, self-help approaches, mindfulness activities, and self-tracking or management tools.



Metadata as Information Cues and Adoptions of Anxiety Apps

We examined the relationship between app adoptions and exhibited metadata information by correlational analysis. As exhibited in Figure 4, the ranking of apps have a significant positive correlation with app price, indicating that the higher price apps have, the lower ranking they have in the search results. The results also showed that the app ranking has a negative correlation with app review, rating, and installation. These results suggest that apps with a higher ranking also have more reviews, installs, and higher ratings.

Another interesting result is that the total number of app permission requests positively correlates with installs. This suggests that apps requesting more app permissions from mobile devices have more installs. The results also show that apps with lower prices request more app permissions from the devices. Furthermore, the ratings and reviews of apps have significant positive correlations with the number of installs, and the price of apps has significant negative correlations with installs (Figure 5). This means that apps with higher ratings and reviews at lower prices have a higher number of installs. We want to note in particular that although these results have significant correlations, the coefficients are only at moderate or low level. It is also important to note that significant correlations only show the relationship between these observational cues that do not represent the cause and effect relations.

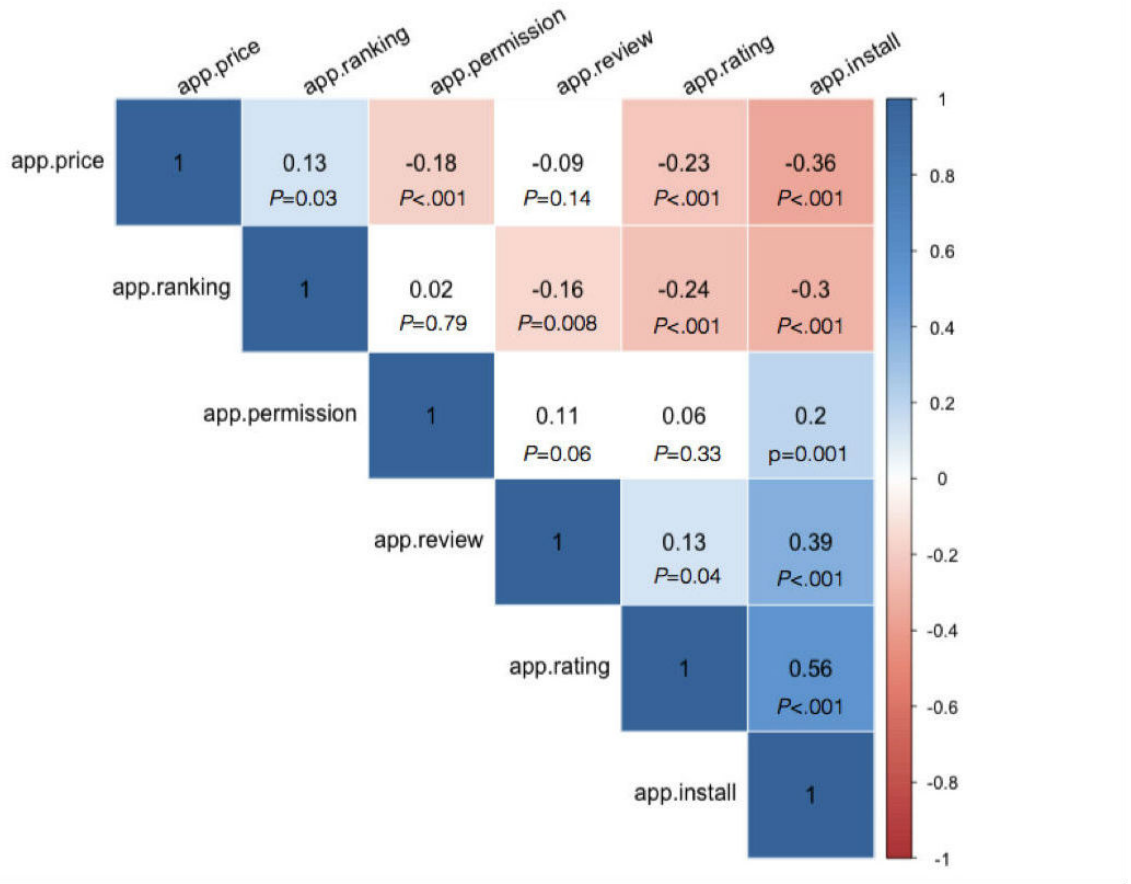
We applied the Kruskal-Wallis test to examine whether different categories of anxiety apps showed significant differences in ratings, reviews, and installs. As shown in Table 3, the results show the significant differences in price, rating, review, and install. According to the post-hoc test, apps in books and reference have significantly lower ratings (P=.05) and installs (P=.01) than apps in other categories. Also, apps in books and reference have a significantly lower amount of reviews than apps in health and fitness (P=.04) and others (P=.002). There is no significant difference among categories in app rankings.

Table 3. Kruskal-Wallis test for price, rating, review, install, and permission requests by apps category.

Category	Mean rank		
	Rating	Review	Install
Books and reference (N=16)	87.16	80.84	89.41
Health and fitness (N=145)	138.83	139.01	139.99
Lifestyle (N=33)	118.47	120.73	118.7
Medical (N=47)	147.73	136.18	134.81
Other (N=33)	153.05	169.66	167.82
Kurskal-Wallis chi-square (df[a]=4)	10.58 *P*=.03	15.227 *P*=.004	13.001 *P*=.01

[a]df: degrees of freedom.

Figure 5. Correlational analysis of information cues and app adoption.



Predictable Effects of Information Cues on Adoptions of Anxiety Apps

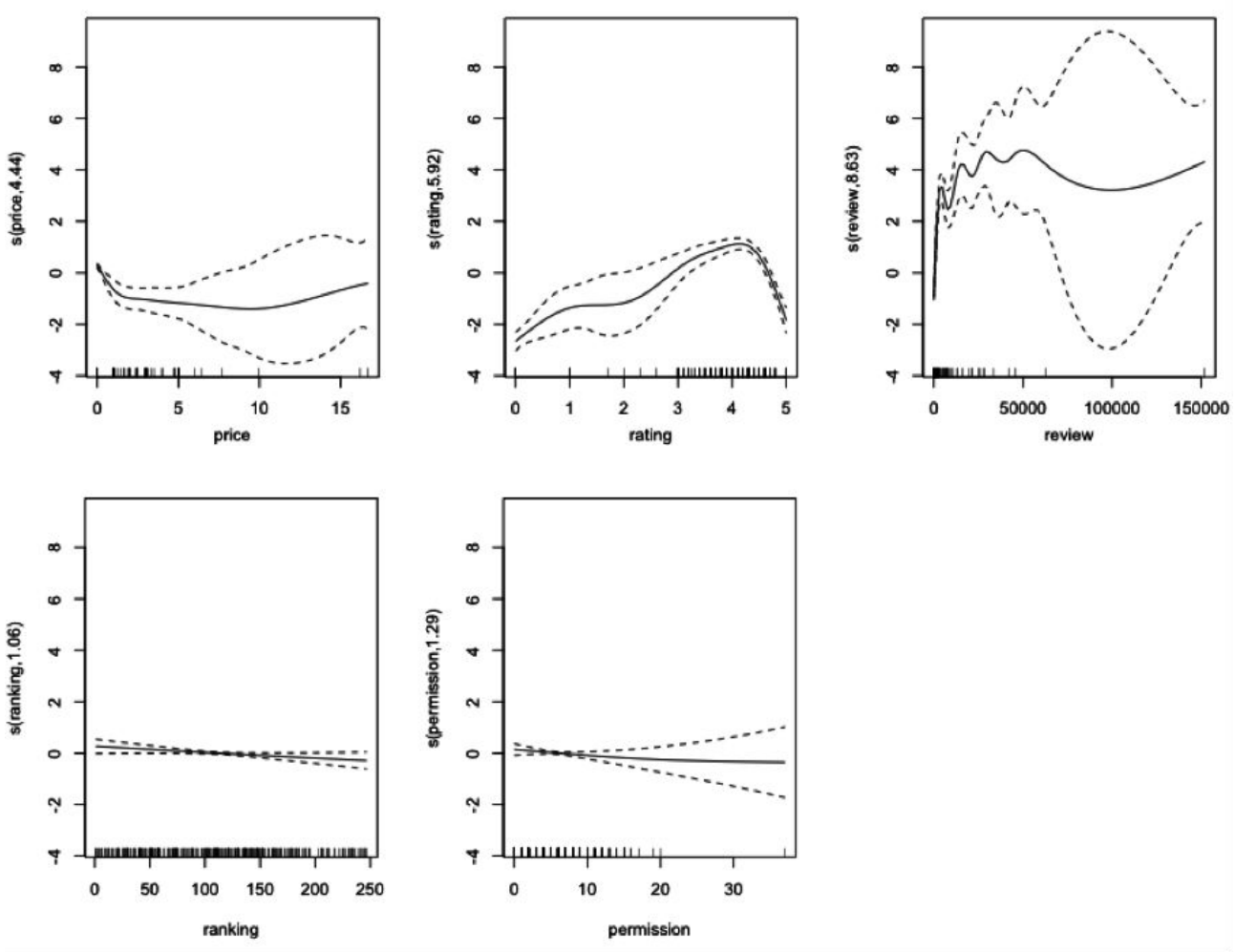
We adopted GAM to predict the impact of 5 metadata information cues (price, rating, review, ranking, and permission) on adoptions of anxious apps. To select the smooth function of parameters for minimizing the prediction error, we used deviance and generalized cross validation score [44] as indicators. Deviance (D) represents the discrepancy between observations and fitted values, and generalized cross validation (GCV) estimates the expected fit of a model to a dataset. The smaller these scores are, the better fit the model has. Thus, we decided to smooth all variables because the model produces the lowest deviance (D=316.24) and GCV score (GCV=1.51). As shown in Table 4, the price, rating, and review have significant predictable effects on app adoption. Note that although ranking cue does not reach a significant level, it is still very close.

Figure 6 displays the direction of predictive impact on app adoption. We found that the expected number of app installs will decrease drastically at first when the price of the app increases. However, the decrease of expected installs becomes gradual while the price increases. This may suggest that when prices of apps are over a certain amount, the number of app installs will remain similar. For rating, the app installs will increase when the rating also increases until the rating reaches nearly 4.4. After this point, the number of installs will start decreasing as the rating increases. This also implies that the high rating apps may not always get high installs. Furthermore, the result shows that the app installs will increase when the number of reviews also increases. Yet, when the app review reaches approximately 50,000, the number of installs will slightly decrease until the number of reviews is over 100,000. For ranking, the higher ranking the app has, the more expected installs the app will have.

Table 4. Generalized additive model (GAM) of anxious app adoption.

Smooth (predictors)	Effective degrees of freedom	*F* value
Price	4.44	9.00 (*P*<.001)
Rating	5.92	44.36 (*P*<.001)
Review	8.63	40.34 (*P*<.001)
Ranking	1.06	3.42 (*P*=.06)
Permission	1.29	1.30 (*P*=.26)

Figure 6. Generalized additive regression plots of information cues.



Titles as Information Cues and Adoptions of Anxiety Apps

An important function of the app title as an information cue is to inform users about the apps. We examined whether the linguistic cues in an app title are related to the users' adoptions of anxiety apps. Considering that app installs, ratings, and reviews are not normally distributed, we applied the nonparametric Mann-Whitney test to examine the difference. Our results show that app titles using the terms relating to anxiety disorders have significantly fewer installs and reviews (Table 5). We also found that apps with titles relating to symptoms have significantly lower installs, ratings, and reviews than those without symptom-related titles. On the other hand, apps with titles relating to mindfulness activities have higher installs, ratings, and reviews than those without mindfulness-related titles. Overall, these results suggest that apps with titles not directly related to anxiety disorders or symptoms, but to mindfulness activities, are more adopted by users.

Table 5. Nonparametric Mann-Whitney test of installs, ratings, and reviews by types of titles.

Metadata information	Title	Mean rank: No (=0)	Mean rank: Yes (=1)	Mann-Whitney *U* (Significance)
Install	Anxiety disorders	141.73	95.59	2270.50 (*P*=.003)
	Symptoms	188.52	101.16	3245.50 (*P*<.001)
	Treatment	137.67	125.53	1763.00 (*P*=.56)
	Self-help	135.51	162.60	1551.00 (*P*=.19)
	Mindfulness	129.16	196.08	1965.50 (*P*<.001)
	Self-tracking tool	137.85	127.34	2548.50 (*P*=.55)
Rating	Anxiety disorders	138.86	116.71	2949.50 (*P*=.15)
	Symptoms	166.60	115.75	5594.00 (*P*<.001)
	Treatment	135.89	147.03	1769.50 (*P*=.59)
	Self-help	136.17	142.20	1842.00 (*P*=.77)
	Mindfulness	129.44	187.65	2255.50 (*P*<.001)
	Self-tracking tool	136.87	132.25	2656.50 (*P*=.79)
Review	Anxiety disorders	141.62	93.59	2279.00 (*P*=.002)
	Symptoms	190.88	99.01	2899.50 (*P*<.001)
	Treatment	137.12	125.90	1768.50 (*P*=.59)
	Self-help	135.28	157.43	1613.50 (*P*=.29)
	Mindfulness	128.87	191.73	2121.00 (*P*<.001)
	Self-tracking tool	137.02	130.61	2620.50 (*P*=.71)

Discussion

Principal Findings

Observation of Information Cues and Anxiety App Adoptions

App Price, Rating, and Review as Information Cues

One of our research questions was to examine the association with metadata information cues and anxiety app adoptions. Our findings suggest that prices, ratings, and reviews not only have significant correlations with adoptions of anxiety apps but also are impactful predictors on app adoptions. For instance, we found that price is a negative predictor of app adoptions. The lower-priced anxiety apps yield higher installs, which corroborate previous findings that most users tend to use apps with lower prices [29-31], even when it comes to mental health apps. Since mental health apps may pose negative influences on users, further examination on the quality of lower-priced mental health apps is needed.

Furthermore, the results indicate that the higher rating the anxiety app has, the more installs the app will have. However, interestingly, this positive relationship between rating and adoption is only predictable before the app rating reaches a certain point (Figure 6). The expected number of app installs will decrease when the app rating is over approximately 4.4. This finding further implies that some apps may have high ratings but do not always have high installs by users. A possible explanation is that users may consider multiple cues rather than a single cue when adopting the app [27]. For example, users may be inclined to select an app with high ratings and high reviews instead of an app with high ratings but low reviews.

Our analyses show that an app review can be a positive predictor of app install. An anxiety app will have more installs when it has more user reviews. Nevertheless, it is important to note that the positive prediction between review and adoption only exists initially. The relationship between review and adoption becomes dynamic when the number of reviews is over a certain point (Figure 6). Overall, as information cues, we found that app price, rating, and review can be important indicators when it comes to the adoption of anxiety apps. Also, the results of rating and review cues may further demonstrate the bandwagon effect on anxiety app adoptions [20,27]. Users may still follow or rely on other users' adoptions to decide which apps to adopt.

App Permission and Category as Information Cues

Our findings indicate that anxiety apps requesting permissions from mobile devices have more adoptions by users, although app permission is not a significant predictor of adoption. We infer that apps with more permission requests may also provide more functions to users. In order to use apps, users may choose to trade off their long-term privacy for immediate gratification because of bounded rationality [45]. This may be the reason why anxiety apps with more permission requests are more adopted by users. Another possible explanation is that users may have less or no knowledge about app permissions; thereby, app permission may not be an important or useful cue for app adoption.

In terms of app category, our findings suggest that apps in books and reference have significantly lower installs, ratings, and reviews than apps in other categories. However, we cannot assert that users prefer anxiety apps in specific categories because apps in other categories may also show up in the search results from other terms, which can increase their adoption by users. Therefore, the app category may not be an effective information cue on app adoption. We suggest that the effect of app permission and category cues on app selection and adoption needs more investigation.

App Ranking as Information Cues

Our results indicate two important findings. First, app ranking generated by an algorithm can vary by individual. Second, apps with a higher ranking on the search results page also have more installs by users, although app ranking is not a significant predictor of app adoption in our model. We also found that anxiety apps with higher ratings and more reviews have higher rankings on the search results page. This indicates that app rating and review may be important factors in the design of an app search algorithm on Google Play.

Observation of Titles and Adoptions of Anxiety Apps

We further investigated influences of an apps' title and discovered two interesting trends. Our results reveal that only a small fraction of anxiety apps use specific anxiety disorders and treatment in their titles. This finding is 2-fold. On the one hand, this may be a progressive sign for reducing the stigma and labeling for users; on the other hand, users may not easily find the apps with clinical information or assistance.

App Title Related to Disorders and Symptoms as Information Cues: Labeling Effect

Approximately 10% of anxiety apps use titles related to anxiety disorders, and 60% of apps have titles related to symptoms. The results show that apps with titles related to anxiety disorders and symptoms have lower adoptions and fewer reviews than others. Since app titles related to disorders or symptoms may label users with disorders or diagnoses [14,46], social or self-stigma of mental disorders may hinder users' adoption of apps and decrease their motivation to provide app reviews. The disorder and symptom-related app titles as information cues may signal a stigma that prevents users' adoptions.

App Title Related to Mindfulness as Information Cues: Positive Enhancement

Mindfulness is an approach to enhance self-awareness, openness, and acceptance to experience and to develop new perspectives on the context through focusing on the present moment [47-49]. Several studies have suggested that mindfulness is beneficial for personal recovery from mental disorders and to an individual's positive well-being [36,50,51]. Interestingly, we discovered that anxiety apps with titles related to mindfulness activities have more installs, reviews, and higher ratings by users. Since app titles related to mindfulness activities (eg, breathing and meditation) signal providing a method to help users reduce their anxiety, users may perceive them to be more useful and applicable. In addition, mindfulness-related titles are not directly associated with disorders and symptoms; this reduces the labeling effect on users. In other words, anxiety apps with mindfulness-related titles signal positive enhancement that may further encourage users' adoption.

Implications of Findings

Our findings can be applied to improving current design mechanisms of the app market for users' selection and adoption of mental health apps. For example, app developers should avoid labeling effects when designing information cues for anxiety apps as suggested by previous research [14]. Considering the sensitivity of mental health issues, we suggest developers employ information cues that endorse positive enhancement to motivate users to adopt and engage with the apps.

From the observational data of anxiety apps, we learn that information cues with social influence may have significant impact on the adoption of apps. It seems that most users incline to "follow the crowd" when adopting anxiety apps. However, this follow-the-crowd strategy may mislead users to adopt an impractical or inappropriate app that may have harmful consequences. To help users select and adopt appropriate mental health apps, we suggest that developers design an information cue that signals the function or purpose of the apps on search results pages. This type of information cue may provide users with a better understanding of the apps and further assist users' adoption of mental health apps.

Limitations and Future Directions

In this study, we only examined anxiety apps on Google Play, which may limit our findings to a specific mental health context and app market. We recommend future studies apply the same approach to other mental health conditions and app markets and compare their results with this study. Although we found the correlational impact of information cues on app adoptions by using observational data of apps, we were unable to identify their cause and effect on app adoption. Therefore, we suggest future studies conduct empirical work based on the assumptive inferences we proposed in this study and investigate the cause and effects of information cues on users' mental health app adoption.

Conclusions

Mental health apps can be a powerful instrument for mental health care and intervention. How to design an app-searching system that can lead users to select the right apps for their mental well-being becomes a challenging issue. Since app adoption is a heuristic process, information cues play important roles. To clarify the impact of information cues on users' app adoption, we examined the relationship between information cues and users' app adoptions by using observational data in an app market. We discovered that app price, rating, and review are important indicators for anxiety app adoptions. On the other hand, the impact of app permission and category cues remain unclear. Most importantly, our findings revealed the importance of app titles on users' selection and adoption of anxiety apps. Although there is still a long way to go for designing an effective search mechanism for mental health apps, our work demonstrates interesting phenomena and provides insight into the information cues and anxiety app adoptions, which will help provide better solutions for the future design of search mechanisms for mental health apps.

Conflicts of Interest

None declared.

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Abbreviations

FDA: Food and Drug Administration
HIPAA: Health Insurance Portability and Accountability Act

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Original Paper

Direct Adherence Measurement Using an Ingestible Sensor Compared With Self-Reporting in High-Risk Cardiovascular Disease Patients Who Knew They Were Being Measured: A Prospective Intervention

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Abstract

Background: Use of appropriate cardioprotective medication is a cornerstone of cardiovascular disease prevention, but less-than-optimal patient adherence is common. Thus, strategies for improving adherence are recommended to adopt a multifaceted approach.

Objective: The objective of our study was to test a system comprising a biodegradable, ingestible sensor for direct measurement of medication ingestion in a group of patients at elevated cardiovascular risk attending a cardiac prevention and rehabilitation program.

Methods: In this prospective intervention trial in a single group of 21 patients running from April 2014 to June 2015, we measured adherence by self-report and adherence determined objectively by the system. The sensor emits a signal when it encounters the acidic environment of the stomach, detectable by an externally worn patch and linked software app. Longitudinal adherence data in the form of daily progress charts for sensed dosing events as compared with scheduled dosing are visible to patients on their tablet computer's medication dosing app, thus providing patients with continuous medication adherence feedback. We sought feedback on patient acceptability by questionnaire assessment. Participants used the system for the 12-week period of their cardiac prevention and rehabilitation program.

Results: Only 1 patient at initial assessment and 1 patient at end-of-program assessment reported often missing medication. The remaining patients reported never missing medication or had missing data. Only 12 (57%) of patients overall achieved system-determined adherence of 80% or more, and 3 patients had scores below 40%. Participants reported high levels of acceptability.

Conclusions: This integrated system was well tolerated in a group of 21 patients over an appreciable time frame. Its ability to measure adherence reveals the sizeable disconnect between patient self-reported adherence and actual medication taking and has

promising potential for clinical use as a tool to encourage better medication-taking behavior due to its ability to provide continuous patient-level feedback.

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KEYWORDS

cardiac prevention and rehabilitation; adherence; mHealth; remote monitoring; cardiovascular diseases; primary prevention; medication adherence; telemedicine

Introduction

Use of appropriate cardioprotective medication is a cornerstone of cardiovascular disease (CVD) prevention, but less-than-optimal patient adherence is common. A meta-analysis and systematic review of 44 prospective studies assessing nearly 2 million participants found that only 60% of patients had good adherence (defined as ≥80%) to CVD medications, and lack of adherence was strongly linked with adverse clinical outcomes [1]. Reasons for nonadherence are multilayered and include patient-, health care provider-, and system-related factors, and thus strategies for improving adherence are recommended to adopt a multifaceted approach [2].

The crucial first step in this process is an accurate assessment of the patient's medication-taking pattern, not just to make the diagnosis of partial adherence or nonadherence, but also to help resolve ambiguities surrounding drug action (or lack thereof) and side effects, the latter being a key determinant of adherence.

Assessing adherence in daily clinical practice can be challenging. While several different methods exist, ranging from the relatively simple (eg, self-reported adherence derived from patient questionnaires, or assessment of prescription refills or pill counts) to more sophisticated techniques (eg, directly observed therapy, urinary metabolite assays, and electronic monitoring devices that record the frequency and time of the opening of a pill bottle), these measures all have limitations [3]. Self-report in particular is subject to recall bias and social desirability, while indirect methods such as pill counts or analysis of prescription refill data are not synonymous with actual medication taking. Urinary drug metabolite assays have shown some promise in hypertension management but can be confounded by "white coat adherence" and do not necessarily reflect longitudinal medication taking [4,5]. This last limitation similarly applies in directly observed therapy, which is also limited by staff time costs and the potential for tablet concealment [3].

Strategies for reliably measuring and promoting medication adherence in daily clinical practice are thus urgently required. Concomitantly, there is widespread evidence for the increasing use of mobile health technologies in CVD risk reduction and patient self-management [6].

Here we describe our experience of using an innovative telehealth system consisting of an ingestible pill-sensor combination to record an accurate dosing history in patients at elevated risk of CVD attending a CVD prevention and rehabilitation program at our institution. We sought to compare this objective, real-time measurement of adherence with that collected by self-report while also determining the feasibility and acceptability of this technology in everyday clinical practice.

Methods

Study Participants and Program Description

The study recruited participants attending the 12-week, nurse-led, multidisciplinary cardiovascular health and rehabilitation program at Imperial College Healthcare NHS Trust, London, UK [7]. Patients were eligible to attend the clinic if they were aged 18 to 80 years and had either established CVD or high multifactorial risk (QRISK2 ≥20%) [8].

The program starts with a detailed initial assessment by each member of the multidisciplinary team, followed by a weekly supervised exercise and educational session and then by an end-of-program assessment. In both assessments, a drug history is recorded and standard questions regarding medication adherence are posed. A key tenet of the program is medical risk factor modification and prescription of appropriate cardioprotective medication at evidence-based doses. Education is provided regarding medication and its indication to promote drug adherence.

We invited consecutive patients attending the baseline assessment from April 2014 to June 2015 to participate in our study. In addition to the criteria for attendance at the clinic, patient enrollment required active use of CVD medications, and we excluded patients due to (1) lack of fluency in English, (2) literacy problems, (3) pill swallowing difficulties, or (4) psychological ill health sufficient to affect study involvement.

Intervention

After we obtained informed consent, we gave study participants instructions during an education session ("on-boarding") on how to use the Lifenote system (Proteus Digital Health, Inc, Redwood City, CA, USA). The system requires the user to ingest a biodegradable sensor (shaped like a small pill) alongside each scheduled medication dosing (Figure 1).

The sensor then emits a signal when it encounters the acidic environment of the stomach, which is detectable externally by a patch worn over the left upper quadrant of the abdomen. The patch then sends a signal via Bluetooth technology to a paired tablet computer or mobile phone loaded with the system's software app. The patches are changed daily and have inbuilt sensors to validate patch application. The system has a positive detection rate of 97% using directly observed ingestion as a reference standard for comparison [9]. At the on-boarding session, scheduled doses for each day of the week were entered according to that patient's prescription, and each successful ingestion was registered as an event on that patient's progress

chart within the software app that matched expected doses with sensed dosing events (Figure 2). Patients had access to telephone technical support to troubleshoot connectivity issues. With regard to medication taking, they received an on-screen notification if 30 minutes had passed without successful registration of a sensed dosing event.

Figure 1. Integrated Lifenote system featuring a tablet computer, ingestible sensor, and externally worn patch.

Figure 2. On-screen representation of the device's scheduled dosing table. Each sensed dosing event is represented by an orange pill in each cell. Columns correspond to days of the week and rows to each scheduled dosing event for that day.

Outcome Measures

Adherence

System-Determined Adherence

We defined adherence as the total number of successful ingestions detected by the patch, expressed as a percentage of the total number of planned ingestion events for that period. We did not apply a time restriction. We excluded periods when a patient was not wearing a patch. A minimum 7-day period of valid data was required to be included in the data analysis.

Adherence by Self-Report

Patients were routinely asked as part of their initial and end-of-program assessments if they "missed taking or altered the dose of your prescribed medicine." The permitted responses were "never," "seldom," "often," "always," and "not applicable."

Acceptability

We assessed acceptability of the system to patients using a questionnaire at the end-of-program assessment.

Data and Statistics

For this study, we extracted sensed adherence data from the system. We then collated descriptive statistics in Stata version 14.1 for Mac (StataCorp LP) and Excel for Mac version 15 (2015; Microsoft Corporation). Data are presented as mean (SD) or, in the case of skewed data, median and range from minimum to maximum. Percentage adherence has been rounded to whole numbers.

Results

We invited 166 consecutive patients who met study eligibility criteria to participate (Figure 3), of whom 38 (22.9%) agreed and provided written, informed consent. Of those, 10 patients withdrew prior to starting to use the system, leaving a remaining 28 participants with use experience. A total of 7 participants ended their use period prematurely for reasons including the following: "Went away on holiday," "preferred app on phone." "didn't want to use the device," "device wasn't for me," and "off-boarded due to adverse event."

Thus, 21 patients with a minimum of 7 days of use experience were the focus of our analysis. Table 1 outlines their baseline characteristics. Median patch wear sensor time for the group, expressed in days of collected data as a percentage of the total number of days where data were expected, was 91%, (range 49%-100%). Patients had a mean age of 62 (SD 12) years, and the majority were male (n=15, 71%) with a mean body mass index of 30.7 (SD 5.0) kg/m^2. A total of 14 (67%) were primary prevention patients (increased CVD risk, type 2 diabetes mellitus), and the remainder were enrolled for secondary prevention (n=7, 33%). Most patients were taking 2 or more CVD drugs at their initial assessment (Table 1); 3 patients were taking a single CVD drug, and 2 patients enrolled with a view to commencing statin therapy during the program but did not start and instead remained on at least one non-CVD drug throughout.

Figure 3. Patient flowchart.

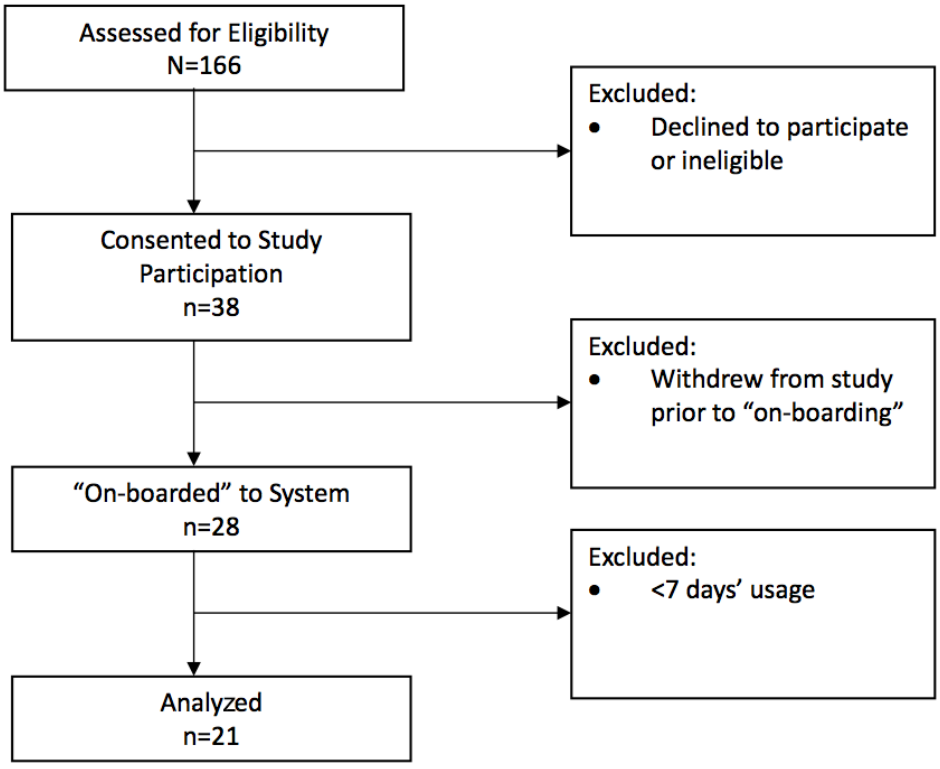
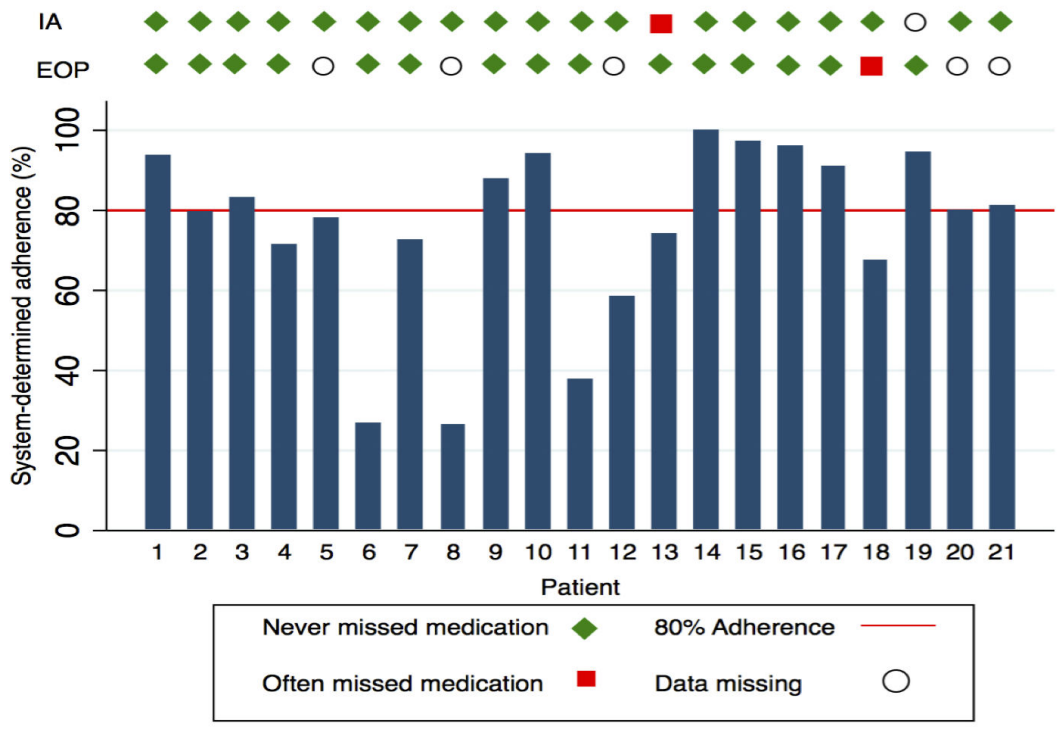


Table 1. Baseline patient characteristics (n=21).

Characteristic	Mean (SD) or n (%)
Age in years, mean (SD)	62 (12)
Male, n (%)	15 (71)
Body mass index in kg/m^2, mean (SD)	30.7 (5.0)
Race/ethnicity, n (%)	
White	15 (71)
Other	4 (19)
Asian	1 (5)
Black	1 (5)
Diagnosis, n (%)	
Primary prevention	14 (67)
Secondary prevention	7 (33)
Cardiovascular drugs prescribed per patient[a] , n (%)	
0	2 (10)
1	3 (14)
2	9 (43)
3	3 (14)
4	3 (14)
5	1 (5)

[a]Antiplatelet agents, statins, fibrates, other lipid-lowering drugs, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, β-blockers, calcium channel blockers, diuretics.

Figure 4. System-determined adherence (%) by participant. Markers indicate self-reported adherence responses at initial assessment (IA) and end-of-program (EOP) assessment.



Self-Reported Adherence

Of the 21 patients, 19 (90%) reported that they never missed medication at baseline and 1 patient reported that they often missed medication (Figure 4). Data were missing for 1 participant at the initial assessment. None of the patients reported seldom missing medications, and none stated that the question was not applicable.

Of the 19 participants who reported never missing medication at the initial assessment, 13 reported never missing medication at the end-of-program assessment (Figure 4). One patient reported never missing medication at their initial assessment and then reported often missing their medication at the end-of-program assessment. One patient who reported at their initial assessment that they often missed their medication reported that they never missed it at their end-of-program assessment. Data were not available on 5 participants at the end-of-program assessment due to loss to follow-up.

System-Determined Adherence

Overall, the proportion achieving good adherence (defined as ≥80%) was 12 of 21 (57%) (Figure 4). The median system-determined adherence was 80%, but there was substantial interindividual variability (26%-100%). Patient 13, who had reported poor adherence at their initial assessment but good adherence at their end-of-program assessment, had a measured adherence of 74%. Conversely, patient 18, who reported good adherence at their initial assessment but poor adherence at their end-of-program assessment, had a measured adherence of 67%.

Acceptability

A total of 8 (38%) patients agreed or strongly agreed with the statement that "the patch was comfortable," while 5 (24%) were neutral and a minority disagreed (Table 2). The majority of the patients 14 (67%) found the system easy to use. Overall, 11 (52%) felt that they were less likely to miss doses using the system, with approximately two-thirds responding that they would continue to use the system in the future, although one-third indicated that they would require amendments before doing so (Table 2).

A single participant experienced an adverse event due to patch-related contact dermatitis.

Table 2. Number (%) of participants' choosing each possible response to questionnaire items regarding acceptability (n=21).

Response	Q1[a]	Q2[b]	Q3[c]	Q4[d]
Strongly disagree	0	0	1 (5)	
Disagree	2 (9)	0	1 (5)	
Neither or neutral	6 (29)	5 (24)	9 (43)	
Agree	7 (33)	9 (43)	5 (24)	
Strongly agree	4 (19)	5 (24)	3 (14)	
No response	2 (10)	2 (9)	2 (9)	
I would continue to use the system				7 (33)
I would use the system if changes were made				4 (19)
I would not use the system				6 (29)
No response				4 (19)

[a]"Using Lifenote meant I was less likely to miss taking my tablets."

[b]"Lifenote was easy for me to use."

[c]"The patch was comfortable."

[d]Desire to continue system use.

Discussion

To the best of our knowledge, this is the first inpatient study using a system featuring an ingestible, biodegradable sensor for the objective assessment of adherence in patients attending a cardiac prevention and rehabilitation program. Self-reported adherence was high at the baseline assessment, with 90% reporting that they never missed medication. However, adherence measured by sensing of events demonstrated that only 57% achieved good adherence (defined as ≥80%) over the course of the program. This is consistent with the literature, where it is well recognized that measurement of adherence by self-report leads to overreporting, in turn due to a combination of factors, including recall bias and social desirability.

What is intriguing is that, despite the fact that participants knew their ingestion event record would be scrutinized, only 1 of the 19 who reported good adherence at baseline changed their reporting of adherence from "good" to "bad" at the end-of-program assessment, while those (n=3) with the worst adherence (<40%) continued to report good adherence at *both* time points. These data, therefore, underscore not only the lack of reliability of self-report as a measure of adherence, but also the psychological complexities of medication-taking behavior.

The only patient who admitted to poor adherence at the initial assessment reported never missing medication at the end-of-program assessment and achieved a sensed adherence of 74%. Although somewhat subjective, this may perhaps represent a positive change in behavior. Indeed, the majority of participants also felt that the system helped them to avoid

missing doses. While some data were missing at the end-of-program assessment due to loss to follow-up, the rate of follow-up attendance in this study compares favorably with the expected typical follow-up attendance rate of approximately 60% for such a program.

The device was well tolerated, with only 1 adverse event (an episode of patch-related contact dermatitis), which is a well-recognized side effect. Despite this being an older population, the majority found the system easy to use. Recent studies in patients with hypertension or diabetes of similar average age also found high levels of acceptability and low levels of adverse events [10,11].

This high level of acceptance likely reflects the permeation of mobile phone or tablet technology into society as a whole. The evidence for mobile health interventions (mHealth) overall is steadily increasing, and one of the most prolific areas of development is CVD risk reduction [6]. Simple interventions such as text messaging have proven effective in improving clinical outcomes in a secondary prevention population, and the same research group is now studying the effect of text messages on medication adherence [12,13].

The main potential of this technology, therefore, relates to not only measurement of adherence reliably but also a strategy to increase adherence. Access to real-time adherence data and progress logs could also be extended to a patient's family or medical team, allowing them to play a much more active role in the patient's medication management and potentially to overcome other common barriers to health care such as limited mobility or distance from care givers or the health care setting [14]. These concepts, however, would need to be tested in the context of well-designed, controlled studies including a determination of cost effectiveness before being put into widespread use.

There are also key limitations to our study that need to be addressed. First, patients choosing to participate in the study were clearly a highly selected group (approximately 20% of those invited), a majority of whom were white, and the results, therefore, may not be reflective of the general population. We expect, however, that the high degree of self-selection would have resulted in higher measured adherence, as those who were more motivated and had good medication behavior were more likely to enter the study.

Second, the duration of the period studied was relatively short (about 3 months) and may not necessarily reflect medication adherence in the longer term.

Third, to register a dosing event, the ingestible sensors had to be coingested with the patient's own medications, and it is entirely possible that participants could have ingested the medication alone, without ingesting the sensor (leading to underestimation of ingested events), or the sensor alone, without the accompanying medication (leading to an overestimation of adherence). Sensors that are coformulated or overencapsulated with prescribed medicines would overcome this issue, but this would also add to the complexity and cost of the intervention.

Fourth, we did not have a control group for comparison and therefore any benefits seen cannot be separated from those resulting from participation in cardiac prevention and rehabilitation alone.

In conclusion, this integrated telehealth system using an ingestible pill sensor demonstrated lower levels of adherence to CVD medications than that indicated by self-report. The technology was both safe and acceptable to patients. Larger studies are needed to determine the system's potential for measuring and promoting adherence on a wider scale.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CVD: cardiovascular disease

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Original Paper

Health App Possession Among Smartphone or Tablet Owners in Hong Kong: Population-Based Survey

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Abstract

Background: Health apps are increasingly used with important implications for health. Hong Kong is one of the most technologically advanced and connected cities—smartphone ownership and Internet access rates are among the highest in the world.

Objective: We investigated the prevalence of health app possession and related sociodemographic factors and health behaviors among smartphone or tablet owners in Hong Kong.

Methods: A territory-wide population-based dual (landline and mobile) telephone survey was conducted in 2016. Respondents were asked whether they had health-related apps on their smartphones or tablets and what functions were available on the apps (eg, tracking physical activity and logging health records). Logistic regression was used to calculate the adjusted odds ratio (aOR) and 95% CI of health app possession for different demographic characteristics, socioeconomic position (education, employment, and income), health behaviors (smoking, alcohol, and physical activity) and health (body mass index and chronic diseases).

Results: Of the 4129 smartphone or tablet owners (81.28%, 4129/5080 respondents), 995 (24.10%) had a health app. Tracking physical activity (67.0% of 995) and logging health records (43.0% of 995) were the most common functions of the health apps. Overall, younger age, higher education, and household income were associated with having health apps (all $P<.001$). Compared with physical inactivity, engaging in moderate physical activity ≥1 day/week was associated with having health apps (aOR 1.45 [95% CI 1.20-1.75] for 1-3 days/week, and aOR 1.32 [95% CI 1.07-1.62] for ≥4 days/week). Having a history of chronic diseases was associated with having health apps (aOR 1.36 [95% CI 1.11-1.68]).

Conclusions: We have shown a lower prevalence of use of information and communication technologies (ICTs) in respondents with lower education and income in the most developed Chinese city. This could be seen as a confirmation of the "Inverse information law," which suggests that those most in need have less use of services and hence receive less benefits from advancements in medicine and health related ICTs.

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KEYWORDS

apps; smartphone; Chinese

Introduction

Globally, the use of smartphones such as Apple's iPhone and Google's Android is rapidly increasing. Smartphones enable users to browse websites, check emails, and socialize. Smartphone apps related to health provide new ways to deliver information, strategies, and tracking capabilities related to the self-management of health and well-being [1]. Health apps include a wide range of functions such as lifestyle monitoring, self-diagnosis of disease, and treatment management [2]. The number of health apps is rapidly expanding [3]; the number was 8000 in 2010 and it tripled in 2015 [4].

Interventions using health apps showed effectiveness for weight loss, glycemic control, smoking cessation, and recovery from alcoholism [5-8]. However, reports on the pattern of health app use such as the prevalence of health app possession or the frequency of use in the general population are scarce. One population-based telephone survey in the United States in 2012 reported that about 19% of mobile phone users had a health-related mobile app, while an updated survey in 2015 reported that the above proportion had increased to nearly 60% [9]. People with higher education and household income are more likely to have health apps because they are more health conscious and have more health information orientation and health literacy [2,10]. One potential theoretical framework explaining the socioeconomic inequalities in the possession of health apps is the communication inequality theory, which defines communication inequalities as the differences among social groups in their ability to access, process, and act on information [11]. For instance, education may provide essential knowledge, confidence, and a sense of efficacy in enabling someone to navigate health information communicated by health apps. Discretionary income may allow a person to own a smartphone as well as to access the Internet and purchase data packages and chargeable health apps. Health app possession may also be associated with other demographic factors as well as health behaviors. The possession of health apps among smartphone owners declines with age, likely due to perceived access barriers to information and communication technologies (ICTs) [9,12-14]. Instead, older people are more likely to seek health information using traditional media such as newspapers or radios. Latino/Hispanic people are more likely to have health apps than white people [9]. Furthermore, obesity is also associated with having health apps [9]. Diagnosis of chronic diseases is associated with seeking more health information through the Internet [14].

Social patterning of health app possession may differ by context. Hong Kong is the most modernized and westernized city in China. However, education levels in Hong Kong are much lower than the West as universal education has been introduced only in recent decades [15]. About 16% of Hong Kong's residents had primary education, and 14% did not receive any formal education [16]. In addition, Hong Kong is a setting with high socioeconomic inequalities and a higher Gini coefficient (0.531 in 2011) than most developed countries [17]. The wide gap between the rich and the poor puts people with a low socioeconomic position (SEP) at a great disadvantage in terms of being able to afford a smartphone or tablet and get access to the Internet. The majority of Hong Kong's population is of Chinese ethnicity (93.6%), making the impact of race or ethnicity on having health apps less relevant. As such, studies investigating the prevalence and determinants of health app possession in a non-Western setting may help produce contextually specific policies and interventions to promote health apps.

Hong Kong has experienced widespread use of smartphones (about 83.3% of adults have used a smartphone in the past 12 months) and the Internet (about 84.3% of adults have used the Internet in the past 12 months), owing to advanced cyber-infrastructure and the low cost of access to the Internet. The smartphone has replaced the personal computer (78.6%) as the most common Web access device [18]. Smartphone ownership and Internet access rates in Hong Kong are among the highest in the world [19]. To our knowledge, no study has reported on health app possession and related factors in Asia. Hong Kong is one of the most developed non-Western cities, where the sociodemographic characteristics are different from the West but the use of smartphones is similarly prevalent. As the first step, we took advantage of a large population-based telephone survey to investigate the prevalence of health app possession and examine related factors such as sociodemographic factors, health behaviors, body mass index (BMI), and chronic diseases among Hong Kong's Chinese adults.

Methods

Sampling

The Hong Kong Family and Health Information Trends Survey (FHInTS) is part of the FAMILY Project, entitled "FAMILY: a Jockey Club Initiative for a Harmonious Society." FHInTS is a regular periodic probability-based telephone survey of the general Hong Kong public, designed to assess opinions and behaviors with regard to family health, information use, and health communication. So far, five waves of FHInTS have been conducted since 2009, and details of previous waves were reported elsewhere [14,20]. The current wave was conducted from January to August 2016 to collect data on ICT use for family and health information, family communication, and well-being.

The survey consisted of landline and mobile samples in the proportion of 4:1. All interviews were conducted by trained interviewers from the Public Opinion Program, University of Hong Kong, which is one of the largest established survey agencies, using the Web-based Computer-Assisted Telephone Interview system. The survey targeted the Cantonese-speaking adult population aged 18 years and over. Landline and mobile telephone numbers were randomly generated using known prefixes assigned to telecommunication services providers under the Numbering Plan provided by the Office of the Communications Authority, which covers nearly all Hong Kong residents [21]. For the landline telephone number samples, when contact was successfully established with a target household, a qualified person was selected from all those present using the "next birthday" method [22]. The person from the household who had the next birthday among all household members who

were aged 18 years or over was selected as the respondent. No second-level sampling, that is, next birthday rule was used for the mobile sample. Interviews were mostly conducted in the afternoons and evenings (2:00-10:30 PM). Ethical approval was granted by the Institutional Review Board (IRB) of the University of Hong Kong / Hospital Authority Hong Kong West Cluster. Verbal informed consent was obtained from the respondents.

Measurements

Health app possession was determined by asking the respondents who reported ownership of smartphones or tablets whether they had any software apps related to health. For those who reported having health apps, we asked them whether their apps had the following functions: logging health records (eg, body weight), tracking physical activity (eg, number of steps walked), tracking calorie intake or meals for weight loss, tracking health measures through a wearable device (eg, blood pressure and heart rate), managing specific conditions and diseases, helping quit smoking and alcohol consumption, tracking baby or child health, monitoring sleep, and acquiring health information. We chose these functions because they are common functions of health apps [2,9].

SEP was measured using educational attainment, employment status, and monthly household income. Educational attainment was categorized as primary or below, secondary, and tertiary or above. Employment status was categorized as full-time, part-time, self-employed, and unemployed. Monthly household income was categorized as <HK $10,000, HK $10,000-19,999, HK $20,000-29,999, HK $30,000-39,999, and ≥HK $40,000 (US $1=HK $7.8).

Smoking was categorized as nonsmoker, current smoker, and ex-smoker. Alcohol consumption was categorized as never drinker, occasional drinker (less than once per month), monthly drinker (1-3 days per month), weekly drinker (at least 1 day per week), and ex-drinker. Frequency of moderate physical activity for 10 minutes in the past 7 days was categorized as none, 1-3 days per week, and 4-7 days per week. BMI (weight in kilograms/height in square meters) was classified as <18.5 (underweight), 18.5 to <23 (normal), 23 to <25 (overweight) and ≥25 (obese). History of doctor-diagnosed chronic diseases (cancer, cardiovascular diseases, respiratory diseases, liver diseases, allergies, and others) was classified as none and any. Other information analyzed included sex, age, and marital status.

Statistical Analysis

To improve the representativeness of the findings, the raw data were weighted using random iterative method [23,24] according to provisional figures obtained from the Census and Statistics Department on the sex-age distribution of the Hong Kong population at the end of 2015 and the educational attainment (highest level attended) distribution in the 2011 census. Chi-square tests were used to assess the differences in sociodemographic characteristics, health behaviors, BMI, and history of diagnosed chronic diseases between smartphone or tablet owners and nonowners. The associations of age, sex, marital status, and SEP with health app possession were analyzed by logistic regression in a model with these variables mutually adjusted and additional adjustment for the mode of survey (landline or mobile). Associations of health behaviors, BMI, and history of diagnosed chronic diseases with health app possession were analyzed in a separate model adjusting for age, sex, marital status, SEP, and the mode of survey. Whether the associations varied by the mode of survey was determined from the heterogeneity across strata and the significance of interaction terms. All analyses were conducted using Stata 13.0 (StataCorp LP, College Station, TX, USA). A *P* value of less than .05 was considered statistically significant.

Results

Of 6890 eligible adults, 5080 were successfully interviewed with a response rate of 73.73% (71.32% (1042/1461) for the mobile survey and 74.38% (4038/5429) for the landline survey). Table 1 shows that of the 5080 respondents, after weighting, 54.89% (2789/5080) were women, 72.32% (3673/5080) were aged 25 to 64 years, and 63.12% (3206/5080) were married or cohabitating. Most respondents (76.34%, 3878/5080) had secondary or higher education and 42.39% (1911/4508) had a monthly household income of HK $30,000 or more (the median monthly household income in Hong Kong was HK $25,000 in 2016) [25]. Only a small proportion of the respondents were current smokers (11.24%, 571/5078) or weekly drinkers (9.76%, 496/5079). More than half (55.02%, 2792/5075) were physically inactive and 41.93% (1654/3945) were overweight or obese (BMI>23). Less than one-third (31.69%, 1610/5080) had a history of diagnosed chronic diseases. Additionally, 19.58% of the respondents had a health app (995/5080).

Table 2 shows that smartphone or tablet owners were younger and had higher educational attainment and household income than nonowners. Smartphone or tablet owners were also more physically active and had less chronic diseases than nonowners. 24.10% (995/4129) of smartphone or tablet owners had health apps.

Table 1. Sociodemographic characteristics, health behaviors, body mass index, diagnosed chronic diseases, and health app possession of the respondents (n=5080).

Demographics	Unweighted, n (%)	Weighted, n (%)
Sex		
Male	2080 (40.94)	2291 (45.11)
Female	3000 (59.06)	2789 (54.89)
Age		
18-24	706 (13.90)	481 (9.47)
25-34	561 (11.04)	879 (17.32)
35-44	594 (11.70)	921 (18.13)
45-54	841 (16.56)	983 (19.35)
55-64	985 (19.39)	890 (17.52)
65 or above	1393 (27.42)	926 (18.23)
Marital status		
Single	1386 (27.28)	1358 (26.73)
Married/cohabitating	3069 (60.41)	3206 (63.12)
Divorced/widowed	625 (12.30)	516 (10.15)
Educational attainment		
Primary or below	1008 (19.84)	1202 (23.66)
Secondary	2131 (41.95)	2443 (48.09)
Tertiary or above	1941 (38.21)	1435 (28.25)
Employment status		
Full-time	1610 (31.69)	1948 (38.34)
Part-time	411 (8.09)	441 (8.68)
Self-employed	225 (4.43)	274 (5.40)
Unemployed	2834 (55.79)	2417 (47.58)
Monthly household income (HK$)		
<10,000	1037 (23.00)	889 (19.72)
10,000-19,999	775 (17.19)	862 (19.12)
20,000-29,999	767 (17.01)	846 (18.77)
30,000-39,999	604 (13.40)	624 (13.84)
40,000 or above	1325 (29.39)	1287 (28.55)
Smoking status		
Nonsmoker	4155 (81.82)	3974 (78.25)
Current smoker	432 (8.51)	571 (11.24)
Ex-smoker	491 (9.67)	533 (10.50)
Alcohol use		
Never	2481 (48.85)	2413 (47.51)
Occasional	1361 (26.80)	1360 (26.77)
1-3 days/month	563 (11.08)	586 (11.53)
1 day or more/week	453 (8.92)	496 (9.76)
Ex-drinker	221 (4.35)	225 (4.43)
Moderate physical activity		
None	2763 (54.44)	2792 (55.02)

Demographics	Unweighted, n (%)	Weighted, n (%)
1-3 days/week	1158 (22.82)	1151 (22.69)
4 days or more/week	1154 (22.74)	1132 (22.29)
Body mass index		
<18.5	422 (10.70)	380 (9.63)
18.5-<23	1951 (49.46)	1911 (48.44)
23-<25	738 (18.71)	738 (18.72)
>25	834 (21.14)	916 (23.21)
Diagnosed chronic diseases		
Yes	1813 (35.69)	1610 (31.69)
No	3267 (64.31)	3470 (68.31)
>**Health app possession**		
Yes	975 (19.19)	995 (19.58)
No	4105 (80.81)	4085 (80.42)

Table 2. Sociodemographic characteristics, health behaviors, body mass index, diagnosed chronic diseases, and health app possession of respondents who owned smartphones or tablets.

Demographics	Smartphone or tablet owners (n=4129), n (%)	Smartphone or tablet nonowners (n=951), n (%)	*P* value[a]
Sex			
Male	1733 (41.97)	347 (36.5)	
Female	2396 (58.03)	604 (63.5)	.002
Age			
18-24	704 (17.05)	2 (0.2)	
25-34	559 (13.54)	2 (0.2)	
35-44	582 (14.10)	12 (1.3)	
45-54	792 (19.18)	49 (5.2)	
55-64	825 (19.98)	160 (16.8)	
65 or above	667 (16.15)	726 (76.3)	<.001
Marital status			
Single	1324 (32.07)	62 (6.5)	
Married/cohabitating	2483 (60.14)	586 (61.6)	
Divorced/widowed	322 (7.80)	303 (31.9)	<.001
Educational attainment			
Primary or below	449 (10.87)	559 (58.8)	
Secondary	1823 (44.15)	308 (32.4)	
Tertiary or above	1857 (44.97)	84 (8.8)	
Employment status			
Full-time	1554 (37.64)	56 (5.9)	<.001
Part-time	368 (8.91)	43 (4.5)	
Self-employed	219 (5.30)	6 (0.6)	
Unemployed	1988 (48.15)	846 (89.0)	
Monthly household income (HK$)			
<10,000	529 (14.30)	508 (62.8)	
10,000-19,999	648 (17.52)	127 (15.7)	
20,000-29,999	673 (18.19)	94 (11.6)	
30,000-39,999	570 (15.41)	34 (4.2)	
40,000 or above	1279 (34.58)	46 (5.7)	<.001
Smoking status			
Nonsmoker	3416 (82.77)	739 (77.7)	
Current smoker	357 (8.65)	75 (7.9)	
Ex-smoker	354 (8.58)	137 (14.4)	<.001
Alcohol use			
Never	1850 (44.82)	631 (66.4)	
Occasional	1224 (29.65)	137 (14.4)	
1-3 days/month	532 (12.89)	31 (3.3)	
1 day or more/week	403 (9.76)	50 (5.3)	
Ex-drinker	119 (2.88)	102 (10.7)	<.001
Moderate physical activity			

Demographics	Smartphone or tablet owners (n=4129), n (%)	Smartphone or tablet nonowners (n=951), n (%)	*P* value[a]
None	2103 (50.99)	660 (69.4)	
1-3 days/week	1077 (26.12)	81 (8.5)	
4 days or more/week	944 (22.89)	210 (22.1)	<.001
Body mass index			
<18.5	321 (10.30)	101 (12.2)	
18.5-<23	1575 (50.55)	376 (45.4)	
23-<25	576 (18.49)	162 (19.5)	
>25	644 (20.67)	190 (22.9)	.06
Diagnosed chronic diseases			
Yes	1223 (29.62)	590 (62.0)	
No	2906 (70.38)	361 (38.0)	<.001
Health app possession			
Yes	995 (24.10)	0 (0.0)	
No	3134 (75.90)	951 (100.0)	<.001

[a]*P* for two-sided chi-square tests.

Table 3. Prevalence (weighted) of health app possession (n=995).

Functions of health apps	Prevalence, n (%)
Track physical activity (eg, number of steps walked)	667 (67.0)
Log health records (eg, body weight)	428 (43.0)
Track health measures (eg, heart rate and blood pressure)	300 (30.2)
Manage specific conditions and diseases	206 (20.7)
Track calories or meals for weight loss	178 (17.9)
Others[a]	92 (9.2)

[a]Others included tracking baby or child health (3.5%, 35/995), acquiring health information (2.9%, 29/995), monitoring sleep (2.4%, 24/995), helping quit smoking (0.7%, 7/995) and alcohol consumption (0.5%, 5/995).

Table 3 shows that common functions of health apps included tracking physical activity (67.0%, 667/995), logging health records (43.0%, 428/995), tracking health measures (30.2%, 300/995), managing diseases (20.7%, 206/995) and tracking calorie intake (17.9%, 178/995). Other functions included tracking baby or child health (3.5%, 35/995), acquiring health information (2.9%, 29/995), monitoring sleep (2.4%, 24/995), helping quit smoking (0.7%, 7/995) and alcohol consumption (0.5%, 5/995).

Table 4 shows that health app possession was generally similar between men and women, except that fewer women had apps for tracking physical activity than men (aOR=0.75 [95% CI 0.62-0.91]). Health app possession decreased with age (*P* for trend <.001). Higher education level and household income were associated with having health apps (both *P* for trend <.001). Patterns of associations of age and education with having health apps were similar across health apps for different functions. Higher household income was also associated with having health apps for tracking physical activity (*P* for trend=.004).

Table 5 shows that compared with physical inactivity, engaging in moderate physical activity more than once per week was associated with having health apps (aOR=1.45 [95% CI 1.20-1.75] for 1-3 days/week, and aOR=1.32 [95% CI 1.07-1.62] for ≥ 4 days/week). The patterns were similar across health apps with different functions. Having a history of diagnosed chronic diseases was associated with having health apps (aOR=1.36 [95% CI 1.11-1.68]), having apps for tracking physical activity (aOR=1.48 [95% CI 1.16-1.89]), and having apps for tracking calorie intake (aOR=1.55 [95% CI 1.02-2.38]). The associations of smoking, alcohol use, and BMI with health app possession were less marked. None of the associations varied by mode of survey (all *P* values for interactions >.05).

Table 4. Adjusted association of sociodemographic characteristics with health app possession among smartphone or tablet owners (n=4129; adjusted for mode of survey and all variables in this table were mutually adjusted).

Demographic characteristics	Overall (n=995), aOR (95% CI)	*P* value	Track physical activity (n=667), aOR (95% CI)	*P* value	Log health records (n=428), aOR (95% CI)	*P* value	Track health measures (n=300), aOR (95% CI)	*P* value	Manage diseases (n=206), aOR (95% CI)	*P* value	Track calories (n=178), aOR (95% CI)	*P* value
Sex												
Men	1		1		1		1		1		1	
Women	0.90 (0.76-1.07)	.23	0.75 (0.62-0.91)	.004	1.06 (0.83-1.35)	.65	0.91 (0.70-1.19)	.50	0.91 (0.65-1.26)	.56	1.17 (0.82-1.66)	.38
Age		<.001		<.001		<.001		.007		.02		.001
18-24	1		1		1		1		1		1	
25-34	1.17 (0.87-1.56)	.30	0.95 (0.69-1.31)	.76	1.12 (0.75-1.66)	.59	1.04 (0.66-1.62)	.88	1.61 (0.92-2.82)	.10	1.11 (0.63-1.95)	.71
35-44	0.99 (0.71-1.39)	.96	0.96 (0.66-1.40)	.84	1.11 (0.69-1.78)	.66	1.24 (0.74-2.08)	.42	1.32 (0.68-2.57)	.41	0.98 (0.50-1.91)	.95
45-54	0.75 (0.53-1.05)	.10	0.68 (0.46-0.99)	.04	0.45 (0.27-0.76)	.002	1.03 (0.60-1.75)	.92	1.09 (0.56-2.14)	.79	0.58 (0.28-1.19)	.14
55-64	0.42 (0.29-0.61)	<.001	0.36 (0.23-0.56)	<.001	0.30 (0.17-0.53)[c]	<.001	0.44 (0.23-0.84)	.01	0.48 (0.22-1.04)	.06	0.35 (0.15-0.78)	.01
65 or above	0.44 (0.29-0.67)	<.001	0.29 (0.17-0.50)	<.001	0.28 (0.14-0.53)	<.001	0.52 (0.26-1.07)	.08	0.65 (0.28-1.47)	.30	0.36 (0.14-0.93)	.03
Education attainment		<.001		<.001		<.001		<.001		.06		.006
Primary or below	1		1		1		1		1		1	
Secondary	1.70 (1.10-2.63)	.02	2.17 (1.11-4.23)	0.02	1.13 (0.56-2.27)	.73	2.75 (0.98-7.76)	.06	2.02 (0.78-5.25)	.15	7.15 (0.96-53.1)	.06
Tertiary or above	2.88 (1.83-4.52)	<.001	3.82 (1.94-7.53)	<.001	2.58 (1.27-5.24)	.009	5.62 (1.97-16.0)	.001	2.56 (0.96-6.85)	.06	10.3 (1.37-77.9)	.02
Employment status												
Full-time	1		1		1		1		1		1	
Part-time	1.00 (0.74-1.36)	.99	0.90 (0.63-1.29)	.57	0.82 (0.52-1.29)	.39	0.85 (0.51-1.41)	.52	1.01 (0.54-1.87)	.98	0.66 (0.33-1.34)	.25
Self-employed	0.94 (0.66-1.33)	.71	1.01 (0.68-1.51)	.96	0.94 (0.55-1.60)	.83	1.08 (0.64-1.83)	.78	1.01 (0.51-2.00)	.99	1.09 (0.53-2.23)	.82
Unemployed	0.94 (0.76-1.16)	.56	0.89 (0.69-1.15)	.36	0.87 (0.64-1.19)	.39	0.85 (0.60-1.20)	.35	1.03 (0.67-1.60)	.88	0.95 (0.61-1.48)	.81
Monthly household income (HK$)		<.001		.004		.21		.19		.14		.40
<10,000	1		1		1		1		1		1	

Demographic characteristics	Overall (n=995), aOR (95% CI)	*P* value	Track physical activity (n=667), aOR (95% CI)	*P* value	Log health records (n=428), aOR (95% CI)	*P* value	Track health measures (n=300), aOR (95% CI)	*P* value	Manage diseases (n=206), aOR (95% CI)	*P* value	Track calories (n=178), aOR (95% CI)	*P* value
10,000-19,999	0.94 (0.65-1.36)	.76	1.04 (0.66-1.66)	.85	1.15 (0.65-2.03)	.63	0.71 (0.37-1.37)	.31	0.37 (0.18-0.78)	0.008	1.00 (0.43-2.34)	.99
20,000-29,999	1.25 (0.87-1.78)	.22	1.34 (0.86-2.10)	.20	1.29 (0.74-2.25)	.36	1.32 (0.73-2.40)	.36	0.61 (0.32-1.17)	.13	1.54 (0.69-3.42)	.29
30,000-39,999	1.28 (0.89-1.85)	.19	1.38 (0.87-2.18)	.17	1.27 (0.72-2.23)	.41	1.19 (0.65-2.20)	.57	0.73 (0.38-1.40)	.34	1.18 (0.51-2.71)	.70
40,000 or above	1.53 (1.09-2.16)	.01	1.58 (1.03-2.44)	.04	1.38 (0.81-2.36)	.24	1.17 (0.65-2.10)	.59	0.87 (0.48-1.59)	.65	1.36 (0.62-2.98)	.44
Marital status												
Single	1		1		1		1		1		1	
Married/cohabitated	0.95 (0.74-1.21)	.66	0.79 (0.60-1.05)	.10	1.08 (0.76-1.54)	.66	0.87 (0.59-1.27)	.47	0.87 (0.54-1.38)	.55	0.98 (0.60-1.61)	.94
Divorced/widowed	0.58 (0.36-0.95)	.03	0.58 (0.31-1.09)	.09	0.68 (0.30-1.52)	.35	0.79 (0.36-1.73)	.56	0.37 (0.12-1.13)	.08	0.70 (0.23-2.14)	.53

Table 5. Adjusted associations of health behaviors, body mass index, and diagnosed chronic diseases with health app possession among smartphone or tablet owners (n=4129; adjusted for age, sex, marital status, education, employment, income, mode of survey; all variables in this table were mutually adjusted).

Demographic characteristics	Overall (n=995), aOR (95% CI)	*P* value	Track physical activity (n=667), aOR (95% CI)	*P* value	Log health records (n=428), aOR (95% CI)	*P* value	Track health measures (n=300), aOR (95% CI)	*P* value	Manage diseases (n=206), aOR (95% CI)	*P* value	Track calories (n=178), aOR (95% CI)	*P* value
Smoking status												
Nonsmoker	1		1		1		1		1		1	
Current smoker	0.89 (0.65-1.21)	.46	0.88 (0.62-1.26)	.48	0.81 (0.49-1.33)	.40	0.77 (0.46-1.28)	.31	0.87 (0.46-1.66)	.68	0.82 (0.42-1.62)	.57
Ex-smoker	1.05 (0.77-1.42)	.77	1.29 (0.91-1.83)	.15	1.07 (0.67-1.71)	.78	1.08 (0.67-1.75)	.75	0.90 (0.48-1.70)	.75	1.06 (0.54-2.06)	.87
Alcohol use												
Never	1		1		1		1		1		1	
Occasional	1.09 (0.90-1.32)	.40	1.19 (0.94-1.49)	.14	1.17 (0.88-1.54)	.28	1.23 (0.90-1.69)	.19	1.40 (0.97-2.02)	.07	0.72 (0.47-1.10)	.13
1-3 days/month	1.13 (0.88-1.44)	.34	1.25 (0.95-1.66)	.12	1.18 (0.83-1.67)	.35	1.32 (0.90-1.93)	.16	0.93 (0.56-1.54)	.77	1.24 (0.78-1.98)	.37
1 day or more/week	0.94 (0.70-1.26)	.66	1.35 (0.98-1.88)	.07	1.12 (0.73-1.72)	.62	1.48 (0.95-2.30)	.08	0.85 (0.45-1.57)	.60	1.33 (0.77-2.33)	.31
Ex-drinker	0.95 (0.55-1.65)	.87	0.99 (0.50-1.94)	.97	0.72 (0.28-1.87)	.50	0.97 (0.37-2.52)	.95	0.26 (0.04-1.95)	.19	0.26 (0.03-1.90)	.18
Moderate physical activity												
None	1		1		1		1		1		1	
1-3 days/week	1.45 (1.20-1.75)	<.001	1.46 (1.18-1.82)	.001	1.53 (1.17-2.01)	.002	1.50 (1.10-2.03)	.009	1.74 (1.21-2.50)	.003	1.84 (1.25-2.70)	.002
4-7 days/week	1.32 (1.07-1.62)	.008	1.21 (0.95-1.55)	.13	1.45 (1.07-1.96)	.02	1.72 (1.24-2.37)	.001	1.32 (0.87-2.01)	.20	1.49 (0.96-2.32)	.08
Body mass index												
18.5-<23	1		1		1		1		1		1	
<18.5	1.18 (0.86-1.61)	.31	1.05 (0.73-1.51)	.79	1.22 (0.82-1.81)	.32	0.89 (0.53-1.48)	.65	1.42 (0.82-2.44)	.21	1.06 (0.58-1.95)	.84
23-<25	0.91 (0.69-1.19)	.49	0.93 (0.67-1.28)	.65	1.19 (0.83-1.70)	.34	0.95 (0.61-1.46)	.80	0.74 (0.42-1.28)	.28	1.42 (0.86-2.36)	.17
>25	1.09 (0.84-1.42)	.52	1.09 (0.80-1.49)	.60	1.19 (0.82-1.71)	.36	1.08 (0.70-1.65)	.73	1.10 (0.67-1.79)	.72	0.81 (0.44-1.50)	.51
Diagnosed chronic diseases												
No	1		1		1		1		1		1	

Demographic characteristics	Overall (n=995), aOR (95% CI)	*P* value	Track physical activity (n=667), aOR (95% CI)	*P* value	Log health records (n=428), aOR (95% CI)	*P* value	Track health measures (n=300), aOR (95% CI)	*P* value	Manage diseases (n=206), aOR (95% CI)	*P* value	Track calories (n=178), aOR (95% CI)	*P* value
Yes	1.36 (1.11-1.68)	.003	1.48 (1.16-1.89)	.001	1.28 (0.94-1.74)	.12	1.24 (0.89-1.73)	.20	1.21 (0.81-1.82)	.35	1.55 (1.02-2.38)	.04

Discussion

Principal Findings

To our knowledge, this study has provided the first evidence of health app possession in one of the most developed non-Western urban settings with highly prevalent ownership of smartphones or tablets. Less than one-quarter (24.10%) of smartphone or tablet owners had a health-related mobile app on their devices. The proportion of health app possession in the total sample was 19.58%. Tracking physical activity, health records, and health measures were common functions of health apps. Respondents who were younger and had higher education and household income were more likely to have health apps. Health app possession was less patterned by lifestyle factors, with only physical activity clearly associated with health app possession. The associations were roughly consistent for health apps with different functions.

Our findings are consistent with previous national surveys in the United States, which showed that people who were younger and had higher educational levels and income were more likely to have health apps [2,9]. Our study adds to existing research by reporting that the associations of these factors with apps for different functions were similar. Older people are less likely to have health apps perhaps because of perceived and practical barriers to new technologies [26,27]. Instead, they tend to seek health information from traditional mass media [14]. However, traditional mass media cannot track real-time health conditions or monitor health behaviors. People with high SEP may be more health conscious and have higher health literacy, while also making more use of health apps [10,28]. However, respondents with low SEP are less likely to have health apps because effective and attractive health apps in the marketplace often cost money to download or use, or need wearable devices such as smart wristbands [29], which may be unaffordable to them. Such people often have poor health status and have greater needs to improve their health [30,31]. Our study also adds to existing research by showing that health app possession was less likely among physically inactive respondents, perhaps also because of a lack of health consciousness or motivation [32]. However, these people also have greater needs to resume regular physical activity, and mobile apps have been reported as an effective way to achieve this [5,33]. Thus we have shown the possible emergence of an ICT use pattern that could be a modern example of the “Inverse Care Law” [34] and “Inverse Information Law” [35,36] in ICTs, which suggests that those most in need in the community may have less care and use of services and hence receive less benefits from advancements in medicine and health related ICTs.

The magnitude of the association of education with health app possession is bigger than in the United States [9], possibly explained by the lower education levels and greater socioeconomic inequalities in Hong Kong. People with extremely low education levels may have difficulties in reading or understanding health information communicated by advanced technologies, suggesting a great potential to improve health communication through health apps in disadvantaged groups when health apps are made easier to use, confirmed to have health benefits, and effectively promoted with greater accessibility at lower costs.

Notably, the possession of health apps for tracking calories or meals for weight loss is less prevalent than in the West [9]. However, we found that while the percentage of overweight and obese respondents in this sample (BMI>23) was more than 40%, the association of BMI with health app possession was not evident. Self-monitoring of dietary intake, which is a systematic observation and recording to increase individuals’ awareness of eating behaviors and food consumed, is one of the key components of behavioral weight loss strategies [37]. Several randomized controlled trials in the United States have found that apps for monitoring calorie intake had a good acceptability and feasibility as well as effectiveness in weight loss, because of low time-consumption, expenditure, and intensity [5,38,39].

In addition, the associations of smoking and alcohol use with health app possession were less marked, possibly because of the lack of apps for smoking cessation or alcohol quitting. Less than 1% of the respondents reported having health apps with the function of smoking cessation, although the prevalence of current smokers was 10.4% in Hong Kong in 2015 [18]. Randomized or quasi-randomized controlled trials reported that quit-smoking text-message programs can increase the rate of quitting [40,41]. However, current apps for smoking cessation have low levels of adherence to evidence-based guidelines such as lack of practical advice on how to quit/how not to relapse and the absence of text message alerts [42].

Limitations

Our study has some limitations. First, we only had information on whether the respondents had health apps on their smartphones or tablets. Given that a few health apps are already installed when a smartphone is purchased, the possession of health apps could not fully represent download or actual use. Second, the

information on health app possession was obtained based on self-report, which could be subject to recall bias. Third, given the nature of the cross-sectional design, we could not determine the temporal sequence of health behaviors and the possession of health apps. Health apps may alter inactive lifestyle, which may lead to reverse causality.

Future Work

Our study suggests several avenues for future research. More detailed information on health app use such as the frequency of use, the reasons for not using the apps, the notifications or the reliability of information provided by health apps should be collected for a better understanding of their low popularity among Hong Kong's Chinese adults. Studies to further examine the characteristics of health app nonpossessors and nonusers, how they fit in with the "Inverse Information Law," and whether or not the "Inverse ICT Law" is emerging are needed in other countries and regions. Further studies are also warranted to identify ways to motivate people to download and use health apps actively to track health, especially for those who are in need of the functions that these apps offer. In addition, as many health apps have been launched for commercial purposes, a more comprehensive evaluation is needed to determine whether such apps are evidence-based, effective, user-friendly, and can provide accurate information [43]. Finally, further studies to develop effective methods for the promotion and use of apps for weight loss or smoking cessation are also warranted.

Conclusions

To our knowledge, this is the first study to provide evidence on the pattern of health app possession in an under-studied developed non-Western setting with high rates of smartphone ownership and Internet coverage. The prevalence of health app possession among smartphone or tablet owners was low in this population, raising the necessity for obtaining a deeper insight into the plausible reasons. Moreover, socioeconomic inequalities and behavioral clustering of health app possession suggested that more resources are needed to promote download and use of health apps after comprehensive evaluation, particularly in disadvantaged groups who are in need of the functions offered by these apps. We have shown a lower prevalence of the use of ICTs among those with lower education and income in the most developed Chinese city. This could indicate the emergence of an "Inverse ICT Law," which suggests that those most in need may have less use of services and hence receive fewer health benefits communicated by ICTs.

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Conflicts of Interest

None declared.

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Abbreviations

aOR: adjusted odds ratio
BMI: body mass index
FHInTS: Family and Health Information Trends Survey
ICT: information and communication technologies
IRB: Institutional Review Board
SEP: socioeconomic position

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Original Paper

Use of and Beliefs About Mobile Phone Apps for Diabetes Self-Management: Surveys of People in a Hospital Diabetes Clinic and Diabetes Health Professionals in New Zealand

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Abstract

Background: People with diabetes mellitus (DM) are using mobile phone apps to support self-management. The numerous apps available to assist with diabetes management have a variety of functions. Some functions, like insulin dose calculators, have significant potential for harm.

Objectives: The study aimed to establish (1) whether people with DM in Wellington, New Zealand, use apps for DM self-management and evaluate desirable features of apps and (2) whether health professionals (HPs) in New Zealand treating people with DM recommend apps to patients, the features HPs regard as important, and their confidence with recommending apps.

Methods: A survey of patients seen at a hospital diabetes clinic over 12 months (N=539) assessed current app use and desirable features. A second survey of HPs attending a diabetes conference (n=286) assessed their confidence with app recommendations and perceived usefulness.

Results: Of the 189 responders (35.0% response rate) to the patient survey, 19.6% (37/189) had used a diabetes app. App users were younger and in comparison to other forms of diabetes mellitus, users prominently had type 1 DM. The most favored feature of the app users was a glucose diary (87%, 32/37), and an insulin calculator was the most desirable function for a future app (46%, 17/37). In non-app users, the most desirable feature for a future app was a glucose diary (64.4%, 98/152). Of the 115 responders (40.2% response rate) to the HPs survey, 60.1% (68/113) had recommended a diabetes app. Diaries for blood glucose levels and carbohydrate counting were considered the most useful app features and the features HPs felt most confident to recommend. HPs were least confident in recommending insulin calculation apps.

Conclusions: The use of apps to record blood glucose was the most favored function in apps used by people with diabetes, with interest in insulin dose calculating function. HPs do not feel confident in recommending insulin dose calculators. There is an urgent need for an app assessment process to give confidence in the quality and safety of diabetes management apps to people with diabetes (potential app users) and HPs (potential app prescribers).

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KEYWORDS

mHealth, mobile applications; telemedicine; diabetes mellitus

Introduction

Diabetes mellitus (DM) requires tight control of blood glucose to minimize complications and mortality [1,2]. However, many people with DM have suboptimal glycemic control [3,4]. Use of mobile phone apps in diabetes management has been shown to modestly improve glycemic control [5-10]. Despite this promise, health apps remain largely unregulated, and diabetes apps have not always had safety approval [11] or incorporated evidence-based guidelines [12,13].

Blood glucose tracking is the most common feature of diabetes apps [5,14], with other features including record of medications, dietary advice, and tracking, such as carbohydrate content calculation, and weight management support [5,11,12,14-16]. Additionally some apps recommend insulin dosing based on users inputs of glucose levels and estimated meal carbohydrate. Meta-analysis of 22 trials including 1657 patients in which use of mobile phone apps supporting diabetes management was compared to usual care or other Web-based supports showed that app use led to a mean reduction in HbA_{1c} of 6mmol/mol that is 0.5% [9]. This compares favorably with the glucose lowering of lifestyle change, namely diet [17] and oral diabetes medication [18].

However, there are concerns about the appropriateness and safety of apps for diabetes self-management [5,11-13,15]. In 2013 only 1 of 600 diabetes apps reviewed in the USA had received FDA clearance [11]. Similarly a review, specifically of insulin dose calculator apps, determined that only one of 46 calculators was clinically safe. The most common issue was that calculators accepted implausible values for blood glucose readings (eg, negative values), yet would still provide an advised insulin dose [15]. HPs are also concerned about app safety [19] and are advised to take care when advising apps to patients [15]. In the United Kingdom, The Royal College of Physicians Health Informatics Unit (London) has developed a checklist for assessing app quality [19]. However, the multitude of factors HPs must consider while recommending apps, including patient familiarity with technology, app features, ease of use, and FDA approval [19] may be burdensome and not practical in day to day clinical care.

Mobile phone ownership rates are increasing. Similar to trends seen in the United States and Canada, where mobile phone ownership is 72% and 67%, respectively [20], 70% of New Zealanders own a mobile phone, making diabetes apps potentially available to most people [21]. Limited research exists into the use of diabetes apps in New Zealand. However with increasing rates of both diabetes prevalence and mobile phone ownership, access to safe apps is essential for both HPs as potential app prescribers and patients as app users [21,22]. In Scotland, a survey of people with diabetes found high mobile phone ownership (67%) with over half reporting an interest in using apps for self-management of diabetes, but app usage in only 7% of responders [23]. The objectives of this study were (1) To establish whether people with diabetes use apps to assist with diabetes self-management and which features are useful or desirable, and (2) To establish whether HPs treating people with diabetes recommend diabetes apps, which features were thought to be useful, and which features were they confident to recommend.

Methods

Study Design and Sample

This cross-sectional observational study used two surveys (see Multimedia Appendices 1 and 2), one for people with diabetes attending a secondary care diabetes outpatient clinic and the second for HPs (who treat people with diabetes) attending a national diabetes conference. Both surveys were multi-choice format, collected, and managed using REDCap electronic data capture tools. REDCap (Research Electronic Data Capture) is a secure, Web-based app designed to support data capture for research studies [24]. The survey questions were derived from criteria in the Mobile app rating scale [25] to address attitudes and practices of both the people with diabetes and HPs. The list of apps was compiled by searching Apple and Android App stores and included the first consecutive ten diabetes apps. We eliminated any apps not specific to diabetes by reviewing app store descriptions. We reviewed the main features from these apps to develop the list of app features. The patient survey asked responders to select any useful app features from a list. Responders could select more than one useful app feature. The HP survey listed app features and used a scale to assess usefulness of app features (from 1 [not at all useful] to 5 [extremely useful]) and their confidence in recommending apps (from 1 [not at all confident] to 5 [extremely confident]).

Patient Survey

The 1177 people with diabetes attending clinics at Capital and Coast District Health Board (CCDHB), Wellington, New Zealand over a 12-month period (10th September 2014 to 10th September 2015) were the sample population. Out of the total patients, 521 patients with an email address in the hospital management system were invited to participate via email. To include a representation of people without a recorded email address in the sample (n=656), every 5th person was telephoned (up to twice) and invited to provide an email address. Of the 131 patients telephoned, 54 (41.2%) were reached, of whom 49 (91%) agreed to participate. Patients without phone numbers or unable to provide an email address were excluded. This generated a sample population of 570 people.

The survey was piloted with the first 30 patients with an email addresses (chronological order of clinic visits). Responses were reviewed after response rate reached 50%. As 4 questions were unanswered by some participants, a “none of the above” option was added. The invitations were sent out to the remaining 540 participants. A further 31 participants were excluded (4 email address errors, 13 gestational diabetes, 10 deceased, 4 did not have diabetes) resulting in a final total of 539 participants. This survey remained open for 3 weeks, with reminders sent to non-responders at one week and two weeks.

Clinical Variables

Additional data on all patients were collected from the hospital management system, including age, and the most recent values within the previous 12 months from date of survey for blood pressure (BP), glycated hemoglobin (HbA_{1c}), urinary

microalbumin to Creatinine ratio (ACR), low density lipoprotein cholesterol (LDL), and total cholesterol to HDL ratio (C:HDL). Prescription of lipid lowering drugs, anti-hypertensive drugs, insulin, or other hypoglycemic medication were also extracted from the medication list from the last visit within the sample period. Type of diabetes was self-reported in the survey (type 1 [T1DM], type 2 [T2DM], other or unknown) and in four participants who had selected 'other' or 'unknown' diabetes type was determined by examination of the clinical records. For categorization of participants by app use, 4 responders who did not indicate if they had a mobile phone or not were included in the non-app group.

Health Professionals' Survey

To obtain data on HPs' knowledge and recommendation of apps to people with diabetes, a second survey was conducted of the HPs attending the annual scientific meeting of the New Zealand Society for the Study of Diabetes (NZSSD) in May 2016. Immediately prior to the meeting all registered attendees (n=286) were invited to participate in the online survey via email. The data from the patient survey was presented at the conference in a 15-min oral presentation and attendees were encouraged to complete the survey. Paper copies of the survey were also available at the meeting. This survey remained open for 2 weeks, with a reminder sent at 1 week.

Data Analysis

Data were imported into SPSS version 24 (IBM). Incomplete responses were included in the analysis. In the patient survey, independent sample *t* tests were conducted to compare mean clinical variables (age, BP, C:HDL, LDL, HbA_{1c}) by type of diabetes, method of recruitment, and whether the responder used a diabetes mobile phone app. Adjustment was made for unequal variances. Normal distribution was assumed for all variables, apart from urinary microalbumin to creatinine for which a Wilcoxin test was used. No statistically significant differences in these variables or in mobile phone app use were found between patients with recorded email addresses and patients phoned for their email address. Therefore, all 189 responses were combined for further analysis. Chi-square tests were used to compare medications and survey responses by type of diabetes. Statistical significance was determined by exact 2-sided *P* values less than .05. In the HP survey, mean values on the usefulness and confidence Likert scales were calculated to compare app features.

Results

Patient Survey

Demographics

The survey was completed by 189 of the 539 patients (35.0% response rate, 158/491 from participants with email addresses, 31/48 from telephone contact). Table 1 shows the characteristics of responders. Responders (N=189) were older, with a mean age of 50.0 years (SD 15.7) than non-responders (N=350), who had a mean age of 45.9 years (SD 16.1; *P*=.004) and had lower HbA_{1c} of 62.2 mmol/mol (SD 14.0) (7.8, SD 1.1%) than non-responders (N=325) with mean of 68.9 mmol/mol (SD 18.2; 8.5, SD 2.3%; *P*<.001). There were no significant differences in the rate and type of anti-hypertensive, lipid lowering, and anti-hyperglycemic medications used between responders and non-responders (*P*=.28, −.32, and −.17, respectively). Clinical variables by type of diabetes are shown in Table 2. As expected, responders with T1DM were more likely to be on Insulin than those with T2DM (*P*<.001) whereas responders with T2DM were more likely to be on anti-hypertensive (*P*<.001) and lipid lowering medication (*P*<.001).

Table 1. Characteristics of patients completing the survey (n=189).

Characteristic	n (%)
Type of diabetes (n=189)	
T1DM[a]	105 (55.5)
T2DM[b]	83 (43.9)
Monogenic	1 (0.5)
Sex (n=189)	
Male	108 (57.1)
Female	81 (42.8)
Ethnicity[c] (n=188)	
European[d]	167 (88.8)
Ma¯ori and Pasifika	14 (7.4)
Indian	8 (4.2)
Chinese	1 (0.5)
Other[e]	7 (3.7)
Education (n=188)	
Postgraduate degree	37 (19.6)
Bachelor's degree	64 (34.0)
Apprenticeship	4 (2.1)
Polytechnic	35 (18.6)
High school graduate	29 (15.4)
Some high school	19 (10.1)

[a]T1DM: type 1 diabetes mellitus.

[b]T2DM: type 2 diabetes mellitus.

[c]Responders could identify with >1 ethnicity.

[d]European includes both New Zealand European and other white ethnicities.

[e]Unidentified (n=3), Sri Lankan (n=1), South African (n=1), Tuvaluan (n=1), Native American (n=1).

Table 2. Clinical variables among responders by type of diabetes.

Clinical variable	Value[a] (n)			*P*
	All responders (N=189)[b]	Responders with T1DM[c] (n=105)	Responders with T2DM[d] (n=83)	
Age (SD)	50.0 (15.7)	43.5 (14.9)	58.4 (12.3)	<.001
years	189	105	83	
SBP[e] (SD)	127.3 (18.8)	122.8 (14.8)	132.9 (21.7)	.004
mmHg	124	69	55	
DBP[f] (SD)	75.3 (10.5)	74.0 (9.0)	77.0 (11.9)	.14
mmHg	124	69	55	
HbA_{1c}[g] (SD)	62.2 (14.0)	61.2 (11.4)	63.7 (16.7)	.27
mmol/mol	7.8 (1.1)	7.7 (1.0)	8.0 (1.4)	
%	180	101	78	
LDL[h] (SD)	2.3 (0.9)	2.4 (0.8)	2.1 (0.9)	.03
mmol/L	166	93	72	
C:HDL[i] (SD)	3.1 (1.3)	2.6 (0.9)	3.8 (1.6)	<.001
	168	93	74	
ACR[j] (Range)	0.8 (0.1-527.2)	0.6 (0.1-97.4)	1.9 (0.2-527.2)	<.001
	174	98	75	

[a]Mean (SD) is used for age, SBP, DBP, HbA_{1c}, LDL and C:HDL. Median (range) is used for ACR.

[b]All responders includes 1 patient with monogenic diabetes.

[c]T1DM: type 1 diabetes mellitus.

[d]T2DM: type 2 diabetes mellitus.

[e]SBP: systolic blood pressure.

[f]DBP: diastolic blood pressure.

[g]HbA_{1c}: glycated hemoglobin.

[h]LDL: low density lipoprotein cholesterol.

[i]C:HDL: total cholesterol to high density lipoprotein cholesterol ratio

[j]ACR: urinary microalbumin creatinine ratio.

Diabetes App Use and Desired App Features

96.2% (181/188) of responders reported owning a mobile phone and 84.0% identified this device as a mobile phone (158/188), (Android 52.6% [80/152], iPhone 44.1% [67/152], Windows 3.3% [5/152]). Of the mobile phone owners 23.4% (37/158) reported using a diabetes app. Over half of app users (54%, 20/37) used the app daily, 22% (8/37) used it for a few days per week, and 14% (5/37) used the app less than weekly; 4 responders never used the app.

Of mobile phone owners, those using diabetes apps were more likely to have T1DM (30/96) than T2DM (n=7/61); (*P*=.006). App users were younger with a mean age of 39.0 years (SD 11.1) compared to non-app users having a mean of 52.5 years (SD 15.6), (*P*<.001). There were no other significant differences in clinical variables between app and non-app users.

The majority of responders were not using diabetes apps (80.4%, 152/189), although 60.5% (89/147) reported they would be interested in trying one. Of the 118 people who answered the question, the reasons for not using an app was not knowing they existed (66.9%, 79/118), feeling confident without one (16.9%, 20/118), discontinued use after having used an app previously 16.9% (20/118).

The features most frequently used by current app users were blood glucose diaries (87%, 32/37), followed by carbohydrate/meal diaries (38%, 14/37) with 22% (8/37) reporting insulin dose calculation devices to be useful (Table 3). Table 3 demonstrates the features app users found useful in their current apps. App users reported the most desired feature for future use in an app was an insulin dose calculator (46%, 17/37; Table 4). Table 5 shows that non-app users reported insulin dose calculators to be the third most desired feature (54.6%, n=83/152). Blood glucose diaries were the most desired app feature amongst non-app users (64.4%, 98/152; Table 5). Non app users with T1DM were more likely to desire an insulin dose calculation device, than non-app users with T2DM, *P*=.01).

Table 3. Features app users find useful in their current app.

Feature	Total with app (N=37), n (%)	App users T1DM[a] (n=30), n (%)	App users T2DM[b] (n=7), n (%)	*P* [c]
Diary of blood glucose levels	32 (87)	25 (83)	7 (100)	.56
Diary of meals and carbohydrate intake	14 (38)	12 (40)	2 (29)	.69
Reminders to check blood glucose	10 (27)	7 (23)	3 (43)	.36
Calculation device for insulin dose	8 (22)	6 (20)	2 (29)	>.99
Blood glucose level guidelines	7 (19)	5 (17)	2 (29)	.60
Personal details and condition information	6 (16)	4 (13)	2 (29)	.57
Calendar of diabetes appointments	7 (19)	5 (17)	2 (29)	.60
Contact details for your diabetes team	4 (11)	2 (7)	2 (19)	.16
Dietary advice	2 (5)	1 (3)	1 (14)	.35

[a]T1DM: type 1 diabetes mellitus.

[b]T2DM: type 2 diabetes mellitus.

[c]A chi-square test was used for calculating *P* values.

Table 4. Additional features app users desire in a future app.

Feature	Total app users (N=37), n (%)	App users T1DM[a] (n=30), n (%)	App users T2DM[b] (n=7), n (%)	*P* [c]
Calculation device for insulin dose	17 (46)	14 (47)	3 (43)	>.99
Diary of blood glucose levels	13 (35)	12 (40)	1 (14)	.38
Diary of meals and carbohydrate intake	13 (35)	10 (33)	3 (43)	.68
Reminders to check blood glucose	12 (32)	9 (30)	3 (43)	.66
Contact details for your diabetes team	11 (30)	8 (27)	3 (43)	.65
Calendar of diabetes appointments	11 (30)	10 (33)	1 (14)	.41
Blood glucose level guidelines	8 (21)	6 (20)	2 (29)	>.99
Dietary advice	8 (21)	6 (20)	2 (29)	>.99
Personal details and condition information	7 (19)	5 (17)	2 (29)	.60

[a]T1DM: type 1 diabetes mellitus.

[b]T2DM: type 2 diabetes mellitus.

[c]A chi-square test was used for calculating *P* values.

Table 5. Desirable app features for a diabetes app amongst non-app users.

Feature	Total non-app users (N=152)[a], n (%)	Non-app users T1DM[b] (n=75), n (%)	Non-app users T2DM[c] (n=76), n (%)	*P* [d]
Diary of blood glucose levels	98 (64.4)	52 (69)	46 (61)	.31
Calendar of diabetes appointments	87 (57.2)[a]	43 (57)	43 (57)	>.99
Calculation device for insulin dose	83 (54.6)	49 (65)	34 (45)	.01
Contact details for your diabetes team	79 (51.9)[a]	42 (56)	36 (47	.33
Diary of meals and carbohydrate intake	73 (48.0)	40 (53)	33 (43)	.26
Reminders to check blood glucose	63 (41.4)	27 (36)	36 (47)	.19
Blood glucose level guidelines	58 (38.2)	29 (38)	29 (38)	>.99
Personal details and condition information	57 (37.5)[a]	32 (43)	24 (32)	.18
Dietary advice	56 (36.8)	26 (35)	30 (40)	.61

[a]Includes 1 additional patient with monogenic diabetes.

[b]T1DM: type 1 diabetes mellitus.

[c]T2DM: type 2 diabetes mellitus.

[d]A chi-square test was used for calculating *P* values.

Health Professionals' Survey

Demographics and Health Professional App Recommendation

The HPs' survey was completed by 115 out of 286 HPs (40.2% response rate, 78 online, 37 paper). Table 6 shows the characteristics of responders. Almost all HPs (96.5%, 111/115) owned a mobile phone and of the 113 who answered, 60.2% (68/113) had recommended an app for diabetes management to a patient. Dieticians were most likely to have recommended an app (83%, 10/12), followed by nurses (66%, 42/64), (*P*=.006). There was no relationship between app recommendation and the number of years of treating diabetes (*P*=.48) or the responder's age (*P*=.49).

Table 6. Characteristics of health professionals completing the survey.

General characteristic	N (%)
Profession (n=115)	
Nurse	65 (56.5)
Doctor	24 (20.9)
Dietitian	12 (10.4)
Podiatrists	6 (5.2)
Other	8 (7.0)
Years treating diabetes (n=111)	
<1	6 (5.4)
2-5	31 (27.9)
6-10	26 (23.4)
> 10	48 (43.2)
Age in years (n=112)	
21-30	9 (8.0)
31-40	21 (18.8)
41-50	34 (30.4)
51-60	42 (37.5)
60+	6 (5.4)

Useful App Features and Confidence Among Health Care Professionals to Recommend Apps

Overall, all five potential app features were considered useful, with more than 60% of responders selecting that these features were useful, very useful, or extremely useful on the scale of scale 1 (not at all useful) to 5 (extremely useful). Equally, the mean usefulness score was higher than 3 for all 5 features. Blood glucose and carbohydrate intake diaries were rated as being the most useful app feature (Figure 1), with the highest mean score of 3.64 (SD 0.948) for usefulness (Table 7).

Glucose diaries were the only type of app which health professionals felt confident to recommend, on an average 3.05 (SD 1.248; Table 7). Responders were the least confident in recommending insulin dose calculators with a mean of 2.38 (SD 1.12) with only 3% of responders being very confident (Table 7 and Figure 2).

Figure 1. Usefulness of app features reported as useful by Health Professionals.

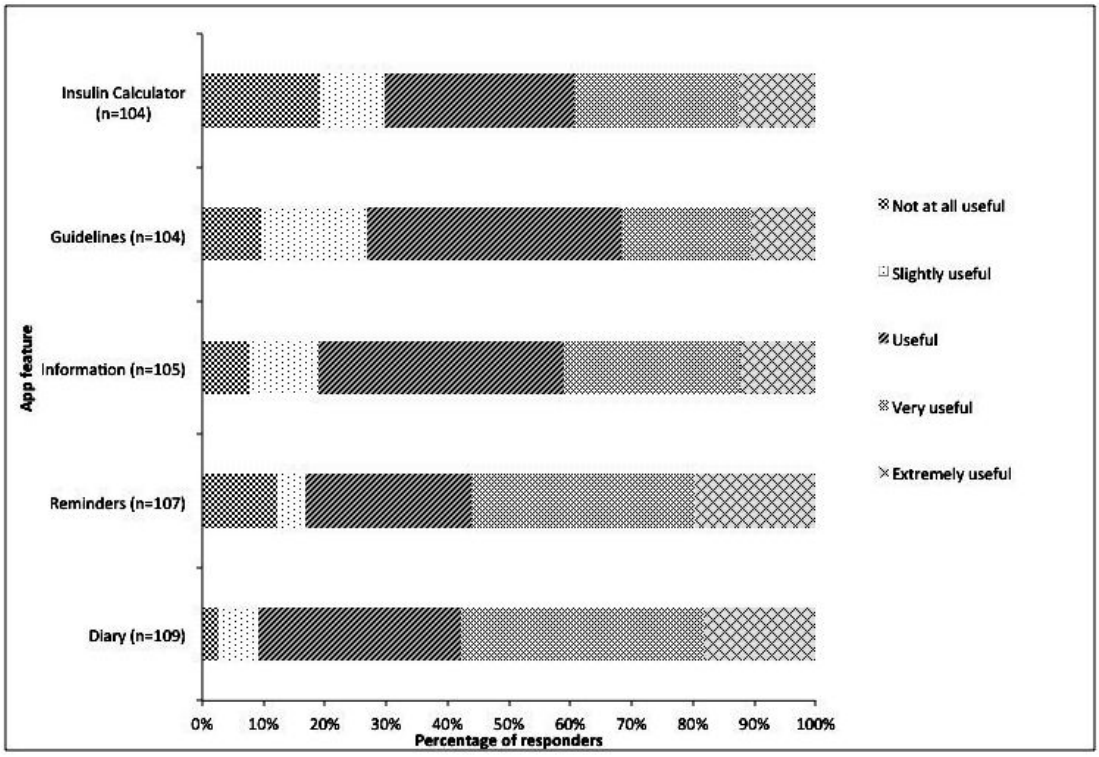


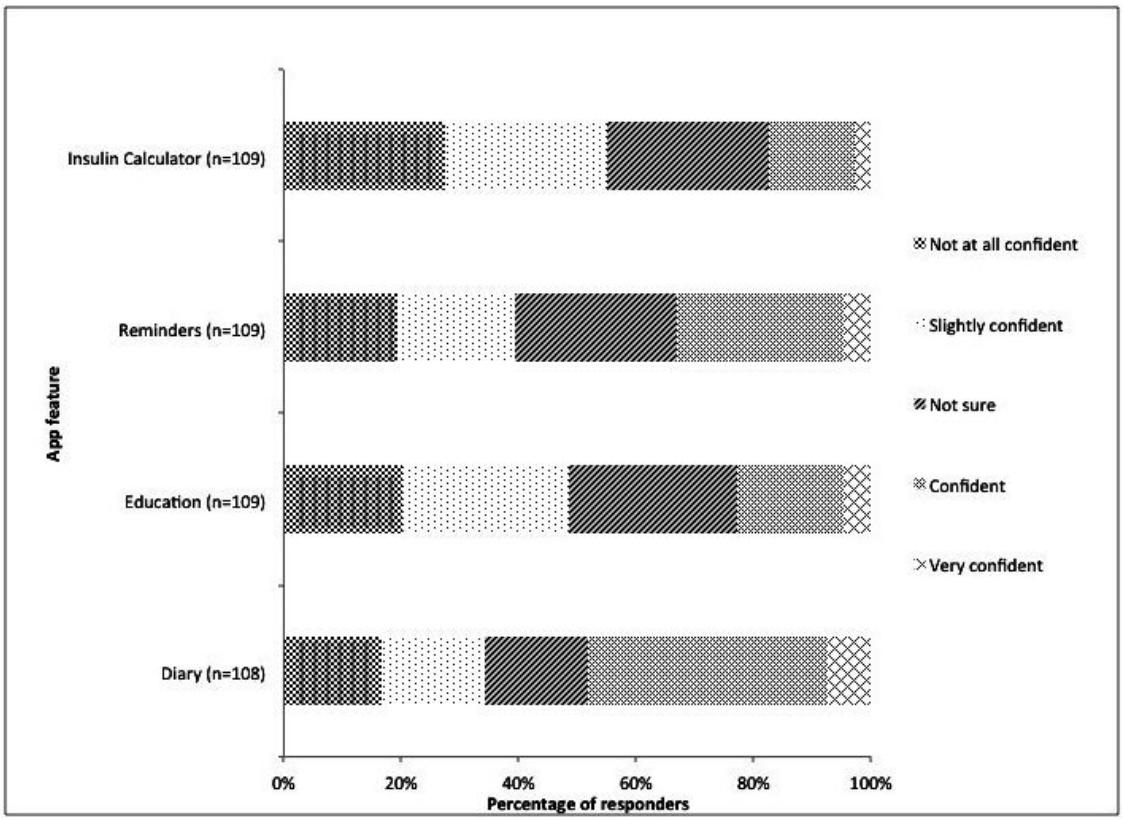
Table 7. Mean scores for perceived usefulness in app features and confidence to recommend apps by health care professionals.

Usefulness		Confidence	
App type	Mean (SD)	App type	Mean (SD)
Diary[a]	3.64 (.948)	Diary	3.05 (1.248)
Reminders[b]	3.47 (1.216)	Reminders	2.79 (1.187)
Information	3.27 (1.068)	Education	2.59 (1.140)
Guidelines	3.06 (1.068)	Insulin Calculator	2.38 (1.120)
Insulin Calculator	3.03 (1.288)		

[a]Diary includes blood glucose diaries and carbohydrate intake diaries.

[b]Reminders are for medication and checking blood glucose.

Figure 2. Confidence to recommend app features reported by health professionals.



Discussion

Principal Findings

In this large sample of people with diabetes attending a secondary care clinic in NZ, 19.6% (37/189) of patients reported using diabetes apps to support their self-management. Diabetes app users were younger and more often had T1DM. The most used app feature in current app users was a blood glucose diary (87%, 32/37). The most desirable feature of a future app was an insulin dose calculation function in app users (46%) and a blood glucose diary in non-app users (64.4%). A Scottish survey has reported similar results and observed that people with T1DM were more likely to desire insulin calculators in an app [23].

Almost two-thirds of HPs responding had recommended a diabetes app to patients. Dieticians were more likely to recommend an app than others. Blood glucose and carbohydrate diaries were considered the most useful feature and HPs were most confident to recommend blood glucose diaries. HPs are the least confident recommending insulin dose calculation functions. Over one-third of HPs desire guidance with app recommendations.

Comparison With Prior Work

Similar to a national American mHealth survey, a large proportion of patients are not using health apps [26]. However, there was a higher rate (20%) of diabetes app use in this patient group compared to the 4% found in a survey of diabetes app use in the USA in 2015 [14] and 7% in Scotland in 2016 [23]. Our findings are consistent with previous surveys showing people using apps are more likely to be younger [26]. It has been suggested that people who are more in need of diabetes care are less likely to use apps [27]; however, we found no significant difference in HbA_{1c} between app users and non-app users. The most favored feature being the blood glucose diary is not surprising given it is the most common feature included in the apps available [5,14]. However some responders are also using health apps that are not specific to diabetes, such as apps for dietary advice.

In contrast with the extensive app problems presented in the literature, over half of the responders with an app reported no problems [5,11-13,15]. This discrepancy may be due to false self-report or responders may have tried multiple apps before finding the one they like. Our study is unable to add significantly to literature about insulin dose calculation problems [15], as only 7 responders reported using their app for insulin calculation. However it is notable that this feature is desired by users and reinforces the importance of having a regulated environment to ensure safety.

The 60.2% of HPs in our survey who had recommended a diabetes app is significantly higher than previously documented amongst physicians across a range of specialties [28], although it is similar to HPs' recommendation for any type of health app [19]. We did not observe any effect of HPs' age on app recommendation, although it is previously well established that younger HPs are more likely to adopt mHealth for diabetes [28].

Strengths and Limitations

A large patient sample size was obtained by contacting all patients seen in the last 12 months with an email address. The risk of overrepresentation by more technology-literate responders through recruitment via email was minimized by also recruiting via telephone and by providing paper surveys at the HPs' conference. The demographic and clinical data of responders and non-responders were compared, and most variables showed no difference. Responders were actually older than non-responders and had better glycemic control. This study focused on the beliefs and opinions of people with diabetes (potential app users) and HPs (potential app prescribers) rather than simply describing apps for diabetes . It is one of the first papers to describe app use in people with diabetes in New Zealand.

This patient sample came from patients in secondary care diabetes clinics, and therefore, app use may be different amongst patients managed in primary care. Similarly, findings may not generalize to patients with poorer glycemic control as responders had statistically significantly lower HbA_{1c} than non-responders. This was a cross-sectional survey that is useful to assess app use at one point in time, but it is likely that people vary their app use and recommendations over time. It was therefore not possible to assess whether the introduction of an app has significant effect on clinical outcomes. Our study did not address the difference in needs in app features between responders on insulin and those not on insulin. Overall the response rates for both surveys were low and responses were limited by self-report and therefore liable to responder bias.

Conclusions

This study shows app usage is relatively low among people with diabetes, while 60.2% of HPs have recommended an app to patients. There is, however, interest amongst people with diabetes and HPs to use diabetes apps, with strong interest in an insulin dose calculator. Apps with this feature have the potential to improve diabetes control. However, the critical problem of app safety remains a barrier to the prescription and use of insulin dose calculators. Further work is needed to ensure apps are safe and provided in a regulated environment. An app assessment process would provide HPs with confidence in the apps they recommend and would ultimately ensure app quality and safety for app users. At present, however, app users and HPs must remain cautious with diabetes apps, especially those in the insulin dose calculator category.

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Authors' Contributions

LB and RG wrote the draft manuscript. All authors discussed the draft and provided comments and suggestions for change.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey for people with diabetes mellitus attending diabetes outpatient clinic.

[PDF File (Adobe PDF File), 18KB - mhealth_v5i6e85_app1.pdf]

Multimedia Appendix 2

Health professional survey for New Zealand Society for the study of Diabetes.

[PDF File (Adobe PDF File), 42KB - mhealth_v5i6e85_app2.pdf]

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Abbreviations

ACR: urinary microalbumin creatinine ratio
Apps: applications
BP: blood pressure
DM: diabetes mellitus
FDA: Food and Drug Administration
HbA $_{1c}$: glycated hemoglobin
C: HDL ratio: total cholesterol: high density lipoprotein cholesterol ratio
HP: health professional
LDL: low density lipoprotein cholesterol
mHealth: mobile health
NZ: New Zealand
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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Original Paper

Assessing User Engagement of an mHealth Intervention: Development and Implementation of the Growing Healthy App Engagement Index

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Abstract

Background: Childhood obesity is an ongoing problem in developed countries that needs targeted prevention in the youngest age groups. Children in socioeconomically disadvantaged families are most at risk. Mobile health (mHealth) interventions offer a potential route to target these families because of its relatively low cost and high reach. The Growing healthy program was developed to provide evidence-based information on infant feeding from birth to 9 months via app or website. Understanding user engagement with these media is vital to developing successful interventions. Engagement is a complex, multifactorial concept that needs to move beyond simple metrics.

Objective: The aim of our study was to describe the development of an engagement index (EI) to monitor participant interaction with the Growing healthy app. The index included a number of subindices and cut-points to categorize engagement.

Methods: The Growing program was a feasibility study in which 300 mother-infant dyads were provided with an app which included 3 push notifications that was sent each week. Growing healthy participants completed surveys at 3 time points: baseline (T1) (infant age ≤3 months), infant aged 6 months (T2), and infant aged 9 months (T3). In addition, app usage data were captured from the app. The EI was adapted from the Web Analytics Demystified visitor EI. Our EI included 5 subindices: (1) click depth, (2) loyalty, (3) interaction, (4) recency, and (5) feedback. The overall EI summarized the subindices from date of registration through to 39 weeks (9 months) from the infant's date of birth. Basic descriptive data analysis was performed on the metrics and components of the EI as well as the final EI score. Group comparisons used *t* tests, analysis of variance (ANOVA), Mann-Whitney, Kruskal-Wallis, and Spearman correlation tests as appropriate. Consideration of independent variables associated with the EI score were modeled using linear regression models.

Results: The overall EI mean score was 30.0% (SD 11.5%) with a range of 1.8% - 57.6%. The cut-points used for high engagement were scores greater than 37.1% and for poor engagement were scores less than 21.1%. Significant explanatory variables of the EI score included: parity (P=.005), system type including "app only" users or "both" app and email users (P<.001), recruitment method (P=.02), and baby age at recruitment (P=.005).

Conclusions: The EI provided a comprehensive understanding of participant behavior with the app over the 9-month period of the Growing healthy program. The use of the EI in this study demonstrates that rich and useful data can be collected and used to inform assessments of the strengths and weaknesses of the app and in turn inform future interventions.

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KEYWORDS

mHealth; social medium; infant obesity; infant development; children; infants; practitioners; primary healthcare

Introduction

Mobile phone ownership is widespread in Australia and internationally [1,2] and many people use their phone to gain information, browse websites, and use apps [1,2]. Ownership of mobile phones is high across all socioeconomic groups and the mobile phone is a promising tool for delivery of behavior change interventions [3,4]. A mobile phone app was used to provide information and support to parents regarding infant feeding for the Growing healthy program in Australia [5].

Capturing the attention of an app user is clearly paramount to the app's potential effectiveness for behavior change. To be successful, apps must continuously and actively engage the user. User engagement refers to the quality of the user experience, the positive aspects of their interaction, and their desire to use the app over longer periods of time or repeatedly [6]. A recently published review on digital behavior change interventions identified that content and delivery, the setting in which the intervention is used, the demographic, and the targeted behavior influences engagement [7]. Furthermore, the Medical and Research Council (MRC) framework emphasized the importance to utilize theoretical models for the development of effective interventions [8]. This was further supported by the findings in a review which explored the effectiveness of mobile phone apps targeting health behaviors [9]. They identified that interventions which utilized health behavior models were more likely to have an impact.

Engagement with technology is inherently complex and multifaceted in its nature and it may be mediated by factors such as family, community, culture, and context [10]. O'Brien and Toms [11] posit that engagement is not static, but a process with four distinct stages: (1) point of engagement, (2) period of engagement, (3) disengagement, and (4) reengagement. Thus, a user's engagement is considered to be operating over a continuum and this may vary within a session and over long time periods [11]. User engagement and its measurement can be either short or long term, with long term engagement reflecting the degree of involvement a user has with the system (eg, an app) over time [12]. There have been multiple approaches to the measurement of user engagement, reflecting the many elements considered to comprise engagement. These include users' physical participation in a specific target behavior and behavior in virtual spaces (eg, frequency of access), although it is the user's psychological state and perceived experience that is most relevant to engagement [10].

Large scale quantitative measures of engagement rely on Web analytics which provide the opportunity to measure behavioral aspects of engagement. Some examples of data that can be collected, but is not exhaustive to, includes frequency of access to the app, page views, push notifications opened, and average time spent on a page [13]. These metrics unlike other engagement measures based on subjective questionnaires and psychological testing can be applied to the study population with no respondent burden. Web analytics provide insight via these proxy measures about the dynamics of participant engagement and its relationship with app effectiveness. They also provide insights regarding areas for app improvements, lower participant attrition, and in turn increased intervention exposure [14,15].

It has been suggested that Web analytics measures can be classed into three main dimensions of engagement: popularity, activity, and loyalty [6]. To achieve a more in-depth understanding of consumer behaviors and their influencers, "engagement indices," accounting for these three dimensions of engagement, have been used to calculate the users' overall interaction with Web-based technologies [16,17]. Engagement indices provide quantitative evidence regarding the strengths and weaknesses of website and app features to optimize participant engagement and sustainable long-term use of the app.

Little work has been done in the mHealth arena with respect to the conceptualization and measurement of user engagement [7,18,19]. The work done has been mainly around apps for patient engagement of those with chronic disease or around public health and behavior change such as increased physical activity and weight loss [20-22]. Few mHealth programs comprehensively use the available data to analyze participant engagement or to consider its associations with primary outcomes [18,20,21,23]. This paper describes the development of a fit-for-purpose engagement index (EI) based on Web metrics that allows large scale implementation. The EI reported in this paper was developed for the Growing healthy program which used a mobile phone app [5] to provide information and support to parents regarding infant feeding. We provide a rationale and description of the development of an EI to measure participants' behavior utilizing the Growing healthy app; describe the assignment of cut-points for poorly, moderately, or highly engaged users; and investigate determinants effecting participants' engagement with the app.

Methods

Growing Healthy Feasibility Study

The Growing healthy program utilized a quasi-experimental design aimed to support parents of young infants with healthy infant feeding behaviors. To enhance intervention effectiveness, the behavior change wheel model [24], as well as the mode of delivery, content, and quality of the program were considered during the development phase.

Eligible participants were offered to use the Growing healthy app and could choose to receive 3 tailored push notifications through the app each week of the intervention (9 months of the baby's age). Although, midway through the intervention implementation period, participants were also sent a weekly email due to identifying technological issues with receiving and

opening push notifications. The weekly emails included the same messages as the push notifications sent each week. Participants who did not own a phone that was compatible with the app were offered access to the Growing healthy website and were sent 3 text messages. Details of the study has been published previously [5]. The focus of recruitment was parents from socioeconomically disadvantaged regions and resulted in 300 participants. Recruitment was conducted via health practitioners, face to face, or Web-based methods. Eligibility criteria included: (1) expectant parents (30+ weeks gestation) or parents with an infant less than 3 months of age, (2) literate in English, (3) living in Australia, (4) 18 years or older, and (5) ownership of any type of mobile phone or Internet access. Further details of the recruitment process and outcomes have been published elsewhere [25]. As Growing healthy was a feasibility study, the sample size was tailored to logistical limitations of the time and funds available to support recruitment. The EI scoring was only performed for participants' data when the participant registered for the Growing healthy app, activated and accessed the app at least once, and used the app and opened push notifications or weekly emails of the Growing healthy program. The focus of this paper was to report the EI for the intervention group.

Study participants completed 3 quantitative surveys: (1) baseline (T1) (infant age ≤3 months), (2) infant aged 6 months (T2), and (3) infant aged 9 months (T3). The surveys included demographic and infant feeding behavior questions. Participants' use of the app was captured and the data was used to develop the EI and evaluate the Growing healthy program.

Engagement Index

The Web Analytics Demystified visitor EI [16] was adapted to develop a composite measure of engagement for Growing healthy app users. This index was chosen because a detailed description on how to develop and apply it was available. The original index comprised 7 subindices which measured: (1) click depth, (2) loyalty, (3) recency, (4) interaction, (5) feedback, (6) brand, and (7) duration index. Figure 1 presents the adapted term-definitions of subindices included in this study (see Multimedia Appendix 1 for questions). All but 2 subindices (brand index and duration index) from the Web Analytics Demystified visitor EI were available from the app database collected in this study. Although measuring all indices is ideal, the Web Analytics Demystified visitor EI protocol emphasized that the calculation can be adapted to suit the program based on data collected [16]. The developed EI provided a score for each participant that measured their overall engagement with the app against a predetermined criteria. The time frame under consideration was from date of registration to 39 weeks (9 months) from the participants' infant's date of birth.

Metrics needed to calculate the subindices (outlined in Figure 1) were identified and extracted from the Growing healthy app database. The key metrics collected included "session duration," "page views per session," and "number of push notifications opened." Furthermore, subjective markers such as feedback and satisfaction captured at the T3 survey (9 month of the baby's age) was also used to calculate the EI score.

Figure 1. The definitions of the subindices for the engagement index designed for the Growing healthy program where i=ith person and j=jth time period and n=3 for Ci, Li, Ii, and Ri (sum of calculation period) and n=37 for Fi.

Sub-indices	Definition	Formula	Calculation period	Final calculation
Click-Depth Index (C_i)	Number of pages a participant viewed per session (1 day) in the app.	$\frac{Sessions\ having\ "at\ least\ 2\ pages\ viewed"}{All\ sessions}$	• Initial C_{i1}= 0-3 months • Interim C_{i2}= 3-6 months • Final C_{i3}= 6-9 months	$=\sum_{j=1}^{n} C_{ij}/n$
Loyalty Index (L_i)	Measures how frequently participants accessed the app from when they commenced the program until the infant's age at nine months.	$1-\left(\frac{1}{Number\ of\ sessions\ accessed\ during\ the\ timeframe\ of\ the\ program}\right)$	• Initial L_{i1}= 0-3 months • Interim L_{i2}= 3-6 months • Final L_{i3}= 6-9 months	$=\sum_{j=1}^{n} L_{ij}/n$
Interaction Index (I_i)	Number of push notifications opened from those sent through the program.	$\frac{Number\ of\ push\ notifications\ opened}{Total\ number\ of\ push\ notifications\ sent}$	• Initial I_{i1}= 0-3 months • Interim I_{i2}= 3-6 months • Final I_{i3}= 6-9 months	$=\sum_{j=1}^{n} I_{ij}/n$
Recency Index (R_i)	The time difference between each session the participant accessed the app.	$\frac{1}{Average\ number\ of\ days\ between\ visits\ for\ each\ period}$	• R_{i1}= days between registration and app activation • R_{i2}= 3-6 months • R_{i3}=6-9 months	$=\sum_{j=1}^{n} R_{ij}/n$
Feedback Index (F_i)	Subjective measure of the participants' satisfaction with the app assessed in the programs nine-month survey (questions included: ease of navigation,	$\frac{Number\ of\ positive\ responses}{All\ quantitative\ questions\ asked\ about\ their\ satisfaction\ with\ the\ Growing\ healthy\ app}$	• F_i= 9 months infant's age	$=\sum_{j=1}^{n} F_i/n$

Equal weight for each of the subindices was assigned to the overall EI score so that each element was equally important in contributing to the measurement of engagement. Four of the subindices were calculated using app data. The feedback index was informed using responses to the 9-month survey (T3) feedback questions. The final formula used to calculate the EI incorporated click depth, loyalty, recency, interaction, and feedback subindices (see equation 1). The EI was then converted to a value between 0 and 100.

Equation 1: Engagement index formula

$$EI=\sum(C_i+L_i+I_i+R_i+F_i)\times 100$$

where EI is engagement index, C_i is click depth index, L_i is loyalty index, I_i is interaction index, R_i is recency index, and F_i is feedback index.

The calculation for each subindex except the feedback index (data were only collected at the end of the program) was done for three time periods, including initial (0-3 months), interim (3-6 months), and final (6-9 months) and were then averaged. This grouping of time periods was chosen because there was an initial intense use of the app followed by infrequent participant use toward the end of the 9-month program. A detailed explanation for the calculation of each subindex follows.

Click Depth Index (Ci)

The number of pages a participant viewed the app in each access session over the total number of sessions in each time period formed the basis of this subindex. Two metrics were used in the calculation of C_i: the number of sessions in the time period and number of pages viewed per session. A threshold of the number of pages viewed per session was applied. There is no benchmark of an effective click depth, that is, "dose" of the interaction in the mHealth environ. Based on the data collected, the median value of 2 pages per session was used as the threshold. The overall score of C_i was the average of each time period calculation: C_{i1}, C_{i2}, and C_{i3}.

Loyalty Index (Li)

This subindex was based on the frequency of app access throughout the 9-month program. L_i was the reciprocal of the number of sessions in each time period. The total score was dependent on when participants activated the app. The overall score of L_i was the average of each time period calculation: L_{i1}, L_{i2}, and L_{i3}.

Interaction Index (Ii)

The number of push notifications opened versus total sent throughout the 9-month program formed the basis of this subindex. Interaction Index was the total number of push notifications opened divided by the number sent in the time period. This was calculated for 3 month time intervals of the infant's age according to when the participant activated the app until the infant reached 9 months of age. The overall score of I_i is the average of each time period calculation: I_{i1}, I_{i2}, and I_{i3}.

Recency Index (Ri)

The number of days between each session was the basis of the recency index. The R_i was calculated for three different time points: (1) the number of days elapsed from registration to when the participant first accessed the app (R_{i1}), (2) the average number of days between sessions when the participant accessed the app between 3 to 6 months (R_{i2}), and (3) 6 and 9 months (R_{i3}). The data were transformed by taking the reciprocal of each R_{i1} to R_{i3}. The overall score of R_i was the average of each time period calculation: R_{i1}, R_{i2}, and R_{i3}.

Feedback Index (Fi)

This subindex was a self-reported measure of participant satisfaction with the app, which was captured in the 9-month survey (T3). Constructive feedback was scored positively as 1 and negatively as 0. The 9-month survey included 37 questions which formed the basis of F_i. Each question (Multimedia Appendix 1) used a 5-point Likert scale response ("strongly agree" to "strongly disagree" and "didn't use"). The responses were dichotomized as either 1 or 0 according to whether they answered an extreme positive response or not; for example: strongly agree=1, agree=0, neither here nor there=0, disagree=0, strongly disagree=0, and didn't use=0. Extreme positive scoring was reversed on the Likert scale for questions worded negatively. Although only app users were eligible for this study, some app users reported using the website rather than the app in the T3 survey (n=15) and thus were not asked the feedback questions. The EI total score for these participants were averaged across the 4 subindices that data were available. In addition, a number of participants (n=102) did not complete the T3 survey. For these participants F_i was zero and the EI was averaged across the 5 subindices.

Statistical Analysis

Basic descriptive data analysis was performed on the metrics and components of the EI as well as the final EI score. To analyze the EI scores, cut-off points were developed based on the distribution of the total samples' EI scores using quartiles. Participants were then categorized as either poorly, moderately, or highly engaged. This method was chosen as there were no existing mHealth interventions that utilized an EI and categorized participants' engagement based on app use.

Group comparisons between poorly, moderately, or highly engaged participants were then conducted using *t*-tests, analysis of variance (ANOVA), Mann-Whitney, Kruskall-Wallis, and Spearman correlation tests were used as appropriate. Consideration of independent variables associated with the EI score were modeled using linear regression models.

The following variables were dichotomized for analysis including:

- Education level: university degree ("degree" or "higher degree") or no university ("high school education or less," "trade certificate," or "diploma")
- Employment status: working or studying ("full or part-time," "casual paid work," and "full or part-time

studying") or not in labor force ("keeping house and/or raising children full-time" and "unemployed or laid off")
- Gross household income: below average ("Aus $1-$119 per week," "Aus $120-$299 per week," "Aus $300-$599 per week," "Aus $600-$799 per week," "Aus $800-$999 per week") average ("Aus $1000-$1499 per week"), above average ("Aus $1500-1999 per week"), or higher income ("Aus $2000 or more per week")
- Marital status: relationship ("married," "living in a defacto relationship") or single ("separated," "divorced," "widowed," "never married")
- Recruitment method: practitioner, Web-based, or family or friends
- Device type: android or iOS
- System type: app only or both app and email

Other independent variables considered included mother's age, country of birth, as well as infant's age at the start of the program, their birth weight, and feeding status at baseline. All analyses were performed using used IBM SPSS Version 23.0.

Results

Of the 300 Growing healthy participants who completed the baseline survey, 75.0% (225/300) met the inclusion criteria for this study. The average age of participants was 30 years, with 62.2% (186/300) being first time parents, 97.0 % (291/300) living with their partner, and 84.0% (252/300) being full-time carers of the infant. The infants' were on average 6.9 weeks old when registration occurred and 56.4 %(169/300) were breastfed.

The EI score had a distribution that was not statistically significant as evidenced by nonsignificant Kolomogorov Smirnov (KS) test at *P* value of .05 and a standard error of skewness (SES) between >−1.96 and <1.96 (SES=0.58). The mean EI score was 30.0% (SD 11.5%) and ranged between 1.8% to 57.6% (see Figure 2). The interquartile ranges were used for categorization, where: (1) poor engagement for scores less than or equal to 21.1% (≤Q1), (2) moderate engagement if scores were between 21.1% and 37.1% (Q1-Q3), and (3) high engagement if score were greater than or equal to 37.1%(≥Q3).

Three variables were significantly associated with high engagement in univariate analysis (see Table 1 for details). Participants most likely to be classed as having high engagement were first time parents (primiparous), who used both the app and opened weekly emails, and had joined the program with a younger infant and were part of the program for longer. Approximately 64% of participants with higher level education (university degree) were classed as having high engagement compared with 55.3% of those with lower levels of education (no university). Additional demographic descriptors for the different engagement levels are shown in Table 1. Engagement index cut-points for scores: poor engagement ≤21.1%, moderate engagement=21.1%-37.1%, and high engagement ≥37.1%. Variables are based on data provided at baseline or T1 (age ≤3 months).

Figure 2. Overall engagement index scores distribution.

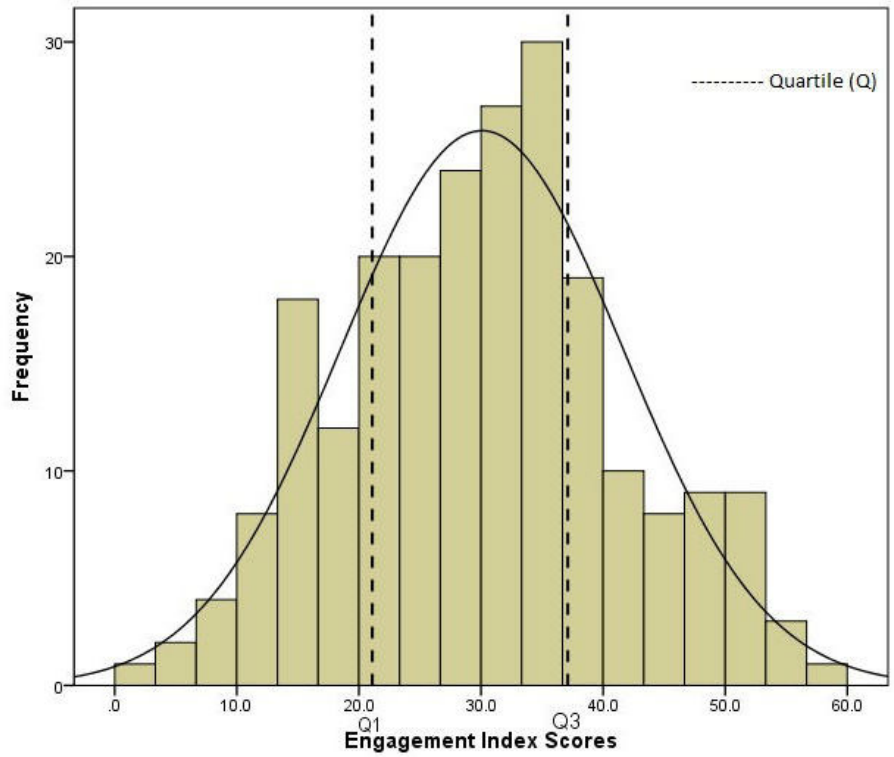


Table 1. Characteristics of growing healthy participants based on engagement index level (n=255).

Variables	Poor engagement (n=56) 15.1 (SD 4.6)	Moderate engagement (n=113) 30.0 (SD 4.3)	High engagement (n=56) 45.0 (SD 5.5)	*P* value
Participant characteristics				
Age (years)[a], mean (SD)	30.3 (4.4)	30.5 (4.4)	30.6 (4.5)	.61
Education (no university)[b], n (%)	31 (55)	61 (54)	20 (36)	.11
Income (higher income)[c], n (%)	14 (25)	36 (31.8)	13 (23.2)	.70
Marital status (relationship)[b], n (%)	54 (96)	110 (97.3)	53 (95)	.59
Employment status (not in labor force)[b], n (%)	51 (91)	97 (85.8)	45 (80)	.14
Parity (Primiparous)[b], n (%)	29 (52)	70 (61.9)	41 (73)	.004[d]
Recruitment method (Practitioner)[c], n (%)	24 (48)	52 (47.9)	30 (48)	.06
Device type (iOS)[b], n (%)	38 (68)	87 (72.5)	36 (64)	.73
System type (both app & email users)[b], n (%)	26 (46)	82 (72.5)	52 (93)	<.001[d]
Infant characteristics				
Age at registration (weeks)[a], mean (SD)	7.3 (3.6)	7.4 (3.6)	5.6 (3.4)	.02[d]
Birth weight (kg)[a], mean (SD)	3.46 (0.591)	3.47 (0.593)	3.47 (0.592)	.20
Gender (male)[b], n (%)	31 (55.3)	53 (46.9)	23 (41.0)	.34
Baseline feeding status[c], n (%)				
Breastfeeding	35 (63)	64 (56.6)	28 (50)	.13
Formula feeding	14 (25)	25 (22.1)	23 (41)	
Mixed feeding	7 (12.5)	24 (21.2)	5 (8.9)	

[a]Pearson correlation; mean, standard deviation (SD) reported.

[b]*t* test; % within group (count) reported.

[c]Based on ANOVA; % within group (count) reported.

[d]Statistically significant engagement level and independent variable <.05.

Of the 14 variables assessed in this study, 8 met the including criterion of $P \leq .25$ in the univariate analysis and were included in the multivariate linear model (full model) [26] presented in Table 2. Similar results were found for 4 variables which were significantly associated with EI scores as presented in the reduced model (see Table 2 for details). Higher EI scores were found among those mothers who were primiparous, using both the app and accessing the email, recruited to the program by their health practitioner and those who registered when their infant was younger.

To better understand the drivers of engagement descriptive analysis of the subindices that made up the overall EI score was performed (Table 3). The click depth index (C_i) median score was 30.8% (IQR: 21.0%-37.2%). Of the 303 pages that were available to view, the mean number of pages viewed was 30 (range: 1-156) and a median of 24. Although, throughout the program, participants viewed a mean of 44.2 pages (range: 1-316) and a median of 29. Figure 3 illustrates the most commonly viewed pages on the app including the number of times each page was visited and the number of participants that visited each page. The solids section was viewed the most and mixed feeding was viewed the least.

Table 2. Linear regression to explore the predictors of infant and participant characteristics with the engagement index scores.

Variable	Univariate model (B)	*P* value	Full model (B)	*P* value	Reduced model (B)	*P* value
R^2			0.154		0.164	
Parity		.004		.006		.005
Multiparous	1.00		1.00		1.00	
Primiparous	4.532		4.147		4.209	
Recruitment method		.06		.07		.02
Family or friends	1.00		1.00		1.00	
Practitioner	5.346		6.423		4.221	
Web-based	2.795		4.267		0.989	
System type		<.001		<.001		<.001
App only	1.00		1.00		1.00	
Both (app and email)	7.977		−6.426		−6.937	
Infant age at T1 (weeks)	−0.477	.02	-0.522	.02	−0.459	.005
Income		.70				
No response	1.00					
Below Average	−0.033					
Average	2.921					
Above Average	0.061					
Higher income	1.181					
Marital status		.59				
Relationship	1.00					
Single	2.208					
Employment status		.14		.08		
Working or studying	1.00		1.00			
Not in labor force	−3.189		−2.927			
Country of birth		.31				
Other	1.00					
Australia	−2.389					
New Zealand	−0.074					
United Kingdom	6.9.41					
Device type		.73				
iOS	1.00					
Android	0.580					
Birth weight (grams)	0.002	.20	0.001	.42		
Gender		.34				
Male	1.00		1.00			
Female	−1.462		−0.440	.77		
Baseline feeding status		.13		.17		
Mixed feeding	1.00		1.00			
Breastfeeding	−0.401		0.524			
Formula feeding	3.124		3.941			

The loyalty index (L_i) average score was 50.8% (IQR: 26.7%-75.7%). The average number of sessions participants visited the app was 11.6 times (range 1-64) and a median of 9. The recency index (R_i) median score was 34.4% (IQR: 10.7%-37.3%). On average participants took 14 days to activate the app (range 0-184 days). The interaction index (I_i) median score was 8.9% (IQR: 1.9%-18.1%). On average, 91.8 (range: 16-216) push notifications were sent and an average of 11.1 (range: 0-70) were opened with a median of 6. Participants who used both the app (including access to push notifications) and opened weekly emails scored lower on the I_i compared with participants who only used the app and only accessed push notifications.

The feedback index (F_i) was calculated for 154 participants as 71 participants either did not complete the 9-month survey, or reported using the website (n=15) and were not asked for feedback about the app. The median score for F_i was 2.7 (IQR: 0-16.2). As presented in Table 4 the app features participants were most satisfied with included the language used, usefulness in sharing the app with another carer, and the quantity of Internet data required to use the app. Participants were least satisfied with the push notifications, including the number of push notifications sent (too few or too many), and many participants experienced technical problems using them. There was a low satisfaction with respect to the videos available on the app which they felt did not cover sufficient information to answer their queries about infant feeding.

Over the duration of the program, there was a decrease in the mean index score for each subindex. The C_i and L_i scores shared similar scores during the initial (0-3 months) and final (6-9 months) period, whereas for the interim period (3-6 months) the mean score was lower for C_i (43.7%) compared with L_i (54.6%). The recency index dropped dramatically after the initial period by 55.4% and continued to track down, whereas the interaction index attained the lowest mean compared with the other subindices at the initial period (21.4%) and trended down over time (See Figure 4).

Table 3. Descriptive statistics of each subindex (N %).

Subindex	Mean	Median	Interquartile range	Range
Click depth index	46.7	45.5	33.3-63.3	0-100
Loyalty index	50.8	50.8	26.7-75.7	0-93.4
Recency index	26.0	34.4	10.7-37.3	0.6-53.7
Interaction index	12.7	8.9	1.9-18.1	0-64.3
Feedback index	13.3	2.7	0-16.2	0-94.6

Figure 3. Number of participants and total number of times participants visited each section of the Growing healthy app. BF=breastfeeding, FF=formula feeding, MF=mixed feeding.

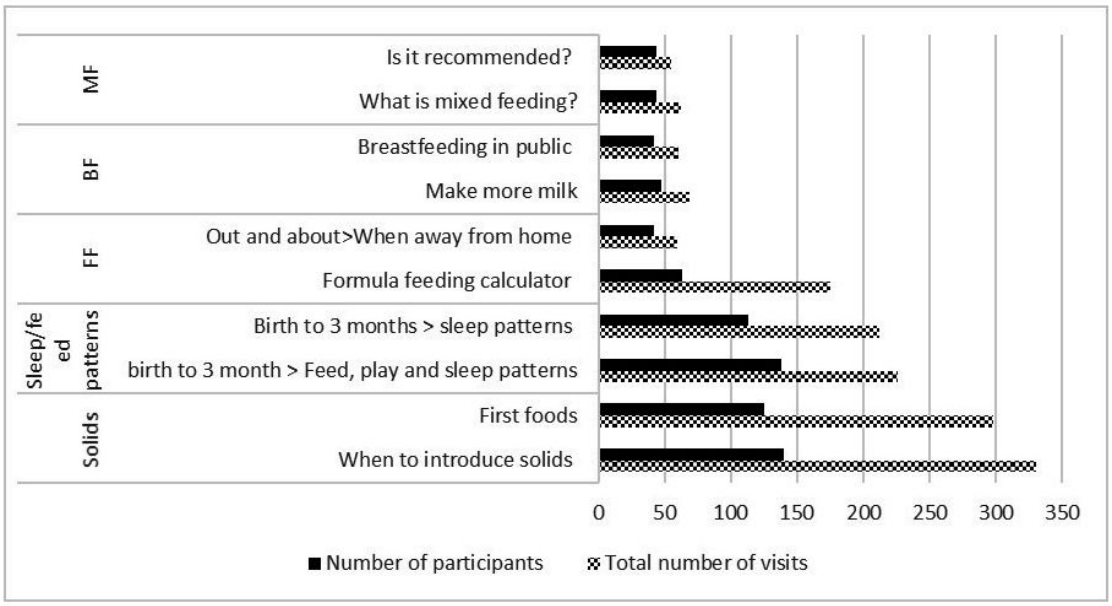


Table 4. Participants' reported satisfaction with aspects of the Growing healthy program (feedback index, F_i; n=154).

Satisfaction questionnaire	Scores (N)[a]
I found the Growing healthy app easy to use	46
I liked the layout or "look" of the app	34
I found it hard to navigate through the app[b]	23
The Growing healthy app didn't take long to load information	45
The Growing healthy app failed to work at times[b]	28
The different sections of the app worked well together	20
The language used in the app was easy to understand	57
The app did everything I expected it to do	31
I couldn't find all of the answers I needed in the app[b]	11
I had to use the search feature to find what I was looking for	14
Using the app was an enjoyable experience	22
I found the app complicated[b]	43
I can trust the information on the Growing healthy app	39
I felt confident using this app	40
I found the information for mums useful	31
I found the information on feed and sleep patterns useful	29
I found the information about breastfeeding useful	20
I found the information about formula feeding useful	17
I found the information on mixed feeding useful	15
I found the information on solid feeding useful	27
I found the videos on the app useful	12
I found the recipe section of the app useful	22
I shared the information from the app with other friends and family	16
I was concerned about the Internet data usage on my phone when using the app[b]	47
I found the information provided easy to understand	36
Overall, I liked the Growing healthy program	36
I would recommend the Growing healthy program to a friend	45
I found it helpful to share the app with my partner or another carer	48
The Growing healthy program covered all of the things about infant feeding that I wanted it to	25
I received push notifications on my phone, from the Growing healthy program[c]	122
The push notification messages often disappeared before I had a chance to tap on them[b]	12
I didn't know how to retrieve push notification messages once they disappeared from screen[b]	12
I would prefer to receive text messages rather than push notifications from the app	19
I was happy with the number of notifications or messages received each week	6
I was happy with the time that the notification was sent to me during the day	18
I found the notifications or messages helpful	16
I found the notifications or messages suited my baby's age and stage of development	23

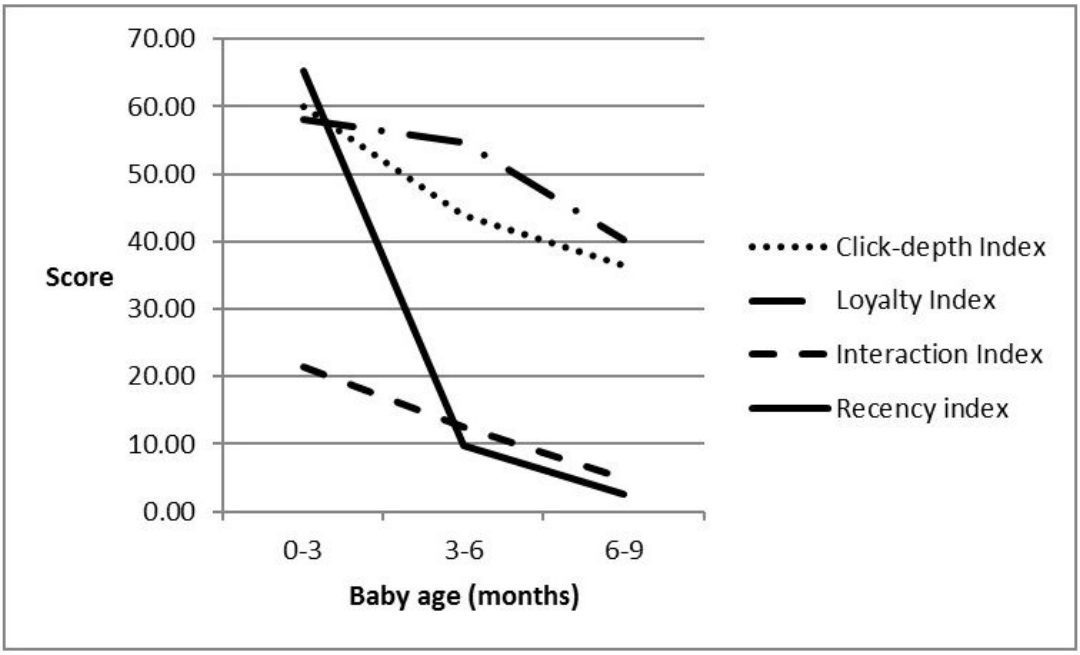
[a]Total scores only include the extreme positive responses based on scoring criteria **.**

[b]Likert scale scoring reversed for these questions: strongly disagree (1), disagree (0), no strong feelings either way (0), agree (0), strongly agree (1), and didn't use (0).

[c]Response option and scoring: Yes, I received weekly push notifications (1), no, I received text messages instead of push notifications (1), and no, I

disabled my push notifications so I didn't receive any weekly messages (0).

Figure 4. The frequency of scores for click-depth index (Ci), loyalty index (Li), interaction index (Ii), and recency index (Ri) at each time point (initial, interim, and final).



Discussion

Principal Findings

This is one of the first studies to develop and implement an mHealth program supporting parents with healthy infant feeding practices through a mobile phone app. To our knowledge, this is the first study to utilize an EI to quantify and categorize participants' engagement level using the app. We found that engagement level was positively correlated with primiparous status, use of both the app and email, exposure to the program for a longer period, and recruitment through health practitioners. Negative correlation was found with age of child at start of program and engagement level.

The identification of the correlates of participant engagement is not only beneficial to inform future enhancements of the Growing healthy program, but more broadly to evaluate mHealth programs. The EI has its origins in measurement of consumer engagement with Web-based products. Adjusting the index to measure engagement with a mHealth program was possible as the metrics measured are the same; only the measurement of the content and behavior will be different [16].

A criterion to categorize participants as poor, moderate, or highly engaged with the Growing healthy program based on their overall EI score was developed. Previously, program engagement has arbitrarily been labeled as high [27] or low [22] based on the frequency participants accessed websites or apps. Few studies have considered participant engagement on the basis of their interaction with multiple intervention elements. In addition, there is not a standardized approach to measuring engagement. For example, a point system to gauge individual user activity with the program features was used in a study targeting reduction of high-risk sexual behaviors. The measures included were frequency of access, profile modification, message views, article views, completion of quizzes, number of pages viewed, and updates of personal goals [23]. Whereas modeling participants' engagement with frequency of access, average daily steps, and the number of days since participants last accessed the program was performed for a physical activity focused mHealth intervention [20].

Participant app use over the 9-month period in this study varied such that engagement was high after initially joining the program but decreased from the 3- to 6-month period. Previous mHealth programs targeting long and short term behavior change have identified similar patterns of use [27-29]. Attrition with mHealth programs is negatively affected by factors such as lack of commitment or motivation to change health behaviors [28], confidence in knowledge about managing the targeted behavior [27], and programs that are perceived as overly burdensome by participants [23]. The Growing healthy program was a "just in time" resource [15] developed to provide infant feeding information up to 9 months of the infants age. Feeding milestones targeted included breastfeeding, best practice formula feeding, timing of the introduction of solids and optimizing dietary exposure to fruit and vegetables, and minimizing exposure to noncore foods. Once that knowledge is obtained, it is likely that participant app use will drop off [30]. When targeting long term behavior change, mHealth developers need to consider ongoing novel strategies that will keep participants engaged. Qualitative findings suggest users prefer to engage with apps periodically [28]. Such findings highlight that we must seek to understand app users' behavior to inform the most appropriate time to engage them to join the program, the factors

that lead to disengagement, and to consider strategies that will maintain their engagement.

Study participants who accessed both the website and the app attained a significantly higher EI score compared with participants who had just used the app. This supports the notion that delivering the intervention using various modes enhances engagement and to the intervention exposure [11,23]. Primiparous participants had significantly higher EI scores than multiparous women. This is congruent with qualitative analysis conducted as part of the development phase for the Growing healthy program (unpublished) where most of the primiparous participants expressed an interest in the program, while multiparous participants suggested the resource would have been more useful as a first time parent. Despite multiparous participants being less engaged, more than one third of those classified as highly engaged were indeed multiparous.

While initial engagement is the initial hurdle for any intervention, sustaining engagement remains the most difficult part of intervention implementation, it is more difficult to achieve [11,23,31]. It has been found that novelty and relevance are main contributors to sustained app user engagement [11,32,33]. The downward trend in engagement subindices scores from 3 to 6 months reported in this study may be a reflection of a lack of perceived novelty in the Growing healthy app throughout the intervention period. This may also explain the lower engagement of multiparous participants (who have developed their thinking around infant feeding already).

The infant's age at baseline (ie, when the app was downloaded) was also strongly associated with higher EI scores. Participants who joined the program when their infant was younger had a higher EI score compared with those who joined when their infant's age was closer to 3 months. Similar to traditional interventions that targeted childhood obesity prevention [34], early recruitment was necessary to increase participant engagement. Early recruitment is likely to increase intervention exposure, which is associated with an increased likelihood of influencing the uptake of the desired behaviors [27]. This is important to target as infant development clearly occurs rapidly within the first year of life. The app was likely to be most useful and provided novel information to mothers if they were recruited from early postpartum or during pregnancy.

Participants who were recruited from their health practitioner were more likely to have higher EI scores compared with those who were recruited on the Web. This may be attributed to mothers' perception that health practitioners are a trustworthy source of information [35]. The involvement of health practitioners such as maternal and child health nurses and practice nurses who do routine infant health checks during the first few years of life [36], are important as a key "referral pathway" to evidence based apps and in turn, to the most effective utilization of apps.

Comparison With Prior Work

Several studies describing mHealth interventions encouraging healthy infant feeding behaviors have recently been published. Delivery modes used in these studies included app [37,38], websites [39,40], and social media [41]. Due to the different delivery modes, the findings of this study cannot be compared with other programs. However, as mHealth interventions are novel modes of delivering health behavior change interventions across health disciplines, similar patterns of engagement have been reported by several researchers albeit using different measures [23,42,43].

Limitations and Strengths

This study has several limitations. First, a number of technological issues were experienced by participants in receiving and opening push notifications. Adaptation were therefore made midway during the program and all participants were sent weekly emails. Second, app quality is an important influencer on participant engagement [44-46]. The participants' responses to the satisfaction survey (feedback index) demonstrated low satisfaction with respect to the push notifications, emphasizing the impact technological difficulties have on participant engagement. Third, the weekly emails contained links to the Growing healthy website rather than the app. Finally, participant behavior on the website, such as the number of pages viewed, was not accessible at an individual level. This explains the increase in loyalty index scores at around 3 to 6 months, as participant access to email links was included. Click depth index scores decreased at that time point because the number of pages viewed on the website could not be measured. Overall, the EI score calculated for these participants is most likely an underestimate of their engagement with the program.

Some features of the Growing healthy program were not measured using the EI because there were difficulties in obtaining individual participants' information such as, participant use of the Growing healthy Facebook group and sharing the app with another carer or sharing information from the app with others (interconnectivity). Although participant interaction with these features was not measured, satisfaction and use of these features was included in the 9-month survey that made up the feedback index.

Some studies have shown that mothers from a disadvantaged background were less likely to use the Internet as a source of information for infant feeding [47]. A strength of our study was that approximately equal number of participants of both high and low educational background were recruited unlike other mHealth programs targeted at addressing infant feeding [48].

To our knowledge, the utilization of an index to measure participant engagement has not yet been implemented in mHealth interventions. The EI provided detailed analysis regarding the frequency participants accessed the app and push notifications, how many pages they accessed per session, and their satisfaction with the program which was measured over 3 time points across the 9 months of the program.

Conclusions

The EI provided a comprehensive understanding of participant behavior with the app over the 9-month period of the Growing healthy program. The participants' engagement with the Growing healthy app was determined by various factors including participant characteristics, novelty, intervention exposure time, and the quality of the app including technological

aspects. Primiparous participants, those who accessed both the emails and the app, those who were exposed to the program for a longer period, and those who were recruited from their health practitioner all had higher EI scores. The use of the EI in this study demonstrates that rich and useful data can be collected and used to assess the strengths and weaknesses of mHealth interventions and in turn inform improvements in their design and delivery.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Participant satisfaction survey.

[JPG File, 376KB - mhealth_v5i6e89_app1.jpg]

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Abbreviations

Ci: Click depth index
EI: engagement index
Fi: feedback index
Ii: interaction index
Li: loyalty index
Ri: recency index
IQR: interquartile range

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Original Paper

Understanding Smart Home Sensor Data for Ageing in Place Through Everyday Household Routines: A Mixed Method Case Study

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Abstract

Background: An ongoing challenge for smart homes research for aging-in-place is how to make sense of the large amounts of data from in-home sensors to facilitate real-time monitoring and develop reliable alerts.

Objective: The objective of our study was to explore the usefulness of a routine-based approach for making sense of smart home data for the elderly.

Methods: Maximum variation sampling was used to select three cases for an in-depth mixed methods exploration of the daily routines of three elderly participants in a smart home trial using 180 days of power use and motion sensor data and longitudinal interview data.

Results: Sensor data accurately matched self-reported routines. By comparing daily movement data with personal routines, it was possible to identify changes in routine that signaled illness, recovery from bereavement, and gradual deterioration of sleep quality and daily movement. Interview and sensor data also identified changes in routine with variations in temperature and daylight hours.

Conclusions: The findings demonstrated that a routine-based approach makes interpreting sensor data easy, intuitive, and transparent. They highlighted the importance of understanding and accounting for individual differences in preferences for routinization and the influence of the cyclical nature of daily routines, social or cultural rhythms, and seasonal changes in temperature and daylight hours when interpreting information based on sensor data. This research has demonstrated the usefulness of a routine-based approach for making sense of smart home data, which has furthered the understanding of the challenges that need to be addressed in order to make real-time monitoring and effective alerts a reality.

(JMIR Mhealth Uhealth 2017;5(6):e52) doi:10.2196/mhealth.5773

KEYWORDS

activities of daily living; aged; remote sensing technology

Introduction

An aging population is a challenge to current models of health care delivery and engagement [1]. Not only will there be a greater proportion of older people in the general population, but the prevalence of chronic disease in the aged will increase health care costs and put pressure on health care services. To service the future needs of an aging population, the elderly will increasingly be encouraged to remain in the community or age in place [2,3]. Smart homes can facilitate early intervention and

aging in place, particularly for people living alone. In Australia, 1 in 4 people aged 65+ years live alone [4]. In-home sensors can provide continuous monitoring to facilitate early intervention through alerts to carers (family, relatives, health care professionals) of acute medical events (ad hoc alerts) and patterns suggesting cognitive or physical decline (notification alerts).

Real-time alerts and visual presentation of data from smart homes sensors are a work in progress. In a 3-month UK pilot study, Sixsmith [5] tested alerts based on unusual motion and absence of motion. Alerts comprised an automated phone call to the residents, and, if they did not answer a call, to a carer. The system produced 61 alerts, 46 of which were false alerts. Trial participants felt that while a few false alarms were acceptable, too many were viewed as intrusive and ongoing false alerts undermined faith in the system. In a Japanese pilot study of smart homes, Ohta et al [6] set up alerts based on transition time between rooms, which were classified as normal or unusual. Unusual transition movement (eg, staying longer than normal in a room) triggered a phone call or an email to a carer. The number of alerts and false alerts was not reported.

Visual presentation is also important for making smart homes a reality. The amount of data generated by continuous monitoring systems can result in information overload [7] unless summarized in a way that allows carers to understand the situation at a glance and make judgment calls about the required response [8,9]. Visual summarization of sensor data is difficult given the need to present spatio-temporal data from a multitude of sensors [10].

In the Sixsmith pilot study [5], no visual information was available to the participants or carers. Ohta et al [6] proposed an example of a display based on room transitions so carers could visually check the current location of the resident based on a limited recent history (a few hours) of movement between rooms. Kaye et al [11], in an extensive smart home trial in Oregon, illustrated 180 days of daily room movement using spiral plots in a 24-hour format. Although cyclical patterns emerged in the spiral plots for strict daily routines, it was not possible to identify or interpret more fluid routines.

Routines are described as “strategically designed behavioral patterns (conscious and subconscious) used to organize and coordinate activities along the axes of time, duration, social and physical contexts, sequence and order” [12]. Human activity is structured into routines, which reflect the cyclical nature of human biological and social behavior, which is organized around a 24-hour clock [13-16]. Although routines are not inherently good or bad, changes to routines can be significant. Maintenance of routines, especially those associated with the activities of daily living, is essential for independent living [17-19]. Furthermore, as aging involves the inevitable decline in cognitive and physical function leading to modification of daily routines to match the altered functionality [20,21], changes to routine may be indicators of underlying issues such as decreases in cognitive health and well-being [22,23]. This study investigated (1) whether routines can be extracted from sensor data and (2) how routines can advance interpretation of sensor data to provide triggers and thresholds for real time, reliable ad hoc alerts.

Methods

Smart Home Sensors

This study presented results from a pilot of Smarter Safer Homes testing ubiquitous home monitoring for the elderly, as described in Zhang et al [24] and Bradford et al [25,26]. Smart homes were installed with a range of sensors. However, this study only looked at data from motion and power sensors. The full list of sensors is shown in Table 1. The study was conducted in accordance with Health and Medical Research Human Research Ethics. The participants in the study agreed to the installation of in-home sensors.

Table 1. In-home sensors for residents.

Sensors	Trigger for sensor firing	Place of installation	Sensor data upload	Data type
Passive infrared motion sensors	Motion within 5 m	Wall (near ceiling) in all rooms	Sends ad hoc as status change	Binary
	Current draw of appliances	Wall power outlets	Pushes 1-minute data every 5 minutes	KwH to binary
Circuit meter	Current draw of stove or oven	Switchboard	Pushes 1-minute data every 5 minutes	KwH to binary
Accelerometer	Movement	Under bed	Sends ad hoc as status change	Binary
Reed switches	On breaking of circuit	Exit doors. Kitchen or bedroom doors	Sends ad hoc as status change	Binary
Acoustic sensor	Water flow	Kitchen	Sends ad hoc as status change	Binary
Environmental sensors	Continuous data collection	Kitchen, bathroom, laundry	Pushes 1 reading every minute	Temperature and humidity
Electronic thermometer	Daily recording of temperature[a]	Indoor usage	Sends ad hoc after measurement	Temperature
Glucometer of blood	Daily recording of blood pressure[a]	Indoor usage	Sends ad hoc after measurement	Glucose
Electronic scales[b]	Daily recording of weight[a]	Indoor usage	Sends ad hoc after measurement	Weight
iPad and Web portal	Residents were given an iPad for their personal use and to consult an app on which summary sensor data appeared and diary for health measurements			

[a]Residents would vary in the regularity and consistency of use of these devices.

[b]Information sent directly to database without the need for user data entry.

Sensor Data and Installation

The data used in this study were collected from passive infrared motion sensors and power use sensors located in participants' lounge, kitchen, bedroom, and bathroom. These sensors were chosen because they were the most reliable and provided the bulk of the data. Motion sensors send data whenever motion is detected. Motion sensors fire on detection of movement, but cannot distinguish between types of movements. Also, movements have to be sufficiently large for sensors to fire. Power use sensors were connected to all key appliances in the kitchen and lounge. Power use sensors send data (KwH) every 5 minutes.

Sensors were installed and maintained by a local technician. The technician was very friendly, and his visits were appreciated by all residents. The most common complaints involved battery replacement and flickering lights on motion and power sensors. Duct tape was used to hide the light on motion sensors, and residents were shown how to switch the light off on power sensors.

Data Preparation and Cleaning

Time (GMT) and date stamped data from motion and power sensors were relayed to a Web-based database and downloaded to Microsoft Access. Each entry identified the residence, room, sensor type (motion or power), and description (eg, kettle). Time was converted into local time, which comprised 16 days of AEST (GMT+10) and 175 days AEDT (GMT+11).

Data were analyzed using Microsoft Access. Prior to analysis, data were cleaned. Standby power was removed for appliances such as televisions and microwaves (based on low wattage) and then converted into binary data (in use or not in use). Missing data because of sensor battery failure or absence from home were identified. Absences over 24 hours were noted, but did not negatively affect daily data or cumulative data. Battery failure was distinguishable because of normal movement in other rooms. For some motion sensors, a notable increase in sensor firing prior to battery failure caused high outliers. High outliers could also occur on days residents received guests or visitors. Mean replacement was used for high outliers (±3×IQR).

Continuous streamed data 24/7 for 3 residents over 181 days resulted in 345,470 data entries. Data were presented as 24-hour radar plots, which reflected daily patterns of movement and power based on cumulative frequency of sensor firing. Data were grouped by hour (± 30 minutes). Radar plots reflected the build-up and change in pattern of movement or power over time. Sharp spikes in the outlines indicated strict adherence to time schedules.

Participants

Residents of an aged care facility living in independent units self-selected for participation in the pilot. To be eligible to participate in the pilot, participants had to be aged over 70 years and have no home care arrangements. Participants with cognitive difficulties were also excluded. Of those who self-selected (N=23), 17 signed consent forms; however, 3 residents withdrew

before the sensors were installed. Retention of participants in longitudinal trials with the elderly was problematic for reasons including morbidity, mortality, relocation, or other. Over the course of the 180 days of the trial, there were further withdrawals. We collected 7 complete sets of data (sensor and interview data at 3 time points); however, only 5 residents were eligible for this study. Participants living in dual occupancy were excluded because multiple occupancy was problematic for interpreting data from the motion sensor used in this trial [11]. The 5 eligible participants were aged between 79 and 88 years (Mean 83.6, SD 3.8). There were more female (n = 4) than male participants (n = 1). Two participants listed primary or secondary school as their highest level of education, 2 had non university certificates or diplomas, and only 1 had a university education. Of these 5, 3 residents were chosen as case studies because they presented opportunities to explore different challenges [27-29]. Pseudonyms were used to ensure anonymity of participants.

Interview and Personal Data

Three interviews were conducted 2, 6, and 8 months after sensor installation. Interviews were recorded and transcribed. Relatives or friends were present at most interviews and contributed to the discussion. Relatives of case study participants were also interviewed separately.

Participants answered a brief questionnaire on preference for routinization using a shortened version of Reich & Zautra's scale [30] (Table 2). The shortened scale consisted of 8 context-relevant statements requiring a true or false answer (eg, "I do pretty much the same thing every day"). A percentage preference for routine was calculated based on the number of positive (preferred routine) responses to these statements.

Table 2. Preference for routinization and outings based on qualitative data and scores for routinization.

Pseudonym	Score[a]	Description	Activity	Regular outings		
				Family	Care facility	Community
Rupert	n/a[b]	Set daily routines that vary little from day to day	Fairly sedentary or cerebral	Low but regular	High	Low
Elizabeth	100%	Routine varies by day of week	Active or always busy	Med	Med	High
Jacqui	63%	Flexible daily routines that also vary by day of week. Travels a lot.	Very active or restless energy	High (daily)	Low	Low

[a]Shortened scale of 8 items [30].

[b]Only answered true to 1 of the 5 statements.

Results

Routines and Routinization Are Highly Individual

Although daily activities comprise many common elements such as eating and sleeping, the way in which activities are organized in time reflects the uniqueness of individual routines [31,32]. The 3 cases reflect very different routines. Rupert, a widower, has an unvarying and sedentary routine. He always has lunch at the residence restaurant (Monday to Saturday), he takes regular daily walks, and on Sundays, he goes to church and has lunch with his son's family. When at home, he spends most of his time in the lounge, watching informational programs. Elizabeth, a widowed housewife, is very busy but has a regular routine. Elizabeth attends bridge club 3 times a week. She also meets up with her daughter at least once a week. At home, she is very busy cooking and housekeeping. Rupert, who had a very regular routine, only answered 1 of the 8 items. He agreed to the statement "I generally stick to a certain scheduled once I have started it." Elizabeth scored 8 out of 8 (100%) on the preference for routinization scale [30] (Table 2).

Jacqui, a widow and former secretary, travels a lot and is frequently away from home for as many as 14 days at a time. She is also not often at home during the day, and her routine is irregular. She scored 5 out of 8 items (63%), indicating a low preference for routinization. Her grandson said: "she's got her routines but sometimes she just doesn't do them."

Sensor Data Match Self-Reported Routines

Results comparing routines constructed from sensor data closely matched resident's self-reported routines, as illustrated in Figure 1 and Figure 2. The congruency between sensor data and self-reported routines was apparent for all 3 residents, suggesting that data were accurate. In addition to matching the self-reported routines, further observations were possible from the radar plots. Elizabeth commented on being a restless sleeper, and this was confirmed by the bedroom motion sensor, especially between 3 am and 6 am and kettle use between 2 pm and 3 pm. Spikes in kettle use around 3:30pm suggested that on the days she was home, she had afternoon tea. However, without the context from self-reported routines, sensor data can be misinterpreted. Elizabeth's television power use suggested that she spent all day watching television, but her interview revealed that she had the television on all day for company as the voices gave her the feeling that "somebody's here with me." Even when watching television, she was generally knitting or crocheting. Self-reported routines personalized the information, giving a much richer insight into Elizabeth's life.

Figure 1. Elizabeth: Radar plot showing cumulative motion in bedroom by time of day (24/7 over 181 days) as indicated by the time of firing of motion sensors. Data is grouped by hour (±30 minutes).

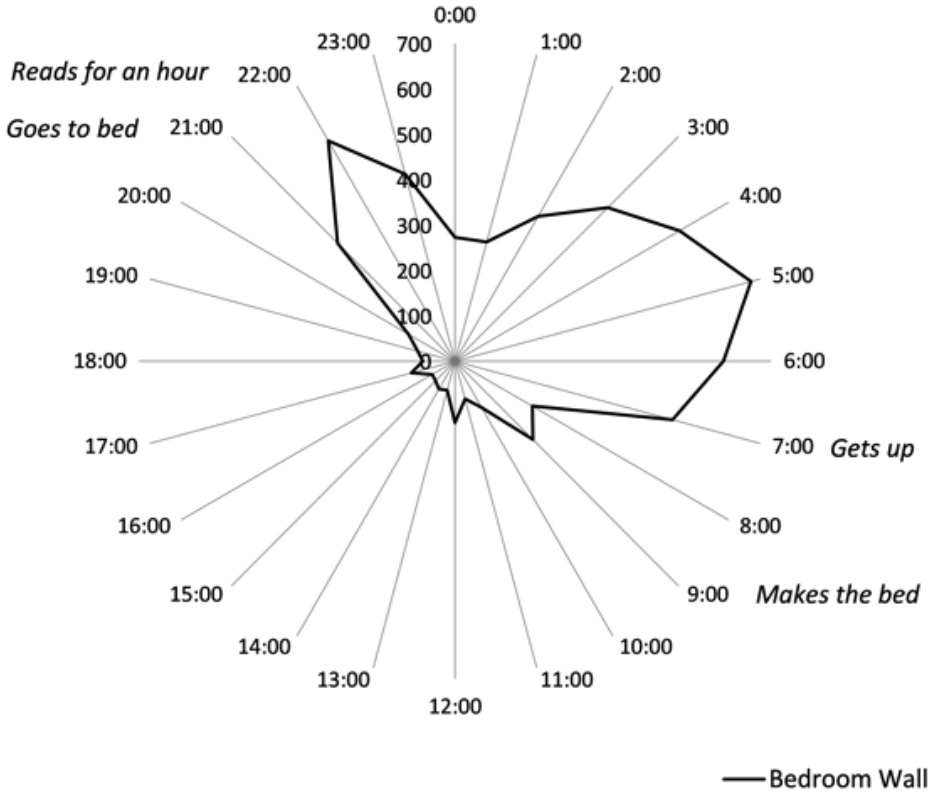
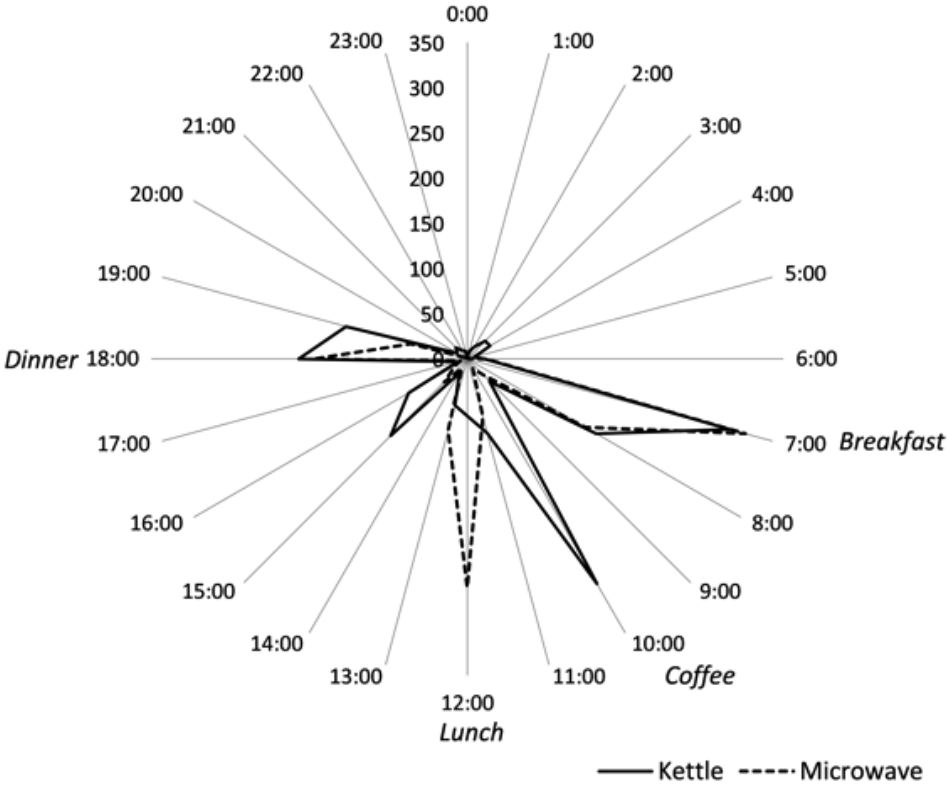


Figure 2. Elizabeth: Radar plot showing kitchen appliance power use (kettle solid line, microwave dotted line) by time of day based on cumulative frequency (24/7 over 181 days). Text in italics reflects the routine activity as per Elizabeth's self-reported routine.



Detecting Change in the Activities of Daily Living Routines

Times series data are traditionally analyzed by examining the component parts: cyclical, seasonal, trend, and irregular variations. In these data, cyclical variation shows as recurring weekly patterns by day of week. Seasonal variation in data includes annual recurrent patterns of temperature and timing of sunset and sunrise by time of year. Trend data is longitudinal change over time, which is important for the detection of slow-onset gradual decline in physical or cognitive abilities over and above cyclical and seasonal data. Finally, irregular variation can explain ad hoc disruption to routines such as illness or death of a spouse.

Cyclical: Understanding Cultural Patterns

Cyclical variation results from the organization of days of the week into work and rest days as well as the annual cycle of holidays. These cultural rhythms appear in the routines of the elderly as a continuation of past habits or indirectly through their contact with relatives. Jacqui's routine absences from home are dependent on the schedule of her relatives. The most direct impact of cultural rhythms on the elderly is the scheduling of community events such as church and bridge club.

Routine absence from home can be clearly identified on radar charts. Monday through Saturday, Rupert has lunch at the residential home restaurant. This regular absence from home is clear from Figures 3 and 4, which use a reverse scale to highlight absence of motion between 12 pm and 2 pm (Figure 3). On Sundays, however, he attends church and has lunch with his family. Figure 4 shows that he is away between 10 am and 3 pm. Understanding the individual's cyclical absences from home help explain variance in data and can reduce the occurrence of false-positive alarms by distinguishing absence from home, from absence of movement due to a fall or other acute medical incident. Knowing an individual's social routine also provides the opportunity to monitor routine activity outside the home using absence of movement.

Figure 3. Rupert: Radar plot using cumulative data to show absence of lounge movement Monday to Saturday. Absence is highlighted using a reverse scale such that no movement appears at the outer edge of the diagram and frequent movement appears at the centre.

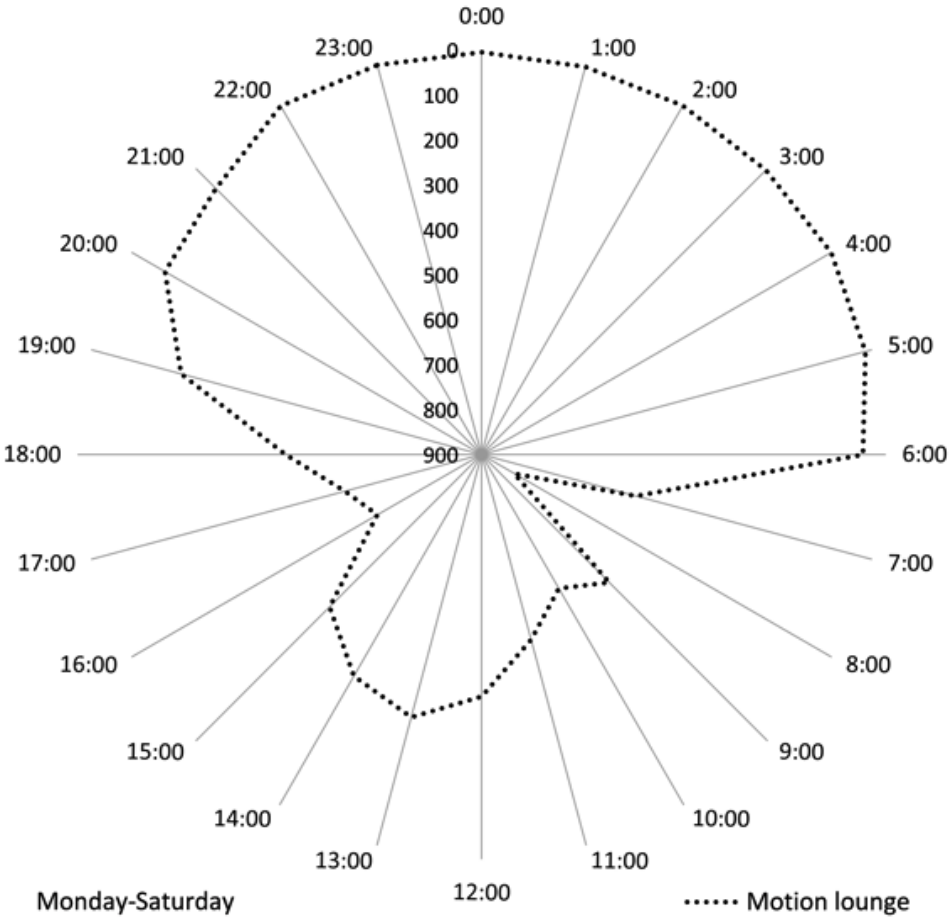
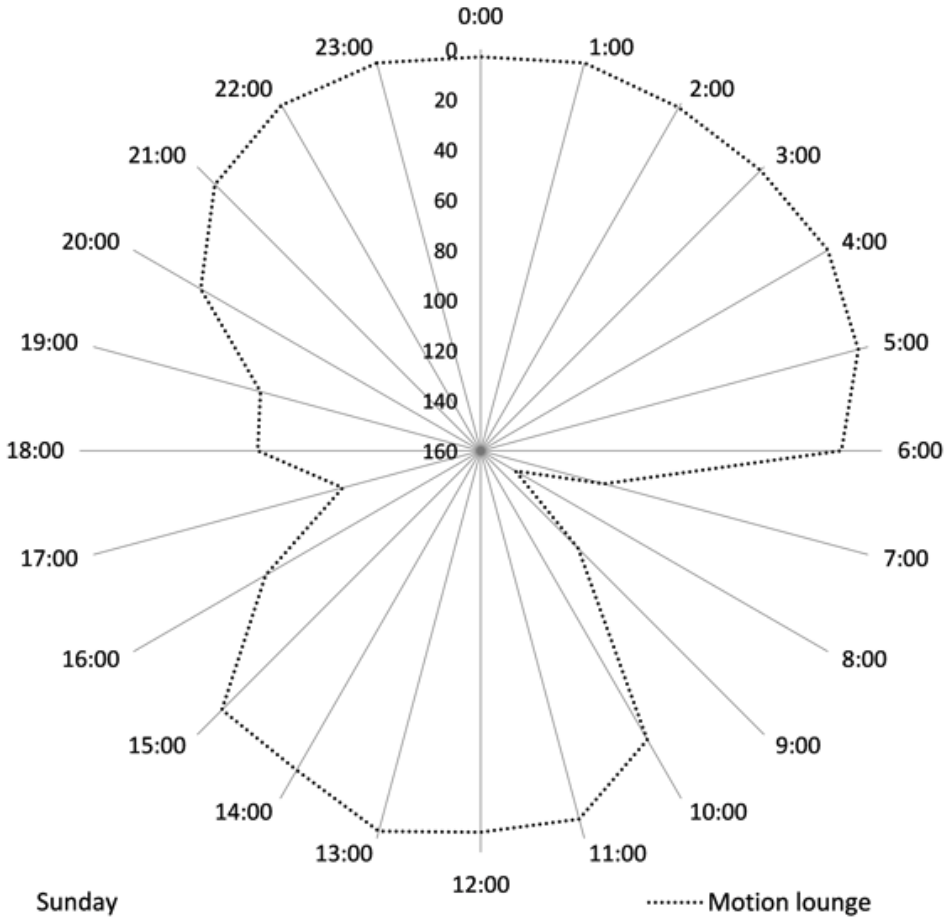


Figure 4. Rupert: Radar plot using cumulative data to show absence of lounge movement on Sundays. Absence is highlighted using a reverse scale such that no movement appears at the outer edge of the diagram and frequent movement appears at the centre.



Seasonal: Understanding the Impact of Weather and Daylight

Routines vary according to the seasons and weather. All residents spoke of changes to routines that were related to the temperature. For example, Elizabeth explained changes in hygiene practice:

> *(Shower time) can vary... in the winter time it will be before an evening meal... if you have your shower... just when the sun's going on down, the room is still a bit warm, because (the sun is) on that side of the house... If you leave it until nine o'clock on a frosty night, it's a lot colder in (the bathroom)... In the summer time I shower every day, but in the cold weather I get lazy and I think... I am not going out tomorrow I won't shower tonight.* [Elizabeth]

In winter, Elizabeth also dresses later in the day. As she stays in her warm dressing gown longer, she also has hot porridge rather than muesli for breakfast. Temperature also affects her level of activity. The results show changes in the frequency of motion associated with temperature. Independent-samples *t* test showed significant differences in movement by room on the coldest and hottest days [33]. Frequency of motion sensor firings in the bedroom was significantly lower on cold days (Mean 34, SD 7.34) compared with hot days (Mean 41, SD 10.72), where t_{92}= −3.6, *P*=.001) and similarly for the bathroom, cold (Mean 20, SD 12.88) compared with hot days (Mean 37, SD 25.39), where t_{92}) = −4.19, *P*=.001. There was no significant difference for the kitchen or the lounge; however, her lounge room is fitted with reverse-cycle air-conditioning.

Above average high or low temperatures can lead to temporary changes in routine. Interview data indicated that Jacqui and Rupert changed their walking routine on hot days, either forgoing walks or changing the time of day. Hot weather can also affect the amount of movement in the home. Elizabeth is more likely to take an afternoon nap: "No, I'm not one to sleep very much, but over the hot weather... I have gone to sleep twice."

Furthermore, the number of hours of daylight varies with seasons. Participants reported timing certain activities with sunset.

> *I mean, I – I walk regularly ... this time of the year I walk every evening just as the sun's going down, for 20 minutes... I go for the walk according to the sun. At the moment I'm going about a quarter past seven ... and then (in winter) it will get to the point where I'll go before dinner.* [Elizabeth]

Daylight savings also have to be accounted for in the data. In this study, because data showed clock time, motion and power use moved backward 1 hour as a result of the change. Clock shifts maintained scheduled activity at the same clock time, but

caused an artificial shift in the time of sunrise and sunset, which must be allowed for in interpreting data and establishing alarms.

These cyclical annual changes affect routines and, consequently, the interpretation of sensor data. Factoring in an understanding of changes in routines that vary annually based on weather and seasonality will further help reduce false positives.

Trend Components: Detecting Gradual Change

Analysis of trend data exposed a gradual change. Using linear regression, and controlling for changes in temperature based on daily maximum temperature, the results showed a deterioration in Rupert's sleep quality over the period of the trial. There was a significant increase in bedroom movement at night (beta =.059, P<.001) and a significant decrease in time between movements (beta = –3.692, P<.002). In parallel, Rupert's activity during the day, as measured by the number of movements in the lounge, significantly decreased (beta = –.65, P<.003) with no significant change in the time between movements (beta = 1.029, P=.27). In other words, Rupert was increasingly restless at night, tossing and turning more frequently and more lethargic during the day. Adding a notification alert for changes to longitudinal data can be used to trigger preventive action.

Irregular Variation: Detecting Acute Events

After cyclical and seasonal changes have been accounted for and preference for routinization and adherence to routine taken into account, irregular variance in data is most likely the result of unexpected events, including illness, acute medical events, and falls. For ad hoc alerts to be effective in early detection and intervention, they need to be reliable. Analysis of the data showed the effect of variability of routines and looked at ways to establish customized thresholds to reduce false alerts.

To set up effective ad hoc alerts based on changes to routines, 2 conditions need to be met: activities should occur at the same time every day (consistency of timing), and routines should be a regular daily occurrence (adherence to routine). Examination of the data in this sample revealed that motion sensor data was more diffuse in time and therefore less reliable than power use data. Residents' radar plots showed that kitchen power data and specifically breakfast power data were the most reliable, both in consistency of timing and in adherence to routine. Lunch and evening meals were less reliable indicators because residents reported regularly dining out as well as varying the time of evening meals according to what was on television. Knowing a person's routine provides valuable insight into understanding variance in data, and together with radar plot, choosing appropriate triggers for alerts; for example, Jacqui revealed that:

> *On the weekend ... I'll either have, bacon, eggs and ... during the week I usually have cereal, fruit, yoghurt, yeah and toast, always toast.* [Jacqui]

Figure 5 summarizes the consistency of key kitchen appliance use at breakfast time. Jacqui is very consistent in her kettle use (no outliers), but she reports having several cups of tea in the morning, which accounts for the spread of data (IQR 1H27M, SD 1H01M). In contrast, Rupert is extremely precise about the time of microwave use (IQR 0H19M, SD 0H13M), whereas Elizabeth's coffee at breakfast, while quite fixed in time, has considerable variability, as indicated by the outliers, because she uses the kettle both before and after breakfast (IQR 0H25M, SD 0H26M).

Routines used to trigger ad hoc alerts should also be a regular daily occurrence. Adherence to routine was calculated based on the number of days when key appliance sensors fired within ±30 minutes of the median time of use (Figure 5). To triangulate the data, kitchen motion sensor firings (breakfast time midpoint ± 1 hour) are also represented. Details for all 3 participants are summarized in Table 3. Rupert ate breakfast between 7:30 am and 7:45 am. He was the most consistent in his habits with very high scores on adherence to routine for both morning microwave use (94.8%, 148/156) and motion in the kitchen (98.2%, 170/173). Elizabeth had breakfast between 7:15 am and 7:45 am. She also scored high on adherence to routine for kitchen motion at breakfast time, but she did not always use her kettle at the same time of day, scoring only 82.2% (120/145) on adherence to this routine. Jacqui generally ate breakfast between 7 am and 7:30 am. Her breakfast routine is the most variable of the 3 residents. She was frequently away from home (47 out of 181 days), and her adherence to routine for "morning kettle use" is low (63%, 62/98), but her "motion in the kitchen" score for adherence to routine is higher (85.7%, 102/119). The data showed both the variation in practice for different routines and the relative reliability of routines for use as alerts.

Table 3. Adherence to breakfast routines.

Description	Jacqui		Rupert		Elizabeth	
	Kettle	Kitchen	Microwave	Kitchen	Kettle	Kitchen
Days absent	47[b]	45[b]	1	1	11	10
Days with data[a]	98	119	156	173	145	145
Days breakfast not taken	36	17	8	3	25	8
Total days with data	181	181	165[c]	177[c]	181	166
Adherence to schedule[d], n (%)	62 (63.2)	102 (85.7)	148 (94.8)	170 (98.3)	120 (82.8)	137 (94.5)

[a]± 0.5 hours of time of the median calculated on all power use between 5 am and 9 am .[b]50 days absent, but on 4 of the days, breakfast was prepared on day of departure.[c]Data missing because sensor not installed till after start date.

[d]Daily adherence to schedule based on median ± half an hour.

The case studies also show 2 examples of ad hoc events that can be clearly traced by changes to routine, illness, and death of spouse. Someone who is ill may stay in bed, stay seated for longer, and forgo regular meals. These changes are detectable with motion and power sensors. Additionally, self-reported information from residents or relatives can narrow down how residents respond to being unwell. Rupert's daughter-in-law, who has remote access to his daily movement data via a secure website, was able to identify when he was ill because of the reduced movement in the kitchen:

> *I look at the kitchen and I know when he's sick because it's down, the usage (motion data) ... And I know definitely when he's sick he doesn't cook for himself.* [Rupert's daughter-in-law]

The first example is an example of illness. On Wednesday and Thursday of Week 3, it appeared that Rupert was unwell. Rupert's normal routine for the same 2 days of the preceding week is shown in Figure 6. Week 3 (Figure 7) is considerably different. Rupert did not go up to the restaurant for lunch as normal, and on the Thursday, he did not use the microwave in the morning for breakfast. There were also different patterns of movement around the home on those 2 days. Movement in the kitchen and bedroom was considerably less than normal. Movement in the lounge was different in both the amount and the timing of movement. Movement in the lounge was considerably higher, the peak of movement in the lounge was later, unusually high, and more prolonged than usual. A possible explanation for this high level of movement in the lounge at that time is that perhaps his family and possibly a doctor had come to visit. A visual inspection of the routine data showed that although his routine had changed he was still moving about the house and spending most of his time in the lounge, which suggested that he was unwell but coping.

The second example is a more persistent change in daily routine. Elizabeth lost her spouse around the time the sensors were first installed. Traumatic events can result in a temporary loss of routine [34]. Therefore, monitoring return to normal can provide evidence of recovery from trauma. The data suggested that Elizabeth did not regularly attend bridge club (1 pm to 5 pm) in the first month following the death of her husband, but resumed her regular attendance around Month 2 (Figure 8). This indicated that with foreknowledge of routines, sensor data could be used to unobtrusively monitor changes to socialization through changes to normal routines.

The main challenges for using sensor data as ad hoc alerts are individual's preference for routinization, adherence to routine, and consistency in timing. Understanding these variations and the cyclical and seasonal variation in timing of routines is important in determining the thresholds for alerts. Having a two-sensor alert (power and motion) could be additional security against false positives and technical issues. Additionally, it is possible to calculate the longest time spent in the room such as the bathroom and the kitchen, rooms, that have very specific purpose, and to set up an alert when maximum length of stay is exceeded as another opportunity for cross-checking alerts related to change in routines.

Figure 5. Breakfast preparation activity by participant. Appliance power use frequency of firing by time between 5:00 and 9:00. Only the appliance that is most consistently used for breakfast is illustrated. Boxes show first to third interquartile range (IQR), with the line of separation indicating the median and the diamond the mean. Whiskers indicate the minimum and maximum and outliers are represented by asterisk for values that fall between 1.5 and 3 IQRs and circles represent outliers that fall outside the 3 IQR.

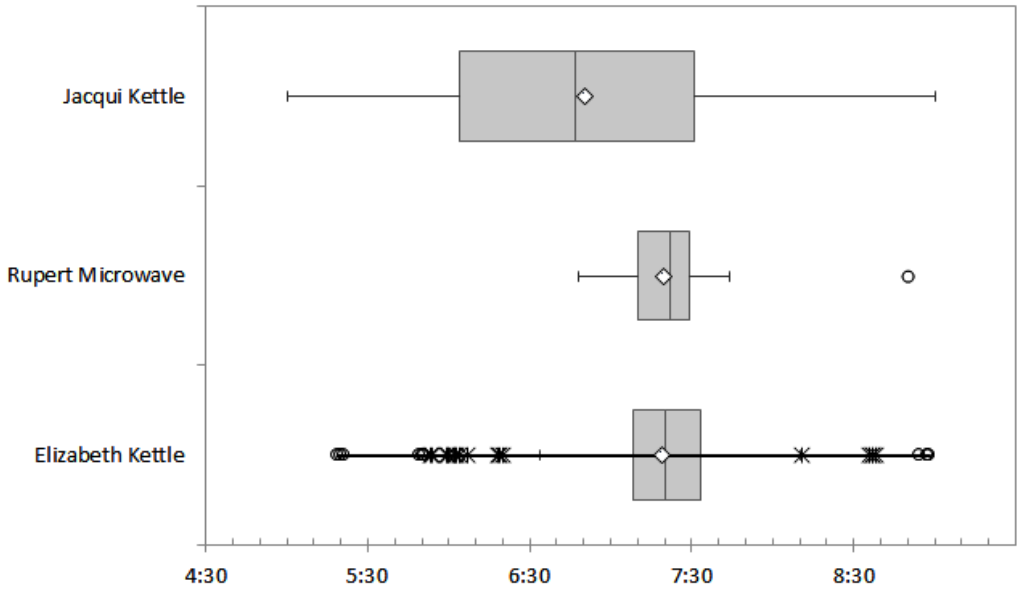


Figure 6. Rupert: Normal household movement Tue & Wed Week 3.

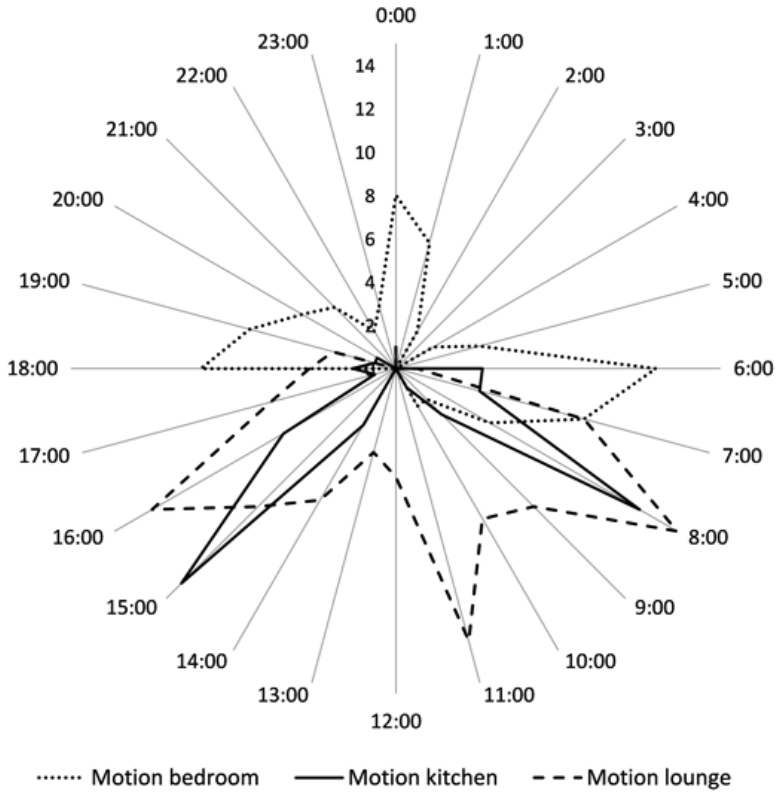


Figure 7. Rupert: Changes in motion due to (assumed) illness. Unusual houshold movement attributed to illness Tues & Wed Week 4.

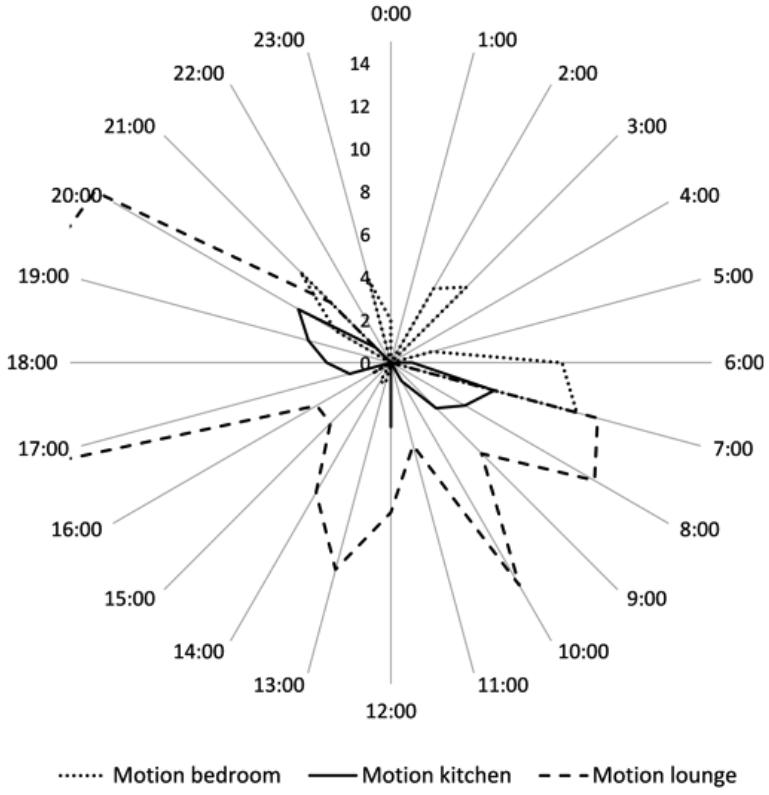
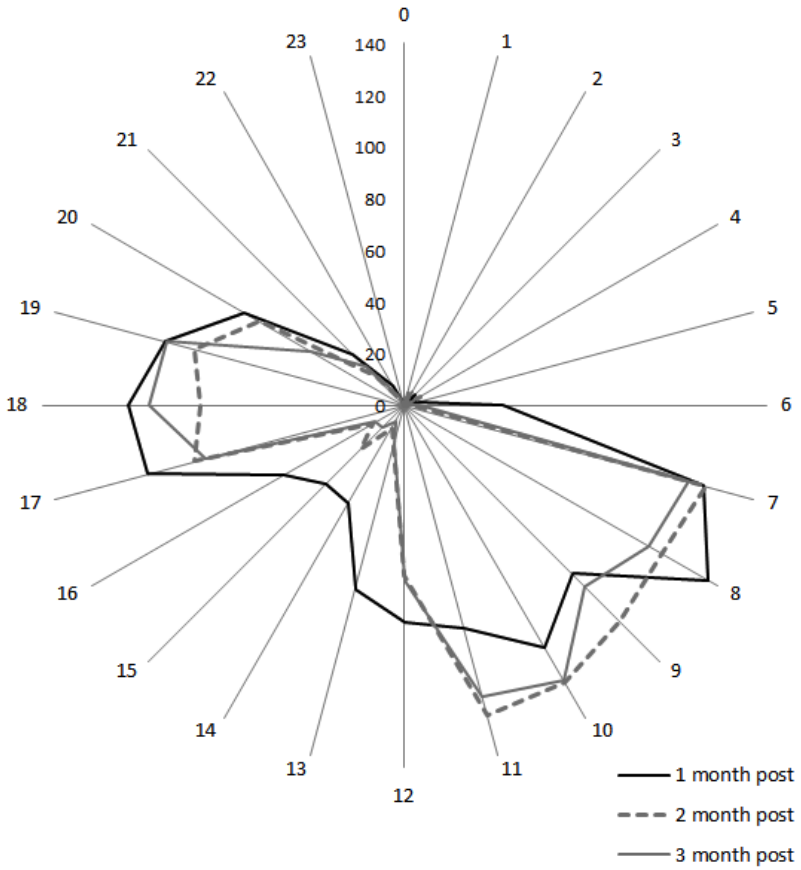


Figure 8. Elizabeth: Changes in lounge movements on bridge club days (Mondays, Thursdays, and Saturdays) 1, 2, and 3 months after the death of her husband showing a return to routine (resumption of bridge club) around Month 2.



Discussion

Principal Findings

This study demonstrated how a routine-based approach could help make sense of the large amounts of data from in-home sensors in such a way as to make the interpretation of data easy, intuitive, and transparent. The routine-based approach can be used to detect both change in sensor data and absence of sensor data for routines that take place outside the home, facilitating the use of alerts for both ad hoc events and gradual change over time. Importantly this study advances understanding of how sensor data can be used in real-world applications for real-time monitoring through an improved understanding of normal variation in routines and behavior (cyclical, seasonal) and a better understanding of the need for customized setups to allow for inter- and intraindividual differences in preference for routinization and in timing of and adherence to different routines. Overall these results support the use of in-home sensors as an extension of existing health care prevention approaches, one which, because of the 24/7 nature of the data, has the potential to facilitate aging in place.

This study builds on earlier work by Kaye et al [11] and others [35] and extends prior research by demonstrating through case studies, specific instances of how routines can be used to monitor the health and well-being of the elderly, and to identify factors that need to be controlled for to improve reliability of interpretation of sensor data for real-world applications.

Routines are an appropriate framework for understanding sensor data because they account for the cyclical nature of everyday living and because changes to routine, including the timing, are important in understanding both physical and psychological well-being [16,36-38]. Routines are particularly appropriate for monitoring the elderly because preference for routinization increases with aging [36,39]. The presentation of data in a 24-hour clock format is important because it includes timing of activities. It is not sufficient to have the skills or the ability to undertake the activities of daily living, but it is also necessary that they be organized into regular routines [14,15]. The 24-hour clock format also makes understanding and interpreting each day’s activity logical and intuitive.

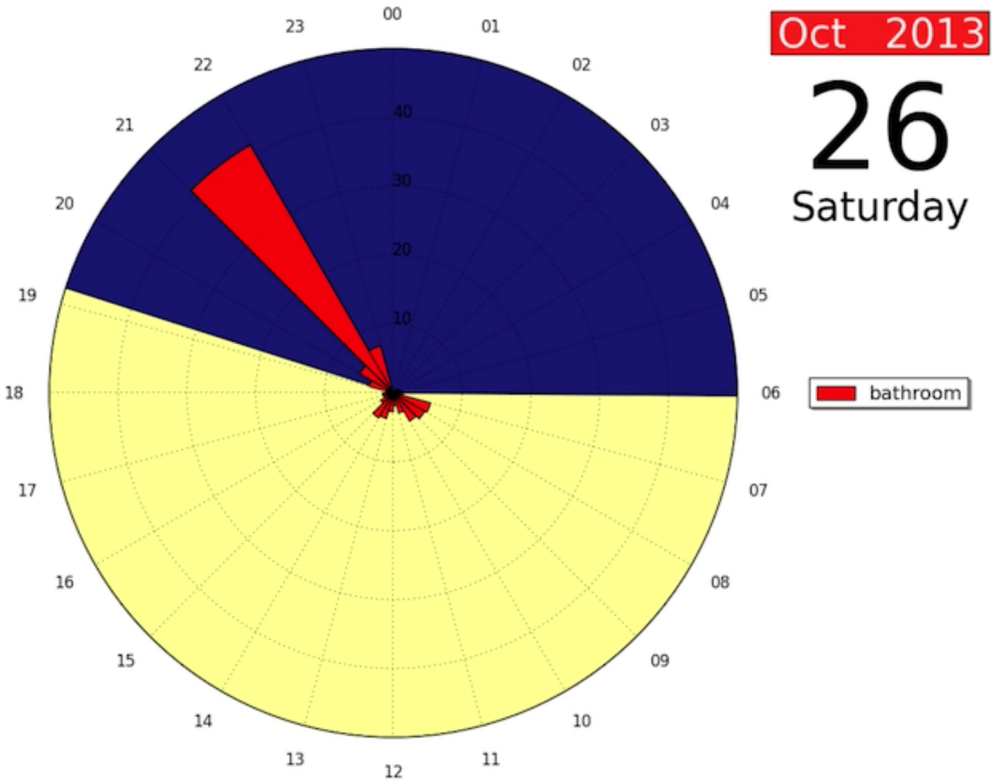
This research also reflected on the challenges of interpreting sensor data for the development of practical applications based on single-point comparisons. Viewing data as cyclical increases the reliability of single-point comparisons by facilitating comparisons of like for like, that is, comparing routines on any given day with the matching activities of the same day in previous weeks. Challenges for interpreting data include allowing for predictable and unpredictable events arising from the local context. First, cultural routines and seasonal change are contextual factors that shape activity over time. Allowance needs to be made for cultural routines such as weekends, holidays, religious practice, as well as seasonal changes of temperature and daylight [40,41]. Second, as noted by Ohta et al [6], the elderly are sensitive to changes in temperature [42]. By incorporating weather data into the system, it is possible to account for the unpredictable effects of precipitation and temperature on daily activity. Knowing, through interview, how temperature and precipitation affect a person's daily routines can further reduce false-positive alerts.

Importantly, prior knowledge of routines and variations in routine personalizes information that is otherwise just numbers. This is especially important if the sensor data are to be used by community services providers who can better know the individuals they care for through the everyday occupations and routines that give structure and meaning to life [31]. Knowledge of routines can be gathered by completion of a Web-based form at the time of installation of sensors, updated as needed, and used to annotate graphical presentation of data in the 24-hour polar charts. Furthermore, prior knowledge of routines makes it possible to rapidly establish ground truth of sensor data and accelerate the establishment of a personalized baseline against which changes in routine can be measured. Finally, only prior knowledge of routines can provide an understanding of activities outside the home and how they contribute to the well-being and quality of life, which could then be used to evaluate how time is apportioned to measure successful aging [43].

Future research should look at testing algorithms to monitor real-time daily activity using data from the same day of the week to allow for normal weekly variation in routine and, based on a 4- to 6-week moving window, to allow for changes in seasonal movement and activities. Daily weather data would need to be incorporated, such as profiles to allow for unseasonal above or below average temperatures as well as precipitation, to account for normal weather-based changes to routine. Data from different sensors should be correlated, for example, kitchen appliance use and motion in kitchen to detect battery failure or technical faults and minimize false alerts. Incorporating room layout and location of exits can additionally allow for interpretation of movement around the home. A two-level alert system, low and high, based on deviation from normal routine could be established. Alerts should be accompanied by a summary of the issues: routine versus actual and a time line of activities. Changes in behavior over time for comparable seasons can look for changing trends.

The user interface should display the 24-hour clock showing movement for key rooms (bedroom, kitchen, bathroom, lounge). Figure 9 shows an example of a user interface showing 24 hours of bathroom movement. An animated version showing 4 months of data can be found in Multimedia Appendix 1. For individuals whose routines differ from day to day, daily data need to be juxtaposed with comparable days of week in order to identify changes in routine. Users of the system should be allowed to adjust alert sensitivity to allow for variation in preference for routinization as well as variation between room use.

Figure 9. Screenshot of user interface showing daily bathroom movement over a period of 4 months using a 24-hour clock format.



Implications

In-home sensors may be able to facilitate aging in place and improve community health care services through the provision of alerts and notifications for early intervention as well as longitudinal health data for improved decision making. They could also potentially complement and reduce the direct costs of care in the community by facilitating routine monitoring. For smart homes to be a reality, it is important to strike a balance between the privacy and independence of the elderly and the effectiveness of monitoring systems. Furthermore, it is important that in-home monitoring provides data that allow carers and relatives to engage with and understand how these technological solutions can enhance care for the elderly, and that these systems are not viewed as a substitute for face-to-face health care, but as a means of improving the effectiveness of current interventions.

Limitations

Although research based on case studies is not generalizable, the results nonetheless provide rich insight into how routines can be used to monitor data in smart homes. There also are limits to the interpretation of data, especially from motion sensors. Most problematic is dual occupancy because sensors cannot distinguish between individuals, and neither can they separate out the activity of visitors to the home. However, new motion sensors under development may overcome this problem. Sensors cannot distinguish between types of motion. Therefore, matching specific daily activities such as getting dressed or doing daily exercises can only be inferred by time of day and room use. Equally because lack of motion could be due to absence from home or a fall, accurate and early fall detection is problematic for motion sensors [5,6,11]. However, new more sophisticated sensors can improve motion detection [44], and some, if not all, of these challenges can be overcome with the inclusion of additional sensors in the home, such as reed switches on doors and cupboards, GPS trackers on key rings, and through data mining or machine learning techniques from data science.

Concerns about ethics with respect to informed consent for technology-based research in the elderly remain problematic. There were some erroneous perceptions by residents who did not fully understand the technology, despite repeated explanations. This was mitigated by involving the relatives of residents in the process. However, it is imperative for smart homes pilots and installations for the elderly to continue to clearly communicate what the technology can do and what it cannot do, to better allay concerns and manage expectations.

Conclusions

This study demonstrated the usefulness of a routine-based approach for making sense of smart home data and furthered the understanding of the challenges that need to be addressed in order to make real-time monitoring a reality, through improved visualization of data and a better understanding of variation in routine, which could improve the effectiveness of alerts and notifications. Future research needs to explore larger longitudinal datasets to test the potential of routines for alerts in order to minimize false positives and negatives and still be able to deliver reliable alerts to the satisfaction of persons being monitored and their carers.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Animation showing 4 months of daily bathroom movement data on a 24-hour clock format.

[MP4 File (MP4 Video), 1MB - mhealth_v5i6e52_app1.mp4]

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Abbreviations

AEDT: Australian Eastern Daylight Time
AEST: Australian Eastern Standard Time
GMT: Greenwich Mean Time
KwH: Kilowatt hour

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Original Paper

A Community-Based Physical Activity Counselling Program for People With Knee Osteoarthritis: Feasibility and Preliminary Efficacy of the Track-OA Study

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Abstract

Background: Physical activity can improve health outcomes in people with knee osteoarthritis (OA); however, participation in physical activity is very low in this population.

Objective: The objective of our study was to assess the feasibility and preliminary efficacy of the use of wearables (Fitbit Flex) and telephone counselling by a physical therapist (PT) for improving physical activity in people with a physician-confirmed diagnosis of knee OA, or who have passed 2 validated criteria for early OA.

Methods: We conducted a community-based feasibility randomized controlled trial. The immediate group (n=17) received a brief education session by a physical therapist, a Fitbit Flex activity tracker, and a weekly telephone call for activity counselling with the physical therapist. The delayed group (n=17) received the same intervention 1 month later. All participants were assessed at baseline (T0), and the end of 1 month (T1) and 2 months (T2). Outcomes were (1) mean moderate to vigorous physical activity time, (2) mean time spent on sedentary behavior, (3) Knee Injury and Osteoarthritis Outcome Score (KOOS), and (4) Partners in Health Scale. Feasibility data were summarized with descriptive statistics. We used analysis of covariance to evaluate the effect of the group type on the outcome measures at T1 and T2, after adjusting for blocking and T0. We assessed planned contrasts of changes in outcome measures over measurement periods.

Results: We identified 46 eligible individuals; of those, 34 (74%) enrolled and no one dropped out. All but 1 participant adhered to the intervention protocol. We found a significant effect, with the immediate intervention group having improved in the moderate to vigorous physical activity time and in the Partners in Health Scale at T0 to T1 compared with the delayed intervention group. The planned contrast of the immediate intervention group at T0 to T1 versus the delayed group at T1 to T2 showed a significant effect in the sedentary time and the KOOS symptoms subscale, favoring the delayed group.

Conclusions: This study demonstrated the feasibility of a behavioral intervention, supported by the use of a wearable device, to promote physical activity among people with knee OA.

Trial Registration: ClinicalTrials.gov NCT02313506; https://clinicaltrials.gov/ct2/show/NCT02313506 (Archived by WebCite at http://www.webcitation.org/6r4P3Bub0)

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KEYWORDS

osteoarthritis; physical activity; sedentary behavior; sedentary lifestyle; wearables; digital technology; fitness trackers; exercise

Introduction

It is well known that physical activity can improve pain, mobility, and quality of life in people with knee osteoarthritis (OA) [1-4]. Being physically active is important in OA management partly due to its effect in managing weight [5-7]; however, participation in physical activity is very low in this population. A 2011 study using accelerometers found that over 90% of people with knee OA did not meet the physical activity guidelines of 150 minutes of moderate to vigorous physical activity (MVPA) per week [8]. A survey of 1713 people with knee or hip OA in Canada reported that fewer than half walked "one or more hours per week for exercise," even among people with mild symptoms [9]. The 2011 Canadian Community Health Survey also found that 57% of people with arthritis were physically inactive during their leisure time, compared with 46% of those without arthritis (Multimedia Appendix 1). These findings concur with a 2013 systematic review that found that only 13% of people with OA met physical activity guidelines [10].

The current public health message is that *being active is good*, but people with OA may have difficulties with MVPA due to pain [11-13]. In this situation, people can still benefit from maintaining a level of light activity. Studies have indicated that a sedentary lifestyle (ie, too much sitting) is a predictor of poor health outcomes [14-18]. The detrimental health effect of sitting too much is independent of the person's activity level. Interestingly, light activities, even done below the moderate-intensity level (eg, daily tasks done while standing or walking slowly), can provide health benefits [19-21]. Hence, there is a need for interventions to both improve the time spent in MVPA and decrease sitting time.

Nowadays, wearable devices are popular in the consumer space to support an active lifestyle. Evidence suggests they may also be beneficial in clinical populations. For example, Talbot et al [22] combined a pedometer-driven walking program with self-management education for people with knee OA and found an average increase of 23% in individuals' daily steps and of 21% in isometric quadriceps muscle strength, compared with an education only group [22]. A 2007 meta-analysis of 8 randomized controlled trials (RCTs) reported a significant difference in the improvement of physical activity among pedometer users compared with controls (mean difference 2491 steps/day, 95% CI 1098-3885) [23].

Compared with pedometers, wearable devices such as fitness bands and smart watches offer additional features, such as the ability to track the intensity of activities and to visualize activity performance over time. These features enable individuals to set specific goals, monitor progress, and obtain real-time feedback on goal attainment. Despite their popularity, the value of wearables to improve physical activity behavior has been challenged. In a review of 13 consumer wearables, Lyons et al [24] concludes that these devices usually include motivational techniques, such as self-monitoring and real-time feedback, but rarely address skills such as action planning and problem solving, which are essential to changing physical activity behavior. In a systematic review of 11 studies evaluating wearables (1272 participants), Lewis et al [25] found preliminary evidence of improvement in physical activity participation and body weight, but no difference when compared with other behavioral change interventions. Only 1 of the included studies was deemed to be of high quality. These results suggest that future research should develop better strategies to incorporate wearables in multifaceted physical activity interventions, rather than evaluating wearables as a standalone tool. Moreover, more rigorous research design should be employed in future RCTs. The purpose of our study was, therefore, to assess the feasibility of a strategy, which combines the use of wearables and telephone counselling by a physical therapist (PT), for improving physical activity behavior in people with knee OA. The results will inform the development of a community-based RCT.

Methods

Study Design and Participant Eligibility

The Track-OA feasibility study [26] used a randomized, delayed-control design, whereby the randomization determined the timing of when the intervention was provided (ie, immediately vs a 1-month delay). As such, preliminary efficacy could be assessed within a conventional RCT (ie, with an intervention group and a control group) at 1 month, while all participants received the intervention after 1 month. This study design is the best suited for complex interventions with components that are likely beneficial and present a low risk to participants (eg, promoting physical activity). By ensuring that all participants receive the intervention at the end of a study, this design might promote protocol compliance.

Eligible individuals were patients who had a physician-confirmed diagnosis of knee OA, or passed 2 criteria for early OA: (1) being age 50 years or older, and (2) having experienced pain or discomfort in or around the knee during the previous year lasting 28 or more separate or consecutive days. In a community-based study by Marra et al [27], 191 of 195 (98.0%) urban-dwelling participants who met these criteria also met the American College of Rheumatology clinical criteria for knee OA [28].

We excluded individuals who (1) had a diagnosis of inflammatory arthritis, connective tissue diseases, fibromyalgia, or gout, (2) had used disease-modifying antirheumatic drugs or gout medications, (3) had knee arthroplasty, (4) were on the waitlist to receive total knee arthroplasty, (5) had acute knee injury in the past 6 months, (6) did not have an email address or daily access to a personal computer with Internet access, (7) had a body mass index of 40 kg/m^2 or more, (8) had received a steroid injection in the last 6 months, (9) had received hyaluronate injection in a knee in the last 6 months, (10) were using medications that impaired activity tolerance (such as β-blockers), or (11) had an inappropriate level of risk for increasing their unsupervised physical activity. Potential participants completed the Physical Activity Readiness Questionnaire (PAR-Q; 2014 version) [29]. If the PAR-Q identified a potential risk, we required physician confirmation to ensure that the person was able to be physically active without the supervision of a health care professional.

We recruited participants from 3 sources: (1) postings on Facebook, Twitter, Kijiji, Craigslist, and the Arthritis Research Canada website, (2) emails sent by the Arthritis Consumer Experts (Vancouver, BC, Canada), a nonprofit patient education organization, to their patient members, and (3) emails sent by the Vancouver Coastal Health Research Institute (Vancouver, BC, Canada) to its staff. Interested individuals were invited to contact the research coordinator, who provided details about the study, screened respondents for eligibility, and obtained their informed consent.

After completing the baseline assessment, participants were randomly assigned to the immediate group or the delayed group in a 1:1 allocation ratio. The delayed group received the same intervention as the immediate group after a 1-month wait. Random numbers were generated in variable block sizes for the random allocation.

Intervention

The intervention involved participants attending a 1.5-hour session, where they received (1) a standardized group education session about physical activity, (2) a Fitbit Flex (Fitbit, Inc, San Francisco, CA, USA), and (3) individual weekly activity counselling with a PT by telephone. The education session, delivered in groups of 2 to 3 participants, addressed the benefits of physical activity, the detrimental effects of sedentary behavior, and ways to be active without aggravating OA symptoms. The counselling component followed the brief action planning approach [30], whereby the PT guided participants to identify their activity goals, develop an action plan, identify barriers and solutions, and then rate their confidence in executing the plan. The process was repeated until the confidence rating reached at least 7 out of 10, indicating that the person was confident about implementing the plan. For sedentary behavior, the PT began by asking participants to estimate their sitting time in a normal day and identify ways to break up the sitting time. They then repeated the goal setting and confidence assessment.

Participants were then provided a Fitbit to be worn at the wrist of the nondominant side to track their physical activity behavior. They were instructed to wear the fitness band 24 hours a day except during water-based activity or when charging the device. The data were wirelessly synchronized with Fitbit's online dashboard that could be viewed only by the participants and their study PTs. During the intervention period, the PT reviewed each individual's physical activity on the dashboard and progressively modified the activity goals during 4 weekly 20-minute telephone calls. Participants could also contact the PT via email. At the end of the intervention, they could keep the Fitbit, but no longer had access to the PT.

Feasibility Assessment

Guided by Bowen et al [31] and Thabane et al [32], the feasibility assessment focused on *implementation*, *practicality*, and *preliminary efficacy*. We measured implementation by the recruitment rate, dropout rate, adherence to the study protocol, and equipment retention. We aimed to achieve the following: (1) at least 80% of eligible individuals agreeing to participate, (2) no more than 10% dropping out, (3) at least 85% adhering to the intervention and assessment protocol, and (4) no more than 10% loss or malfunction of the 20 SenseWear accelerometer devices (BodyMedia, Pittsburgh, PA, USA) used in the study (for measuring the primary outcome; see below). We assessed practicality by self-reported adverse events and adherence to the assessment protocol. Specifically, participants were required to wear a SenseWear armband monitor for at least 20 hours during at least 4 of the 7 days of each evaluation period [33] and to complete all questionnaires within 7 days of the scheduled date. We assessed preliminary efficacy by examining outcome measures at baseline, and at the end of months 1 and 2.

Outcome Measures

The primary outcome was mean time spent in bouted MVPA per day. We defined a bout as at least 10 consecutive minutes at the level of at least 3 metabolic equivalent tasks (METs; ie, the lower bound of MVPA), with allowance for interruption of up to 2 minutes below the threshold [34]. Participants received a SenseWear Mini armband sensor by courier and wore it 24 hours a day for 7 consecutive days, with the exception of removal for water-based activities. Unlike Fitbit, which is a commercial activity tracker with important limitations in measurement accuracy [35], SenseWear is a research-based accelerometer and sensor with established measurement properties [36]. Tierney et al [37] showed that SenseWear is a valid tool for estimating energy expenditure during daily activities in people with arthritis (intraclass correlation coefficient 0.72). Additional analysis was performed with a cutoff at 4 or more METs, which reflects an activity level of brisk or faster walking (ie, purposeful activities) [38].

Secondary outcomes were the mean time spent in sedentary behavior, the Knee Injury and Osteoarthritis Outcome Score (KOOS) [39,40], and the Partners in Health Scale [41]. Compared with Fitbit, SenseWear is a superior outcome measure because of its ability to differentiate between sedentary and light activities [36]. We calculated the mean daily time spent with an energy expenditure of at least 1.5 METs, occurring in bouts of more than 20 minutes during waking hours [18,21,42,43]. The KOOS consists of 5 subscales: Pain, Symptoms, Activity of Daily Living, Sports and Recreation Function, and Knee-related Quality of Life. It was originally developed for people recovering from anterior cruciate ligament and meniscus injury and has been validated in people with OA [39,40]. The Partners in Health Scale is a 12-item measure designed to assess perceived self-management capacity via subjective knowledge of the health condition and treatment, and perceived self-management behavior (eg, adopting a healthy lifestyle) (Cronbach alpha=.82) [41]. We also tracked self-reported adverse events (falls, cardiovascular and musculoskeletal events) [44] using a monthly log completed by the participants.

Table 1. Baseline characteristics of immediate intervention and delayed intervention participants.

Characteristics	All (N=34)	Immediate intervention (n=17)	Delayed intervention (n=17)	*P* value[a]
Women, n (%)	28 (82)	14 (82)	14 (82)	N/A[b]
Age in years, mean (SD)	55.5 (8.6)	52.3 (9.7)	58.7 (6.0)	.03
Marital status, n (%)				.40
Married or common law	25 (74)	11 (65)	14 (82)	
Separated or divorced	5 (15)	4 (24)	1 (6)	
Widowed, never married, or other	4 (12)	2 (12)	2 (12)	
Gross annual household income in Can $, n (%)				.52
≤12,000	2 (6)	1 (6)	1 (6)	
12,001-24,000	1 (3)	0	1 (6)	
24,001-40,000	2 (6)	0	2 (12)	
40,001-60,000	5 (15)	4 (24)	1 (6)	
60,001-80,000	0	0	0	
80,001-100,000	3 (9)	2 (12)	1 (6)	
>100,000	14 (41)	7 (41)	7 (41)	
No answer	7 (21)	3 (18)	4 (24)	
OA[c] diagnosis, n (%)				.73
Yes	20 (59)	11 (65)	9 (53)	
No, but met the "likely OA" criteria	14 (41)	6 (35)	8 (47)	
"In general, would you say your health is…", n (%)				.15
Excellent	6 (18)	5 (29)	1 (6)	
Very good	11 (32)	5 (29)	6 (35)	
Good	13 (38)	4 (26)	9 (53)	
Fair	4 (12)	3 (18)	1 (6)	
Poor	0	0	0	
"Compared with 1 year ago, how would you rate your health in general now?", n (%)				.25
Much better	1 (3)	1 (6)	0	
Somewhat better	1 (3)	0	1 (6)	
About the same	27 (79)	15 (88)	12 (71)	
Somewhat worse	5 (15)	1 (6)	4 (24)	
Much worse	0	0	0	
Number of comorbid conditions, median (25th; 75th percentile)	2.5 (2.0; 4.0)	3.0 (2.0; 4.0)	2.0 (2.0; 3.0)	0.53
Body mass index in kg/m^2, mean (SD)	27.2 (4.7)	29.1 (4.5)	25.4 (4.2)	0.02

[a]*P* values were based on exact chi-square tests for categorical variables (nonmissing data), and 2-sample *t* tests for continuous variables.

[b]N/A: not applicable.

[c]OA: osteoarthritis.

Table 2. Feasibility assessment.

Feasibility component	Criteria	All participants (N=34)	Immediate group (n=17)	Delayed group (n=17)
Recruitment rate	≥80% of eligible individuals agreeing to participate	74% (34/46 eligible)	N/A[a]	N/A
Dropout rate	≤10% of participants dropping out	0%	0%	0%
Adherence to intervention and assessment protocol	≥85% participants adhering to the study protocol	88% (30/34 enrolled)	88% (15/17 enrolled)	88% (15/17 enrolled)
Loss or malfunction of SenseWear	≤10% SenseWear loss or malfunction	0%	0%	0%

[a]N/A: not applicable.

Sample Size and Data Analysis

With the resources available for the feasibility study, we aimed to recruit 30 participants within an 8-week period. We used descriptive statistics to summarize the feasibility variables and baseline variables of the 2 groups. We explored preliminary efficacy using intention-to-treat analysis. Q-Q plots were used to assess normality of the outcome variables. We conducted analysis of covariance to evaluate the effect of the group type (immediate vs delayed) on the outcome measures assessed at the end of 1 month (T1) and 2 months (T2), after adjusting for blocking and baseline (T0). We assessed 3 planned contrasts of changes in outcome measures over the measurement periods. The first contrast compared T0 to T1 between the 2 groups to determine whether the intervention was superior to the control. The second contrast compared T0 to T1 in the immediate group against T1 to T2 in the delayed group. The third contrast compared T0 to T1 in the immediate group against T0 to T2 in the delayed group. The last 2 models assessed whether the 1-month delay had an impact on the effect of the intervention.

We assessed the impact of missing data on the estimated effects of group assignment using imputation methods as described in van Buuren [45]. Specifically, we generated 10 imputed values using alternative random variates derived in a linear regression model, which included group, sex, baseline age, and baseline body mass index as predictors. We repeated the analyses using the 10 imputed values, and compared the conclusions and estimates against the main analysis, which assumed that data were missing at random.

Ethics Approval

The research protocol was approved by the University of British Columbia Clinical Research Ethics Board (application number: H14-02631), was registered with ClinicalTials.gov (NCT02313506), and has been published in the peer-reviewed literature [26].

Results

Between January and March, 2015 (7 weeks), 149 people expressed an interest to participate, and 46 met the eligibility criteria. Of those, 34 were enrolled and completed the study (Figure 1). The majority of participants were women (n=28, 82%), with the immediate group (mean age 52.3, SD 9.7 years; n=17) younger than the delayed group (mean 58.7, SD 6.0 years; n=17). A total of 20 participants (59%) reported a diagnosis of OA, and 14 (41%) met the "likely OA" criteria without a diagnosis. Among the participants, 17 rated their health as "very good" or "excellent." The mean body mass index was 27.2 (SD 4.7) kg/m^2, with the immediate group (mean 29.1, SD 4.5) higher than the delayed group (mean 25.4, SD 4.2) (Table 1).

Feasibility

Our recruitment strategy identified 46 eligible individuals; of those, 34 (74%) enrolled and none dropped out (Table 2). All but 1 participant adhered to the intervention protocol. All participants completed the assessments as per protocol at T0 and T1. Participants were required to wear a SenseWear (the primary outcome measure) for at least 4 days [46], with each day requiring less than 4 hours of off-body time to be included in the analyses. All 34 participants met these wear criteria at T0 (mean number of days worn: 5.9, SD 0.3; mean off-body time: 23.1, SD 13.6 minutes) and T1 (mean number of days worn: 5.6, SD 0.7; mean off-body time: 24.8, SD 18.0 minutes). At T2, 31 participants adhered to the wear criteria (mean number of days worn: 5.7, SD 0.6; mean off-body time: 38.4, SD 27.9 minutes). In the delayed group, 1 participant did not complete the outcome measures.

Preliminary Efficacy

Figure 2 shows the results of outcome measures from 3 time points. Prespecified contrast analyses revealed a significant effect whereby the immediate group improved in the MVPA (≥3 METs) time at T0 to T1 compared with the delayed group (contrast coefficient –31.1, 95% CI –56.6 to –5.7; *P*=.02) (Table 3). We also found a significant effect in the Partners in Health Scale scores at T0 to T1 (contrast coefficient 10.9, 95% CI 2.5-19.3; *P*=.02). The planned contrast of the immediate group at T0 to T1 versus the delayed group at T1 to T2 showed a significant effect in sedentary time (contrast coefficient –83.6, 95% CI –154.1 to –13.1; *P*=.03) and the KOOS symptoms subscale (contrast coefficient 6.9, 95% CI 0.4-13.5; *P*=.048), favoring the delayed group at T1 to T2. We found no significant effect in any outcome measures in the contrasts comparing the immediate group at T0 to T1 with delayed group at T0 to T2.

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart. IQR: interquartile range.

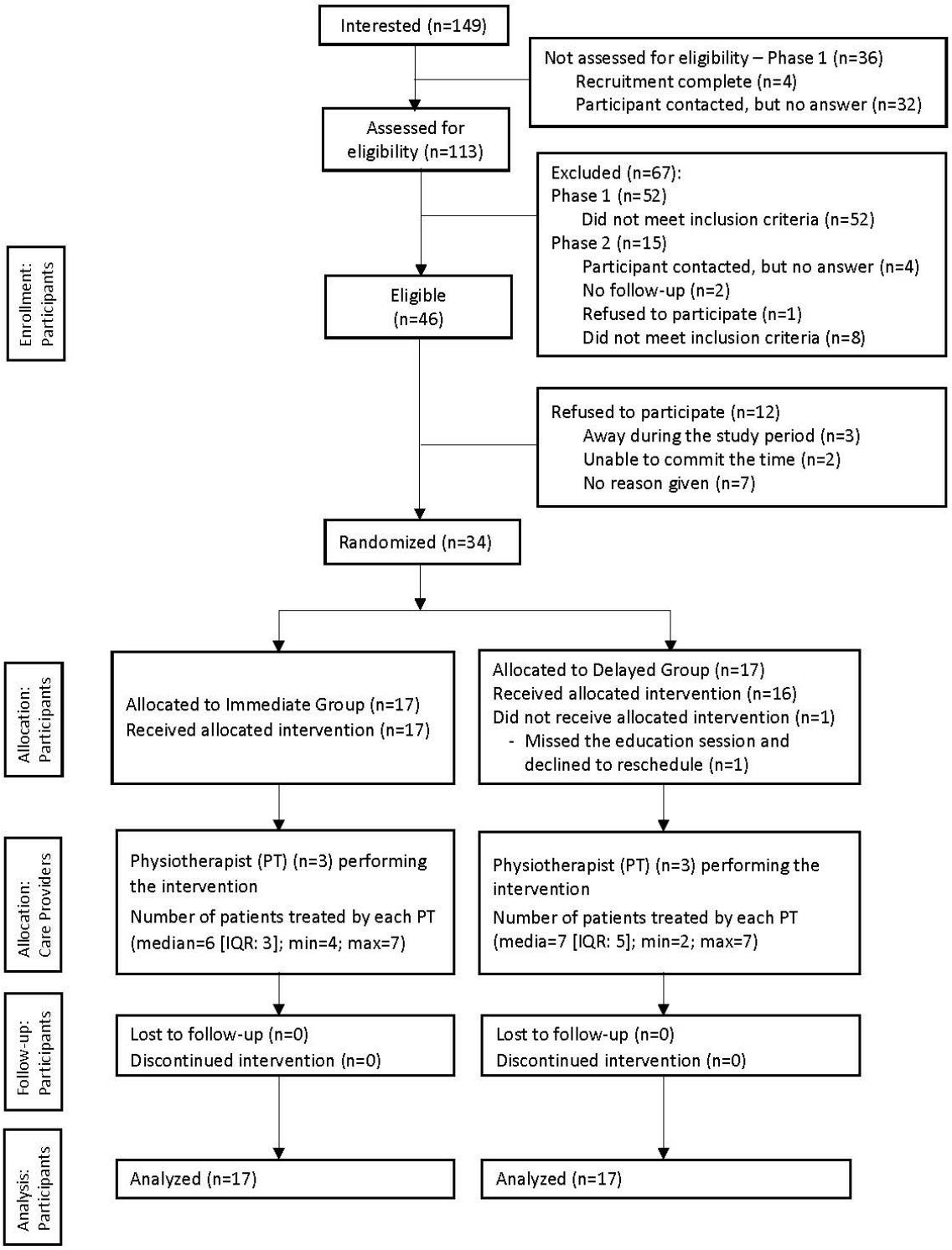

Figure 2. Results of outcome measures. (A) Bouted moderate to vigorous physical activity (≥3 metabolic equivalent tasks [METs]). (B) Bouted moderate to vigorous physical activity (≥4 METs). (C) Bouted sedentary time. (D) Knee Injury and Osteoarthritis Outcome Score (KOOS) symptoms subscale. (E) KOOS pain subscale. (F) KOOS activities of daily living subscale. (G) KOOS sports and recreation subscale. (H) KOOS quality of life subscale. (I) Partners in Health Scale.

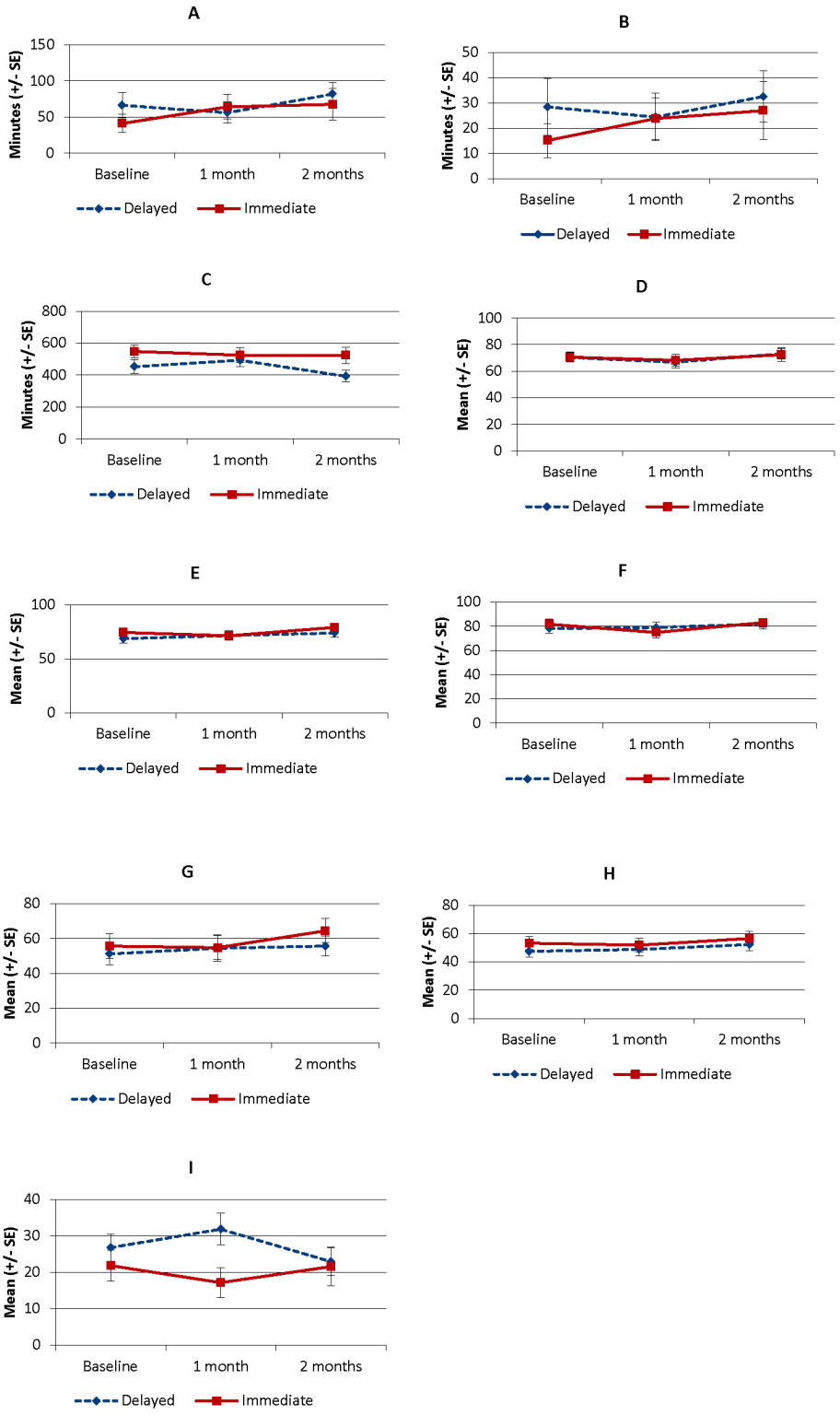

Table 3. Participant outcomes and results of contrast analyses.

Outcomes	Immediate intervention (n=17)			Delayed intervention (n=17)			Adjusted group effect immediate intervention vs delayed intervention coefficient (95% CI)[a]		
	Baseline	1 month	2 months	Baseline	1 month	2 months	Contrast 1	Contrast 2	Contrast 3
Daily bouted MVPA[b]: ≥3 METs[c] (minutes), mean (SD)	41.3 (51.6)	64.2 (70.5)	67.7 (85.8)	66.5 (71.0)	56.0 (60.1)	81.9 (64.4)	–31.1 (–56.6 to –5.7)	4.6 (–19.6 to 28.9)	–11.0 (–31.1 to 9.1)
Daily bouted MVPA: ≥4 METs (minutes), mean (SD)	15.1 (27.9)	23.8 (34.0)	27.0 (44.6)	28.4 (46.3)	24.5 (39.0)	32.6 (40.5)	–10.5 (–23.4 to 2.4)	1.2 (–9.6 to 12.0)	–4.7 (–12.0 to 2.6)
Daily bouted sedentary time[d] (minutes), mean (SD)	548.4 (169.1)	524.9 (192.1)	523.9 (200.2)	453.3 (180.5)	492.8 (164.8)	393.1 (144.2)	51.4 (–18.4 to 121.3)	–83.6 (–154.1 to –13.1)	–46.3 (–109.0 to 16.4)
Knee Injury and Osteoarthritis Outcome Score[e] subscales, mean (SD)									
Symptoms	70.6 (15.8)	68.3 (18.4)	72.5 (20.2)	70.4 (14.9)	66.8 (18.2)	73.2 (15.4)	–1.3 (–7.5 to 5.0)	6.9 (0.4 to 13.5)	3.8 (–3.9 to 11.4)
Pain	74.5 (16.2)	71.4 (17.5)	79.1 (13.0)	68.6 (16.1)	71.6 (15.2)	74.0 (15.4)	3.9 (–4.9 to 12.6)	3.4 (–4.3 to 11.1)	5.0 (–3.8 to 13.8)
Activities of daily living	81.8 (17.1)	75.1 (19.7)	83.0 (14.9)	78.3 (15.9)	79.1 (18.9)	82.2 (17.1)	7.2 (–1.4 to 15.8)	7.8 (–1.2 to 16.9)	8.4 (–0.8 to 17.6)
Sport and recreation function	55.6 (29.5)	54.7 (28.3)	64.4 (28.4)	51.2 (26.0)	54.4 (31.4)	55.6 (22.6)	3.6 (–8.2 to 15.4)	–0.5 (–11.0 to 10.0)	3.2 (–7.9 to 14.4)
Knee-related quality of life	53.3 (18.4)	51.8 (19.5)	56.6 (20.2)	47.4 (16.1)	48.9 (19.3)	52.3 (18.0)	2.6 (–5.0 to 10.3)	3.7 (–3.0 to 10.4)	5.5 (–2.0 to 13.0)
Partners in Health[f], mean (SD)	21.9 (17.6)	17.2 (17.0)	21.6 (21.9)	26.8 (15.3)	31.9 (17.9)	22.9 (15.2)	10.9 (2.5 to 19.3)	–0.3 (–10.3 to 9.7)	1.9 (–6.0 to 9.8)

[a]Outcome and baseline times are as follows: contrast 1: immediate intervention T0 to T1 vs delayed intervention T0 to– T1; contrast 2: immediate intervention T0 to T1 vs delayed intervention T1 to T2; contrast 3: immediate intervention T0 to T1 vs delayed intervention T0 to T2. Contrast models were adjusted for block sizes and baseline outcome measure.

[b]MVPA: moderate to vigorous physical activity, performed in bouts ≥10 minutes.

[c]METs: metabolic equivalent tasks.

[d]Sedentary behavior was performed in bouts >20 minutes.

[e]Scores range from 0 to 100, with higher being better.

[f]Scores range from 0 to 96, with lower being better.

Results from the imputation analysis (data not shown) were in line with the main missing-at-random analysis, in estimates, standard errors, and *P* values of group effects. This suggests that the presence of missing data did not have an important effect on the findings. No adverse event associated with the intervention was reported by participants during the study.

Discussion

This study demonstrated the feasibility of a behavioral intervention, supported by the use of a wearable device, to promote physical activity. While our strategy yielded a recruitment rate below the goal of 80%, we exceeded the target in participant and equipment retention in a community-based study. Since our eligibility criteria were in line with other physical activity intervention studies involving people with knee OA [4], we will use the same eligibility criteria and plan sufficient time for participant recruitment in the future RCT. Furthermore, with 88% of participants adhering to the study protocol and no adverse events reported, we have shown that the intervention and study protocol can be delivered within the resource constraints.

Our results have also demonstrated preliminary efficacy of the physical activity counselling program, with the immediate group showing a trend of improvement in MVPA (≥3 METs) and the Partners in Health Scale compared with the delayed group at T0 to T1. Also, changes in MVPA appeared to be similar in both groups after they received the intervention. These findings are in line with previous studies on physical activity interventions, which generally result in short-term improvement (within 6 months) [4].

Results on sedentary behavior, however, were unexpected. While there was no noticeable effect at T0 to T1 between the 2 groups on these outcome measures, the intervention appeared to have a more favorable effect in the delayed group (T1 to T2) than in the immediate group (T0 to T1). One plausible explanation may be due to the counselling protocol. Although the program had separated physical activity and sedentary behavior into 2 counselling conversations, our approach might

be more suitable for motivating people to be active than for encouraging them to sit less. We instructed the PTs to begin by asking participants about what they did to achieve the desired behavior (ie, being more active and sitting less) in a normal day. While this approach was logical for participants to set goals about their preferred physical activities, it might be less intuitive to think of ways to reduce sitting time, especially for those who had a sedentary occupation (eg, office workers or long-distance truck drivers). For them, focusing on what to do to reduce sitting highlighted the reality that participants had little control over this behavior, and therefore it might be challenging for them to set achievable goals. Similar issues have been raised by several recent systematic reviews on interventions to change activity behavior [47-49]. They concluded that, although programs targeting physical activity or combined activity and sedentary behavior are effective at improving physical activity participation, only the ones that are designed to change sedentary behavior achieve the best results in reducing sitting time. Given the challenge, it was possible that our study PTs needed time to practice and become comfortable with the sedentary counselling protocol. This might have contributed to the trend of improvement among participants who received the intervention later in the study. In light of the findings, we have refined the sedentary behavior counselling protocol with the study PTs and provided training sessions. The revised PT training protocol has been applied to 3 ongoing RCTs that are examining the efficacy of the program for patients with knee OA, rheumatoid arthritis, and systematic lupus erythematosus (ClinicalTrial.gov identifiers: NCT02315664; NCT02585323; NCT02554474). The first 2 registration numbers are for OA studies and the last number is for a study in people with rheumatoid arthritis and systemic lupus erythematosus.

Our result in the KOOS symptoms subscale was similar, with a significant difference found between the immediate group at T0 to T1 and the delayed group at T1 to T2. The reason for this is unclear, but it should be viewed in the context of the lack of a significant difference in other KOOS subscales, which are also associated with symptom severity. It should be noted that we did not adjust the analysis for multiple comparisons; hence, we cannot rule out the possibly that the results were due to chance.

This study has several limitations. First, we did not assess the full spectrum of feasibility. Although the study has identified strengths and areas of improvement for the intervention, we did not address *demand* (ie, intent to use) and *acceptability* (ie, intent to continue use and satisfaction) by people with arthritis [31]. Second, our sample was relatively active as indicated by the high bouted MVPA (≥3 METs) minutes at baseline. Since patients who are inactive are more likely to need active intervention, improvement in our recruitment strategy is needed to ensure that we reach this population in the full RCTs. Finally, 82% of participants were women. Since men and women may respond to behavioral interventions differently, additional efforts are required to enroll men in order to permit analyses to examine the effect of sex on the behavioral and disease-related outcomes.

These limitations notwithstanding, in the Track-OA study we have developed a physical activity counselling program that is practical and can be implemented in a full RCT. We have also demonstrated that it is feasible to use an objective physical activity measure (ie, SenseWear) for data collection in the community. The results have contributed to refining the counselling protocol, the recruitment strategy, and the timeline for a series of studies to evaluate the efficacy of this program.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Arthritis by physical activity. Data from Government of Canada, generated from: http://66.240.150.17:9600/PHAC/readPPReports.jsp?l=en&folder=iDE8F756E1ED845419EE7457066BB23D5.

[PDF File (Adobe PDF File), 64KB - mhealth_v5i6e86_app1.pdf]

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Abbreviations

KOOS: Knee Injury and Osteoarthritis Outcome Score
METs: metabolic equivalent tasks
MVPA: moderate to vigorous physical activity
OA: osteoarthritis
PAR-Q: Physical Activity Readiness Questionnaire
PT: physical therapist
RCT: randomized controlled trial

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Original Paper

Mobile Device Accuracy for Step Counting Across Age Groups

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Abstract

Background: Only one in five American meets the physical activity recommendations of the Department of Health and Human Services. The proliferation of wearable devices and smartphones for physical activity tracking has led to an increasing number of interventions designed to facilitate regular physical activity, in particular to address the obesity epidemic, but also for cardiovascular disease patients, cancer survivors, and older adults. However, the inconsistent findings pertaining to the accuracy of wearable devices for step counting needs to be addressed, as well as factors known to affect gait (and thus potentially impact accuracy) such as age, body mass index (BMI), or leading arm.

Objective: We aim to assess the accuracy of recent mobile devices for counting steps, across three different age groups.

Methods: We recruited 60 participants in three age groups: 18-39 years, 40-64 years, and 65-84 years, who completed two separate 1000 step walks on a treadmill at a self-selected speed between 2 and 3 miles per hour. We tested two smartphones attached on each side of the waist, and five wrist-based devices worn on both wrists (2 devices on one wrist and 3 devices on the other), as well as the Actigraph wGT3X-BT, and swapped sides between each walk. All devices were swapped dominant-to-nondominant side and vice-versa between the two 1000 step walks. The number of steps was recorded with a tally counter. Age, sex, height, weight, and dominant hand were self-reported by each participant.

Results: Among the 60 participants, 36 were female (60%) and 54 were right-handed (90%). Median age was 53 years (min=19, max=83), median BMI was 24.1 (min=18.4, max=39.6). There was no significant difference in left- and right-hand step counts by device. Our analyses show that the Fitbit Surge significantly undercounted steps across all age groups. Samsung Gear S2 significantly undercounted steps only for participants among the 40-64 year age group. Finally, the Nexus 6P significantly undercounted steps for the group ranging from 65-84 years.

Conclusions: Our analysis shows that apart from the Fitbit Surge, most of the recent mobile devices we tested do not overcount or undercount steps in the 18-39-year-old age group, however some devices undercount steps in older age groups. This finding suggests that accuracy in step counting may be an issue with some popular wearable devices, and that age may be a factor in undercounting. These results are particularly important for clinical interventions using such devices and other activity trackers, in particular to balance energy requirements with energy expenditure in the context of a weight loss intervention program.

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KEYWORDS

mobile; devices; physical activity; weight reduction; adults

Introduction

Obesity is a major health concern in the United States, with estimates of overweight or obese Americans >20 years old ranging between 68.5-75.3% [1,2]. Despite efforts to curb the obesity epidemic, its prevalence remains high [1-3]. Moreover, only 1 in 5 Americans meet the physical activity recommendations set forth by the Centers for Disease Control (CDC) of at least 150 minutes of moderate-intensity activity (defined as approximately 3-6 metabolic equivalents of task [METs]) or 75 minutes of vigorous-intensity exercise (>6 METs) per week [4]. The ubiquitous nature of mobile devices, including smartphones and wearable devices, makes them potentially useful to increase physical activity levels, and improve adherence to exercise programs. According to the Pew Research Center, approximately 80% of Americans own a smartphone [5]. Additionally, the landscape for wearable technology has changed drastically over the past 5 years, with nearly 400 devices commercially available [6] and over 127 million wearable devices sold in North America alone in 2016 [7]. Between 2013 and 2018, the wearable device market is expected to grow ten-fold, from under US $2 billion dollars to US $19 billion dollars [7]. The wide adoption of wearable technology in the United States offers unique ways to track behavior, and possibly to intervene effectively and efficiently to help users or patients adopt a healthy lifestyle.

There is mounting evidence that mobile health strategies and wearable devices could improve health behavior interventions, in particular for chronic conditions across the socioeconomic gradient [8-11] and across age groups [12]. Although it is not clear whether smartphone apps and wearable devices are effective for weight loss [13] or physical activity prescription [14,15], these devices may still be useful to increase physical activity participation levels, and thus could potentially improve quality of life regardless of weight loss outcomes [16-19]. Nonetheless, and despite technological advancements, it is still unclear how accurate recent smartphones and wearable devices are with respect to activity tracking, and what factors affect accuracy. For instance, Case et al [20] show that a convenient sample of wearable devices and smartphone apps are accurately counting steps, albeit in a young population sample (mean age 28.1 years, standard deviation [SD] 6.2). Wen et al [21] showed that step counting is also accurate in a small sample (5) but that activity duration, energy expenditure, and sleep patterns are not adequately captured by current devices. Recently Kroll et al [22] also showed that heart rate may not be accurately measured by wrist-worn devices, in particular if the user is not in sinus rhythm. The devices of interest do not measure step count directly, but do so by using tri-axial accelerometer data collected at the wrist or at the waist [23], and use proprietary algorithms to infer step count. Moreover, these algorithms assume a normal gait, which is not affected by pathologies or loss of lower limb strength. Therefore, where a device is worn (such as wrist or waist, dominant hand or nondominant hand) could affect step counts. Preliminary work suggests that devices measuring at the wrist tend to undercount steps in a laboratory setting compared to waist-based devices, but that in free-living conditions, the trend is reversed [24]. Additionally, at low speeds, accelerometers on commercial wearable devices may not be precise enough to accurately count steps [23], for instance for post-stroke patients who may need to wear wrist-based devices at the ankle [25], or for older users. Older patients exhibit loss of muscular strength, which can affect gait patterns [26-28], and consequently may lead to mobile devices either overcounting or undercounting steps in this specific population.

The discrepancies between such studies suggest that it is useful to assess what potential variables affect step count. It is not known whether user characteristics such as weight, height, gender, or age affect the accuracy of step counting for such tools. Age is a particularly interesting variable, given the evidence on gait changes among older adults [26,27], variations in accelerometry data in older adults [28], as well as the additional walking need of older adults [29-32]. Moreover, height, weight, and dominant hand are also variables of interest since the devices considered in this study do not count steps directly; rather, they infer step counts based on internal accelerometer data at the wrist or at the waist. Walking 10,000 steps per day is a widely recommended goal to meet the current guidelines of the CDC [33-35], even though it may fall short in terms of energy expenditure and health benefits [36]. Smartphones and wearable devices are both commonly used technologies to monitor and track physical activity, and could possibly help users adhere to a healthy lifestyle [37], so it is critical to properly assess the step counting accuracy of such commonly used devices, with a particular focus on age groups.

The purpose of this paper is to address this gap in the current literature for a representative set of five wrist-worn devices (Apple Watch, Samsung Gear S2, Garmin 735XT, Garmin Vivofit, Fitbit Surge), two smartphones (iPhone 6s Plus, Nexus 6P) and the research-grade ActiGraph wGT3X-BT. This selection was made to reflect the two most common mobile operating systems (OSs; namely Android and iOS), the range of price points, and the most commonly purchased device brands (Fitbit, Garmin) available on the market. To this effect, we model and assess the accuracy of recent smartphones and wearable devices across three age groups.

Methods

Device Selection

As of 2016, there are an estimated 394 wearable devices from 266 companies that are capable of activity tracking [6], not including smartphones or smartphone apps, with a majority of these devices being worn at the wrist. We selected a representative sample of the most recent wrist-based devices (2015 and later) and smartphones that counted steps without the need of an additional foot pod (small accelerometer device that can be affixed to shoe laces). Since foot pods measure walking or running cadence directly, they are typically more accurate than devices measuring at the wrist or at the hip. Most current devices can communicate with a foot pod using Bluetooth or Bluetooth Low Energy and thus can have greater accuracy. However, foot pods can be burdensome for the user. Therefore, we restricted this study to wrist-worn devices and smartphones (hip measurement). Additionally, we selected devices to reflect the most popular brands on the market (Garmin

and Fitbit), as well as the various price points of such tools, ranging from under US $100 (Garmin Vivofit) to over US $400 (Garmin 735XT). Two mobile OSs currently share over 98% of the mobile OS market, with Android comprising over 80% of sales (multiple brands, multiple models) between 2009 and 2016, and Apple's iPhone (multiple models) representing an additional 18% [38,39]. Consequently, we added both leading mobile OS's newest devices (ie, the Android Huawei-manufactured Google Nexus 6P and the iPhone 6S Plus). Both devices include step counting capabilities. We also included the smart-watches of the leading mobile OSs (ie, the Apple Watch 2 for iOS, and the Samsung Gear S2 for Android). Finally, we included ActiGraph's wGT3X-BT as a research-grade wearable device for physical activity. We decided to refrain from incorporating physical activity mobile apps in the study since the counts are intrinsically linked to each device's internal step counter, and therefore it would be difficult to disentangle the measurements from the devices and measurements from the apps, especially given the proprietary black-box nature of such systems. Moreover, with over 165,000 apps for health and fitness alone [40], this approach fell beyond the scope of this study, but rather within the scope of an app evaluation [14,15].

Participant Recruitment

After receiving approval from the University of Florida Institutional Review Board (IRB201601145), we recruited participants using flyers that were disseminated across campus. Twenty participants were recruited in each of the following age groups: 18-39 years, 40-64 years, and 65-84 years, for a total of 60 participants. Subjects were recruited among people without a contraindication to exercise, and who were able to walk comfortably on a treadmill for 20 minutes at a speed between 2 and 3 miles per hour.

Research Procedures and Data Collection

The purpose and the protocol of the study were explained to participants, who were then consented by the study team (AL, MDS). Each participant received a US $10 gift card for participating in the study, and were instructed that they would be asked to do two walks of 1000 steps on a treadmill, at a self-selected speed between 2 and 3 miles per hour. Participants were instructed that the treadmill would be started at 2 miles per hour, upon which they would start walking without holding onto the treadmill, and steps would be recorded. The speed was progressively increased to an acceptable level by the study team (AL, MDS), as instructed by the participant. After consent, participants self-reported sex, age, height, weight, and dominant hand. In the first 1000-step walk, the Fitbit Surge, Garmin Vivofit, and Apple Watch were attached to the right wrist of the participants, and the Samsung Gear S2 and Garmin 735XT were attached to the left wrist. This choice was dictated by the width of each device. The iPhone 6S Plus was attached to the right hip with a belt clip, and the Nexus 6P was affixed to the left hip. Devices were then swapped right to left and vice versa in the second 1000-step walk. The Actigraph wGT3X-BT was kept centered at the back of the waist during both walks. The number of steps were tallied with a manual tally counter by one of the team members (AL, MDS). The number of steps for each device was recorded at the end of each walk. Additionally, the Apple Watch and the Samsung Gear S2 were not synchronized to their respective smartphones (iPhone 6S Plus and the Nexus 6P) to ensure reliability of the data.

Statistical Methods

We computed summary statistics for the participants' characteristics. To estimate the counted steps from each device while controlling for correlated observations and covariates, we fitted a repeated measures mixed-effects model, in which the participant was the independent sampling unit. The outcome of the model was steps counted by the devices (ie, the smartphones, the actigraph, or the wrist-based devices); the distribution of this outcome was not skewed. The predictor variables in the full model included age, sex, body mass index (BMI), dominant hand, device, age-by-variable interactions, and device-by-variable interactions. Age-by-variable interactions included age-by-sex, age-by-BMI, age-by-dominant hand, and age-by-device. Similarly, device-by-variable interactions included device-by-sex, device-by-BMI, and device-by-dominant hand. The order of the predictors was fixed in the order listed above. An unstructured covariance model was assumed, which accounted for unequal variance across devices. We used a backwards selection strategy [41] for the full model in every cell. Predictor variables were removed by considering added-last tests (based on Cronbach alpha=0.05) until we arrived at the reduced, final model. We then computed estimated steps and confidence intervals for each device from the final model.

In the model, age was categorized as: 18-39 years old, 40-64 years old, and 65-84 years old. Our preliminary analysis revealed that there was no significant difference in left- and right-hand step counts for each device. Therefore, we averaged the measurements obtained from the two walks for each participant-by-device for modeling. In addition, we set a cutoff of 250 steps as a likely point of device failure (less than 1 out of every 4 steps counted). All step outcomes less than 250 were excluded from the model. We chose to use BMI as a predictor in place of height and weight, as these two variables were highly correlated and would introduce collinearity to the model. We conducted all analyses using SAS 9.4 (SAS Institute, Cary, NC).

Results

We summarized the characteristics of the study participants in Table 1. The age of our study participants ranged between 19 and 83 years, with an average of 49.5 (SD 19.4). Overall, 60% (36/60) of the study participants were female. This percentage is the highest in the 65-84 year old group, in which 73.7% (14/19) of the participants were female. Overall, 90% (54/60) of the study participants were right-handed. The BMI of the study participants ranged between 18.4 and 39.6, with an average of 25.2 (SD 4.6). The BMI was lowest in the 18-39 year old group with a mean of 23.0, and highest in the 65-84 year old group, with a mean of 27.0.

Table 1. Participant characteristics. One BMI observation was missing.

Characteristics	Total (N=60)	Age 18-39 (n=21)	Age 40-64 (n=20)	Age 65-84 (n=19)
Age, mean (SD)	49.5 (19.4)	26.2 (5.1)	53.7 (7.0)	70.9 (4.3)
Sex, n (%)				
Female	36 (60.0)	11 (52.4)	11 (55.0)	14 (73.7)
Male	24 (40.0)	10 (47.6)	9 (45.0)	5 (26.3)
Dominant hand, n (%)				
Right	54 (90.0)	20 (95.2)	19 (95.0)	15 (79.0)
Left	6 (10.0)	1 (4.8)	1 (5.0)	4 (21.0)
BMI, mean (SD)	25.2 (4.6)	23.0 (2.7)	25.7 (4.6)	27.0 (5.4)

Table 2. Steps by device by age group (averaged across two measurements).

Device	Age					
	18-39 (n=21)		40-64 (n=20)		65-84 (n=19)	
	Mean	SD	Mean	SD	Mean	SD
Actigraph	1003.9	6.3	986.1	44.4	995.0	43.4
Apple Watch	964.9	59.0	970.9	38.4	1015.9	118.8
Fitbit Surge	959.7	57.6	943.9	81.5	945.6	85.5
Garmin 735XT	987.8	37.9	994.0	29.4	978.7	38.2
Garmin Vivofit	994.5	11.5	992.3	22.6	953.5	170.3
iPhone 6S Plus	1021.2	186.4	1035.0	129.6	1018.0	56.9
Nexus 6P	997.1	41.3	988.3	26.1	900.9	158.3
Samsung Gear S2	988.0	16.0	959.4	84.2	969.1	47.9

Table 3. Final reduced model type 3 fixed effects.

Effect	Numerator Degrees of Freedom	Denominator Degrees of Freedom	F value	*P*-value
Age group	2	55.8	0.79	0.4599
Sex	1	48	0.05	0.8164
BMI	1	47	2.30	0.1358
Dominant hand	1	54.4	2.10	0.1532
Device	7	49.5	3.56	0.0036
Age group x device	14	76.3	2.00	0.0287

Table 4. Predicted means of steps for each device by age (adjusted for BMI, dominant hand, and sex).

Device	Age 18-39	Age 40-64	Age 65-84
Actigraph, mean (CI)	1008.7 (989.2, 1028.2)	997.2 (976.8, 1017.6)	1002.7(984.4, 1021.1)
Apple Watch, mean (CI)	970.2 (934.4, 1006.0)	980.1 (942.9, 1017.4)	1023.6 (987.0, 1060.2)
Fitbit Surge, mean (CI)	965.0 (930.0, 999.9)	950.8 (913.7, 988.0)	953.3 (917.5, 989.0)
Garmin 735XT, mean (CI)	993.9 (973.5, 1014.4)	1003.3 (983.5, 1023.2)	986.4 (967.7, 1005.0)
Garmin Vivofit, mean (CI)	999.8 (956.3, 1043.4)	1002.9 (957.4, 1048.3)	961.2 (916.3, 1006.2)
iPhone 6S Plus, mean (CI)	1026.5 (964.7, 1088.2)	1045.1 (980.4, 1109.8)	1025.7 (961.4, 1090.1)
Nexus 6P, mean (CI)	1002.4 (956.2, 1048.6)	981.8 (932.8, 1030.9)	908.6 (860.7, 956.4)
Samsung Gear S2, mean (CI)	993.3 (966.6, 1020.1)	966.7 (939.2, 994.3)	976.8 (950.1, 1003.6)

We summarized the step counting characteristics of the study devices in Table 2.

We summarized the results from the mixed-effects models in Table 3 and Table 4. In the final model, we identified one significant interaction after backwards selection: age-by-device (P=0.030; Table 3). The other interactions, including the device-by-BMI interaction, were not significant and therefore removed from the final model. Device was also a significant predictor of step count (P=0.004; Table 3).

Based on the final model, we produced model-based estimates of the steps counted by each device stratified by age group (Table 4). We considered undercounting as devices with counts that differed from 1000 in a statistically significantly fashion, with predicted means under the 1000 step target. Similarly, overcounting was considered a statistically significant count over 1000. The estimated steps from the Actigraph, Apple Watch, Garmin 735XT, Garmin Vivofit, and iPhone 6S Plus were not significantly different from 1000, across the age groups. Conversely, the Fitbit Surge consistently significantly undercounted steps. The estimated steps from Fitbit Surge for the 40-64 and 65-84 year old groups were 950.8 (95% CI 913.7-988.0) and 953.3 (95% CI 917.5-989.0) respectively, which were significantly lower than the targeted 1000 steps.

The steps counted by the Fitbit Surge for the 18-39 age group were 965.0 (95% CI 930.0-999.9), which is much closer, but still significantly lower than 1000. In addition, the Nexus 6P undercounted steps in the 65-84 year old group, with an estimated count of 908.6 steps (95% CI 860.7, 956.4). The Samsung Gear S2 undercounted steps in the 40-64 year old group, with an estimated count of 966.7 steps (95% CI 939.2, 994.3). However, the same device did not significantly undercount steps for the older age group, with an estimated count of 976.0 steps (95% CI 950.1, 1003.6).

Discussion

Principal Findings

The ubiquity of smartphones and other wearable devices, and their various physical activity tracking functionalities, have led to an increasing reliance on such devices as tools for participation in exercise programs. Such functionalities include step tracking, global positioning system functions (eg, distance, pace, elevation, map), heart-rate monitoring (either wrist-based, or with a chest strap), or calorie expenditure. Although some evidence suggests that step-counting is accurate for some wrist-worn devices and smartphone apps [20,21], this is not consistent across all walking speeds, in particular lower speeds [23], or whether devices are worn at the wrist or waist [24]. Given the proprietary nature of algorithms inferring step counts from tri-axial accelerometer data, it was important to identify variables that potential impact the step count accuracy of such devices, in particular age, height, weight, and dominant or nondominant hand.

Our study indicates that height, weight, BMI, and dominant hand do not seem to impact the accuracy of step-counting devices. Conversely, our results suggest that the Fitbit Surge undercounted steps for all age groups, the Nexus 6P underestimated step counts for the 65-84 year old group, and the Samsung Gear S2 underestimated step counts for the 40-64 year old age group, but not the older age group (Table 4). Our hypothesis is that subtle gait changes and slower walking among older populations could explain why some devices tend to undercount steps in these groups. This theory is consistent with the findings of Fortune et al [23] linking walking speed and accuracy. Therefore, device manufacturers should ensure that algorithms inferring step counts from tri-axial accelerometer data be updated to account for such subtle changes. However, the Samsung Gear S2 only underreported step counts in the middle age group. This result is somewhat surprising, as we would anticipate that the devices underestimating step counts would perform worse in the older age group than in the middle group, if the main factor affecting count was gait changes associated to aging. A possible explanation is that the level of conditioning could be a confounding factor in our study, as strength and endurance training affect gait in older age groups [31]. Indeed, lack of strength in older adults is associated with gait changes [26-28]; this explanation also remains consistent with the findings in Fortune et al [23]. Therefore, additional work is needed when controlling for physical fitness levels. Additionally, unlike Tudor-Locke et al [24], we did not observe significant differences in step counting between waist- and wrist-based devices. Although Case et al [20] report good accuracy for their devices, their population sample was significantly younger, and their convenient device selection did not intersect with ours. Moreover, in previous studies [20,23,24] all devices used were at least 2 years old; the difference observed could be explained by technological and/or algorithmic changes in the devices used. Finally, Wen et al [21] reported that step counting for their choice of devices is accurate. However, the sample size of participants in that study was significantly smaller, and their study focused on longitudinal consistency (eg, internal validity of devices) rather than comparison between devices.

A major strength of this study is that, to the best of our knowledge, it is the first that evaluates the impact of age, BMI, and dominant hand on the accuracy of the newer generation of wearable devices and smartphones with respect to step counting. Although BMI and dominant hand do not appear to impact the ability of devices to estimate step counts, age does affect estimates of step counts for some devices. Therefore, additional work needs to be done to evaluate the impact of wrist patterns and gait on the accuracy of step counting, and explore what other potential factors influence the results. Nonetheless, from a physical activity program adherence and weight loss perspective, one could argue that since less accurate devices tend to underestimate step counts, they should still be recommended for tracking steps, and could lead to additional exercise.

Limitations

A potential weakness of the study is that we tested step counting in idealized conditions, indoor, on a treadmill. In real-world conditions, especially difficult terrain, we may see far more variation in step counts, given the changes in gait and wrist movements. Additionally, it is not uncommon to see different

gaits between normal walking conditions versus walking on a treadmill.

Conclusion

Over the past 5 years, wearable devices, smartphones, and apps have become more ubiquitous, and have become widely recommended tools of behavioral change for weight loss by the general press, the health and fitness industry, and health care providers. In this study, we evaluated the accuracy of a selection of recently available wearable wrist-worn devices and smartphones with respect to step counting, as well as the impact of several variables of interest, most notably age. Our final reduced model after backward selection shows that BMI, height, weight, and dominant hand do not seem to impact the accuracy of step count. However, age does affect accuracy, and some devices tend to underestimate the number of steps walked by older users of wearable devices. This finding may be a minor issue for people trying to lose weight by adhering to a 10,000-step walking program, as they may walk more than planned. However, older and/or slower participants focusing on increasing physical activity may be negatively affected, and may struggle mentally if they fall short of 10,000 steps. What is not clear yet is whether current levels of physical fitness and activity impact the accuracy of such devices; this warrants further investigation.

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Authors' Contributions

FM was responsible for the conception of the study, data collection, and editing of the manuscript. YG was responsible for the study design, data collection and analysis, and writing and editing of the manuscript. JB was responsible for the writing and editing of the manuscript. MJG was responsible for the analysis, writing, and editing of the manuscript. AP was responsible for the analysis, writing, and editing of the manuscript. MDS and AML were responsible for data collection. TWB was responsible for the conception of the study, and writing and editing of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
CDC: Centers for Disease Control
MET: metabolic equivalent of task
OS: operating system
SD: standard deviation

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Letter to the Editor

Response to “Development and Validation of the User Version of the Mobile Application Rating Scale (uMARS)”

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KEYWORDS

mobile apps; mhealth; app quality

We read with interest the article, “Development and Validation of the User Version of the Mobile Application Rating Scale (uMARS)," by Dr Stoyanov et al [1]. The authors report on the development and validation of the user version of the Mobile Application Rating Scale (uMARS). If applied appropriately, this scale has the potential to improve the quality and standardization of reporting, and assist in the progress of the scientific evidence base in mHealth research. The uMARS is based on the original ‘expert’ Mobile Application Rating scale (MARS), which consists of items identified from a literature search of web and mobile application (app) quality rating criteria, and that were tested for reliability using 60 wellbeing apps from the iTunes store [2]. The authors report on how the MARS was adapted into the uMARS for lay users by simplifying items and removing those that require professional or content expertise. Both scales are similar in structure, and include objective quality subscales: engagement, functionality, aesthetics and information quality, as well as a subjective quality subscale.

A reliable measure of app quality for end-users is urgently needed as health apps continue to proliferate without rigorous evaluation [3]. Although there have been notable attempts to measure the quality of mHealth apps, there is as yet no widely accepted standardized method for end-users [4-6]. This limits the ability to identify and scale-up successful apps, thereby limiting the population impact of mHealth [3,7].

While there is no doubt that the development of the MARS and uMARS represent significant progress towards greater consistency and transparency in mHealth, we would argue that it would be further strengthened by both a clear conceptual definition of app quality as well as a theoretical framework for testing app quality. To that end, we propose considering how the perception of app quality differs between experts (health professionals, researchers, app developers) and lay/end-users. For example, a health professional assesses the quality of a health app in order to identify apps to recommend to their patients. On the other hand, an end-user will assess the quality of a health app with the intent to use it. Indeed, evidence suggests that health professionals consider clinical effectiveness of mHealth apps to be most important, whereas consumers are looking for a seamless user experience, reduced data entry burden, and integration with their health care experience [8,9]. An important implication of these differences is that the simple adaptation of ‘expert’ items of the MARS may not accurately and adequately reflect the ‘end-user’ perspective on app quality. More research is needed to understand how expert and end-user

perspectives on app quality differ in terms of their expectations, needs, preferences and attitudes.

Secondly, the authors have used current literature to inform the development of the MARS and the uMARS. However, because the field is in its infancy, the development of an mHealth quality scale cannot rely solely on this inductive approach as there is much we do not know about how mHealth apps are accessed and evaluated by users. We suggest that the authors examine the substantial body of theoretical research on usability and engagement with technology to improve the comprehensiveness of the uMARS.

We also recommend more research on how the perception of quality varies with respect to these technologies, especially from the user perspective. For example, there are clear distinctions between the functionality, programmability, interactivity and features of internet-based interventions and mobile apps. While web-based interventions imply that a user accesses information via the Internet from any connected device, mHealth involves a complex relationship between a user and their portable, personal mobile device [10]. Additionally, mobile apps offer greater functionality, personalisation and real-time interactivity. Thus, although there are many similarities between web and mobile app interventions, more research is needed to inform how effectively items describing the quality of a web based intervention translate into items measuring mobile app quality.

Finally, the MARS and uMARS are relatively new advances in mHealth, and to date the MARS has been applied to the review of a handful of apps, including mindfulness apps [11], heart failure symptom monitoring apps, self-care management apps [12], and weight management apps [13]. Although there is an urgent need for consistent and transparent evaluation and reporting of app quality, especially from the user perspective, much more research is needed to validate the uMARS before it can be widely adopted and included into standardised mHealth reporting guidelines such as mERA and CONSORT-EHEALTH [14,15]. Further reducing the length and complexity of the response options of the uMARS will make it easier for researchers and others to apply the scale in their research.

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Conflicts of Interest

None declared.

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