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Contents

Viewpoint

Toward an Ethically Founded Framework for the Use of Mobile Phone Call Detail Records in Health Research

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Abstract

Data derived from the plethora of networked digital devices hold great potential for public benefit. Among these, mobile phone call detail records (CDRs) present novel opportunities for research and are being used in a variety of health geography studies. Research suggests that the public is amenable to the use of anonymized CDRs for research; however, further work is needed to show that such data can be used appropriately. This study works toward an ethically founded data governance framework with social acceptability. Using a multifaceted approach, this study draws upon data governance arrangements in published health research using CDRs, with a consideration of public views and the public's information expectations from mobile network operators, and data use scenarios of CDRs in health research. The findings were considered against a backdrop of legislative and regulatory requirements. CDRs can be used at various levels of data and geographic granularity and may be integrated with additional, publicly available or restricted datasets. As such, there may be a significant risk of identity disclosure, which must be mitigated with proportionate control measures. An indicative relative risk of the disclosure model is proposed to aid this process. Subsequently, a set of recommendations is presented, including the need for greater transparency, accountability, and incorporation of public views for social acceptability. This study addresses the need for greater clarity and consistency in data governance for CDRs in health research. While recognizing the need to protect commercial interests, we propose that these recommendations be used to contribute toward an ethically founded practical framework to promote the safe, socially acceptable use of CDR data for public benefit. This pattern needs to be repeated for the appropriate use of new and emerging data types from other networking devices and the wider internet of things.

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KEYWORDS

mobile phone data; ethical framework

Introduction

Background

The number of mobile connections, including the internet of things (IoT), already exceeds the world population and is rapidly approaching 9 billion [1]. It is difficult to find an adequate adjective to represent the magnitude of data being generated as we go about our daily lives. This number will only increase with further technological developments and major investments. Apart from smartphones, advances in smart homes, smart cities, and autonomous vehicles; immersive technologies such as virtual and augmented reality; and wider applications of artificial intelligence are all increasing in permeation [2]. Data derived from our use of the plethora of increasingly connected digital devices hold great potential for public benefit as well as for generating massive income and contributing to economic growth. There is much debate over the definition of public benefit. We define it here as work having real-world value or practical application, with the clear potential to improve the life of individuals or wider society [3]. With such rapidly developing technologies and their societal impact, it is imperative that

principles are in place for proper data governance, and such principles are lagging behind the advancing pace [2]. In a seminal paper, Letouzé and colleagues observed the need for mobile phone data, when they noted the absence of a clear holistic ethical and regulatory framework to guide research using call detail records (CDRs) [4].

CDRs are generated passively each time a mobile phone user connects to a mobile network, either by voice call or text message. CDRs are collected irrespective of whether the user has a standard mobile phone or a smartphone that functions as a small personal computer with internet access, social media connectivity, apps, games, etc. The record includes the starting time of the call (or message), its duration, the caller's and receiver's phone numbers, and their locations. Locations are estimated from the positions of activated cell towers, but more precise locations can be generated through tower triangulation and Wifi connections. Mobile network operators (MNOs) receive billions of CDRs globally and use them for billing, monitoring data usage, and understanding and targeting customers according to their mobile phone use [5].

Mobile phone CDRs present novel opportunities for research and are being used in a variety of health geography studies. In a recently published article, we reviewed the wide uses of CDRs and showed their benefits in research across many countries, particularly low- and middle-income countries where mobile phones are a lifeline due to the lack of landline connections and population administrative systems [5]. Examples include cholera surveillance in Haiti and the Ivory Coast [6,7], air pollution in Italy [8], visitor movement to monitor malaria in Zanzibar [9], and dengue epidemics in Pakistan [10]. We also conducted research with the public to gain their views on the use of mobile phone CDRs for health research. This indicated that people are content for their anonymous CDRs to be used in research, provided that appropriate safeguards are in place. However, study participants highlighted that the terms and conditions should be clearer, as should information to phone users on data collection, sharing, and uses in research [11].

Collating these ideas, our aim was to work toward an ethically founded framework for the socially acceptable use of mobile phone CDRs, particularly in health research. We propose that the design and findings of this study will have value in developing data governance guidelines for other areas of research using CDRs for public benefit and wider network applications. As such, in addition to MNOs and the research community, our target audience includes policy makers; funding bodies; ethical, scientific, and publication review committees; and others involved in shaping how person-based data are used and protected.

Approach

This study is based on a multifaceted approach that draws upon data governance arrangements in published health research using CDRs; public engagement and their information expectations from mobile operators; and data use scenarios of CDRs for health research, all against a backdrop of legislative and regulatory requirements.

We first briefly outline the legislative and regulatory backdrop to set the scene. The current European (EU) legislation for personal data and their usage is the General Data Protection Regulation (GDPR) 2016 (2016/679/EU) that came into force in May 2018 [12]. Other jurisdictions have similar legislation, and in addition, may have specific legislation such as the Privacy and Electronic Communications (EC Directive) Regulations 2003 (2002/58/EC) [13]. Essential to these frameworks is the requirement to use personal data within lawful provisions and to safeguard individual privacy. Importantly, the GDPR encompasses pseudonymized data in its scope of personal data. This is defined as follows:

> *Pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.* [13]

This means that it is not necessarily sufficient to remove the commonly recognized identifiers from a dataset to render it anonymous, which will therefore have a bearing on the lawfulness of CDR data usage. Where data are not fully anonymous, general data processing can be carried out lawfully, provided that it can be justified under (at least) one of the provisions in Article 6 [12]. Crucially, although many jurisdictions have privacy legislation and regulations, they are often mutually inconsistent as a geographically bounded patchwork. This misalignment is problematic for networked operations, since they are necessarily international operations [14].

In addition to complying with all relevant legislation, data uses are found to abide by ethical principles with respect to individuals and the public. The Menlo report [15] set out four important principles for computer and information-security research, namely, beneficence, respect for persons, justice, and respect for the law and public interest. This report was important in shaping our study because it set out to show the new potential for risks to individual privacy with the expansion of information and communications technology-based research, unless there is a corresponding reinterpretation of ethical principles and their application, to provide the groundwork for ethically defensible research [15]. The four principles were explained by Letouzé [4] to demonstrate their relevance to CDR research:

1. Beneficence: understanding risks and benefits. Efforts should be made to maximize the probability and magnitude of research benefits while recognizing that the risks and benefits in using CDRs are not always immediately apparent and will depend on specific project objectives. Furthermore, commercial considerations need to be taken into account when framing the work.
2. Respect for persons. The issue of consent is gaining attention among privacy concerns on using and sharing CDR data. In general, there appears to be little provision to allow consumers to exclude unwanted uses of their data. Going forward, this issue should be considered, particularly

with legislative changes due to the introduction of the GDPR.

3. Justice: bias and inequalities. This principle highlights the issues of equality and fairness in how risks and benefits are distributed. It is known that not everyone is able to contribute data and benefit from research using CDRs. Efforts should be made to understand and correct biases in CDR data to ensure that the findings are representative of society.
4. Respect for the law and public interest. There is a need to engage properly in legal due diligence. In addition, there is an ethical position to support social acceptability. This includes being transparent about how CDR data are collected, shared, and used and being accountable for actions taken.

The Organization for Economic Cooperation and Development guidelines set out eight principles for fair information practices. Briefly, these cover data collection limitations, data quality and relevance, purpose specification, data use limitations, security safeguards, openness, data subject rights, and accountability [16]. These principles, set out in 2012, are highly relevant to research using CDRs and other networked data, where as yet, there is no overarching ethical framework to safeguard individuals.

A review of the data governance arrangements in published studies was included in the design of our recent review [5]. The level of available detail varied, but we aimed to state whether data were anonymized or aggregated, the approval processes, and the data access arrangements. The purpose of this exercise was to assess current reported practice and learn from good examples. Although the majority of the studies we reviewed [5] used data from low- and middle-income countries, the researchers using the data were multinational, and MNOs operate internationally across jurisdictional boundaries. The public view on the use of CDRs for health research is an underresearched area, and our study is the only one known to date [11]. We draw upon the series of workshops we conducted with the public to incorporate their views into proposals for the ethical use of CDRs in research. There were four workshops; the first was a pilot (N=25) to inform the three subsequent groups (N=61 each). All the workshops were based in Wales, United Kingdom, and included a range of general public participants. Two were held at Swansea University and one at a further education college. The format included an initial questionnaire to gauge knowledge, a presentation of research using CDRs, a discussion of risks and benefits, and an exit questionnaire to assess postworkshop views.

In addition to relying on published research using CDRs, we created scenarios of CDR use with and without additional datasets in order to develop an indicative relative disclosure risk model. These were selected in discussion with local Health Board staff and based on questions of potential interest to the Board. There is a wealth of literature on anonymization and disclosure risk, drawing attention to the fact that just because data have been through a process of anonymization, they might not be immune to reidentification risks. We used the principles in the Anonymisation Decision-Making Framework [17] to model the likely disclosure risks in our example scenarios. These principles take into account factors including dataset size, data accessibility (open vs controlled), data granularity, user knowledge, means available, and motivation. This guidance, discussions with Health Board staff, and our knowledge of working with data informed the development of the model. We then analyzed findings from a review [5], the public views [11], and the data use scenarios to propose a set of recommendations for the appropriate use of CDRs in health research.

Results and Discussion

Data Governance Arrangements in Published Studies

The extensive structured literature review on the use of mobile phone CDR data for health research revealed some common patterns in operational data governance regimes [5]. Datasets were provided to researchers at different levels of spatial granularity and over variously restricted time periods to mitigate risks. These varied by study or programs of study. In some cases, data were subjected to several layers of anonymization, and the true geolocations of cell phone masts were masked. The use of anonymized (or strongly pseudonymized) data was the norm, with few studies outside this model and with many additionally using aggregation and suppression of rare or extreme records. However, researchers reported that the use of overstringent measures sometimes precluded some potentially valuable research analyses. The requirement for formal ethical review varied, but proposals were routinely submitted to an internal ethics workgroup, and, in some cases, to an independent external group for wider considerations such as political implications, societal benefits, and risk versus utility. There were no known privacy breaches in relation to the data supplied for the studies included in the review [5].

The MNO Orange issued a Data for Development Challenge on mobile phone data based on 5 million Ivory Coast customers' data over a 4-month period [18]. Researchers were tasked with using the data in a way that could potentially contribute to the socioeconomic development of the country. CDRs were anonymized by Orange Ivory Coast and processed by Orange Labs in Paris. In addition, the geographical locations of the cell phone masts were masked to protect the commercial interests of Orange. Four datasets of differing granularities were then released to researchers: (1) tower-to-tower data for the number and duration of calls between a pair of towers aggregated by each hour; (2) high spatial resolution data of individual movement trajectories on a random sample of 50,000 individuals for a 2-week time period only; (3) similar data for the entire observation period but with reduced spatial resolution to reduce the likelihood of identification; and (4) social network subgraphs using the CDRs generated by 5000 randomly selected individuals, divided into 2-week time periods [18]. A similar process was followed when Orange issued a second challenge, this time using data from Senegal. Orange established two ethics groups to review the proposals for data use: an internal ethics workgroup and an external panel of international experts [19,20].

For studies not involved with the Orange challenges, anonymized data were provided by the MNO apart from one study wherein researchers were provided with a raw dataset and undertook the anonymization process themselves [21]. High-

and low-volume users were excluded from the analyses of this study to protect privacy. Another study stated that they followed the Groupe Spéciale Mobile Association privacy guidelines, which advise that any analyses on mobile phone records should be done using deidentified data and that individual-level data should not leave the MNO servers [22]. In this case, the data were analyzed remotely, and only aggregated data were released externally. Other studies explicitly stated that they used only aggregated data in their analyses. Where studies used additional datasets, they tended to integrate these with, or overlay them onto, the CDRs rather than use individual-level data linkage. In addition to ethical review by the MNO (where present), some studies reported seeking additional ethical approval from their institution before beginning their research study.

Pubic Views and Concerns

A variety of concerns about CDR usage were expressed during the public workshops. Participants were worried about location data being sold to (potential) employers or insurers and the risk of disclosure for individuals living in remote areas. There were questions about whether data were being anonymized and aggregated to a sufficient standard and whether informed consent had been gained for identifiable data to be collected in the first place. Perceived risks included disclosure and data misuse and the increased possibility of reidentification from the use of multiple datasets. Participants made suggestions for what could be done to address these concerns; the most frequent was to have transparent terms and conditions, followed by provision of more information to phone users on the types of data being collected and how they are used. Stronger information governance featured highly, with a need for more legal sanctions for data misuse, the option to opt out, and the provision of more information on governance and security processes. The majority felt that information about the use of anonymized mobile phone data for research should be included in the terms and conditions [11].

Relative Risk Model for Use of Call Detail Records

Data modeling exercises using semihypothetical scenarios were carried out to suggest a relative risk model for using CDRs in conjunction with publicly available or restricted access data. We based this on the information about CDR use from our review, as we did not have access to these data. The assessments took into account a number of assumptions. In terms of anticipated benefits, it is acknowledged that a phone might be carried by someone other than the contract holder and any MNO population coverage is partial; therefore, these issues may affect generalizability. Additionally, at least some of the research questions could be addressed by means other than using CDR data. However, the use of mobile phone data is an emerging area of work and presents novel opportunities, the full extent of which has not yet been realized. The outcome of the data modeling exercises is an indicative model, as it is not possible to assess absolute risk from this process. The risk estimates are based on the concept of reasonable effort, rather than what could be ascertained by a highly motivated, malicious intruder, but they do factor in potential repercussions due to the release of CDR data. We used six types of scenarios for illustration, some based on macro CDR data and some based on small-cell CDR data, but of course, other combinations are possible. Macro CDR location data are based on tower-to-tower communications and triangulation. Small cells are devices placed by MNOs within venues to capture local granularity, for example, inside a building or shopping mall. The scenarios were macro CDR data alone, small-cell CDR data alone, macro CDRs with publicly available datasets, small-cell CDRs with publicly available datasets, macro CDRs with restricted-access datasets, and small-cell CDR data with restricted-access datasets. It is assumed that all data are used in anonymized form, but in practice, MNOs often also aggregate the data for further risk mitigation. Publicly available datasets (such as weather, pollution levels, or disease incidence) are taken as aggregated. Restricted-access datasets (such as health records from hospitals or primary care) may be anonymized or aggregated depending on permissions and approvals. Details of the scenarios with their likely indicative risk profiles are shown in Multimedia Appendix 1. Considering these scenarios, we suggest the following relative disclosure risks:

1. Macro CDR data: It is considered highly unlikely that the majority of studies based solely on macro-level CDR data would present a significant risk to individual or group identity disclosure. There is a small possibility that the identity of some individuals in a dataset could be compromised through the use of location data patterns in CDRs, but this would require significant specialist effort. Provided that extreme records or very rare conditions/events are excluded, the risks of macro CDR–based studies should be low.
2. Small-cell CDR data: The sole use of small-cell CDR data in research studies is considered unlikely to present a significant risk to individual or group identity disclosure, unless particular groups, rare/sensitive conditions, or rare events are being studied. Because of the small geographies involved, the risks of working with small-cell CDR–based data are likely to be low or low-moderate, depending on the nature of the study.
3. Macro CDR data with publicly available datasets: The use of macro CDR data in conjunction with publicly available datasets is considered unlikely to present significant risk to individual or group identity disclosure, unless particular groups, rare/sensitive conditions, or rare events are being studied via the association of more than one temporospatial dataset. The indicative risk level is therefore considered to be low-moderate.
4. Small-cell CDR data with publicly available datasets: It is considered that the use of small-cell CDR data in conjunction with publicly available datasets may present significant risk to individual or group identity disclosure. This is because, although the data are not linked at the individual level, it may be possible to associate the datasets temporospatially and thus to home in on small number (or individual) records due to the use of specific locations. The indicative risk level is therefore considered to be moderate.
5. Macro CDR data with restricted-access datasets: The use of macro CDR data in conjunction with restricted-access datasets is considered likely to present significant risk to individual or group identity disclosure. This is because of the sensitivity and granularity of the restricted-access data

(such as general practice or hospital records), even if the data are not linked at the individual level. The model of access for the use of such combinations of data should be given serious consideration, with access within a data-safe haven likely to provide greater safeguards than external data release. The indicative risk level is therefore considered to be moderate to high.

6. Small-cell CDR data with restricted-access datasets: This scenario is similar to point number 5 mentioned above, but presents greater risks because of the use of small-cell CDR data in conjunction with restricted-access datasets. As such, it is considered highly likely to present significant risk to individual or group identity disclosure. This is because more specific locations are used along with individual health records, and consequently, access to such combinations of data should be given the utmost consideration. The indicative risk level is considered to be high.

The resulting indicative relative disclosure risk model is shown in Table 1.

Recommendations for the Use of Call Detail Records for Public Benefit

Drawing the information together from the combined findings of the review [5], public views [11], and data use scenarios, we propose the following recommendations to promote the safe, socially acceptable use of mobile phone CDR data for public benefit. While recognizing the need to protect commercial interests, we propose that these interests be taken into consideration to contribute toward an ethically founded practical framework for developmental initiatives and research programs involving the use of CDR data wherever the work takes place. These recommendations are for MNOs and stakeholders—all the people involved in shaping how CDR data are used and protected:

1. The anticipated public benefit of the proposed data use should be clearly articulated and be sufficient to justify the potential risks of harm to data subjects.
2. All relevant legislative, regulatory, and governance approvals and data provider permissions should be sought with due diligence at the planning stage to ensure compliance.
3. Clear information (embodied in contract, as necessary) should be provided to stakeholders on expectations and responsibilities. This should include a description of the proposal, the placement of any small cells, and likely risks and benefits, so that informed decisions can be made by responsible parties.
4. Public views and preferences should be taken into account, beyond the strict requirements of legislation, to promote inclusivity and social license in the use of CDR data.
5. Learning from other initiatives and sharing good practice in data governance for the use of CDRs should be an ongoing process to avoid ethical pitfalls.
6. Due regard should be paid to modeling likely risks in research scenarios using CDR data with or without additional datasets on a case-by-case basis, so that appropriate safeguards at data access and release of results can be applied accordingly.
7. Transparency should be a fundamental consideration when communicating the likely risks and benefits of CDR data usage, including anticipated public benefit and lessons learned to inform future work.
8. Efforts should be made to engage with the public to provide information on the research uses of CDR data, potential public benefits, and possible opportunities to be involved in influencing the research agenda.
9. The terms and conditions of service should be made more accessible and clearer to data subjects in terms of design and content as part of a transparent data governance model.
10. The use of the best quality data at a granularity that enables the research question to be addressed without compromising privacy and security should be promoted.
11. Appropriate privacy notices on what data are collected; in which formats they are used; and for what purposes, by whom, and to whom they are sold/shared should be provided.
12. A high priority should be placed on having a robust, flexible data governance framework and being overtly accountable and responsible across all operations pertaining to the use of person-based data.

Table 1. Indicative relative disclosure risk model.

Data	Implication	Indicative level
Macro CDR[a] data alone	Highly unlikely to present a significant risk to individual or group identity disclosure	Low
Small-cell CDR data alone	Unlikely to present a significant risk to individual or group identity disclosure	Low-moderate
Macro CDR data with publicly available datasets	Unlikely to present a significant risk to individual or group identity disclosure	Low-moderate
Small-cell CDR data with publicly available datasets	May present a significant risk to individual or group identity disclosure	Moderate
Macro CDR data with restricted datasets	Likely to present a significant risk to individual or group identity disclosure	Moderate-high
Small-cell CDR data with restricted datasets	Highly likely to present a significant risk to individual or group identity disclosure	High

[a]CDR: call detail record

Summary Discussion

CDRs have been used successfully in a wide variety of health geography studies, with varying data governance regimes. Engagement with the public drew out valuable issues on the social acceptability of using CDRs in research. The relative risk model sets out a hierarchy of likely disclosure in different data use scenarios. Although this is only indicative, it can be used as a guide to inform data use proposals on a case-by-case basis. The resulting set of recommendations is a culmination of all aspects of the work to contribute to a framework for the safe, socially acceptable use of CDRs in research. Concerns have been raised regarding the ethics of using mobile phone data in research and the potential threat to privacy. This, for the most part, has stemmed from the absence of any clear ethical and regulatory framework to guide this type of research and the use of networked data more broadly [4,14]. The recommendations can be taken forward to address this identified lack of consistency. These recommendations are in accordance with the Menlo and Organization for Economic Cooperation and Development guidance [15,16] and consolidate their principles to add specific guidance in relation to the use of CDR data for research by adding the previously nonexistent evidence base gained via a review of data governance in published research, modeling risks in data use scenarios, and importantly, incorporating public views on the social acceptability of CDR data use.

Most published research reported results using anonymized data, and many went further to protect against reidentification by way of aggregation. Nevertheless, examples of how anonymization and aggregation do not guarantee privacy are abundant in the literature [23-27]. Moreover, breaches in group privacy do not rely on the reidentification of individuals. People who belong to certain groups on the basis of their gender, sexual orientation, ethnicity, or political preferences could become visible in CDR data and targeted [4,28]. Anonymization is a key concept in data protection legislation, and anonymized data are generally considered as data from which the data subject is no longer identifiable. However, the bar is set high in relation to the potential for reidentification and the risks related to this possibility. The essence of the EU GDPR is that if a data controller retains the key to reidentifying the data subject, the information should be more accurately considered pseudonymized rather than anonymized [29]. This has implications for the use of CDRs, as such data remain within the scope of the legislation. Depending on how the data are held and managed, it may be necessary for a data controller to justify that the data governance safeguards are in place and for the costs and effort involved in reidentification to be so remote or disproportionate that the data are effectively anonymized. This should include a consideration of physical, technical, and procedural controls around the data, for privacy by design, as well as controls applied directly to the data [17]. It is also important to consider the point at which data are anonymized and where this anonymization takes place. Data controllers have to comply with the GDPR if their work uses data pertaining to EU citizens, irrespective of whether their organization is based within the EU [13]. The GDPR also includes a requirement for transparent privacy notices on how data are collected and used, with relevant opt outs that are as easy to reverse as they are to agree [30]. As identified via our public workshops, clear, user-friendly, noncoercive information should be provided in the terms and conditions [11]. Furthermore, because of the finer granularity in data collection and possible risks, privacy notices should also be considered in locations where small cells are sited.

Proper ethical and societal principles are important for the use of person-based data, even when the data have been anonymized. Whichever data are to be used, due diligence should always be applied to ensure the proposed data uses are appropriate and safe. Generation of a digital footprint via active and passive data collection is increasing both in volume and scope. Mobile phones are among the most longstanding of networked devices, but many other data sources are coming to the fore via the IoT and other data-hungry advances [2]. It has been noted that when using our phones and other devices, we are trading our privacy for convenience, with many people finding the conventions of interaction obscure or inexplicable [31]. It has further been argued that with the increase in networked devices and the cultural and functional changes impacting society, as individuals, we will find ourselves in an “ethical bind” where we need to use the device, but cannot do so without surrendering data to the network [32]. Although it is appreciated that certain data are necessary for MNOs and other operators, there needs to be an ethical balance, so that individuals are not overlooked and treated as a commodity. For this reason, we need appropriate ethically founded data-governance frameworks with social acceptability in order to respect individual choice and use data for public benefit [17].

What This Study Adds

This is the first-known study to use a multifaceted approach to propose recommendations for the ethically founded use of CDRs in research. Our findings are based on known practice in CDR use, public viewpoints, and a consideration of relative risk in data use scenarios. As such, it is a novel study that can be used as a model for other new and emerging personal data types in the increasingly networked digital world.

Limitations

The main limitations of this study are related to the scenarios for data modelling, since we were unable to access the data in order to make a quantifiable risk assessment. This could be a topic for future work. However, it is worth pointing out that accurately quantifying disclosure risk from data use scenarios is not a trivial exercise, since it varies with many factors. As such, while recognizing that our model is only indicative, we recommend that data use proposals are assessed for risk on a case-by-case basis, making use of the principles proposed. In addition, although we chose to illustrate the model with six scenarios, other combinations are also possible. This could include a consideration of different health conditions, data volumes and granularities, access conditions, and other variables.

Conclusions

This study has addressed the identified need for greater clarity and consistency in data governance for mobile phone CDRs in

research. While recognizing that it is important to protect commercial interests, we propose that the recommendations be used to contribute toward an ethically founded practical framework to promote the safe socially acceptable use of CDR data for public benefit. With the increase in passive and active data collection from individuals using networked devices, this pattern needs to be repeated for the appropriate use of new and emerging data types from other applications and the wider IoT. Future work should consolidate these findings to assess the value of the recommendations as part of an ethically founded data-governance framework for the use of mobile phone CDR data and their wider applicability.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Scenarios of the use of call detail records for health research.

[PDF File (Adobe PDF File), 218KB - mhealth_v7i3e11969_app1.pdf]

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Abbreviations

CDR: call detail record
EC: electronic communications
EU: European Union
GDPR: General Data Protection Regulation
IoT: internet of things
MNO: mobile network operator

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Review

Training Cognitive Functions Using Mobile Apps in Breast Cancer Patients: Systematic Review

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Abstract

Background: Breast cancer is an invalidating disease and its treatment can bring serious side effects that have a physical and psychological impact. Specifically, cancer treatment generally has a strong impact on cognitive function. In recent years, new technologies and eHealth have had a growing influence on health care and innovative mobile apps can be useful tools to deliver cognitive exercise in the patient's home.

Objective: This systematic review gives an overview of the state-of-the-art mobile apps aimed at training cognitive functions to better understand whether these apps could be useful tools to counteract cognitive impairment in breast cancer patients.

Methods: We searched in a systematic way all the full-text articles from the PubMed and Embase databases.

Results: We found eleven studies using mobile apps to deliver cognitive training. They included a total of 819 participants. App and study characteristics are presented and discussed, including cognitive domains trained (attention, problem solving, memory, cognitive control, executive function, visuospatial function, and language). None of the apps were specifically developed for breast cancer patients. They were generally developed for a specific clinical population. Only 2 apps deal with more than 1 cognitive domain, and only 3 studies focus on the efficacy of the app training intervention.

Conclusions: These results highlight the lack of empirical evidence on the efficacy of currently available apps to train cognitive function. Cognitive domains are not well defined across studies. It is noteworthy that no apps are specifically developed for cancer patients, and their applicability to breast cancer should not be taken for granted. Future studies should test the feasibility, usability, and effectiveness of available cognitive training apps in women with breast cancer. Due to the complexity and multidimensionality of cognitive difficulties in this cancer population, it may be useful to design, develop, and implement an ad hoc app targeting cognitive impairment in breast cancer patients.

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KEYWORDS

cognitive impairment; breast cancer; cognitive training; intervention; mobile-based interventions

Introduction

Cancer is a major public health problem worldwide and the second leading cause of death in the United States. In 2017, Siegel and colleagues [1] reported 1,688,780 new cases and estimated 600,920 deaths. Breast cancer is one of the most common cancers around the world [2]. It is the most common cancer diagnosed in women, affecting about 1 in 8 women in the United States during their lifetime (12.4%), and it is the second most common cause of death by cancer in women [3].

The incidence rate is strictly associated with age: 95% of new cases are registered in women older than 40 years; only 1.5 cases per 100,000 are registered in young women (20 to 24 years). The incidence is higher for older women: 421.3 cases per 100,000 women are registered in women 75 to 79 years old; the median age at diagnosis is 61 years [3]. Prognosis is related to cancer stage: 5-year survival rate is 100% for stage 0 and I, 93% for stage II, 72% for stage III, and 22% for stage IV [3]. In the last 20 years, we have witnessed a decline in overall cancer mortality. This is especially true for breast cancer mortality: the death rate steadily decreased by 38% from 1989 to 2014. This is due especially to decreases in smoking and advances in early detection and treatment [1].

The advances made in breast cancer treatment offer women greater prospects of cure and a better quality of life. However, cancer treatment has some deleterious acute or long-term side effects that impact women's physical, functional, emotional, financial, and social lives [4]. Along with depression and anxiety [5], cognitive impairment is a short- or long-term outcome or side effect of breast cancer and its treatment and the treatment of other diseases such as stroke [6], HIV and hemophilia [7], and multiple sclerosis [8]. In recent years, empirical evidence has risen regarding significant cognitive impairment following breast cancer treatments in survivor women. The American Cancer Society/American Society of Clinical Oncology Breast Cancer Survivorship Care Guideline [9] showed that 75% and 35% of patients report cognitive impairment during treatment and after treatment, respectively. In addition, in everyday clinical practice, women with breast cancer often complain about cognitive difficulties in different domains of cognition. For example, these cognitive impairments include problems with concentration, executive function, memory [9] and, especially in patients treated with chemotherapy, problems with visual memory, information processing speed, and verbal memory [10]. Cognitive impairments could also reduce the quality of life, lead to distress, and have a negative impact on women's working, societal, and family life [9].

Cognitive impairment can have multifactorial causes. Runowicz and colleagues [9] reported that insomnia, depression, fatigue, surgery, anesthesia, different type of cancer treatments and cancer itself could cause cognitive impairment. For example, a meta-analysis conducted by Jim and colleagues [11] showed that breast cancer survivors treated with chemotherapy suffer small and limited observed cognitive deficits. This is especially true for the domains concerning verbal and visuospatial ability. However, other difficulties also concern memory and attention deficits due to chemotherapy. These symptoms, generally known as *chemobrain* or *chemofog*, are experienced by a lot of women treated with chemotherapy [4]. Bakoyiannis and colleagues [12] conducted a systematic review on the impact of endocrine therapy on cognitive functions of breast cancer patients. They especially investigated difficulties in 5 cognitive domains: verbal memory, verbal fluency, attention and working memory, motor speed, and psychomotor speed. They concluded that endocrine therapy may alter cognitive functions in these women.

However, the exact mechanism underlying cognitive impairment is not clear. For example, empirical evidence exists on the role of stress and coping styles [13], direct neurotoxic injury, telomere shortening, oxidative stress, cytokine dysregulation, estrogen-mediated effects, genetic polymorphism [14], peripheral proinflammatory cytokines [15], decreased estrogen levels, and structural brain changes [16] in cognitive impairment following cancer treatment.

Moreover, there are uncertainties regarding the nature and magnitude of cognitive impairment in breast cancer patients [17] and also regarding the most effective treatment to target these kinds of cognitive difficulties [9]. In their review on pharmacological and nonpharmacological interventions to manage cognitive alterations after chemotherapy, Chan and colleagues [18] concluded that pharmacological interventions to manage cognitive alterations after chemotherapy for breast cancer are not well supported by current empirical evidence. On the other hand, some kind of cognitive training—computerized cognitive training, cognitive behavioral therapy, memory training, speed of processing training, psychoeducation, Tibetan sound—and physical interventions may be useful. However, further studies are needed in order to provide guidelines and concrete recommendations for clinical practice [18].

Overall, these psychological interventions for cognitive impairment are time- and money-consuming. They may result in a huge burden for patients because they are often delivered in an in-patient context [17]. The development and delivery of home-based or Web-based interventions may have advantages over traditional clinic-based ones. However, there is a scarcity of these kinds of innovative interventions for cognitive training.

Starting with the introduction of the World Wide Web in our daily lives, the internet has increasingly become an essential part of modern living. A recent report by the Pew Research Center states that in the developed nations, the number of people who use the internet or a mobile phone remains high throughout the years (around 86% from 2015 to 2018) and that in the developing world the rate is increasing constantly (from 62% of the population using the internet or owning a mobile phone in 2013 to 64% in 2018) [19]. A common misunderstanding is that the elderly, compared to younger people, are less interested in technology. However, older people are rapidly gaining more interest in the subject [20], and the rate of people aged 65 years and above using the internet grew from 14% in 2000 to 58% in 2015. Internet use for other age groups is growing as well: internet use from 2000 to 2015 increased from 70% to 96% for people aged 18 to 29 years, from 61% to 93% for people aged 30 to 49 years, and from 46% to 81% for people aged 50 to 64 years. These statistics are especially interesting because they could indicate the promise of development of innovative Web-based interventions also targeting elderly people. Traditional health care interventions have been delivered through face-to-face meetings with clinicians. However, eHealth and mHealth uses have increasingly spread in the last decades [21].

The two leading platforms for health-related mobile apps are iOS and Android. As of 2014, more than 100,000 mHealth apps had been released [22,23]. mHealth apps permit real-time and bidirectional interaction with the patient [23]. This transformation brings changes even in the diagnosis and treatment of cancer.

Several mHealth apps have been developed to inform patients; enhance communication, consulting, and symptom self-management and monitoring; and improve health record access and maintenance and clinical decision making [24]. However, little is known about apps directly aimed at improving cognitive functioning in patients reporting cognitive difficulties. No apps have been specifically developed to counteract cognitive difficulties in breast cancer survivors. Thus, we aimed to identify effective apps to train cognitive function and counteract cognitive impairment in both clinical and nonclinical populations. Another aim was to evaluate their efficacy and assess whether they could be also used to counteract cognitive impairment in breast cancer patients. Thus, we focused on their distinctive features in terms of targeted populations and the specific cognitive domains being trained.

Methods

Our search strategy was designed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines [25]. A flowchart of the systematic review is shown in Figure 1.

To identify articles for our review, we searched PubMed and Embase databases for the terms smartphone, mobile, and app. The searched cognitive domains were memory, attention, concentration, verbal fluency, motor speed, psychomotor speed, problem-solving, executive function, visuospatial function, language, and cognitive control. In particular, the string of terms included:

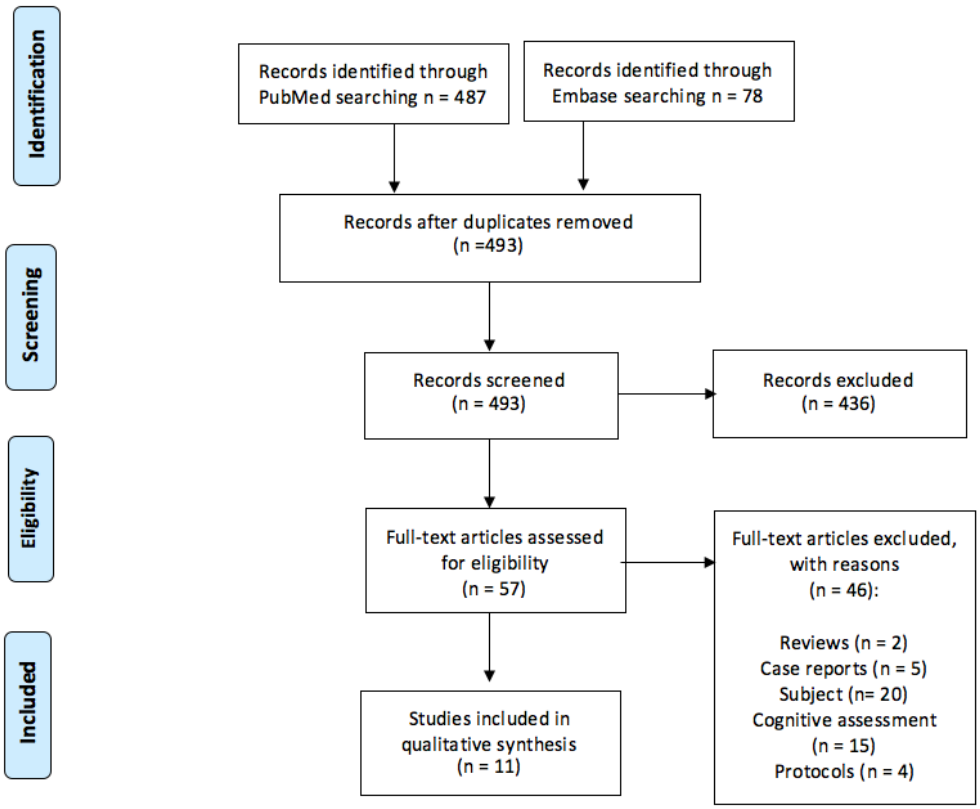
- Smartphone app or mobile app
- Cognitive function or memory or attention or concentration or verbal fluency or motor speed or psychomotor speed or problem solving or executive function or visuospatial function or language or cognitive control

The search was limited to the English language. No restriction was placed on the year of publication. The search was completed in February 2018.

Two authors independently reviewed the titles and abstracts to identify relevant papers. We extracted only those papers with the main focus on the use of a mobile-based app (mobile phone or tablet-based) to deliver cognitive training. About 10% of the papers were double screened, and disagreements in data extraction were resolved through discussion with a third author.

The second step consisted of a full article screening. We excluded papers that were (1) reviews, case reports, or protocols; (2) abstracts for conferences; or (3) related to apps that assess cognitive functions without training them.

Figure 1. Flowchart of the systematic review.



Data collection included information on authors, title, publication date, study aim, sample characteristics, clinical or nonclinical populations, cognitive domains trained, app exercise descriptions, assessment and feedback, app evaluation and efficacy, training with the experimenters, and whether the device was given to the study participants.

Results

Studies Selected

A flowchart of the systematic review is shown in Figure 1. We retrieved a total of 493 articles. We selected 11 articles after a

full-text screening. We excluded 2 reviews (eg, [21,26]), 5 case reports (eg, [27-31]), and 4 protocols (eg, [32,33]). The other studies were excluded for content reasons, for example: some studies did not use apps to train cognitive functions [22,34-47], and others were excluded because they used apps only to assess—and not to train—cognitive functions [48-58]. Our 11 selected studies focus on the cognitive domains of attention, memory, problem solving, cognitive control, executive function, visuospatial function, and language (reported in Table 1).

Sample Characteristics

Our search returned 11 studies that include 819 participants. The number of participants in these studies ranged from 9 to 626. Weighted by sample size, the mean age of participants was 36.2 years. However, there is a huge heterogeneity in participant ages among these 11 studies: ages ranged from 50 months to 96 years. In particular, 1 study focused on preschool children with a mean age of 60 months [59], while 4 papers focused especially on older adults with a mean age over 68 years [60-63].

Nearly all of the studies were performed in developed countries. Almost half of the studies (5/11, 45%) were conducted in North America: 4 were performed in the United States [60,61,64,65] and 1 in Canada [63]. Three were conducted in Europe: 2 in Italy [59,66], and 1/11 in Norway [67]. Two studies were conducted in Asia: 1 in Taiwan [62] and 1 in Jordan [68]. Only 1 study was conducted in Oceania (Australia [69]). In addition to this heterogeneity in cultural provenance, the 11 identified studies have a moderate variability in the kind of population in which they evaluated the app for the cognitive training. No studies involved breast cancer patients. Ten of 11 studies involved adults or elderly people. One study focused on adults affected by brain injuries [65], 1 on cognitively impaired patients with multiple sclerosis [66], and 1 on patients with early stages of Alzheimer disease [68]. Three papers focused on healthy elderlies [60-62] while 1 study chose a population of older adults with and without subjective cognitive complaints and mild cognitive impairment [63]. One study focused on adults with mild to moderate depression [64] and 1 on overweight or obese adult [69]. Just 1 paper from our search specified healthy young adults [67]. Only 1 study focused on children with mild to severe language impairments or delays [59]. Inclusion and exclusion criteria were different in all of the studies. Only 3 studies [65,67,69] included control groups.

Aim

The majority of the selected papers had a primary aim to evaluate the apps in terms of usability, acceptability, feasibility, and user satisfaction [59-61,63,66-68]. Only 2 articles [62,65] chose to describe the development and improved design of the apps. Only 1 paper [64] had as the main aim to assess and improve depressive symptoms by comparing 3 different apps, 1 of which is explicitly aimed at improving depression through a cognitive control exercise. Just 1 study had the explicit aim of investigating the efficacy of the app in improving cognitive functioning [69].

App Characteristics

App availability on the market was checked by searching in the main app stores (App Store and Google Play); however, none are available to the general public. The same search was conducted on online test catalogs, such as Pearson Assessments or Psychological Assessment Resources Inc, but no apps from the studies were found. In all of the studies, app users were asked to respond with a touchscreen.

Table 1. App developers, app names, and cognitive domains being targeted in each study.

Author, year	App name	Attention	Problem solving	Memory	Cognitive control	Executive function	Visuospatial function	Language
Arean and colleagues, 2016 [64]	Project: EVO				✓			
Blackburne and colleagues, 2016 [69]	NoGo				✓			
Bless and colleagues, 2014 [67]	—	✓						
Hill and colleagues, 2015, and Hill and colleagues, 2018 [60,61]	Attention Training Application	✓						
Lorusso and colleagues, 2018 [59]	—							✓
Lu and colleagues, 2017 [62]	Brain Win	✓		✓		✓	✓	✓
Powell and colleagues, 2017 [65]	ProSolv		✓					
Shellington and colleagues, 2017 [63]	Healthe Brain			✓		✓	✓	
Tacchino and colleagues, 2015 [66]	Cognitive Training Kit (COGNI-TRAcK)			✓				
Zmily and colleagues, 2014 [68]	ADcope – Spaced Retrieval Exercise			✓				

Bless and colleagues [67] explored the feasibility and effectiveness of an app that enables people to train auditory attention. They developed the app in-house, but they did not give it a name. Participating in this study were healthy adults; they were given an iPod touch and asked to perform a consonant-vowel dichotic listening task. According to the forced-attention condition of the standard consonant-vowel dichotic listening paradigm, during this task each participant was presented simultaneously with 2 different syllables via earphones: while one was presented to the left ear, the other

was delivered to the right. Syllables, made by consonants and vowels, were read by a male, native Norwegian speaker with constant voice intonation and intensity. Before the beginning of the task, each participant was told via message on the display to pay attention only to the syllable delivered to the left or the right ear. After hearing the syllables, participant had to choose the correct syllable from 6 multiple choice answers. Each training session, about 6 minutes long, included 6 blocks with 5 pairs of syllables. Syllables were presented in 400 to 500 ms with an interval of 4000 ms between each pair. At the end of each session, participants were shown feedback of their correct answers. Results were stored on the device and available to the researcher at the end of the study.

Lorusso and colleagues [59] developed an app to improve semantic competence and structural knowledge in children with learning impairments. It was part of an integrated system. The aim of the study was to evaluate learnability, usability, user satisfaction, and the quality of the interaction in children playing with this integrated system. The app was used on a supplied tablet; it scanned the tag that the experimenter had placed under some toys (plastic animals). When the children scanned the tag under the toys, the app displayed a menu with 5 different activities that were all related to this specific animal. The first was an informative activity in which children were given some interesting information about this specific animal. The second one was a storytelling activity that directly connected to a website with stories and tales related to the animal. The third was a visual activity with several picture and photos of this specific animal. The fourth presented a song strictly related to the chosen animal. The last one was a puzzle activity in which children were asked to put together pieces of a puzzle representing this specific animal. The authors chose all these activities because they enrich semantic knowledge and organization. After the completion of each the task, the child was given feedback by picture or sound. The app also provided a text-to-speech tool to listen to written information.

Characteristics of the included studies and related apps are presented in Multimedia Appendix 1 and 2.

Shellington and colleagues [63] examined the feasibility and utility of an app called HealtheBrain, which was focused on improving visuospatial executive function and working memory. Participants of this study were older adults with or without subjective cognitive complaints and mild cognitive impairment. They received HealtheBrain to improve cognitive functioning through a specific physical exercise called Square Step Exercise. Before the beginning of the exercise, the app offered participants the opportunity to have a tutorial about the use of the app and then to calibrate the step length. The square step exercise had 35 progressive stages and the participants had to start to form the first one. In order to go from 1 level to another, the subject had to complete at least 80% of each task. For each step, participants had to memorize 4 to 8 walking and stepping sequences and repeat them. When they reached the goal, an item was added to their virtual garden and they could get to the next level. They were asked to exercise at least 3 times per week over the next 3 weeks, and subjects were invited to contact the researchers with any question or technical issue.

In 2015, Hill and colleagues [60] developed an app to train attention. More recently [61], they decided to improve it considering the problematic issues identified in their previous study. Both studies focused on the usability, acceptability, and feasibility of the Attention Training Application. The experimental design of the study in 2018 was very similar to the pilot study in 2015. Before the start of exercise, 2 preliminary sessions were established: in the first session an examiner met with a participant in order to introduce them to the device (iPad or iPad Mini). Prior to the beginning of the trial, participants could exercise using the device for a week to become familiar with its functioning. The app was then introduced in the second session. Written instruction was given to participants, and they were able to contact the experimenter to receive further information and instructions on the use of the app and device. This app delivered a program targeting attention and was based on the dual n-back training paradigm. This cognitive domain was improved by different exercises: in the first one a visual stimulus was presented, in the second one an auditory stimulus was given, and in the third step visual and auditory stimuli were presented together. The visual stimulus was a grid split in 8 parts with a square in 1 of them. The auditory stimuli were spoken letters. Given that the authors follow the n-back paradigm, the exercise requested subjects to report the correct answer of the exercise presented n trial before. At the end of each trial, the app sends a visual stimulus so the participants know immediately if the answer is the correct one. The Attention Training Application was adaptive: if participants performed well, the exercise increased in difficulty. The differences between the 2 versions of the app consisted mostly in modified elements to help the user better comprehend how to use the app and correctly perform the exercise. In 2018, the authors added some preliminary training features: a first session with the experimenter that presented the iPad and a week to become familiar with the device. Moreover, feedback was modified in the second version. While the 2015 app gave negative feedback to users (a red X indicated each wrong answer), this was removed in 2018 because participants generally reported frustration and confusion with it. Finally, the response time changed from 3 seconds to 5 seconds. The paradigm followed, and the exercise and adaptive style of exercise presentation remained the same.

Lu and colleagues [62] developed a prototype of an app called Brain Win. The app was directed to older people and evolved through 2 cycles of design and evaluation. The app involved 4 tasks and 6 games to train 5 cognitive domains: attention, executive function, memory, language, and visuospatial function. The 6 implemented games directly relate to real-life experience and daily activities of older adults:

1. My Calendar: discrimination task to train attention, executive function, and memory. Participants identify the correct date and time.
2. Go to Market: visuomotor task to train attention, executive function, memory, and visuospatial function. Participants draw the route to the market place.
3. Shopping in the Market: calculation task to train attention, executive function, and memory. Participants buy items

with a limited budget and make calculations using the item prices.

4. Finding Objects During a Phone Call: discrimination task to train attention, memory, language, and executive function. Participants listen and find correct items on the screen.
5. Super Singer: respelling task to train attention, memory, language, visuospatial function, and executive function. Participants reorganize character cards with song lyrics, listening to or reading them.
6. Go to the Zoo: discrimination task to train attention, memory, and executive function. Participants recognize and remember the noise made by the zoo animals and identify them.

Each game was supported by visual and auditory instructions. Buttons and icons had a realistic appearance and participants were asked to test the app in their home. Feedback sounds were presented at the end of each task. There was also the possibility to check the game scores or participant's position in a ranking table.

The Arean and colleagues [64] study aimed at testing the efficacy of 3 apps in relieving depressive symptomatology. These 3 apps were called Project: EVO, iPST, and Health Tips. In our review, we are mainly interested in Project: EVO, which trained cognitive control in order to improve cognitive symptoms. The other 2 apps were used to control treatment (Health Tips) and conduct psychotherapy intervention to improve depression (iPST). The participant had to use just 1 of the 3 apps: if they owned a mobile phone but not an iPad, the experimenter gave them one to use. Project: EVO is an exercise to train cognitive control and is designed as a video game. As the participants improved their proficiency with the game over time, the app increased the difficulty of the exercises. The app had an internal system to remind individuals to complete the exercise.

Blackburne and colleagues [69] tested the efficacy of the NoGo app that considered cognitive restraint—and specifically inhibitory control—to be used for weight control in obese adults. In particular, the app trained 3 domains: unhealthy eating, smoking, and alcohol consumption. Each game had 2 distinct tasks: Go and NoGo trials, in which a timer appeared next to an image that remained the same and started to countdown, and the Stop trial, in which participants had to choose the healthy food image as fast as possible. In this exercise, the image changed from healthy to unhealthy after the countdown began. Participants had to tag the correct answer if the Go tone was produced; if the NoGo tone was reproduced instead, participants had to hold back from answering. The stimuli order changed in each game so that the individuals could not anticipate and predict the next image and could not respond based on their previous experience with the game. The difficulty level was modulated by the timer and by the number of images presented (with a maximum of 12 images). The app collected data such as reaction time, game level, correct responses, and errors. The researcher could gain access to the data at the end of the training session.

Powell and colleagues [65] aimed at developing and testing an app called ProSolv, a problem-solving app developed by the authors after focus groups and interviews. In this study, the device was not provided; an inclusion criterion was that each participant must own a mobile phone and have access to the internet. The ProSolv program included 3 steps plus FAQ and help pages. The first was a face-to-face meeting with a coach; during this session, each participant could learn and test the app with the help of the expert and the program manual. In the second, a Web-based tutorial introduced the conceptual model of problem solving and its usefulness in everyday activities. Next, use of the app was explained in a video. The third step consisted of participants using the app to create a problem-solution list and remember each step to solve problems in a more effective way. The app comprised 4 pages: Welcome to the ProSolv app, My problem, My solution, and My contact. With the app, individuals could evaluate each problem-solution on the list by rating it with 1 to 5 stars.

Tacchino and colleagues [66] described the Cognitive Training Kit (COGNI-TRAcK). In their study, the app was used as a cognitive rehabilitation intervention based on working memory exercises in a sample of patients with multiple sclerosis. The authors stated that COGNI-TRAcK could be used to implement 3 types of working memory. The first task targeted visuospatial working memory and presented a sequence of visual stimuli, with participants asked to touch the corresponding location where the stimuli had appeared on the screen. The second task was an operation n-back exercise in which participants were presented with 2 numbers on the screen. If the instruction on the screen said N=0, participants had to touch the sum of the 2 numbers as the right answer. When the instruction said, for example, N=1, they had to touch on the screen the sum of the numbers previously presented. The third was a dual n-back exercise in which each patient was presented with a single number on the screen. Similar to the first n-back task, if the instruction said, for example, N=1, participants had to remember and recall the number presented in the previous exercise by touching it on the screen. All the information collected by the app was directly stored in a database with 3 sections: (1) Patient contained participant data; (2) Exercise and Treatment contained information about the assignment, workload, record of the exercise, and length of the intervention; and (3) Setting contained the characteristics of the configuration of the app. The main feature of the app was the possibility to implement the workload and regulate its intensiveness.

The study by Zmily and colleagues [68] focused on the usability of a subtask of an integrated app named ADcope. The app was developed for mobile devices and aimed to support Alzheimer disease patients in their daily routines. During the study, patients were given a tablet with the app along with clear instructions on how to use the device and app. Patients were asked to perform exercises while sitting together in a room. The app had sections for improving user quality of life and a support module, but for our review, we focused on the third section, which aimed to exercise patient memory in 2 ways. Audio-Assisted Memory Training played audio files of patient biographical information and then quizzed them about the information. The Spaced Retrieval exercise, whose usability was the main focus of the

study, comprised 2 phases. The first assessed users' current memory recall ability by presenting them with information followed, after some delay, by a question with 4 multiple choice answers. This exercise could use text information or a simple figure. The difficulty of the exercise could be operationalized by measuring the length of the delay between the information and the quiz. If the individual gave the right answer after a certain period of time, the app would increase the difficulty by increasing the time delay. The training phase (the same as the assessment) comprised 10 questions with a delay length based on the assessment results. After the participant completed the trials, written feedback appeared on the display. The app also has text-to-speech tools enabling patients to have the information read aloud.

Cognitive Domains

Overview

As shown in Table 1, the cognitive domains trained by the identified apps are attention, problem solving, memory, cognitive control, executive function, visuospatial function, and language. Nine out of 11 studies considered the usefulness of the app for the training of just 1 cognitive domain at a time (cognitive control [64,69], attention [60,61,67], language [59], problem solving [65], and memory [66,68]). The remaining 2 studies considered more than 1 cognitive function: Lu and colleagues [62] investigated attention, memory, executive function, visuospatial function, and language; Shellington and colleagues [63] investigated memory, executive function, and visuospatial function.

Cognitive Control

Cognitive control was trained in studies by Arean and colleagues [64] and Blackburne and colleagues [69]. Both of these authors stated that app usage could improve cognitive control as a mean to enhance other conditions: depression for Arean and colleagues [64] and obesity for Blackburne and colleagues [69]. Cognitive control in the paper by Arean and colleagues [64] was trained with an app that is designed as a video game that modulates cognitive control abilities. Blackburne and colleagues [69] instead reported the efficacy of cognitive control training in food consumption in an obese population.

Problem Solving

People with cognitive impairment following brain injury often lack problem-solving skills, and a Web-based approach could be useful in rehabilitation [65]. The ProSolv app from Powell and colleagues [65] could be a useful tool to help solve this issue. The deficit in problem-solving was trained through the creation of a personalized problem-solution list and with the possibility to use the app as a resource for remembering the steps to effective problem solving.

Memory

This cognitive dimension was analyzed in different samples and with different meanings by the authors. Tacchino and colleagues [66] and Zmily and colleagues [68] explored how to train memory in patients with diseases that cause cognitive impairments: multiple sclerosis and Alzheimer disease, respectively. As they referred to different kinds of populations, the authors explored different kinds of memory. Tacchino and colleagues [66] focused on working memory training, which can lead to changes in a healthy individual's brain structures that can improve cognitive function, useful in the daily life. The improvement is demonstrated in cognitively impaired patients as well. Their study focused on multiple sclerosis, as it is a cognitively disabling condition and affects all age groups. Another disease that has serious effects on cognitive impairment is Alzheimer disease. Memory impairment in Alzheimer disease patients was the focus of the work of Zmily and colleagues [68], which focused on recall ability training to help individuals retain critical information longer and consequentially improve their quality of life.

The research of Lu and colleagues [62] and Shellington and colleagues [63] investigated memory impairment in older populations. Shellington and colleagues [63] considered older adults with and without subjective cognitive complaints and mild cognitive impairment. In the study, the authors tried to train memory through physical activities. They stated that physical exercise was associated with higher cognitive function and used a square step exercise that was proven to train memory skills. Lu and colleagues [62] studied age-related memory decline and its effect on recollection ability during information finding and retrieval in healthy older adults. Memory was trained with 4 tasks: discrimination, visuomotor, respelling, and calculation.

Executive Function

Lu and colleagues [62] reported some evidence on age-related decline in executive function and performance; these abilities are generally affected by decreases in working memory functioning and by the perception of time. Deficiency in this domain is related to future functional impairment. Neurochemical, localized, and process aging theories indicate that age-related cognitive changes also affect executive functioning. Brain Win, the app developed by authors, stimulated executive function in all game contexts with 4 types of tasks (discrimination, visuomotor, respelling, and calculation). Shellington and colleagues [63] studied executive function related to physical exercise. They considered physical activities as a means to train executive function. Their app, Health*e* Brain, suggested a series of exercises, called square step exercises, to implement the cognitive domain.

Visuospatial Function

Brain Win, the app developed by Lu and colleagues [62], stimulated the visuospatial function with 2 tasks: Go to the Market and Super singer. Brain Win was specifically developed to improve visuomotor ability in older adults; visuospatial function is affected by age-related cognitive changes including visuospatial attention, memory, and orientation decline. Visuospatial function is the focus of the work by Shellington and colleagues [63] as well. Their study combined physical activities with cognitive training. In particular, they focused on a series of activities called square step exercises. These exercises could be described as a visuospatial working memory with a cued stepping response also known as mind-motor exercise.

Attention

Four studies considered the cognitive domain of attention. In particular, Bless and colleagues [67] focused on an app to train auditory attention, based on the forced-attention conditions of the consonant-vowel dichotic listening paradigm. Individuals have to listen to different auditory stimuli simultaneously in both ears while paying attention to only 1 of the sounds. According to the authors, this paradigm could be considered as an analog task in some everyday life situations in which people are asked to effectively master different and confounding auditory events. The authors reported that some deficits in auditory attention could also be found in clinical conditions like schizophrenia, preterm–born adolescents, dyslexia, and aging. In their study, the authors tried also to see if the trained task has transfer effects on cognitive interference and attentional task in daily visual and auditory domain activities.

The Attention Training Application by Hill and colleagues [60,61] is based on the dual n-back training paradigm and targets attention in elderly people. The authors reported that through aging, some aspects of attention could tend to decline—for example, with increasing age, the ability to divide or switch attention could decline. Attention is a cognitive function that has a pervasive influence on several daily activities. Thus, its training may also lead to improvements in other cognitive performance aspects and enhance the appropriateness of several daily life activities. Specifically, the authors highlighted that the effect of the dual n-back task could be transferred to other cognitive abilities.

Also, the Brain Win app, developed in a working prototype for older adults by Lu and colleagues [62], targets the cognitive domain of attention. This app directly stimulates attention with 4 types of games addressing discrimination, visuomotor, respelling, and calculation tasks.

Language

Two studies directly focused on training the cognitive domain of language. Lu and colleagues [62] started by reporting evidence of a decline of language functioning in elderly people. Specifically, neurochemical, localized, and process aging theories demonstrate age-related cognitive changes affecting language. Language is connected with various cognitive aspects; a decline in this domain could also affect sentence understanding and text recalling. In Brain Win, the app developed by the authors, language is stimulated through 2 context games (Finding Objects During a Phone Call and Super singer) that were connected to 2 types of abilities, discrimination and respelling, respectively. Lorusso and colleagues [59] focused on improving language ability in children with language impairment and typically developing children. Their system aimed to improve semantic competence and structural knowledge with various activities. The system is made up as an integrated combination of a tablet, a group of plastic toys, the near field communication technology, and a custom app that allows children to play with various activities to train specific cognitive processes and abilities such as mental representation, conceptual networks, and semantic versus structural world knowledge. These aspects are especially relevant in speech and language development and functioning.

Efficacy

Only 3 out of 10 studies directly evaluate the apps in improving cognitive abilities. Blackburne and colleagues [69] evaluated the efficacy of the NoGo app in having an impact on cognitive control and in particular on inhibitory control. Compared to a control group, the authors found in people using the app an increase of cognitive restraint evaluated with a self-report questionnaire. Regarding the exercise conveyed by the app, authors showed a significant effect in improving inhibitory control in the training group. Other measured outcomes were self-reported food consumption and attitudes toward food and diet. Results demonstrated the effectiveness of the app in improving even these aspects.

Bless and colleagues [67] concluded that the training of auditory attention through an app is feasible and successful. After 21 days of practicing, participants were found to have an increase in auditory attention. This is supported by the fact that the training group showed an increase in the performance of the exercise itself and in brain activation measured with functional magnetic resonance imaging.

Finally, Powell and colleagues [65] focused on the efficacy of their app and evaluated its effectiveness in improving problem-solving ability, but no significant effects of the cognitive training were found in comparing an intervention group using ProSolv and a control group performing traditional cognitive training. Other authors focused attention on subjective evaluations of their apps [59,61-63,66,68], but these studies lack of data regarding the effects produced by the apps on cognitive abilities.

Discussion

General Considerations

This systematic review provides a useful, clear, and comprehensive overview of the current state of the art in available apps for cognitive training. However, this work also raises some critical issues regarding the application of this kind of training in clinical and research practice for breast cancer patients. While some issues are broader and relevant to the field of cognitive training apps, others are more specific and directly related to their application in a cancer patient population.

General Issues in Cognitive Training Apps

The majority of the articles included in this review have the primary aim of evaluating app usability, acceptability, feasibility, and user satisfaction; only a few of them directly focus on demonstrating efficacy in improving cognitive functioning. Only 2 [67,69] out of 11 studies report significant and quantitative amelioration in cognitive performance. Even if feasibility is important, it should be noted that the objective efficacy of the apps has not been measured in the majority of the relevant articles. For several apps, we could not establish whether the training effectively improved the targeted cognitive domains.

In addition, some definitional and conceptual issues about cognitive functions also emerge. Specifically, there is a vast heterogeneity in the definition and conceptualization of cognitive

function across studies, with similar cognitive domains being labeled in different ways (eg, executive functions may include visuospatial attention, attention, and so on). Moreover, targeted cognitive functions are not unique or consistent across studies, with only marginal overlap between studies. Some cognitive functions (eg, memory) cover heterogeneous abilities (eg, working memory, short-term memory, long-term memory) encompassing specific functions that can be selectively impaired in some diseases and not in others. Thus, it is difficult to draw conclusions on which cognitive domain could benefit from app training. Given the aforementioned issues, it is critical to properly evaluate the clinical efficacy and effectiveness of these apps.

Specific Issues in Cognitive Training Apps Applied to Cancer Patients

Taken together, these results show that there are apps that are best candidates to target cognitive functions generally impaired in women with breast cancer. However, the feasibility, usefulness, and efficiency of cognitive training in this particular population should not be automatically taken for granted.

Relevant articles included in our review employed highly heterogeneous samples of subjects: only a few apps have been tested on patients, such as people with Alzheimer disease [68] or multiple sclerosis [66]; most have been evaluated on a healthy general population sample of adults or children. This heterogeneity is also indicative of the different needs of these diverse populations.

People with breast cancer may benefit from using available interventions or to-be-developed apps for this specific category of patients. In fact, breast cancer patients somehow reside in a class between mildly or severely cognitively impaired patients and healthy general population subjects because they display objective cognitive impairments or report cognitive problems [9] but they still can properly work and have an active and preserved social life. On one hand, they do not display a degenerative disease with a progressive worsening of global or selective cognitive functioning. On the other hand, they are aware of and worried that their cognitive worsening could interfere with daily routines and everyday life. Thus, they are strongly motivated to be involved in a cognitive training program. Worthy of note, breast cancer patients usually display a high level of distress symptoms and serious psychological side effects [5,9] that can influence subjective perception of cognitive functioning and could potentially interfere with training activities.

Finally, the summarized papers, apart from Lu and colleagues [62] and Shellington and colleagues [63], reported training interventions on a single cognitive domain. However, women with breast cancer often display difficulties and deficits in several cognitive domains. Thus, it could be relevant to design, develop, and implement an ad hoc app targeting the various cognitive function domains for breast cancer patients.

Conclusion

Our study highlights the fact that cognitive training apps are becoming more present in rehabilitation of different diseases. It is noteworthy that none of them has been developed to counteract cognitive impairment in breast cancer patients, a specific population in which short- and long-term cognitive difficulties have been underlined. Thus, currently there are no available cognitive training apps that meet the needs of breast cancer survivor women. Available apps lack strong specificity for oncological breast patients both from the point of view of the cognitive functions that should be addressed and for the psychological complexity that these patients display. In fact, the psychological and physical impact of breast cancer on cognitive impairment should be taken into account as well. As a specific population with specific needs, it is necessary to create an app that considers their deficit as different from the deficit that another population of patients could have (eg, neurodegenerative conditions). Medicine is evolving to consider not only the patient's physical safety but also a personalized approach to disease [70,71]. From the patient empowerment perspective, it is very important to give breast cancer survivors reliable means to improve and train their cognitive functioning because of the huge impact of cognitive complaints on the quality of life and patient empowerment [72]. Moreover, women with breast cancer may benefit from using a mobile or Web-based tool to improve cognitive functioning, effectively manage their daily activity, and properly cope with everyday difficulties. This would be especially helpful to foster breast cancer patient perceived self-efficacy and manage their anxious and depressive symptomatology. We conclude that further studies should test the feasibility, usability, and effectiveness of available cognitive training apps in women with breast cancer. Because of the complexity and multidimensionality of the cognitive difficulties affecting this cancer population, it may be useful to design, develop, test, and implement an app with the specific aim to train cognitive impairment in breast cancer patients.

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Authors' Contributions

GM and LV reviewed the literature and wrote the main part of the review. SFMP, DM, KM, and GP supervised the work, reviewed the manuscript, and provided conclusions.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary of study characteristics in terms of study type, aim and sample.
[PDF File (Adobe PDF File), 61 KB - mhealth_v7i3e10855_app1.pdf]

Multimedia Appendix 2
Summary of main aspects of apps and their evaluation.
[PDF File (Adobe PDF File), 70 KB - mhealth_v7i3e10855_app2.pdf]

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Abbreviations

COGNI-TRAcK: Cognitive Training Kit

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Original Paper

Sensor-Based Passive Remote Monitoring and Discordant Values: Qualitative Study of the Experiences of Low-Income Immigrant Elders in the United States

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Abstract

Background: Remote monitoring technologies are positioned to mitigate the problem of a dwindling care workforce and disparities in access to care for the growing older immigrant population in the United States. To achieve these ends, designers and providers need to understand how these supports can be best provided in the context of various sociocultural environments that shape older adults' expectations and care relationships, yet few studies have examined how the same remote monitoring technologies may produce different effects and uses depending on what population is using them in a particular context.

Objective: This study aimed to examine the experiences and insights of low-income, immigrant senior residents, family contacts, and staff of housing that offered a sensor-based passive monitoring system designed to track changes in movement around the home and trigger alerts for caregivers. The senior housing organization had been offering the QuietCare sensor system to its residents for 6 years at the time of the study. We are interested in adoption and discontinuation decisions and use over time, rather than projected acceptance. Our research question is how do cultural differences influence use and experiences with this remote monitoring technology? The study does not draw generalizable conclusions about how cultural groups interact with a given technology, but rather, it examines how values are made visible in elder care technology interactions.

Methods: A total of 41 participants (residents, family, and staff) from 6 large senior housing independent living apartment buildings were interviewed. Interviews were conducted in English and Korean with these participants who collectively had immigrated to the United States from 10 countries.

Results: The reactions of immigrant older adults to the passive monitoring system reveal that this tool offered to them was often mismatched with their values, needs, and expectations. Asian elders accepted the intervention social workers offered largely to appease them, but unlike their US-born counterparts, they adopted reluctantly without hope that it would ameliorate their situation. Asian immigrants discontinued use at the highest rate of all residents, and intergenerational family cultural conflict contributed to this termination. Social workers reported that none of the large population of Russian-speaking residents agreed to use QuietCare. Bilingual and bicultural social workers played significant roles as cultural navigators in the promotion of QuietCare to residents.

Conclusions: This research into the interactions of culturally diverse people with the same monitoring technology reveals the significant role that social values and context play in shaping how people and families interact with and experience elder care interventions. If technology-based care services are to reach their full potential, it will be important to identify the ways in which cultural values produce different uses and responses to technologies intended to help older adults live independently.

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KEYWORDS

immigrants; ubiquitous sensing; acculturation; passive monitoring; independent living; family caregiving; culturally appropriate technology

Introduction

Background

The availability of long-term care provided by family and professional caregivers is projected to fall short of growing demand in the United States [1]. Technology-based care services have been presented as a potentially elegant solution to the issue of insufficient numbers of elder care workers and family caregivers as well as a means to address disparities in access to care for the growing elder immigrant population in the United States. The most well-diffused technology to support aging in place is sensor-based passive remote monitoring [2]. Sensor systems are used to monitor the activity and movement within the living space of older adults with the goal of detecting deviations from one's normal routine and long periods of inactivity that may indicate an emergency. These systems are passive in that they require no action on the part of the older adult, unlike "active" personal emergency response systems (PERS) requiring that a button is pushed to actively call for help. Older adults often want to avoid making their adult children's busy lives more complicated because of their health problems and do not want their children to be overly concerned about them [3]. Passive remote monitoring has the potential to support this goal.

Where Cultural Values and Monitoring Technologies Intersect

The notion that technology is value-neutral and asocial is disputed by research that reveals how socially embedded technologies are—from their conceptualization through performance in real-world situations [4-6]. In the case of gerontechnology, technology developers—who are always socially and culturally positioned—are designing for people who are differently socially and culturally positioned. A device designed to support independent living is typically conceptualized and engineered by relatively young men who envisage their user as someone who is old, possibly with chronic conditions, and who prioritizes living at home [7]. Technology is also socially embedded because devices have particular goals that necessarily prioritize values: for example, risk management may be prioritized over privacy or social interaction. This social science insight that technology is social and embedded with values challenges the assumption of a neutral relationship between health technology, thereby challenging neutrality with regard to culture in which values are formed and acted upon [8]. The conceptualization of remote monitoring as both a technical and always social practice makes evident the need for research on the associated social and cultural meanings.

A number of studies have examined racial and ethnic differences in the use of assistive devices for mobility in the United States and have found that older adults of color have higher utilization than non-Hispanic whites [9-11]. The higher use appears to be driven by an acknowledged underlying need to compensate for the loss of functioning [9,10] and prevent falls [12] but can be impacted by a lack of financial resources [11,13] or difficulties in access [13,14].

Understanding cultural context is critical for understanding the implementation and use of information technology [15]. Cultural factors can influence how information technologies such as remote monitoring may produce different effects. In an ethnographic study of a personal emergency response system in Sweden and the United States, acceptance and use by participants were affected by how they connected the technology to their respective health care systems [16]. Swedish older adults received the emergency response system as part of a publicly provided home care service through their care workers and regarded access to current technologies through the welfare system as a right. In contrast, older American adults understood the service as a good they purchase as customers. American older adults expressed more hesitations about the technology-based service that made them less likely than their Swedish counterparts to use it [16]. A comparative study of home monitoring systems with Korean and Korean American older adults similarly revealed that cultural factors impact acceptability. The study identified impactful cultural factors of independent living because of immigration and loosened filial tradition, satisfaction with health care services, and technology capacity building by the government [17]. Both of these studies underscore the need to examine cultural contextual factors in research on acceptance and experiences with monitoring technologies by older adults.

Examining possible cultural differences in the use of elder care technologies is also important in the context of a growing immigrant population in the United States and the need for new solutions to address the cultural gaps in care services for these aging populations. In this study, we examine the experiences of immigrant, senior housing residents with a sensor-based passive monitoring system offered to them on a voluntary basis by a subsidized senior housing organization. The sample population is uniquely diverse, with senior housing resident participants from 10 countries. This research into the interactions of culturally diverse people with the same monitoring technology reveals the significant role that social values and context play in shaping how people and families interact with and experience technology-based elder care interventions.

Acculturation by Elder Immigrants in the United States

The US immigrant older adult population jumped from 2.7 million in 1990 to 4.6 million in 2010, an increase of almost 70% within 20 years [18]. According to 2010 Census estimates, immigrant elders comprise 11.9% of all adults aged 65 years and older in the United States. This demographic shift reflects large-scale changes in patterns of migration, with Asians becoming one of the largest pan-ethnic immigrant groups since mass migration from this region began in 1965. Migration from other countries such as former Soviet republics has also reflected changes in geopolitics since the fall of the Soviet Union, with the population of Russian speakers more than tripling from 1990 to 2010 [19].

For immigrant studies, acculturation has been often operationalized as the extent to which immigrants adopt host cultures [20]; however, researchers are increasingly understanding acculturation as a blending of different cultural

values into immigrants' adaptation process rather than as a linearized process toward acceptance [21-23]. For example, although Asian elder immigrants in the United States may retain filial piety as a core value that supports intergenerational care [24,25], they also modify its application to new cultural realities in the United States where independence is emphasized [16,20]. Studies have shown a trend among Korean, Chinese, and Indian elder immigrant groups toward a preference for more independence from their adult children [20,26], describing how these groups may associate filial piety with emotional social support rather than direct care [16,26].

With family care expectations in flux, help-seeking behavior outside of family systems is an important area of focus. For one, research indicates that the complexity of navigating value systems, language, customs, lifestyle, and the Westernization of their children prevents Chinese and Korean immigrants from seeking help from English-speaking service providers [27,28]. A filial piety framework has been used to explain barriers to seeking formal elder care services, yet this principle does not fully address the dynamics of elder health and long-term care services when they are accessed by immigrants. Confucianism encompasses other principles seldom employed in health and social services research in the United States that may promote understanding of immigrant elders' behaviors. One such value that we employ in this study is the primacy of a benevolent, trusting relationship between a governing authority and subject (the literal translation is king and citizen) that is rooted in the principle of paternalism, which can be thought of as the extension of the family to the larger social whole [24,29]. Aspects of Confucian value systems are likely relevant along with filial piety, and these values may be pieces that help compose a stronger understanding of Asian immigrants' interactions with extrafamilial health and home care services.

Much hope has been placed in the use of technologies to remotely monitor health and safety in ways that are more broadly accessible and acceptable. We take as a starting point that new practices developed around technology for elder care are social practices and that technologies are embedded with values. Providers cannot assume that all users hold the same values that shape their experiences with a given technology. Applying an understanding of acculturation as a process can provide insights into immigrant older adults' interactions with remote monitoring technologies. Immigrant elders' adaptation of new technology can be understood as a cultural integration process in which they develop their own meaning of care technologies while calibrating their own cultural values with those of their host culture. Examining interactions with technology through the lens of immigrant older adults can lead to greater and more successful utilization of these innovations in everyday life.

Methods

The Technology Intervention and Field Site

The field site is 6 subsidized independent living residential buildings owned by a large senior service and housing not-for-profit, mission-driven organization in a US metropolitan city. The housing organization had been offering QuietCare to its residents for a highly subsidized rate of US $5 to 15 per month for 6 years at the start of this study, so implementation issues typical for new technologies had long been worked out. QuietCare comprised 5 interconnected sensors placed in predetermined locations throughout the resident's apartment (bathroom door, bedroom door, apartment door, refrigerator, and environmental temperature sensors). Family members and social workers can access information about changes in movement from the individual's norm that may indicate a problem. The system also triggers alerts when certain sensors detect no movement (eg, if there is no motion through the bedroom door in the morning, if someone does not come out of the bathroom in a given time, or when no movement in the home is detected for a period of time). The system is connected to a telecare call center that first tries to reach the older adult, followed by family emergency contacts, and in some cases, the emergency medical service (EMS) is contacted when no one can be reached. The study received ethical approval from The Committee for Protection of Human Subjects, University of California, Berkeley.

Participants and Recruitment

In-depth semistructured interviews were conducted in English and Korean with elder residents, family members, and staff. As depicted in Table 1, a total of 41 participants were interviewed. Family members and residents were interviewed once, and social work staff were interviewed twice. All participants were US citizens, and all residents had multiple chronic conditions. Residents had incomes less than $36,120; a total of 5 participants had incomes less than $18,050. The majority of the residents had completed high school.

There were a total of 23 current users of Quietcare, of which 8 were not recruited because of serious health issues and dementia (n=4) and because they did not speak English or Korean (n=4). Of the remaining 15 current users, all were invited and agreed to participate in the study. We invited each of the 8 residents who had discontinued the system in the past 12 months and 3 refused to be interviewed: 2 were Chinese American and 1 was Korean American. The resident participants included individuals born in the United States, Poland, Czech Republic, Puerto Rico, Peru, Malaysia, Japan, China, and South Korea. Multilingual social workers were able to explain the reasons for discontinuation of the system among those who refused to be interviewed and could speak about resident use and discontinuation over a 6-year period since QuietCare had been available.

Table 1. Study participants.

Participant group	Number of participants interviewed	Number of foreign-born participants
Residents	20 (including 5 who had discontinued the QuietCare system)	11
Emergency contacts	11 (2 who had discontinued)	4
Staff[a]	10	7
Total	41	22

[a]All but 2 staff were interviewed twice; 2 supervisors were interviewed only once because they did not have regular interactions with residents who use QuietCare, and all their knowledge and experience with the system could be discussed in a single interview.

Family members were recruited with the permission of participating residents. Some older adults did not want to burden their family member with the request, and 11 family members who served as emergency contacts were invited and agreed to be interviewed. These were daughters, sons, granddaughters, sisters, and 1 long-term home aide born in China, Korea, Guyana, India, and the United States. All technology, housing, and social work staff who had contact with the technology participated. The 10 staff members included 3 US- and 7 foreign-born participants from Russia, China, Israel, India, and Korea. Staff members were multilingual. Language and cultural congruence between staff and the residents was often achieved. All social work staff were women (n=6), and all housing and technology staff were men (n=4).

Data Collection and Analysis

The first author conducted all but 5 interviews and attended all interviews. The Korean interviews were coconducted by an interviewer who was fluent in Korean and English. The interviews were semistructured. Social work staff were interviewed twice: once before interviewing residents and family members and once after. This provided the time needed for an in-depth discussion about their experiences promoting the technology, the opportunity to triangulate the interviews, and the opportunity to follow up with social workers on cultural differences they perceived were at play in residents' experiences with the technology. Residents and family members were asked about how they made decisions about adoption (and when relevant, discontinuation) and about their experiences with the system. Residents were invited to tell their story of how they came to live in the senior housing building, and they discussed their immigrant histories and family situations. Social workers were asked about their observations of adoption and system discontinuation decisions and processes, about their own experience of using the system and daily interactions with the sensor-generated data, and about cultural differences in adoption decisions and experiences of their residents. Some had worked at the organization since before QuietCare was offered, so they were able to speak about the 6 years of experience working with residents and QuietCare.

Audio-recorded interviews were transcribed verbatim. The 5 interviews conducted in Korean were transcribed in Korean and then translated into English. The first author conducted the analysis and discussed cultural translations and clarified meanings with the researcher who conducted the Korean interviews. All interviews were coded beyond the point of conceptual saturation to reduce the potential for coder bias. Transcripts were imported into Dedoose (University of California, Los Angeles), which is a software that facilitates the management of qualitative data.

A multistep coding process of grounded theory was used, beginning with open coding and followed by axial coding in which categories of codes were connected so that dominant themes could emerge to produce an explanation of patterns in the ideas heard across interviews [30,31]. Examples of themes are "fear of burdening adult children" and "appeasing social worker." As part of this constant comparison method, themes were compared and contrasted across individual interviews [31]. The interview guides and a detailed description of the study participants and analytic methods can be accessed in the study by Berridge et al [32].

Results

Values Made Visible

The reactions of immigrant older adults to the passive monitoring system reveal a tension between their values, needs, and expectations on the one hand and the values embedded in the technology on the other. Here, we describe themes of cultural difference in response to the sensor system: differing expectations for how one should receive care and support and reactions of hope versus skepticism that the sensors will help, different reactions to the involvement of family members as emergency contacts, and experiences of intergenerational family cultural conflict. We also provide insights into the work of the multilingual and bicultural social workers as cultural navigators, including linguistic and cultural barriers to successful marketing and service delivery on the part of the technology company.

Russian social workers explained that none of the more than 200 Russian-born residents saw enough added value above the active PERS to adopt passive monitoring, citing that most of them had Medicaid, which covers PERS. Social workers observed that their Russian clients felt that they should be provided hands-on support and favored "concrete care" over remote monitoring. One social worker explained that Russian residents ask the rhetorical question, "Why should I depend on a piece of plastic for my life?" Another described what she called "socialist thinking," noting that Russian elders grew up in a country where they received free education. She recalled how a resident had approached her in anger because a fellow resident was in need of help but was only offered the passive monitoring system:

> *She came in and she was very angry with me. She said why doesn't Sarah have a home aide? She*

> *deserves a home aide. Why hasn't [the housing organization] provided her one?*

The social worker recalled having a difficult time explaining to this Russian-born resident that her neighbor did not have a home aide, despite her need, because she was not eligible for Medicaid and could not afford to pay out of pocket. These residents preferred in-home human support and expected that it be accessible.

Contrasting values also surfaced in the response of many Chinese- and Korean-born residents to one of the primary purposes of passive monitoring. The assumption that an older adult wants an early intervention if she is severely ill was challenged by some of these residents who stated that "When the time comes, I am ready." They expressed a desire to avoid prolonging a severely impaired life and to pass away when the time came. This relationship with death involves a high degree of acceptance and differs from a desire to intervene to the end, characteristic of the US health care system [33]. Along similar lines, optimism about the efficacy of passive monitoring as a safety feature was shown to be a cultural commitment. Social workers reported that English-speaking and US-born residents adopted the technology because they had a fall history and genuinely hoped it would help them, whereas Asian-born residents were less optimistic that it would help them, accepting the monitoring system only if they had no one to depend on or little family contact.

Burdening and Intergenerational Family Cultural Conflict

A common theme among Asian elder immigrants was their experience of intergenerational family cultural conflict, which was most often reflected in their disappointment over being asked by their children to live in a senior housing building. Compared with their US-born residents, Chinese- and Korean-born residents who adopted the sensor system were particularly concerned about troubling or burdening their children. In combination with the family cultural conflict surrounding shifting norms, frequent false alerts of passive monitoring created a tension that led Korean and Chinese American residents to discontinue the system at the highest rate compared with all other users. Social workers attributed this in large part to role conflict. One explained:

> *So they have the image that they do not want to bother their children. I think because especially this Asian group now, they have experienced so many wars...they have so many things suffering feeling unfairly treated for their whole life but they will not say it. Even at this time that they do not think a parent mother should bother the adult children, but rather, they should protect and take good care of the children and when they grow older they don't want to become the burden.*

This feeling that the false alarms caused them to be a burden on their children was particularly disturbing to women who were accustomed to taking care of their younger family members and did not wish to become the care recipient in the family while living away from the family in senior housing. Social workers reported that it was not the family members who were bothered by the false alerts, but rather, the older adult:

> *It is not the children who are complaining: "Why did QuietCare call during the night when there was a false alarm?" Or "Why did they call me when I am busy during the day?" The children of course will feel bad, but they do not say, "Okay, cut it off." They do not say that. It is the senior: "Oh please, please." They even beg me, "Please let me go. I did not want to bother them [their adult children]."*

The experience of causing burden rather than alleviating it in the context of new norms of living apart contributed to the high rate of discontinuation among Asian immigrants. These residents concluded that the technology was useless and burdened their family members.

The Role of the Cultural Navigator

Social workers who were multilingual and able to relate to residents who had emigrated from the same country or region as they had served as buffers to the outside world that frequently involved discrimination and poor treatment. One Russian-speaking social worker explained:

> *But the environment – I mean social workers speak Russian the social worker speaks Chinese – residents feel less stress with them, but in the real life outside world it is stressful.*

The relationships immigrant residents had with their social workers were important because they were some of the few people who patiently sought to understand them and their concerns and because they represented a safe space in the context of what could be a hostile outside environment. These relationships served as leverage during decision making about remote monitoring adoption, which the social workers were responsible for achieving.

All social workers noted that their relationship with their clients was key to getting them to adopt the technology. A Chinese-speaking social worker explained:

> *The Asian group, I don't think they are so much interested in it [passive monitoring]. I have to say to you, I think they accept it because I promoted it...I think there still is one or two in the program because I promoted it. I know they don't like it. But then it's only five dollars. To "let's not give [social worker's name] a hard time" or something. Comparing cultures, if I can use the authority even though I'm not an authorized person, but because "oh, staff say this and even though I prefer not to, okay let me have it." If they have a choice to make their decision, they would not want to have it but they have it because I promoted it.*

Chinese and Korean residents may have accepted monitoring because their social workers wanted them to have it. Their perceived relationship with their social workers was important to them for reasons that are unique to their experiences as immigrants who placed a high value in their formal and informal networks, as part of their everyday transactions.

As immigrants, social workers also drew on their experiences and skills navigating cultural difference to promote the technology. One explained:

> *Culturally there's a big difference. So when we approach difference language groups, it's different. I have to switch my channel [laughs]. It doesn't mean respect or disrespect which group but it is a way of presenting something to a certain language group. For example, for certain groups you cannot be too passive, you have to explain and then you have to take the lead.*

Social workers who were immigrants were aware of the work they did to "switch channels" while interacting with residents from a variety of backgrounds who had different expectations of how they should be treated and how services are offered. When discussing the passive monitoring system, they delicately navigated word choice so as not to disturb or put off residents. A social worker described the difficulty they had discovering a word that would not convey intrusiveness:

> *We are very, very cautious about the words we use. We cannot say there's an image, we cannot say we are monitoring, we cannot say we are watching you, but then eventually what's the word I can use [laughs]?! We're very careful. We try not to use monitor, we try not to use image, then all of a sudden, what to tell them? [laughs].*

Eventually, through trial and error, social workers found that residents understood the example of a "sweeping motion" the buildings' sensors detect to open and close doors as people step into the entries. Still, they encountered residents who did not trust that the sensor system was not a camera. A social worker noted:

> *In the beginning [the residents] just don't believe us...but I still have to be very careful about monitoring and picture. We definitely don't say that.*

Due to their cultural positioning and close relationships with residents, social workers had valuable insights about barriers to adoption among immigrant residents. Social workers organized information meetings to advertise the sensor system, holding both single language and simultaneously translated meetings in Korean, Chinese, Russian, and English, but they were unable to bridge all language barriers. A language line was used by the telecare call centers, but all signal alerts that went through the telecare center were responded to in English. The operator would call using English to learn first if the resident needed help before dialing in the appropriate language line. For residents who did not speak English, having the telecare operator call in response to a signal and greet them in English was troubling. Through an initial attempted conversation, the operator would realize that the person was there but that they do not speak English. At that point, they would either look up the resident's preferred language listed on that resident's file or hear the resident repeating their preferred language in English and connect a translator on the phone through a language line. The reason the initial call was not made in the preferred language appeared to be a combination of timing and cost savings: the language line was an expense when used, so if a resident did not respond to a call or was not home, that time would be wasted money. Sometimes family members were conferenced in to translate, as an Indian-American son of a Hindi-speaking resident explained:

> *They will call her first and then they'll call us and say we have her on the other line and can you help us talk to her?*

This delayed language access presented a problem for some residents because it was alarming and confusing. A Russian-speaking social worker stated that the Russian residents were scared when a voice comes on in English:

> *They scared for this. A lot of people. Even people who live here a long time, like let's say like 20 years.*

A Chinese-speaking social worker described how she tried to prepare residents for this:

> *When I introduce it to the non-English speaking group, I will tell them they are supposed to be provided language. But just in case, you have to at least learn one word: "Chinese, Chinese, Chinese!" I would tell them. If unfortunately, an emergency happens, then you need help but you don't speak English, then this is the word you have to learn.*

A Chinese resident said that this is less easy in practice. "When stressed," she explained, "you forget everything so you speak Chinese." Residents described how being in an emergency, afraid, and possibly in shock could make one sensitive to incomprehensible words.

Language barriers also emerged in in-person interactions over the sensor system when social workers were unable to mediate. A Korean-speaking resident had discontinued the sensors after a false alert triggered a call to EMS and they broke her door to enter, not knowing she was not home. She explained, as she became visibly upset over an incident that occurred 2 years prior:

> *So the super came and he came for this, and saw the door and said I have to compensate for the door. So I have to pay for the door. So I haven't even done anything wrong, I wondered why I should pay for it, but you know, I couldn't say anything back in Korean, in English, so I haven't said anything to the super. The super who manages this apartment said that since I broke the door, I should, we should, pay for it. So I was like, I haven't done anything wrong, I have no sin, the firefighters broke it like this and they're asking me to pay, so I haven't said anything and I couldn't speak English and I just left.*

False alerts that caused EMS to arrive was a source of intense embarrassment for all residents who experienced it. The added language barrier when dealing with the consequences contributed to an unforgettable negative experience with the technology.

Another issue social workers drew our attention to is what they called a lack of cultural awareness and humility expressed by the technology company and their representatives. For one, the name of the product is not translatable into Korean, so an extra

step is required to educate residents about what the system is. A social worker explained:

> *I have to teach clients to pronounce QuietCare in English so people know what they're talking about. I write it out for them. The company does not have flyers in other languages.*

She also described culturally insensitive company representatives and lack of diverse representation on product media:

> *Two white ladies from QuietCare came to present. They were far from sensitive and don't understand their clients.*

Social workers felt that this lack of cultural humility and awareness may have served as a deterrent to some residents. Social workers also noted how images of Asian elders were not included on any of the company-provided materials or website and that human diversity in marketing is limited to the depiction of African Americans and Latinos.

Discussion

Principal Findings

This study contributes to the limited literature on cultural specificity and remote monitoring technology. Our sample and qualitative methods drew out expectations and values at play that shed light on decisions made by Russian-speaking elders to decline the intervention and immigrant Asian elders' reluctant adoption and high discontinuation rate. Our findings are consistent with previous research that illustrates how expectations rooted in cultural values and specific health care system contexts influence the embrace, reluctant use, or rejection of technologies [24,25]. Here, we highlight and discuss key themes that emerged at the point of acceptance or rejection of the QuietCare system, points of discontinuation, and the role of intergenerational family cultural conflict and the social worker as a cultural broker.

The first theme presented was the clash between Russian-speaking residents' expectations for support and the support offered to them by the technological intervention. None of the more than 200 Russian-speaking residents accepted remote monitoring. Social workers attributed this to the desire for hands-on care ("Why should I depend on a piece of plastic for my life?") and the expectations that this should be provided to them based on sociopolitical norms of publicly provided services. They understood this rejection of the intervention they were offering among this group of residents to be grounded in "socialist thinking" and expectations for support in old age that represented "concrete care."

Chinese and Korean residents responded altogether differently than Russian-speaking residents and most US-born residents. Traditional Confucian values dictate that there is a filial obligation to provide for one's elders in later life. With the breakdown of the traditional family network as a consequence of migration and modernization, Asian elders were in a quandary in regard to who they can turn to for support. They were aware of the demands of their own children, yet they were not fully acculturated to the expectation of service from outside their families. Social workers observed, and QuietCare users and former users confirmed, that residents from Asian countries generally did not believe the technology would be useful to them, and those who accepted it did so only when they lacked frequent family contact or alternative supports. These residents lacked hope that the intervention would help them and adopted the intervention reluctantly after social workers pressure them.

Social workers contrasted their Russian-speaking client's tendency toward hard questioning about the technology with Asian resident's reluctance to ask questions. Bicultural social workers expressed this in terms of passivity and the desire not to upset them. Recall the Chinese-born social worker who explained, "I think they accept it because I promoted," an observation echoed by the Korean-born social worker. We can think of this dynamic of reluctant adoption so as not to make waves in the context of the Confucian values of filial piety and governing authority and subject and also a way to reciprocate in their relationships with those who help them, namely, the social workers they work with.

The principle of governing authority and subject emphasizes the fulfillment of loyalty to honorable leaders [29] and obeying a superior based on mutual trust and benevolence [24]. Social workers were the access point for needed public services, including the Department of Housing and Urban Development-subsidized housing in which they worked and residents lived. In this position, social workers represent government and authority. Findings indicate that the social workers' promotion of the sensor system was successful despite the lack of enthusiasm by residents because these residents showed mutual respect for their social workers in a form of obeying organizational expectations embedded in the value of governing authority and subject, in return for the services provided. Bilingual and bicultural social workers were attentive to norms of a hierarchical age order and provided language support to residents, satisfying Asian older adults' needs to be respected with proper filial traditions. Resident participants effusively expressed gratitude for their social workers during the interviews because they experienced the outside community as hostile or discriminatory in contrast to the safety and support they experienced in the residence buildings that social workers oversaw. The older adults' acceptance of monitoring can be understood as behaviors of role fulfillment and gratitude for the social workers who provide emotional and material support. Older adults appeared to suppress their personal desire to reject the intervention in favor of promoting peace by obeying their social workers who represent a governing authority and not "giving social workers a hard time" by declining the recommendation to adopt.

Given this reluctant adoption reported by and about Asian immigrant residents, it is no surprise that this group would have the highest discontinuation rate, but we find that intergenerational family cultural conflict is also contributing to the decision to terminate the use of QuietCare. When false alarms caused unnecessary interruptions for their children at work or long drives to check on them, these residents were more likely to immediately terminate monitoring services out of concern that it was bothering their children. Social workers

pointed out that it was not the children who complained about false alerts but the older adults. Korean and Chinese elders' strong concerns could be situated within the cultural value of prioritizing the best interest and success of their children, even perhaps over their own well-being. This can also be explained as "saving face" behaviors that allow one to avoid any embarrassing situation. Korean and Chinese residents may be very sensitive to self-disclosure issues, considering the false alert may cause a threat to maintaining their self-esteem. These residents expressed to their social workers fears of burdening their children and often concealed feelings of sadness about living in a senior housing building to avoid burdening their children. These findings indicate that when implementing remote monitoring interventions, it is important to be attentive to possible differences regarding sensitivity to self-disclosure.

The findings also highlight the ways in which technology providers could better support a culturally diverse older population and their families. Social workers attempted to bridge certain gaps, including language line services that did not quite substitute for a native speaker as a first response. Social workers also described how companies need to think beyond language and better understand and represent their audience in outreach materials. Furthermore, both gerotechnology companies and immigrant older adults stand to benefit from culturally sensitive technologies that are targeted specifically to the concerns of older immigrants whose priorities may be more multifaceted than developers and service providers imagine [34]. Certainly, older adults should not be expected or pressured to adopt passive remote monitoring technologies that they feel miss the mark or to continue using technologies that are causing significant negative disruptions to their lives or relationships.

The aim of this analysis was not to predict the various ways in which immigrants from particular countries will respond to home health care technologies. We certainly do not claim that Russian-speaking immigrant elders will uniformly reject passive remote monitoring. Rather, the findings illustrate that the development and implementation of successful interventions require contextualization in social values, which are always culturally inflected. Uniformity of user representations of older adults in technology design and implementation creates barriers to successful use. Indeed, older adults are not a user group but have diverse needs, expectations, and reactions to technologies intended to support them and their caregivers [34-39]. Moreover, the findings highlight why the impact of a particular technology is not fully predictable and should not be imposed on top of existing care practices, but rather, developed alongside these practices [34,40], all of which will benefit from an appreciation for cultural nuance.

Limitations

This study is exploratory and did not include significant numbers of each user group to make generalizable inferences. Social workers referred to residents using their own grouping terms: "Asian residents and Russian-speaking residents," 2 groups within which we can expect much cultural variation. Our participants' own grouping of these residents prevents description of potential cross-country differences. We also note that our findings rely more heavily on reports from social workers regarding cultural differences they observed than on such observations by residents or family members. This is a limitation, and future work with larger sample sizes might examine older adults' assessments of cultural aspects of remote monitoring technologies in greater depth.

Conclusions

This study contributes to our understanding of culturally inflected experiences with gerontechnologies and provides insights into its discontinuation for immigrant older adults. Social workers served as the cultural brokers of passive monitoring, and their relationships with immigrant older adults was were informed through their unique immigrant experiences. A more complete understanding of how users, potential users, and discontinued users interact with and experience remote monitoring technology requires an appreciation of the sociocultural context in which these technologies are introduced. This need is more urgent with the growing older population that includes a growing older immigrant population. Successful adoption of gerotechnologies by immigrant older populations could potentially lead to lower costs of long-term care and overall improved quality of life, but only if they can be culturally and practically relevant to these populations. The contextual lens we offer allows us a deeper understanding of the disparate rates of adoption and discontinuation of a sensor-based passive remote monitoring technology intended to help older adults live independently longer.

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Conflicts of Interest

None declared.

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Abbreviations

EMS: emergency medical service
PERS: personal emergency response systems

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Original Paper

Correlates of Stress in the College Environment Uncovered by the Application of Penalized Generalized Estimating Equations to Mobile Sensing Data

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Abstract

Background: Stress levels among college students have been on the rise for the last few decades. Currently, rates of reported stress among college students are at an all-time high. Traditionally, the dominant way to assess stress levels has been through pen-and-paper surveys.

Objective: The aim of this study is to use passive sensing data collected via mobile phones to obtain a rich and potentially less-biased source of data that can be used to help better understand stressors in the college experience.

Methods: We used a mobile sensing app, StudentLife, in tandem with a pictorial mobile phone–based measure of stress, the Mobile Photographic Stress Meter, to investigate the situations and contexts that are more likely to precipitate stress.

Results: Using recently developed methods for handling high-dimensional longitudinal data, penalized generalized estimating equations, we identified a set of mobile sensing features (absolute values of beta >0.001 and robust z>1.96) across the domains of social activity, movement, location, and ambient noise that were predictive of student stress levels.

Conclusions: By combining recent statistical methods and mobile phone sensing, we have been able to study stressors in the college experience in a way that is more objective, detailed, and less intrusive than past research. Future work can leverage information gained from passive sensing and use that to develop real-time, targeted interventions for students experiencing a stressful time.

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KEYWORDS

psychology; stress; mobile sensing; college campuses

Introduction

Stress levels among college students have been on the rise for years [1]. According to a recent large-scale nationwide survey, rates of student stress continue to climb as more than half of students (57%) reported experiencing “more than average stress” [2]. In the workplace, it has been conservatively estimated that stress costs the United States economy up to US$125 billion annually [3]. Although not directly measured in dollars and cents, evidence for the negative impact of stress on college students can be observed through hampered academic performance, as 30% of students noted that stress caused them to receive a lower grade on an exam or course, fail or drop a course, or it interfered with thesis or practicum work [2].

Broadly, stress can be defined as any sort of negative event related to demand, threat, or harm. Following a stressful event

is a biological and behavioral response geared toward altering the present situation or otherwise adapting to the stressor [4]. Along with hindering academic performance, stress is thought to be related to a host of negative emotional states and health outcomes, including depression, obesity, and cardiovascular disease [5-7]. Indeed, as levels of stress have risen among college students, so have issues related to mental health [2]. Not surprisingly, a survey of college counseling center directors indicated that a clear majority (90%) of centers reported an increase in severe psychological problems among students [8].

A primary source of stress for students is academics. Stress because of class attendance and homework were among leading stressors in one study of college students [9]. Further, research suggests that in addition to academic performance, students are also stressed by a pressure to succeed and about concerns regarding postgraduate planning [10]. Of course, in the college environment, stressors other than those academic in nature also exist. Interpersonal aspects of a student's life, such as worrying about forming friendships, fitting in socially, and getting along with roommates, were reported as stressful elements by students [11]. In addition, environmental sources of stress, such as financial difficulties, and changes in eating and sleeping patterns also contribute to levels of student stress [11,12].

Until recently, the dominant method for sampling information about students' lives came by way of daily and weekly diaries where details about students' thoughts, experiences, behaviors, and activities could be recorded over a specified time range. Indeed, approaches such as this have shed light on various aspects of a college students' life, including interpersonal student relationships, drinking behavior, and coping with stressors [13,14]. However, diary methods can be time intensive for participants and typically rely entirely on retrospective self-report of activities, a task that is known to be susceptible to various forms of bias—chiefly a bias due to cognitive and memory limitations [15]—resulting in inaccurate reports of the frequency and severity of events.

With the widespread adoption of mobile phones in recent years, new approaches have been developed to use mobile phones for studying real-time or nearly real-time behaviors and attitudes [16]. Mobile phones can be used to collect both ecological momentary assessments (EMAs), such as a brief stress inventory, and automatic passive sensing data (eg, audio and location data collected via microphones and phone GPS). Researchers have successfully related mobile phone sensing features to mental health in a clinical setting [17,18]. Wang and colleagues [19] were among the first to adapt this technology to better understand student mental health with the creation of the StudentLife continuous sensing app. With the StudentLife app, researchers have been able to capture daily fluctuations in students' mental and emotional well-being by linking passive sensing features (eg, sleep, location, social interaction) to aspects of standard health-related questionnaires [19-21].

Based on prior research using primarily self-report measures, aspects of the college experience are clearly stressful for students ranging from interpersonal relationships to academic achievements. However, one issue with this work is that these measures are often obtained once per term and are thus subject to the limitations and biases of retrospective self-report measures, which makes it difficult to paint an accurate picture of how stress manifests itself in the daily lives of students. Recently, a proof-of-concept study using passive mobile phone sensing investigated the relationship between passive sensing measures and various mental health outcomes (eg, depression, loneliness, stress) [20]. This proof-of-concept study demonstrated the utility of mobile phone sensing apps despite having focused on a relatively small number of sensing-derived features. Here, we expand on this work by focusing on a considerably larger number of passive sensing features to comprehensively categorize a day in the life of a college student and also make use of recently developed advances in modeling, such complex, longitudinal data. As examples of the mobile sensing features become available, inferences can be made about the quality and quantity of an individual's interpersonal relationships by conversation features or phone usage, about academic-related activity by time spent in study locations, about sleep through a combination of sensing features (eg, periods of movement, presence of light, phone usage), about exercise by the time spent in gymnasiums, and so on. Moreover, these features can be examined not only daily, but also at a finer grain within a day. Looking at the data more minutely could help fingerprint meaningful behavioral patterns in relation to stress. For example, it could be the case that phone usage decreases dramatically during evening hours when stressed, but not globally across the day. Thus, the purpose of this study is to further the understanding of stress dynamics on college campuses by leveraging a dataset rich in passive sensing features to accurately, and naturally, capture possible stressors in the lives of students. Whereas prior work has largely focused on a small number of features, we are able to use an array of mobile sensing features and then subsequently analyze these data with recently developed methods that both account for statistical dependencies inherent in longitudinal data and perform feature estimation and selection on high-dimensional data [22]. By doing so, we are able to identify a collection of mobile sensing features across the domains of social activity, location, and ambient noise that are related to stress levels across the academic term.

Methods

Participants

Data were collected from 95 participants who agreed to provide mobile sensing data across the winter or spring terms. Demographic information was missing for one participant. Of the 94 participants with complete demographic information, 56% percent were female (53/94). The mean age of participants was 21 (range 18-28) years. This study was approved by the Dartmouth Committee for the Protection of Human Subjects.

Mobile Sensing

The StudentLife app was used to collect sensing data and to administer EMAs; a version of the app exists for both Android and iOS operating systems. The app continuously collects and records students' sleep, physical activity, phone usage, location, and sociability data in addition to randomly administering EMAs probing stress once a day. Data from StudentLife is uploaded

to a secure server (encrypted and transmitted through HTTPS) whenever a participant is both using WiFi and charging their phone, which they were encouraged to do daily.

Conversations and Ambient Sound

Social interaction was measured by the number of independent conversations and their respective durations. Critically, to protect participants' privacy, raw conversation data was never recorded or analyzed. Instead, relevant features were extracted from the audio stream and used to identify the presence of a human voice and infer a human voice and conversation patterns. In this way, the number of conversations along with their respective durations were calculated. These conversation-related features, along with features related to ambient sound, were subsequently uploaded to a secure server [19,23].

Sleep

Sleep features were inferred through a combination of passive sensing features (ambient light, audio amplitude, movement activity, screen on/off). In this way, three features were computed: sleep onset, wake time, and sleep duration. This measure of sleep has been shown to be accurate within +/–30 minutes for total sleep duration [19].

Location

Density-based spatial clustering of applications with noise (DBSCAN) [24] was used to cluster GPS coordinates to uncover where students were spending a significant amount of time. Every building on campus was mapped with respect to its primary function; thus, the amount of time a participant spent at locations such as dining centers, the gym, and study locations could be measured along with their total distance traveled and the number of different places visited. The institution where this study was conducted was an ideal environment for extracting location-based data because more than 90% of students live on campus and first first-year students are required to reside on campus during their first year of school. Further, all students are required to have a campus meal plan for the entirety of their education.

Mobile Phone Usage

The total number of phone lock and unlock instances was computed along with the total duration a phone was unlocked during the day.

Epochs

There is a large amount of daily variability in a student's schedule; thus, we also looked at data not only over the course of a day but within the following three epochs: 9 am to 6 pm (day), 6 pm to 12 am (evening), and 12 am to 9 am (night). Accordingly, we could estimate and add the relative occurrences of behaviors within each epoch compared to their daily totals as features.

In total, across the different sensing-based features (conversation, sleep, location, and phone usage) and within the previously mentioned time epochs (9 am-6 pm, 6 pm-12 am, 12 am-9 am), 60 passive sensing variables were computed.

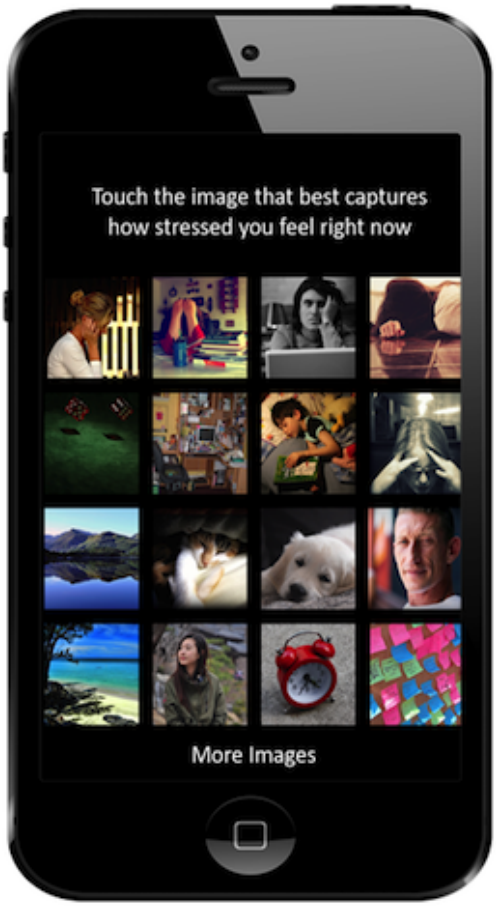
Measures

The Mobile Photographic Stress Meter (MPSM) was used to measure stress (Figure 1) [25]. The MPSM is a series of 16 images depicting varying levels of stress (1 depicts a relaxing beach, and 16 displays someone on the verge of breaking down). The user simply taps the image that best describes their current stress level. Critically, usability is an important aspect of any mobile phone app. In a pilot study, along with demonstrating item validity, the majority of MPSM users enjoyed using the mobile stress meter, reporting comfort, ease of use, and an overall positive impression of the app [25]. In addition, participants were asked to indicate their level of stress on a scale from one (not at all) to five (very much); this stress scale was not used in the main analyses but was used to validate the relationship between stress and the MPSM.

Analyses

Datasets across a variety of disciplines are quickly increasing in complexity and dimensionality with the onset of new data collection technologies. In typical studies, the number of observations is much larger than the number of features or covariates. When referring to high-dimensional data in this context, the number of features nears or even reaches the number of observations. In addition, these datasets become even more complex when collected over time. Recently, researchers have proposed a technique to estimate models for longitudinal data with high-dimensional covariates [26]. More specifically, Wang and colleagues [26] combined techniques used for analyzing clustered and longitudinal data (ie, generalized estimating equations [GEE]), an extension of the generalized linear model to accommodate clustered and longitudinal data, with penalized regression methods. This resulted in a technique known as penalized generalized estimating equations (PGEE). An advantage of these recently developed techniques is that, in contrast to previous work that focused on a few features out of many possible mobile sensing features, this technique enables us to use a greater number of mobile sensing features and feature elimination to prune uninformative ones. In this study, PGEE were used to simultaneously estimate and select features from the 61 (all the sensing features plus a time variable) variables contributing to stress with the package PGEE in the R environment [22,26,27]. Like GEE, PGEE fit a marginal regression model to the data and require the selection of a working correlation matrix; further, it can yield consistent estimates even if the working correlation structure is incorrectly specified [22,26]. Here, the independence correlation matrix was used as the working correlation matrix, and the smoothly clipped absolute deviation (SCAD) penalty was used as the penalization function due to its efficiency and lack of bias compared to other penalization techniques (eg, least absolute shrinkage and selection operator [LASSO]) [22,28]. To select the optimal tuning parameter, five-fold cross-validation was implemented. Additionally, robust variance was calculated for effective inference.

Figure 1. The Mobile Photographic Stress Meter (MPSM) is a pictorial, user-friendly way to measure stress.

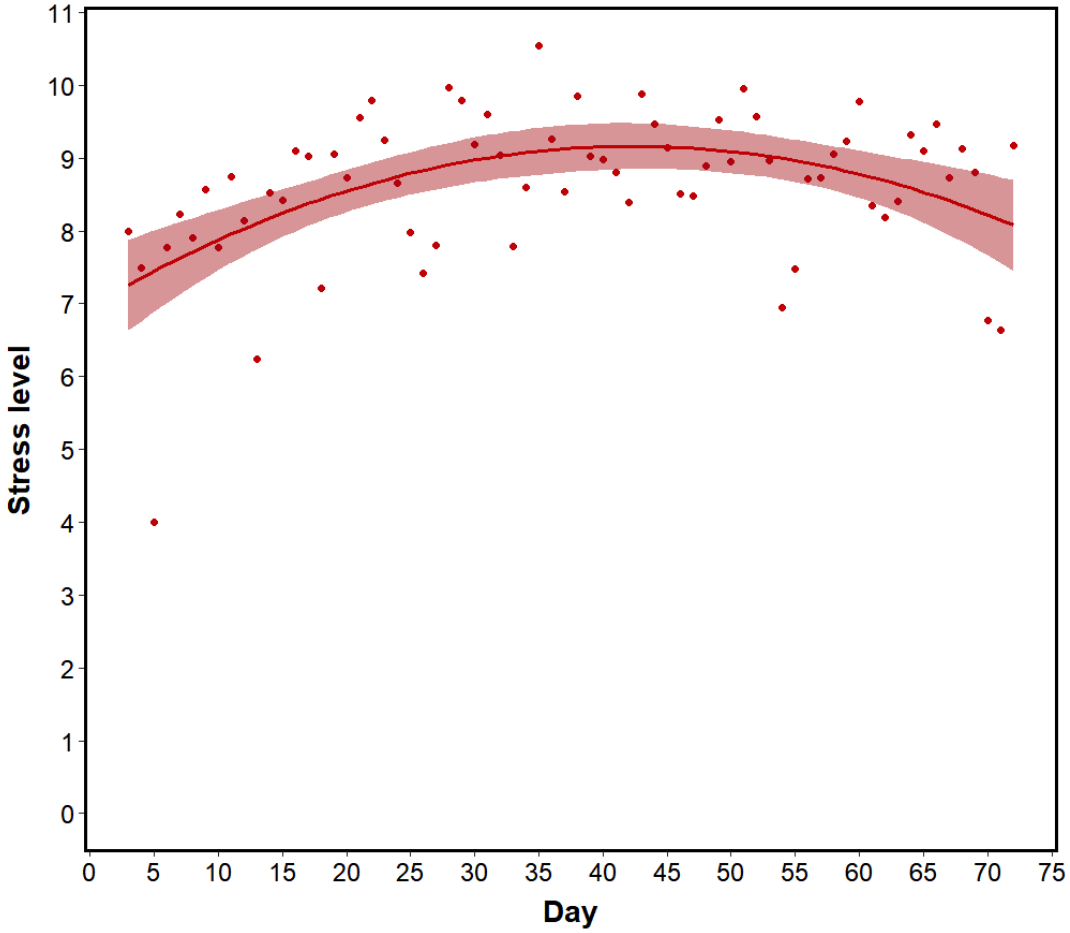


Results

Before any analyses, the data were cleaned to remove participants who encountered technological complications with their mobile phone or who failed to respond to more than 50% of the MPSM survey used to measure stress. Additional days were discarded when extreme outliers were observed in the location data (distance >0.975 quantile). The aim here was to remove days when students may have taken a day trip during the term; spending the majority of the day traveling severely skewed location-based data. After this step, the remaining 72 participants had 43.1 days of data on average (SD 11.8). Across these participants, the overall rate of failure to respond to the MPSM survey prompts was 18.57% (576/3101). Next, with the cleaned dataset the relationship between stress (self-reported, range 1-5) and the MPSM was assessed using a mixed-effect model with random subject intercepts. Supporting the MPSM pilot data, MPSM and self-reported stress were strongly related (beta=2.037, SE 0.076, $P<.001$) providing further validity for the MPSM as a measure of stress. Of general interest was understanding how reported stress unfolded across the term. Thus, the relationship between stress and time was also assessed. A mixed-effect analysis incorporating fixed linear and quadratic time effects, random subject intercepts, and random slopes for both the linear and quadratic effects of time revealed a significant linear effect (beta=1.282, SE 0.509, $P=.02$) and a significant quadratic effect (beta=–1.203, SE 0.491, $P=.02$) of time on the MPSM measure of stress, indicating that stress increased across the term but also experienced a bump near the middle of term presumably reflecting stress brought on by midterm exams (Figure 2). This quadratic effect is similar to the patterns observed in past research [20].

Correlation matrices are used to visually assess relationship patterns between variables in high-dimensional data. However, in this dataset, looking at correlations between sensing features may be misleading due to the clustered and unbalanced nature of the data. Thus, Figure 3 was created to aid in visualizing the relationship between stress and the set of sensing features. The estimates in the figure represent the *t* values from a series of pairwise mixed-effect analyses regressing stress with each of the variables in the dataset. From Figure 3, one can see a few themes emerging. For example, it appears that the majority of sensing features seem to be inversely related to stress. Generally, it also appears that a variety of sensing features see a decrease in usage/occurrence during the evening epoch when stress is high.

Figure 2. Average daily stress over the course of the term. The shading represents the 95% confidence interval around the fitted values.



Unlike mixed-effect models, GEE (and, as a result, PGEE) are not "full-likelihood" models [29]. Thus missing data must be accommodated differently, here imputed before model fitting. Missing MPSM data points were imputed using Kalman smoothing. Each subject's trajectory of MPSM scores was treated as a structural time series model and Kalman smoothing was then used to impute the missing values in the time series [30]. In the resulting completed dataset, 10 skewed covariates were transformed using log or log(x+1) transformations (eg, distance traveled, unlock duration). Finally, the outcome variable and covariates were standardized [31] and analyzed using PGEE. Of the 61 features used in the analysis, six were found to be significantly related to levels of stress by the PGEE analysis. Time spent in dining centers (beta=–0.024, robust z=–2.968), distance traveled between 6 pm and 12 am (beta=–0.021, robust z=–2.670), and mean audio amplitude between 6 pm and 12 am (beta=–0.031, robust z=–2.074) were found to be inversely related to stress, whereas time spent in study locations (beta=0.071, robust z=3.569), proportion of time spent conversing between 9 am and 6 pm (beta=0.030, robust z=2.706), and the proportion of conversations occurring between 9 am and 6 pm (beta=0.021, robust z=2.616) were found to be positively associated with stress (Table 1).

Figure 3. Relationship between stress and sensing features using t values to depict the relationship in a pairwise fashion. Amp: amplitude; convo: conversation; day: sensing data across an entire day; dist: distance; dur: duration; loc: location; num: number; prop: proportion of sensing data occurring within a time period; std: standard deviation.

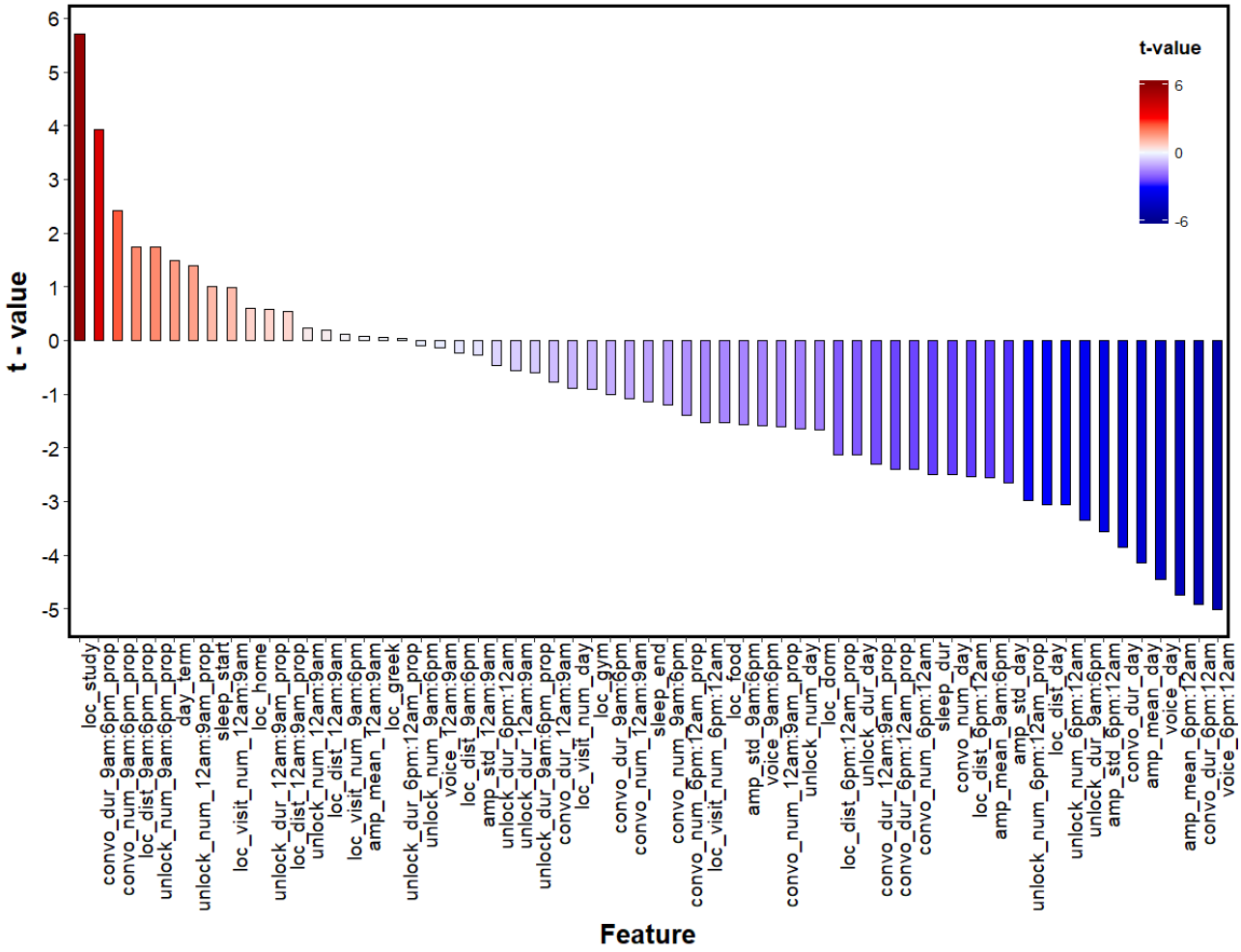


Table 1. Features related to stress as selected by the penalized generalized estimating equations (PGEE) analysis.

Feature	Estimate	Robust standard error	Robust *z*
Time in study locations	0.071	0.020	3.569
Proportion of conversation duration from 9 am-6 pm	0.030	0.011	2.706
Proportion of conversation number from 9 am-6 pm	0.021	0.008	2.616
Distance traveled from 6 pm-12 am	–0.021	0.008	–2.670
Time in food locations	–0.024	0.008	–2.968
Mean audio amplitude 6 pm-12 am	–0.031	0.015	–2.074

Discussion

Principal Findings

Using the MPSM and continuous passive sensing, we were able to measure stress and richly sample the daily life of a college student. From the resulting dozens of features, we were able to select the features best predictive of stress while accounting for the clustered nature of the data. The finding that time spent in study locations was the strongest predictor of stress provides a novel and unobtrusive index to assess school-related strain and meshes well with past research indicating that academics were a serious stressor for students [9,10]. We were also able to identify an environmental factor identified by past research related to stress [11,12] as students were spending less time in food locations when reporting greater amounts of stress. Further, we were able to uncover novel aspects of movement and speech patterns that were associated with stress. In the evening, stressed students were around less noise and showed reduced patterns of movement between 6 pm and 12 am. During the day, stressed students spent a greater proportion of time conversing between 9 am and 6 pm, and they exhibited a greater proportion of conversation between 9 am and 6 pm.

Of note was that four of the six variables selected related to specific time epochs, which underscores the importance of

looking at these data not only aggregated across a day but at finer scales within a day. For example, past work did not observe a significant relationship between daily stress levels and speech duration across the day, although there was a modest relationship between the two measures [20]. It may have been the case that a relationship similar to the association we observed between stress and relative conversation between 9 am and 6 pm was present but masked by aggregating the data across the day.

From these data, we can more accurately begin to conceptualize what a "stressful" day looks like for a college student. Over the course of the day, students are eating less and spending more time in study locations. They are around more conversation during the day while they move to and from class, but are not socializing with others during the evening, a time that many would consider more leisurely. In lieu of socializing during evening hours, students are spending time in a quiet place, possibly engaged in studying or other sedentary pursuits. Put differently, it could be the case that being around others during the evening shields students from stress, a finding that fits well with the notion that social support moderates life stress levels [32].

Finally, by using PGEE, we were able to take advantage of a complex dataset. This technique has many applications beyond examining passive sensing data and may be of use to any researcher who has a large dataset collected over time. As the authors of the R package PGEE mention, large longitudinal datasets are becoming commonplace in fields such as health, economics, genomics, and the behavioral sciences. To illustrate PGEE, the authors apply their method to a yeast cell cycle gene expression dataset to identify factors that play an important role in the transcription of genetic information from DNA to mRNA [22,26]. Further use cases for PGEE could be realized in longitudinal genomic studies where genetic data are collected and single nucleotide polymorphisms are related to some sort of phenotype outcome at the person level (eg, breast cancer or asthma). At a level higher than the genome, PGEE could also be of use to those in the realm of health economics. For example, determining the most important predictors of life expectancy in a country over time from a large number of demographic, socioeconomic, and cultural variables. Finally, PGEE could be applied to future passive sensing projects in the mobile health domain. For instance, mobile sensing could be paired with wearable technology (eg, a smart band) to uncover what physiological and environmental variables precipitate cigarette craving.

Limitations and Future Directions

Although the purpose of this study was to examine stress in a particular population (college students), future studies may want to include individuals from a variety of institutions and age groups (eg, high school or workplace), which could provide valuable insights into boosting education quality and workplace productivity. A strength of this study was that it was conducted at a relatively small, self-contained college campus that has an extremely high number of students living on campus; however, it could be challenging to take this project to scale at a larger, more urban university where the number of students living off campus is much higher. An additional limitation of this study is that the granularity of location data does not permit strong inferences concerning student activities while in locations such as libraries. Although we know students in a library are most likely studying, college libraries are large buildings; they could be socializing or working more casually. Another interesting avenue to explore would be the placement of Bluetooth beacons within buildings to expand the spatial resolution of the location data. Bluetooth beacons would allow one to detect whether a student is working in an open, causal section, a quiet-only zone, or to discover whether a student may have rented out a private cubicle.

Conclusion

In sum, we used a picture-based measure of stress (MPSM) alongside modern mobile phone sensing technology to gain a better understanding of stressors affecting college students. By taking this approach, we have been able to study stressors in the college experience in a way that is more objective, detailed, and less obtrusive than past research. With this knowledge, future work can leverage information gained from passive mobile sensing and use that to develop real-time, targeted interventions for students experiencing increased stress.

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Authors' Contributions

AWD, WW, RW, ATC, and JFH contributed to study design. AWD, WW, RW, and JFH collected and analyzed the data. AWD, JFH, and DDW prepared the manuscript. All authors approved the final version of the manuscript for submission.

Conflicts of Interest

None declared.

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Abbreviations

EMA: ecological momentary assessment
GEE: generalized estimating equations
MPSM: Mobile Photographic Stress Meter
PGEE: penalized generalized estimating equations

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Original Paper

A Smartphone App to Assess Alcohol Consumption Behavior: Development, Compliance, and Reactivity

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Abstract

Background: There are disadvantages—largely related to cost, participant burden, and missing data—associated with traditional electronic methods of assessing drinking behavior in real time. This potentially diminishes some of the advantages—namely, enhanced sample size and diversity—typically attributed to these methods. Download of smartphone apps to participants' own phones might preserve these advantages. However, to date, few researchers have detailed the process involved in developing custom-built apps for use in the experimental arena or explored methodological concerns regarding compliance and reactivity.

Objective: The aim of this study was to describe the process used to guide the development of a custom-built smartphone app designed to capture alcohol intake behavior in the healthy population. Methodological issues related to compliance with and reactivity to app study protocols were examined. Specifically, we sought to investigate whether hazard and nonhazard drinkers would be equally compliant. We also explored whether reactivity in the form of a decrease in drinking or reduced responding ("yes") to drinking behavior would emerge as a function of hazard or nonhazard group status.

Methods: An iterative development process that included elements typical of agile software design guided the creation of the CNLab-A app. Healthy individuals used the app to record alcohol consumption behavior each day for 21 days. Submissions were either event- or notification-contingent. We considered the size and diversity of the sample, and assessed the data for evidence of app protocol compliance and reactivity as a function of hazard and nonhazard drinker status.

Results: CNLab-A yielded a large and diverse sample (N=671, mean age 23.12). On average, participants submitted data on 20.27 (SD 1.88) out of 21 days (96.5%, 20.27/21). Both hazard and nonhazard drinkers were highly compliant with app protocols. There were no differences between groups in terms of number of days of app use (P=.49) or average number of app responses (P=.54). Linear growth analyses revealed hazardous drinkers decreased their alcohol intake by 0.80 standard drinks over the 21-day experimental period. There was no change to the drinking of nonhazard individuals. Both hazard and nonhazard drinkers showed a slight decrease in responding ("yes") to drinking behavior over the same period.

Conclusions: Smartphone apps participants download to their own phones are effective and methodologically sound means of obtaining alcohol consumption information for research purposes. Although further investigation is required, such apps might, in future, allow for a more thorough examination of the antecedents and consequences of drinking behavior.

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KEYWORDS

alcohol drinking; smartphone apps; smartphone; mobile phone; research app development; compliance; reactivity

Introduction

Background

Advantages associated with real-time (or near real-time) methods of assessing alcohol consumption behavior for research purposes have been widely documented in recent years [1-3]. Such methods—which are increasingly electronic in nature—are advocated on the basis of how they allow data to be captured repeatedly in the natural environment and in the absence of the researcher [2,3]. This facilitates the collection of actual intake information rather than the summary data commonly elicited from more traditional retrospective methods of assessing drinking. As such, recall and response biases are thought to be minimized and the ecological validity of the data is consequently enhanced [3]. Real-time methods additionally reduce the quantity of missing data and can yield a diverse and potentially very large sample [4,5]. Crucially, real-time data enable variations in behavior to be examined across time and in concert with cognitive, affective, environmental, and physiological factors. In this way, the antecedents and consequences of drinking behavior can also be investigated [2,3].

Real-time electronic methods of collecting alcohol consumption information for research purposes have evolved rapidly over the last two decades. Early studies typically featured hand-held electronic devices [6,7] or interactive voice response systems [8,9]. In the case of the former, participants used the device as an electronic diary; in the latter, the interactive voice response system was programmed to call participants on researcher-supplied cellular phones so that an automated questionnaire could be administered. Short message service (SMS) text messaging protocols have also been employed. In such studies, SMS text messages direct participants to follow a link to complete a Web-based survey via their mobile browser [10] or ask them to respond to simple questions about their alcohol consumption via text [11]. With the advent of smartphones, researchers have increasingly been programming study-specific apps for use in such studies. In most cases, this involves either providing participants with a phone preloaded with the app [12,13] or loading the app onto participants' own phones and downloading the data at the end of the experimental period [14].

There are a number of disadvantages associated with utilizing the aforementioned electronic protocols. There are costs, for instance, associated with programming, supplying, and training participants to use electronic devices that are not their own [15-18]. Participants must also be provided with some means whereby they can recharge these devices [16]. If they have their own mobile, they will be carrying 2 devices during the experimental period, which might prove unduly burdensome and reduce compliance. Questionnaires completed via cell phone browsers do not always scale well to all mobile devices and require internet connectivity [19]. Surveys conducted via SMS text messages are necessarily limited in scope and, in the absence of internet connectivity, potentially costly to participants [20]. In all cases, participants are required to visit the lab at least twice during the experimental period; they must collect the device or have the program loaded onto their own phone plus undergo training, and they must return the device or have the data downloaded off their phone [18,21]. These disadvantages potentially diminish some of the benefits of using electronic devices to collect real-time alcohol intake behavior; specifically, sample size and diversity may be a function of the cost of supplying the device to those willing and able to attend the lab, and data may go unrecorded where internet connectivity or cost to the participant is an issue.

Using apps participants download to their own smartphones, without ever visiting a lab, might enable researchers to more fully realize the benefits of collecting alcohol consumption information electronically and in real time. Smartphone penetration currently stands at upward of 70% across many developed nations and is growing rapidly across developing ones [22]. Across the United States, United Kingdom, and Australia, more than 93% of 18 to 34 year olds own a smartphone [23]. Taking advantage of high smartphone ownership rates by using participants' own devices represents a substantial cost reduction both in terms of equipment and training. Asking individuals to download apps via marketplace vendors and having data stored on the phone until it can be automatically uploaded to a server via a Wi-Fi connection alleviates the participants' need to visit the lab and reduces the likelihood of data being lost or going unrecorded. Advantages of real-time assessment related to completeness of data, sample size, and diversity might therefore be preserved in studies employing apps downloaded to participants' smartphones.

Nonetheless, there are a number of development and methodological concerns pertaining to assessing alcohol consumption behavior via smartphone apps that warrant further investigation. Given that any app must be programmed for 2 different, frequently updating operating systems with distinct deployment protocols, researchers are likely to require the assistance of 1 or more app programmers in the development phase. The literature offers little guidance regarding the software development process as it relates to the behavioral sciences [24]. Examples of how to effectively manage and integrate the requirements and expectations of multiple stakeholders when developing apps for behavioral studies are consequently required.

Although several recent studies have reported promising results with regard to the validity of app-based methods of capturing alcohol intake information [25-27], issues related to app protocol compliance and reactivity have received less attention. Compliance refers to the extent to which participants adhere to study requirements and protocols throughout the experimental period, whereas reactivity describes a process whereby the monitoring of a behavior results in a change in that behavior [1-3]. Simply completing traditional alcohol intake assessment and screening measures has been found to decrease consumption among heavy drinkers and reduce self-reported hazardous drinking behaviors [28-30]. However, it is unclear if this reactivity arises as a function of drinking behavior. Individuals characterized by more risky consumption patterns may, more likely than others, alter their behavior in response to monitoring. Although commentators generally report little evidence of reactivity in real-time studies of alcohol intake, they also note further investigation is required [1,21,31-33]. Reactivity is a

phenomenon that can emerge for several reasons. Participants might become more aware of the behavior and become consequently motivated to implement change, or the demands of the protocol might provoke a tendency to satisfice [31]. In any real-time study of alcohol intake, a decrease in drinking could be evidence of the former, whereas a decrease in responding "yes" to the behavior (and therefore in having to respond to further questions) might suggest the latter.

Objectives

In this paper, we describe the process used to guide the development of a custom-built smartphone app designed to capture alcohol intake behavior in the healthy population for research purposes. We also evaluate methodological issues related to compliance with and reactivity to study protocols as a function of hazard and nonhazard drinker status. We expect individuals in both hazard and nonhazard groups will be equally compliant. Reactivity in the form of a decrease in drinking will be minimal or confined to the hazard group, whereas individuals in both groups will be susceptible to reactivity in the form of reduced responding.

Methods

App Development

The CNLab-A app represents the outcome of an iterative development process that included elements of agile software design, namely requirements analysis, feature and interface design, and app implementation [24,34].

Requirements Analysis

In the requirements analysis phase, the research team determined key variables of interest. To this end, empirical definitions of excessive and binge drinking and variables derived from validated retrospective measures of drinking were examined [35-39]. We aimed to elicit data that would assist in establishing percentage of drinking and nondrinking days, daily and average total standard drinks, daily and average drinking rate, highest drink count in 2 hours, and blood alcohol content (BAC). After soliciting advice from the programmer and giving due consideration to the ethical implications, we decided that although the date and time of app submissions would be automatically logged, geolocation would not be recorded because of concerns that such data may undermine efforts to preserve user anonymity [40,41]. In early iterations of the app, responses related to date of birth, sex, height, and weight were also recorded. Date of birth and sex details were utilized to link data from the app with information collected via other means (eg, Web-based surveys or in the lab). Height and weight were used to determine BAC. In this early iteration, all data were uploaded to a dedicated commercial Web-server company account. Given the concerns articulated in the literature regarding privacy and the secure storage of behavioral data [40,41], latter iterations of the app did not include any demographic questions; instead, a unique identification number was generated for each participant, and the data were uploaded to a secure server. In this way, app data were not linked to any personal information.

In this phase, the research team also considered assessment design. Studies reliant on real-time (or near real-time) monitoring of behavior tend to employ event- or time-based sampling [32]. In the case of the former, participants record the behavior as it happens or shortly thereafter; in the latter, behavior is recorded in response to signals that occur multiple times a day, often at random [32]. Occasionally, both assessment methods are utilized simultaneously [32]. As substance use is episodic in nature, event-based assessment is considered an appropriate method for tracking both frequency and timing of use [1]. Therefore, we determined this would be the most pertinent method of collecting alcohol consumption information. However, a disadvantage of event-based monitoring is that it is difficult to assess compliance, that is, there is no way to verify that participants record all events as required [32]. To combat this limitation, we required the app to send participants twice-daily prompts asking them if they had consumed alcohol since the last submission. This served to remind participants to record drinking if they had forgotten to do so. In this regard, we adopted a similar assessment protocol as Dulin and colleagues; they also employed an event-based assessment along with daily notifications reminding participants to record drinking [25]. We additionally required the app to prevent participants from submitting data more than 24 h into the past or more than 15 min into the future to prevent back and forward filling.

Finally, the content for each assessment was based on the key variables of interest. Drink type formed the central element of each assessment as, once selected, all subsequent items were dependent on this choice (Figure 1). For instance, selecting mid strength beer as the drink type in the app automatically determined the alcohol content and serving size options. In Australia, mid strength beer has an alcohol content of 3.5% and is available, at least in licensed and retail venues, in various standard serving sizes [42,43]. Table 1 details drink type, alcohol content, and serving size options available in the app (Table 1). These options were not meant to be exhaustive but were designed to capture typical drink types, average alcohol content, and standard serving sizes sold in Australia. The final aspect of assessment involved selecting a start and finish time for drinking.

Decisions made during the requirements analysis phase were documented via an iterative storyboard process. This ensured that the research team and programmer had access to a common record.

Feature and Interface Design

Feature and interface design was informed by app software capabilities and in consultation with the programmer. During this phase, iOS app prototypes were developed and deployed in response to design decisions and feedback from the research team. Deployment was via Test Flight, which allowed invited users to test beta versions of iOS apps.

Figure 1. Flowchart of assessment pathway and screenshots from the CNLab-A app. On opening, CNLab-A asks users if alcohol has been consumed in the last 24 hours. Thereafter, participants are asked if they have consumed alcohol since their last submission. If they indicate (by pressing "No") that no drinking has occurred, the app can be closed. If participants indicate drinking has occurred (by pressing "Yes"), images of common alcoholic beverages (including beer, wine, cider/premix, spirit/liqueur, and cocktail) are displayed (1). Type of beverage consumed is selected by touching the appropriate image on the screen. Quantity and size consumed for each beverage is indicated via a simple scroll option menu (2). Alcohol content as a function of beverage type is prefilled. This process is repeated by tapping "Back" in order to add as many drink types as required. Erroneously entered data can be deleted by swiping left. Prior to submitting data, the start and end time of drinking must be specified, again using a scroll option menu (3). Participants are able to either report drinking in separate sessions or they can leave the app open so as to record beverages as they are consumed. The latter option still allows participants to use other features on their phone. Participants can access a history of their submission dates and times (but not their drinking data) via the "History" button. At the conclusion of the experimental period, an automated message thanks participants; gives them simple feedback regarding the number of days they consumed alcohol, total standard drinks consumed, and average daily consumption; and, asks them to remove the app from their smartphone.

We determined response selection would be via touch screen and scroll menus. At the commencement of each assessment, for instance, when participants were asked if they have consumed alcohol since their last submission, they indicated "Yes" or "No" by touching either option on the screen. Similarly, it was decided that drink types would be presented on 1 touch screen as a set of images with captions so that participants could readily identify and select their beverage. Images were designed using Inkscape, a freely available vector graphic software package. In the case of beer, images for mid and light-strength were opaque versions of the full-strength visual. Quantity and size options were available via a simple scroll option menu. Likewise, a scroll menu presented dates and times (in 15-min intervals) for recording of drinking start and end time. Participants pressed "Submit" to upload (to the server) and end the assessment. Any submission that failed to upload because of lack of internet connectivity would automatically be uploaded when connectivity was reestablished. Figure 1 shows screenshots of the app interface (Figure 1). The app icon was also designed during this phase. A discreet pattern and app name were chosen to minimize the likelihood friends or family of the participant would realize they were taking part in an alcohol-related study.

App Implementation

One of the potential advantages of using electronic means of assessment in the behavioral sciences relates to penetration. Such methods can provide investigators with large, diverse samples if facilitated by appropriate implementation decisions related to development and deployment. To that end, the research team decided to develop a native app to be run locally on iOS and Android platforms with marketplace deployment via Apple iTunes and Google Play, respectively, to optimize app availability. However, because of funding limitations, only an iOS version of the app was initially alpha and beta tested.

Table 1. Drink types, alcohol content, and serving size options available in the CNLab-A app.

Drink type	Alcohol content (%)	Serving sizes
Beer		
Full strength	4.8	Glass 200 mL; pot/middy 285 mL; can/bottle 375 mL; schooner 425 mL; pint 570 mL
Mid strength	3.5	As above
Light strength	2.7	As above
Wine		
White/Champagne	12.0	Glass 150 mL
Red	13.0	As above
Fortified wine		
Port, sherry, marsala, madeira, vermouth, etc	18.0	Glass 60 mL
Cider/premix spirit		
Most ciders and premix drinks including alcopops	5.0	Bottle 300 mL; bottle 330 mL; can 375 mL; bottle 500 mL
Spirit/liqueur		
Rum, gin, vodka, brandy, tequila, whiskey, liqueurs, etc	40.0	Standard 30 mL; double 60 mL
Cocktail		
Various	40.0	1 shot 30 mL; 2 shots 60 mL; 3 shots 90 mL; 4 shots 120 mL

Alpha testing involved a small sample of individuals (N=8, mean age 38.13 years, SD 16.54; range 18-68 years, 37.5% female) and was designed to identify programming bugs and oversights. Beta testing comprised a slightly larger group (N=19, mean age 37.37 years, SD 9.73; range 22-68 years, 68.4% female) and focused on eliciting user feedback (via email) post testing. During both the test studies, individuals were asked to keep a hardcopy record of any data submissions so that app data could be checked for accuracy. Average time to submit drinking information during testing was 34 seconds.

Suggestions provided by individuals involved in this phase and that were incorporated into the final version of the app included making an instructional video explaining how to use CNLab-A available to participants [44], providing post experimental summary feedback regarding total standard drinks consumed and average daily intake, along with several minor changes to the app user interface. Otherwise, testers indicated that compliance with app protocols was not onerous. They all reported using a mix of real-time and prompt-based submissions.

The requirements analysis and feature and interface design phases took almost 4 months, whereas the alpha and beta testing of the app implementation phase spanned approximately 8 weeks. We had 3 meetings with the programmer in the early stages of development and then a further meeting toward the completion of the feature and interface design phase. All other communication was via email. The final production version of the app was eventually made available on both iOS (8.4+) and Android (Kitkat 4.1+) platforms. As operating systems evolve, both apps will be audited to ensure they continue to function as required.

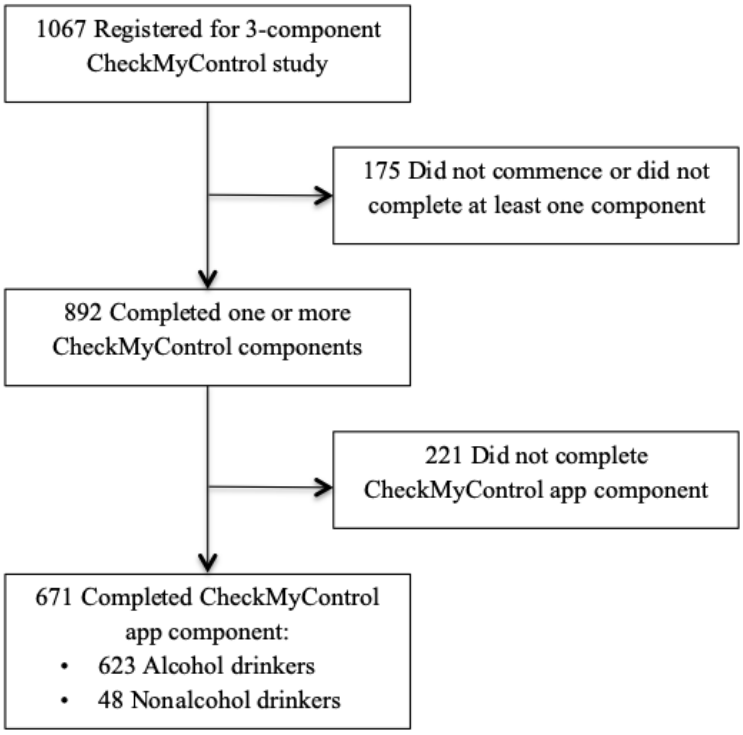
Participants and Procedure

This study was based on data from 671 participants (mean age 23.12 years, SD 7.24; range 16-56 years, 70% female) that form a subset of an ongoing project—entitled CheckMyControl—investigating the relationship between alcohol use and various social and cognitive factors in the healthy population. This subsample completed the app component of the project (Figure 2). Participants were recruited via adverts posted in and around the University of Melbourne, researcher networks, and social media posts; as such, they formed a convenience sample. Individuals were eligible to take part in this study if they were fluent in English and aged 13 years or older. The University of Melbourne Human Research Ethics Committee approved the study in accordance with the standards for ethical research of the National Health and Medical Research Council.

After reading a plain language statement and providing informed consent, participants answered a Web-based researcher-devised demographic survey and the Alcohol Use Disorders Identification Test (AUDIT) [39]. The demographic survey included questions pertaining to country of birth, first language, and place of residence. Participants were also asked if they had ever been diagnosed with an alcohol or substance use disorder. Participants were then required to download and use the CNLab-A smartphone app to record alcohol use for 21 days.

They were compensated Aus $10 for time spent completing Web-based surveys and Aus $0.50 each day information about alcohol consumption was submitted via the app (regardless of whether alcohol had been consumed or not). Participants received a bonus Aus $9.50 if app data were submitted on all 21 days. The maximum participants could be reimbursed was Aus $30.

Figure 2. Flow diagram following Consolidated Standards of Reporting Trials guidelines of study participation.



Measures

The AUDIT is a 10-item screening measure that asks participants to respond to questions assessing alcohol intake, problems, and dependence with reference to the preceding 6 months. Participants were categorized into hazard (n=286) and nonhazard (n=385) groups based on their score, with scores of 8 or more indicative of hazardous alcohol consumption [45]. Previous studies have shown the AUDIT is a valid instrument for assessing alcohol misuse among adolescents—sensitivity (Sn)=.71; specificity (Sp)=.84—university students (Sn=.75-.89; Sp=.73-.82), and the general population (Sn=.92; Sp=.94) in various countries, including Australia (Sn=.93; Sp=.82) [39,46-48].

CNLab-A is a freely available custom-built app that can be used to record alcohol intake for research purposes. Once downloaded, CNLab-A requires participants to allow it to send them notifications. One notification is preset to 8 am, whereas the other can be set to suit the user. Although participants are directed at the outset to record alcohol consumption as it happens (or as soon thereafter as possible), notifications serve to prompt individuals to input information twice daily in case they neglect to do so when drinking. Thus, alcohol intake data can be submitted at any time, either in response to notifications or while drinking. A unique identification code, provided to participants during the Web-based component of the study, is required before the app opens. CNLab-A has previously been found to be a valid measure of alcohol intake [27].

Statistical Analyses

Independent *t* tests and Chi-square analyses were conducted to determine whether hazard and nonhazard groups were matched demographically. Homogeneity of variance was assessed using Levene Test, where this assumption was violated, adjusted *t* values and associated degrees of freedom were reported. Effect sizes were computed for *t* tests using *r* values; they were interpreted according to Cohen guidelines: 0.10=small, 0.30=moderate, and 0.50=large effect [49].

Participants were considered compliant with app protocols if they responded to at least 1 notification each day for the 21-day experimental period. We assessed both number of days of use and submissions per day as a function of gender, age bracket (13-19 years, 20-29 years, and ≥30 years), and hazard and nonhazard group status using *t* tests and 1-way analysis of variance. Reactivity was assessed using linear growth model analyses, conducted using SPSS 24 (IBM). These analyses examined (1) change in drinks consumed each day and (2) change in daily (“yes”) responding over the 21-day experimental period as a function of AUDIT group membership. In the first analysis, drinks per day (within persons; level 1) were nested within individuals (between persons; level 2); in the second, daily (“yes”) response rate (within persons; level 1) was nested within individuals (between persons; level 2). Time was centered on the first day of data collection (Day 0); each unit of time represented an interval of 1 day [50]. All mixed models were estimated using restricted maximum likelihood [51]. Initially, slope variance and autocorrelation were included in both models, but they were removed when parameter estimates for these effects were found to be very small (<0.01).

Results

Descriptive Statistics

At the time of testing, 39.9% (268/671) of the sample was aged under 20 years, 46.2% (310/671) was aged 20 to 29 years, and 13.9% (93/671) was aged 30 years or over. In Australia, individuals in the 18 to 29-year-old age bracket are more likely

than others to consume alcohol in a manner that increases their short-term risk of alcohol-related injury, whereas almost 19% are at risk of long-term alcohol-related harm [52]. Most participants were born in Australia (66.8%, 448/671), spoke English as their first language (80.0%, 537/671), and lived in urban regions (88.1%, 591/671). Census data show 67% of the Australian population is locally born and 79% speak English as their first language [53]. Most Australians (86%) reside in urban regions [54]. A small number of participants indicated they identified as an Indigenous Australian (0.6%, 4/671). This was less than what the census data suggest as typical for the state (Victoria) in which this study took place (0.8%) [53]. However, this difference is likely a product of our recruitment campaign. As advertisements for the study were posted in and around the University of Melbourne, the sample contained a large number of young tertiary-aged participants (85.7%, 575/671). The proportion of indigenous students studying at this institute in 2016 stood at 0.6% [55].

Before commencing the 21-day recording period, the minority of participants (2.2%, 15/671) indicated they had never consumed alcohol; the majority (92.8%, 623/671) described themselves as regular drinkers. A small proportion indicated they had been diagnosed with an alcohol (0.3%, 2/671) or substance (0.4%; 3/671) use disorder. Hazard and nonhazard groups did not differ significantly with regard to age, t_{669}=1.02, P=.31 or years of education, $t_{654.11}$=1.65, P=.10. There was a significant association between gender and AUDIT group membership, χ^2_{671}=5.96, P=.02. The odds of being a hazardous drinker were 1.51 times higher for males than females (95% CI 0.22-2.01). There were significant differences between the AUDIT scores of the hazard (mean 12.45, SD 4.30) and nonhazard (mean 4.64, SD 3.59) groups, $t_{547.67}$=24.94, P<.001. Mean alcohol intake indices recorded via CNLab-A are detailed in Table 2.

Compliance

On average, participants used CNLab-A 20.27 (SD 1.88) days out of 21 (96.5%); 96.0% (644/671) of participants completed at least 1 submission per day for the entire 21-day experimental period. There were no significant differences as a function of gender t_{669}=0.83, P=.41, or age bracket, $F_{2,668}$=0.34, P=.71, with regard to number of days of use. Moreover, there were no differences between hazard and nonhazard groups, t_{669}=0.69, P=.49. As data submission was either event- or notification-contingent, there was no upper limit to the number of drinking sessions participants could report using the app. Participants received a maximum of 42 notifications asking them to record information about their drinking. They submitted data, on average, 2.00 (SD 0.41) times per day.

With regard to the average number of responses per day, there were no significant differences as a function of gender, t_{669}=0.65, P=.51, or age bracket, $F_{2,668}$=1.08, P=.34. In addition, there were no differences on the basis of AUDIT group membership, t_{669}=0.61, P=.54. There were 27,355 data points captured via the app in total.

Table 2. Average alcohol intake indices as recorded via CNLab-A app (21 days), including hazard (n=286) and nonhazard (n=385) group totals and differences.

Drinking indices	Total, mean (SD)	Hazard, mean (SD)	Nonhazard, mean (SD)	t_{669} [a]	95% CI	Pearson correlation r
Days drinking	5.32 (4.17)	6.90 (4.02)	4.15 (3.90)	8.91	2.14-3.35	.33
Total drinks[b]	24.26 (25.41)	37.45 (28.09)	14.47 (17.75)	12.16	19.27-26.70	.43
Drinks per day	1.20 (1.25)	1.86 (1.38)	0.71 (0.86)	12.45	0.97-1.33	.43
Drinks per day drinking	3.98 (3.02)	5.53 (2.92)	2.83 (2.56)	12.45	2.27-3.12	.43
Hourly rate of drinking	2.20 (2.09)	2.60 (2.14)	1.89 (2.00)	4.41	0.40-1.04	.17
Highest drink count in 2 hours	4.14 (3.15)	6.03 (3.37)	2.79 (2.09)	14.34	2.80-3.69	.48
4/4+ intake[c]	2.16 (2.58)	3.48 (2.83)	1.19 (1.86)	11.89	1.91-2.67	.42
6/6+ intake	1.31 (1.92)	2.26 (2.27)	0.61 (1.20)	11.14	1.35-1.94	.40
8/8+ intake	0.85 (1.44)	1.51 (1.70)	0.36 (0.94)	10.41	0.94-1.38	.37
12/12+ intake	0.31 (0.80)	0.58 (1.06)	0.10 (0.43)	7.26	0.35-0.61	.27
20/20+ intake	0.07 (0.31)	0.12 (0.41)	0.03 (0.20)	3.55	0.04-0.15	.14

[a]P values all <.001.

[b]Drinks refer to self-reported alcohol consumption in Australian standard drinks (1 drink=10 g alcohol).

[c]4/4+ (and so forth) intake refers to occasions where 4 or more drinks were consumed in 1 episode.

Table 3. Parameter estimates for linear growth model of drinks per day as a function of hazard and nonhazard Alcohol Use Disorders Identification Test group membership.

Parameter	Estimate (SE)	*t*/z [a]	*df*	*P* value	95% CI
Fixed effects (intercept, slopes)					
Intercept (Day 0)	0.67 (0.08)	8.68	2301.73	<.001	0.52 to 0.82
Time	–0.01 (0.01)	–1.80	13418.00	.07	–0.02 to 0.001
Hazard	1.48 (0.11)	13.26	2301.73	<.001	1.26 to 1.70
Hazard by time	–0.03 (0.01)	–3.50	13418.00	<.001	–0.04 to–0.01
Random effects ([co-]variances)					
Between-person (level 2) intercept	0.74 (0.06)	12.28	— [b]	<.001	0.63 to 0.87
Within-person (level 1) residual	7.54 (0.09)	81.91	—	<.001	7.37 to 7.73

[a]*t* test value for fixed effects parameters; Wald z value for random effects parameters.

[b]Not applicable.

Table 4. Parameter estimates for linear growth model of daily ("yes") responses per day as a function of hazard and nonhazard AUDIT group membership.

Parameter	Estimate (SE)	*t*/z [a]	*df*	*P* value	95% CI
Fixed effects (intercept, slopes)					
Intercept (Day 0)	0.32 (0.02)	18.24	982.85	<.001	0.28 to 0.35
Time	–0.003 (0.001)	–3.63	13418.00	<.001	–0.004 to –0.001
Hazard	0.15 (0.03)	5.99	982.85	<.001	0.10 to 0.20
Hazard by time	–0.004 (0.001)	–3.53	13418.00	<.001	–0.006 to –0.002
Random effects ([co-]variances)					
Between-person (level 2) intercept	0.08 (0.01)	16.86	— [b]	<.001	0.07 to 0.09
Within-person (level 1) residual	0.14 (0.002)	81.91	—	<.001	0.14 to 0.15

[a]*t* test value for fixed effects parameters; Wald z value for random effects parameters.

[b]Not applicable.

Reactivity

Table 3 details parameter estimates for fixed and random effects of the linear growth analysis model for change in drinks consumed each day. With regard to fixed effects, the nonhazard group reported consuming significantly fewer standard drinks (0.67) on Day 0 than the hazard (0.67+1.48=2.15) group. The nonhazard group showed no significant decrease in consumption over the 21-day experimental period, whereas the hazard group demonstrated a slight but significant decrease in drinking over the same period (0.04 standard drinks per day). Within-person variance (7.54) equates to 2.75 SD units; thus, 95% of observed residuals were between ±5.49 units of their fitted values. The intercept variance (0.74) corresponds to 0.86 SD units; therefore, 95% of the population varied between ±1.72 units of the typical intercept for their group (Table 3).

Table 4 shows parameter estimates for fixed and random effects of the linear growth model for change in daily ("yes") responses. The nonhazard group responded ("yes") significantly less often (0.32) on Day 0 than the hazard (0.32+0.15=0.47) group. A slight but significant decrease in responding was evident for both the nonhazard (–0.003 per day) and hazard (–0.003+(–0.004)=–0.007 per day) groups. Within-person variance (0.14) equates to 0.37 SD units; thus, 95% of observed residuals were between ±0.75 units of their fitted values. The intercept variance (0.08) corresponds to 0.28 SD units; therefore, 95% of the population varied between ±0.57 units of the typical intercept for their group (Table 4).

Discussion

Principal Findings

In this study, we aimed to describe the development and implementation of a custom-built smartphone app devised to measure real-time (or near real-time) alcohol consumption behavior in the healthy population. Designed for use in the research arena, the app was a product of an iterative process that included elements typical of agile software design. Decisions made during each phase of development were informed by a desire to create an app that the participants could download onto their own smartphones without ever having to visit the lab. We anticipated this might minimize disadvantages—such as equipment and training costs, participant burden, and missing data—often associated with using some types of electronic protocols, while simultaneously enhancing benefits pertaining to sample size and diversity. We additionally explored methodological factors related to app protocol

compliance and reactivity as a function of hazard and nonhazard drinker status.

Compliance with app protocols was high. Participants were required to submit data about their drinking (regardless of whether they had consumed alcohol or not) at least once per day for 21 days. On average, they uploaded data on 96.5% of days, and there were no differences between hazard and nonhazard groups with regard to the number of days of app use or the number of responses per day. Presumably, the use of daily payments and an end-of-study bonus (for 21 consecutive days of data submissions) incentivized responding. In previous alcohol intake-based studies utilizing various electronic methods of collecting data—including SMS text messaging [56], hand-held electronic devices [57], and interactive voice response systems [8]— incentivized responding resulted in similarly high rates of compliance. It should be noted that when the measure is freely available via marketplace vendors, the size of the sample can quickly balloon. As such, it is important to not only balance the burden of protocol compliance with the incentive offered but it is also necessary to consider overall budget constraints and ensure there are some swift means of limiting access to the app if required.

Our results suggest there was some slight degree of reactivity—particularly among hazardous drinkers—to the app protocol. Though the effect was small, the hazard group decreased their intake significantly over the experimental period: 0.80 standard drinks in 21 days, which represented a 2% decrease in total standard drinks for this group. By contrast, nonhazard drinkers showed no significant reduction in consumption over the same period. This accords with evidence from other studies demonstrating some reduction in alcohol consumption only because of measurement among hazardous drinkers [28,29]. Even though participants received no feedback about their drinking during the assessment period, it is possible that those in the hazard group were motivated to modify their intake because the act of recording it made them more aware of their behavior. Equally, the knowledge that they were being monitored may have induced them to drink less. Considered a manifestation of the Hawthorne effect, social desirability is thought to underpin this type of assessment reactivity [58]. It is also possible that reductions in consumption were the result of satisficing; that is, participants may have responded “yes” to drinking less often over time to avoid having to submit further information via the app. Both hazard and nonhazard groups showed a significant reduction in the frequency of responding “yes” to drinking over the 21-day period. However, the rate of this reduction was very small: nonhazard participants decreased “yes” responding by 0.06 and hazard participants by 0.14 in 21 days. As such, this reduction might be a reflection of increased familiarity with the app over time, rather than satisficing; that is, participants may have summarized their drinking across a day into fewer submissions once they became more familiar with the app.

There is some debate in the literature regarding reactivity to real-time measures. Several investigators postulate such assessment reduces the likelihood of reactivity related to social desirability as participants record data in the absence of the researcher [31]. Bates and Cox found participants were, for example, more likely to reveal lifetime alcohol consumption details when they completed surveys outside, as opposed to inside, the lab [59]. Other researchers speculate real-time methods are particularly susceptible to reactivity effects because assessments are completed in close proximity to the behavior, giving participants time to consider their actions [1], though it has also been suggested that repeated surveying may reduce reactivity via habituation [60,61]. Nonetheless, there is consensus that reactivity is generally an overlooked facet of real-time research and further investigation is required [21,31,62]. It is possible, for instance, that reactivity differs according to the population. Our finding that hazardous drinkers reacted to the app protocol to a greater extent than nonhazard drinkers would certainly support this supposition. Our data also suggest app-based alcohol-related intervention studies would benefit from the inclusion of a measurement-only control condition to disentangle the effects related to reactivity from those linked to the intervention.

Limitations

Several limitations to this study must be noted. Although representative of the population at large in terms of country of birth, first language, and usual place of residence, young female university students predominated in our sample. Although current research suggests men and women are equally likely to download and use health-orientated smartphone apps [63,64], women in Australia typically drink less than men and are consequently at decreased risk of alcohol-related harm [52]. Nonetheless, our hazard group reported drinking alcohol a third of the time during the experimental period and, on average, consumed in excess of 5 standard drinks per episode. According to Australian guidelines, this pattern of consumption places them at increased risk of both short-term alcohol-related injury and lifetime harm from alcohol [65]. Notwithstanding, future studies would be required to determine if similar rates of app compliance and reactivity are evident in a sample dominated by young men. Similarly, older individuals might respond in different ways to app-based protocols designed to assess alcohol consumption behavior. A recent survey found 59% of Australians over 65 years are willing to use or already utilize technology designed to track health [66]. In addition to research showing age has not been identified as a barrier to participation in mental health studies [67], this suggests older individuals might respond well to alcohol-related research apps. Moreover, as age-related illness and associated difficulties pertaining to condition severity, transportation, and inconvenience do inhibit participation in research [67], apps people access via marketplace vendors and download to their own smartphones may possibly boost participation in this age group. Future studies would nonetheless be required to fully consider app compliance and reactivity among older individuals. Finally, we did not examine if different assessment periods impact compliance and reactivity in diverse ways. A shorter experimental period might, for instance, diminish the effect of reactivity, though this may limit how effectively the app captures variability of intake. This is another potential area for further research.

Conclusions

In conclusion, we examined the feasibility of developing and employing an app—downloaded by participants to their own smartphones—designed to collect alcohol intake information for research purposes. We demonstrate how utilizing apps such as CNLab-A can yield a potentially large sample representative of the population. Both hazard and nonhazard participants appeared highly compliant when using app protocols. Although there was some evidence of reactivity in our study, especially among hazardous drinkers, effect sizes were small. Our findings suggest the CNLab-A app—or potentially 1 similar—is a methodologically sound means of examining alcohol consumption behavior across time. In future, such apps can be paired with those that chart cognition, affect, or social and environmental factors in real time to facilitate a more thorough investigation of the antecedents and consequences of drinking behavior.

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Conflicts of Interest

None declared.

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Abbreviations

AUDIT: Alcohol Use Disorders Identification Test
BAC: blood alcohol content
SMS: short message service
Sn: sensitivity
Sp: specificity

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Original Paper

Impact of Training and Integration of Apps Into Dietetic Practice on Dietitians' Self-Efficacy With Using Mobile Health Apps and Patient Satisfaction

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Abstract

Background: The use of mobile health (mHealth) apps in dietetic practice could support the delivery of nutrition care in medical nutrition therapy. However, apps are underutilized by dietitians in patient care.

Objective: This study aimed to determine the feasibility of an intervention consisting of education, training, and integration of apps in improving dietitians' perceived self-efficacy with using mHealth apps.

Methods: Private practice Accredited Practising Dietitians who were not regular users or recommenders of mHealth apps were recruited into the intervention. The intervention consisted of 2 phases: (1) a workshop that incorporated an educational lecture and skill-building activities to target self-efficacy, capability, opportunity, and motivation factors and (2) a 12-week intervention phase allowing for the integration of an app into dietetic practice via an app platform. During the 12-week intervention phase, dietitians prescribed an Australian commercial nutrition app to new (intervention) patients receiving nutrition care. Existing (control) patients were also recruited to provide a measure of patient satisfaction before the apps were introduced. New patients completed their patient satisfaction surveys at the end of the 12 weeks. Usability feedback about the app and app platform was gathered from intervention patients and dietitians.

Results: A total of 5 dietitians participated in the study. On the basis of an analysis of variance with the Tukey post hoc tests, the educational and skills training workshop component of the intervention produced immediate improvements in mean ratings for dietitians' self-efficacy with using mHealth apps compared with baseline (P=.02), particularly with regard to *familiarity with apps* factor (P<.001). The self-efficacy factor *integration into dietetic work systems* achieved significant improvements from baseline to 12 weeks (P=.03). Patient satisfaction with dietetic services did not differ significantly between intervention (n=17) and control patients (n=13). Overall, dietitians and their patients indicated that they would continue using the app platform and app, respectively, and would recommend it to others. To improve usability, enhancing patient-dietitian communication mediums in the app platform and reducing the burden of entering in meals cooked at home should be considered.

Conclusions: Administering an educational and skills training workshop in conjunction with integrating an app platform into dietetic practice was a feasible method for improving the self-efficacy of dietitians toward using mHealth apps. Further translational research will be required to determine how the broader dietetic profession responds to this intervention.

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KEYWORDS

dietetics; medical nutrition therapy; mHealth; patient satisfaction; smartphone

Introduction

Background

Mobile health (mHealth) apps targeting lifestyle-related behaviors, such as nutrition and exercise or fitness, are abundantly available in commercial app stores [1] and could be a potential medium for addressing the poor dietary and physical inactivity factors that are determinants of obesity and chronic diseases [2]. A previous review has outlined the areas in which dietitians can consider using apps to support their delivery of nutrition care in medical nutrition therapy [3], including streamlining of nutrition assessment, to maximize the time dietitians can spend on nutrition behavioral counseling [3]. Apps can also permit more timely and individualized patient-centered nutrition monitoring and evaluation and enable dietitian feedback [3].

Overall, 61.9% (353/570) of international dietitians report using mHealth apps in patient care and most commonly for patient education and self-monitoring of dietary behaviors [4], whereas use within the entire nutrition care process was less apparent [4,5]. The capability, opportunity, and motivations for dietitians in using mHealth apps in practice (behavior) were assessed using the behavioral system termed the Capability, Opportunity, Motivation-Behavior (COM-B) model [6]. In particular, this behavioral analysis identified that dietitians lacked both the capability and motivation to use apps [4]. Behavior change and performance of a behavior is also predicted by self-efficacy [7,8]. Perceived self-efficacy, defined as an individual's beliefs about their capability to learn and perform particular behaviors [9], is considered to be an important precursor to the adoption of new technologies [10].

Dietitians indicated that, in part, their lack of capability and motivation and subsequent low self-efficacy toward using apps were because they were unfamiliar with the best apps to use and recommend and where apps could add value to nutrition care [4,11]. It was also found that the opportunity to use apps in practice was limited because of the lack of supportive physical infrastructure. According to the behavior change wheel, intervention functions are those that have the potential to address the deficits in the COM-B components [6]. Intervention functions identified as being able to increase dietitians' app use behavior included education and skills training of dietitians and environmental restructuring, such as through the provision of physical app-based infrastructure [4].

Coaching and training workshops also enable individuals to gain mastery and proficiency in requisite skills, thereby increasing their self-efficacy toward new technologies [10]. Mastery experiences to build confidence in one's abilities through successful performances are among the most effective influences on self-efficacy [7,9]. In addition, physical opportunities to engage in repeated practice of the behavior can facilitate mastery experiences [12]. Integration of mHealth apps into existing dietetic work systems may provide greater incentive for dietitians to adopt apps into their practice and build self-efficacy for their use [4,13].

Most platforms designed to support dietitians in managing their practice and patient records are software- or Web-based interfaces [14,15], including the Academy of Nutrition and Dietetics Health Informatics Infrastructure tool [16]. However, platforms with additional connectivity to apps are emerging. Such platforms can, for example, allow patients to obtain a brief automated nutrition assessment based on dietary guidelines and receive basic educational resources before being connected with a dietitian [17]. These platforms may also facilitate remote monitoring and evaluation of patient progress, allowing dietitians to send near real-time feedback on patient health behaviors via motivational messages [15,18-21]. Although many commercial diet-tracking nutrition apps exist, few have a platform for the exchange of data and for dietitians to view their patients' app records [22]. The commercial Australian Easy Diet Diary app (Xyris Software Australia Pty Ltd, High Gate Hill, Australia) is an exception and links into a connected app platform that has been designed to support Australian dietitians in their provision of medical nutrition therapy to patients.

Objectives

The aims of this study were twofold. The primary aim was to assess the feasibility of an intervention consisting of education and integration of apps into dietetic practice in improving dietitians' perceived self-efficacy toward using mHealth apps in patient nutrition care. The secondary aim was to establish whether patient satisfaction would be enhanced following the integration of apps into dietetic services.

Methods

Study Design

Approval for this study was granted by the institutional human research ethics committee (approval number 2018/004). This was a pre-post study design involving 2 phases. In the first phase, dietitians attended an educational and training workshop with perceived self-efficacy with mHealth apps assessed before and after the workshop. The second phase of the study involved a 12-week trial. Dietitians were provided with the practical opportunity to use apps with their patients through a connected app platform that integrated apps into their dietetic practice. New patients who were counseled by these dietitians, hereafter referred to as *intervention patients*, were compared with existing patients who received dietetic consultation before the educational and training workshop, hereafter referred to as *control patients*.

Recruitment and Participants

The study was advertised to dietitians via dietitian-specific electronic newsletters, websites, and social media pages as an educational and training workshop on how to enhance nutrition care through the incorporation of mHealth apps into practice. To be eligible, dietitians had to be (1) Accredited Practising Dietitians (APDs) working in the private practice setting (a minimum of 14 hours per week), (2) not regularly using or recommending mHealth apps in current patient care in dietetic practice (defined as using apps no more than 1-2 times per month), (3) not having used the Easy Diet Diary Connect platform (Xyris Software Australia Pty Ltd, High Gate Hill,

Australia), and (4) willing to attend the in-person educational and skills training workshop in Sydney, Australia. Provisional APDs (ie, those in the first year of practice and still in a mentoring program) were excluded as they were deemed to have less practical dietetic experience and were more likely to have received education on the usage of apps at university. Dietitians were reimbursed Aus $200 for their time in participating in the study and recruiting patients. Dietitian participants were enrolled in February and March 2018.

Intervention patients recruited by their consulting dietitian were eligible to participate in the study if they (1) were 18 years or older; (2) had a health condition or chronic disease that would require self-monitoring of dietary intake; (3) were new patients; and (4) owned an iPhone, as the Easy Diet Diary app was only available on the iOS platform. Intervention patients with initial consultations with their dietitian between April and May 2018 were recruited into the study. Control patients had to be existing patients of the dietitian who had received at least one consultation with their dietitian before the study period but had not been receiving nutrition care for more than 6 months. Control patients were matched to intervention patients for gender and age range. These patients provided a retrospective measure of patient satisfaction with dietetic care before dietitians received the education and training and app platform. An Aus $10 shopping voucher was offered as an incentive to intervention and control patients following the completion of the patient satisfaction survey.

Intervention

This intervention included 2 components: an educational and training workshop and a 12-week intervention phase where dietitians used the connected app platform. The intervention functions included in this study were designed to target the capability, opportunity, and motivation factors of the COM-B model [6] that previous research identified may facilitate increases in mHealth app uptake [4] (Table 1). Self-efficacy is also a predictor of behavior change [7,8]. Therefore, the intervention also addressed all 4 sources of influence on self-efficacy—mastery experiences, vicarious experience, social persuasion, and somatic and emotional states [7,9]—to improve dietitians' beliefs in their capability to use apps in their practice.

Educational and Skills Training Workshop

All eligible dietitians were required to attend the face-to-face 4-hour educational and skills training workshop held on a weekday during business hours in Sydney, Australia. At the workshop, dietitians were provided with education on how a range of apps (eg, Easy Diet Diary, Noom Coach by Noom Inc., New York, US, and FoodSwitch by The George Institute for Global Health, Sydney, Australia) could be used at each step of the nutrition care process to support patient nutrition care based on the most current evidence [3], and case study activities were used to apply this knowledge and build mastery of skills. To overcome a key psychological capability barrier for dietitians around the lack of awareness of the best apps to use in dietetic practice [4], the workshop also educated dietitians about the range of commercially available mHealth apps. Dietitians were trained to appraise and evaluate the quality of these nutrition apps.

Practical and interactive opportunities familiarized dietitians with how to download and navigate through common functions of diet-tracking nutrition apps not only to gain further mastery experiences but also to enhance psychological capability. Support and modeling were provided by the workshop facilitator (JC) and other participating dietitians. Finally, dietitians were trained in the use of the commercial app platform (Easy Diet Diary Connect). Relevant patient tools and information resources were created, including instructions on how to download, install, and use the companion app Easy Diet Diary.

12-Week Intervention Phase

In the 12 weeks following the workshop, dietitians were instructed to provide standard nutrition counseling and care. For the intervention patients, dietitians were also to prescribe the Easy Diet Diary app as a dietary record for dietary assessment and self-monitoring and to review these app records via the Easy Diet Diary Connect platform. Control patients were not prescribed any apps. Enablement and physical opportunities to enhance dietitians' self-efficacy for using mHealth apps were provided through the app platform. Researcher support was made available during this period for any difficulties encountered with the app or app platform.

Easy Diet Diary and Easy Diet Diary Connect Platform

As dietitians prefer country-specific food databases [13], the Easy Diet Diary [23] app (Figure 1) was selected for implementation as the app primarily draws upon the Australian Food and Nutrient Database AUSNUT 2011-2012, which contains foods specific to the Australian food supply. The relative validity of the energy and macronutrient output from the app when compared with 24-hour recalls has been previously established [24]. Unique to the app is also its ability for users to send data directly to their dietitian, which can be analyzed further and used in dietary assessment via access through the FoodWorks nutrient analysis software (Xyris Software Australia Pty Ltd, High Gate Hill, Australia) [25].

The release of a secure Web browser–based interface, the Easy Diet Diary Connect platform [26] (Figure 2), allows dietitians to view their patient's dietary records from the Easy Diet Diary app in real time. The Easy Diet Diary Connect platform makes patient food records and energy and macronutrient intake breakdowns for each day available to the dietitian for reviewing. The interface also automatically displays in a chart format a qualitative analysis of dietary intake based on food groups compared against recommended serves from dietary guidelines. Charts to monitor self-reported weight are also accessible.

Table 1. Intervention functions included in the education and training workshop and 12-week intervention phase that targeted deficits in the sources of behavior (capability, opportunity, and motivation) as classified by the Capability, Opportunity, Motivation-Behavior (COM-B) model, and the sources of self-efficacy, according to Bandura.

Intervention functions	Sources of behavior targeted	Sources of self-efficacy targeted
Education-component of workshop: education to impart knowledge, awareness, and instructions about how apps could be used to support the nutrition care process and dietetic services; what the best apps to recommend to patients are; and the limitations of apps particularly with regard to their quality and accuracy of commercial mHealth apps.	Psychological capability, reflective motivation, and automatic motivation	Social or verbal persuasion
Training-component of workshop: training to provide opportunity to behavioral practice, develop and master skills with using apps, and achieve personal performance accomplishments, particularly through case study activities to apply apps across the nutrition care process; appraisal and evaluation of app quality; hands-on experience with downloading/accessing, using and navigating through different functionalities of apps, including Easy Diet Diary and Easy Diet Diary Connect platform. *12-week intervention phase*: enablement by environmental restructuring through the provision of the Easy Diet Diary Connect platform to integrate patient use of the app into dietetic practice and continued practice with reviewing patient app records via Easy Diet Diary Connect platform	Physical and psychological capability and physical opportunity	Mastery experiences
Expert and credible workshop facilitator who is a dietitian, modeling and demonstrating competent use of apps and platform, participant modeling of successes in using apps, working in small groups during workshop activities when using apps, and platform to allow participants to observe others similar to them for social comparison, social support, and successful accomplishment in using apps	Social opportunity	Vicarious experience
Workshop facilitator provision of supportive feedback on participants' behavior and performance to enable them to refine their skills with using apps; persuasion and exhortation of participants that they have the capability to master app use even in difficult situations, such as short consultations, to give dietitians provisional self-efficacy and the belief and support for attempting the behavior; encouragement provided by workshop facilitator and other participating members; and ongoing workshop facilitator support with app/app platform use during the 12-week intervention phase for enablement	Social opportunity, reflective motivation, and automatic motivation	Social or verbal persuasion
Positive and encouraging workshop environment, with minimization of situations that arouse stress and anxiety; continued and regular prescription of Easy Diet Diary to patients, so that use becomes easy and habitual in dietetic practice	Automatic motivation	Somatic and emotional states

Figure 1. Screenshots of the Easy Diet Diary app (Xyris Software Australia Pty Ltd).

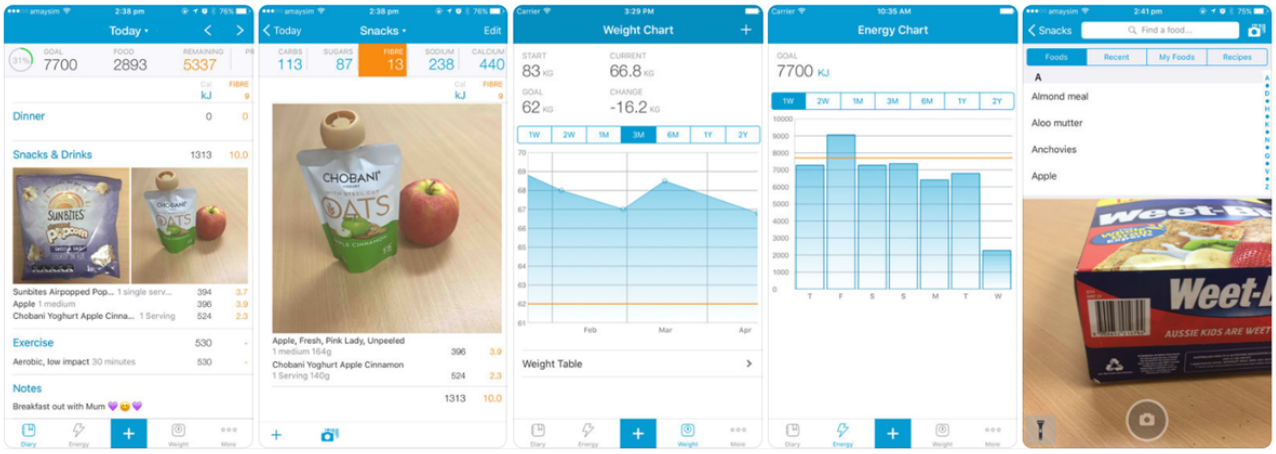
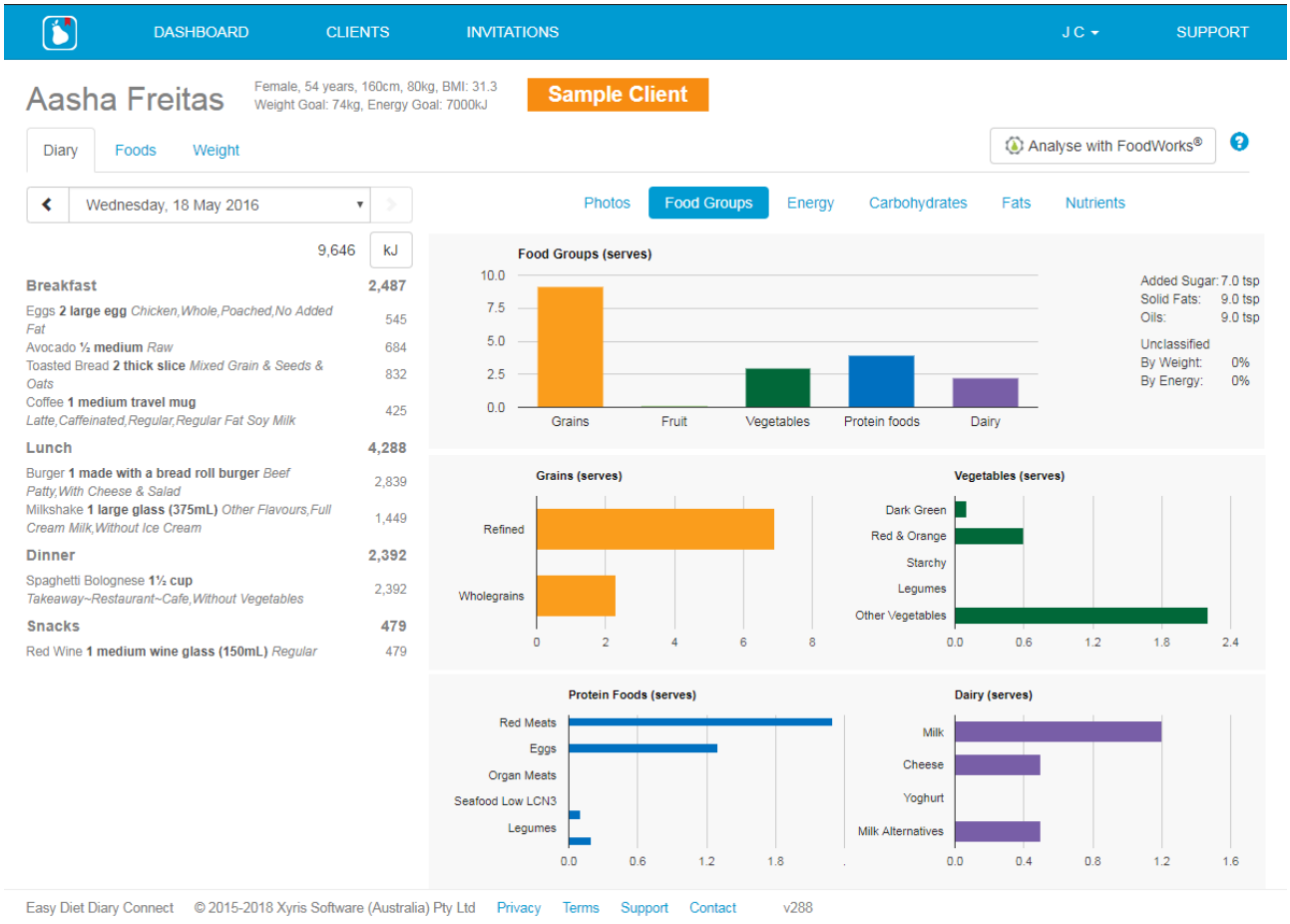


Figure 2. Screenshot of the Easy Diet Diary Connect platform (Xyris Software Australia Pty Ltd).



Outcome Measures

Primary Outcome

The primary outcome variable of this study was the change in ratings for dietitians' self-efficacy with using mHealth apps. Self-efficacy was measured via Web-based surveys at 3 time points: at baseline (1 week before attending the workshop), after the educational and skills training workshop (post workshop), and at the end of the 12-week intervention period. A 16-item validated survey tool for measuring self-efficacy with using mHealth apps among dietitians was used [27].

Secondary Outcomes

The secondary outcome was the impact of the intervention on patient satisfaction with the dietetic services and nutrition care provided assessed using a satisfaction questionnaire adapted from a previously validated tool designed for outpatient dietetic services [28]. The questions relating to written information were altered to relate to general tools used in dietetic practice, so as to also capture the impact of the mHealth app on patient satisfaction.

Control patients completed the survey at the beginning of the 12-week intervention period to provide a measure of patient satisfaction with dietetic care before the apps were introduced, and intervention patients completed it at the end of the 12-week intervention. Control and intervention patients were also asked to provide details regarding whether they had used mHealth apps before coming to see their dietitian. Both groups recorded their age and gender in the survey (as age may determine how *savvy* they are with technology).

Additional outcome measures collected from dietitians included personal app use and recommendation of apps in patient care, derived from a previously piloted and validated survey administered to dietitians [4]. Other basic demographic questions including age, gender, and length of dietetic practice were also collected.

Process Outcomes

Process evaluation for the intervention was conducted to provide feedback to inform future larger-scale dissemination. To evaluate the training workshop, dietitians completed a Web-based questionnaire after the workshop regarding their satisfaction with the workshop content and delivery style and provided free-text comments on suggestions for future modification and improvement of the workshop. At the end of the 12-week intervention period, dietitians were asked to indicate their practices around reviewing app records.

The validated 10-item System Usability Scale (SUS) survey, with minor modifications whereby the term *system* was substituted for *app platform* or *apps*, was used to collect an assessment of system usability [29,30]. Additional questions based on an acceptability questionnaire for a mobile diabetes management system, WellDoc [31], were included in the 12-week dietitians survey to understand whether the app platform was helpful to them and their patients in terms of their

relationship and the additional care and the acceptability of the amount of time spent performing tasks on the app platform. Open-ended questions were also included to gather any feedback from dietitians and patients regarding the usability and any suggested improvements to the features and functionality of the connected app platform and app, respectively.

Data Analysis

A mixed-methods approach was used for data analysis. Descriptive statistics were generated for quantitative measures such as participant demographics and outcome variables (mHealth app self-efficacy and patient satisfaction). Analysis of variance (ANOVA) followed by the Tukey post hoc tests was conducted to determine any differences in the mean changes in items measuring dietitians' self-efficacy with using mHealth apps between time points. Logistic regression models were conducted to assess any differences between patient satisfaction ratings (dependent variable) from intervention and control patients (independent variables), adjusting for other covariates including the dietitian that patients saw, patient age, gender, and previous experience with using mHealth apps. All statistical analyses were performed using SPSS statistical software, version 22.0 [32]. The SUS scores were calculated based on the original method described by Brooke [29], with scores above 70 considered to reflect acceptable usability [30,33]. Qualitative inductive thematic analysis was used to code open-ended responses into themes.

Results

Participant Characteristics

Overall, 31 dietitians responded to the screener survey, of which 2 were partial responses and 22 were excluded based on the eligibility criteria. Of the 7 eligible dietitians, 2 were unable to attend the workshop, but the other 5 dietitians attended and completed the 12-week intervention. All the participants were female and aged between 46 and 65 years and with over 20 years of experience in practicing. The most common practice areas were in weight management (n=4) followed by diabetes (n=3).

Of the 5 dietitians, 4 had personally used apps and 3 had personally used health apps. As per the inclusion criteria, all participating dietitians did not frequently use apps in their practice (1-2 times per month or less), all citing that a lack of awareness about the best app to use was a key barrier. Other barriers included a lack of time to discuss apps in a consultation (n=2), lack of infrastructure (eg, no access to Wi-Fi; n=2), topics covered by apps not relevant to clientele (n=1), and apps being too hard to use (n=1).

They had all previously recommended apps to their patients, 1 to 2 times per month (n=3) or 1 to 2 times per year (n=2). On average, they had recommended 3.4 apps (SD 0.9) over the past year to patients, with the Low FODMAP Diet informational app by Monash University, Melbourne, Australia recommended by all, and 2 dietitians having recommended Easy Diet Diary previously.

Furthermore, 13 of 19 control patients who attempted the patient satisfaction survey completed it. In addition, 23 intervention patients provided consent to being issued the survey at the end of the 12-week intervention, with 17 patients completing the survey. Intervention and control patient demographics are outlined in Table 2. The majority of patients had not used an mHealth app before coming to see their dietitian and none had previously used the Easy Diet Diary app.

Impact of Intervention on Outcomes

Dietitians' Self-Efficacy With Using Mobile Health Apps

On the basis of the mean overall ratings for the dietitians who participated in the intervention, there was a significant improvement in overall self-efficacy with using mHealth apps (ANOVA $F_{2,12}$=7.0; P=.01). The Tukey post hoc test revealed significantly higher postworkshop mHealth app self-efficacy ratings compared with baseline (P=.02), which were sustained at 12 weeks (P=.01; see Table 3).

Table 2. Demographics of intervention (n=17) and control patients (n=13) who completed the survey (N=30).

Characteristics	Intervention patients, n	Control patients, n
Age (years)		
18-30	2	2
31-40	7	5
41-50	1	3
51-60	2	0
More than 60	5	3
Gender		
Female	14	13
Male	3	0
Use of a mobile health app before coming to see their dietitian		
Yes	5	4
No	12	9

Table 3. Dietitians' self-efficacy with mobile health apps before and after attending the educational and skills training workshop on apps as well as after 12-weeks of practical opportunities to use mobile health apps in their practice. The mean ratings for individual items and factors are presented. One-way analysis of variance was conducted followed by the Tukey post hoc test.

Self-efficacy item[a]	Baseline rating	Post workshop		End of 12 weeks	
		Rating	*P* value	Rating	*P* value
Familiarity with apps factor	5.8	8.9[b]	.001	8.8[b,c]	.001
When I currently recommend/in the past have recommended mobile health apps to patients	4.6	8.2[b]	.005	8.4[b,c]	.004
When I am familiar with which mobile health apps to recommend	7.0	9.6[b]	.07	9.2[b,c]	.02
Training and support factor	7.5	9.3[b]	.01	8.6[c,d]	NS[e]
When someone else has helped me get started	8.0	9.8[d]	NS	8.6[c,d]	NS
When I can call someone for help when I get stuck	8.6	10.0[d]	NS	8.6[c,d]	NS
When there is no one around to tell me how to use them as I go	4.8	7.8[d]	NS	7.8[c,d]	NS
When someone has shown me how to use them first	8.6	9.6[d]	NS	9.4[c,d]	NS
Efficiency and effectiveness of nutrition care factor	6.6	7.6[d]	NS	8.1[c,d]	NS
To improve the efficiency of consultations	7.2	7.4[d]	NS	7.6[c,d]	NS
To improve the effectiveness of nutrition interventions	7.2	8.2[d]	NS	8.6[c,d]	NS
To improve patient health outcomes	7.0	8.4[d]	NS	9.0[c,d]	NS
When I need to deliver nutrition interventions	7.2	8.0[d]	NS	9.2[c,d]	NS
When I need to conduct nutrition assessments	7.0	8.2[d]	NS	8.8[c,d]	NS
When there is a short consultation time	5.0	5.2[d]	NS	5.2[c,d]	NS
When patients ask me about using mobile health apps	5.4	7.8[b]	0.03	8.6[b,c]	0.005
Integration into dietetic work systems factor	7.0	8.1[d]	NS	8.8[b,c]	0.03
When apps are integrated into my existing patient management systems	6.2	7.2[d]	NS	7.8[c,d]	NS
When there is an app platform where I can view patient mobile health app records/data	6.8	8.0[d]	NS	8.8[c,d]	NS
When I want patients to self-monitor their behaviors	8.0	9.2[b]	.001	9.8[c,d]	.001
Mean overall rating	108.6	132.4[b]	.02	135.4[b,c]	.01

[a]Dietitians rated each item from 0 indicating *I am not able at all*, to 5 indicating *Moderately certain I am able*, and to 10 indicating *Completely certain I am able*.

[b]Significant difference from baseline.

[c]Nonsignificant difference from post workshop.

[d]Nonsignificant difference from baseline.

[e]NS=nonsignificant $P>.05$.

Attendance at the educational and skills training workshop significantly improved dietitians' familiarity with apps ($F_{2,12}=21.2$; $P<.001$) from baseline to the postworkshop ($P<.001$) and 12-week measures ($P<.001$) as well as across all items that this self-efficacy factor was comprised. Significant improvements from baseline were also observed in the postworkshop self-efficacy ratings for the training and support factor but not in the subitems. There were no statistically significant differences between postworkshop and 12-week ratings for this factor or for the other 3 factors, individual mHealth app self-efficacy items, or mean overall self-efficacy.

Despite significant improvements in the efficiency and effectiveness of nutrition care factor subitem regarding patient queries with using mHealth apps, 1-way ANOVA revealed no significant differences between any of the 3 time-point measurements for this factor ($F_{2,12}=2.3$; $P=.1$). With the implementation of the connected app platform in the 12-week phase, ratings for the integration of apps into dietetic work

systems factor significantly improved from baseline to 12-week measures (*P*=.03). The factor subitem regarding patient self-monitoring of health behaviors significantly improved post workshop (*P*=.001), with self-efficacy maintained at 12 weeks (*P*<.001).

Patient Satisfaction

Table 4 presents the mean patient satisfaction ratings for intervention and control patients based on each item as well as for the 4 factors of the tool, including perceived health benefits, staff presentation and interpersonal skill, fulfilled expectations, tools and materials, and overall satisfaction. Both intervention and control patients agreed or strongly agreed with the majority of satisfaction items and rated the overall satisfaction with the dietetic services they received as good to very good.

Logistic regression showed no difference in patient satisfaction with dietetic services between intervention and control patients, when adjusting for their dietitian (χ^2_2=1.8; *P*=.4). Additional adjustment for patient age, gender, and experience with mHealth apps did not change this finding (χ^2_5=6.0; *P*=.3).

Table 4. Patient satisfaction ratings with dietetic services.

Patient satisfaction item[a]	Intervention patients (rating from 1 to 5)	Control patients (rating from 1 to 5)
Perceived health benefits	3.9	4
The care I received from the dietitian has improved my general health	4	4.2
The care I received from the dietitian has improved the results of my medical treatment	3.6	4
The care I received from the dietitian has helped me achieve my health goals	3.9	3.8
The care I received from the dietitian has helped me to feel healthier	4.2	4.1
Staff presentation and interpersonal skill	4.6	4.6
The dietitian listened carefully to what I had to say	4.6	4.6
The dietitian was attentive to my needs	4.6	4.5
The dietitian came up with a good plan for helping me	4.5	4.5
The dietitian was well presented	4.6	4.7
The dietitian was polite and courteous	4.7	4.7
The dietitian was friendly	4.8	4.8
Fulfilled expectations	4.5	4.6
The nutrition care I received was helpful	4.4	4.5
The nutrition care I received met my expectations	4.2	4.4
I would recommend the nutrition service provided by my dietitian to other members of the community	4.7	4.8
Tools and materials	4.4	4.3
The tools were of a high standard	4.4	4.1
I found the tools very easy to understand	4.4	4.3
The tools were easy to use	4.3	4.3
The tools made sense	4.4	4.3
The tools were well presented	4.3	4.3
Overall, how would you rate your satisfaction with the services provided by your dietitian?[b]	4.8	4.5

[a]Patients rated items 1 to 18 from 1=strongly disagree to 5=strongly agree.

[b]Patients rated item from 1=very poor to 5=very good.

Table 5. Dietitian satisfaction with the educational and skills training workshop component of the intervention.

Items	Rating[a], mean (SD)
The theory and practical components of the workshop improved my understanding of the topics covered	4.4 (0.55)
This workshop helped me develop skills applicable to my professional practice	4.2 (0.45)
I can see how the knowledge and skills I am learning can be put to use in my future professional work	4.2 (0.45)
I have come to feel more confident about my ability to use apps in my dietetic practice and in patient nutrition care	4.4 (0.89)
Feedback provided during the workshop was helpful to my learning	4.6 (0.55)
Overall, I was satisfied with the quality of this workshop	4.6 (0.55)

[a]Dietitians rated each item from 1=strongly disagree to 5=strongly agree.

Process Evaluation

Overall, dietitians agreed or strongly agreed that they were satisfied with the quality of the workshop (Table 5). All dietitians who attended indicated that they would recommend this workshop to colleagues, with 1 participant relaying how she "thoroughly enjoyed the workshop and learned a lot." Dietitians' favorite parts of the workshop included the *practical elements* that provided them with hands-on experience with using apps as well as the demonstrations by the workshop facilitator on how to use the connected app platform: *Being shown how to use the Easy Diet Diary platform*. Activities and information to raise awareness about the quality and range of different apps available to use in patient nutrition care and dietetic practice were also cited as a liked aspect of the workshop: *Learning pros and cons about various apps*. The workshop helped to transform dietitians' psychological states and motivations toward using apps, with 1 dietitian describing how the workshop "Made me feel positive towards integrating apps in my work" or "I'm looking forward to integrating Easy Diet Diary into my practice."

For improvement of the workshop, feedback revolved mainly around timing, such as breaking up the workshop to allow for breaks and reconsidering the length of the workshop. The educational lecture component of the workshop was recognized to be important and interesting. However, suggestions were made to transfer some of the time allocated for knowledge exchange to even more skill-based training and opportunity for gaining practical experience with apps. For example, 1 dietitian mentioned:

> *While interesting the theoretical background was a little long.*

Another dietitian stated:

> *Needed more time with the hands-on. Would have like[d] to play with a variety of apps rather than just slides [learning about them].*

Drawing further upon the social support of colleagues, it was also expressed that the workshop could be improved by allowing for more mastery of skills:

> *It may have been useful to practise via role play.*

Dietitians' Reviewing of App Data

Before participation in this intervention, 4 of the 5 dietitians reviewed their patients' progress with the mHealth apps recommended and 1 never did—predominantly talking about the progress made with the app without looking at the data (n=3), the other saw the data as to:

> *...just provide back up information rather than tracking.*

For all dietitians, a key barrier to reviewing patient app records involved inadequate knowledge, experience, or confidence regarding which apps would allow for reliable data sharing. Furthermore, dietitians perceived that there was a lack of time in the actual appointment for reviewing the records.

Following the intervention, dietitians reviewed their patient app records more frequently than at baseline, with 3 of the 5 dietitians reviewing app data in some consultations—without reference to the data, or through reviewing data on their patient's smartphone, or via the connected app platform. In addition, 1 dietitian reviewed their patient app records via the connected app platform on their computer at every consultation, and another dietitian reviewed records through the platform even between consultations and subsequently provided encouragement emails to her patients.

For these 2 dietitians who reviewed their patients regularly (ie, at every consultation or in between consultation), they strongly agreed that the connected app platform had been helpful to their practice, whereas those reviewing patient app records less frequently agreed or were neutral. They also agreed that their relationship with their patients has improved because of this app platform system, whereas those who did not review regularly provided a neutral response. The majority agreed or strongly agreed (4/5) that their patients had found the integrated app platform to be helpful in addition to usual dietetic care.

Easy Diet Diary Connect Usability and Acceptability

Dietitians rated the usability of the Easy Diet Diary Connect platform with a mean rating of 73 (range: 57.5-100). All dietitians indicated they would continue to use the app platform and recommend it to others. Qualitative feedback from dietitians revealed that the connected app platform was easy to use and a good tool in patient care for "Tracking of food and nutrient intakes." Dietitians found that the app platform provided an additional source of information to assist with the tailoring of nutrition interventions:

> *It gave me the information I needed to modify the patient's education, in a clear concise form*

Additional features that were suggested to improve the platform included the "option for more nutrients." Dietitians also wanted further communication mediums to be integrated within the connected app platform, for example, the "Ability to send patients SMS messages from platform." However, dietitians did note the varied responses in patient willingness to share their health data:

> *A couple of them were too uncomfortable to link me in (they were in the older age group).*

In addition, 1 dietitian encountered technical issues, citing that "being unable to access my [connected app platform] account made it very difficult," to review patient records in a timely manner; this created a loss in momentum and motivation to continue using the app platform.

When used in conjunction with the app platform, dietitians believed that Easy Diet Diary was a "great app but just don't have the time to deliver and monitor—I will recommend this app for people to self monitor." Time constraints around teaching patients how to use the app were raised, with particular consideration around patients' own self-efficacy with using mHealth apps:

> *As I have a structured consultation, I found it difficult to include the app introduction and downloading in the consultation, therefore they were asked to download in their own time, which they often didn't. It was also very time consuming for me to monitor patients and give feedback between consultations, it really depends on each patient re understanding and motivation with technology.*

There were mixed responses from dietitians toward the acceptability of the amount of time spent performing tasks on the app platform per patient. Overall, 1 dietitian disagreed and 3 were neutral, whereas the dietitian who reviewed apps in every consult agreed that the time spent was acceptable. On average, dietitians spent 13 min (range 5-15 min) per patient on app platform–related activities (eg, teaching patients how to download and set up the app and viewing their app records). The majority (4/5) of dietitians agreed that the app platform helped to improve the amount of time they spent on dietary assessment.

Easy Diet Diary App Usability From Patients' Perspectives

A mean SUS rating of 77 (range: 55-100) for the Easy Diet Diary app was indicated by patients. All except 1 patient would continue using the app. This patient cited that the reason for not continuing use was because the app was:

> *Not particularly compatible with alternative nutrition approaches e.g. Keto/paleo/5:2.* [r5, female, 31-40 years old]

All patients reported they would recommend the app to others.

The key themes emerging from patient feedback about the aspects they liked about the app included that it was easy to use. Functionalities within the app identified as enhancing the ease of use were related to the logging of dietary intake. These included the copy and paste functionality, "Easy to copy and paste daily meals to other days. e.g. if you have the same breakfast everyday" [r3, female, >60 years old], barcode scanner, "barcode scanner was excellent" [r5, female, 31-40 years old], and recent function, "(took me a little time to identify that one)... Saved me much time in keeping my records up to date" [r15, male, 51-60 years old].

Patients found the app useful for tracking calories and nutrients:

> *Counting the calories & seeing how much protein & calcium in my diet.* [r10, female, 31-40 years old]

The feature to highlight selected nutrients of interest in the app was liked:

> *The days total and the option to choose what one is of most importance to me to quick tally in the orange writing.* [r16, female, 18-30 years old]

Some patients made comparisons between the Easy Diet Diary app and other nondietitian-designed commercial nutrition apps:

> *It's also not as pushy as MyFitnessPal. [r1, female, 31-40 years old].*

However, there was not necessarily an understanding of how the Easy Diet Diary app was different or better compared with other apps:

> *Although it does seem similar to others out there, such as My Fitness Pal [sic]. I'm not sure what would differentiate it from the rest. But useful nevertheless.* [r12, female, 31-40 years old]

One patient relayed how the app had been supportive in helping her achieve her health goals and improving her health outcomes:

> *The ap[p] has helped me to lose weight and over time help me with my diabetes- am aiming to remove the meds all together.* [r15, male, 51-60 years old]

Another patient reflected upon needing to be more adherent to using the app to self-monitor their dietary intake:

> *I need to be disciplined and complete my daily diet intake every day* [r7, female, >60 years old]

The notes section of the app was highlighted as facilitating communication and accountability between the patient and their dietitian and, thus, also creating a sustained interest to continue using the app. Of the patient, 1 described how:

> *I was happy to be using it with my dietician [sic], knowing that they would and could be checking what I had been logging regularly. It kept me more accountable.* [r12, female, 31-40 years old]

Nevertheless, it was perceived that the app could offer more tailored features to complement their dietitians' approach and nutrition care goals:

> *Tailored target setting based on nutrition approach e.g. Less emphasis on calories, good fats vs bad fats etc.* [r5, female, 31-40 years old]

Opinions on the Easy Diet Diary app food database varied between patients. Some patients identified the database as being an aspect they liked: "I also liked the preloaded nutritional value of products that I can buy from the shops" [r16, female, 18-30

years old], particularly also given that the app used an Australian database of foods:

> *It's [the app is] Australian so has a lot of Australian products and foods included.* [r1, female, 31-40 years old]

However, this same participant also expressed challenges with being unable to find certain food options. She suggested that the database should contain more generic food items and less supermarket brands, especially for common food items such as bread and milk:

> *There's not a generic "sourdough" you have to choose a random supermarket brand which may or may not be similar.*
>
> *For the low-fat (light blue) milk option, it forces you to choose one that's omega enriched. Why isn't there just a standard option for this?*

To increase the relevance of the database, regular updating was suggested: "Keeping up to date more items" [r11, female, 31-40 years old], as well as refining the database of foods to make searching of foods easier and quicker:

> *Many products are in the app, however, are not easy to find. Suggest that a food type heading be add[ed].* [r9, male, >60 years old]

Others wanted the types of food available in the database to be expanded, for example, to include fast food options:

> *Getting many of the take away type foods into the ap[p]. Eg Red Rooster Tropical Pack.* [r15, male, 51-60 years old]

For patients who cooked meals at home themselves, they reported it as being burdensome to enter all the ingredients to these meals:

> *No general cook at home recipes so had to add each individual ingredient annoying.* [r14, female, 31-40 years old]
>
> *I also wish it was easier to add meals I've made myself where I don't know the nutritional value.* [r16, female, 18-30 years old]

This raised concerns around the inaccuracies and difficulty of matching foods consumed to those available in the database:

> *I do a lot of own cooking & recipes don't have calorie count in them so hard to find exactly what you're eating.* [r10, female, 31-40 years old]

It was suggested that features to share food items could be incorporated:

> *Being able to share food items with another person.* [r13, female, 51-60 years old]

Although 1 patient had indicated that they liked the app's ability to take photos, they also offered a suggestion for improvement by allowing the app to:

> *Access to photos—the first few times I took photos on my phone and then wanted to upload them into easy diet diary, but I don't think this is possible. You have to take the photos through easy diet diary [sic].* [r12, female, 31-40 years old]

Easy Diet Diary App Usability From Dietitians' Perspectives

Dietitians also provided some input around the usability of Easy Diet Diary with their patients. The limited compatibility across both iOS and Android platforms was a practical constraint:

> *The only challenge I have had is that you suggest the Easy Diet App and then find out the patients has a Samsung.*

Patient experience and familiarity with using apps and the age of patients were practical considerations for dietitians when prescribing the app to their patients, for example:

> *It was user friendly for people who were used to using apps.*
>
> *I have older patients who are not well and they struggled to use it.*

Other features dietitians suggested to be included or improved were:

> *an integrated exercise monitor—most patients ignored entering ex[ercise] as it was too complicated and difficult to enter accurately. Also to make it easier to enter personal recipes.*

Discussion

Principal Findings and Comparison With Other Literature

To our knowledge, this is the first study to provide evidence for the feasibility of an intervention designed to train, educate, and provide opportunities for dietitians to improve their self-efficacy with using mHealth apps. Preliminary findings indicate that the workshop was effective in improving dietitians' self-efficacy with using mHealth apps, with the effects maintained at 12 weeks. There were no apparent gains in patient satisfaction with nutrition care or dietetic services when prescribing an app to their patients. Both dietitians and their patients expressed willingness to continue using the connected platform and app. However, feedback on the inadequate time for administering the app during the consultation and the burden of logging meals and multi-ingredient recipes indicates that further investigation into streamlining app use in the nutrition care process is needed.

Marked improvements in dietitians' self-efficacy with using mHealth apps were observed after attending the educational and skills training workshop component of this intervention. This is attributable to the workshop targeting the 4 sources of information proposed by Bandura that impact the development of individuals' self-efficacy beliefs [7,9]. The workshop addressed barriers around dietitians' lack of understanding about the best apps to use with patients and enabled them to acquire knowledge and familiarity around apps and to develop mastery of skills with using apps in various aspects of patient nutrition care. More importantly, the training allowed dietitians to build self-beliefs in their abilities to use mHealth apps through

successful performance and practice of using the apps in a relaxed and engaging environment with expert facilitation and modeling and peer-to-peer support.

The progress made with dietitians' self-efficacy toward using mHealth apps also aligns with understanding drawn from research into computer self-efficacy. Computer self-efficacy research models propose that antecedents of computer self-efficacy include prior performance experiences with using computers, computer knowledge, behavioral modeling in computer training, social support, and encouragement provided by similar others, such as colleagues [34-38], which coincide with the areas targeted by this workshop.

Personal accomplishments and successes with performing a task can raise individuals' beliefs and expectations in their own capabilities [7,9]. The inclusion of a connected app platform in the 12-week phase provided further opportunities for mastery experiences. Dietitians had the opportunity to engage in additional mHealth-related tasks such as reviewing patient records to develop a stronger efficacy with implementing and integrating mHealth apps into their work systems. There was no significant increase in overall mHealth app self-efficacy ratings between postworkshop and 12-week measures. However, the maintenance rather than the decline of self-efficacy scores at 12 weeks is likely to be attributable to the sustained effort and increased frequency of prescribing apps to patients and using the connected app platform and the resilience to barriers and challenges [7].

When considering patient acceptance of using mHealth technologies in their chronic disease management, the relationship of a patient with their health practitioner can influence their perceived ease of use of an app [39]. As such, the implication is that when apps are prescribed by dietitians who have a good rapport with patients, this may reduce resistance to change and increase intention to use the app [39]. Furthermore, the accountability offered through dietitians reviewing their patients' progress in the connected app platform was found to motivate patients to continue using the app. This is consistent with the supportive accountability model, which proposes that human support provided by a trustworthy expert coach, such as a dietitian, can enhance adherence to online behavior change interventions [40].

In the hospital setting, mHealth apps are indicated to improve patient experience, with 1 study determining that the use of mHealth apps during a hospital visit was able to increase the outpatient experience ratings by 17.7% [41]. However, such enhancements to patient satisfaction between intervention and control patients from the use of apps in patient care were not observed in this study. An explanation for the lack of significant improvements between groups may be the high satisfaction that control patients had toward impact, professionalism, and expectations toward dietetic care and services. This is consistent with the literature whereby patient satisfaction was higher with medical nutrition therapy for hypercholesterolemia delivered by dietitians than with the usual care offered by physicians [42]. Furthermore, these findings provide evidence that apps do not have any detrimental impact on patients' perceptions over the quality of nutrition care.

The SUS score of above 70 achieved from patients' assessments of Easy Diet Diary app indicates a *good* rating, suggesting that the app is an acceptable product [30,33]. However, the scores are comparatively lower than those of a quality assessment carried out by an expert dietetics app assessor, where it was ranked equal first with a perfect SUS score from among 28 popular nutrition weight loss apps [22]. In another study investigating a modified researcher version of the Easy Diet Diary app, the majority of participants also found the app easy to use and the barcode scanner to be useful [24]. However, only 52% of individuals agreed or strongly agreed that "the foods they usually eat were easy to find on the app" [24], which is comparable with the qualitative feedback of patients who found it difficult to match or locate their consumed food among all the choices.

Challenges relating to entering of home-cooked recipes have similarly been found in the researcher-version of the Easy Diet Diary app, where 64% of participants agreed that they often had to include their own recipes into the app [24]. It would be expected that as education and health behaviors change with dietetic intervention, there may subsequently be an increase in the frequency of meals cooked at home. Increased frequency of home-cooked meals is associated with improved diet quality and a greater likelihood of normal range body mass index and normal percentage body fat [43,44]. Therefore, a consideration for dietitians when prescribing apps in nutrition care is that over time as patients' dietary habits change and there is more home cooking, it may become less convenient to use apps to log intake.

Although the usability of electronic health records (EHRs) by physicians is well studied [45], little is known about the usability of electronic platforms to support dietitians' use of patient data from apps. The Easy Diet Diary Connect platform has a comparative SUS score to evaluations of certain EHRs [46]. However, other literature has highlighted that physicians perceive EHRs to have poor usability amidst a range of other limitations relating to inefficiencies from improper integration and interference with face-to-face patient care [45].

Country-specific mHealth apps and technology are valued by app users, patients, and dietitians alike [13,47] and present more accuracy for dietary assessment when used in the appropriate country's context [24,47-49]. A specific *My Coach* function is available for Canadian dietitians to connect with patients using the Dietitians of Canada eaTracker app or website [21]. eaTracker provides the opportunity for a greater degree of nutrition care tailoring through personalized goal setting rather than general caloric intake targets [50,51]. myPace is a European dietitian-researcher–developed platform containing 3 interfaces (dietitian Web interface, patient mobile, or Web interface) and designed specifically to support the dietitian-patient relationship for sustainable weight loss and weight management [18,19]. The myPace platform allows dietitians to directly send motivational messages to their patients, a feature that dietitians felt was missing from the Easy Diet Diary Connect platform.

Future Directions and Strengths and Limitations

The low response rate to this study and the small sample size of dietitians and patients is a clear limitation to the interpretation

of results. This study was not powered for statistical analysis. However, the finding of some significant result of improved mHealth app self-efficacy for dietitians from such a small sample provides indication of its potential efficacy if a larger sample was to be obtained. As the study only recruited a small number of private practice dietitians, future dissemination of this intervention could offer the educational and skills training workshop outside business hours and across different locations, to allow for more private practice dietitians to attend.

A possible source of bias is that the dietitians who volunteered to participate in this study had a greater interest in engaging with technology and, thereby, were likely to have higher motivation for developing self-efficacy with using mHealth app technologies. Furthermore, this study only recruited dietitians who were not regular users of apps in their practice. With some redesigning of workshop content to offer education and training on more specific and advanced skills, it is likely to also be beneficial for increasing the mHealth app self-efficacy of existing app users, given that prior experience with using apps can predict stronger self-efficacy [36].

There is also translation potential of delivering such an intervention to doctors, nurses, and other health professional groups who, like dietitians [4], are commonly using apps in their own clinical practice [52,53]. The older and more experienced medical and health professionals would likely benefit more as junior doctors seem to be adopting apps already [54,55]. Overall, less than 10% of doctors had recommended mHealth apps to their patients [52]. The key barriers to not recommending apps align with those expressed by dietitians [4], including that the doctors had never thought about recommending them, followed by uncertainties over the evidence base, safety, the best apps to recommend, and efficacy of apps [52], all of which could be addressed through education and training.

From this study, short-term benefits of the educational and skills training workshop and integration of the connected platform were observed on dietitians' self-efficacy with using mHealth apps in their practice. However, it would be necessary to conduct an extended study to examine how dietitians' self-efficacy with using apps and their app use within the practice are sustained. Long-term changes to patient satisfaction following implementation apps into patient care should also be measured. In this study, parameters on the effectiveness of the intervention on patient outcomes were only provided through the mHealth app self-efficacy tool. It would be pertinent to examine the impact of the intervention on patient biochemical and anthropometric outcomes directly in future studies.

Conclusions

This study has demonstrated the feasibility of improving dietitians' self-efficacy with using mHealth apps in their practice through the implementation of an intervention that provided dietitians with education and skills-based training to develop capability, motivation, and mastery of performance with using apps. Determining further strategies to improve the integration of app platforms into the various patient health management systems used by dietitians and other health and medical practitioners could provide further opportunities for health professionals to build mHealth app self-efficacy so that the benefits of apps in health care service delivery can be realized. The qualitative findings of this study have provided a rich source of information on the usability of the app platform and the associated app in dietetic practice and patient care, and the suggested improvements should be considered by app developers. However, being a feasibility study in nature, further translational research is required to determine the impact of the intervention on long-term mHealth self-efficacy for the broader dietetic profession and for patient outcomes.

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Authors' Contributions

JC and MAF contributed to the conception and design of the study. JC developed the intervention materials, conducted the research, analyzed the data, and drafted the first version of the manuscript. MAF contributed to writing and reviewed the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

JC declares no conflicts of interest. MAF has developed food- and nutrition-based apps for research purposes. She has received funding for other research from the Australian Research Council, the National Health and Medical Research Foundation, NSW Health and Cancer Council NSW. The authors received no remuneration from the developer (Xyris Software Australia Pty Ltd) of the commercial app and app platform used in this study. Xyris was not involved in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Abbreviations

ANOVA: analysis of variance
APD: Accredited Practising Dietitian
COM-B: Capability, Opportunity, Motivation-Behavior
EHR: electronic health records
mHealth: mobile health
SUS: system usability scale

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Original Paper

A Mobile Health Wallet for Pregnancy-Related Health Care in Madagascar: Mixed-Methods Study on Opportunities and Challenges

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Abstract

Background: Mobile savings and payment systems have been widely adopted to store money and pay for a variety of services, including health care. However, the possible implications of these technologies on financing and payment for maternal health care services—which commonly require large 1-time out-of-pocket payments—have not yet been systematically assessed in low-resource settings.

Objective: The aim of this study was to determine the structural, contextual, and experiential characteristics of a mobile phone–based savings and payment platform, the Mobile Health Wallet (MHW), for skilled health care during pregnancy among women in Madagascar.

Methods: We used a 2-stage cluster random sampling scheme to select a representative sample of women utilizing either routine antenatal (ANC) or routine postnatal care (PNC) in public sector health facilities in 2 of 8 urban and peri-urban districts of Antananarivo, Madagascar (Atsimondrano and Renivohitra districts). In a quantitative structured survey among 412 randomly selected women attending ANC or PNC, we identified saving habits, mobile phone use, media consumptions, and perception of an MHW with both savings and payment functions. To confirm and explain the quantitative results, we used qualitative data from 6 semistructured focus group discussions (24 participants in total) in the same population.

Results: 59.3% (243/410, 95% CI 54.5-64.1) saved toward the expected costs of delivery and, out of those, 64.4% (159/247, 95% CI 58.6-70.2) used household cash savings for this purpose. A total of 80.3% (331/412, 95% CI 76.5-84.1) had access to a personal or family phone and 35.7% (147/412, 95% CI 31.1-40.3) previously used Mobile Money services. Access to skilled health care during pregnancy was primarily limited because of financial obstacles such as saving difficulties or unpredictability

of costs. Another key barrier was the lack of information about health benefits or availability of services. The general concept of an MHW for saving toward and payment of pregnancy-related care, including the restriction of payments, was perceived as beneficial and practicable by the majority of participants. In the discussions, several themes pointed to opportunities for ensuring the success of an MHW through design features: (1) intuitive technical ease of use, (2) clear communication and information about benefits and restrictions, and (3) availability of personal customer support.

Conclusions: Financial obstacles are a major cause of limited access to skilled maternal health care in Madagascar. An MHW for skilled health care during pregnancy was perceived as a useful and desirable tool to reduce financial barriers among women in urban Madagascar. The design of this tool and the communication strategy will likely be the key to success. Particularly important dimensions of design include technical user friendliness and accessible and personal customer service.

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KEYWORDS

pregnancy; maternal health services; healthcare financing; cell phone; mobile applications; telemedicine; maternal mortality; health expenditures; marketing of health services; developing countries; Madagascar

Introduction

Background

Despite widespread political commitment to improve accessibility and utilization of skilled care during pregnancy by user fee exemption policies, out-of-pocket payments (OPP) remain the predominant mode of health care financing in several sub-Saharan countries [1]. However, the costs for skilled care frequently exceed the savings or assets that can be accessed at one time by a low-income household, potentially leading to medical impoverishment [2-4]. Besides selling assets or receiving emergency funds or loans by family or friends, personal or household savings can help protect from the financial burden of health shocks [1,5]. However, setting money aside on a regular basis to save for health care is difficult for the poor, who often face the need for imminent expenses, which undermines long-term saving goals [6]. Therefore, expectant mothers from low-income households in sub-Saharan Africa (SSA) often do not seek skilled birth attendance or emergency obstetric care to avoid the large costs associated with delivery [7].

Within the last decade, mobile phone ownership has grown exponentially, and mobile communication has become pervasive in SSA. Today, more than 70% of worldwide mobile phone subscriptions come from low- and middle-income countries (LMICs) with more than 74 subscriptions per 100 people in SSA in 2016 [8,9]. In the footsteps of this mobile phone revolution have followed mobile payment systems, colloquially known as Mobile Money (MM), which commonly utilize low-tech systems such as unstructured supplementary service data to enable financial transactions without the need for a bank account. MM is suitable for virtually all widely used handsets independent of smartphone capability or internet access, and it allows subscribers to send, save, and receive funds on a digital platform held by a mobile operator. Funds and transactions are typically denoted in the national currency, allowing saving with little purchasing power volatility and transactions without conversion fees. Cash can be converted into electronic value (and vice versa) at retail stores or agents [10]. With almost 80% of adults in SSA not having access to formal banking services, economies are increasingly relying on mobile payment systems [11]. In turn, this allows financial inclusion of households with low transaction volumes or limited access to the formal banking system [12].

Leveraging this technological development, mobile payment–based hospital insurance or a savings mechanism enables low-income households to set aside funds exclusively for health care. In Kenya, an electronic health savings account including e-vouchers and microinsurance schemes to improve health care access was launched in 2008 [13,14]. In addition, a mobile phone–based payment and savings platform allowing clients to send, save, and spend funds specifically for medical treatment in contracted health facilities has been commercially available in Kenya since 2016 [15]. To date, this system has reached 1.4 million registered users, and it has facilitated the payout of US $4.8 million [16]. Among the variety of medical conditions, maternal health care seems particularly well suited for a medical savings scheme as expenses are mostly predictable both in their timing and amount. However, these mechanisms have yet to be systematically applied to maternal health care savings.

In Madagascar, a low-income country with a maternal mortality rate of 353 per 100,000 [17,18], financial obstacles are a major cause for a lack of access to basic health care during pregnancy, with 44% of pregnant women not seeking skilled birth attendance [19,20]. Although Madagascar implemented a user fee exemption policy for maternal health care services in 2008, out-of-pocket costs for routine drugs and laboratory tests or hospitalizations remain a major obstacle for seeking skilled care [21]. Experimental introduction of free-at-point-of-care services in rural southeastern Madagascar in 2014 increased the use of formal health care by 65%, with antenatal visits increased by 25% [22]. The following year, a government policy aiming to establish universal health insurance coverage created a *basket fund* pooling public, donor, and private contributions to remove user fees [23]. This has helped to reduce out-of-pocket spending on health care from 31% in 2013 to 22% in 2015 [24].

Nevertheless, many health care providers remain unable to meet their costs without charging user fees. Less than 6% of Madagascans have a formal bank account, and the risk of impoverishing health expenditures as a result of pregnancy is high [18,25]. However, in parallel, many countries in SSA have undergone rapid digitization. In Madagascar, the mobile phone

subscription rate increased 14-fold over the past decade, from less than 3 subscriptions per 100 people in 2005 to 42 subscriptions per 100 people in 2016 [8]. These figures suggest that mobile phones may be a promising tool to improve financial access to skilled health care delivery. However, little is known about current saving habits, use of mobile phones, and mobile payment systems among pregnant women in Antananarivo, particularly those from low-income households.

Objectives

This mixed-methods study is among the first to identify the major opportunities and challenges related to the implementation of a Malagasy Ariary denoted mobile phone–based payment and savings platform, the so-called Mobile Health Wallet (MHW), for maternal health care in low-resource settings. A 2-stage cluster sampling design was used to randomly select 412 pregnant women and new mothers among basic health center visitors in urban areas of Antananarivo, Madagascar. To confirm, explain, and complete the quantitative survey results, we used qualitative data from 6 semistructured focus group discussions (FGDs) in the same population (24 participants in total). We assessed the following characteristics: (1) perceived obstacles to skilled birth attendance, (2) saving methods and habits, (3) usage of mobile phones and mobile payment systems, (4) perception of the usefulness and acceptability of MHW for maternal health care, and finally (5) media access and consumption for program information purposes.

Methods

Study Design

We used quantitative population-representative survey data and qualitative FGDs in a sequential explanatory mixed-methods design [26,27]. The quantitative part was used to measure the prevalence of multiple characteristics relevant among pregnant women in Madagascar. The qualitative data contributed to a deeper understanding of the respective findings. Integration of both methods occurred during the sampling and analysis stage. Participants were sampled from the same study populations for both the survey and FGDs. The analysis was integrated by using similar thematic coding for major barriers and facilitators of the MHW. Results were then triangulated for each of the themes across data sources.

Study Setting

The study was conducted in Atsimondrano and Renivohitra, 2 out of 8 districts within the region of Analamanga, Madagascar. Both districts are mostly urban and include Antananarivo, the capital of Madagascar. These districts were chosen because of their high levels of mobile phone usage and good stability and coverage of mobile networks, allowing the implementation of an MM-based savings system.

Quantitative Methodology

A quantitative survey was developed for the Madagascan context to collect general information on structural and contextual elements of MHW for skilled health care during pregnancy. To quantify the need for MHW, we elicited information about household income, use of mobile phones and mobile payment services, and savings methods and mechanisms during pregnancy.

Sampling

We conducted a 2-stage cluster-random sampling of women utilizing routine antenatal care (ANC) or routine postnatal care (PNC) in the public-sector health facilities in the Malagasy districts of Atsimondrano and Renivohitra. In the first stage, we randomly sampled public-sector health facilities in these 2 districts. To be eligible to be included in our sampling frame, the facilities needed to be approved by the Ministry of Health. Out of 38 public-sector health facilities in the 2 districts, we randomly selected 14 with equal probability. We excluded 4 as they were characterized by at least one of the following 3 exclusion criteria: (1) they refused to participate in this study, (2) they did not perform ANC at a minimum quantity (defined as less than 10 ANC visits per week in 2016), or (3) they were not reachable within 2 hours from the city center of Antananarivo by public transportation. The last exclusion criterion was applied to allow easy access by data collectors for this and follow-up studies. From the remaining 10 public-sector health facilities, 8 were so-called CSBs (*French: Centres de Santé de Base* or basic government-run health care centers) and 2 were referral hospitals. Most of the randomly selected facilities provided elective maternal health care only on specific days of the week. In the second stage, we thus randomly sampled 2 facilities for each calendar day during the period from November 29, 2017 to January 22, 2018 out of the sampling frame of those randomly selected clinics that were open on that day. All women utilizing ANC or PNC on the selected clinic days were eligible to participate in the survey interview and were approached for consent to participate. Sampling occurred on 23 working days in total. For sample size determination, a number of 83,297 pregnant women at a given moment in the study area was calculated on the basis of 2017's population size of 1,851,024 for the districts Atsimondrano and Renivohitra and 4.5% of the women in the population were considered pregnant at a given moment as estimated by the Malagasy Ministry of Health (nonpublished data). Using the open source Web-based calculator OpenEpi Version 3 (Rollins School of Public Health, Emory University, USA), with a 95% CI and a 0.05 significance level, a sample size of 383 was deemed sufficient [28]. Out of a total of 416 eligible women, 412 gave consent and were included in the study. Participant recruitment was done by the data collectors while at a health facility.

Data Collection

A total of 3 experienced interviewers (2 women and 1 man), who were native speakers of Malagasy, were recruited from the Analamanga region as data collectors. Training included a 1-day standardized curriculum. Data collectors identified themselves to participants as independent researchers, who were not associated with the health care facility. Supervisors were present throughout the study period to ensure data quality and accuracy. Data collectors administered a paper-based questionnaire, which covered sociodemographic and economic characteristics, saving habits, mobile phone access, previous experience with mobile payment systems, and intended place to give birth, as well as multimedia consumption.

Data Analysis

We calculated descriptive statistics for the study sample including percentages, means, and 95% CI. The poverty status was estimated on the basis of the poverty line of US $1.90, referring to 2011 dollars, and taking into account US inflation (corresponding to US $2.03 in 2016). With a Purchasing Power Parity factor for Madagascar of 847.2 in 2016, the poverty line was calculated to be at 1719.8 Ariary (Ar) a day or 51,594 Ar a month [29]. Monthly revenue per household member was calculated by dividing the household's monthly income by the household size. Quantitative data were analyzed using Microsoft Excel version 15.32 (Microsoft Corporation, USA).

Qualitative Methodology

FGDs focused on assessing the motivation, expectations, and general attitude of a mobile phone–based savings and payment platform for skilled health care during pregnancy among clients.

Sampling

Criterion-based purposeful sampling was employed with the goal of obtaining information-rich data [30]. The criteria considered included women in reproductive age being pregnant at the time of sampling or having recently given birth, visiting a public health facility for ANC or postpartum care. As validity, meaningfulness and insights generated from qualitative inquiry have more to do with the information-richness of the cases selected and the observational capabilities of the researcher, sample size was determined on the basis of saturation of themes across FGDs [31]. We included 2 to 5 participants per group discussion. Women who took part in the questionnaire of the quantitative component of the study were excluded from participation in FGDs. If, upon consultation with local colleagues or upon piloting tools, we found that combining participants by a certain characteristic (economic status, age, etc) was impeding or undermining the quality of data collected, we altered the makeup of FGDs to be more sensitive to a particular dynamic.

Data Collection

Data collection occurred during the same time period as the quantitative survey (between November 29, 2017 and January 22, 2018). FDGs were led by a trained and experienced interviewer from the study team and were audio-recorded for analysis. FGDs were conducted in Malagasy, transcribed verbatim, and translated into English by 2 bilingual speakers. The qualitative instrument contained 15 open-ended questions relating to barriers to skilled care, attitudes, and habits toward health care savings and motivation, expectations, and general attitude toward the MHW for health care during pregnancy. All data collection activities took place at the health care facility in a separate room, ensuring confidentiality during the interview and discussions.

Data Analysis

Moreover, 2 of the authors conducted content analysis. A deductive approach was used to identify common themes, which were hand-coded and analyzed by the authors NM and ER. Each interview transcript was coded, and codes were grouped into categories on the basis of commonalities and patterns. Themes arising from the qualitative component were matched unto themes employed by the questionnaire survey such as finance-related issues during pregnancy, barriers toward saving, and potential benefits seen for the application of MHW [32].

Ethics Approval and Consent to Participate

Ethical clearance for the study was obtained from the Heidelberg University Hospital Ethics Committee (No. S-703/2017) and the study was approved by the Madagascan Ministry of Health. Written informed consent was obtained from all study participants before enrollment and participants were informed that participation would not affect their access to health care or the quality of care they receive. All participants were explicitly given the right to refuse participation.

Results

Quantitative Results

A total of 412 participants were included in the study. Table 1 shows the selected characteristics of study participants. The mean age of participants in the quantitative section was 25 years (range: 15-45 years). A total of 63.3% (261/412, 95% CI 58.6-68.0) of participants had at least attended the first year of secondary school and 94.1% (386/410, 95% CI 91.8-96.4) were literate. At the time of the survey, 77.9% (321/412, 95% CI 73.9-81.9) and 22.1% (91/412, 95% CI 18.1-26.1) of women attended ANC or PNC, respectively. Moreover, 70.9% (292/412) of participants answered questions regarding both average household income and household size, allowing their poverty status to be calculated with regard to the extreme poverty line of US $1.90 per person per day (2011 value, adjusted for purchasing power parity, 1719.8 Ar per day, 2016 value). Among those participants with data on poverty status, 56.0% (164/292, 95% CI 50.8-61.2) lived in extreme poverty. A total of 89.2% (260/292, 95% CI 86.0-92.4) of households had an income of less than 400,000 Ar per month (equivalent to US $126). Despite the overall low-income level, 58.7% (203/346, 95% CI 53.5-63.9) of participants owned a television (TV), whereas 76.1% (265/348, 95% CI 71.6-80.6) of the households did not own a vehicle (ie, bicycle, moped, car or any other wheel drive). The majority of the participants' households (289/405, 71.4%, 95% CI 67.0-75.8) had access to a source of electricity, that is, municipal electricity supply, solar or generator.

Table 1. Selected characteristics of study participants in the quantitative component.

Sociodemographic characteristics	Statistics, n (%)
Age group in years (N=411)	
15-18	61 (14.8)
19-21	84 (20.4)
22-25	108 (26.3)
26-30	82 (20.0)
31-35	39 (9.5)
>35	37 (9.0)
Marital status (N=412)	
Single	22 (5.3)
Married	269 (65.3)
Partnership	121 (29.4)
Widowed	0 (0)
Divorced	0 (0)
Number of children (N=412)	
0	152 (36.9)
1	130 (31.6)
2	76 (18.4)
3	30 (7.3)
4	11 (2.7)
>4	13 (3.2)
Highest school attended (N=412)	
None	8 (1.9)
Primary	143 (34.7)
Secondary	166 (40.3)
Bac[a]	53 (12.9)
Higher	42 (10.2)
Occupation (N=406)	
None	173 (42.6)
Merchant	102 (25.1)
Farmer	43 (10.6)
Teacher	10 (2.5)
Other	78 (19.2)
Income and wealth assets	
Monthly household revenue band (N=351)	
<50,000 Ar[b]	44 (12.5)
50,000-100,000 Ar	53 (15.1)
100,000-200,000 Ar	137 (39.0)
200,000-400,000 Ar	79 (22.5)
>400,000 Ar	38 (10.8)
Vehicle ownership (N=348)	
None	265 (76.1)

Sociodemographic characteristics	Statistics, n (%)
Bicycle	33 (9.5)
Moped	30 (8.6)
Moped and bicycle	3 (0.9)
Car	10 (2.9)
Car and other vehicle	7 (2.0)
Television ownership (N=346)	
Yes	203 (58.7)
No	143 (41.3)
Electricity at household (N=405)	
Yes	289 (71.4)
No	116 (28.6)
Mobile phone access and experience with Mobile Money	
Mobile phone ownership (N=412)	
Personal phone	209 (50.7)
Not personal, but family phone	122 (29.6)
No personal or family phone	81 (19.7)
Knowledge about MM[c] (N=412)	
Never heard about MM	39 (9.5)
Knowing about MM without having used it	226 (54.9)
Having ever used MM	147 (35.7)

[a]Bac: Baccalauréat (A-level, European Qualifications Framework Level 4).

[b]Ar: Ariary.

[c]MM: Mobile Money.

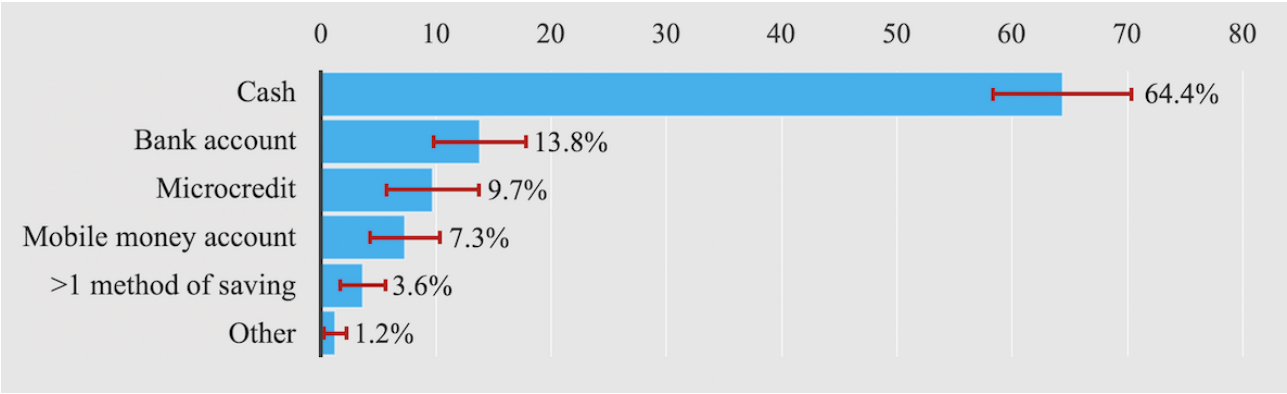
Use of Mobile Phones and Mobile Payment Services

A total of 80.3% (331/412, 95% CI 76.5-84.1) of participants made regular use of a mobile phone (50.7% and 29.6% owned or had access to a mobile phone within the immediate family, respectively). Out of 4 mobile phone providers active in Madagascar, 96.3% (319/331, 95% CI 94.3-98.3) of women with phone access were registered with either one or both of the 2 most popular operators and 18.7% (62/331, 95% CI 14.5-22.9) of these were registered with more than one provider at the time of the survey. Almost all respondents had heard about mobile payment services (90.5%, 373/412, 95% CI 87.7-93.3). However, only 35.7% (147/412, 95% CI 31.1-40.3) of these women had ever used it before. Of those, 67.4% (93/138, 95% CI 59.5-75.3) reported to use MM services solely for receiving funds from or sending funds to relatives and friends or for making cash withdrawals at registered agents. Surprisingly, 26.1% (36/138, 95% CI 18.7-33.4) used the technology additionally or solely for saving, whereas at the time of the survey, none of the phone operators offered a dedicated mobile savings account. Payment of bills and services using MM was uncommon (3.6%, 5/138, of MM users). One quarter of MM users reported ever having sent money to relatives for health care and only 1.4% (2/139) had ever used MM to pay for drugs or services at a health care facility. A total of 3 quarter of the users (75.0%, 99/132, 95% CI 67.6-82.4) reported to use MM technology between 1 and 4 times per month.

Savings Habits and Mechanisms

Despite a low average household income, when asked if they put money aside in the form of savings, 59.3% (243/410, 95% CI 54.5-64.1) said yes, whereas 40.7% said they did not. The most prevalent method was household cash savings (64.4%, 159/247, 95% CI 58.6-70.2; Figure 1). Of those saving money, 55.4% did so on a regular basis, whereas 44.6% only saved on special occasions. 69.5% (171/249, 95% CI 63.7-75.3) of participants saved for delivery or newborn care. Only 34.4% (85/247, 95% CI 28.5-40.3) of participants who did save used formalized savings mechanisms such as a bank or MM account or used a microcredit scheme especially for saving.

Figure 1. Saving methods among pregnant women and new mothers in Antananarivo (Atsimondrano and Renivohitra districts), Madagascar. N=247. Error bars represent 95% CIs.



Intended Place of Delivery

A total of 33.8% (132/391, 95% CI 29.1-38.5) of pregnant women stated the intention to deliver in a basic health care facility, whereas 52.2% (204/391, 95% CI 47.2-57.2) stated an intention to deliver in a community hospital. Only 5.1% (20/391, 95% CI 2.9-7.3) of women planned to deliver at home. Overall, 5.6% (22/391, 95% CI 3.3-7.9) of respondents mentioned the intention to deliver in a private hospital.

Media Access and Consumption Habits

A total of 67.4% (277/411, 95% CI 62.9-71.9) and 55.5% (228/411, 95% CI 50.7-60.3) of the participants reported having regular (at least once a week) access to radio and TV, respectively (Figure 2). They cited 34 radio stations and 12 TV channels that they listened to or watched, with the most popular radio station (Radio Record) and TV channel (TV plus) being cited by 18.3% (50/274, 95% CI 14.1-22.5) and 25.9% (59/228, 95% CI 20.7-31.1) of the women, respectively. Reported times of radio listening were spread across the day, whereas TV watching mainly took place during the evening hours from 5 pm to 8 pm (Figure 3). Only 20.6% (84/408, 95% CI 16.7-24.5) of the respondents were connected to the social media platform Facebook and most of the users (82.1%, 69/84, 95% CI 73.9-90.3) consulted the platform on a mobile device.

Figure 2. Media consumption among pregnant women and new mothers in Antananarivo (Atsimondrano and Renivohitra districts), Madagascar. TV: N=228. Radio: N=277. Error bars represent 95% CIs.

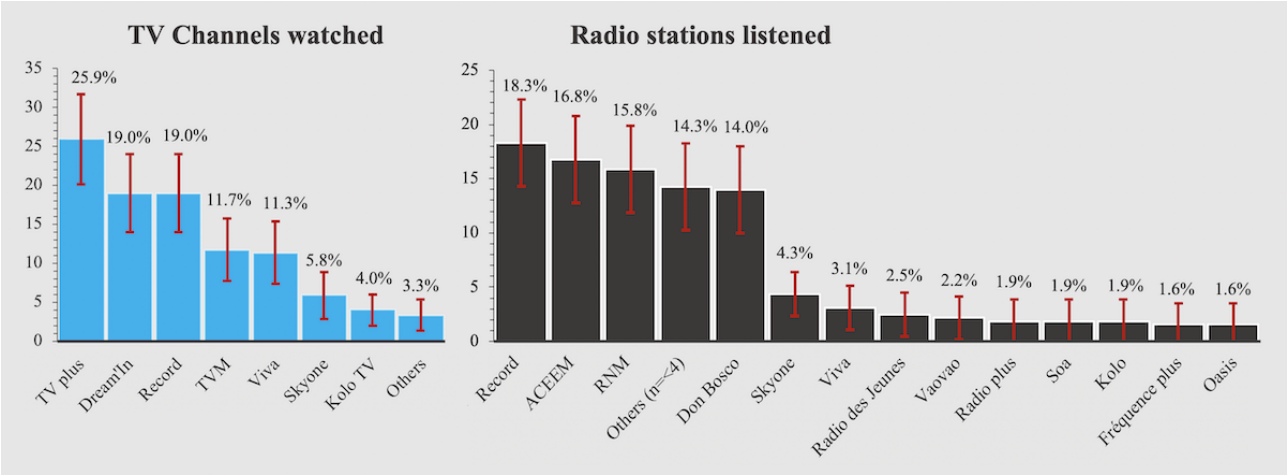
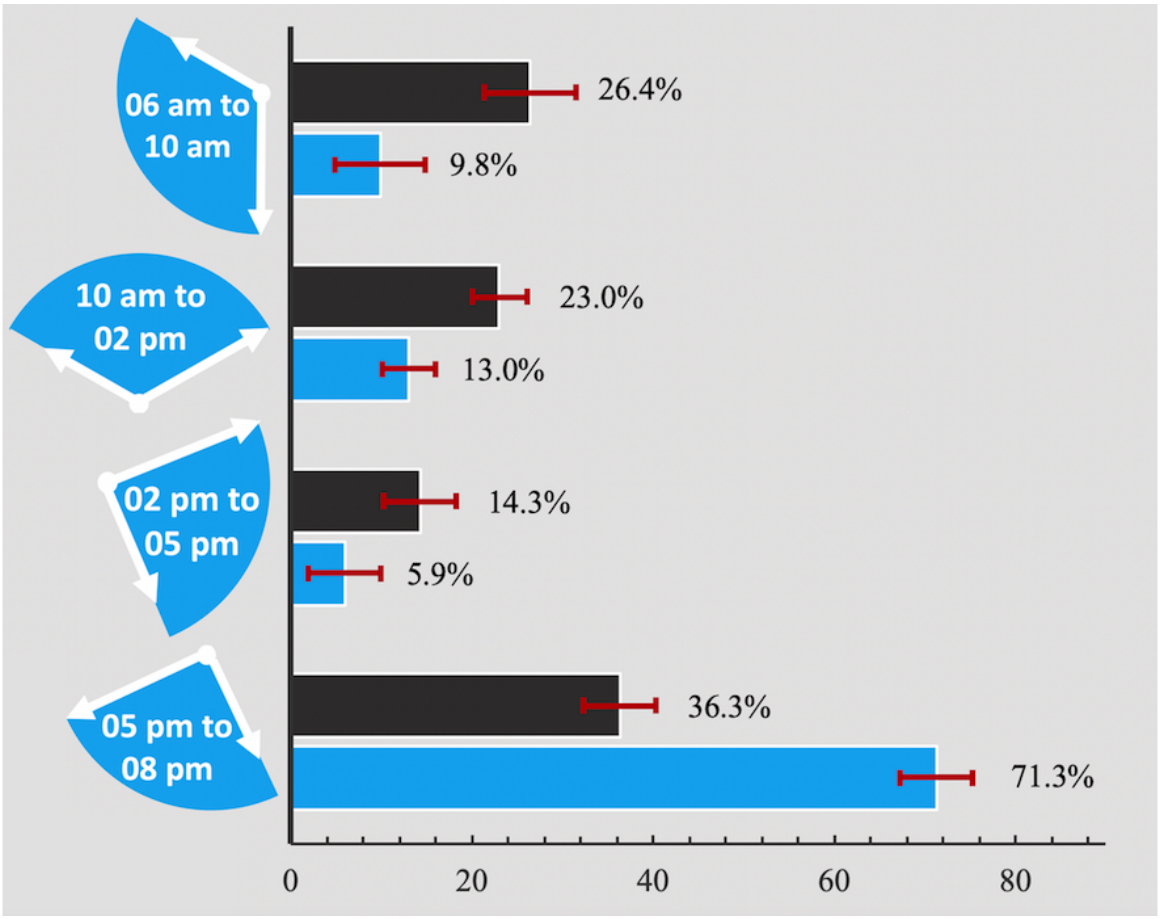


Figure 3. Day time of media consumption among pregnant women and new mothers in Antananarivo (Atsimondrano and Renivohitra districts), Madagascar. TV: N=228 (blue). Radio: N=277 (black). Error bars represent 95% CIs.



Qualitative Results

Barriers to Utilizing Skilled Care

A total of 24 participants attended 6 sessions of FGDs. The average age of the participating women was 23.3 years (range: 14-39). FGDs revealed that major barriers to skilled care included inadequate information (particularly on the medical necessity, health benefits, availability, and costs of maternal health care services), financial obstacles, and cultural aspects. Some respondents explained that even minor expenses (ie, for iron and folic acid supplements) prohibited pregnant women from seeking institutional care. Several of the respondents stated that fear of unexpected and expensive hospitalization in case of complications detected during a routine ANC visit made them hesitate to seek skilled care. One pregnant woman stated her thoughts:

> *I am wondering if It will be a normal birth or if it will require surgery. I see the other [women] and I become anxious: When the delivery is normal, we don't have any problem and can pay for it. But if it happens to be a complicated delivery, we need an operation and spend a lot of money.* [Pregnant woman]

Another aspect contributing to financial obstacles for seeking skilled care was nonconsistent prices at the provider level. Participants stated that prices for drugs and services vary over time and among individual patients (including among patients treated at the same public-sector health facility), thereby adding to the unpredictability of costs. Time constraints caused by the necessity to generate income to cover daily costs of living were cited as an obstacle for women who did not have a regular job, as explained by the following respondent:

> *They [unemployed women] are busy searching for income. Instead of coming for an antenatal care visit they have to work. They don't have time to spend here [at the health center].* [Young mother]

Overall, it was agreed that costs for home deliveries without qualified birth attendance or traditional birth attendance were more predictable and generally cheaper than facility-based births and were the preferred alternative for delivery if savings appeared to be insufficient. Cultural aspects including low prioritization of maternal health care and general skepticism toward skilled care were further commonly cited obstacles:

> *I am afraid of going to hospital because you have mainly students there and you are used for their op [surgical] training, so people are really afraid and don't go there anymore. They are all trainees and that is scary. And even for small problems – for instance you [the birth process] take longer, they are not patient to wait and send you directly to the operating room.* [Pregnant woman]

Savings Habits and Mechanisms

Respondents mostly saved on a weekly or monthly basis by putting aside a part of their cash earnings in a savings box at

home. However, participants acknowledged that expenses such as school fees, funeral costs, or other substantial unforeseen financial crises within the family frequently endangered their health care savings:

> *When I will be in the 8th month of my pregnancy, I will begin to buy baby clothing. I don't save but hope - I really pray for it - that the baby will come at the time my husband will receive his salary. We do not have the possibility to save. But when I save and there is nothing else left, I break the savings box...I really pray that I will deliver the baby around pay day.* [Pregnant woman]

A major motivation to use formalized savings mechanisms was to preclude savings from being used other than for the intended savings goal. However, the majority of FGD participants expressed only low levels of frustration when savings goals were not met. Some respondents stated that borrowing money for health care from a relative or friend was culturally accepted and common under such circumstances:

> *I bring my savings to the post office. Because if I keep it home, I will use it. When I don't have [money] I have no choice but using it. Now when the delivery date is approaching, I will take it in person because they [the financial institution] don't give it to someone else. Only to the owner.* [Pregnant woman]

Attitude and Expectations Toward a Mobile Phone–Based Health Care Savings Platform

FGD participants perceived the concept of MHW for maternal health care as generally beneficial. A particular value was seen in conditional funds that can only be spent on maternal health care. However, respondents emphasized that inaccurate or incomplete information about benefits or restrictions of the service could inhibit its acceptance and use by the target population. A comprehensive sensitization campaign was deemed crucial by respondents for a successful implementation of the service and should certainly include personal contact between program agents and users. Ease of use of MHW and personal customer support by a health worker or dedicated agent were mentioned by some respondents to be essential for acceptance by the population:

> *Once the money is in it [the platform] you are not allowed to take it. This point is what attracts me because the saving remains untouched, not like with savings box. That is the money dedicated to face delivery. Or to buy drugs.* [Pregnant woman]

Discussion

Principal Findings

This study revealed 3 salient findings. First, the target population in the peri-urban areas of Antananarivo is relatively privileged with regard to the Madagascan average, with relatively high rates of secondary school attendance and media access and almost universal literacy. Although more than half of the study group falls below the World Bank absolute poverty line of US $1.90 per day, this proportion is still well below the average for the entire country. Second, although the concept of MM was familiar to almost all respondents, and mobile phone access was widespread, only a minority were currently using the technology, predominantly for sending and receiving money between friends and relatives but less commonly as a savings tool. The use of MM to pay for health care services was infrequent. Third, in this study's FGDs, many participants raised the issue of financial limitations to accessing ANC and PNC resulting from OPP and opportunity costs. Participants reported difficulties in saving for health care and reported a variety of informal tools to help them save. Interest in a mobile phone–based savings and payment platform such as the MHW was raised by nearly all participants. To our knowledge, this study includes the first qualitative research analyzing general and financial barriers of access to skilled health care for pregnant women in the capital of Madagascar.

Our findings are generally consistent with data of the *Enquête Nationale sur le Suivi des indicateurs des Objectifs du Millénaire pour le Développement* (ENSOMD—national survey on the progress toward the Millennium Development Goals), conducted by the Madagascar National Institute of Statistics in 2012 to 2013. This report listed financial restrictions as a major obstacle toward health care for pregnant women in Antananarivo [20]. However, conversely, issues about fear of lack of drugs and absence of health care staff were not raised by the participants of our FGDs. This might reflect the urban and peri-urban setting of this study resulting in lower staff absenteeism (because of high visibility of the health centers) and better supply routes for drugs and materials. Another potential explanation could be the difference in location of interviews, whereas this study was conducted in public-sector health facilities, ENSOMD interviews were held in pregnant women's homes, potentially reducing barriers to reporting system deficiencies.

In addition to the ENSOMD survey, only 2 other studies have analyzed obstacles to health care access for pregnant women in Madagascar, though neither focused on financial birth preparedness. One study investigated the available sources of funds utilized to pay for obstetric emergency care in a hospital in Mahajanga, a town in northwestern Madagascar [5]. One in 6 households included in the study was able to pay the costs incurred during hospital admission from routine income or savings. Borrowing money from family and friends was needed in most cases to complete payments for maternal health care services. These findings are in line with our results, albeit for a different urban area of Madagascar. However, the study was limited in scope (including 103 mothers in a single hospital) and only focused on emergency obstetric and neonatal care in a referral hospital rather than focusing on financial preparation. The second study, conducted in Fort Dauphin, an urban center in the southeast part of the island [33], identified lack of knowledge (as observed in this study), risky practices, delay in seeking medical care, and family and community expectations as major obstacles. We suspect that these factors are rather specific to the region under study, which is known to be one of the poorest areas of the country and with high levels of influence exerted by traditional social norms [33,34]. A further obstacle—the distance of travelling to the next health care

facility—was not an important barrier among the population in this study, likely because Antananarivo is densely populated and the average distance to the nearest health care facility is relatively short [35].

The results show that despite national policies promising free ANC and delivery in Madagascar, in practice, the majority of obstacles to ante, perinatal, and postpartum health care access cited by the participants were of a financial nature [21]. High and highly variable financial contributions, that is, for complementary clinical diagnoses or the treatment of complications, represent a tremendous burden for poorer women and can create fear of engaging with formal health care. Not a single facility observed in this study had price information visibly displayed within the center. Indeed, among all our respondents from FGDs, a considerable lack of knowledge about prices for health care services was identified. Indeed, services that were free of charge were unknown, and prices for specific services were unclear. The women in this study feared pregnancy-related complications and the need for unexpected additional care because of the threat of impoverishment because of high health care expenditures.

Unpredictable pricing of health care services can have a number of different origins, including the following: discontinuous availability of drugs and consumables that are donated and thus free of charge at point of care, prices set by individual health care centers and outside of official regulations, as well as costs differing by the individual health worker providing care. In all these cases, the lack of transparency and absence of predictable and clearly communicated costs of pregnancy-related care are likely to discourage pregnant women from taking advantage of health care services and motivate them to search for alternative care outside of the formal sector. Transparency of prices was mentioned as a critical issue by respondents to plan for delivery, and it needs to be taken into consideration by policy makers or program managers considering the implementation of an MHW in Madagascar.

Rotating Savings and Credit Associations or community savings groups, known in Madagascar as “tontines” [36,37], were not cited by respondents, and they do not seem to play a major role for health care financing in the study setting. Similarly, the role of the Madagascan *Fonds d’Équité* (an “equity fund” established by the Ministry of Health to finance health expenditures for the poorest section of the population) was suggested to be modest. One reason may be reluctance to be stigmatized as in need of financial help, as to benefit from these funds, patients need to prove their neediness and register at the community level (Malagasy: Fokontany) [38]. Taken together, our findings underline the importance of identifying and implementing novel means of health care financing to eliminate or mitigate OPPs, facilitate financial birth-preparedness, and reduce the risk of health shocks. MHW may play an important role for inclusion in health care in LMICs [39].

Limitations

This study has several limitations. First, we recruited study participants in randomly selected public-sector health facilities, and the questionnaire and FGDs occurred in this setting. This means that all the participants were privileged by already having access to public health care. We decided for this method of sampling as it gave us the opportunity to include a representative number of pregnant women and young mothers and as this group of women will be included during a planned intervention study to examine the impact of an MHW on skilled birth attendance in Madagascar. Future research should include women without preexisting access and women who had decided not to engage with the public-sector health facilities, who are likely a poorer subpopulation. Second, this study focused on the urban and peri-urban areas of Antananarivo. This setting was chosen on the basis of key informant advice regarding better mobile phone network coverage and high levels of mobile phone usage in the area. Rapidly increasing mobile phone usage in other, including rural, areas of Madagascar may make the country-wide application of MM-based savings systems feasible in the near future. However, the chosen setting may have led to sampling bias. Inhabitants of the study area, for instance, were on average of higher socioeconomic status relative to the country average. Further research is needed to determine the acceptability of an MHW in rural and noncapital urban areas. Third, this study only evaluates perception of usefulness and practicability of the MHW by pregnant women. However, as widely described for several resource-low settings, successful implementation and sustainability is not only solely dependent on the acceptance by the target population but also by other stakeholders such as community heads, health care professionals, and health officials. Additional research on the acceptance of the tool by other health care stakeholders is therefore needed. Fourth, solutions for demand-side affordability alone will not be sufficient to deliver adequate antenatal and obstetric care. Concurrent improvements in health care infrastructure and staff skills will also be necessary. Finally, our results may not apply to other countries. Nevertheless, given the current gap in the literature, our results may be informative to researchers and policy makers in similar settings in SSA.

Conclusions

Financial obstacles are a major cause of limited access to skilled maternal health care in low-resource settings and especially in urban Madagascar. A mobile phone–based savings and payment platform for skilled health care during pregnancy was perceived as a useful tool to reduce financial barriers among women in the capital of Madagascar. Key factors that may contribute toward a successful implementation of MHW among this population include the following: (1) a high willingness to save, (2) broad mobile phone usage, (3) cultural acceptance of a mobile payment and savings tool, and (4) the perceived usefulness of the system by pregnant women. However, to enhance the access toward maternal health care by the tool, a number of financial obstacles need to be tackled. Out-of-pocket costs of basic treatment were high, and transparency about free services and prices was inadequate. A culturally sensitive communication and sensitization strategy and comprehensive technical support will be essential to fill the existing gap of knowledge and overcome cultural restrictions. Future research must determine whether and how a mobile phone–based payment platform can enhance access to improve maternal health care delivery and ultimately maternal health outcomes.

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Authors' Contributions

NM designed the study protocol, performed data collection and analysis, and wrote the manuscript. PMFE cross-checked the data analysis and critically revised the manuscript. ER was involved in data collection, transcription and translation of qualitative data, and analysis of qualitative data. JWDN and TB contributed to the study design and protocol and made critical revisions to the manuscript. JVE and SK revised the study protocol, were involved in data collection and analysis, and revised the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ANC: antenatal care
ENSOMD: Enquête Nationale sur le Suivi des indicateurs des Objectifs du Millénaire pour le Développement (national survey on monitoring the indicators of the Millennium Development Goals)
FGDs: focus group discussions
LMICs: low- and middle-income countries
MHW: Mobile Health Wallet
MM: Mobile Money
OPP: out-of-pocket payment
PNC: postnatal care
SSA: sub-Saharan Africa
TV: television

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Original Paper

Accuracy of Apple Watch Measurements for Heart Rate and Energy Expenditure in Patients With Cardiovascular Disease: Cross-Sectional Study

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Abstract

Background: Wrist-worn tracking devices such as the Apple Watch are becoming more integrated in health care. However, validation studies of these consumer devices remain scarce.

Objectives: This study aimed to assess if mobile health technology can be used for monitoring home-based exercise in future cardiac rehabilitation programs. The purpose was to determine the accuracy of the Apple Watch in measuring heart rate (HR) and estimating energy expenditure (EE) during a cardiopulmonary exercise test (CPET) in patients with cardiovascular disease.

Methods: Forty patients (mean age 61.9 [SD 15.2] yrs, 80% male) with cardiovascular disease (70% ischemic, 22.5% valvular, 7.5% other) completed a graded maximal CPET on a cycle ergometer while wearing an Apple Watch. A 12-lead electrocardiogram (ECG) was used to measure HR; indirect calorimetry was used for EE. HR was analyzed at three levels of intensity (seated rest, HR1; moderate intensity, HR2; maximal performance, HR3) for 30 seconds. The EE of the entire test was used. Bias or mean difference (MD), standard deviation of difference (SDD), limits of agreement (LoA), mean absolute error (MAE), mean absolute percentage error (MAPE), and intraclass correlation coefficients (ICCs) were calculated. Bland-Altman plots and scatterplots were constructed.

Results: SDD for HR1, HR2, and HR3 was 12.4, 16.2, and 12.0 bpm, respectively. Bias and LoA (lower, upper LoA) were 3.61 (–20.74, 27.96) for HR1, 0.91 (–30.82, 32.63) for HR2, and –1.82 (–25.27, 21.63) for HR3. MAE was 6.34 for HR1, 7.55 for HR2, and 6.90 for HR3. MAPE was 10.69% for HR1, 9.20% for HR2, and 6.33% for HR3. ICC was 0.729 (P<.001) for HR1, 0.828 (P<.001) for HR2, and 0.958 (P<.001) for HR3. Bland-Altman plots and scatterplots showed good correlation without systematic error when comparing Apple Watch with ECG measurements. SDD for EE was 17.5 kcal. Bias and LoA were 30.47 (–3.80, 64.74). MAE was 30.77; MAPE was 114.72%. ICC for EE was 0.797 (P<.001). The Bland-Altman plot and a scatterplot directly comparing Apple Watch and indirect calorimetry showed systematic bias with an overestimation of EE by the Apple Watch.

Conclusions: In patients with cardiovascular disease, the Apple Watch measures HR with clinically acceptable accuracy during exercise. If confirmed, it might be considered safe to incorporate the Apple Watch in HR-guided training programs in the setting of cardiac rehabilitation. At this moment, however, it is too early to recommend the Apple Watch for cardiac rehabilitation. Also, the Apple Watch systematically overestimates EE in this group of patients. Caution might therefore be warranted when using the Apple Watch for measuring EE.

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KEYWORDS

mobile health; heart rate; energy expenditure; validation; Apple Watch; wrist-worn devices; cardiovascular rehabilitation

Introduction

Mobile health has been growing tremendously in the last decade. Future perspectives are promising for further growth and integration of mobile technology in health care. One type of technology that is particularly interesting for mobile health is the wrist-worn device capable of monitoring a large variety of parameters including heart rate (HR), energy expenditure (EE), steps taken, distance traveled, and in the near future possibly even oxygen saturation, blood glucose, and cardiac arrhythmia [1-2]. Demand in patient population is also rising, with recent studies showing that up to one-third of patients with chronic heart disease use personal heart rate monitors and over two-thirds of patients who don't already use a heart monitor reporting that they appreciate heart monitoring as being important for home-based exercise [3].

Wrist-worn devices have the ability to monitor vital parameters and provide the user with an overview and feedback on the collected data. Validation studies comparing assessments by these devices to clinically approved measurements are often lacking. The Apple Watch uses photoplethysmography (PPG) with optical sensors at the wrist to measure HR. EE is calculated with algorithms that are not openly disclosed [4].

Validation studies have been done to evaluate the accuracy of HR, EE, and other measurements in healthy subjects for a variety of fitness trackers [4-16]. Boudreaux et al [6] tested eight devices for accuracy of HR and EE measurements on healthy subjects and found that HR accuracy from wearable devices differed at different exercise intensities with an increasing underestimation of HR at higher exercise intensities. It was also found that EE estimates were inaccurate. They conclude that wearable devices are not medical devices and users should be cautious when interpreting results of activity monitoring. Shcherbina et al [12] tested seven devices on healthy subjects and found that HR measurements were within acceptable error range (5%). However, none of the tested devices had EE estimates within an acceptable range.

Modern health care is shifting its focus to home-centered health care with the aid of mobile technology. This study aimed to assess if commercially available mobile health technology such as the Apple Watch could be used for monitoring home-based exercise in future cardiac rehabilitation programs. The purpose of this study was to evaluate the accuracy of the Apple Watch with regard to HR and EE measurements during exercise in patients with cardiovascular diseases.

Methods

Ethics

This study was conducted in accordance with the declaration of Helsinki and approved by the local institutional review board (registration number S58592). A written informed consent was obtained from every patient before inclusion in the study.

Patient Recruitment

Patients were recruited at the cardiovascular rehabilitation consultation of the University Hospitals Leuven (Leuven, Belgium). All patients scheduled for a cardiopulmonary exercise test (CPET) as part of their cardiovascular rehabilitation program were consecutively included; one patient was excluded due to inability to use the VO_2 mask due to recent laryngeal surgery. Patients were equipped with the Apple Watch during their CPET.

The participant number of 40 patients was determined based on the results of Wallen et al [4] considering a power of 0.5 and probability of type I error of 5%. This sample size is in line with comparable studies [4-7,10,12] of wrist-worn health-tracking devices where participant numbers ranged from 20 to 60 patients.

Device and Data Collection

The Apple Watch (Apple Inc) is a wrist-worn commercially available device that uses PPG for HR assessment. For this study, the Apple Watch Sport 42 mm (first generation) was used. The device was bought commercially and handled according to the manufacturer's instructions.

The device was attached to the patient's left wrist. Weight and height of the patient were recorded in the iPhone Health app before the test was started. On the Apple Watch Workout app, the option Indoor Cycling was chosen. On this app, the workout was started at the beginning of the resting phase of the CPET. Registrations were stopped at the same cutoff point as the stopping of the CPET because of patient exhaustion (cycling <60 rotations per minute).

Data were extracted using the iPhone Health app and the iPhone Health Export app. The Health app provided HR at 5 second intervals and EE at 2 to 3 second intervals. HR was converted to mean HR per 30 seconds; EE was analyzed as cumulative EE over the duration of the CPET test.

Other information collected included demographic data (gender, age, and anthropometrics: weight, height, body mass index [BMI]), peak oxygen uptake (peak VO_2), VO_2, and carbon dioxide (VCO_2). The heart rate reserve (HRR) of each patient was calculated as the difference between the maximum and minimum HR as measured by electrocardiogram (ECG).

Exercise Protocol

Patients performed a CPET test in normal conditions, having eaten and taken their routine medication, often including a beta-blocker. During this exercise test, participants wore the Apple Watch on their left wrist and wore a metabolic system (Jaeger Oxycon, Vyaire Medical Inc) for breath oxygen uptake and carbon dioxide output measurements and a 12-lead ECG (Cardiosoft, General Electric Company) for recording HR and heart rhythm. During the CPET, the ECG was constantly monitored by one of the researchers for cardiac arrhythmia. All

tests were performed in a laboratory setting at a controlled room temperature of 21°C to 23°C.

The CPET started with 1 minute of seated rest. The exercise then started at 20 watts and load was increased with 20 W/min [17]. This protocol was adjusted to a faster or slower increase in cycling resistance depending on physical fitness and based on previous CPET records.

Statistical Analysis

Descriptive data are reported as mean and standard deviation or as median and range. Gas analysis data from indirect calorimetry (VO_2 and VCO_2) served as criterion measurement for calculations of EE (kilocalories per minute). For conversion of VO_2 and VCO_2 to caloric expenditure (kcal), the Weir equation [18] was used: kcal/min = ([1.1xRQ]+3.9)xVO_2.

Twelve-lead ECG was used as criterion measurement for HR (beats per minute).

For analysis purposes, HR was analyzed for three 30 second intervals: one interval at the initial 30 second of the test (seated rest, HR1), one in the middle of the CPET time (moderate intensity based on test duration, HR2), and one interval prior to and including maximal performance level (HR3). EE was compared for each patient for the entire duration of the test.

Mean difference (MD) and standard deviation of the mean difference (SDD) were calculated. MDs were tested for normality using the Shapiro-Wilk test. Bland-Altman plots were constructed. Bias (MD) and limits of agreement (LoA, MD±1.96*SDD) were plotted on the Bland-Altman plots. Mean absolute error (MAE) and mean absolute percentage error (MAPE) were calculated for HR and EE. Intraclass correlation coefficient (ICC) estimates were calculated for each set of data based on an average measures, absolute agreement, 2-way mixed-effects model.

Visual examination of the Bland-Altman plots was used to rule out systematic error; bias and LoA were used to assess for clinical applicability. ICC was calculated to determine the correlation between Apple Watch measurements and gold standard measurements. Limits for ICC were used as suggested by Fokkema et al [10]: an ICC >0.90 was considered excellent, 0.75 to 0.90 was good, 0.60 to 0.75 was moderate, and <0.60 was low.

For all statistical tests, the alpha level adopted for significance (2-tailed) was set at $P<.05$. All statistical analyses were performed using SPSS Statistics version 25 (IBM Corp).

Results

Patient Characteristics and Exercise Capacity

A total of 40 patients (32 male, 8 female) were included in this study. All patients had established cardiovascular disease: ischemic heart disease (28/40), valvular heart disease (9/40), and other type of heart disease (3/40). Further patient characteristics are depicted in Table 1. All participants performed the exercise test until exhaustion. Numeric test results are summarized in Table 2.

Table 1. Patient characteristics.

Characteristics	Value
Age in years, mean (SD)	61.9 (15.2)
Male gender, n (%)	32 (80)
Weight (kg), mean (SD)	79.0 (16.2)
Height (cm), mean (SD)	171.1 (9.3)
Body mass index (kg/m^2), mean (SD)	27.0 (5.0)
Cardiac disease type, n (%)	
Ischemic heart disease	28 (70)
Valvular heart disease	9 (23)
Other	3 (8)
Cardiovascular risk factors, n (%)	
Family history of cardiovascular disease	20 (50)
Hypertension	18 (45)
Hypercholesterolemia	23 (58)
Hypertriglyceridemia	10 (25)
Overweight (body mass index ≥25)	27 (68)
Obesity (body mass index ≥30)	9 (23)
Diabetes mellitus (total)	8 (20)
Diabetes mellitus (type 1)	1 (3)
Diabetes mellitus (type 2)	7 (18)
Smoking (total)	27 (68)
Ex-smoker	26 (65)
Current smoker	1 (3)
Atrial fibrillation	5 (13)
CPET[a] parameters	
CPET time (sec), mean (SD)	512 (194)
VO_2 peak[b] (L/min), mean (SD)	1.72 (0.89)
VO_2 peak (mL/kg/min), mean (SD)	21.8 (11.6)
Heart rate reserve (bpm), mean (SD)	56 (29)

[a]CPET: cardiopulmonary exercise test.

[b]VO_2 peak: peak oxygen uptake.

Heart Rate

SDD for HR1, HR2, and HR3 was 12.4, 16.2, and 12.0, respectively. Bias (ie, mean difference) and LoA were 3.61 (–20.74, 27.96) for HR1, 0.91 (–30.82, 32.63) for HR2, and –1.82 (–25.27, 21.63) for HR3. MAE was 6.34 for HR1, 7.55 for HR2, and 6.90 for HR3. MAPE was 10.69% for HR1, 9.20% for HR2, and 6.33% for HR3. The ICC was 0.729 (P<.001) for HR1, 0.828 (P<.001) for HR2, and 0.958 (P<.001) for HR3. Following the previously mentioned limits, this can be interpreted as a moderate correlation for HR1, a good correlation for HR2, and an excellent correlation for HR3. Bland-Altman plots and scatterplots comparing Apple Watch and ECG registration are depicted in Figure 1.

The Bland-Altman plots are depicted in A, B, and C and compare mean values on the x-axis ([Apple Watch + gold standard]/2) with the difference of the values on the y-axis (Apple Watch – gold standard). Bias and limits of agreement are depicted as horizontal lines. The plots depicted in D, E, and F directly compare values measured by the Apple Watch (x-axis) versus ECG measurements (y-axis). All plots show a good correlation of measurements without a systematic error.

Table 2. Sample size, correlation, and agreement between Apple Watch and reference methods for heart rate at start (seated rest, HR1), middle (moderate intensity, HR2), and maximal performance level (HR3), and energy expenditure (n=40).

Characteristics	HR1[a] (bpm)	HR2[b] (bpm	HR3[c] (bpm)	Energy expenditure (kcal)
Gold standard measurement, mean (SD)	69.9 (14.5)	94.6 (20.6)	126.5 (30.9)	40.6 (32.4)
Gold standard measurement, standard error	2.30	3.26	4.88	6.49
SDD[d], mean (SD)	3.61 (12.4)	0.91 (16.2)	–1.82 (12.0)	30.47 (17.5)
Upper LoA[e]	27.96	32.63	21.63	64.74
Lower LoA	–20.74	–30.82	–25.27	–3.80
MAE[f]	6.34	7.55	6.90	30.77
MAPE[g] (%)	10.69	9.20	6.33	114.72
ICC[h] (*P* value)	0.729 (<.001)	0.828 (<.001)	0.958 (<.001)	0.797 (<.001)

[a]HR1: heart rate, seated rest.

[b]HR2: heart rate, moderate intensity.

[c]HR3: heart rate, maximal performance level.

[d]SDD: standard deviation of difference.

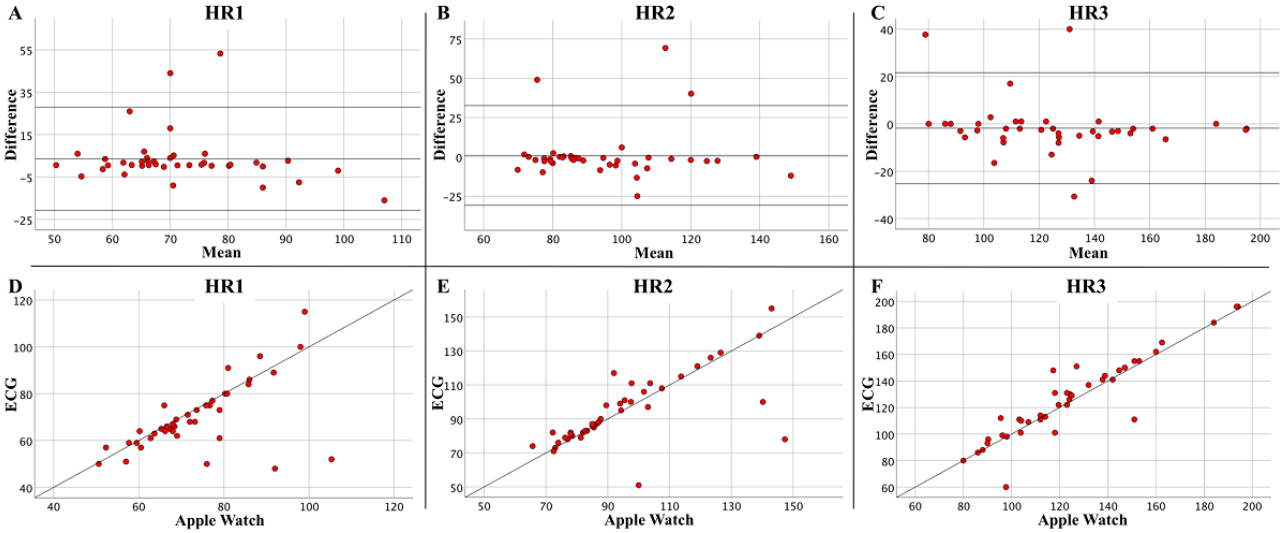
[e]LoA: limits of agreement.

[f]MAE: mean absolute error.

[g]MAPE: mean absolute percentage error.

[h]ICC: intraclass correlation coefficient.

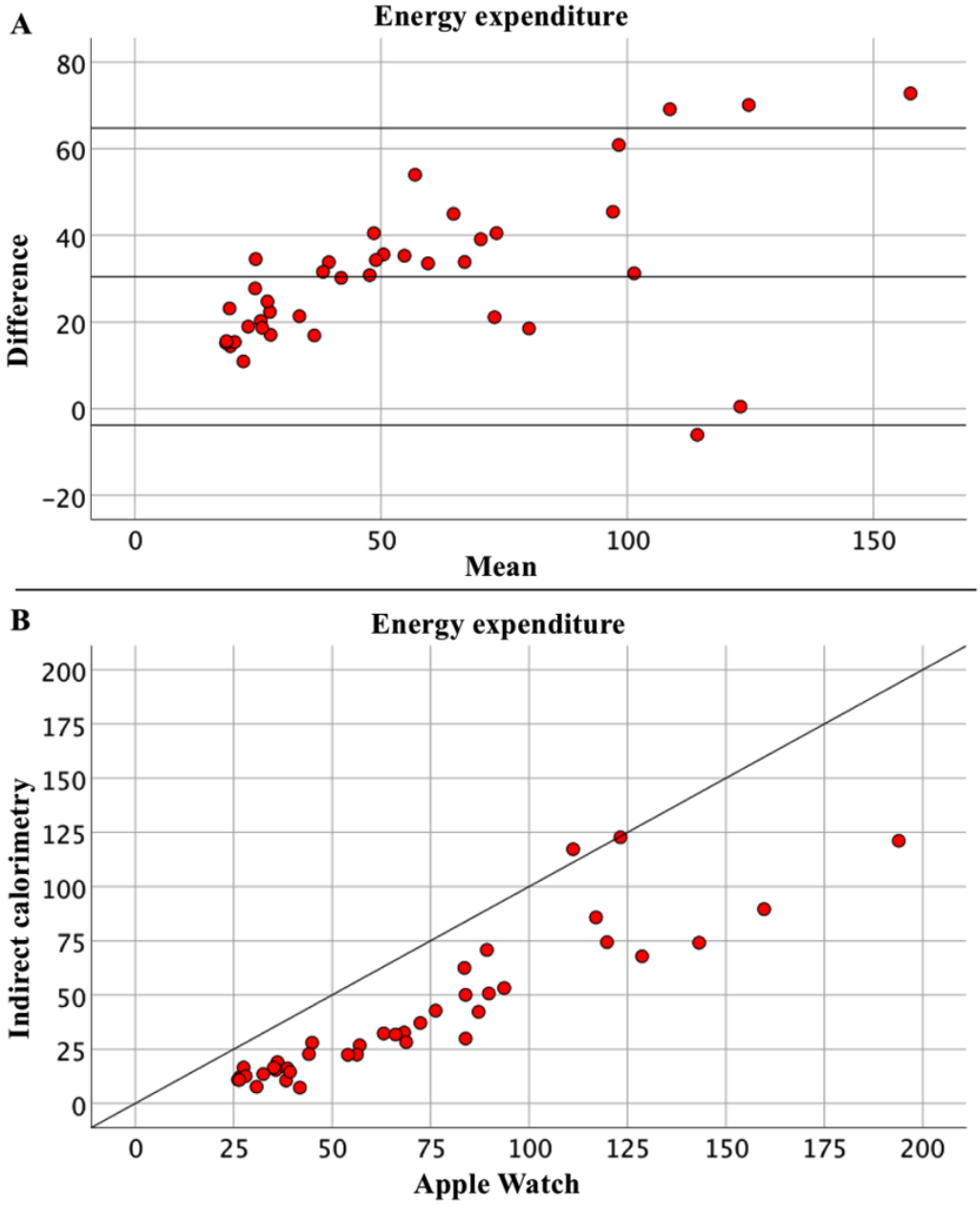
Figure 1. Heart rate (HR) measurements (bpm) by the Apple Watch are compared with gold standard electrocardiogram measurements for HRs at start (seated rest, HR1), middle (moderate intensity, HR2), and maximal performance level (HR3) of the cardiopulmonary exercise test.



Energy Expenditure

SDD for EE was 17.5. Bias and LoA were 30.47 (–3.80, 64.74). MAE was 30.77; MAPE was 114.72%. The ICC for EE was 0.797 (*P*<.001), which can be interpreted as a good correlation. Bland-Altman plot and a scatterplot directly comparing Apple Watch and indirect calorimetry are depicted in Figure 2. A systematic error is seen with an overestimation of EE by the Apple Watch.

Figure 2. Energy expenditure (EE) measurement (kcal) by the Apple Watch is compared with gold standard indirect calorimetry. The Bland-Altman plot compares mean values on the x-axis ((Apple Watch + gold standard)/2) with the difference of values on the y-axis (Apple Watch – gold standard) (A). Bias and limits of agreement are depicted as horizontal lines. The plot depicted in part B directly compares values measured by the Apple Watch (x-axis) versus indirect calorimetry measurements (y-axis). A systematic error is seen with an overestimation of EE by the Apple Watch.



Discussion

Principal Findings

For HR, accuracy, as evaluated by the SDD, was best at peak exercise intensity and lowest at moderate exercise intensity. ICC was highest at peak exercise intensity and lowest for resting HR. On the other hand, bias was largest for resting HR and smallest at moderate intensity. Bland-Altman plots and scatterplots show a good correlation of measurements without a systematic error. MAPE is highest at seated rest and lowest at maximal intensity. MAPE range is between 6.33% and 10.69%.

When relating these numbers to clinical practice and thus to actual HR measurement, the numbers for bias can be considered low (ie, no systematic error is made when measuring HR with the Apple Watch). The SDDs are within an acceptable range to be clinically relevant. MAPE values are considered low compared to EE values and compared to earlier studies.

Our results thus show good accuracy of HR measurements by the Apple Watch when compared to the gold standard ECG measurements when tested in patients with known heart disease.

For EE, SDD was 17.5, and bias was 30.47. The ICC is 0.797, which is considered good correlation. MAPE is 114.72%, which is high when compared to the MAPE range of HR measurements. The SDD is within an acceptable range for clinical practice. The bias, however, is quite large, meaning a

systematic error with an average of 30.47 kcal per CPET test is made when using the Apple Watch for measuring calories compared to indirect calorimetry.

This systematic error is also seen when analyzing the scatterplot directly comparing the Apple Watch with indirect calorimetry: measurements of indirect calorimetry correlate with higher values measured by the Apple Watch. On the Bland-Altman plot, values are situated around a positive bias of 30.47 with almost all values being in the positive range.

It can thus be concluded that during CPET the Apple Watch systematically measures a higher value for EE than indirect calorimetry when measured in patients with known heart disease.

Studies comparing wrist-worn devices and in particular the Apple Watch with gold standard methods have already shown a good accuracy of HR measurement and a generally poor accuracy of EE measurement [4-7,11-13]. Similar ranges for MAPE for HR and EE were found in earlier studies [5,9]. Accuracy of EE measurement was found to vary depending on type of exercise and exercise intensity with a lower device error for running versus walking but a higher device error at higher levels of intensity for both running and walking [12]. In other studies, it was already shown that in healthy subjects the Apple Watch overestimated EE during cycling and resistance exercise [6].

Multiple studies aimed to validate commercially available devices for clinical practice, and Shcherbina et al state that there is an ongoing need to do so [12]. To our knowledge, this is the first study that evaluates accuracy of HR and EE monitoring by a wrist-worn device such as the Apple Watch in patients with proven cardiovascular disease.

In our study, it was shown that in patients with cardiovascular disease, the Apple Watch measures HR during exercise with clinically acceptable accuracy: there was no systematic error and bias was small compared to ranges of HR recommended in rehabilitation programs. If further studies confirm these results, it might be considered safe to incorporate the Apple Watch in HR-guided training programs in the setting of cardiac rehabilitation. At this moment, however, data remains uncertain, and although the wearable can be used to track activities and motivate patients, it is too early to recommend the Apple Watch for clinical usage in a cardiac rehabilitation setting.

EE measurements were not accurate, with a tendency of the Apple Watch to systematically overestimate EE during CPET testing. Caution should therefore be taken when using the Apple Watch in rehabilitation programs in which caloric balance is important (eg, weight loss programs in the setting of cardiac rehabilitation).

Limitations

This study has limitations. HR was assessed in patients with known cardiac disease; this group was, however, a heterogeneous group with the majority of patients having ischemic or valvular heart disease. No subgroup with known arrhythmia was included. We therefore cannot state that accuracy of HR monitoring is good in all types of patients with known heart disease. Further studies are needed in patient groups with different types of cardiovascular disease to fully assess validity of the Apple Watch in these subgroups.

This study was nonrandomized. Due to the high proportion of included patients who suffered from ischemic heart disease, there is a male predominance of study participants (80%). Subgroup analysis showed no significant difference between male and female groups for mean difference. However, this analysis is prone to error due to small patient size. Shcherbina et al showed that the error rate for measurement in males was significantly higher than the error rate in females [12]. Further studies are needed to assess if there is indeed a difference in registration.

Further, exercise intensity was evaluated based on cycling resistance (test duration) only, by using a proportion of the maximally achieved resistance. Assessing ratings of perceived exertion would have added useful information.

EE was only assessed with data available through Apple general software. As mentioned in other studies [4], algorithms used to determine EE are not disclosed by the manufacturers. An independent study with transparent cooperation of manufacturers would be an interesting next step.

This study cannot distinguish between subgroups in which limitations inherent to PPG measurement are evident (eg, patients with darker skin tone, larger wrist circumference, higher BMI) [12]. During the CPET, the wrist was kept still while cycling, so no error should be expected from arm movement.

To increase comparability between standard measurements and Apple Watch measurements, it was decided to stop measurement at the exact moment the patient stopped the exercise. No measurements were thus performed in the resting phase after the CPET.

Conclusion

Our results show that in patients with cardiovascular disease, the Apple Watch measures HR with clinically acceptable accuracy for 30 second averages of indoor cycling with the wrist kept stable. If confirmed, it might be considered safe to incorporate the Apple Watch in HR-guided training programs in the setting of cardiac rehabilitation. At this moment, however, it is too early to recommend the Apple Watch for cardiac rehabilitation. Also, the Apple Watch systematically overestimates EE in this group. Caution should therefore be taken when using the Apple Watch for measuring EE.

Conflicts of Interest

None declared.

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Abbreviations

bpm: beats per minute
BMI: body mass index
CPET: cardiopulmonary exercise test
ECG: electrocardiogram
EE: energy expenditure
HR: heart rate
HRR: heart rate reserve

ICC: intraclass correlation coefficient
LoA: limits of agreement
MAE: mean absolute error
MAPE: mean absolute percentage error
MD: mean difference
PPG: photoplethysmography
SDD: standard deviation of difference
VCO_2: carbon dioxide
VO_2: oxygen uptake

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Original Paper

Development and Evaluation of a Mobile Decision Support System for Hypertension Management in the Primary Care Setting in Brazil: Mixed-Methods Field Study on Usability, Feasibility, and Utility

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Abstract

Background: Despite being an important cardiovascular risk factor, hypertension has low control levels worldwide. Computerized clinical decision support systems (CDSSs) might be effective in reducing blood pressure with a potential impact in reducing cardiovascular risk.

Objective: The goal of the research was to evaluate the feasibility, usability, and utility of a CDSS, TeleHAS (tele–*hipertensão arterial sistêmica*, or arterial hypertension system), in the care of patients with hypertension in the context of a primary care setting in a middle-income country.

Methods: The TeleHAS app consists of a platform integrating clinical and laboratory data on a particular patient, from which it performs cardiovascular risk calculation and provides evidence-based recommendations derived from Brazilian and international guidelines for the management of hypertension and cardiovascular risk. Ten family physicians from different primary care units in the city of Montes Claros, Brazil, were randomly selected to use the CDSS for the care of hypertensive patients for 6 months. After 3 and 6 months, the feasibility, usability, and utility of the CDSS in the routine care of the health team was evaluated through a standardized questionnaire and semistructured interviews.

Results: Throughout the study, clinicians registered 535 patients with hypertension, at an average of 1.24 consultations per patient. Women accounted for 80% (8/10) of participant doctors, median age was 31.5 years (interquartile range 27 to 59 years). As for feasibility, 100% of medical users claimed it was possible to use the app in the primary care setting, and for 80% (8/10) of them it was easy to incorporate its use into the daily routine and home visits. Nevertheless, 70% (7/10) of physicians claimed that the time taken to fill out the CDSS causes significant delays in service. Clinicians evaluated TeleHAS as good (8/10, 80% of users), with easy completion and friendly interface (10/10, 100%) and the potential to improve patients' treatment (10/10,

100%). A total of 90% (9/10) of physicians had access to new knowledge about cardiovascular risk and hypertension through the app recommendations and found it useful to promote prevention and optimize treatment.

Conclusions: In this study, a CDSS developed to assist the management of patients with hypertension was feasible in the context of a primary health care setting in a middle-income country, with good user satisfaction and the potential to improve adherence to evidence-based practices.

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KEYWORDS

telemedicine; clinical decision support system; cardiovascular disease; hypertension

Introduction

Hypertension is a major modifiable cardiovascular risk factor responsible for substantial morbidity and mortality worldwide. It causes around 9.4 million deaths every year [1]. According to the World Health Organization, the prevalence of this condition in adults older than 25 years is 29.2% in men and 24.8% in women [2], which results in a global prevalence of over 1 billion people. Despite this high prevalence, the blood pressure control levels are as low as 30% of treated patients worldwide [3].

In the last three decades, clinical practice guidelines addressing hypertension management invariably recommended that cardiovascular risk assessment must be a core feature of hypertension care [4-7]. Brazilian guidelines also recommend the systematic assessment of cardiovascular risk during hypertension management and the use of statins if needed [8]. Cardiovascular and cerebrovascular diseases are the leading causes of death in low- and middle-income countries (LMIC) [1], including Brazil [9], and are responsible for the increasing use of health system resources, quite often from preventable complications. Despite Brazilian Society of Cardiology recommendations on the use of multiple risk scores to assess cardiovascular risk and advocacy of the use of a global risk assessment based in the 10-year Framingham heart score risk [8,10], Brazilian physician adherence to its use is poor [11].

To face these challenges, the health systems in LMIC struggle to improve their quality and overcome underfunding and lack of resources [12]. In Brazil, a large country with a decentralized health system, primary care physicians have limited access to point-of-care information resources that could assist clinical decision making and improve quality of care. In this context, mobile health (mHealth) technologies might be used to ease the access of health programs to a large number of individuals at relatively low cost [13-16]. When integrated to clinical decision support systems (CDSSs), mHealth technologies might increase the accuracy of diagnosis and treatment [12]. However, most studies were performed in high-income countries, implying that mHealth is still at an early stage of development in low-income countries [13,14,17].

Most of the literature that evaluated CDSSs in the management of hypertension focused on outcomes, with mixed results [18-22]. Despite the recommendation of international and Brazilian medical societies, few CDSSs addressing hypertension included the assessment of cardiovascular risk and few studies in LMIC evaluated what characteristics were responsible for implementation failure or success or addressed feasibility and user satisfaction in the primary care setting [23,24]. No study evaluated the use of a CDSS in the care of patients in Brazil. Thus, we conducted this study to develop a CDSS that integrates cardiovascular risk assessment, monitoring of blood pressure, nonpharmacological measures, and guidance to drug prescription. We also aimed to test the feasibility of implementing it in Brazilian primary care units as well as to assess its usability and utility, identifying facilities and barriers to its use.

Methods

Design of the Study

This study was conducted in four steps, according to the Medical Research Council framework [25].

Identify Gaps in Usual Care Through Literature Review

We assessed epidemiological studies and systematic reviews on hypertension management as well as feasibility studies, randomized controlled trials, and systematic reviews on CDSSs to evaluate which gaps were already known. Additionally, the topic was discussed in meetings with Brazilian health system stakeholders and primary care physicians to identify other issues.

Identify Components of the Intervention Through Discussion With Experts

Meetings and internal workshops were conducted to discuss the topic with primary care physicians. Primary care physicians, internal medicine specialists, cardiologists, and endocrinologists discussed the gaps with experts in information technology to identify solutions and components of an intervention.

Clinical Decision Support System Development

The CDSS, named TeleHAS (tele–*hipertensão arterial sistêmica*, or arterial hypertension system), was developed based in clinical practice guideline recommendations. Brazilian and international guidelines assessing hypertension as a main subject or in the context of other comorbidities such as diabetes or chronic renal disease [4,5,26-31] were reviewed, and clinical rules for hypertension and cardiovascular risk management were derived and organized into a decision tree (Multimedia Appendix 1). In case of conflicting recommendations, the one with the best level of evidence, most compelling recommendation, or latest publication was chosen. When a guideline recommendation was not available or was considered outdated, rules based on best scientific evidence were used, including evidence-based summaries, synopses, or syntheses.

The decision tree was then organized as a CDSS on a modular basis and installed on a tablet using the Android 4.1 operating system.

The CDSS consists of a structured clinical evaluation assessing identification, medical history, physical examination, current medications, and laboratory and image test results (Textbox 1). Only the patient name and date of birth were considered mandatory fields. The interface was developed to be intuitive and self-explanatory. Data requested were manually entered and included variables of interest in the management of hypertensive patients: blood pressure, lipid profile, renal function tests, microalbuminuria or proteinuria, liver enzyme tests, and electrocardiogram, among others. Body mass index, estimated glomerular filtration rate using the Cockcroft-Gault formula [32], and cardiovascular risk based on the Framingham score [33] were calculated using the data entered and displayed immediately on screen. After data are entered, the CDSS presents suggestions and recommendations about pharmacologic and nonpharmacologic interventions including physical activity, diet recommendations, and medication dosages and interactions (Figures 1 and 2).

After patient registration, any subsequent consultation was recorded in the database in a file under the patient name. Data were recorded in TeleHAS and transmitted to a telehealth care central whenever internet connection was available. The CDSS was updated if problems were identified. A Web-based data panel was developed to help researchers access the database.

The CDSS was electronically tested to verify that recommendation results matched the prespecified decision tree. Manual insertion of data by a physician was later performed to verify the recommendation response suitability. After adjustments, TeleHAS was submitted for analysis to an expert panel comprising 2 cardiologists and 3 primary care physicians, known as technical reference, for a period of 7 days. Structured questionnaires and semistructured interviews were used to assess strengths, inconsistencies, and satisfaction with the device use. The participants were asked to classify their general impression of the CDSS as very appropriate, appropriate, indifferent, or inappropriate. It was then readjusted with the necessary changes according to the criticisms and suggestions from the expert panel.

Textbox 1. The five main menus of TeleHAS.

- Identification: patient name, date of birth, mother's name, and sex
- Comorbidities: may be used to select other diseases or risk factors presented by the patient
- Physical exam: blood pressure, waist circumference, weight, and height
- Laboratory studies: lipid profile, biochemical panel, echocardiography, and electrocardiography data
- Medications: several blood pressure medications categorized by class

Figure 1. TeleHAS open screen and main menu.

Figure 2. TeleHAS previous diseases and alerts menu.

Evaluate Feasibility Through Field Study

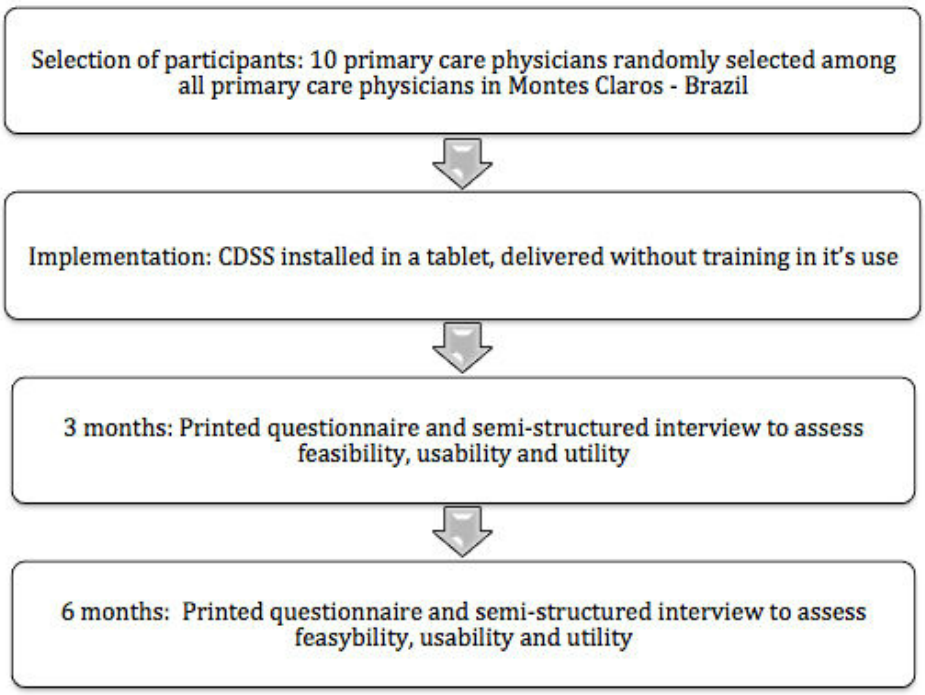
The field study was conducted in Montes Claros, the largest city in the north of the Minas Gerais state (population 361,000), 270 miles north of the state's capital. It has a human development index of 0.77 [34], slightly above the Brazilian average. The municipal primary care system is composed of 88 primary health centers in urban and rural areas with health teams composed by one physician and one nurse and a variable number of community health workers. Despite the existence of a university and two medical schools, clinicians have limited access to specialist referral and continuing education due to the distance to the country's main centers.

All 66 primary care physicians from Montes Claros were invited to attend a lecture on hypertension diagnosis and management. Of the 63 attendees, 51 agreed to join the study and 10 were randomly selected. The selected doctors used TeleHAS in routine care of hypertensive patients to build up their impressions about the CDSS for 6 months. Physicians planned and individualized the frequency of blood pressure measurements for each patient.

A nurse and an information technology technician held biweekly visits to address issues and resolve difficulties in the CDSS use and allow data transfer to the TeleHAS network server through a 3G connection available only on the nurse's tablet due to its high cost in Brazil.

Paper-based questionnaires evaluating feasibility, usability, and utility of the CDSS were developed and applied with semistructured interviews at the end of 3 and 6 months (Figure 3). Perceived feasibility, usability, and utility questions were rated on a Likert scale from 1 (strongly disagree) to 5 (strongly agree) [35]. The final score was defined as the mean of the scores for all of the questions.

Figure 3. Study design.



Data Analysis

Categorical variables were presented as frequencies and proportions. As the sample size of physicians was small, continuous variables were expressed as median and interquartile range. Data analyses were performed using SPSS Statistics for Windows version 21.0 (IBM Corp).

Ethics Statement

The study was approved by the ethics committee of the Universidade Federal de Minas Gerais, Minas Gerais, Brazil. Informed, written consent was obtained from all participants contributing data to the study.

Results

Expert Panel

All specialists considered the initial menu, identification, comorbidities, medicine, and complementary exam screens as adequate (Table 1). Doctors unanimously considered the TeleHAS interface, alert content, appearance, and speed of alert generation adequate. They generally reported that TeleHAS used the best available evidence and suggested changes based on literature or use of alternative guidelines when needed. The suggested changes were incorporated in the software.

Specialists perceived TeleHAS as an intervention that could change clinical practice.

> *The CDSS helps in the process of decision making for treatment of patients with hypertension, both in pharmacologic and nonpharmacologic therapy.* [Family physician]

> *I believe it can be very helpful to control high blood pressure.* [Cardiologist]

There was a unanimous impression that the device has the potential to deliver updated information to health care providers and education promotion is a major feature of its use. It was highlighted that the device has the potential to promote implementation of evidence-based recommendations.

> *Great potential to promote best scientific evidence implementation for the individual patient.* [Family physician]

When asked about the feasibility of TeleHAS in the clinical setting, all participants agreed it was feasible.

> *TeleHAS has the potential to improve clinical practice quality, and it's applicable to the routine of primary care services.* [Family physician]

One primary care physician considered the physical exam screen inadequate. He stated that he would like to enter data about other conditions not associated with hypertension or cardiovascular risk such as glycemic control and data from skin, respiratory, and abdomen semiology. He suggested that a free-text field could be added to address this demand.

Field Study

Participant characteristics are described in Table 2. Age varied from 27 to 59 years (median 31 years). The median length of professional experience in a primary care setting was 2.5 years (ranging from 0 to 20 years) and time working in the municipality was 1.5 years.

During the 6 months of field study, participant physicians registered 535 patients in the TeleHAS database and performed 632 consultations.

Feasibility, Usability, and Utility

Quantitative analysis of impressions for feasibility, usability, and utility is described in Tables 3-5.

Although doctors were motivated to use TeleHAS, finding the time to enter data was a major concern. Physicians believed it caused significant delay in the daily routine and developed alternative forms of use to deal with this challenge. Some used the CDSS in educational groups and on days specifically scheduled to attend patients with hypertension. Others used it daily when attending a patient with hypertension. Due to the scarce time available, some of them attended patients without the CDSS and filled it out later, saving remarks for the next appointment. In the case of one clinician, this choice was due to fear of patient opinion.

> *...I was concerned that they might find I was distracted or writing something else, like sending messages during the consultation.* [Clinician]

Work duplication was also identified as a problem, and clinicians demanded a printed handout to deliver to patients and attach to the patient record at the end of the consultation.

Table 1. Expert panel perception of TeleHAS for each screen (n=5).

Screen	Rating		
	Very adequate, n (%)	Adequate, n (%)	Inadequate, n (%)
Initial menu	3 (60)	2(40)	0 (0)
Identification	3 (60)	2 (40)	0 (0)
Comorbidities	1 (20)	4 (80)	0 (0)
Physical exam	0 (0)	4 (80)	1 (20)
Medicine	2 (40)	3 (60)	0 (0)
Complementary exams	1 (20)	4 (80)	0 (0)

Table 2. Characteristics of primary care physicians in the study (n=10).

Variable	Value, n (%)
Sex, female	8 (80)
Time since graduation (years)	
<5	7 (70)
5-10	1 (10)
>10	2 (20)
Specialty	
Angiology	1 (10)
Family medicine	2 (20)
Geriatrics	1 (10)
Occupational medicine	1 (10)
Pediatrics	1 (10)
None[a]	4 (40)
Self-reported knowledge of information technology	
Inadequate	2 (20)
Satisfactory	4 (40)
Good	3 (30)
Excellent	1 (10)
Use of any form of technology before TeleHAS, yes	9 (90)
Computer available in the workplace for routine use, yes	0 (0)
Internet access in the workplace, yes	5 (50)
Internet use frequency	
Daily	9 (90)
Monthly	1 (10)
Completed continuing education on management of hypertension or cardiovascular risk in the last year, yes	6 (60)
Major sources of continuing education	
Guidelines	3 (30)
Books	2 (20)
Articles	1 (10)
Congress	1 (10)

[a]Residency is not a prerequisite for doctors who work in primary care in Brazil.

Table 3. Feasibility score on a 5-point scale by item (n=10).

Item	Score mean
The CDSS[a] can be used in the primary care setting.	4.5
It can be used in home visits.	4.2
It is easy to incorporate in work routine.	4.0
Internet connection is not essential for the use of the CDSS.	3.6
The CDSS does not cause significant delays in daily routine.	3.0

[a]CDSS: clinical decision support system.

Table 4. Usability score on a 5-point scale by item (n=10).

Item	Score mean
My overall evaluation of the CDSS[a] is good.	4.5
The CDSS screens are easy to understand.	4.5
The definitions of comorbidities are clear and unambiguous.	4.1
The CDSS fields are easy to complete.	4.3
The CDSS is intuitive and requires no previous training to use.	3.4
The CDSS is stable, and no errors occur during use.	3.0

[a]CDSS: clinical decision support system.

Table 5. Utility score on a 5-point scale by item (n=10).

Item	Score mean
I believe that the CDSS[a] might improve the treatment of hypertensive patients.	4.5
Reading the recommendations of the CDSS, I had access to new information on hypertension and cardiovascular risk.	4.1
According to my previous knowledge, I believe the recommendations generated by the CDSS are appropriate.	4.1
The CDSS was useful to calculate the cardiovascular risk of hypertensive patients.	3.8
The CDSS was useful to promote cardiovascular disease prevention actions among my patients.	4.3
The CDSS helped me treat my patients.	4.6
I used the recommendations to modify the behavior of my patients.	4.0
I would recommend the CDSS to my colleagues.	4.7

[a]CDSS: clinical decision support system.

With regard to usability, during the interviews, all physicians classified the identification screen as practical and simple to use. Clinicians also reported the comorbidities screen as simple and intelligible.

Although TeleHAS was designed to be intuitive, some physicians believed training was essential for its proper use, even though clinicians did explore its features and learned the hidden tasks it was designed to do (eg, the majority found out that date of birth could be inserted by the keyboard or by a cursor displayed after continuously pressing the data field).

Most clinicians stated that other chronic conditions should be addressed in the CDSS and requested the option to enter glucose levels, diabetes mellitus complications such as diabetic foot, and other classes of medication for associated conditions such as methimazole, insulin, metformin, isosorbide and cilostazol.

Some clinicians observed errors during CDSS use. The most discussed one was that the software would sometimes stop working. This was due to a fault in the Android system that would stop functioning if the tablet enter key was pressed twice. No primary health care center had Wi-Fi connection available. System actualizations and data transfer to the TeleHAS database server occurred whenever Wi-Fi connection was available, at the physician's home or during the visit by the nurse and information technology technician. Eventually, due to the absence of 3G coverage or inadequate connection speed, the nurse needed to set up an appointment with the physician in the city to proceed with data transfer.

With regard to utility, physicians reported that TeleHAS eventually changed clinical practice. Some of them changed their blood pressure measurement techniques by reading the description available in the CDSS. Others started to measure blood pressure in 3 positions to complete all the fields available in TeleHAS.

For the physical exam screen, clinicians suggested a change in the sequence available in the CDSS, as they normally make the first measure with the patient seated.

> *Sometimes I entered the measure in the wrong field, because I start with the patient seated. Then I had to enter the measures again, after other measures.* [Family physician]

It was perceivable that clinicians worked with different levels of systematization. Only three of them calculated cardiovascular risk systematically using the 10-year global risk assessment score chart. Physicians perceived TeleHAS as helpful in promoting cardiovascular risk assessment and prevention actions.

Some clinicians perceived the CDSS fulfillment and recommendations delivered as repetitive.

> *After a while, you get tired of reading the same things. You don't have much time available [to deal with the repetitive content].* [Clinician]

However, some considered the repetition a CDSS strength.

> *Sometimes we remember to guide the patient only about medication, and we forget to talk about*

> *nonpharmacologic treatment. The alerts are repetitive, but it helps us to remember.* [Family physician]
>
> *I used to forget to ask about the salt in their diet. With the CDSS, I remembered to ask about it with every patient.* [Geriatrics]

The accuracy of the CDSS cardiovascular risk calculation was considered unsatisfactory by 30% (3/10) of participants. In the interviews, this issue was often discussed. The clinicians reported that the cardiovascular risk calculator sometimes presented spurious results and made them confused about the correct estimated risk. This error was found to occur when the date of birth was not entered or entered incorrectly.

Discussion

Principal Findings

This field study designed to evaluate the feasibility and usability of a CDSS to assist hypertension and cardiovascular risk management found that it is feasible to implement such technology in a primary care setting in a middle-income country with good satisfaction by health professionals. Equally important, the study elicited strengths and faults of the CDSS and helped identify facilities and barriers for TeleHAS implementation.

In Brazil, primary care physicians are commonly young and inexperienced doctors, frequently recently graduated [36,37], and in this study the majority of participants were women with less than 5 years of professional experience after graduation. Participant clinicians' profiles were variable regarding clinical experience and expertise, clinical specialty, intimacy with information technology, and forms of knowledge update. Primary care physicians often used the CDSS in their work routine and inserted a large amount of data in the TeleHAS database. They reported having learned new skills and knowledge through TeleHAS, felt comfortable using its guidance to change their practice and make clinical decisions, and rated the CDSS as having good usability and usefulness for knowledge dissemination, with potential influence for better hypertension management.

This feasibility study showed several barriers for the implementation of TeleHAS, including health professional issues, telecommunication structure, and health system infrastructure. Physician resistance to adopting information technologies is one of the main barriers for implementation, often due to poor satisfaction with physical characteristics of digital technologies, difficulties with their use, and low effectiveness of devices [38]. In our TeleHAS evaluation, clinicians reported good satisfaction with the CDSS, and it is presumable that this will facilitate its use in large scale. In this sample, the previous use of information technology was low. Clinicians did have some difficulties managing the software and tablet, and although it did not deeply affect the use of the CDSS, some physicians had the perception that training would be needed for TeleHAS use. More effort should be made to improve the CDSS to make it as intuitive as possible for better scalability.

With regard to the telecommunication structure, problems with internet connection, poor broadband coverage, and high cost of 3G limited data transfer to the TeleHAS database server. Problems in telecommunication structures that limit dissemination of mHealth services in LMIC are similar to those seen in LMIC medical care, like services limited in scope, unevenly distributed across geographic areas, and of variable quality when available [39]. This issue was mitigated because TeleHAS was designed to function without an internet connection, but it is still required for data transmission and system update. Support by government policies to improve the quality of telecommunication structure is important to avoid future greater limitations for TeleHAS use.

Barriers to CDSS use were also identified. Low computerization of the primary health centers was a major limitation for the CDSS implementation. There was a perceptible demand for communication technologies in primary health system and much of the demand presented by physicians was related to the need to register and organize patient records and clinical data. This is in agreement with CDSS usability tests performed previously. In a study to assess the usability of a CDSS for the management of diabetes, the absence of electronic medical records was also pointed out as a major barrier for system definitive implementation in primary care [40]. Combination of CDSS with electronic health records, communication technologies integration in the structure of health care, and progressive computerization of primary health centers should stimulate use of these technologies.

Another major barrier for TeleHAS use in primary care was health professionals' excessive workload. The work duplication generated by the need to register data in the tablet and in the patient records limited the use of the CDSS. In a meta-analysis of 311 unique studies on CDSSs, including 148 randomized controlled trials, several features have shown to be predictors of improved health care process measures, including integration with charting or order entry system with no need for additional clinician data entry [41]. Although TeleHAS was developed to be fully integrated into primary health care routine, its use as part of clinician workflow must improve to avoid work duplication. This was not possible at that time due to the fact that all primary care units, just like the majority of primary care units in Brazil, still use paper-based patient records. In the expert panel, a primary care physician suggested a free-text field to allow data entry of other conditions. As it was not our goal to substitute the paper-based patient records at that time, we opted not to make the change, but we included it in an updated version of TeleHAS. Despite the work duplication that we could not avoid, clinicians reported that it was possible to use the CDSS in their work routine and managed to find alternative ways to use it. A feasibility study of an mHealth app to assist nurses in the management of hypertension also found that professionals with heavy workloads felt the app demanded work duplication and was an extra burden in an already increasing workload [23]. Integration of the CDSS with the electronic health record in the primary care workflow may improve usability and reduce health professionals' workload issues, enhancing its impact in clinical practice.

Task shifting to other health professionals is proposed as a solution to improve quality of care in chronic diseases. CDSSs designed to integrate the work of health professionals have been developed and may be the way for TeleHAS to diminish data entry requirements by clinicians. In a study performed in India, physicians and community health workers used a CDSS designed to address hypertension and assess cardiovascular risk. It was observed that such technology might aid to standardize the care and empower other health workers to help in cardiovascular risk assessment and patient care [24]. Care in primary health centers is unequal, as clinicians work with different strategies and environments and have different levels of knowledge and clinical experience. Despite the cardiovascular risk calculation in TeleHAS having errors and confusing some of the clinicians, the majority found the CDSS useful to calculate and manage the patients' cardiovascular risk. This was probably because not all physicians performed systematic cardiovascular risk assessment before TeleHAS use, and this became part of their routine practice after they started using the CDSS. By asking for standardized data entry and providing repeated reminders about health care, mHealth technologies such as TeleHAS may help in health care standardization.

This study was designed to test and improve a CDSS and used qualitative assessments rather than clinical outcomes. However, its findings are very important, as usability testing is an essential step before software implementation in clinical practice or testing the impact in clinical outcomes. Poor usability may lead to various undesirable effects, ranging from user dissatisfaction and failed implementations to endangered patient safety [42]. This step was essential to test if TeleHAS was properly designed, assess its acceptance by the physicians, identify the necessity of improvements, and strengthen the CDSS for better adaptation to face the challenges for its implementation in clinical practice in order to obtain better results in blood pressure control and clinical outcomes. Data from individual patients were not addressed, so it is not possible to analyze the characteristics of the population in which the CDSS was applied or assess the impression of patients on the CDSS use by a clinician. The CDSS was improved, with optimization in the design of the screens and cardiovascular risk assessment and increased participation of health care practitioners other than doctors. The alerts were updated and information on diabetes control was added. Its impact on hypertension and diabetes control is being assessed in a large-scale study in 39 primary care units. Usability assessment will be performed with all health care practitioners in order to have a more representative sample of Brazilian primary care professionals.

Conclusions

In this study, a CDSS developed to assist in decision making in hypertension and cardiovascular risk assessment was feasible in the context of the primary care setting, with good user satisfaction and possible positive impact on the implementation of guidelines, recommendations, and best available evidence. The study provided the opportunity to strengthen TeleHAS to face the barriers identified in its implementation. The CDSS is currently being tested in a large-scale clinical study to access clinical end points and the possibility to scale up its use for the primary care setting within the country and in other LMIC.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Example of TeleHAS decision tree.

[PDF File (Adobe PDF File), 66KB - mhealth_v7i3e9869_app1.pdf]

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Abbreviations

CDSS: clinical decision support system
CNPq: Conselho Nacional de Desenvolvimento Científico e Tecnológico
FAPEMIG: Fundação de Amparo à Pesquisa de Minas Gerais
FINEP: Financiadora de Estudos e Projetos
LMIC: low- and middle-income countries
mHealth: mobile health
TeleHAS: tele–hipertensão arterial sistêmica (arterial hypertension system)

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Original Paper

Impact of Use Frequency of a Mobile Diabetes Management App on Blood Glucose Control: Evaluation Study

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Abstract

Background: Technology has long been used to carry out self-management as well as to improve adherence to treatment in people with diabetes. However, most technology-based apps do not meet the basic requirements for engaging patients.

Objective: This study aimed to evaluate the effect of use frequency of a diabetes management app on glycemic control.

Methods: Overall, 2 analyses were performed. The first consisted of an examination of the reduction of blood glucose (BG) mean, using a randomly selected group of 211 users of the SocialDiabetes app (SDA). BG levels at baseline, month 3, and month 6 were calculated using the intercept of a regression model based on data from months 1, 4, and 7, respectively. In the second analysis, the impact of low and high BG risk was examined. A total of 2692 users logging SDA ≥5 days/month for ≥6 months were analyzed. The highest quartile regarding low blood glucose index (LBGI) and high blood glucose index (HBGI) at baseline (t1) was selected (n=74 for group A; n=440 for group B). Changes in HBGI and LBGI at month 6 (t2) were analyzed.

Results: For analysis 1, baseline BG results for type 1 diabetes mellitus (T1DM) groups A and B were 213.61 (SD 31.57) mg/dL and 206.43 (SD 18.65) mg/dL, respectively, which decreased at month 6 to 175.15 (SD 37.88) mg/dL and 180.6 (SD 40.47) mg/dL, respectively. For type 2 diabetes mellitus (T2DM), baseline BG was 218.77 (SD 40.18) mg/dL and 232.55 (SD 46.78) mg/dL, respectively, which decreased at month 6 to 160.51 (SD 39.32) mg/dL and 173.14 (SD 52.81) mg/dL for groups A and B, respectively. This represents a reduction of estimated A_{1c} (eA_{1c}) of approximately 1.3% (P<.001) and 0.9% (P=.001) for T1DM groups A and B, respectively, and 2% (P<.001) for both A and B T2DM groups, respectively. For analysis 2, T1DM baseline LBGI values for groups A and B were 5.2 (SD 3.9) and 4.4 (SD 2.3), respectively, which decreased at t2 to 3.4 (SD 3.3) and 3.4 (SD 1.9), respectively; this was a reduction of 34.6% (P=.005) and 22.7% (P=.02), respectively. Baseline HBGI values for groups A and B were 12.6 (SD 4.3) and 10.6 (SD 4.03), respectively, which decreased at t2 to 9.0 (SD 6.5) and 8.6 (SD 4.7), respectively; this was a reduction of 30% (P=.001) and 22% (P=.003), respectively.

Conclusions: A significant reduction in BG was found in all groups, independent of the use frequency of the app. Better outcomes were found for T2DM patients. A significant reduction in LBGI and HBGI was found in all groups, regardless of the use frequency of the app. LBGI and HBGI indices of both groups tend to have similar values after 6 months of app use.

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KEYWORDS

diabetes mellitus; mHealth; self-management; blood glucose self-monitoring; evaluation studies

Introduction

Background

Diabetes mellitus (DM) is a chronic disease with a major impact on morbidity and mortality as well as socioeconomics [1]. This impact is because of its high prevalence and incidence as well as the associated acute and chronic complications, which are caused by poor glucose control [1]. Therefore, self-management of blood glucose (BG) is the standard of care for people with diabetes [2]. On the basis of previous studies, it has been found that for those with type 2 diabetes (T2DM) BG can be maintained through physical activity, healthy diet, and weight loss [3-5]. For people with type 1 diabetes (T1DM), it is more difficult to control through diet and exercise. Despite this, current studies suggest that those with T1DM and T2DM do not adhere to these recommendations [4,6]. Mobile health (mHealth) apps could be a solution to promote adherence to physical activity and weight reduction regimens. However, current apps require intensive one-on-one or group lifestyle coaching [7].

Technology has long been used in self-management and to improve treatment adherence in people with diabetes [8-10]. Systems based on telephone coaching, short message service support, or telemedicine have proven effective in increasing management adherence and, consequently, improving glycemic control [9,10]. Currently, the global implementation of mobile phones has fostered the development of apps for diabetes management, which have become primary tools for decision support and disease management for both people with diabetes and health care providers [11]. However, some of these apps have not been proven to work in real life, and some studies have observed that they generally do not meet the basic requirements for engaging the patient [12-14].

Retrospective studies of diabetes management apps have recently been reported, which have demonstrated a reduction in mean glucose [15-18], glycated hemoglobin (HbA_{1c}) levels, and the risk of hypoglycemia for patients who used an app frequently [18-20]. However, many of these studies have focused on the improvement of BG control for adherent patients rather than on the level of adherence needed to obtain this impact on glycemic control [21,22]. For this reason, other recent reviews have demonstrated that very few of these apps use this information to provide users with personalized feedback, education, or motivation [23,24].

Thus, starting from the premise that an app that promotes patient education toward their disease and assists in increasing the efficacy of their treatment and self-regulation is needed, we have performed an analysis on a current mHealth app to devise a methodology to make apps more effective for this purpose. The primary objective of this study was to evaluate the effect of the use frequency of a diabetes management app on glycemic control in participants with DM. The results presented in this paper correspond to 2 retrospective analyses. The first analysis consisted of examining the effect of the use frequency of a diabetes management app on the reduction of estimated HbA_{1c} levels. The goal of the second study was to examine the app's impact on the low blood glucose index (LBGI) and high blood glucose index (HBGI).

SocialDiabetes System

SocialDiabetes is an independent digital health care platform for diabetes management, created by people with diabetes to transform the everyday life of patients by unlocking the potential of data-driven innovation and community development. The platform is complete with a mobile app and a desktop solution that empowers diabetes patients to actively engage in their own care. A global vision of the platform and its characteristics are shown in Figure 1.

Using the SocialDiabetes app (SDA), patients can sync their BG data from their meter to their phone and add any other relevant information in real time (ie, exercise, food, and lifestyle). Professional practitioner care teams employed by the app are connected to the patients through the SDA care Web platform and can remotely monitor and track their progress. Data are accessible to both patients and health care providers. In the near future, SDA will incorporate a community platform. Its intention is to bring the possibility of facilitating communication not only between the patient and physician but also between all patients with diabetes with similar characteristics. In this manner, each patient will be able to explain their experience to others.

Some basic tools such as remote monitoring of patients, HbA_{1c} estimation, carbohydrates calculators, alerts, and reminders characterize the platform. As they encourage patient personalization, the app also provides personalized insulin dose recommendations, connection with health care professionals, meal planning, exercise coaching and charts, and insights about the parameters and statistics of every patient.

The objective of this study was to demonstrate by means of 2 analyses on 2 independent indicators of glycemic control that the impact of a diabetes management app on glycemic control is more related to its monthly users' usage in a consistent manner rather than daily, weekly or monthly high-frequency use. When we talk about consistency, we are referring to a habit that is followed on a regular basis and over a long period. So, the use of the app is a part of his/her diabetes management routine. In other words, the frequency of use necessary to generate consistency is a specific parameter for each individual. Therefore, the frequency of use is not a determinant for glycemic control as long as it is sufficient to generate a consistent use of the app. Thus, users logging into the app on a monthly basis for a long time can have an impact on glycemic control regardless of whether their frequency of use is high or low.

Figure 1. General scheme of the SocialDiabetes integrated platform.

Methods

Description of Study Participants

In this study, 2 different measures for glycemic control have been conducted: the first evaluating the HbA_{1c} levels through the frequency of use of the app and the second examining its impact on LBGI and HBGI.

To perform the study, a subset of informed consenting users of the SDA database was first selected. The inclusion criteria were 18 years old or more, more than 1 year with diabetes, and no complications. An additional engagement inclusion criterion was applied, which consisted of an analysis of an app usage report where users who were logging in at least 5 days per month during at least 6 months (logging ≥5 days/month for ≥6 months) were selected. Users have been previously distinguished according to T1DM and T2DM as disease management between the two is often very different. Finally, to have an adequate sample of users and to obtain more accurate results, a different inclusion/exclusion criterion was used for each of the 2 analyses.

Reduction of Estimated Glycated Hemoglobin

A total of 211 users of the SDA were included in the analysis, among which 144 (68.2%) participants had T1DM and 67 (31.8%) had T2DM. For this analysis, a mean BG inclusion criterion was applied, where participants with mean BG levels at baseline more than or equal to 183 mg/dL (representing eA_{1c} ≥8%) were selected.

Among the users, 19 (9%) had a body mass index (BMI) less than 18.5, 98 (46.4%) had between 18.5 and 25, 74 (35.1%) had between 25 and 30, and 20 (9.5%) had greater than 30. Almost half of the selected users (99/211) were diagnosed between 10 and 30 years ago, 40.3% (85/211) was diagnosed less than 10 years ago, and the other users (27/211) were diagnosed over 30 years ago.

In addition, 144 (68.2%) users had T1DM, of which 57.6% (83/144) were male and 42.4% (61/144) were female. The mean age of males was statistically higher than that of females, 34.8 (SD 4.22) years versus 31.93 (SD 3.14) years, respectively. Conversely, participants with T2DM constituted 31.8% (67/211) of the total participants, with 74.6% (50/67) being male and 25.4% (17/67) being female. In this case, the mean age of males was higher than that of females, 53.2 (SD 4.02) years for males and 49.1 (SD 4.11) years for females.

The cohort was split into 2 groups according to the intensity of app engagement: group A represents the high-engagement group (logging ≥15 times/month for ≥6 months) and group B represents the low-engagement group (logging 5-10 times/month for ≥6 months). Applying this criterion, group A represents 57% (82/144) of T1DM participants and 67% (45/67) of participants with T2DM. The other participants for both T1DM and T2DM were included in group B, representing 43% (62/133) of T1DM and 33% (22/45) of T2DM participants.

BG levels at baseline, month 3, and month 6 were calculated using the intercept of a regression model based on data from months 1, 4, and 7, respectively. Estimated HbA_{1c} was calculated at baseline, month 3, and month 6 using linear regression analysis as described in the study by Holmes et al [22]. Paired *t* test was used to test the mean difference between baseline, month 3, and month 6.

Reduction of Risks of Hypoglycemia and Hyperglycemia

A total of 2692 users of the SDA were analyzed, of which 2248 (83.5%) of the participants had T1DM and 444 (16.5%) of the participants had T2DM. The inclusion criterion of this analysis consisted of engagement.

Among the subset selected, 161 (6%) participants had a BMI less than 18.5, 1146 (42.6%) had between 18.5 and 25, 779 (28.9%) had between 25 and 30, and 606 (22.5%) had greater

than 30. More than half of them were diagnosed less than 10 years ago (1404/2692), 37.5% (1010/2692) were diagnosed between 10 and 30 years ago, and the other users (278/2692) were diagnosed over 30 years ago.

Of the participants, 2248 (83.5%) had T1DM, of whom 59% (1326/2248) were male and 41% (922/2248) were female. The mean age for the males was statistically higher than that of the females, 36.7 (SD 4.98) years versus 31.81 (SD 3.34) years, respectively. Conversely, participants with T2DM constituted 16.5% (444/2692) of the total participants, with 79.3% (352/444) being male and 20.7% (92/444) being female. In this case, the mean age of males was higher than that of females, 55.2 (SD 4.22) years for male and 48.7 (SD 4.41) years for females.

The cohort was split into 2 groups according to the intensity of app engagement: group A, the high-engagement group (logging ≥60 times/month for ≥6 months), and group B, the low-engagement group (logging 5-10 times/month for ≥6 months). Applying this criterion, group A represents 86% of T1DM participants (1944/2248) and 66% of participants with T2DM (292/444). The other participants for both T1DM and T2DM were included in group B, representing 14% (304/2248) of T1DM and 34% (152/444) of T2DM participants.

The LBGI and HBGI were calculated according to the methods described in the study by Nathan et al [25]. It is well known that these indexes correlate with the risk of having hypoglycemia and hyperglycemic events, respectively [26].

From each group, the highest quartile regarding LBGI and HBGI at baseline (t1) was selected (n_1=486 and n_2=73 for group A; n_1=76 and n_2=38 for group B, where n_1 and n_2 refers to the number of T1DM and T2DM users respectively). Changes in HBGI and LBGI at month 6 (t2) were analyzed. Paired *t* test was used to compare HBGI and LBGI at baseline with those at month 6.

Results

Reduction of Estimated Glycated Hemoglobin

Baseline BG results for T1DM groups A and B were 213.61 (SD 31.57) mg/dL and 206.43 (SD 18.65) mg/dL, respectively, which decreased to 175.15 (SD 37.88) mg/dL and 180.60 (SD 40.47) mg/dL by month 6, respectively. The mean baseline BG reduction was 18% (*P*<.001) and 13% (*P*=.001) for groups A and B, respectively. For the T2DM groups, baseline BG level was 218.77 (SD 40.18) mg/dL and 232.55 (SD 46.78) mg/dL, respectively, which decreased to 160.51 (SD 39.32) mg/dL and 173.14 (SD 52.81) mg/dL by month 6 for groups A and B, respectively. The mean baseline BG reduction was 27% (*P*<.001) and 26% (*P*<.001) at month 6 for groups A and B, respectively. All statistical results are summarized in Table 1 and can be seen in Figures 2 and 3.

On the basis of BG reduction, this corresponds to a reduction of eA_{1c} of approximately 1.3% and 0.9% for T1DM groups A and B, respectively, and 2% for both T2DM groups A and B, respectively, and the statistical results are enumerated in Table 2 and represented in Figures 2 and 3.

Reduction of Hypoglycemia and Hyperglycemia Risk

T1DM baseline LBGI results for groups A and B were 5.2 (SD 3.9) and 4.4 (SD 2.3), respectively, which decreased to 3.4 (SD 3.3) and 3.4 (SD 1.9) by month 6, respectively; a reduction of 39% (*P*=.005) and 22% (*P*=.02), respectively, in the mean. The baseline HBGI results for groups A and B were 12.6 (SD 4.3) and 10.6 (SD 4.03), respectively, which decreased to 9.0 (SD 6.5) and 8.6 (SD 4.7) by month 6, respectively. The mean reduction in baseline HBGI was 30% (*P*=.001) and 22% (*P*=.003) for groups A and B, respectively.

For T2DM users, the baseline LBGI results for groups A and B were 1.52 (SD 1.15) and 2.62 (SD 1.76), respectively, which decreased to 1.13 (SD 1.14) and 2.12 (SD 0.96) by month 6, respectively. The mean reduction in baseline LBGI was 25% (*P*=.01) and 19% (*P*=.03) for groups A and B, respectively. For HBGI, the baseline results for groups A and B were 9.71 (SD 4.63) and 9.70 (SD 4.34), which decreased to 4.27 (SD 4.26) and 5.57 (SD 2.61) by month 6, respectively. The mean reduction in baseline HBGI was 56% (*P*<.001) and 44% (*P*<.001) for groups A and B, respectively.

Table 1. The evolution of blood glucose in type 1 diabetes and type 2 diabetes users.

Type and engagement	N	Blood glucose		
		Baseline, mean (SD)	Month 3, mean (SD)	Month 6, mean (SD)
Type 1 diabetes				
High	82	213.61 (31.57)	177.45 (37.31)	175.15 (37.88)
Low	62	206.42 (18.65)	179.46 (30.99)	180.60 (31.57)
Type 2 diabetes				
High	45	218.78 (40.18)	171.99 (44.77)	160.51 (39.32)
Low	22	232.55 (47.78)	162.52 (41.65)	173.14 (49.08)

Figure 2. Timeline evolution of estimated blood glucose (left) and estimated glycated hemoglobin (right) for users with type 1 diabetes mellitus.

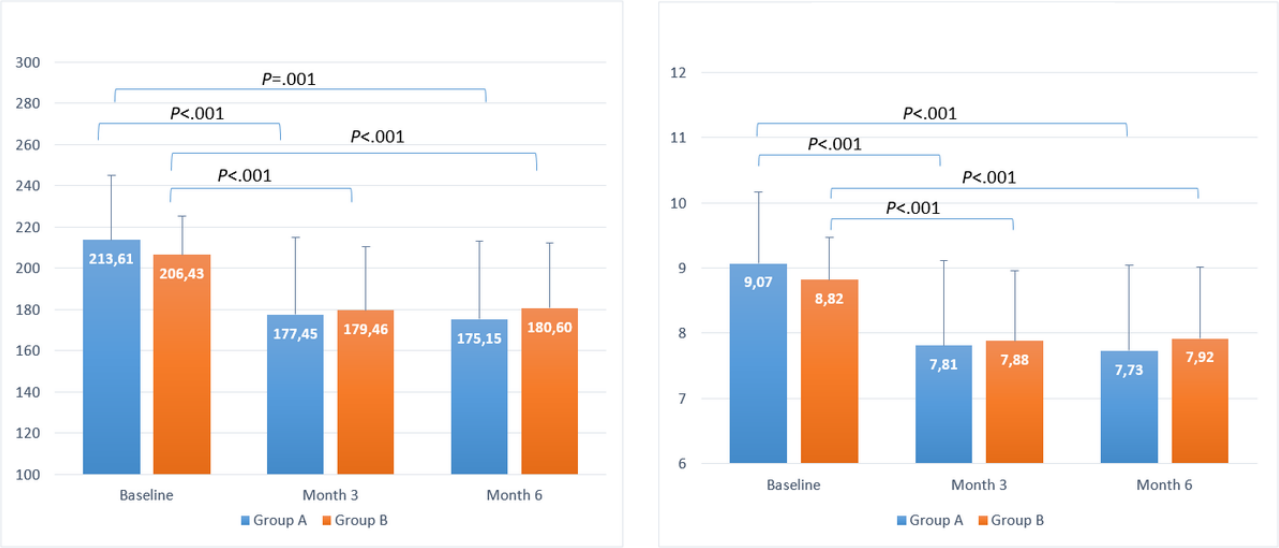


Figure 3. Timeline evolution of estimated blood glucose (left) and estimated glycated hemoglobin (right) for users with type 2 diabetes mellitus.

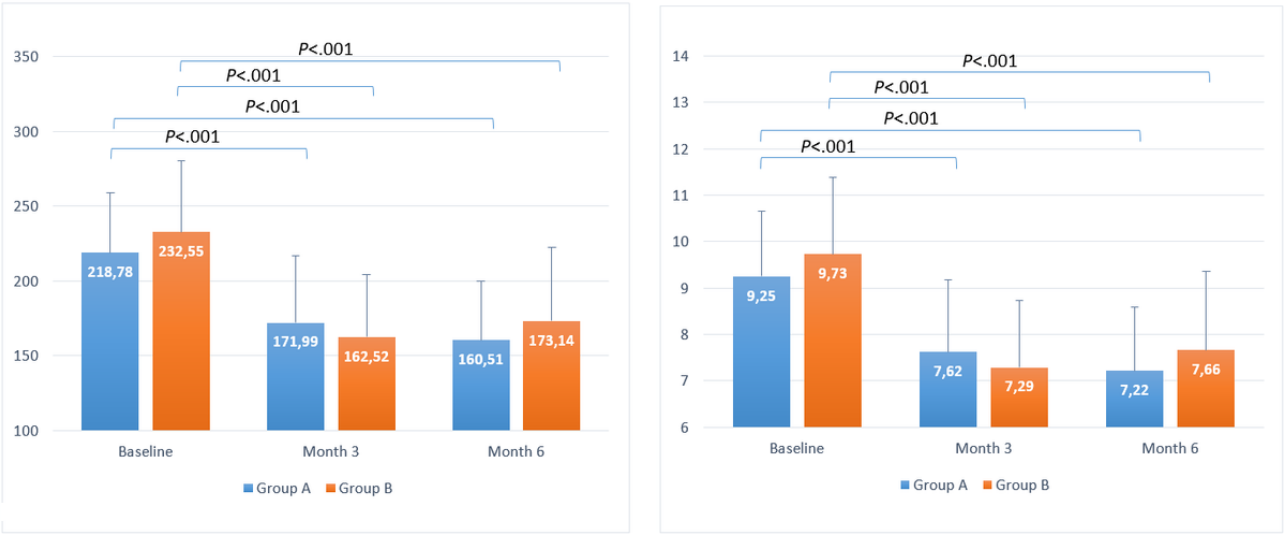


Table 2. The evolution of estimated glycated hemoglobin in type 1 diabetes and type 2 diabetes users.

Type and engagement	N	Glycated hemoglobin		
		Baseline, mean (SD)	Month 3, mean (SD)	Month 6, mean (SD)
Type 1 diabetes				
High	82	9.07 (1.10)	7.81 (1.30)	7.73 (1.32)
Low	62	8.82 (0.65)	7.88 (1.08)	7.92 (1.10)
Type 2 diabetes				
High	45	9.25 (1.40)	7.62 (1.56)	7.22 (1.37)
Low	22	9.73 (1.66)	7.29 (1.45)	7.66 (1.71)

For T1DM users, the baseline LBGI results for groups A and B were 4.72 (SD 1.93) and 4.4 (SD 1.34), respectively, and decreased at t2 to 2.92 (SD 2.20) and 3.45 (SD 1), respectively; this was a reduction of 39% (P=.005) and 22% (P=.02), respectively, in the mean.

Baseline HBGI results for groups A and B were 12.72 (SD 3.79) and 11.07 (SD 3.07), respectively, and decreased at t2 to 8.92 (SD 5.35) and 8.61 (SD 3.86), respectively; this was a reduction of 30% (P=.002) and 22% (P=.004), respectively, in the mean. All statistical results are summarized in Table 3 and shown in Figures 4 and 5.

Table 3. The evolution of both low blood glucose index and high blood glucose index for type 1 diabetes and type 2 diabetes users.

Type and engagement	N	Low blood glucose index		High blood glucose index	
		Baseline, mean (SD)	Month 6, mean (SD)	Baseline, mean (SD)	Month 6, mean (SD)
Type 1 diabetes					
High	486	4.44 (1.34)	3.45 (1.00)	9.73 (1.66)	8.61 (3.86)
Low	76	4.72 (1.93)	2.92 (2.20)	12.72 (3.79)	8.92 (5.35)
Type 2 diabetes					
High	73	2.62 (1.76)	2.12 (0.96)	9.70 (4.34)	5.57 (2.61)
Low	38	1.52 (1.15)	1.13 (1.14)	9.71 (4.63)	4.27 (4.26)

Figure 4. Timeline evolution of low blood glucose index (left) and high blood glucose index (right) for users with type 1 diabetes mellitus.

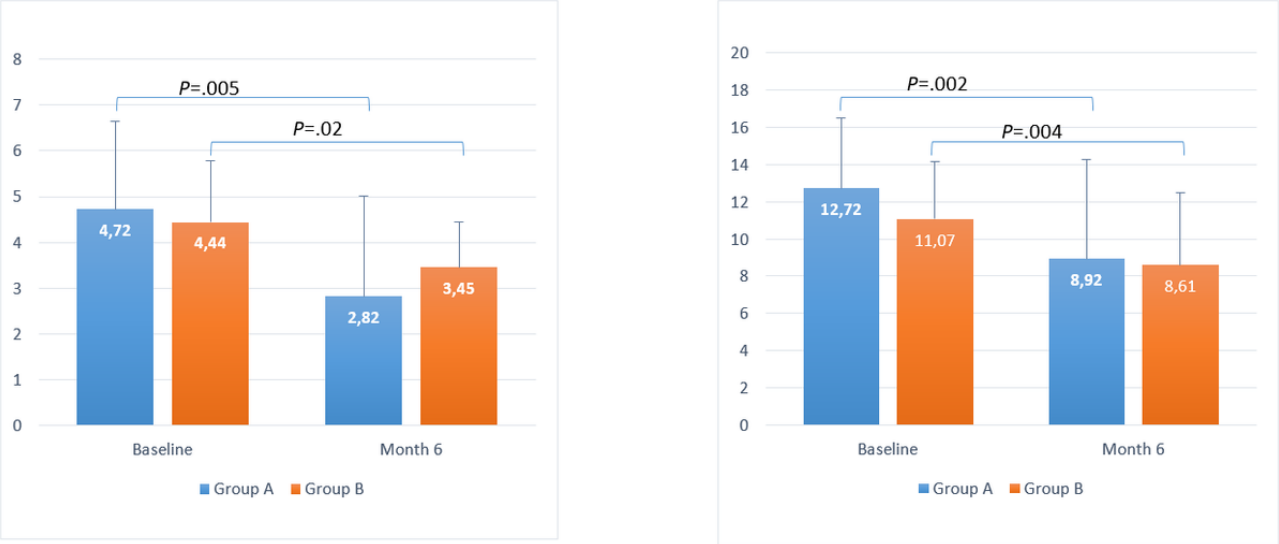
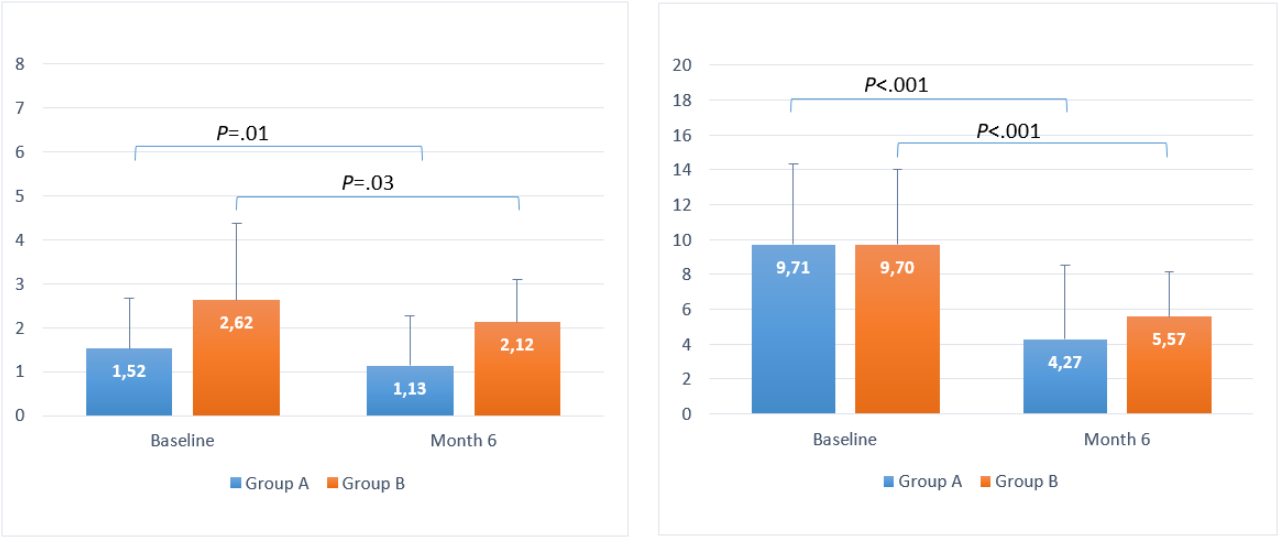


Figure 5. Timeline evolution of low blood glucose index (left) and high blood glucose index (right) for users with type 2 diabetes mellitus.



Discussion

Principal Findings

Significant reductions in BG levels were found in all groups, independent of the use frequency of the app. We also found better outcomes for participants with T2DM.

Significant reductions in LBGI and HBGI were found in all groups, regardless of the use frequency of the app. LBGI and HBGI of both groups tended to have similar values after using the app for 6 months.

We also found a slight increase in the estimated HbA_{1c} between 3 and 6 months. However, as *P* value shows in all cases, this increment is not significant.

The positive change in both HbA_{1c} and risk indices for hypoglycemia and hyperglycemia, regardless of the frequency of use of the app by users, demonstrates the initial hypothesis, arguing that frequency of app use is not as important as the consistency and continuity of use. Thus, our hypothesis states that consistent and continuous app use results in an improvement of glycemic control, regardless of use frequency.

SDA has been shown to help patients by improving disease management, even during infrequent app use. Our guess is that this is because of the patient's ability to learn disease management skills through the app, which aids in decision making and enables users to recognize specific situations, even without constant support from the app. Therefore, the higher-frequency use does not translate directly into improved performance or benefits, but rather an optimum between frequency and consistency is required.

Limitations

In this study, we considered the limited number of participants and the access difficulty to the SDA database as study limitations. The main problem was the need of a project manager or an expert from the company to solve problems associated with the database to facilitate data reorganization. Therefore, there was a lack of communication between the app entity and our research group, which caused access to the SDA database to be difficult. In addition, because of this lack of reorganization, a significant amount of data was lost. For this reason, the number of participants was less than expected.

In more detail, 11,542 users were analyzed from more than 12,000 registered users in the SDA database with the accepted ethical consent. The problem was based on an error in the link that allowed users to save their controls. Sometimes, the link failed, and consequently, the controls were lost. A huge number of users were not able to register their own controls and could not be evaluated. Despite this, the number of users to be evaluated was enough because more than 95% of users could be evaluated.

The patients that have been analyzed in this study have been taken directly from the database and analyzed retrospectively. So, we do not have complete data on other sources of support/care/teaching that they may have had. However, in surveys conducted by the company in patient samples, no differences were detected between the different groups of patients.

Conclusions

SDA is the first app that demonstrates that *the more use, the better* belief is not always optimal. In the case of SDA, the results are similar for both cases of lower-frequency and higher-frequency users. Using SDA may favorably impact glycemic control. Moreover, it is one of the few apps that may improve self-management for both T1DM and T2DM patients. As previously stated, the patient can learn how to manage his or her disease with this app, which increases patient empowerment and improves self-management, even for a very low use frequency.

Hence, we propose an innovative app, *SocialDiabetes*, as a self-management platform for people with any type of diabetes that aims to help people with diabetes live healthier, more comfortable lives. Through the activity of the patient, SDA provides tools, guidelines, and advice to the patient so that he/she can improve his/her management, knowledge, and self-care motivation toward his/her disease.

Pending studies to be carried out in the future include the study of the user's experience and how this experience can improve patient empowerment. The improvement in the quality of life should also be studied.

Acknowledgments

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Conflicts of Interest

JV has worked in SocialDiabetes as the Chief Researcher Officer and also received research support. The terms of this arrangement have been reviewed and approved by the University of Girona in accordance with its policy on objectivity in research.

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Abbreviations

BG: blood glucose
BMI: body mass index
DM: diabetes mellitus
eA$_{1c}$: estimated A$_{1c}$
HbA$_{1c}$: glycated hemoglobin
HBGI: high blood glucose index
LBGI: low blood glucose index
mHealth: mobile health
SDA: SocialDiabetes app
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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Original Paper

Validation in the General Population of the iHealth Track Blood Pressure Monitor for Self-Measurement According to the European Society of Hypertension International Protocol Revision 2010: Descriptive Investigation

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Abstract

Background: High blood pressure is one of the most common reasons why patients seek assistance in daily clinical practice. Screening for hypertension is fundamental and, because hypertension is identified only when blood pressure is measured, accurate measurements are key to the diagnosis and management of this disease. The European Society of Hypertension International Protocol revision 2010 (ESH-IP2) was developed to assess the validity of automatic blood pressure measuring devices that are increasingly being used to replace mercury sphygmomanometers.

Objective: We sought to determine whether the iHealth Track blood pressure monitor meets ESH-IP2 requirements for self-measurement of blood pressure and heart rate at the brachial level and is appropriate for use in the general population.

Methods: This study was a descriptive investigation. ESH-IP2 requires a total number of 33 participants. For each measure, the difference between observer and device blood pressure and heart rate values is calculated. In all, 99 pairs of blood pressure differences are classified into 3 categories (≤5, ≤10, and ≤15 mm Hg), and 99 pairs of heart rate differences are classified into 3 categories (≤3, ≤5, and ≤8 beats/min). We followed these protocol procedures in a convenience sample of 33 participants.

Results: iHealth Track fulfilled ESH-IP2 requirements and passed the validation process successfully. We observed an absolute difference within 5 mm Hg in 75 of 99 comparisons for systolic blood pressure, 78 of 99 comparisons for diastolic blood pressure, and 89 of 99 comparisons for heart rate. The mean differences between the test and standard readings were 4.19 (SD 4.48) mm Hg for systolic blood pressure, 3.74 (SD 4.55) mm Hg for diastolic blood pressure, and 1.95 (SD 3.27) beats/min for heart rate. With regard to part 2 of ESH-IP2, we observed a minimum of 2 of 3 measurements within a 5-mm Hg difference in 29 of 33

participants for systolic blood pressure and 26 of 33 for diastolic blood pressure, and a minimum of 2 of 3 measurements within a 3-beat/min difference in 30 of 33 participants for heart rate.

Conclusions: iHealth Track readings differed from the standard by less than 5, 10, and 15 mm Hg, fulfilling ESH-IP2 requirements. Consequently, this device is suitable for use in the general population.

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KEYWORDS

blood pressure determination; heart rate determination; validation studies; telemedicine

Introduction

Background

High blood pressure (BP) is one of the most common reasons why patients seek assistance in daily clinical practice [1-7]. In addition, patients who have normal BP levels at age 50 years have a 90% lifetime risk of developing hypertension [8,9]. Hypertension is the second most frequent cause of cardiovascular diseases, which are the main cause of morbidity and mortality in the world [4,8,9]. Thus, BP maintains a strong, continuous, gradual, consistent, predictive, and independent relationship with the appearance of serious cardiovascular complications, such as peripheral arterial disease, stroke, heart attack, sudden death, or heart failure, or with renal pathologies.

Screening for hypertension is therefore fundamental, and many interventions are available, both pharmacologic and nonpharmacologic, to control such pathology and its consequences [3,5,6]. Because hypertension is identified only when BP is measured [10], accurate measurements are key to the diagnosis and management of this disease [11-13].

Mercury sphygmomanometers are being used less and less due to prohibitions against the use of mercury. Automatic BP devices are therefore replacing mercury sphygmomanometers [13-15].

To assess the validity of these automatic BP devices, 3 different protocols are used: that of the Association for the Advancement of Medical Instrumentation (AAMI) [16], that of the British Hypertension Society [17], and that of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) [18], which combined the previous protocols. The ESH protocol was revised in 2010 (ESH-IP2) [19] to be more demanding than the previous one. These 3 protocols are for adults in the general population.

Objectives

The purpose of this study was to validate an automatic monitor that measures BP, iHealth Track, in the general population, following ESH-IP2 [19].

We hypothesized that the iHealth Track for home BP monitoring would show validated measures of BP and heart rate (HR), and would meet the requirements of ESH-IP2 in the general population.

Methods

Study Design

This study was a descriptive investigation to validate the iHealth Track device for the measurement of BP in the general population according to ESH-IP2 [19] and the Strengthening the Reporting of Observational Studies in Epidemiology criteria [20].

Ethical Information

The Clinical Research Ethics Committee of Hospital Clínico San Carlos in Madrid, Spain, approved this study (number 18/504-O_P).

This study complies with the ethical principles of the Declaration of Helsinki [21], including amendments from 2000 to 2013.

All participants were informed about the study and gave written informed consent to participate.

The Devices

Omron M3 IntelliSense

The reference device used in the study was the Omron M3 IntelliSense (Omron Healthcare, Inc, Kyoto, Japan), which was validated according to the ESH-IP2 [22]. It consists of an automatic oscillometric sphygmomanometer for the automatic measurement of BP and HR at the arm. The device has 2 available sleeve sizes: a standard size that fits arm circumferences of 22 to 32 cm and a larger size for arm circumferences of 32 to 42 cm.

iHealth Track

The device to be validated was the iHealth Track automatic device (KN-550BT; iHealthLabs Europe, Paris, France), which records brachial BP with the oscillometric method, with a range of pressure of 0 to 300 mm Hg (measuring accuracy ±3 mm Hg) and an HR range of 40 to 180 beats/min (measurement accuracy ±5%).

The systolic BP (SBP), diastolic BP (DBP), and HR are displayed on a liquid crystal display screen. The device has enough memory for 99 measurements. In addition, this unit can be used with Apple Bluetooth 4.0 devices and certain Android Bluetooth 4.0 mobile phones, by means of an app called Health MyVitals, which means that it allows for storage of BP and HR data in wireless devices connected to an iHealth Track and tracks data graphically and visually.

Textbox 1. Blood pressure (BP) and heart rate (HR) measurement protocol.

- BPA: entry BP and HR, with the standard device (Omron M3 IntelliSense).
- BPB: device detection of BP and HR with the test instrument (iHealth Track). This measurement is used to determine the correct functioning of the test instrument with the participant and is discarded from further analysis.
- BP1: with the standard device.
- BP2: with the test instrument.
- BP3: with the standard device.
- BP4: with the test instrument.
- BP5: with the standard device.
- BP6: with the test instrument.
- BP7: with the standard device.

The unit weighs approximately 348 g (batteries and sleeve included). It required 4 AAA batteries with an approximate capacity of 250 measurements. The included standard cuff fits the circumferences of the arm in a range of 22 to 42 cm.

Participants and Recruitment

We recruited a convenience sample of participants in Plasencia, Spain, from a family medical practice known to one of us.

According to the protocol review [19], we included 33 evaluable participants in the study who met the selection criteria, that is, all the inclusion and none of exclusion criteria. The inclusion criteria were men and women of at least 25 years of age, of whom at least 10 were men and 10 were women. The exclusion criteria were having a sustained arrhythmia, circulatory problems contraindicating the use of the cuff, or being pregnant.

Study Protocol

The validation team consisted of a single researcher with experience in the measurement of BP.

The measurement room was at a comfortable temperature and without any factors that could influence the measurements, including noise and distractions [18,19].

Each participant reported his or her sex and date of birth. We registered weight, height, and body mass index (BMI, calculated using the Quetelet index, where BMI = weight in kilograms / height in meters squared) and measured the arm circumference to ensure that the cuff size was adequate. Subsequently, the participant relaxed for 10 minutes and 9 consecutive BP measurements were taken on the same arm, with the left arm at heart level, according to ESH-IP2 [18,19]. Measurements were taken alternating the Omron M3 IntelliSense (5 times) and the iHealth Track (4 times), as Textbox 1 outlines.

During measurement, participants remained calm, quiet, sitting, and not moving, with the back straight, keeping the feet on the floor in a parallel position, without crossing the legs. They rested the arm on a flat surface, with the palm of the hand upward and the elbow slightly flexed so that their arm was at the height of the heart. The interval between BP measurements was 30 to 60 seconds [19].

All measurements were made in the same room.

Data Analysis

We performed statistical analyses using IBM SPSS Statistics, version 19 (IBM Corporation). The results are expressed as mean (SD). According to the normality tests of the Shapiro-Wilk test, we analyzed nonparametric data by the Wilcoxon-Mann-Whitney test and parametric data by means of the Student *t* test for independent samples. Statistical significance was set at $P<.05$.

We based the accuracy of a device, according to ESH-IP2, on comparisons between the test device (iHealth Track) and the reference device (Omron M3). For each participant, we first compared the device measurements BP2, BP4, and BP6 with the standard measurements BP1, BP3, and BP5, respectively, and then with the standard measurements BP3, BP5, and BP7, respectively. We classified the differences between these 2 devices separately for both SBP and DBP according to whether their values were within 5, 10, or 15 mm Hg [19] and, for HR, according to whether their values were within 3, 5, or 8 beats/min.

We analyzed and expressed results according to ESH-IP2 requirements to determine whether the device passed or failed the validation protocol. Part 1 and part 2 of the validation process concern the number of differences in the requested ranges for individual measurements (99 measurements) and for individual participants (33 participants), respectively [19].

We used Bland-Altman plots to represent the relationship of the SBP difference (device reference) and mean SBP (device and reference); DBP difference (device reference) and mean DBP (device and reference); and HR difference (device reference) and mean HR (device and reference).

Results

Participants

We screened a total of 33 participants. There were 13 men and 20 women. Table 1 shows their age, weight, height, BMI, and arm circumference, as well as the comparison of these according to sex.

Table 1. Sociodemographics characteristics of the participants.

Characteristics	Total group (N=33)		Men (n=13)		Women (n=20)		*P* value
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range	
Age (years)	47.94 (17.21)	25-87	45.85 (16.66)	30.0-84.0	49.30 (17.85)	25.0-87.0	.58[a]
Weight (kg)	72.45 (10.47)	54-92	75.54 (9.10)	61.0-90.0	70.45 (11.02)	54.0-92.0	.18[b]
Height (cm)	167.06 (5.51)	158.0-178.0	171.0 (3.48)	165.0-178.0	165.0 (5.16)	158.0-175.0	.001[b]
Body mass index (kg/m^2)	25.88 (2.85)	20.32-31.14	25.80 (2.43)	22.41-29.39	25.93 (3.15)	20.32-31.14	.9[b]
Arm circumference (mm)	285.76 (21.80)	230.0-320.0	293.08 (13.76)	260.0-310.0	281.0 (24.90)	230.0-320.0	.12[b]

[a]Nonparametric Wilcoxon-Mann-Whitney test.

[b]Parametric independent Student *t* test. $P<.05$ was considered statistically significant, with a confidence interval of 95%.

BP Measurements

Figure 1 shows the validation results for the iHealth Track BP device according to ESH-IP2. The table shows the numbers of measurements differing from the standard device, Omron M3, by 5, 10, and 15 mm Hg or less, for SBP and DBP, according to ESH-IP2 [19]. The mean differences between the standard device and the tested device were 4.19 (SD 4.48) mm Hg for SBP and 3.74 (SD 4.55) mm Hg for DBP.

These analyses showed an absolute difference within 5 mm Hg in 75 of 99 pairs of differences for SBP and in 78 of 99 pairs for DBP (vs at least 73 for SBP and 65 for DBP following ESH-IP2 requirements). We observed an absolute difference within 10 mm Hg in 93 of 99 comparisons for SBP and in 89 of 99 comparisons for DBP (vs at least 87 for SBP and 81 for DBP following ESH-IP2 requirements). Additionally, 94 of 99 comparisons exhibited an absolute difference within 15 mm Hg for SBP an DBP (vs at least 96 for SBP and 93 for DBP following ESH-IP2 requirements). Therefore, we successfully completed part 1 of the device validation for BP.

For part 2 of ESH-IP2, 29 of 33 individuals had a minimum of 2 of 3 comparisons within a 5-mm Hg difference for SBP, and 26 of 33 participants met this requirement for DBP (vs at least 24 of 33 participants for SBP and DBP following ESH-IP2 requirements). On the other hand, 3 comparisons exceeded the 5 mm Hg requirement for SBP and DBP in 3 of 33 participants (vs a maximum of 3 participants for SBP and DBP following ESH-IP2 requirements). Because these 2 conditions were validated, we successfully completed part 2 of the device validation for BP.

Thus, part 3 of the iHealth Track device validation also was passed, because parts 1 and 2 were both validated for SBP and DBP.

Figure 2 shows the validation results for the iHealth Track HR device according to ESH-IP2. The numbers of measurements differing from the standard Omron M3 device by 3, 5, and 8 beats/min or less are reported for HR. The mean difference between the standard and the tested device was 1.95 (SD 3.27) beats/min.

These analyses showed that 89 of 99 comparisons had an absolute difference within 3 beats/min, 91 of 99 comparisons had an absolute difference within 5 beats/min, and 93 of 99 differences had an absolute difference within 8 beats/min. Therefore, we successfully completed part 1 of the device validation for HR.

For part 2 of ESH-IP2, 30 of 33 individuals had a minimum of 2 of 3 comparisons within a 3-beats/min difference for HR. On the other hand, none of the 33 participants had 3 differences exceeding 3 beats/min. Because these 2 conditions were validated, we successfully completed part 2 of the device validation for HR.

Thus, part 3 of the iHealth Track device validation was passed, because parts 1 and 2 were both validated for HR.

With these results, the iHealth Track device meets ESH-IP2 validation criteria for both BP (SBP and DBP) and HR for use in the general population.

These results coincide with the Bland-Altman plots showing the differences in measurements between the iHealth Track device and the Omron M3 for SBP (Figure 3), DBP (Figure 4), and HR (Figure 5).

Figure 1. Validation results for the iHealth Track blood pressure device according to European Society of Hypertension International Protocol revision 2010 (ESH-IP2). Accuracy is determined by the number differences in these ranges both for individual measurements (Part 1) and for individual subjects (Part 2). To pass, a device must achieve all the minimum pass requirements shown. Pass requirements are as required by the EHS-IP2; achieved are as recorded by the device. DBP: diastolic blood pressure; SBP: systolic blood pressure.

Part 1		**≤5 mm Hg**	**≤10 mm Hg**	**≤15 mm Hg**	**Grade 1**	**Mean (mm Hg)**	**SD (mm Hg)**
Pass requirements	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	75	93	94	Pass	4.19	4.48
	DBP	78	89	94	Pass	3.74	4.55
Part 2		**2/3 ≤5 mm Hg**	**0/3 ≤5 mm Hg**		**Grade 2**		**Grade 3**
Pass requirements		≥24	≤3				
Achieved	SBP	29	3		Pass	Pass	
	DBP	26	3		Pass	Pass	
Part 3							Result
							Pass

Figure 2. Validation results for the iHealth Track heart rate (HR) device according to European Society of Hypertension International Protocol revision 2010 (ESH-IP2). Accuracy is determined by the number differences in these ranges both for individual measurements (Part 1) and for individual subjects (Part 2). To pass, a device must achieve all the minimum pass requirements shown. Pass requirements are as required by the EHS-IP2; achieved are as recorded by the device.

Part 1		**≤3 beats/min**	**≤5 beats/min**	**≤8 beats/min**	**Grade 1**	**Mean (beats/min)**	**SD (beats/min)**
Pass requirements	Two of	73	87	96			
	All of	65	81	93			
Achieved	HR	89	91	93	Pass	1.95	3.27
Part 2		**2/3 ≤3 beats/min**	**0/3 ≤3 beats/min**		**Grade 2**		**Grade 3**
Pass requirements		≥24	≤3			Pass	
Achieved	HR	30	0		Pass		
Part 3							Result
							Pass

Figure 3. Bland-Altman plot of systolic blood pressure (SBP) measurement differences between the iHealth Track (test) and the Omron M3 (reference) devices in 33 participants. Mean SBP difference is the systolic difference between the devices; mean SBP is the mean systolic average values of the devices.

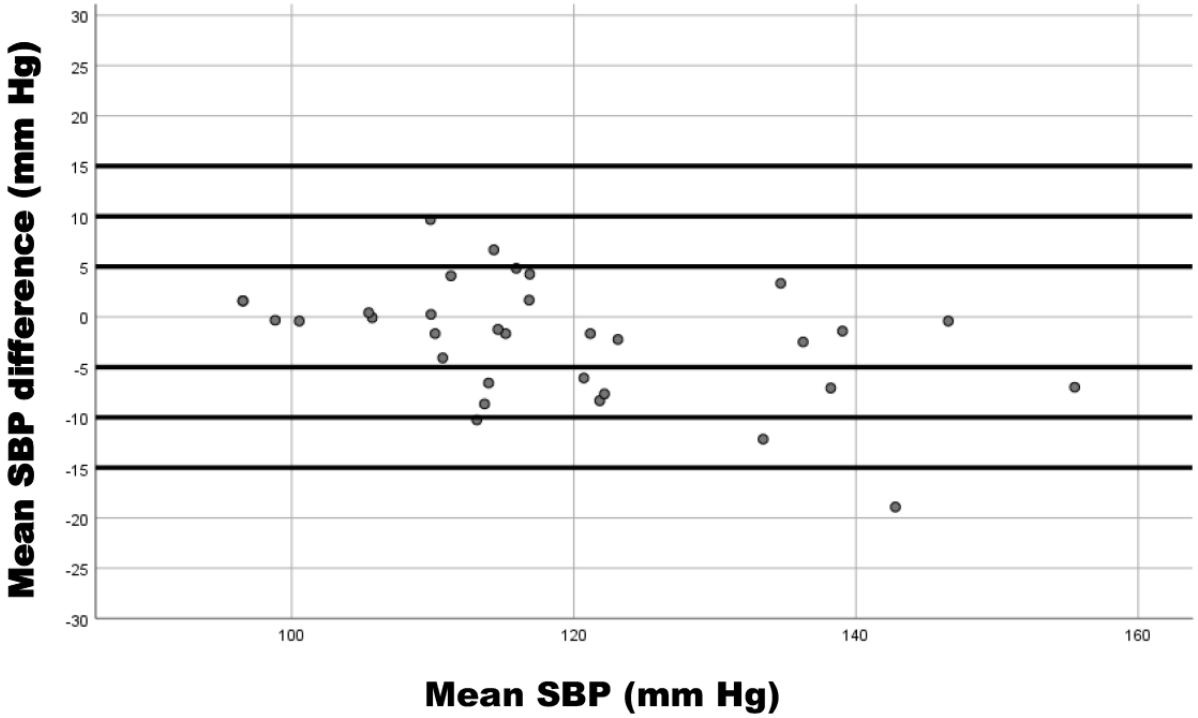


Figure 4. Bland-Altman plot of diastolic blood pressure (DBP) measurement differences between the iHealth Track (test) and the Omron M3 (reference) devices in 33 participants. Mean DBP difference is the diastolic difference between the devices; mean DBP is the mean diastolic average values of the devices.

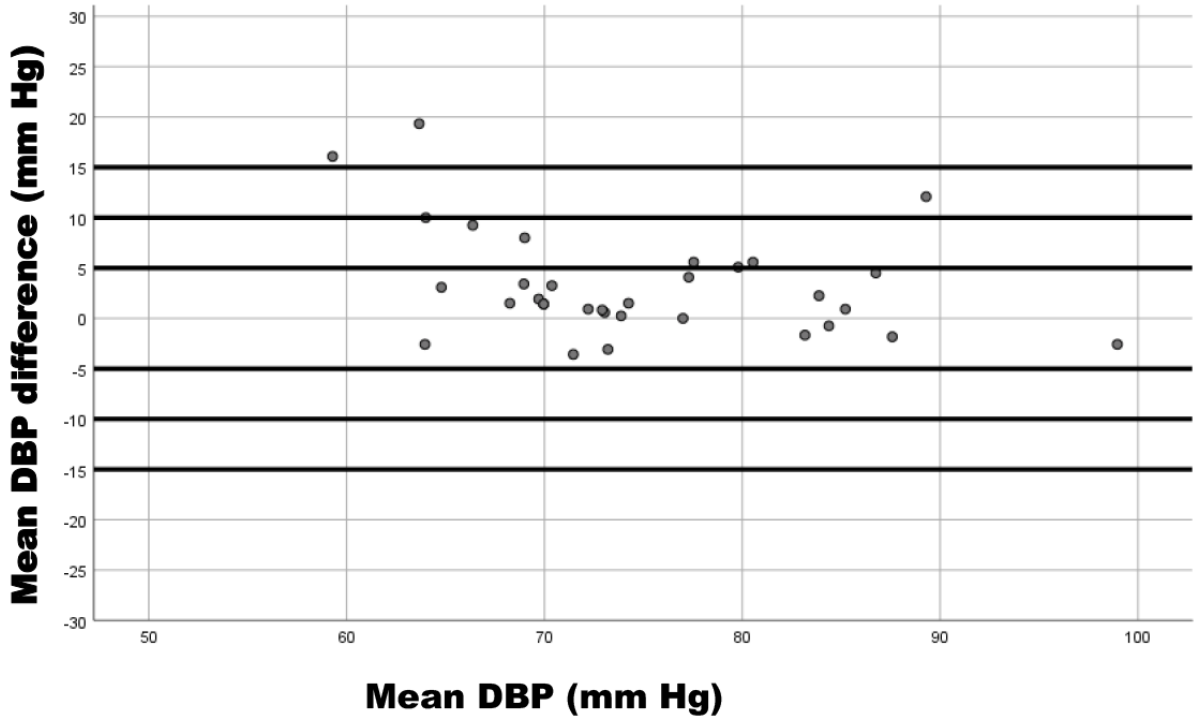
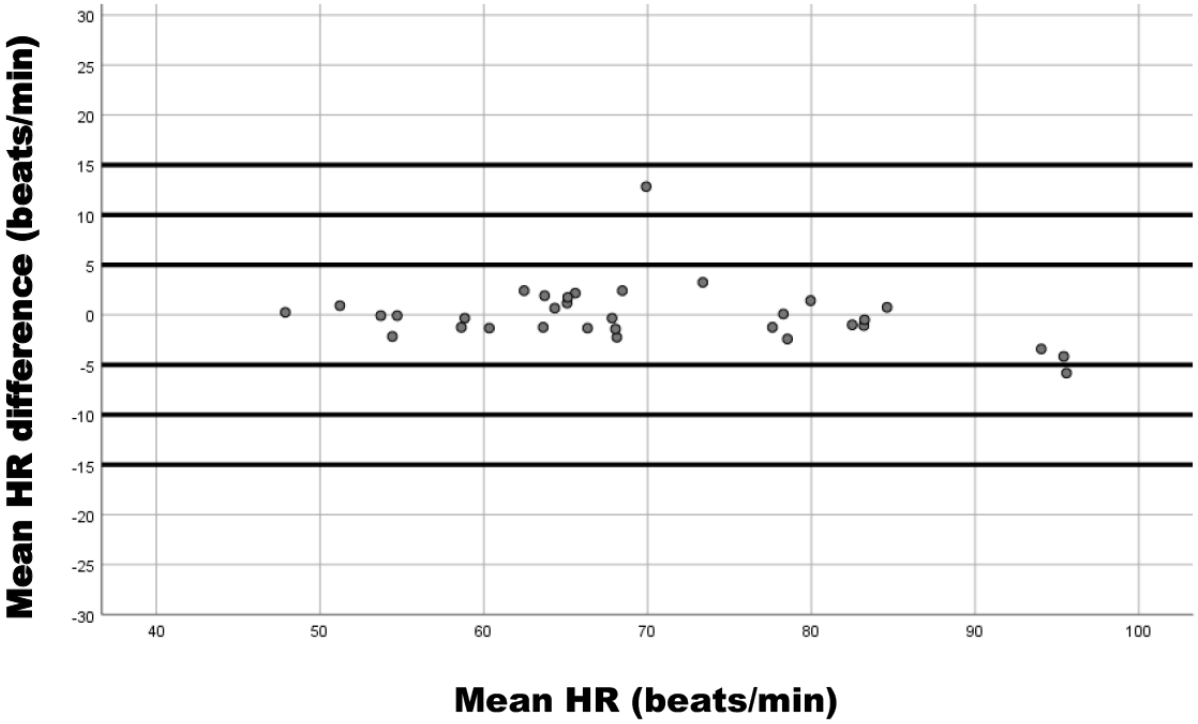


Figure 5. Bland-Altman plot of heart rate (HR) measurement differences between the iHealth Track (test) and the Omron M3 (reference) devices in 33 participants. Mean HR difference is the heart rate difference between the devices; mean HR is the mean heart rate average values of the devices.



Discussion

Principal Results

The results obtained from this research are important because they are the first to show that the iHealth Track device successfully passed both parts of the validation process according to the ESH-IP2 review in the general population [19]. However, these results cannot be extrapolated to other specific populations, such as older, diabetic, or pregnant individuals, because we have not addressed these conditions.

Regarding the validation protocols, the presence of several protocols for this function [16-19] is problematic for several reasons. Manufacturers cannot perform the 3 protocols and experts focus on their own protocols (eg, the AAMI is followed more in the United States and the ESH is followed in Europe), and it is impossible to compare several validation studies that are governed by different principles [23].

Limitations

In this study, we used the ESH protocol, first published in 2002 [18] and revised in 2010 [19], which has many advantages over previous ones [16,17], but also has some limitations.

First, ESH-IP2 does not specify the number of validation studies needed to validate the instrument, although a few findings suggest that a device should be validated in no fewer than 2 different centers separately [22-24]. In this regard, the protocol of the AAMI recommends conducting more than 1 study but does not specify the number of studies or devices [16]. Therefore, it is important to check the validity of BP measurement devices before widespread application in clinics and homes.

Second, the specific conditions required for the participants recruited in the study exclude children and young people, thus omitting data on the hypertensive population between 18 and 25 years of age.

Third, although we calculated the sample size, consecutive sampling bias should be considered, and a simple randomization sampling process could be more adequate for future studies.

Fourth, ESH-IP2 mentions no explicit criteria for a validation process in specific populations, and we highly recommended that this be taken into consideration in its next revision.

Fifth, although sphygmomanometers measure SBP, DBP, and HR, no version of the international protocol of the ESH considers validating HR. Hence, we have added such a validation based on the protocol criteria in BP and establishing, in this case, the required differences based on the scale of values found after HR measurements, being even more demanding than the ESH.

Conclusion

The results of this study are relevant because they show that an automatic wireless device that measures BP and HR and that can also be linked to new technologies meets the requirements of ESH-IP2.

We highly recommended that the accuracy of iHealth Track be assessed in other specific populations, such as pregnant women, older people, patients with arrhythmia, and so on, using other types of sampling. Also, it would be convenient to extend the validation equipment in order to reduce intraobserver error.

Conflicts of Interest

None declared.

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Abbreviations

AAMI: Association for the Advancement of Medical Instrumentation
BP: blood pressure

DBP: diastolic blood pressure
ESH: European Society of Hypertension
ESH-IP2: European Society of Hypertension International Protocol revision 2010
HR: heart rate
SBP: systolic blood pressure

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Original Paper

Mobile Health Features Supporting Self-Management Behavior in Patients With Chronic Arthritis: Mixed-Methods Approach on Patient Preferences

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Abstract

Background: Patients with chronic arthritis (CA) ideally apply self-management behaviors between consultations. This enduring, tedious task of keeping track of disease-related parameters, adhering to medication schemes, and engaging in physical therapy may be supported by using a mobile health (mHealth) app. However, further research is needed to determine which self-management features are valued most by adult patients with CA patients.

Objective: The aim of this study was to determine the preference of features for an mHealth app to support self-management behavior in patients with CA. In addition, we aimed to explore the motives behind these ratings.

Methods: A mixed-methods approach was used to gather information from 31 adult patients (14 females), aged 23 to 71 years (mean 51 [SD 12.16]), with CA. Structured interviews were conducted to gather data pertaining to preferences of app features. Interviews were analyzed qualitatively, whereas ratings for each of the 28 features studied were analyzed quantitatively.

Results: In general, patients with CA favored the use of features pertaining to supporting active and direct disease management, (eg, medication intake and detecting and alarming of bad posture), helping them to keep a close watch on their disease status and inform their health care professional (eg, providing a means to log and report disease-related data) and receiving personalized information (eg, offering tailored information based on the patient's health data). Patients strongly disliked features that provide a means of social interaction or provide incentivization for disease-related actions (eg, being able to compare yourself with other patients, cooperating toward a common goal, and receiving encouragement from friends and/or family). Driving these evaluations is the finding that *every patient with CA hurts in his/her own way*, the way the disease unfolds over time and manifests itself in the patient and social environment is different for every patient, and patients with CA are well aware of this.

Conclusions: We have offered an insight into how patients with CA favor mHealth features for self-management apps. The results of this research can inform the design and development of prospective self-management apps for patients with CA.

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KEYWORDS

mobile applications; arthritis; self-management

Introduction

Background

Chronic arthritis (CA) is an umbrella term for inflammatory diseases that affect about 20% of the US and European population [1,2]. Symptoms include joint pain, swelling, stiffness, and instability and joint destruction or bony ankylosis, resulting in progressive impairment of mobility when insufficiently controlled [3]. Patients are often limited in their day-to-day activities owing to these symptoms. Effective drugs to treat CA are available but require a long-term commitment. In addition, patients are recommended to participate in frequent physical therapy to improve mobility, cardiovascular endurance, postural control, and muscle strength. Increasingly, self-management is becoming a basic principle in treatment efforts. Patients are required to keep a close watch on their disease parameters to swiftly identify changes in disease status and adapt medication intake or exercise regimens. Thus, managing CA is a complex and demanding activity [2]. Not surprisingly, patients often fail to comply with this strict and enduring treatment regimen [4-6]. This is unfortunate, as long-term health outcomes depend on these self-management behaviors and as successful self-management of CA promotes physical and emotional well-being of the patient and reduces health care costs [7,8].

Supporting Self-Management Behaviors

A possible (partial) solution may come in the shape of mobile health (mHealth) apps incorporating features to support and motivate patients with CA to engage in and adhere to self-management behaviors. Several theories and models exist to inform mHealth app designers in which such features may motivate and support patients. The Persuasive System Design (PSD) model [9] starts from the assumption that technology can be designed to change attitudes or behaviors through persuasion and social influence [10]. Therefore, the PSD model contains 28 design principles divided over 4 umbrella categories: primary task support (eg, setting tailored goals), dialogue support (eg, sending reminders), social support (eg, providing social norms), and system credibility support (eg, listing third-party endorsements). Another established framework, the taxonomy of Behavior Change Techniques (BCTs) incorporates 26 techniques to inspire mHealth designers [11]. Being different from the PSD model, BCT principles do not start from *persuasive design principles* but rather emanate from *behavior change theories*. Consequently, authors link their techniques to the underlying theories of behavior change, for example, the technique of giving rewards is linked to operant conditioning.

Several researchers use one or a combination of the aforementioned frameworks, for example, to evaluate the presence of features to support self-management behaviors [9,12-18]. Despite different underlying epistemologies, several PSD principles and BCTs overlap in the way they manifest themselves in mHealth apps. Therefore, Geuens et al [19] compiled the 2 frameworks and presented a list of 28 unique *motivational* features to support and motivate self-management behaviors in mHealth apps.

Presence of and Preference for Self-Management Features in Mobile Health

With regard to CA, Geuens et al [20] conducted a systematic review of persuasive principles and BCTs present in current health apps. The authors coded 28 mHealth apps. They found that the most used category of persuasive principles was system credibility, in particular, avoiding banners and advertisements and providing information on who contributed to the development of the app. Task support was the second most used category and mainly comprised the option to compute a Disease Activity Score. Only a few apps supported physical exercise. Next was dialogue support, consisting of sending out reminders with respect to medication intake. Surprisingly, social support principles were lacking in all but one app.

Although the aforementioned study provides information on what self-management features are found in mHealth apps, it does not inform us of how these features are evaluated by patients with CA *themselves*. In 2015, Revenäs et al conducted 4 consequent workshops with 5 adult patients with rheumatoid arthritis, 5 health care professionals, and 2 Web developers [21]. They found that patients with CA preferred 2 major components for a Web-based or mobile app: a calendar for goal setting, planning, and recording of disease-related parameters and a community to receive support from peers. Another study by Revenäs et al with 26 individuals with rheumatoid arthritis, not on mHealth but internet services, also identified several key features to support physical activity for patients with rheumatoid arthritis [22]. They identified the following core features: up-to-date and evidence-based information, self-regulation tools, social interaction, personalized set-up, attractive design, and access to the internet service. To the best of the author's knowledge, no other studies report on preferred self-management mHealth features with *adult patients with CA*. This is unfortunate as a lack of patient involvement in the design and selection of self-management features in apps may negatively impact acceptance of such mHealth apps.

However, recent studies document the preferences of patients with juvenile idiopathic arthritis (JIA), aged 10 to 24 years. Waite-Jones et al [23] conducted semistructured focus groups and individual interviews with 9 young people, 8 parents, and 8 health care professionals. The findings from this study suggested that an app for self-management of juvenile arthritis should provide young people with the ownership and control of an engaging tool that (1) gives information, (2) monitors symptoms, (3) offers reminders, and (4) provides social support. Cai et al [24] equally used focus groups as part of a qualitative, user-centered design approach involving 29 young people with JIA, 7 parents, and 21 health care professionals from the rheumatology team. The major themes that they identified to inform app development were (1) remote monitoring of symptoms such as pain and swelling/stiffness of joints, overall mood, stress and sleep, and physical activities, well-being; (2) treatment adherence, that is, tracking medication and exercise schemas and sending out reminders; (3) education and support (giving links to educational sites, support groups and JIA-related services, and providing information on juvenile arthritis); and, in later phases, themes related to the following were also mentioned: (4) providing incentives, (5) privacy, (6) ease-of-use,

(7) integration of clinical tools support, and overall (8) attractiveness of design.

These qualitative studies on JIA inform us of desired design features for mHealth apps by young patients with JIA and their caretakers. However, mHealth features that are found supportive by older patients with CA are only studied in the aforementioned work by Revenäs et al. Apart from the medical differences [25], patients with juvenile and adult arthritis may have age-related differences in disease self-management. When using mHealth for self-management of CA, differences in technology proficiency between adolescents and adults may become apparent [26], resulting in a different way of using mHealth apps. Wyatt et al [27] recommended age specificity as one of the key elements for a good design of an mHealth app. Hence, there is a clear need to further study preferences of adult patients with CA with regard to mHealth features supporting disease management.

The Contribution of This Study

In this study, we aimed to evaluate, in a quantitative and qualitative manner, how adult patients with CA evaluate design features supporting self-management behaviors embedded in mHealth apps. First, we aimed to understand *which features are rated positively and which are rated negatively*. Second, we aimed to explore the reasons patients with CA provide to explain these scorings, in a qualitative manner. *What are the reasons underlying positive or negative scorings?* The broader goal of this study was to inform researchers and developers of mHealth apps on which features are desired by patients with CA themselves, to promote long-term adoption of the app.

Methods

This study employed a mixed-methods approach, a quantitative analysis of how patients rated mHealth features and a qualitative analysis of interviews.

Participants

Participants (see Table 1) were randomly selected from patients visiting the medical ambulatory center of the rheumatology division of the University Hospital Gasthuisberg in Leuven, Belgium, in the fall of 2017. Ethical approval for this study was granted by the ethics committee of the University Hospital Gasthuisberg with protocol number S-59012. Patients were recruited before their appointment with their rheumatologist. Information was provided about the intent of the interview and patients were asked to sign a consent form detailing the collection, processing, and storing of data collected during the interview. Patients could stop the interview at any time. Inclusion criteria were that patients should be diagnosed with CA and be at least 18 years. Data related to the current disease status (age, sex, years since diagnosis and disease-related parameters) were collected from the hospital's registries, coupled with the respective patient's interview data, and anonymized. We aimed for a purposively heterogeneous yet representative sample of patients with CA. In total, 31 patients (14 females), aged 23 to 71 years (mean 51 [SD 12.16]), were recruited over the course of 4 months. Patients with CA in this study varied with regard to their medical disease status.

Data Collection and Analysis

Both qualitative and quantitative data were collected during the interviews. The qualitative data contained the complete recording of the interview, that is, answers to the first part of the interview (open questions related to disease management) and the second part (scorings on 28 features and additional comments). Audio recordings were made during the interviews and transcribed verbatim. Semistructured interviews were conducted before or after a consultation with a rheumatologist and took place in the same building. The first part of the interview started with an open question asking patients to describe how they currently managed their condition. Next, the interviewer followed up by asking about medication, physical therapy, and the use of technology to support them. The second part of the interview consisted of questions that polled the favorability of 28 possible features of an mHealth app for patients with CA (based on [19], see Textbox 1) supporting self-management behaviors. Patients with CA were asked to provide a Likert score between 1 (strong dislike) and 5 (strong like). In addition, patients were invited to further comment on why they gave this scoring and were encouraged to ask for clarification whenever the intent of a feature was not clear. After the 28 features were reviewed, the interviewer asked once more for additional comments on their evaluation. Interviews ranged between 8 and 31 min, with an average of 14 min.

Qualitative Data Analysis

The qualitative data were entered and coded in NVivo 11 (QSR) according to a thematic analysis process as described by Braun and Clarke [32]. In the first phase, 2 researchers and coauthors of this paper (JG and VVA) familiarized themselves with the data and provided initial codes for all data (the data provided in the first part of the interview, the explanation of the rating for the 28 mHealth features, and the closing of the interview). In a next round, themes were derived, grouping the different mHealth features based on emerging topics. A final coding round was conducted, unearthing the underlying core concept and design implications (see Table 2).

Quantitative Data

The scoring of patients with CA was based on the 5-point Likert scale, related to how patients evaluated the 28 features of an mHealth app, and was entered in Microsoft Excel for descriptive statistics. Given the face-to-face interview, there were no missing data. Data were further inspected according to the process described by Gaskin [30]. As a suspicious answer pattern was found (ie, limited variance and providing only ratings of 5), patient 19 was omitted from the dataset. SPSS was used for conducting 2 one-sample *t* tests (one-tailed, alpha=.05), with a Bonferroni correction (based on 28 tests) to correct for inflation of the false-positive error rate. Data were exported to comma-separated value files and imported in a Python [31] worksheet for further processing and the rendering of violin plots to illustrate sample distribution as well as a box plot.

Table 1. Patients participating in interviews and focus groups, with gender, age, and disease-related scores. Scores varied from 0.00 to 7.20 (out of a possible 0 to 10) on the Bath Ankylosing Spondylitis Disease Activity (BASDAI) (mean 4.02 [SD 2.26]) and 0.00 to 9.50 (out of a possible 0 to 10) on the Bath Ankylosing Spondylitis Functional Index (BASFI) (mean 4.07 [SD 2.66]).

Participant	Sex	Age (years)	Diagnosis (years)	BASDAI[a]	BASFI[b]
Patient 1	M	48	33	2.60	2.50
Patient 2	F	48	30	7.80	6.90
Patient 3	M	54	26	3.30	5.70
Patient 4	M	59	9	0.80	0.50
Patient 5	F	34	9	__[c]	—
Patient 6	M	55	39	1.80	5.70
Patient 7	M	66	47	3.40	4.10
Patient 8	F	71	46	4.40	5.00
Patient 9	M	47	22	6.40	9.50
Patient 10	F	51	18	3.60	2.90
Patient 11	M	45	10	3.50	5.20
Patient 12	M	23	10	0.80	0.00
Patient 13	F	58	27	7.00	6.70
Patient 14	M	63	44	0.00	0.00
Patient 15	F	41	12	7.10	8.10
Patient 16	F	59	14	6.50	7.30
Patient 17	F	56	7	4.00	2.20
Patient 18	F	69	34	2.70	1.90
Patient 19[d]	M	38	1	Excluded	Excluded
Patient 20	M	39	15	1.10	1.40
Patient 21	F	38	14	3.70	2.30
Patient 22	M	57	14	5.80	5.70
Patient 23	F	41	16	5.40	4.40
Patient 24	F	61	9	7.00	5.90
Patient 25	F	46	14	5.10	5.30
Patient 26	M	29	8	1.30	0.00
Patient 27	M	59	41	4.70	2.20
Patient 28	M	54	27	7.20	6.40
Patient 29	M	49	27	3.80	7.00
Patient 30	F	67	14	6.90	6.90
Patient 31	M	48	27	1.20	1.90
Average (%)	53 M	53	21	4.02	4.07
SD	—	12.16	12.65	2.26	2.66

[a]BASDAI: Bath Ankylosing Spondylitis Disease Activity [28].

[b]BASFI: Bath Ankylosing Spondylitis Functional Index [29].

[c]Missing data.

[d]Patient 19 was excluded from the quantitative analysis because he rated all features a 5.

Textbox 1. Mobile health (mHealth) features selection for which a 1 to 5 Likert rating was asked during the interview. Patients were asked for their rating of the feature which was asked for as described below. The general descriptor (marked in italics) is provided for the convenience of the reader but was not provided to the patient.

Disease activity scoring: You are asked to enter measurement results in an app. The app automatically calculates several useful disease-related scores instead of you having to calculate these scores by hand.

Exercise scheduling: You want to be able to walk a distance of 5 miles in a few months. The app calculates the right exercise schedule to guide you toward this goal.

Exercise instructions: You are required to perform a set of exercises. The app provides detailed instructions on how to perform each exercise.

Exercise assessment: Sensors measure whether you are executing an exercise the right way. You are able to perform the exercise a few times before the measurement is actually started.

Medication reminders: You are required to take your medication at fixed intervals. The app reminds you when you need to take your medication.

General Information: You are able to read general information about arthritis in the app.

Tailored information: The information in the app is specific for your type of arthritis.

Personalized information: The information in the app is specific to you personally.

Pain analysis: The app is able to predict possible causes of pain from the collected data.

Logs for reporting: You are able to save information about your condition in the app to show to your physician.

Disease tracking: The app automatically collects data relevant to your disease.

Graphs: You are able to consult graphs and data based on your own data.

Rewards: You are able to collect rewards based on your execution of exercises.

Praise: You are encouraged during your physical therapy through motivational messages.

Gamification: Would you like the app to provide exercise instructions in a playful manner, for example, by using playful sounds or collecting badges or points?

Social media sharing: The app shows other users that you have been taking the most steps this week and you are able to share this on social media.

Social identification: You are able to view limited data of other users with the same condition.

Social comparison: You are able to compare yourself to other users

Competition: You are able to challenge other users to, for example, walk the longest distance.

Cooperation: You are able to work together with other users to achieve a common goal.

Encouragement: As you are executing your exercises, family and friends are able to send you motivational messages.

Goal setting: You are able to choose your goal, and the app will guide you toward this goal.

Context-awareness: The app tells you the weather is nice and there is a beautiful park nearby and suggests you go for a walk.

Styling: You are able to personalize the app, for example, change colors, set a profile picture, and choose what is shown.

Posture detection: The app detects bad posture and suggests correcting your posture.

Verifiability: The app shows scientific articles that describe the design and development of the app.

Expertise: The app shows physicians, therapists, and researchers that helped create the app.

Surface credibility: The app does not contain advertisements.

Table 2. Example of coding of the qualitative data into coding nodes, a category and subcategory.

Phase of the interview and content	mHealth[a] feature	Grouping themes	Design implications	Core concept
Start				
Interviewer: To start the interview, can you tell how you manage the disease?	__[b]	—	—	All patients hurt in their own way
Patient: Well, you are confronted with it on a daily basis, it is actually a part of your life.	—	—	—	All patients hurt in their own way
Rating and explanation of 28 mHealth features				
Interviewer: While you are executing your exercises, family and friends are able to send you motivational messages through the app.	Encouragement	Social interaction	No need for social sharing or comparing, CA[c] is a private matter	All patients hurt in their own way
Patient: For me, personally, that is not that important. I like to keep that private. My disease should not take the upper hand in my social encounters. I score it a 2.	—	—	—	All patients hurt in their own way
Closing of the interview				
Interviewer: Would you like to have an app containing these features?	Posture detection	Disease action support	—	All patients hurt in their own way
Patient: I think so. Perhaps not all features, I would use particularly the feature with posture.	—	—	—	All patients hurt in their own way
Interviewer: What [features] would you not use?	—	Social interaction	No need for social sharing or comparing, CA is a private matter	All patients hurt in their own way
Patient: Everything related to other users. All of that. The disease is very personal, it is different for everyone?	—	—	—	All patients hurt in their own way

[a]mHealth: mobile health.

[b]Not applicable.

[c]CA: chronic arthritis.

Results

General Results

Overall, out of the 28 features supporting self-management behavior, 11 received a scoring significantly higher than 3 (*neither like* and *neither dislike*) and 6 received a scoring significantly lower than 3. Table 3 lists the features sorted on mean scorings with *t* values, *P* values, and CIs. Figure 1 provides an overview of the scorings, ordered from the highest average (left) to the lowest.

Upon qualitative analysis, we grouped features into the following themes to structure our results: *Disease action support*, *Disease insight*, *Information*, *Incentivization*, *Social interaction*, *Credibility*, and *Personalization*. Both quantitative and qualitative data will be discussed further below according to these themes. Next, we will argue for a core concept underlying these themes and scorings and provide implications for the selection and design of supportive self-management features.

Themes and Mobile Health Features

Disease Action Support

The *Disease action support* theme contains those features that support patients' *active* behaviors; executing disease related actions such as physical therapy, improving physical well-being, or medication intake all have a direct effect on health-related outcomes (Figure 2). In general, we found that patients with CA welcomed features that support the active management of their disease, all features scored above 3, of which 5 out of 7 were significant.

Table 3. Quantitative results of the interviews. Features are sorted based on the mean score.

Feature	Mean	*T* value	*P* value
Logs for reporting	4.60	14.102	<.001[a]
Surface credibility	4.43	6.916	<.001[a]
Posture detection	4.23	5.798	<.001[a]
Medication reminders	4.20	5.541	<.001[a]
Disease tracking	4.13	5.461	<.001[a]
Personalized information	4.13	4.41	<.001[a]
Pain analysis	4.10	4.748	<.001[a]
Tailored information	4.00	3.808	.001[a]
Exercise scheduling	3.97	4.455	<.001[a]
Exercise instructions	3.93	3.619	.001[a]
Exercise assessment	3.93	3.683	.001[a]
Graphs	3.63	2.567	.02
Goal setting and guidance	3.57	2.246	.03
Verifiability	3.50	1.822	.08
Disease activity scoring	3.43	1.692	.10
General information	3.23	0.763	.45
Expertise	3.23	0.879	.39
Context-awareness	3.10	0.379	.71
Styling	2.97	−0.126	.90
Praise	2.83	−0.604	.55
Gamification	2.53	−1.848	.08
Rewards	2.40	−2.34	.03
Encouragement	1.90	−4.557	<.001[b]
Cooperation	1.80	−5.288	<.001[b]
Social comparison	1.57	−8.746	<.001[b]
Social media sharing	1.53	−9.337	<.001[b]
Competition	1.50	−7.883	<.001[b]
Social identification	1.40	−11.379	<.001[b]

[a]Significant higher score than mean.

[b]Significant lower score than mean.

Figure 1. Scoring of features for a mHealth application for CA patients (*denotes significance).

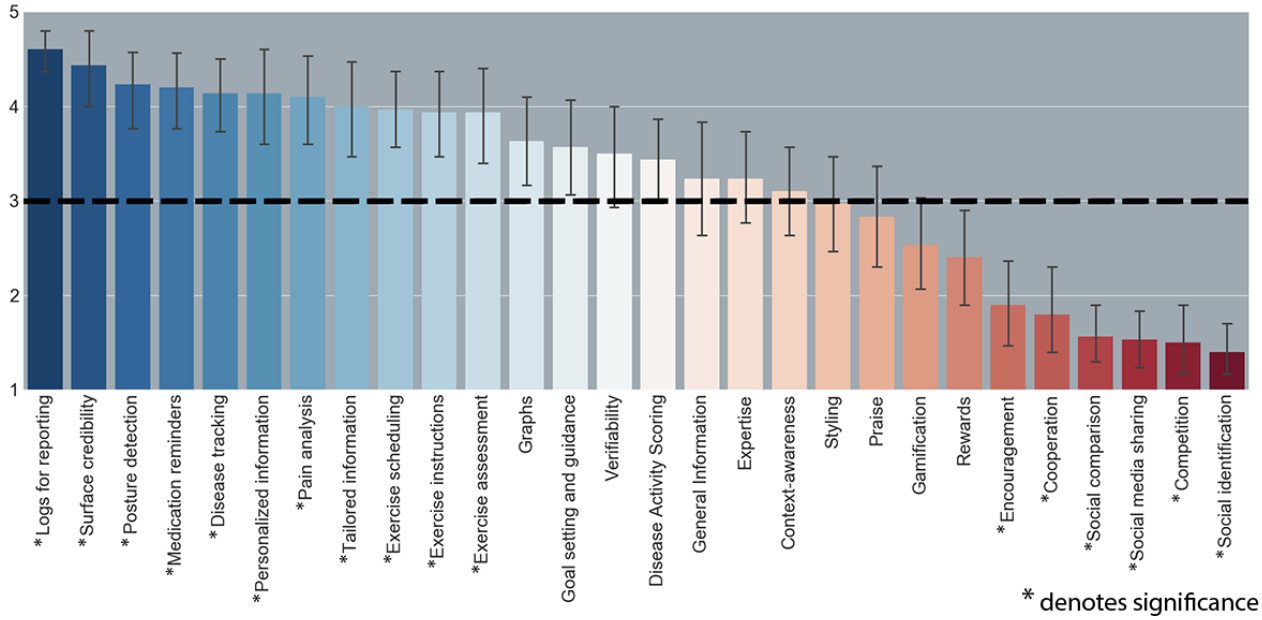
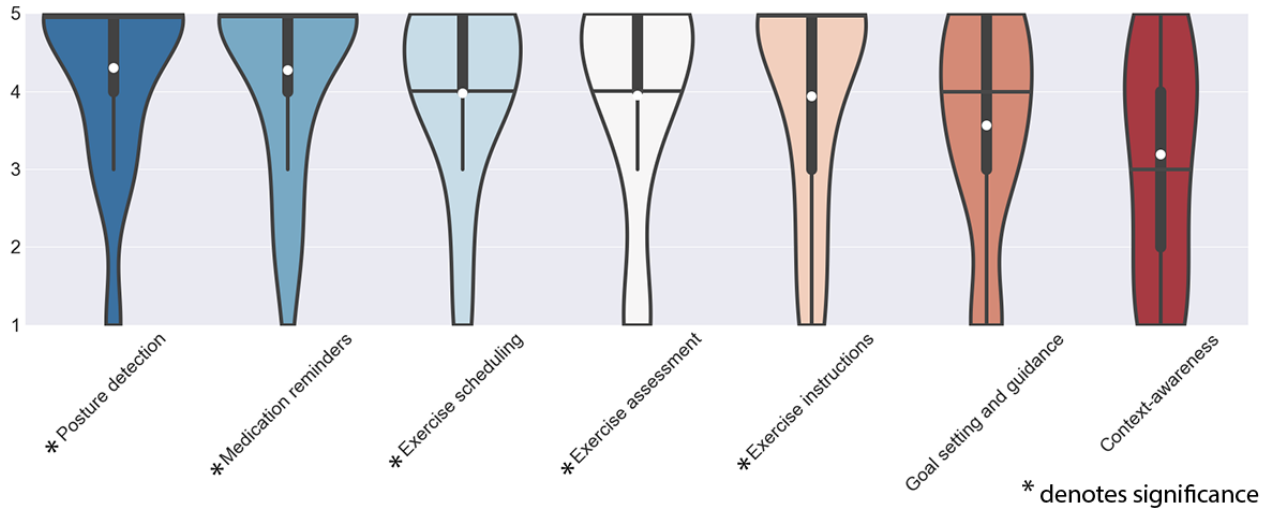


Figure 2. Scores of features in the group of disease action support. The white dot denotes the mean value, the horizontal black bar denotes the median value, the thick black bar denotes the interquartile range and the thin black bar denotes the 95% confidence interval.



Medication reminders (μ_x=4.20, σ_x=1.17) was rated highest in this theme. Patients favored reminders on when to take medication:

> *That is top, the morning medication is not a problem, but the evening medication I sometimes forget because of other activities, so a 5.* [Patient 18]
>
> *Now, I do not experience problems with this as I have to take medication daily. But there have been periods where I had to take medication only twice a week, and that was more complicated. So yes, a 4.* [Patient 21]

The few patients who were less positive typically expressed they had other means to remind them:

> *I usually use my alarm clock to remind me about my medication, so let's give this a 3 out of 5.* [Patient 26]

Posture detection (μ_x=4.23, σ_x=1.15) also scored highly positive. Patients liked an app to detect their posture and flag them when their posture was bad, as emphasized during the interviews by several patients:

> *[..] to use a sensor on their back to detect posture, and flagging whether it was good or bad. I do think this would be good for me to have. So, this is a feature to which I say yes.* [Patient 23]
>
> *Ideally, this would be a kind of clothing you can where and in which your posture measured at multiple points, and then tells you "You are sitting wrongly."* [Patient 3]

Exercise scheduling (μ_x=3.97, σ_x=1.17), *Exercise instructions* (μ_x=3.93, σ_x=1.39), and *Exercise assessment* (μ_x=3.93, σ_x=1.36) received similar positive scores. Patients liked features to make them more physically active, provide instructions on how to do it, and particularly, how to do it well:

> *All initiatives [to get me moving more] are welcome, I can't say no to that.* [Patient 22]

> *I find it particularly important that an app can give instructions on how to do it better. Other features I care less for.* [Patient 26]
>
> *You may exercise as often as you want, but if you do them wrong, there is absolutely no point. So, I definitely welcome anything that would help in this respect.* [Patient 15]

Goal setting (μ_x=3.57, σ_x=1.36) and *Context-awareness exercise support* (μ_x=3.10, σ_x=1.42) although still being rated above 3 did not reach significance. When asked whether they would want to be able to choose a goal and be guided toward this, some patients expressed skepticism about the capabilities of an mHealth app to be able to deliver. Patients also questioned whether the extent of personalization that is needed would be offered by an app:

> *This may be useful if it is personalized. You have to be able to make changes or signal when it is going too fast. Because this is really different for every patient. A healthy person can build endurance but someone who has pain, like me − I feel better one day compared to another − has to be able to get a pass from time to time. So, a 3 if I can make changes and indicate why and flag where it hurts.* [Patient 3]

As for context-awareness support, the same skepticism was encountered. Moreover, it seemed that some patients had a harder time imagining this.

Many patients also expressed their confidence in physical therapists over an mHealth app in this regard. In general, patients highly valued their sessions with the therapist and would not like to see them replaced by an app:

> *I think you're better off going to a physical therapist where everything is explained in more detail and where you are shown how to do the exercises. They can also correct you when you're doing an exercise the wrong way.* [Patient 27]

Disease Insight

The *Disease insight* theme contains features that allow patients to keep a closer watch on their disease and give a deeper insight and/or to communicate about their disease status to health professionals. However, contrary to the *Disease action support* theme, these features do not directly support actions, but rather, they may have an indirect impact on health-related outcomes (Figure 3). The features of this theme were also rated favorably by patients; all features were scored above 3, and 4 out of 5 features were significant.

Logs for reporting (μ_x=4.60, σ_x=0.61) received the highest rating of all 28 features. The interviewed patients favored the ability to log and save data related to their condition in the app and, in particular, to have a way to generate a report of these data to show to their rheumatologist:

> *That might be a good feature to have. I have an appointment with my rheumatologist every 8 weeks and every time I get home, I remember things I should have asked or mentioned.* [Patient 30]
>
> *It seems a useful feature because you forget things rapidly. When [the healthcare professionals] ask you questions but you have already forgotten that something has happened.* [Patient 29]

However, for this feature to be useful, patients also emphasized that it should be easy to use:

> *I'm on the edge. On one side, I think it's great but on the other side… it has to be really easy to enter data, it should not take up too much time.* [Patient 23]

Disease tracking (μ_x=4.13, σ_x=1.12) and *Pain analysis* (μ_x=4.10, σ_x=1.25) were also highly favored. Patients liked the app to automatically collect data related to their condition and liked the app to predict the possible causes of pain based on collected data:

> *If that were possible, yes, please, a 5!* [Patient 9]
>
> *That seems interesting. You typically feel [the cause of pain] yourself but it couldn't hurt to have a confirmation.* [Patient 22]

Yet, here too, patients were skeptical about an app being able to do this:

> *If it measures correctly because I currently have an app but that's not impressive [...] It really has to be able to display reality.* [Patient 23]

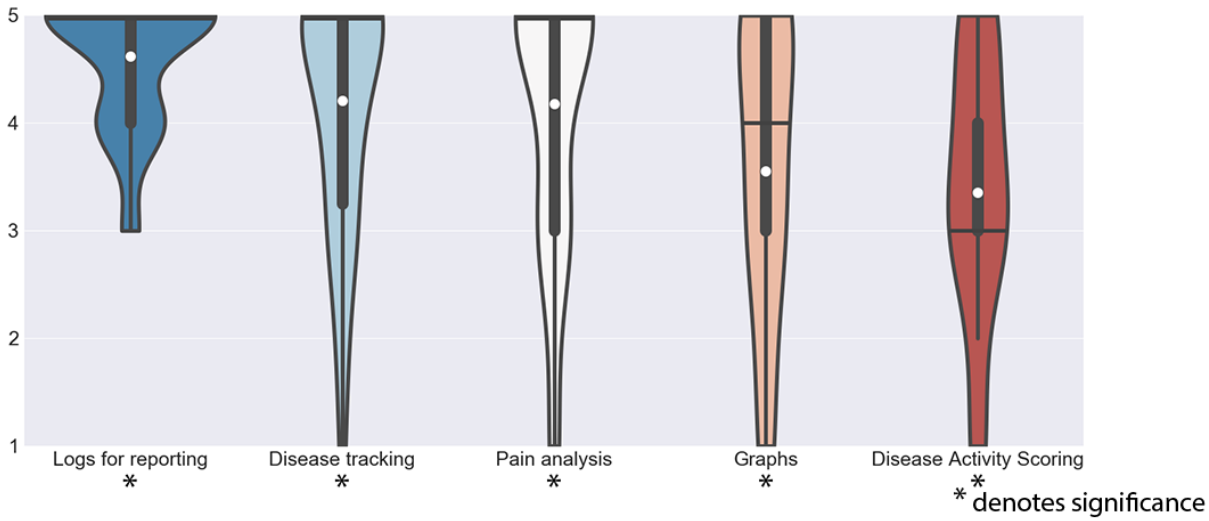
Graphs (μ_x=3.63, σ_x=1.33) were rated positively by some but not all patients. Those patients who were in favor often linked the use of graphs to be able to communicate to professionals, similar to the afore-discussed *logs for reporting*:

> *I think [this feature] is really useful. If they ask me how my last week was and I feel bad right now, then my entire week was bad. If I had a graph, I could show them [my healthcare professionals].* [Patient 3]

Disease activity scoring (μ_x=3.43, σ_x=1.20) was rated lowest in this theme and did not reach significance. Although not expressing dislike, none of the patients currently did this, and consequently, most patients did not see the use for themselves:

> *I would rate this a 3 out of 5 because I wouldn't use [the feature]. I think it's only useful when your disease is still changing. My condition has been stable for the past 20−25 years.* [Patient 27]
>
> *I'm always asking myself: what's the benefit for me? I'm not going to fill in another questionnaire when, in the end, I don't know more than I know right now. My situation is optimal right now, I don't have a lot of problems with my condition, I try not to think about my condition.* [Patient 4]

Figure 3. Scores of features in the group of disease insight. The white dot denotes the mean value, the horizontal black bar denotes the median value, the thick black bar denotes the interquartile range and the thin black bar denotes the 95% confidence interval.



Information

The group of information contains those features that provide either general, tailored (disease-related, at the group level), or personal information on arthritis to the patient (Figure 4). Here scores vary depending on the degree of how tailored information is offered.

Personalized information (μ_x=4.13, σ_x=1.38) as well as *tailored information* (μ_x=4.00, σ_x=1.41) were found favorable by most patients, acknowledging a need for information to help them understand the disease better:

> *That seems useful. When you feel something you haven't felt before […] You attribute every new pain you feel to your condition but maybe you are missing some valuable sign which has nothing to do with your disease.* [Patient 3]

General information (μ_x=3.23, σ_x=1.65), however, was rated only 3.23 out of 5 on average (SD 1.65). Patients did not feel a strong need to read general information related to arthritis in the app. In this case, they would use Google or ask their therapist:

> *You don't need to create an entire book in an app. I can also receive information from my therapist.* [Patient 27]

> *I don't need this. I can also Google everything.* [Patient 3]

Credibility and Styling

The group of credibility contains features related to how the app can increase perceived credibility or be styled to personal liking (Figure 5) by banning advertisements, providing information on the makers, or allowing styling. Scores diverge in this last group, whereas surface credibility (banning advertisements) was highly valued; other features are less outspoken, but still rated positively overall.

Surface credibility (μ_x=4.43, σ_x=1.12) was rated highly. Patients with CA did not want to see advertisements in an mHealth app. However, patients also expressed an understanding that the development and maintenance of such an app comes with a cost and that it had some form of payment:

> *That's the stories of all apps, either you pay or you get ads. I would prefer to not have ads and pay for the app. I would think that the pharmaceutical and medical sector could also learn from the data. Everyone gets better.* [Patient 3]

Verifiability (μ_x=3.50, σ_x=1.48) and *Expertise* (μ_x=3.23, σ_x=1.43) received mixed scores. We polled the importance of listing the people who contributed to the app and or means to verify the content of the mHealth app. Some patients found this highly valuable, but others did not care much:

> *I would like to be able to validate the content of the app. You can read enough on the internet that isn't true. I would like to know for sure that the content is scientifically grounded. […] I only know a few people in one hospital, I won't recognize any one of the specialists listed in the app so I don't think that's useful.* [Patient 3]

> *I only know one rheumatologist in one hospital. If this application would be used nationwide, I wouldn't recognize the people in the app anyhow.* [Patient 3]

Styling (μ_x=2.97, σ_x=1.43) equally received mixed scores; some patients liked being able to add a picture or change the background, whereas other patients were indifferent. Overall, it seemed like a nice feature to have but not an essential feature:

> *This is OK for me, but it is not necessary a 3.* [Patient 18]

Figure 4. Scores of features in the group of Information. The white dot denotes the mean value, the horizontal black bar denotes the median value, the thick black bar denotes the interquartile range and the thin black bar denotes the 95% confidence interval.

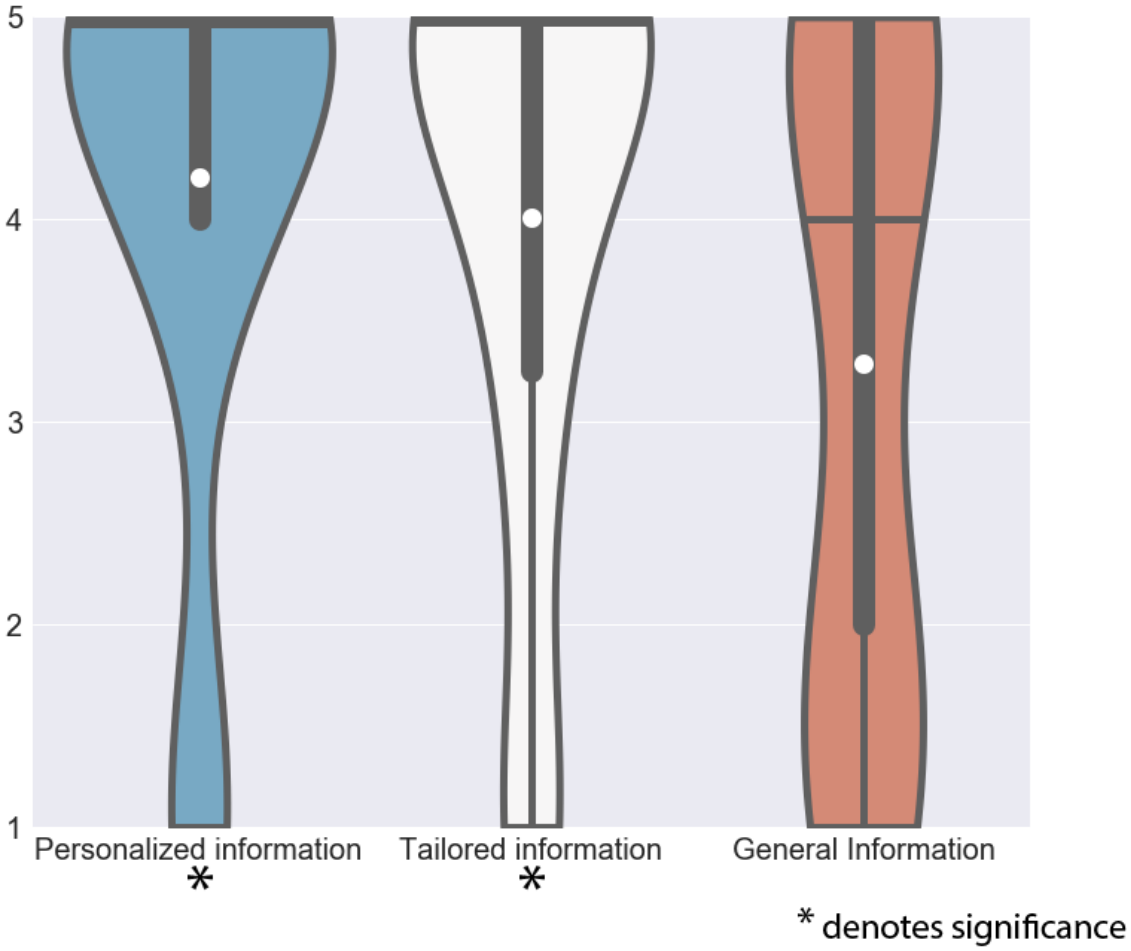
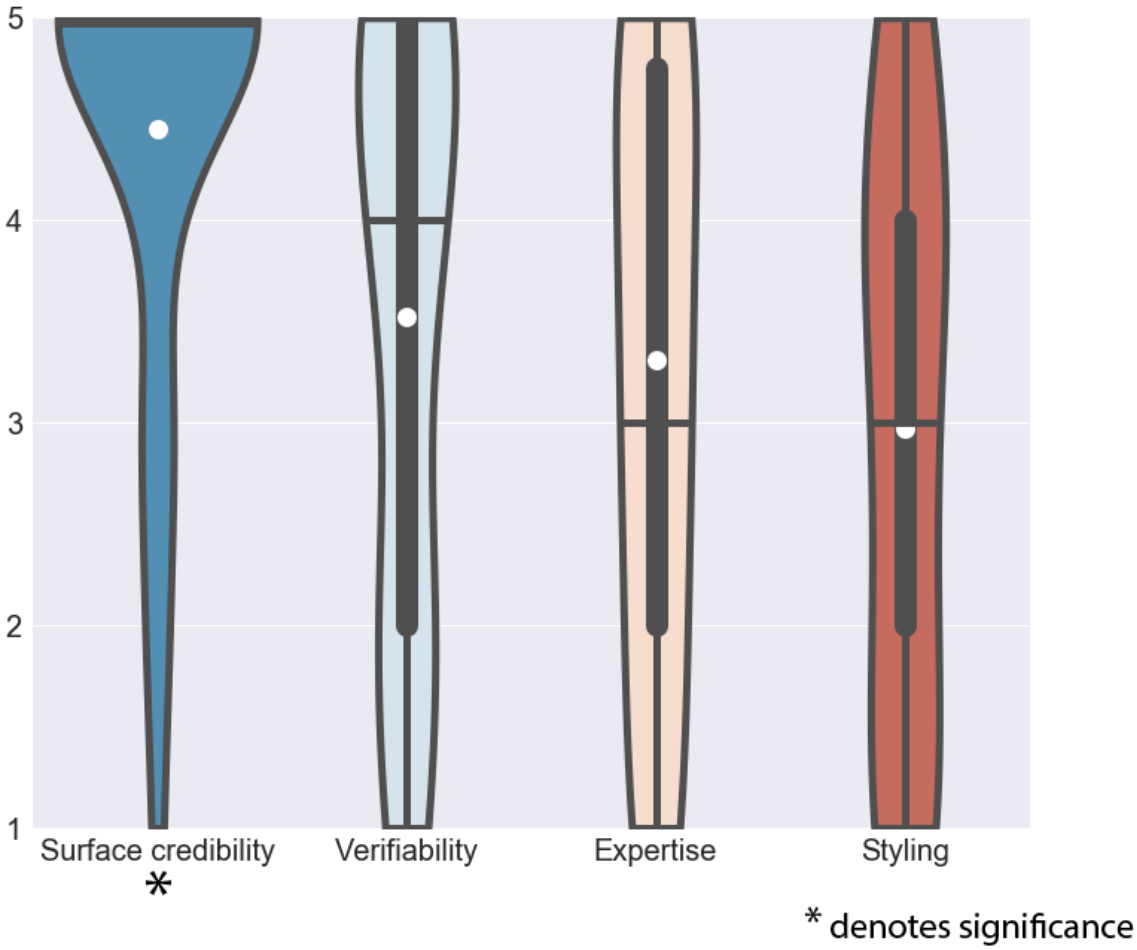


Figure 5. Scores of features in the group of Credibility & styling. The white dot denotes the mean value, the horizontal black bar denotes the median value, the thick black bar denotes the interquartile range and the thin black bar denotes the 95% confidence interval.



Incentivization

The theme of incentivization contains features aimed at increasing a patient's motivation to execute a certain behavior (Figure 6) by providing rewards and giving praise by adding playful elements through gamification. Overall, this theme did not receive positive scores; in fact, none of the features' mean score scored higher than 3.

Praise (μ_x=2.83, σ_x=1.49), *Rewards*(μ_x=2.40, σ_x=1.38), and *Gamification* (μ_x=2.53, σ_x=1.36) received mixed to negative evaluations. *Although s* ome patients liked a positive message offered via the app to motivate them, most patients categorized these as *extrinsic* motivators. They emphasized that they engaged in disease actions such as physical therapy to get better not to receive incentives:

> *Rewards are not necessary for me, I do my physical therapy because it's good for my health.* [Patient 18]
>
> *Getting praising messages is less important than actually reminding me to sit straight or do my exercises. I would like it more when I get a message telling me I'm doing something wrong. [...] Those rewards are not going to take away my pain.* [Patient 3]
>
> *That's for children. Although, it might be useful for some people... maybe children with CA.* [Patient 27]

Social Interaction

The group of social interaction contains features related to interacting, sharing, and comparing via social media or directly with others through the app (Figure 7). This theme scored the lowest of all themes, with all 6 features' average score being below 2.

Receiving *Encouragements* from friends and relatives (μ_x=1.90, σ_x=1.30), *Cooperation* (μ_x=1.80, σ_x=1.22), and *Competition* (μ_x=1.50, σ_x=1.02) all received significant low scores. Patients felt their disease was of a personal matter, and certainly, patients did not want to be a burden to others:

> *I practice for myself, not to compare myself to others, like "Oh look I can't do this, and this patient can." What is important to me is what I can do.* [Patient 15]
>
> *When I'm exercising, I'm exercising for myself. I don't need to involve others.* [Patient 22]

Figure 6. Scores of features in the group of Incentivization. The white dot denotes the mean value, the horizontal black bar denotes the median value, the thick black bar denotes the interquartile range and the thin black bar denotes the 95% confidence interval.

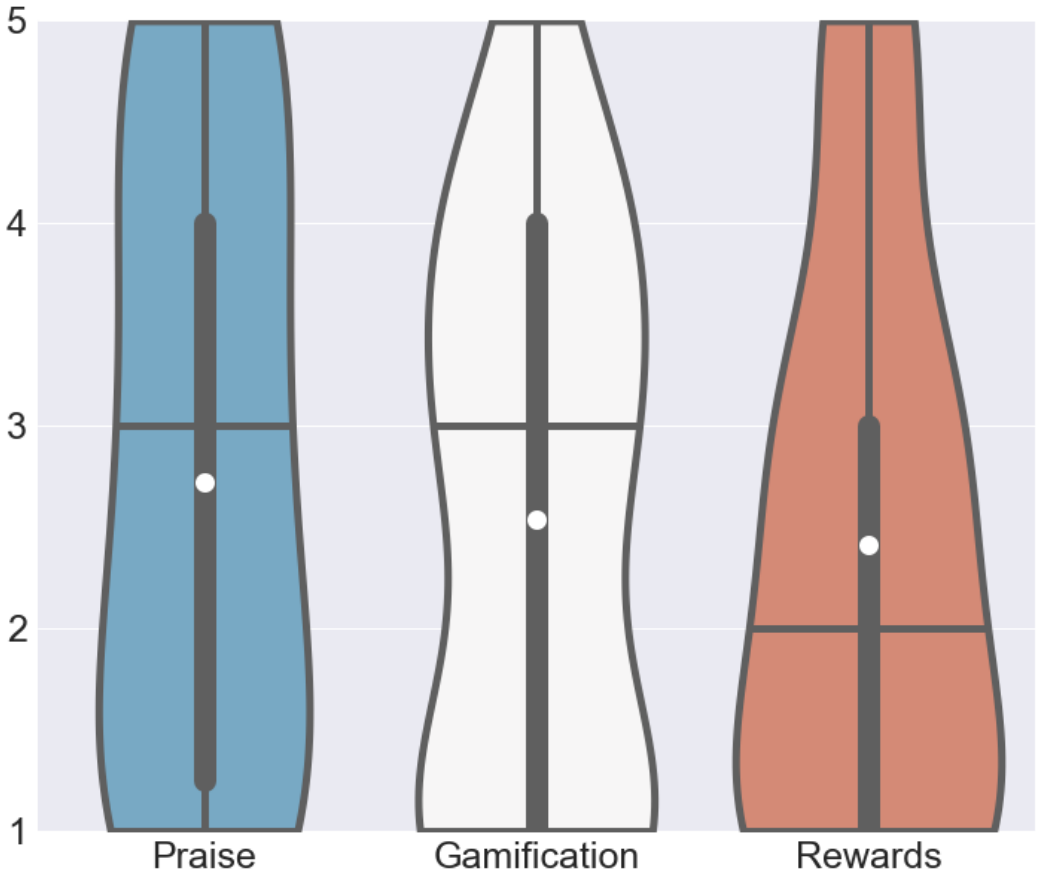
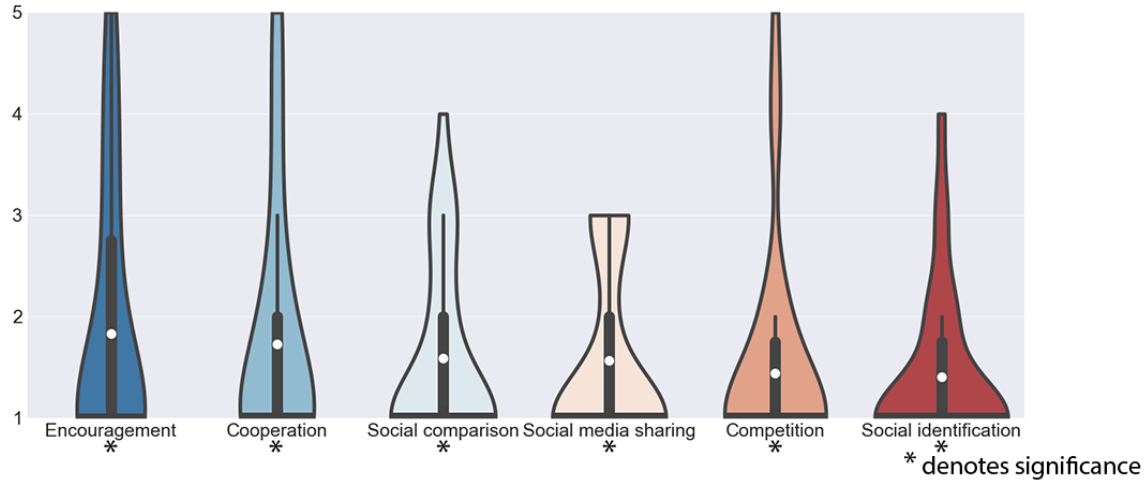


Figure 7. Scores of features in the group of Social interaction. The white dot denotes the mean value, the horizontal black bar denotes the median value, the thick black bar denotes the interquartile range and the thin black bar denotes the 95% confidence interval.



Social media sharing (μ_x=1.53 σx=0.85), *Social identification* (μ_x=1.40, σ_x=0.76), and *Social comparison* (μ_x=1.57, σ_x=0.88) received a similar significant low score. While acknowledging that other patients may find this useful, patients with CA in our sample expressed a strong dislike, often explaining that they felt their disease was a private matter not to be shared via social

media. They also did not think there was much to be learned from others as every patient experiences CA differently:

> *The people in my surroundings know my condition and want me to tell them as little as possible about my disease. I don't want to bore them with my condition.* [Patient 3]
>
> *It's possible that other people need to see this kind of information but I am not interested in seeing this type of data.* [Patient 3]
>
> *I guess this could be interesting [for others] but personally, this is a medical condition and is differently for everyone. I would not like to share it on the internet.* [Patient 26]

Core Concept: Every Patient Hurts in His or Her Own Way

To further our insights into the quantitative data, that is, scorings, we conducted an additional round of qualitative analysis. We identified that throughout the interviews, patients stressed that CA is a lifelong disease with periods of chronic pain and fatigue flaring up, often invisible yet profoundly impacting the patient and his/her surroundings. The way the disease unfolds over time and manifests itself in the patient and social environment is different for every patient, and patients with CA are well aware of this:

> *This disease is personal for everyone and so different to everyone.* [Patient 20]
>
> *Everyone has pain in his own way.* [Patient 16]
>
> *This may be useful if it is personalized. You have to be able to make changes or signal when it is going too fast. Because this is really different for every patient. A healthy person can build endurance but someone who has pain, like me − I feel better one day compared to another− has to be able to get a pass from time to time. So, a 3 if I can make changes and indicate why and flag where it hurts.* [Patient 3]

This awareness that no 2 patients with CA are alike also surfaced in the often careful articulation of scorings; our participants voiced their opinion clearly but then added that other patients with CA might have a different view:

> *I don't need this. But it could be that there are patients that need this. It is, of course, different for everyone.* [Patient 3]

Hence, *all patients hurt in their own way*. Understanding that each patient with CA has a unique experience of living with this chronic and painful disease, with frequent invisible manifestations of symptoms, allows for a deeper understanding of their evaluation of self-management features. On the basis of this understanding, we derived the following implications for the design of mHealth apps, illustrated in Figure 8.

Design Implications

No Need For Social Sharing or Comparing, Chronic Arthritis Is a Private Matter

As mentioned earlier, patients explained that their disease was a personal matter. Moreover, many patients struggled with the social acceptance of the disease and did not want to burden their friends, family, or other patients. Hence, patients with CA saw no use in sharing or comparing the disease status or reaching out for social support:

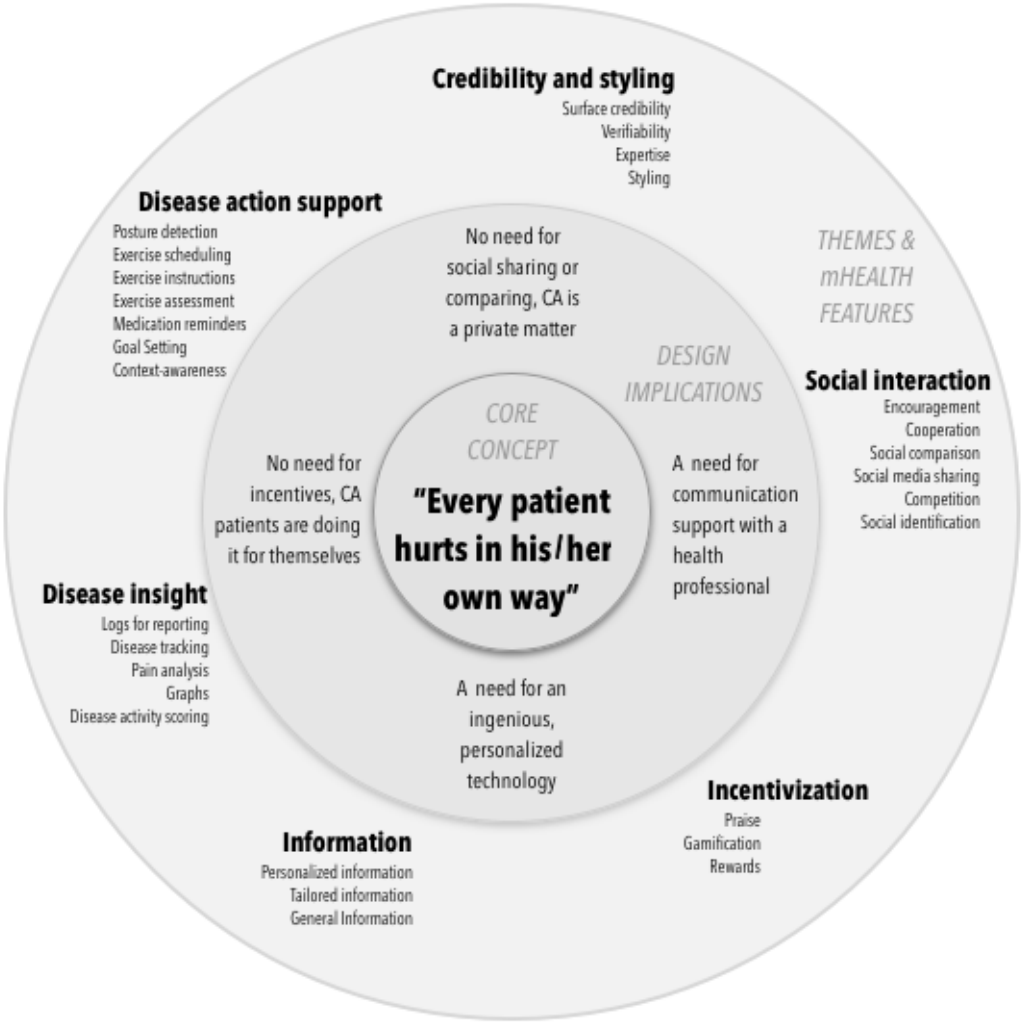
> *People know my disease and prefer me to mention it as little as possible. I do not want to be a drag.* [Patient 3]
>
> *The pain can be excruciating but what I want to emphasize is that CA patients have to face a second struggle, and that is the acceptance by their environment [...] It is hard to explain every time that "no, today I cannot join you for a walk, no I cannot participate in this fun activity." This causes a psychological pressure. I have often been confronted with people saying "you are simply using the disease as an alibi to do nothing all day."* [Patient 28]
>
> *That I would like to see [receiving encouragements]! When I was lying in the hospital for 9 months, even my own mother did not come for a visit.* [Patient 9]
>
> *I like to keep this to myself. My disease should not dominate my social encounters.* [Patient 20]

No Need For Incentives, Chronic Arthritis Patients Are Doing It For Themselves

Patients emphasized consistently they were engaging in disease management activities for themselves, to get better. Incentives in the form of rewards or praise would not help them get better and certainly not take away the pain. Consequently, they saw no use for *external* motivators coming from others or from an app:

> *I exercise for myself, not to compare myself to others, not "Oh, I can only do this, and that other patient still can do more." The most important thing to me is what I can do myself.* [Patient 15]
>
> *To be reminded to maintain a certain posture is more important than receiving "Congrats!" [...]. I prefer to be reminded that I am doing something wrong, I do not need to be rewarded.* [Patient 3]
>
> *I don't need that [rewards]. I'm doing this because it is good for my health, for my well−being.* [Patient 18]

Figure 8. Image illustrating the relation of the core concept to design implications and themes and mHealth features.



A Need For Communication Support With a Health Professional

The highest rated feature in our study was *Logs for reporting*, a feature that supports communication with health professionals. Again, from an understanding that every patient with CA is different, it is important for them to make health professionals understand the specific peculiarities they are confronted with. Patients frequently reported forgetting disease-related events during the months between doctors' appointments. Some patients addressed this issue by keeping a paper diary in which they noted events such as pain, stiffness, and medication intake. By being able to keep track of such events (logs and graphs), this may help specialists to provide a better diagnosis and hence the best possible care:

> *It seems a useful feature because you forget thing rapidly. When [the healthcare professionals] ask you questions but you have already forgotten that something has happened.* [Patient 29]
>
> *Yes, because the rheumatologist is better able to follow−up on your condition, and there is less chance of coming to a wrong conclusion.*
>
> *Interviewer: Do you mean that the rheumatologist then has a better picture?* [Patient 30]
>
> *Yes, the doctor is better informed and will be more able to tailor the treatment.* [Patient 30]

A Need For Ingenious, Personalized Technology

Finally, many participants expressed reservations about the extent to which sensor and phone technology would be truly able to realize this *promise* of personalized self-management features. Patients were often skeptical and gave high scores in a *conditional* manner. Patients who ended up giving a lower score often did not believe that the app would be able to be technically performant or be personalized enough:

> *If the content is very heavily personalized to my needs, I would like this. But only if I can still adapt the schedule based on my progress because I might not feel well every day*
>
> *Interviewer: Sensors measure whether you execute an exercise the right way* [Patient 3]
>
> *And how exactly would that work?Interviewer: Well, your mobile phone would connect to sensors to measure what movements you make. So the phone can do this? Wow, that would be great then, a 4.* [Patient 21]

> *It has to be quite ingenious to work, for now, I don't know.Interviewer: Well, that's the purpose.* [Patient 3]
>
> *Well it if works, I say OK, a 5, but I doubt it a bit. My physical therapist can tell me: "OK, you can bend till there, but if you feel you can't, please stop." If an app is supposed to give these instructions... Personally, I think that will be very hard to realize. There are so many different variants of arthritis that it will be really hard to program.* [Patient 3]

Patients with CA value this bond with physical therapists who could deliver highly personalized therapies. Many patients stressed that they valued the face-to-face contact and would not like to see the therapist be replaced by an app:

> *We have known each other for years, we do these exercises together. When we are lying on the ground and I doubt how to do it, then I look at how he is doing it. You don't lose time because you need to practice that hour anyhow. Otherwise, you would need to look at an instructional video.* [Patient 3]

Discussion

Principal Findings

To summarize our findings, patients with CA valued the use of self-management features that support active and direct disease management. In this regard, they welcomed features that support medication intake, posture detection, and physical exercise. Patients also welcomed features that help them keep a close watch on their disease status and contribute to their health professional's understanding of their disease. In this regard, they liked to have logs to communicate and analyze disease parameters such as pain and provide doctors with more insights on when and how this was manifested. The need for personalized and tailored insights was also reflected in the *information theme*. These findings are in line with the findings of earlier studies [15,22-24,33,34]. Interpreting these results in light of the self-management roles identified by Lorig et al [35], it becomes apparent that our sample of participants finds value in those mHealth features that support medical management tasks (ie, tasks to manage the condition such as taking medication, adhering to a special diet, or using an inhaler).

However, the patients with CA in our sample did not support features that support role management (ie, maintaining, changing, and creating new meaningful behaviors or life roles) or emotional management (learning to manage emotions such as anger, fear, frustration, and depression). In contrast with aforementioned studies, we did not find support for embedding features relating to social interaction [20]. This finding may be counterintuitive at first sight as it is generally acknowledged that social support is beneficial for a patient's therapeutic trajectory [24,35-37] and paramount for a patient's acceptance of the disease [38].

One possible explanation could be the difference in exposure to peer support and/or the use of social networking technology between younger and older age groups, as described by Vaterlaus et al [26]. However, by acknowledging that all patients with CA hurt in their own way, another possible cause may relate to disease duration: patients who have lived with CA for a longer time have learned to manage and understand the peculiarities of their disease as well as the impact on their social environment. Our sample of participants represents an older group of patients who have experienced *the waxing and waning* of the disease [35]. Although adolescents might be on their way of getting control over their condition, and actively looking for support from peers and or external confirmation through incentives, older patients with CA may have come to realize that their disease is a personal matter and may try to limit the *direct* impact on their social circle. It may be that for older patients with CA, acceptance is promoted, not by centralizing the disease itself but rather by undertaking meaningful activities in a social context despite the disease [39-44].

A third possible explanation may be that some of the studies that find positive evaluations of social interaction assume an in-person delivery, whereas the features we researched are inherently delivered through an mHealth app. Patients may prefer social interaction in real life but may not want the same interactions to occur through the means of an mHealth app.

In addition, our study did not find support for including mHealth features with regard to incentivization (ie, praise, rewards, and gamification). This is again in contrast with earlier studies [22-24]. Again, it may be that our older sample has come to live with *shifting perspectives* where sometimes wellness and sometimes illness move to the foreground [45]. It has been well documented that the major concern of patients with arthritis is pain management [46], and this was no different among our sample. As the disease progresses and patients age, pain management may become increasingly central to disease management of CA. Considering this, the use of *playful* extrinsic motivators may be considered irrelevant; our sample emphasized how such features would not help combat pain.

Finally, the different outcomes may also be the result of different research methods. Whereas prior studies rely on focus groups where participants explored and discussed possible features, our method started from an individual rating of given features. Often, our patients gave a negative scoring but added that other patients may feel differently. Interestingly, while acknowledging differences among patients with CA, patients in our sample were univocal in their dismissal of incentivization and social interaction features. These findings show the importance of inclusive methods in the development of mHealth apps. Although the BCT of Michie et al [47] and PSD model of Oinas-Kukkonen et al [9] offer inspiring models enlisting myriad BCTs or persuasive principles, an additional step is required to select those most preferred by specific audiences.

To conclude, this finding promotes a participatory design process for mHealth apps, involving patients, health care professionals, and developers in the creation of the app, but it equally promotes empirical measurement [48] and preference ranking of features [49]. Using a blend of inclusive methods ensures that those features deemed most useful by all stakeholders (caregivers and patients) end up in the app [50].

Limitations and Future Work

We interviewed 31 patients and asked them to rate 28 features of an mHealth app for patients with CA. We described these features and gave extra information when asked for. Even though these steps were taken with care, some features may have remained elusive for patients to imagine. This may have been further influenced by a lack of past experience with mHealth and information and communication technology. It may have been difficult for some patients to see how these features would unfold and impact them. Unfortunately, we did not measure internet use, technology habits, and education or occupation and cannot verify how this impacted attitudes of patients with CA toward mHealth features. Hence, we suggest future studies to ask for this information. We also suggest future studies to provide examples of features being incorporated into existing apps or prototypes, for example, in the form of screenshots, to make them more tangible.

Furthermore, as we used the same order of self-management features for all patients (see Textbox 1), we may have introduced order effects. It may have been that patients with CA experienced fatigue toward the end of the interview and provided less information and/or different scorings. However, the richness in the results from the qualitative data analysis suggests that if there was an order bias, it was small. Moreover, owing to the semistructured nature of the interviews, whenever patients felt the need to digress from the order and express ideas differing from the fixed list of questions, they were free to do so. Our interviews show that they frequently did.

Finally, although we aimed for a heterogeneous sample of patients with regard to age, gender, and disease parameters, it is still a predominant white sample. With a median age of 53 years, living on average for 21 years with the disease already, the patients with CA in this study represent an older CA population. Hence, extrapolation to other younger adult populations needs to be done with care. In particular, ratings toward incentives, gamification, and social interaction may differ. On the basis of the psychological processes underlying the development of chronic pain (eg, fear avoidance versus fear endurance [46,51]), other researchers have shown the presence of subpopulations in chronic patients [43,52,53]. Further research could investigate how different subtypes further impact preferences for features and how mHealth apps may need further tailoring. Follow-up studies with different patient populations from different genders, ethnic backgrounds, socioeconomic status, and with different disease subtypes and/or comorbidities are needed.

Conclusions

Data emerging from 31 interviews with patients with CA provided valuable insights into which mHealth app features are favored and which are disliked by patients. Patients had strong negative opinions regarding social features, stemming from the individual nature of managing one's disease. They often remarked how everyone's disease progress is different and how they did not want to bother others with their suffering. In addition, they did not want to receive incentives for completing disease-related actions as they claimed to be intrinsically motivated to get better. They did, however, have a strong preference for features, which enable them to keep better track of their condition and report these data to their health care professionals. They favored receiving tailored information, based on their own data, but at the same time questioned the possibility for an mHealth app to achieve this level of tailoring. We hope the results of this research can inform mHealth app developers as to which features are most valuable to include in an mHealth app for patients with CA.

Conflicts of Interest

None declared.

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Abbreviations

BCT: Behavior Change Technique
CA: chronic arthritis
JIA: juvenile idiopathic arthritis
mHealth: mobile health
PSD: Persuasive System Design

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Original Paper

Development and Long-Term Acceptability of ExPRESS, a Mobile Phone App to Monitor Basic Symptoms and Early Signs of Psychosis Relapse

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Abstract

Background: Schizophrenia relapses are common, have profound, adverse consequences for patients and are costly to health services. Early signs interventions aim to use warning signs of deterioration to prevent full relapse. Such interventions show promise but could be further developed. This study addresses 2 developments: adding basic symptoms to checklists of conventional early signs and using a mobile phone app ExPRESS to aid early signs monitoring.

Objective: This study aimed to (1) design a pool of self-report items assessing basic symptoms (Basic Symptoms Checklist, BSC); (2) develop and beta test a mobile phone app (ExPRESS) for monitoring early signs, basic symptoms, and psychotic symptoms; and (3) evaluate the long-term acceptability of ExPRESS via qualitative feedback from participants in a 6-month feasibility study.

Methods: The BSC items and ExPRESS were developed and then adjusted following feedback from beta testers (n=5) with a schizophrenia diagnosis. Individuals (n=18) experiencing a relapse of schizophrenia within the past year were asked to use ExPRESS for 6 months to answer weekly questions about experiences of early signs, basic symptoms, and psychotic symptoms. At the end of follow-up, face-to-face qualitative interviews (n=16; 2 were uncontactable) explored experiences of using ExPRESS. The topic guide sought participants' views on the following *a priori* themes regarding app acceptability: item content, layout, and wording; app appearance; length and frequency of assessments; worries about app use; how app use fitted with participants' routines; and the app's extra features. Interview transcripts were analyzed using the framework method, which allows examination of both *a priori* and *a posteriori* themes, enabling unanticipated aspects of app use experiences to be explored.

Results: Participants' mean age was 38 years (range 22-57 years). Responses to *a priori* topics indicated that long-term use of ExPRESS was acceptable; small changes for future versions of ExPRESS were suggested. *A posteriori* themes gave further insight into individuals' experiences of using ExPRESS. Some reported finding it more accessible than visits from a clinician, as assessments were more frequent, more anonymous, and did not require the individual to explain their feelings in their own words.

Nevertheless, barriers to app use (eg, unfamiliarity with smartphones) were also reported. Despite ExPRESS containing no overtly therapeutic components, some participants found that answering the weekly questions prompted self-reflection, which had therapeutic value for them.

Conclusions: This study suggests that apps are acceptable for long-term symptom monitoring by individuals with a schizophrenia diagnosis across a wide age range. If the potential benefits are understood, patients are generally willing and motivated to use a weekly symptom-monitoring app; most participants in this study were prepared to do so for more than 6 months.

Trial Registration: ClinicalTrials.gov NCT03558529; https://clinicaltrials.gov/ct2/show/NCT03558529 (Archived by WebCite at http://www.webcitation.org/70qvtRmZY).

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KEYWORDS

schizophrenia; psychotic disorders; recurrence; telemedicine; mobile health; mHealth; eHealth; mental health

Introduction

A total of 80% of those with first episode psychosis relapse within 5 years [1,2], which often leads to unplanned admissions [3-5], increased personal distress [6], vocational disruption [7], worse residual symptoms [8], and risk of suicide [9-11]. Interventions using early signs of deterioration (eg, increased anxiety and insomnia) to prompt timely preventative action can forestall relapse [12-14] but could be further developed by improving relapse prediction and increasing engagement with long-term early signs monitoring [15]. This study addresses 2 such developments: (1) adding basic symptoms to checklists of conventional early signs and (2) using mobile phone technology to aid early signs monitoring.

Basic symptoms are subtle, subjective changes in individuals' experiences of themselves (eg, difficulty managing attention) and the world around them (eg, more vivid colors) that predict first episodes of psychosis [16,17] and might predict relapses [18-20]. The most comprehensive studies to date have been retrospective [18,19]. One prospective study [21] examined 10 items resembling basic symptoms, but the authors did not explicitly state that these were basic symptoms or specify how they were measured [19]. There is a clear need for a well-powered, prospective study to establish whether combining basic symptoms with conventional early signs improves relapse prediction. We plan to carry out such a study using a phone app to facilitate monitoring, in line with recent developments in mobile health (mHealth) for psychosis.

In this study, we describe the development and long-term acceptability of ExPRESS, a phone app that monitors basic symptoms and conventional early signs of psychosis relapse on a weekly basis, and the basic symptoms checklist (BSC), the pool of self-report items used to assess basic symptoms in the app. Both as a research tool and in clinical practice, an app potentially has numerous advantages over face-to-face [22], postal [23], or text message-based [24] assessments of early signs of relapse. An app can be accessed at times and places convenient to the patient, as mobile phones tend to be carried around from place to place and their use is often integrated within daily life [25]. Monitoring early signs with an app is less resource intensive, intrusive, time consuming, and burdensome than weekly visits from a researcher or clinician. People with a schizophrenia diagnosis find apps acceptable for short-term self-monitoring [26] and prefer them to text message–based systems [27]. Native phone apps are preferable to Web-based systems, being less dependent on a good data or Wi-Fi connection and, therefore, more accessible in rural locations and for low-income users [25]. Furthermore, apps can include automated features such as reminders, generation of graphs, and secure upload of data, which might enhance user experience and increase engagement.

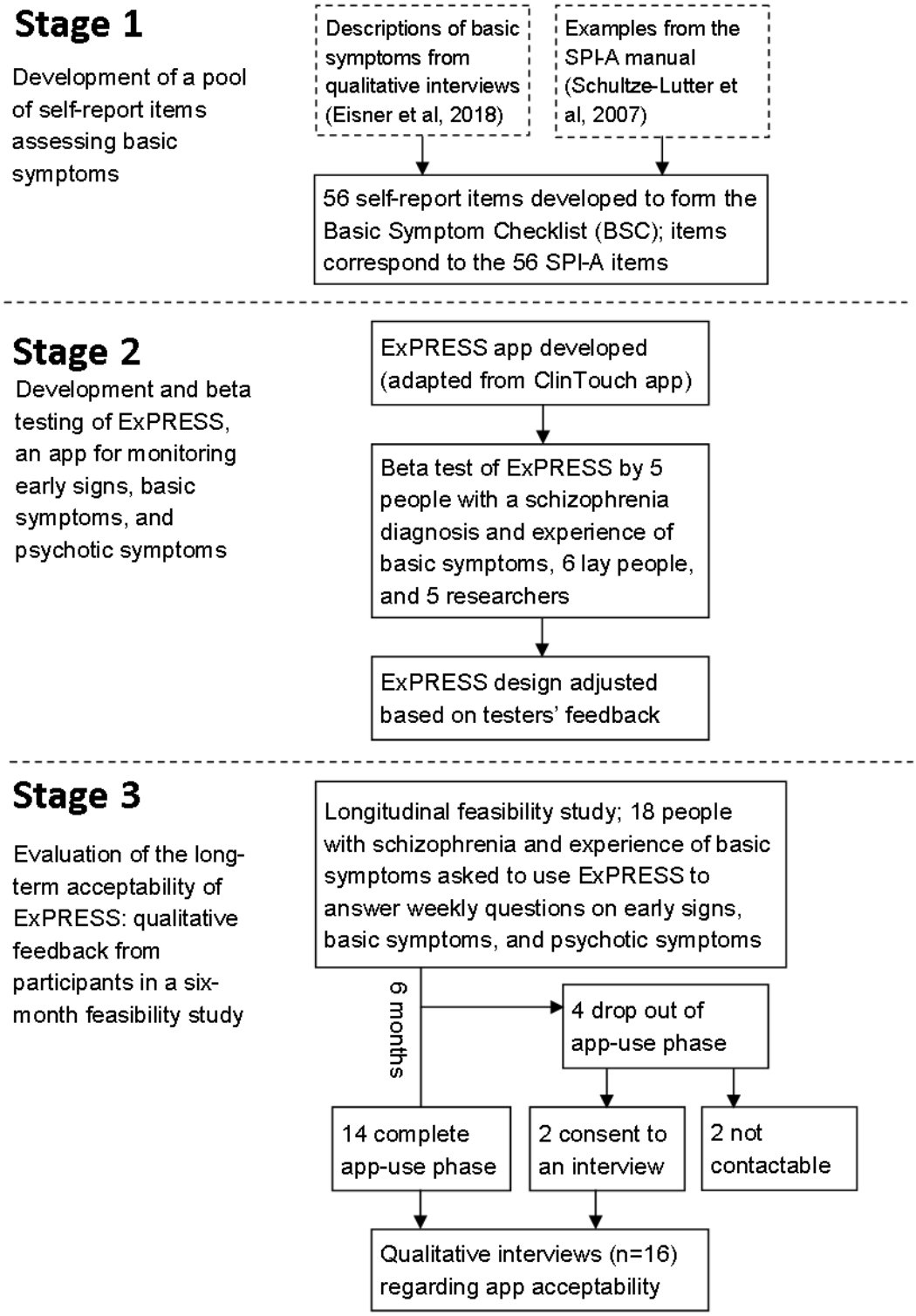
We know of 9 published studies that have prospectively assessed symptom course using a phone app [26-34] but none testing an app to monitor early signs of psychosis relapse. Only 1 study to date has evaluated a symptom monitoring app for longer than 6 months [34], and none in a sample with established psychosis. Much current literature relies on satisfaction ratings of apps for psychosis [25,33-35]. Only a few studies include qualitative feedback from people with psychosis regarding actual [28,36,37] or hypothetical [38-41] acceptability of apps to monitor or ameliorate psychosis symptoms. Most had relatively young samples, likely to be more *au fait* with this technology (*digital natives*) than is typical of those with chronic psychosis, and none examined psychosis patients' experiences of long-term native phone app use.

Integrating user feedback into the design of mobile phone apps and psychological interventions is best practice [28,36,42-44] and improves engagement with digital tools for psychosis [45]. Ben-Zeev et al [25] recommend that researchers publish descriptions of app development, including specific ways the design was influenced by user feedback. Accordingly, we provide details of the ExPRESS app design and how it was changed in response to feedback during beta testing. We then describe a qualitative analysis of in-depth feedback from longitudinal feasibility study participants regarding the actual acceptability of the app (*a priori* themes), as recommended in a recent systematic review [46]. Framework analysis [47] allowed us to also consider *a posteriori* themes to further understand patients' experiences of long-term symptom monitoring with a phone app. The rich qualitative data provided valuable information on how people with psychosis use symptom monitoring apps, whether they perceive any value from doing so and what challenges they might encounter.

We describe 3 stages of the study (Figure 1), with the following 3 aims:

1. Stage 1: To design a pool of self-report items assessing basic symptoms (BSC);
2. Stage 2: To develop and beta test a mobile phone app ExPRESS for monitoring early signs, basic symptoms, and psychotic symptoms; and
3. Stage 3: To evaluate the long-term acceptability of ExPRESS by gathering qualitative feedback from participants in a 6-month feasibility study.

Figure 1. Flow diagram of study design. BSC: Basic Symptom Checklist; SPI-A: Schizophrenia Proneness Instrument, Adult Version.



Methods

Stage 1: Basic Symptom Item Pool

A pool of 56 self-report basic symptoms items was developed to form the BSC. Item wording was based on qualitative interviews in which participants described basic symptom experiences before psychosis relapse [19] and descriptions and examples given in the Schizophrenia Proneness Instrument, Adult Version manual (SPI-A) [48]. Our retrospective study [19] is one of the few to collect quotations from English-speaking participants regarding basic symptoms, making it an ideal foundation for an English-language self-report measure. Items were specifically designed for mobile phone app completion and had a 7-point visual analog scale with 2 anchors (*Not at all*; *A great deal*).

Stage 2: ExPRESS App Development

Overview of ExPRESS

The software was adapted from ClinTouch [26], a symptom-monitoring app assessing 12 Positive and Negative Syndrome Scale (PANSS) [49] and 2 Calgary Depression Scale (CDS) [50] items. ClinTouch and ExPRESS are compared in Table 1. They share their look, feel, and general functionality, but features such as item content and alert frequency differ, as does the period of monitoring studied.

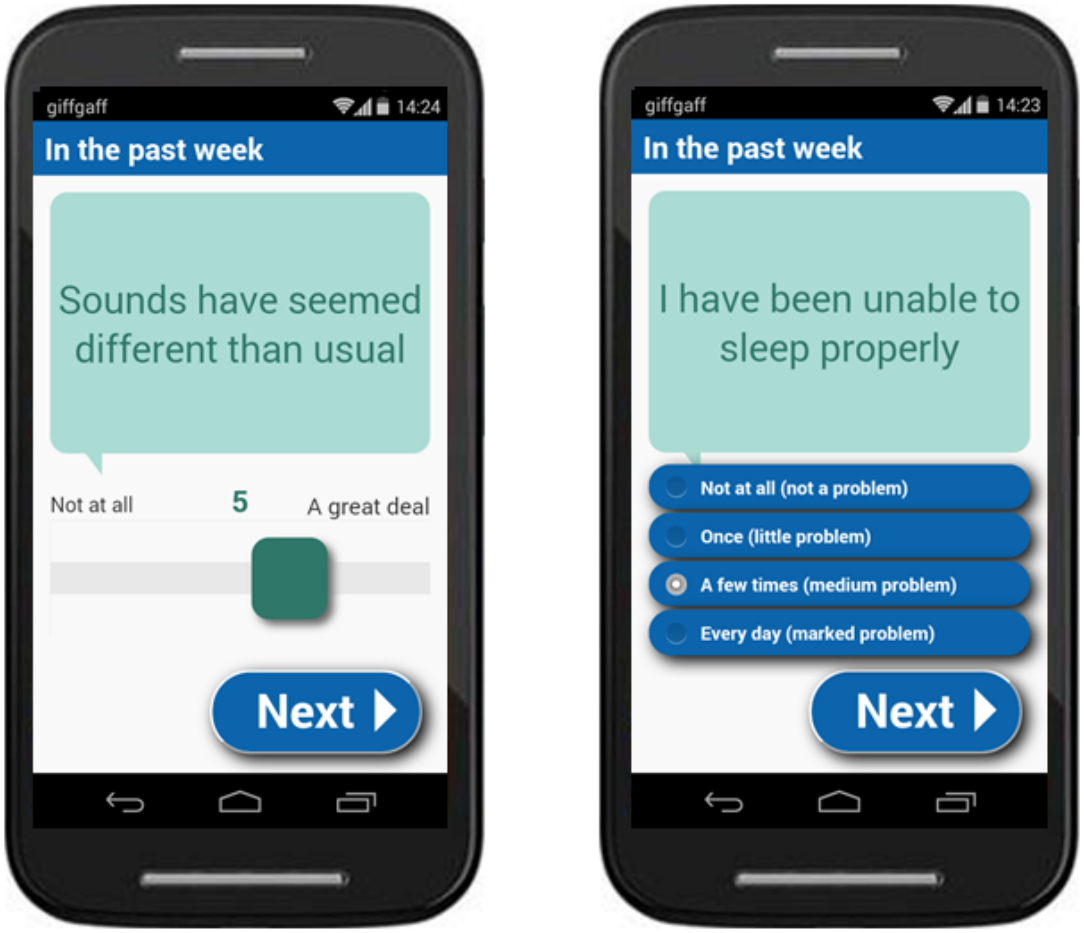
ExPRESS includes a pool of 5 PANSS and 2 CDS items, plus items from the BSC, the early signs scale (ESS) [51], fear of recurrence scale (FoRSe) [52], and optional personalizable items. All assessments relate to the past week, with PANSS, CDS, BSC, and personalizable items answered by moving a sliding bar along a 7-point visual analog scale and ESS and FoRSe items scored on a 4-point ordinal scale (Figure 2). Individuals do not use all items but select a subset of relevant items (≤5 from BSC; ≤5 from ESS or FoRSe; and ≤5 personalizable items) for monitoring, together with all 7 PANSS and CDS items. PANSS and CDS items include additional follow-up questions (eg, *This stopped me from doing things*) contingent on the user's answer to an initial question (eg, *I have heard voices*). The total number of questions to be answered per week ranges from 26 to 53, with the average number asked in this study being 42.

Table 1. Comparison of ClinTouch and ExPRESS app design.

App feature	ClinTouch app	ExPRESS app
Items		
Items scored on a 7-point visual analog scale, using a sliding bar with 2 anchors	12 PANSS[a] items: delusions, hallucinations, suspiciousness, grandiosity, anxiety, depression, guilt, somatic concern, passive apathetic social withdrawal, hostility, excitement, and conceptual disorganization; and 2 Calgary Depression Scale items: depression and hopelessness	5 PANSS items: delusions, hallucinations, suspiciousness, grandiosity, and anxiety; 2 Calgary Depression Scale items: depression and hopelessness; Basic Symptoms Checklist (56 items); and optional personalizable items
Items scored on a 4-point Likert scale	None	Early Signs Scale (34 items) and Fear of Recurrence Scale (3 items)
Items that can be personalized (eg, based on baseline interview)	PANSS delusions items (≤2)	Basic Symptoms Checklist (≤5), Early Signs Scale or Fear of Recurrence Scale (≤5), personalizable items (≤5), and PANSS delusions items (≤2)
Extra features		
Wallpaper	Yes	Yes, with new photos
Daily diary	Yes	Yes
Graphs of delusions and hallucinations	Yes	Yes
Useful numbers	Yes	Yes
Alerts		
Frequency of alerts	6 pseudo-random occasions per day	Once per week
Alert day(s)	Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, and Sunday	Wednesday, 1.30 pm
Time window for answering the questions	15 min	24 hours
Snooze options	Snooze for 5 min	First snooze for half an hour and second snooze for 22.5 hours
Data upload		
Data upload	Wireless upload using mobile internet	Wireless upload using mobile internet
Data storage	Secure server at the University of Manchester	Secure server at the University of Manchester

[a]PANSS: Positive and Negative Syndrome Scale.

Figure 2. Screenshots of an example basic symptom item (left) and early signs item (right) displayed on the ExPRESS (Experiences of Psychosis Relapse: Early Subjective Signs) app.



ExPRESS alerts the participant to answer questions once a week (1.30 pm on a Wednesday), using a beep and visual notification. The participant has 24 hours to answer. They have the option to snooze the app and receive additional alerts after 0.5 and 22.5 hours. Using the mobile phone's internet connection, ExPRESS automatically uploads participants' responses to a secure server maintained by the University of Manchester, where responses are accessible to the research team via a password-protected Web interface.

As in ClinTouch, participants could choose to personalize the app by changing the wallpaper and could view automatically generated graphs of recent responses to delusions, hallucinations, and mood items. There was also a daily diary for the individual's own reference (not uploaded) and a section containing useful numbers (eg, Samaritans).

Beta Testing

ExPRESS was beta tested on a variety of mobile phone handsets by psychology researchers (n=5) and lay people (n=6) for 1 week each. Separate, one-off beta tests were then conducted by patients (n=5) with a schizophrenia-spectrum diagnosis (Diagnostic and Statistical Manual of Mental Disorders, 4th Edition; DSM-IV) and experience of basic symptoms. Participants were given an overview of ExPRESS and were asked to perform a series of in-app tasks (observed by the researcher) and to provide comments using a structured app-evaluation form (Multimedia Appendix 1). Their feedback and the researcher's observations were collated, and proposed changes to ExPRESS were discussed by the research team. Given the study's finite resources, namely, computer programmer time, changes that improved the app's functionality and were in line with its overall purpose were prioritized (eg, adding *in the past week* to all questions to clarify which period they refer to).

Stage 3: 6-Month Feasibility Study and Qualitative Interviews

Feasibility Study

Patients (n=18; convenience sample) were recruited from 3 NHS Mental Health Trusts in the North West of England to participate in a 6-month, single-arm, open longitudinal feasibility study (see study protocol for full details [53]; Research Ethics Committee reference 14/NW/1471). They were trained on ExPRESS (on their own phone, if compatible, or on a study phone) and asked to use it weekly for 6 months or until relapse, whichever was sooner. Participants received supportive telephone calls from the researcher (weekly for the first 4 weeks and monthly thereafter) to encourage participation and troubleshoot any difficulties with app use. Those using ExPRESS on a study phone received weekly text messages to their own phone number to remind them to use the app. For

participants giving additional consent, app assessments were sent to a named clinician. Notes on all telephone calls and face-to-face meetings with participants during the follow-up period were included in the study feasibility diary. At the end of follow-up, all participants were invited (via telephone) to take part in a qualitative interview, including those who had dropped out of the app use phase (n=4, of whom 2 were uncontactable). Quantitative findings from the longitudinal feasibility study are reported elsewhere.

Inclusion criteria for the longitudinal feasibility study were as follows: schizophrenia-spectrum diagnosis (DSM-IV); at least 1 acute psychotic episode in the past year (exacerbation of psychotic symptoms lasting at least 2 weeks and requiring a management change, including admission) or at least 2 acute episodes in the past 2 years, including index episode; reporting basic symptoms (assessed using SPI-A), which began or increased before a previous psychotic episode; currently prescribed antipsychotic medication; age over 18 years; fluent in English; fixed abode; sufficiently stable to take part; no current alcohol or drug dependence (Structured Clinical Interview for DSM-IV, [54]); and providing informed consent.

Qualitative Interviews

Qualitative interviews were conducted at the end of the 6-month feasibility study by 2 researchers (EE and NB) using a topic guide (Multimedia Appendix 2; piloted with 1 lay participant) covering: item content, layout, and wording; app look and feel; length and frequency of assessments; worries about app use; how app use fitted with participants' routines; the app's extra features; and other experiences of using the app. Both interviewers were female PhD researchers with Master's degrees and experience conducting qualitative interviews; EE had met all interviewees 6 months earlier, whereas NB had spoken to them via telephone only. Participants knew that EE had developed the app as part of her PhD research and that NB was covering maternity leave.

Interviews were conducted in participants' homes or a nearby NHS service, ranged from 7 to 53 min (mean 20 min), and were audio-recorded. Immediately afterward, the interviewer made notes in a reflective journal (eg possible themes, topic guide additions, and contextual details). In 3 cases, a nonparticipant was also present in the interview, in accordance with the study's lone-worker policy. The researcher telephoned 1 participant shortly after the interview to clarify a point they had made. However, because of time limitations, transcriptions were not returned to participants for comment and participants were not asked to give feedback on the findings. Data saturation was not reached, despite all consenting, eligible individuals (feasibility study participants) taking part.

Framework Analysis

The research team conducted a framework analysis (Table 2) of interview transcripts and the study feasibility diary. The framework method allows a combination of deductive and inductive coding to be used [47]. This was appropriate as there were specific issues that we set out to investigate (*a priori* themes, eg, participants' views on the item wording), while also allowing space to explore unanticipated aspects of participants' experiences (*a posteriori* themes).

Reflexivity

EE is a PhD researcher investigating measurement of basic symptoms using a mobile phone app; SB (a clinical psychologist) and RD (a psychiatrist) have worked extensively with individuals with psychosis, both in a clinical and research capacity; and SB and NB are involved in several studies investigating digital health interventions (DHIs) for this population. Although the multidisciplinary nature of the research team promoted consideration of a variety of interpretations, we inevitably brought certain expectations and assumptions to the interview and analysis process, for example, an attachment to the app's features that we had designed and hoped would be well received. Several steps were taken to minimize potential bias. Questions in the topic guide were worded in an open, neutral manner that avoided indicating researchers' opinions. Interviewers were careful not to put pressure on participants to answer in a certain way. All ideas, insights, discussions, and decisions during data collection and analysis were documented in a reflective journal. The first author also avoided reading any closely related literature (qualitative studies of app interventions) during the analysis process to avoid biasing her interpretation.

Table 2. Framework analysis method with details regarding its use in this study.

Stage	Description	Procedure	Details of this stage in this study
1	Transcription	Audio-recorded interviews transcribed verbatim	EE[a] transcribed all 16 interviews verbatim.
2	Familiarization	Read transcript and listen to audio recording	SB, RD, and NB each read 2 of the first 3 interview transcripts, and EE listened to audio-recordings and read transcripts of all 16.
3	Coding	Read transcript line by line and apply a code describing why that section is important	EE, SB, RD, and NB independently coded ≥2 of the 3 transcripts. *A priori* codes (eg, *item wording* and *clinician access*) were predefined by EE based on the topic guide (deductive coding), and inductive coding was used for other potentially relevant topics.
4	Developing a working analytical framework	Researchers compare codes and agree a set of codes for subsequent transcripts	EE, SB, RD, and NB met and discussed their coding; differences were resolved and a working analytical framework agreed. The discussion was audio-recorded for reference and noted in the reflective journal.
5	Applying the analytical framework	The working analytical framework is applied to subsequent transcripts	EE recoded the first 3 transcripts and then coded the remaining 13 transcripts and feasibility diary using the working analytical framework; NVivo was used to manage this process. The framework was updated where necessary (eg, new code needed), with changes discussed periodically with SB, RD, and NB. A final framework was agreed, and EE recoded all 16 transcripts and the feasibility diary for consistent coding across the dataset.
6	Charting data into the framework matrix	Data are summarized in a framework matrix. Illustrative quotations are included	EE charted the data into 2 framework matrices: 1 containing *a priori* codes and the second containing *a posteriori* codes. Both matrices consisted of 1 row per participant and 1 column per code, with codes grouped into provisional themes and subthemes. Draft framework matrices were discussed by EE, SB, RD, and NB and updated as necessary for the final versions.
7	Interpreting the data	Researchers keep notes on analytical insights during the analysis process. The team discusses these insights periodically and works toward an interpretation of the data	EE kept notes in a reflective journal during analysis. Analysis meetings were audio-recorded, with notes taken. EE used the reflective journal to revisit previous ideas and consolidate these with new insights during analysis. Once the final themes and subthemes had been agreed by the whole team, EE drafted a write-up of the findings. The team critiqued the draft before agreeing a final version.

[a]All initials used in this table are author initials.

Results

Stage 1: Basic Symptom Item Pool

The final wording of the 56 self-report basic symptom items is presented in Table 3, with corresponding SPI-A item numbers. Beta testers and longitudinal feasibility study participants generally reported that the items had face validity and the item wording was acceptable. A total of 6 changes in response to feedback from participants in this study and piloting in nonclinical samples are indicated in Table 3.

Stage 2: ExPRESS App Development

Beta Testing

Demographic and clinical characteristics of patient beta testers and changes made to ExPRESS in response to their feedback are shown in Tables 4 and 5, respectively. Aside from the comments summarized in Table 5, beta testers were extremely positive about the ExPRESS app.

Stage 3: 6-Month Feasibility Study and Qualitative Interviews

Participants

The demographic and clinical characteristics of participants are shown in Table 4, with basic characteristics of individual participants shown in Table 6 and retention shown in Figure 1. Participants were mostly white British, single, unemployed, and living alone, with a diagnosis of schizophrenia and an average age of 38 years. In total, two-thirds of the sample was male and almost half had accessed further or higher education. Although average PANSS positive scores suggest mild to moderate symptoms, these were nonnormally distributed with some participants reporting virtually no positive symptoms and others reporting much higher symptom levels.

A Priori Themes: Long-Term Acceptability of App Use

A priori themes and subthemes are outlined in Multimedia Appendix 3. Participants found ExPRESS acceptable: they were generally very positive about the specific aspects of the app discussed in qualitative interviews and most would be willing to use it weekly for more than 6 months as part of their day-to-day life.

Table 3. Basic symptoms checklist item pool, with corresponding Schizophrenia Proneness Instrument Adult Version item numbers.

Schizophrenia Proneness Instrument Adult Version item number	Basic symptom checklist item wording
A1.1	Doing new things has been more stressful than usual
A1.2	Crowds or people have been more stressful than usual
A1.3	Doing things in a hurry has been more stressful than usual
A2.2	I have felt empty and flat
A3	I seemed to care less about people than I usually do
B1	I have found it very hard to do two things at once
B2	I have found myself more easily distracted than usual
B3	My concentration has been worse than usual
B4	I have been forgetting things I've done less than an hour before
B5	My thoughts have been slower than usual
B6	I haven't had the energy for thinking
C1	Even simple choices have been difficult
C2	Random thoughts have popped into my head
C3	My mind has sometimes gone blank
C4	It's been hard to follow what people say
C5	I have found it hard to say what I mean
C6	I forgot things I was told almost immediately
D1	It's been hard to decide what I'm feeling
D2	I have felt more emotional about everyday things
D3	My head's been buzzing with lots of thoughts
D4	Random things seemed to have a personal meaning for a moment
D5	People have looked somehow different than usual
E1-E5	I've had some unusual feelings in my body
E6	It sometimes felt like part of my body had swollen up or shrunk
F1	Light has seemed very bright
F2	I have sometimes seen flashes of light
F3	Things have looked the wrong size
F4	I have noticed sounds more than usual
F5	Sounds have seemed different than usual
F6	My body has sometimes felt like it didn't belong to me
O1[a]	Sometimes thoughts and images that are unimportant and have no special meaning keep repeating over and over in my mind and I can't push them away
O2.1	Sometimes I have mixed up real and imaginary things
O2.2	Sometimes I have mixed up real and imaginary memories
O3[a]	Sometimes I take things literally when they are not meant that way. For example, I sometimes misunderstand sayings or metaphors
O4.1	Things seemed closer or further away than they actually were
O4.2	Things have seemed to change shape
O4.3	Colors have seemed different than usual
O4.4	Sometimes when I looked in the mirror I looked different
O4.5	Things that I saw sometimes seemed to move
O4.6[b]	Things have looked wonky or like there was more than one

Schizophrenia Proneness Instrument Adult Version item number	Basic symptom checklist item wording
O4.7	Judging distance or size has been hard
O4.8	Lines have looked somehow wrong
O4.9	If I stared at something and then looked away I could still see it afterwards
O4.10	I have had “tunnel vision”
O5.1	I could sometimes hear sounds that didn’t seem quite real
O5.2[a]	Sometimes I hear sounds which I heard a few minutes ago or even hours before
O5.2	Sounds have sometimes seemed to continue after I know they have stopped
O6.1	Things have smelt different from usual
O6.2	Things have tasted different from usual
O6.3	Objects have felt different from usual
O7	At times I could not take my eyes off something
O8	Everything around me has seemed somehow not real
O9.1[a]	Sometimes I make certain movements even though I had no intention to, like I have lost control of my body
O9.2[a]	I have sometimes spoken without meaning to
O10	My body has sometimes got “stuck” for a short time
O11	I have had to think about things that I usually do automatically

[a]Wording updated in response to piloting in nonclinical sample.

[b]Wording updated in response to feedback from beta tester in this study. Original wording: *Things have looked crooked or like there was more than one*.

Table 4. Clinical and demographic characteristics of the 2 patient samples.

Characteristics	Beta testers (n=5)	6-month feasibility study (n=18)
Age (years), mean (SD)	45.8 (21.0)	37.9 (9.9)
Gender (male), n (%)	2 (40)	12 (67)
Positive and Negative Syndrome Scale positive, mean (SD)	—[a]	15.4 (5.4)
Diagnosis, n (%)		
Schizophrenia	3 (60)	14 (78)
Schizoaffective	2 (40)	4 (22)
Education, n (%)		
Secondary	2 (40)	10 (56)
Further	1 (20)	5 (28)
Higher	2 (40)	3 (17)
Employment, n (%)		
Employed	1 (20)	2 (11)
Voluntary work	0 (0)	1 (6)
Retired	2 (40)	1 (6)
Unemployed	2 (40)	14 (78)
Ethnicity, n (%)		
Asian or Asian British	0 (0)	1 (6)
Black or black British	1 (20)	2 (11)
White British	4 (80)	15 (83)
Marital status, n (%)		
Single	5 (100)	14 (78)
Married	0 (0)	2 (11)
Separated	0 (0)	2 (11)
Living arrangement, n (%)		
Alone	2 (40)	12 (67)
With family	2 (40)	4 (22)
Supported accommodation	1 (20)	2 (13)

[a]Beta testers were not assessed using the Positive and Negative Syndrome Scale.

Table 5. Changes made to the app or training protocol in response to feedback from patient beta testers.

Comment or suggestion [participant number]	Change made to the app	Added to the app training protocol
Item wording		
PANSS[a] follow-up questions are confusing; it seems like items are repeated [P1]	Change not possible; PANSS items validated	Explanation of branching follow-up questions
Items phrased in own words may be invasive [P1]	__[b]	Check participant is happy with item wording before use in the study
Alter *crooked* to *wonky*, basic symptom item O4.6 [P3]	Altered the wording of the item as suggested	—
Did not realize that PANSS follow-up questions are contingent on previous answers [P5]	—	Explanation of branching items; follow-up items are contingent on response to initial item
Item content		
I had to generalize in some cases. Specifics occurred to me later [P2]	—	Reassurance not to worry if cannot remember everything
Items did not seem very closely connected [P2]	—	Description of item types and how they are connected
Participant would not want to answer items about certain symptoms once unwell [P5]	Added to instructions: If you don't feel comfortable answering, please feel free to ignore the alert	If you do not feel comfortable answering, please feel free to ignore the alert
When items are not applicable, might wonder why you asked about them [P5]	Added to instructions: Explanation that some are standard items; they might not apply at the moment	Explanation that some are standard items; they might not apply at the moment
Sliding bar		
One PANSS item is scored in the opposite direction [P1]	—	Explanation that 1 item is scored in the opposite direction
1-7 scale felt odd; a 1-10 scale might be better [P2]	Change not possible; PANSS items validated	—
Tended to answer to the extreme (1 or 7) [P2]	—	Suggestion to leave room for improvement or deterioration when answering items
4-point scale		
Change anchor wording so that the *number of times a week* is first [P1]	Anchor wording changed as suggested	—
Previous selection sometimes stays for next item [P3]	This bug was fixed	—
Alerts		
Afternoon best as gets up late because of medication [P3]	Moved the alert time to afternoon (1.30 pm)	—
Reminder when the 24 hours is nearly finished [P3]	Added extra reminder after 23 hours	—
During work lunch break would be best [P5]	Moved the alert time to 1.30 pm	—
Would like to be able to set own alert time [P5]	Not changed; consider for future app version	—
Would like to be able to set the snooze duration [P5]	Not changed; consider for future app version	—
Worries		
Worried that the items might be negative or might tell him to do something negative [P3]	—	Reassurance that the items are the same each time and will never tell you to do anything
Worry that other people might get hold of the answers [P4]	—	Reassurance that only the research team can see the uploaded answers

Comment or suggestion [participant number]	Change made to the app	Added to the app training protocol
Worry that someone picking up phone might see psychosis mentioned in the app [P5]	—	Explanation that answers are not visible after upload; guidance on putting a lock on the phone
General		
Make more accessible to standard mobile phones [P2]	—	Participants can borrow a study smartphone
Smartphones take some getting used to [P2]	—	Participants without smartphone experience will need more training
Prefer menu button to be in the top left corner [P3]	No change; not an issue for most participants	—
A back button would be helpful [P3]	Not changed; consider for future app version	—

[a] Positive and Negative Syndrome Scale.

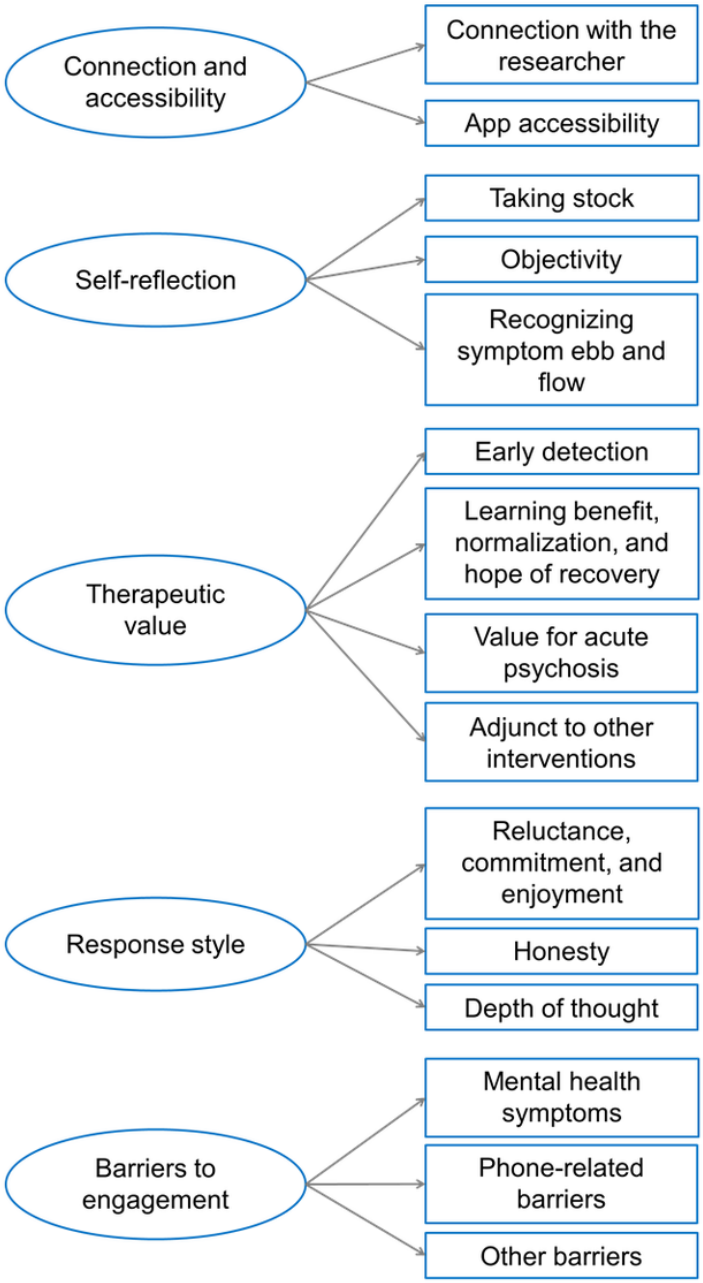
[b]Cells in this table are empty in cases where the column is *not applicable*, ie, no changes were made to the app or training protocol.

Table 6. Basic characteristics of individual participants.

Participant	Age (years)	Gender	Baseline Positive and Negative Syndrome Scale positive subscale score[a]
P204	51	Female	20
P205	28	Female	15
P206	36	Male	7
P207	35	Male	26
P208	42	Female	11
P209	51	Male	18
P211	28	Male	16
P214	40	Female	22
P215	37	Male	18
P223	37	Male	7
P224	22	Male	21
P225	48	Male	16
P227	41	Male	19
P230	57	Male	16
P231	22	Female	9
P235	39	Male	12
P236	41	Male	16
P239	28	Female	8

[a]Possible range: 7 to 49.

Figure 3. Summary of a posteriori themes and subthemes.



A Posteriori Themes: Benefits of and Barriers to Long-Term App Use

Overview of A Posteriori Themes

A total of 5 *a posteriori* themes were derived from inductive coding of interview transcripts: connection and accessibility, self-reflection, therapeutic value, response style, and barriers to app engagement. Overall, these themes relate to the perceived benefits of, and possible barriers to, app use in this population. Participants were not directly asked about these themes in the topic guide but disclosed them spontaneously when discussing their experiences of using the app during the previous 6 months. *A posteriori* themes and subthemes are summarized in Figure 3.

Connection and Accessibility

Overview

This theme brings together participants' comments that relate to the importance of their connection with the researcher and the extent to which they found the app easy to access. Participants compared their interactions with both the researcher and the app to their interactions with mental health staff.

Connection With the Researcher

The connection with the researcher and a sense of belonging to the study were very important for some participants who found reminder texts and regular telephone calls positive and encouraging:

> *You've really done a lot because you are taking part every day [laughs] just reminding me every day, is part of it. It's as if we are together!* [P206]

This participant completed the app assessment every week during the 6-month study period; therefore, it might be that participants' degree of engagement with the app is dependent on the rapport with the person facilitating delivery, in this case the researcher. One individual felt it was important to know who was receiving her app answers, not just from a confidentiality point of view but also so she knew who she was talking to:

> *So sometimes, you'd be constantly thinking "well who are you telling all this to and what's the point?"* [P239]

Filling in the app was not just a self-reflective exercise for this participant but one involving communication with a specific person.

For some participants, it took time to build a rapport with the researcher, with 2 commenting that they found the initial meeting somewhat stressful, but participating got easier once they built a rapport. One individual who was generally anxious about telephone calls was happy to receive calls during the study. The researcher noted in the reflective journal (reflective journal, data analysis phase):

> *Phone calls were acceptable. It probably helps that I had met all participants in person and discussed symptoms in detail face-to-face before the phone assessments. Rapport was already established and they had already shared significant info with me without me freaking out or causing them any problems*

Several participants commented that it was reassuring to know that somebody was looking at their app responses:

> *It was just nice to know that there would be somebody looking over you...so that was quite comforting in a way. [P208]*

Some seemed to view the study as almost an extension of clinical care:

> *I also think it depends on the individual person, how they effectively view the phone calls cos, if you have a care coordinator and your care coordinator checks up on you it's just like that so... I don't see it kind of different.[P205].*

Conversely, 1 participant emphasized that her care coordinator did more than simply assess mental state:

> *She helps me with other things...so it's nice that you've got someone there for you.* [P239]

App Accessibility

The majority of participants (83%; 15/18) owned a smartphone and a few mentioned in the interview that they used apps for other things, which made using an app to communicate about their mental health *a natural thing* [P205]. For example, 1 participant reported using apps such as Facebook and WhatsApp so included the app as part of his social network:

> *But it benefitted more than Facebook cos it's really talking about my health.* [P206]

Some individuals seemed to enjoy the app because they experienced it as similar to a person:

> *It's almost like somebody's speaking to you...asking me questions like "how's your day been?" or "how's your week been?"* [P205]
>
> *It becomes like a...little friend.* [P208]

However, others liked it because they did not have to talk to a person, reporting:

> *You feel... you can open up more. I know it sounds weird.* [P214]

Strikingly, those who liked the app because they did not have to talk to a person had high symptoms during follow-up, whereas those who described the app as conversation-like all had low symptoms. It is possible that certain features of an app make it nonthreatening to someone who is wary of disclosing high symptoms; for example, an app might be experienced as more neutral and less judgmental than a person as it does not give any verbal or nonverbal feedback.

Participants reported other ways in which they found the app more accessible than mental health staff. One individual noted that the app asked questions more frequently and regularly than he typically saw his care coordinator, which he found useful:

> *They [the questions] come every week, she [care coordinator] come like four weeks, three weeks, two weeks, so, but this is reminding me of what I'm supposed to do, all the time.* [P206]

Another tended not to seek help from his care coordinator when he was having a bad week because he was *a bit stoic* [P236] and did not want to bother her but he still answered the app at these points, which enabled the care coordinator to offer additional help when necessary. Similarly, it was noted in the study feasibility diary that 1 participant filled in the app once during relapse at a point that he was not willing to do a telephone interview, suggesting that, for some, an app could be more accessible in cases where a patient is unwell and unwilling to talk.

Self-Reflection

Overview

Participants spontaneously reported a number of ways in which the app helped them to reflect on their own mental health. Not only did completing the app provide a time to take stock of things but it also enabled them to reflect on their experiences more objectively and to notice patterns in their experiences over time.

Taking Stock

The process of answering questions on the app prompted participants to take time to think about their mental health each week (*It makes you realize, you know, take sort of stock of where you're at* [P214]), which they believed they would not have done otherwise (*Like I had to say to myself "think about your week" cos sometimes I don't think about the week* [P239]). By eliciting regular self-reflection, the app might serve a similar

function to talking to a confiding person, as sharing experiences often provides an opportunity to reflect and process them:

> *My mum asks me like how's my day been or I just automatically tell her so by the time I'm coming to do the questions it's like well I've already spoke to mum about this and that so it's just a reminder of that.* [P205]

Objectivity

The process of answering the questions gave participants the opportunity to translate their subjective experiences into an objective format:

> *I found that the more I used it, the more I started looking objectively at my life* [P205]

This provided some individuals with a sense of the realness of their experiences, especially with the help of the graphs:

> *When you look at the analysis of the data collected...you can objectively see.* [P205]

Participants theorized that having access to objective data representing their symptoms, particularly in the graph form, might enable a shared understanding of their experiences, both with the care team (*Maybe help themselves to understand a little bit better* [P227]) and potentially with the general public (*If it can help people in the future understand a little bit better about what we go through* [P227]). Developing a shared understanding with the care team might facilitate help seeking. One participant who had sought help for an emerging relapse in the past but had not been taken seriously suggested:

> *If you were to answer the questions and go to the doctor and say "look, these are my results, you can see clearly there's a change, and these are my experiences," that would be substantial evidence for the doctor to then sit up and take note.* [P205]

Recognizing Symptom Ebb and Flow

Taking time to reflect every week and to articulate their experiences in an objective format helped participants notice the level of their symptoms and to recognize ways in which this varied over time, providing a long-term perspective on the ebb and flow of symptoms:

> *They come and pass, they come and pass away* [P205]

Several participants acknowledged the potential value of the app in spotting fluctuations in their symptoms:

> *If it's something could spot my mood going up and down and things it might be useful.* [P207]
>
> *It would gauge how well you were.* [P230]

Therapeutic Value

Overview

Although a few people could not think of anything that they found helpful about the app when asked directly and 1 participant stated that he did not find the app particularly useful as he is *already aware of everything* [P207], the majority of participants reported finding the app beneficial.

Early Detection and Staying Well

If the app was used in a clinical setting, the intention would be to help patients and clinicians spot predefined early signs and intervene to prevent a full relapse from occurring. Several participants spontaneously identified this as a potentially valuable outcome of using the app (*It can be like a toolkit for you...A toolkit for like er staying well really...A wellness reaction plan you know. A "wrap"* [P230]), with 1 participant suggesting that using the app would help her and others recognize changes in their symptoms in response to stressors:

> *It could help people identify, cos like for me, now that I've used an app, I'm thinking when I know my stressors are coming I'd like to have the app there available so that I can do it and then see "oh is it like my thoughts are changing.*" [P205]

Recognizing patterns in their symptoms allowed some participants to take action to help themselves stay well during the study. For example, 1 participant reported that using the app meant that she recognized that she felt unwell the week before her monthly depot was due:

> *Cos it gets you into a pattern of realizing when you're a bit down, when you're a bit, you know, dodgy type thing.* [P208]

The realization that she was feeling down because her depot was due reassured her (*I thought that the levels in my depot was probably going down a bit and I was ready for another depot. That's what that helped me to realize. And that helped to keep me calm by using the phone app* [P208]) and meant that she was able to use *PRN* (*pro re nata)* medication (medication that can be taken when required) at this time. Thus, using the app could help patients to take more responsibility in managing their mental health in conjunction with their care team.

Learning Benefit, Normalization, and Hope of Recovery

For many, the opportunity for self-reflection provided by the app was a valuable experience that increased their understanding of psychosis:

> *I think it probably made me understand my illness a little bit better. The voices and all.* [P211]
>
> *It's been eye opening.* [P208]

Although, for some, this brought the more uncomfortable realization that:

> *I'm not as well as I thought I was.* [P227]

Although not formally assessed in the study, 1 participant appeared to have a sealing-over recovery style, a form of avoidance coping common in people recovering from psychosis [55]. This individual did not wish to continue using the app for longer than 6 months as he did not like being reminded of his symptoms:

> *I just don't feel like looking back on myself in a way if you see what I mean.* [P223]

In contrast, another participant initially worried that thinking about her experiences every week would remind her that she was ill but actually, it had the opposite effect (normalization):

> *I thought oh it'd make you feel like oh you're ill, you know. It's just a constant reminder: you answer the questions and the results show that you're ill. But, if anything, it showed that you have this illness but you're normal, you have normal feelings and emotions and anybody can have them at any time.* [P205]

There were several ways in which this participant found the app normalizing: (1) it helped her to discuss symptoms in a normalizing way (*Cos when I was talking to mum about some of the questions it was like – yeah, she feels that, at times. Ok she doesn't hear voices but she feels down and things like that and just that normalization of talking to somebody about the study and then explaining to them how it was*. [P205]); (2) the fact that there was an app for tracking symptoms was normalizing in itself because of the availability of apps for lots of everyday things; and (3) taking part in the study was normalizing as there must be other people with similar experiences (*It was like a normalization so, cos I knew I was taking part and many others but I don't know to what degree their psychosis is but like it's just a normalization of like well we have this psychosis.* [P205]).

This participant found that the normalizing effect of the app facilitated a sense of acceptance of her experiences, enabling integration rather than sealing over (*It was just an acceptance it's part of me and it's normal life. Like I didn't differentiate it from "oh this is a part of me that I don't know about and I don't like." It was just a part of me that I could just carry on living with.* [P205]), and gave her hope that she could recover (*Afterwards I'd just be like "I can get better. I can get better!" there was just, there was this hope that I had when I was using it.* [P205]). She speculated that, had she been filling in the app for a few years, seeing the pattern would have helped her to see the extent of her recovery to date:

> *My answers to the questions three years ago... would have been completely negative and so to see the change in that, then I would have been like "Yeah actually...I can see I am getting better."* [P205]

Value in Acute Psychosis

Two participants commented that the app would be useful during the acute phase of psychosis:

> *I think it's good for maybe someone that's just gone into hospital.* [P239]

One thought that using the app during an initial episode of psychosis might help people to be more recovery-focused (*I think like if you got most people with psychosis to do it when they're like at their worst illness... I think it would, it'd have a bearing on them being more positive about the illness and being more positive about how they could get through it, with it rather than against it*. [P205]) and that it might help mitigate memory loss associated with the acute phase:

> *Like for me when I was talking about my illness, the more I got ill, the more I couldn't remember. And I, I think that's to do with psychosis sometimes, your memory's not so good.* [P205]

Value in Conjunction With Other Interventions

All participants in the study were prescribed a maintenance antipsychotic during the follow-up period, but 1 participant in particular [P206] found the app complemented this well in that it increased his medication adherence by providing a sense of accountability. As this participant felt that he should be honest on the app and he did not want the researcher or his care coordinator to see that he had not taken his medication, this motivated him to continue taking it:

> *With this app, it's, even when I want to stop my medication, you know, I won't tell lie that I didn't take my medication, so it will now tell me "ah, you need to take your medication because tomorrow when you are doing this... you have to be sincere... so you should take your medication!" [P206].*

Participants also noted the value of the app in conjunction with other interventions, for example, cognitive behavioral therapy (CBT) or occasional use of PRN medication.

Response Style

Overview

This theme relates to participants' comments regarding the way they completed the app: whether they did so reluctantly or willingly, how much thought they put into their responses to the app's questions, and whether they were honest in these.

Reluctance, Commitment, and Enjoyment

Participants reported that the app was sometimes annoying but sometimes helpful. Although a few people seemed to genuinely enjoy the process of completing app entries (*I did enjoy answering the questions... I didn't see it as a chore.* [P230]), most others viewed it as a chore (*Not really anything to enjoy actually doing the app... It's not like you're playing a computer game or you know*. [P236]), but one which hopefully had some benefit (*The questions do help you a bit.* [P214]). Several participants expressed some reluctance at using the app at times but usually did it anyway because of finding it easier than talking about how they felt [P224] or because they were committed to taking part in the study (*I thought no I've agreed to do it so I'll carry on doing it.* [P227]). Moreover, 2 participants described a process of motivating self-talk to persuade themselves to complete the app:

> *I just kept saying to myself "you've nearly finished, you've nearly finished, it's not forever."* [P214]

> *I had to say to myself "think about it...just answer the question" you know.* [P239]

One participant who had enjoyed the app was extremely committed to it, even describing 1 week that he returned early from staying overnight in another city specifically to do the app:

> *I didn't go away with the phone so, on Thursday when I woke up in the morning I just told my friend... "I have to go back to Manchester cos I'm supposed to do this thing yesterday"... so I rushed down.* [P206]

Honesty

A number of participants commented that they answered the app honestly, despite, in some cases, feeling some paranoia about it or finding it tricky to force themselves to think about their week:

> *I just had to say to myself "tell the truth, think"... I had to say to myself "think about your week."* [P239]

One participant reported during a telephone call with the researcher (noted in the study feasibility diary) that he had begun to answer the app more honestly: although his app responses appeared to indicate that he was getting unwell, he was in fact just being more honest.

Second Guessing Answers Versus Answering Without Deep Thought

Some participants appeared to put a lot of thought into answering the questions, for example, by second-guessing their own answers:

> *Even as I was doing it I was thinking well was that right, maybe I should have put something else, you know, different number.* [P236]

Conversely, others reported that they answered without deep thought:

> *I didn't really think about it [laughs slightly] you know.* [P235]

One participant commented that he did not record small fluctuations in his mental health on the app:

> *I don't allow it to stay long, so that's why I don't put it there.* [P206]

Barriers to App Engagement

Overview

Participants noted a number of barriers, which prevented them from engaging with the app more fully. Mental health symptoms and phone-related barriers interfered with app use in some cases, though these rarely prevented app engagement entirely.

Mental Health Symptoms Interfered

Positive symptoms interfered with app engagement in several cases, but the extent of this interference varied. One participant had very high levels of positive symptoms that he did not believe were symptoms of an illness; he did not want to continue with the app because he believed it was irrelevant to him, making him feel like an *experimental rabbit* [P215]. Other participants with positive symptoms were happy to carry on with the study but they occasionally delayed answering questions or missed them for a week and sometimes they took longer to answer:

> *Sometimes it takes a lot longer cos I've got the voices going on at me so it, it takes longer cos I have to argue with them, and I have to really concentrate on what's on the phone...and then it's absolutely knackering. I know it sounds weird cos all I'm doing is answering questions.* [P214]

Overall, 2 participants relapsed during the study. One of these individuals stopped using the app the week before he met study criteria for relapse, having used it virtually every week beforehand. Thus, for some, stopping the app might be a sign of imminent relapse, an observation that is consistent with findings of a previous study in which early signs of relapse were monitored using postal questionnaires [23]. The second relapsing participant stopped using the app the week after meeting relapse criteria, meaning that the app assessments in the previous few weeks could be used to predict relapse. Encouragingly, both participants were happy to continue with the app once the relapse had resolved:

> *It was only that time when er I was really unwell ...I was just so unwell that I couldn't do it but then after that I went back into it. [P230].*

Mood symptoms affected a few participants' ability to engage with the app (*when I was really low... I just didn't communicate with anyone anyway* [P227]). Although 1 commented that *even when things were not so good for me, it's still easy to answer it* [P239], she pointed out that mental health staff can take into account how you are feeling when asking questions in a way that the app cannot:

> *When you've got people coming to you...they can perk you up or get through it and eventually answer the questions.* [P239]

She also suggested that her mental state at the time of answering the app might affect how she answered; for example, if she was feeling happy when answering them, she might forget that she was feeling down at other points in the week.

Phone-Related Barriers

A total of 13 people used a study phone during follow-up. Some found the study phone a barrier, stating that they did not tend to look at it regularly, did not take it out with them, sometimes struggled to use the unfamiliar handset, were worried about it being broken or stolen, and that they might forget to charge it. This issue was mitigated to some extent by the researcher sending a weekly reminder text message to participants' own phones.

Lack of smartphone experience was a barrier in some cases, with 1 participant accidentally deleting the app from the phone and 2 others commenting that their lack of smartphone experience prevented them from accessing the app's extra features. Unlike a *digital native*, who would probably have explored the app's features of their own accord, they only used its basic functions. One participant with little smartphone experience described a general anxiety about using phones, including for telephoning and text messaging; another commented:

> *Sometimes I get tired of looking at a phone.* [P239]

Other Barriers

Some participants expressed skepticism regarding certain aspects of the study such as whether the research would find anything useful (*You don't gonna find patterns. I'm pretty sure*. [P215]), the validity of translating experiences into numbers (*You get a more of an insight I would say with erm [pause] people's opinions and thoughts and that rather than turning them into numbers and statistics.* [P236]), and how the researcher would work out what the answers on the app meant (*I just think about*

the other person on the other side having to sit there and read the questions. How do they work it out? [P239]). If not addressed, such skepticism might hinder app engagement as beliefs and attitudes predict intentions and behavior [56].

Lack of literacy was a significant barrier for 1 participant and prevented him from continuing with the study:

> *Basically I'm not very good at reading and spelling...that's the reason really...I didn't really want to say last time I seen you...I felt a bit embarrassed...* [P225]

A number of more minor barriers were recorded in the study feasibility diary. Participants missed 1 or 2 weeks of app use because of being physically unwell, lending their phone to someone else, being busy, oversleeping, being on vacation in the United Kingdom, or being abroad. The study policy was for participants not to complete the questions when they were abroad (because of lack of local support in the destination country). However, allowing participants to do so might increase their access to help at such times as life events, even positive ones, are associated with relapse [57,58].

Discussion

Overview

This study describes the development and testing of ExPRESS, the first mobile phone app to monitor basic symptoms and conventional early signs of psychosis relapse. It also outlines the development of the BSC, a pool of self-report items that can be used to monitor basic symptoms as putative relapse predictors. It has the longest duration of any study testing a symptom monitoring app in a sample of individuals with established psychosis and is the first study to qualitatively examine psychosis patients' experiences of using an app over a 6-month period. Framework analysis of interviews with patients enabled us to examine both *a priori* (acceptability) and *a posteriori* themes (wider app experiences).

Principal Findings

A priori themes related to the actual acceptability of the ExPRESS app and its use in day-to-day life. Participants found the app acceptable in terms of the way it looked, length of assessments, item content, item wording, and response format. As assessments were only weekly and the 24-hour response window meant they could answer when convenient, most (including those with jobs) reported that the app fitted well with their routine and they would be happy to use it for longer than 6 months as part of their day-to-day life. This contrasts with feedback from participants using Clintouch [36], an app with several symptom assessments per day, who were unwilling to use it for longer than 2 weeks and thought it would not fit well with employment. The authors of the latter study suggest that symptom monitoring for relapse prevention might require less frequent assessments than Clintouch [36], which is consistent with recommendations of minimum fortnightly monitoring during early signs interventions [59]. This study shows that with less frequent monitoring, people are willing to use a symptom monitoring app for significantly longer.

In contrast with clinicians' hypothetical views [39,60,61], most participants were happy with a clinician having automatic access to their responses. The absence of difficulties while using ExPRESS, which automatically uploads data to the researcher, might have mitigated concerns about automatic uploads in our sample. Indeed, a recent systematic review found that actual acceptability of various aspects of DHIs tended to be higher than hypothetical acceptability [46]. Similarly, after using a mood monitoring app for 3 months as part of the Automated Monitoring of Symptoms Severity study, participants with bipolar disorder were generally willing for clinicians to access the data [62]. However, although clinician access was viewed by participants as potentially valuable, the practical and legal implications of such access require further consideration if apps are to include this feature.

Participants in this study did not report significant worries about the app, except for 2 reporting some paranoia about it and 2 who worried about hospitalization, neither of which prevented engagement. The fact that these worries did not hinder app engagement might be because the research study and the app itself came from a trusted source, namely, a university. Previous qualitative studies with participants with early psychosis [41] have reported that endorsement by a trusted source, such as a university or health service, is likely to allay participant concerns about privacy and security issues.

Virtually no one used the app's extra features such as the daily diary, graphs, or helpful numbers because they did not remember being told about them. Given that participants would have used the graphs had they known about them, more emphasis should be placed on these features during the app training session to ensure that participants are aware of them.

The *a posteriori* themes encapsulate participants' wider experiences of using the app, including participants' connection with the researcher, accessibility of the app, self-reflection, the therapeutic value of the app, participants' response styles, and barriers to app engagement. A number of observations and inferences can be made from the first theme, *connection and accessibility*. The person who the patient sees as administering the app appears to have a key role; taking time to build up a rapport in face-to-face sessions might increase app engagement. Regular telephone calls and text messages from the researcher were important to participants, consistent with findings that the acceptability of DHIs is higher when patients have access to remote support [46,63-65] and that using technology can help patients and clinicians maintain a connection between appointments [37,66]. Reviews indicate that telephone support is acceptable to those with severe mental illness [67,68]. In this study, even a participant who was generally anxious about telephone calls found them acceptable as he had met the researcher previously. This is an important finding for researchers and clinicians seeking to assess symptoms remotely via telephone. Although it is unlikely that patients will be willing to discuss their symptoms over the telephone with a stranger, 1 or 2 meetings in which symptoms are discussed face-to-face might be sufficient for them to feel comfortable discussing them over the telephone.

Although participants found it reassuring to know that someone could see their weekly symptom reports, and some viewed this as an extension of clinical care, others emphasized that clinicians do more than simply monitor symptoms. Thus, as in previous studies with both patients and staff, participants in this study suggested that self-monitoring apps should enhance rather than replace face-to-face appointments [36,60]. Nevertheless, as participants in a recent study hypothesized [41], some found an app more accessible than mental health staff, reporting that they are more open about their symptoms on an app, they can complete it at points when they are unwilling to speak to someone, it is more frequent than their usual contact with a clinician, and it removes the feeling of inconveniencing someone to report symptom increases. Furthermore, several participants with low symptoms described the app in positive, anthropomorphic terms (eg, as a friend), supporting previous findings that individuals can develop strong connections with mobile phones [69].

Some of these qualities (eg, openness, acceptance, friendliness) overlap with descriptions of therapeutic alliance with respect to DHIs [70,71]. Those with psychosis [71] or depression and anxiety [70] have reported a positive therapeutic alliance with DHIs in the absence of a therapist. In the latter case, higher levels of alliance were associated with greater engagement in self-monitoring tasks [70], implying that therapeutic alliance might be an important consideration when evaluating symptom-monitoring apps such as ExPRESS. However, it is often difficult to disentangle the therapeutic alliance attributable to the DHI and to the person administering it [70]. Future studies using ExPRESS could examine therapeutic alliance with the app and the researcher using self-report measures such as the Mobile Agnew Relationship measure [71] and the Agnew Relationship measure [72], respectively.

The second theme, *self-reflection*, suggests that using a symptom monitoring app prompts patients to reflect regularly on their experiences and to express them in an objective way. Doing so enables them to recognize the ebb and flow of their symptoms and to share their experiences with others. This can have surprisingly therapeutic results, at least for some people, as summarized in the third theme, *therapeutic value*. Participants recognized the potential value of an app such as ExPRESS for early detection of deterioration, with many reporting that using such an app increased their understanding of their psychosis. This facilitated self-management in some cases, which can be empowering for patients [28,73,74]. It also appeared to have a normalizing effect for some, which seemed to aid an integrative recovery style.

Conversely, patients with a sealing-over recovery style might not be willing to use a symptom monitoring app as it provides regular reminders of past or current symptoms. Previous studies have framed participants' discomfort with being regularly reminded of their symptoms as a side effect of the *biographical disruption* experienced by individuals coming to terms with a diagnosis of a chronic disorder [36]. These 2 explanations tap into the idea that regular symptom monitoring reminds patients of their symptomatic status, which can threaten their already fragile view of themselves. They are consistent with findings that a sealing over recovery style predicts low engagement with mental health services more generally [75] and with findings from patients with bipolar disorder [63,76].

Particularly for early psychosis patients, an app is more like their usual communication with others making it potentially destigmatizing compared with usual care [41]. Participants emphasized the potential value of the app for those in the acute phase of psychosis. However, such individuals might require additional support with app use as acute patients do not engage with symptom monitoring apps as well as remitted patients [26]. Nevertheless, with support, using an app during the early stages of a first episode of psychosis might prompt a more recovery-focused approach.

Participants also underlined the potential value of using a symptom monitoring app such as ExPRESS in conjunction with other interventions such as maintenance antipsychotics and CBT. Indeed, self-monitoring is by no means a new concept and has long been used in the context of CBT as a means of fostering *collaborative empiricism*, with its therapeutic effects reported across a wide variety of psychological disorders [77]. Although often used clinically, there was a decline in self-monitoring research since the 1980s [78]. Nevertheless, the advent of mHealth has seen this revived to some extent [79]. For example, a recent randomized controlled trial comparing app-based symptom monitoring (Clintouch app) with usual care found a significant reduction in positive symptoms in the early psychosis subsample, though not in a sample with chronic psychosis [80]. Similarly, studies using mHealth to prompt medication adherence have had promising results [81,82].

The fourth theme, *response style*, indicates that patients are generally willing to use a symptom monitoring app, if they can see the benefit, despite it being a chore. Most participants in our study reported answering honestly, despite concerns raised by patients and staff in previous studies that people might underplay or overplay their symptoms on the app to elicit or reduce care [36,60]. Nevertheless, this study also suggests that, if a patient reports increased symptoms, it is worth considering the possibility that they have begun to answer more honestly rather than that their symptoms have actually increased.

The final theme, *barriers to engagement*, summarizes several factors, which might hinder app engagement; it is useful to identify these so that they can be addressed to increase app engagement in future studies and potentially in clinical practice. Although both psychotic symptoms and mood symptoms interfered with app use to some extent, especially in patients lacking insight, most individuals with high symptoms engaged well with the app, albeit more slowly than others. Similarly, a recent study [33] found that baseline psychotic or depressive symptoms did not predict app completion rates, although negative and agitation symptoms did in a subgroup of study completers, although Ben-Zeev et al [29] reported that app completion was not associated with cognitive functioning, negative symptoms, or persecutory ideation. These findings contrast with surveys of digital health experts, who suggested that poor cognitive functioning and severe symptoms might negatively impact engagement with DHIs [83].

Use of a study phone was reported as a barrier by some, as participants did not tend to integrate this with their daily life as

they would their own phone. Although previous qualitative study participants have also expressed a preference for their own phones [27,36], a recent study in an early psychosis sample found no difference in completion rates between those using study phone and those using their own phone [33]. Other key barriers that could be addressed to increase app engagement included lack of smartphone experience, skepticism regarding the app, the study policy to not use the app while abroad, and lack of literacy. Although the latter was also reported as a potential barrier by a third of participants in a recent qualitative study, they nevertheless found mobile phones more accessible than paper-based alternatives [41].

Strengths and Limitations

The range of clinical histories within the sample is an important strength of the study; there was a substantial proportion of participants with longstanding illness and high levels of residual symptoms and a wide age range. Precautions were taken by the researchers to avoid biasing their interpretation during the interview and analysis process.

A number of limitations should be borne in mind when considering the results of this study. The sample size was modest, and despite the range of participants, this is not a representative sample, so findings should be interpreted with caution. Participants had all consented to use an app as part of a research study so they might be an unusual subset of patients who are particularly interested in mHealth. We did, however, seek to interview all 4 people who dropped out of the study; 2 were uncontactable but the remaining 2 were interviewed. It is possible that socially desirable responding might have biased reported views as half the participants were interviewed by the researcher who conducted app training and all other study procedures. This said, half the interviews were conducted by a new researcher, potentially reducing this bias. The mean interview length was relatively short for a qualitative study, but there was a wide range. Nevertheless, as illustrated by the reported participant quotations, the study was still able to gather rich, detailed information about patient experiences of using ExPRESS.

Future Research

Having demonstrated the long-term acceptability (reported here) and feasibility (reported elsewhere) of the ExPRESS app, the next step will be to conduct a longitudinal study with sufficient power to examine the hypothesis that adding basic symptoms to conventional early signs improves relapse prediction. If such a study shows that basic symptoms do predict relapse, the app can then be tested as a clinical tool.

Conclusions

Symptom monitoring apps have the potential to help services move toward more preventative strategies, in which symptom deteriorations are tackled early, rather than reactionary strategies, in which deteriorations are only addressed once they warrant crisis intervention. Although high caseloads often limit the frequency of face-to-face appointments, this study suggests that participants find it acceptable to use technology (phone calls, texts, and a symptom-monitoring app) to maintain contact between face-to-face meetings. Although undoubtedly many clinicians already adopt similar strategies with younger patients, this study suggests that it is possible and acceptable to do so across a wide age range, including with older patients who are less familiar with technology. As long as the potential benefits are understood, patients are generally willing and motivated to use a weekly symptom monitoring app; virtually, all participants in this study were prepared to do so for more than 6 months.

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Conflicts of Interest

SB is a director of Affigo CIC, a not-for-profit social enterprise company spun out of the University of Manchester in December 2015 to enable access to social enterprise funding and to promote ClinTouch, a symptom-monitoring app, to the NHS and public sector.

Multimedia Appendix 1

App evaluation form used during Stage 2 beta testing.

[DOCX File, 23KB - mhealth_v7i3e11568_app1.docx]

Multimedia Appendix 2

Topic guide used during Stage 3 qualitative interviews.

[DOCX File, 20KB - mhealth_v7i3e11568_app2.docx]

Multimedia Appendix 3

A priori themes and subthemes: long-term acceptability of Experiences of Psychosis Relapse: Early Subjective Signs.

[DOCX File, 24KB - mhealth_v7i3e11568_app3.docx]

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Abbreviations

BSC: Basic Symptoms Checklist
CBT: cognitive behavioral therapy
CDS: Calgary Depression Scale
DHI: digital health intervention
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, 4th Edition

ESS: Early Signs Scale
FoRSe: Fear of Recurrence Scale
mHealth: mobile health
NHS: National Health Service
PANSS: Positive and Negative Syndrome Scale
PRN: As needed (from Latin, pro re nata)
SPI-A: Schizophrenia Proneness Instrument, Adult Version

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Original Paper

Experience of Using an App in HIV Patients Older Than 60 Years: Pilot Program

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Abstract

Background: New technologies can promote knowledge of HIV infection among patients suffering from this disease. Older patients with HIV infection represent an increasingly large group that could benefit from the use of specific apps.

Objective: The aim of the study was to observe the acceptability and use of a mobile app on HIV infection in patients at least 60 years old and offer them the possibility of anonymously establishing contact with their peers.

Methods: A series of clinical and psychosocial parameters were studied in 30 HIV-infected patients of over 60 years. The patients must be at least 60 years old, with a follow-up in the outpatient clinic for at least 1 year and without pathologies that limit his or her life expectancy to less than a year. They must know how to read and write. To be part of the group assigned to the app, they had to have their own smartphone and confirm that they were connected to the internet from that device. Overall, 15 of them were randomized to use an app and 15 were in the control group. All tests were repeated after 6 months.

Results: The median age of patients was 66.5 years. Among them, 29 patients had an undetectable viral load at baseline. The median number of comorbid diseases was 2. Overall, 11 of them lived with their partners and 19 lived alone. They spent an average of 5 hours a day sitting down, and 56% (17/30) of them referred high physical activity. They scored 4 out of 5 for general quality of life perception. Moreover, 80% (24/30) presented high adherence to their treatment, and the average number of concomitant medications was 5. In the 6-min walking test, they covered a distance of 400 meters, and 3 of them desaturated during the test. The 15 patients made frequent use of the app, with 2407 sessions and an average of 7 min and 56 seconds time of use with a total of 13,143 screen views. During the 6 months of the trial, 3 non-AIDS events took place. There were no significant modifications to body mass index, blood pressure measurements, lipid profile, or immuno-virology information data. There were no differences in the questionnaire scores for perception of quality of life, confessed physical activity, or antiretroviral treatment (ART) and non-ART treatment adherence.

Conclusions: Significant differences between studied parameters were not objectified in these patients, possibly because this trial has significant limitations, such as a small sample size and only a brief follow-up period. However, patients did use the app frequently, making this a possible intervention to be proposed in future subsequent studies.

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KEYWORDS

HIV; aging; internet

Introduction

Background

The proportion of older adults infected with HIV grows progressively [1], not only because of increased survival of cohorts but also because of an increase in the number of new diagnoses in this group of population [2,3]. With the increasing age of our patients, the possibility of AIDS diagnosis event, serious non-AIDS events (osteoporosis, renal failure, vascular events, non-AIDS cancers, and neurocognitive impairment), or metabolic conditions (diabetes, hypertension, and hyperlipidemia) that are associated with increased morbidity and mortality rises [4,5]. All these conditions are encompassed in the concept of comorbidities. These patients are a population group in which the accumulation of different types of medications and the potential for toxicity and interactions will also be greater [6]. The social stigma that accompanies HIV infection is not negligible, especially in patients of older age; so being able to share their experience with their peers could lead to reducing feelings of loneliness and stigmatization. The use of these technologies in smartphones (mobile health) has also been developed in the HIV-infected population, although a specific HIV-infected older adults' experience has not been reported yet [7,8]. Probably, compared with the younger infected ones, older adults are a differentiated group, who are less accustomed to the use of new technologies and have a special interest in being informed not only about HIV infection but also about the comorbidities associated with age. In addition, the isolation is greater in older individuals, so an app specifically designed for this group could be useful [9].

New technologies allow the creation of virtual communities that help to maintain the anonymity of the individual while allowing interaction with other peers [10]. The creation of peer support groups formed with reference and access to tips for health promotion and commented on by medical personnel news may have beneficial effects in this population. Anonymity could favor those people who would not participate in face-to-face activities or with fear of losing their privacy and those who could benefit from being supported by peers. This can be especially important in older people belonging to generations in which HIV infection or sexual condition was associated with a certain stigma in Spain [11].

Objectives

The GoSHAPE 2015 program was supported by Gilead to promote the use of new technologies and the empowerment of patients. In this context, we deliver the development of an app. Being a pilot study, our objective was to observe the acceptability and use of a mobile app on HIV infection in patients at least 60 years old as well as offer the possibility of establishing anonymous contact between peers.

Methods

Investigative Team

The study was led by Costa del Sol Hospital Internal Medicine Unit (Marbella, Spain), in collaboration with the Pharmacy unit, the department of clinical investigation, and a local nongovernmental organization (Concordia). The approval of the local ethics committee was obtained, and all the patients signed informed consent before any study performance.

A prospective observational study was conducted in 2 phases. An app with different content was designed, and afterward, this app was tested with the patients over 6 months. The name of the app was e-ging (Figure 1). After registering, the patients accessed the menu screen, where they could choose among the different options of the app.

The app consisted of 3 different sections, which can be seen in Figure 2:

- News (medical, health care, social, and healthy aging): Always focusing on commenting on news about HIV infection that was being spread in the national and international press. Some of the news was "What is osteoporosis and why is it produced?," "alcohol causes 250,000 deaths from liver cancer per year," "the dangers of high blood pressure," "the epidemic of loneliness as a threat to health," "the link between HIV and heart attack," and "advances in the vaccine against HIV."
- Reports: Information in understandable language about key aspects of the infection, such as the meaning of CD4 and viral load, antiretroviral treatment (ART) components, vaccine effectiveness, and smoking habit. Some of the reports were "What does CD4 and viral load mean?," "What vaccines should I take?," "What are opportunistic infections?," "The importance of papilloma virus," and "WHO recommendations on physical activity."
- Chat: Designed for the purpose of anonymously exchanging opinions between patients. The patients were explicitly explained that the comments of the chat would be analyzed (in frequency, content, and number of participants) at the end of the study.

Both the news and the reports were uploaded by the research team, not by the patients, and both sections could be marked with *like* by the patients.

To have access to the app contents, the patients received a user number in a closed envelope and an access password assigned at random by computer software external to the project. Each user number had an avatar assigned to it as a profile to reinsure patient anonymity. To maintain privacy, the external aspect of the app and its name (e-ging) did not make any reference to HIV infection, and its use required a username and password each time the app was to be accessed.

Selection of Participants

Before recruiting the patients who collaborated in the study, a survey was conducted among all the patients aged at least 60 years in our HIV infection clinic, with a view to exploring their knowledge about the internet and new technologies [12]. Later, 30 of them were recruited. The patients must be at least 60 years old, with a follow-up in the outpatient clinic for at least 1 year and without pathologies that limit his or her life expectancy to less than a year. They must know how to read and write. To be part of the group assigned to the app, they had to have their own smartphone and refer that they were connected to the internet from that device. They were offered to enter the study according

to their usual consultation. The patients who used the internet on their mobile phone (15) were offered to download the app, and those who did not have internet access on their mobile (the other 15) constituted a control group. There was no randomization.

Scheme of Visits and Information Collected

The app remained in operation for 6 months, after which it was canceled. During this time, clinical follow-up was the usual in both groups of patients (with or without app), with a visit to consultations every 4 to 6 months. No specific action was developed with the control group.

Figure 1. Interface of the app.

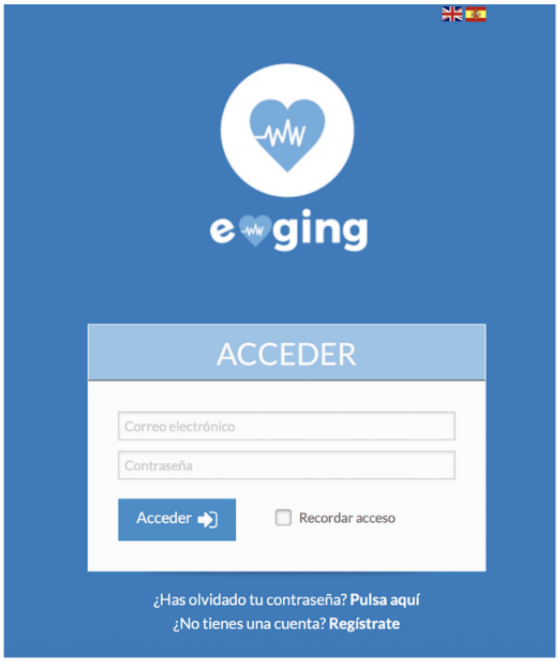
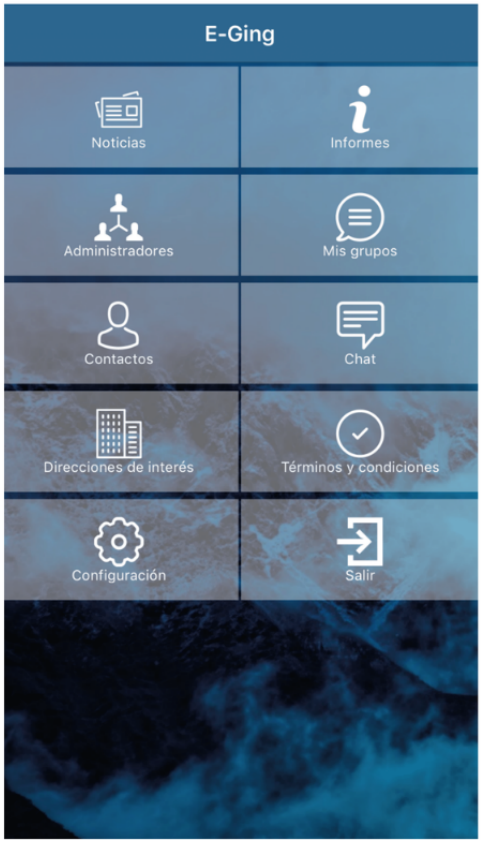


Figure 2. Menu screen.



The following information was collected at baseline 6 months later:

1. Education level (referred by the patient himself).
2. Anthropometric information and blood pressure (taken in consultation, twice in recumbent position after 3-5 min of rest in that posture).
3. Blood count parameters: CD4 lymphocytes and viral load, lipid profile, and estimated glomerular filtrate using Chronic Kidney Disease Epidemiology Collaboration [13].
4. Comorbidities: cancer, diabetes, hypertension, dyslipidemia, osteoporosis or fractures, liver disease, cognitive deterioration, and tobacco consumption (for all these: yes or no). This information was taken from the patients' medical records, if the patients had recorded this diagnosis between the clinical judgments.
5. Medication: type of ART received and chronic non-ART medication.
6. Adherence to ART and non-ART medication: calculation using dispensation of ART registries provided by the pharmacy unit, followed by the Simplified Medication Adherence Questionnaire (SMAQ) [14].
7. Adherence to chronic non-ART medication: the Morisky-Green-Levine questionnaire [15].
8. WHOQOL-BREF, World Health Organization Quality of Life Questionnaire (short version): it evaluates physical and Psychological quality of life, social relationships and satisfaction with health care and social services [16].
9. International Physical Activity Questionnaire (IPAQ): classifies weekly physical activity as high, moderate or low [17].
10. 6-min walking test (6MWT): reflects the physical capacity of an individual to perform the physical activities of daily life.

In addition to these questionnaires, patients were asked to rate their quality of life perception ranging from 1 (worst) to 5 (best), and the same for the perception of health.

Analytical parameters and 6MWT results were collected to explore if a short intervention could improve physical, functional, and analytical status of our patients.

Data Analysis

For the analysis of the chat at the end of the experience, a dictionary of words and terms of interest was put together to be able to discard irrelevant words for the purpose of the project. The choice of relevant terms was agreed to by the research team. Once the dictionary was available, an algorithm was implemented that searched for coincidences in all chat messages. The terms were grouped into areas for this purpose, and in these areas, words were classified as *key words*, which is the term or expression that we want to quantify, or its *variants*, which are variations of that word or expression. With this structure, a search was implemented in the whole chat. The areas into which the key words have been grouped are as follows: pathologies, medications, nutrition, healthy attitudes, sanitary and professional centers, psychological, and emotional. In the pathologies area, a second analysis of key words was made and grouped into the following areas: cardiovascular disease, cancer, HIV, and osteoporosis. The contents of the chat were analyzed by 3 members of the research group so that the comments were framed in the context of these key words.

After closing the app, the possibility was offered to send a brief written opinion about the experience of using the app to the 15 individuals who had downloaded it.

Quantitative data are provided as medians with an interquartile range, and qualitative information is given as percentages. A nonparametric procedure (Mann-Whitney U) was used to compare quantitative variables, and proportions were compared using the chi-square test. IBM SSPS 20 was used for statistical analysis.

Results

Population Characteristics

Baseline characteristics of the patients are shown in Table 1. All of them were receiving ART.

As for physical activity measured according to the IPAQ, 2/30 patients (7%) referred low activity, 11/30 (37%) moderate, and 17/30 (57%) high. They stated that they spent 5 hours sitting down (0-12). The quality of life perception was 4 (2-5). With that same scale, the perception of health was 3 (2-5).

The number of concomitant medications was 5 (0-12), and 17/30 (57%) patients were using at least four medications.

There were no significant differences found between the group that downloaded the app and the control group in any of the variables mentioned.

Over the 6 months of this project, there was no registry of any AIDS events, but there were 3 non-AIDS events: one sudden death in the group not assigned to use the app and 1 heart attack and colon cancer in 2 patients in the app use–assigned group.

There was no significant modification in body mass index parameters, blood pressure, lipid profile, or immuno-virology information data. There was no significant modification of the distance covered in the 6MWT. There was no significant modification in the perception of quality of life questionnaire scores, confessed physical activity, or ART or non-ART adherence. Table 2 shows the main analytical parameters, adherence to treatment, quality of life, and the 6MWT results at baseline and 6 months, without any significant differences being observed in any case.

Use of the App

The app was in use between April 30, 2017, and October 31, 2017. During these 6 months, 19 reports and 75 news were uploaded. There was a total of 2407 sessions and an average session time of 7 min and 56 seconds. The screen views ascended to 13,143, with an average of 5.46 screens per session.

The most visualized screens were the *Chat* (4046 views) and *News* (890) screens, at a considerable distance behind them were *Contacts* (96), *Reports* (90), and *Useful addresses* (66).

Table 1. Baseline characteristics of the patients (N=30).

Demographic characteristics	Statistics
Age in years, median (range)	65.5 (60-78)
Female, n (%)	5 (17)
HIV infection, median (range)	
Years since diagnosis	11 (2-31)
Years since beginning of ART[a]	10.5 (2-28)
Way of transmission, n (%)	
Men who have sex with men	11 (37)
Heterosexual	17 (57)
Former injection drug user	1 (3)
Unknown	1 (3)
CD4 lymphocyte nadir (cell/μL), median (range)	195 (4-851)
Number of lines of ART during life, median (range)	4 (1-11)
Comorbidities	
Number of comorbidities, median (range)	2 (0-6)
Dyslipidemia, n (%)	18 (60)
Hypertension, n (%)	14 (47)
Diabetes, n (%)	11 (37)
Chronic liver disease, n (%)	9 (30)
Active tobacco consumption, n (%)	11 (37)
Cancer, n (%)	
Former	4 (13)
Active	1 (3)

[a]ART: antiretroviral treatment.

News and Reports

There were 75 news publications in different categories: HIV (34 published), healthy aging (27), project information (7), social and psychological (5), and Information and Communication Technologies (ICT) use and the elderly (2). A total of 135 likes were received, the most liked being “On going” (5 likes), “How walking a dog can help the elderly comply with physical exercise recommendations” (5), “How to get brown in a healthy way” (5), “Welcome!” (4), “A cure for HIV?” (4), “Food for people with HIV” (4), “Is the flu vaccine less effective in overweight people” (4), “A monthly injection can maintain AIDS virus confined” (4), and “Spain fails in recommended calcium intake” (4). There were 22 news comments, the most commented paper being “Around 5000 patients have HIV infection in Malaga province” (3 comments).

Chat Analysis

As an example, in the section corresponding to *psychological*, the key words were happiness, emotion, sadness, surprise, restlessness, and greetings. Within the key word *sadness* were included chat comments such as “you lose the desire of everything,” “today I’ve been very dejected and sad,” “we all have a bad day,” “I’m pulling, I have head like a pot of crickets,” “I never dream,” “I’m fed up,” “I do not know anything about anyone,” “I’m worried, without knowing anything,” “this heat kills me,” “hello guys you’re going to forgive me I’m not for nothing,” “it was a horrible time and without being able to talk to anyone, it passes very badly,” “I have the body as if I had been beaten,” “no one knows what it is,” “absolutely nobody in my family knows anything,” “I’m bored,” “my friends do not know after twelve years,” “that’s why it was so hard for me to admit it, it cost us much assimilate, fuck has cost me,” “I do not understand how people are so denied,” and “what a pity, we are the only survivors.”

Table 2. Evolution of the main parameters evaluated.

Parameter	Baseline	6 months	*P* value
Analytical parameters			
CD4 lymphocyte (cell/μL), median (range)	723 (166-1251)	811 (178-1833)	.08
HIV-1 viral load <50 copies/mL, n (%)	29 (96)	28 (93)	.44
Total cholesterol, median (range)	190 (106-306)	178 (106-285)	.77
HDL[a]-cholesterol, median (range)	49 (21-81)	47 (23-94)	.24
LDL[b]-cholesterol, median (range)	116 (37-190)	108 (44-195)	.95
Triglycerides, median (range)	115 (28-519)	118 (50-274)	.19
Adherence, n (%)			
ART[c] adherence >95%	26 (87)	27 (88)	.56
ART adherent (Simplified Medication Adherence Questionnaire)	24 (80)	22 (73)	.66
Non-ART adherent	20 (66)	17 (58)	.49
Questionnaires			
WHOQOL-BREF Physical quality of life (score)	69	69	.13
WHOQOL-BREF Psychological quality of life (score)	75	78	.19
WHOQOL-BREF Social relationships (score)	69	69	.32
WHOQOL-BREF Satisfaction with health care and social services (score)	75	69	.13
IPAQ[e]: moderate-high activity, n (%)	28 (93)	27 (92)	.16
Perceived QOL[f] (score)	4	4	.22
Perceived health status (score)	3	4	.19
6-min walking test (meters)	400	410	.76

[a]HDL: High density lipoprotein.

[b]LDL: Low density lipoprotein.

[c]ART: Antiretroviral Treatment.

[d]WHOQOL-BREF: World Health Organization Quality of Life Questionnaire (short version).

[e]IPAQ: International Physical Activity Questionnaire.

[f]QOL: Quality of life.

As we already stated, terms were grouped by categories, where we can find the following:

- Nutrition: terms related to the nutrition field were mentioned 104 times, where *coffee* was the most frequently mentioned term.
- Health care environment (sanitary and professional centers): terms related to health care environment were mentioned 187 times, with *doctor* being the most named term (124).
- Healthy attitudes: terms related to healthy attitudes were mentioned 273 times, the most mentioned terms were *beach* (94) and *walking* (87).
- Medications: terms related to medications were mentioned 115 times, the most named terms were medication or treatment (28) and *acenocoumarol* (24).
- Pathology or disease: terms related to pathology or disease were mentioned 414 times, especially *weight or height* (76), *blood pressure* (76), cancer (24), *heart or heart attack* (21), *depression* (20), and *diabetes* (18).
- HIV: was quoted 184 times, with references to health care environment above all (*doctors*, *internal medicine outpatient consultation room*, *Costa del Sol Hospital*, and *in good hands*) being 157 and only 9 direct references to HIV.
- Psychology and emotional: terms related to psychology and emotional were mentioned 554 times, the most used terms (or similar) being *greetings* (305), *happiness* (135), *emotion* (70), *anxiety or mood* (27), *surprise or wishes* (11), and *sadness ormelancholy* (6).

The chat participants described the experience as purely positive; it allowed them to create “a space for freedom in which they could talk to other elderly patients infected,” they found “nice people with my same problems,” and all of them would repeat the experience. All the patients that downloaded the app referred that their knowledge about the infection had increased and their feelings of *secret* or *taboo* toward the disease had lessened.

Discussion

Principal Findings

In our experience, the use of a mobile app in older adults infected with HIV has translated into a frequent use of this app, with just over 2400 sessions and an average time of use of almost 8 min for each one of them. Far from being a collective that shies away from mobile app use, it is quite clear that if this population's interest is stimulated toward these apps, they will make use of them and make the most of the information they have to offer. The fact that the navigation in each session implies an average of 5 screens in each one of them also shows user's interest for the different sections of the app and that navigation is certainly dynamic. The most frequently viewed screens were *Chat* (over 4000 times) and *News* (over 800 times), which reveals that patients were clearly interested in the social relationship that the app implied and in commenting on latest medical news.

The population of our study responds to a pattern of comorbid and polymedicated patients (a median of 5 medications excluding antiretroviral), diagnosed at around 50 years of age and with a decade of ART use. Although the perception of their health was 3 over 5, the perception of quality of life was higher (4 out of 5), which definitely shows certain optimism about their own life in spite of the illness, verified again in the WHOQOL-BREF results, where the psychological quality of life results were higher than the physical quality of life ones. The high appreciation of health care and social services also stands out (75 over 100).

The use of the app was not associated with clinical or analytical parameter changes in patients. Changes in this type of parameters are probably not to be expected in this type of elderly population in such a short period as 6 months and also because of the low number of patients included in each group (n=15) of this pilot study.

Analysis of the chat reveals that the main area of concern for patients is disease in general, a lot more than HIV, referring to typically age-related pathologies rather than the chronic infection itself. The analysis of feeling-related terms reveals a positive attitude, with frequent mention of happiness.

Strengths and Limitations

Compared with other studies [18], our study population had physically active perception of itself (over 50% referred high physical activity), which could also be related to a better perception of their psychological welfare. Indirectly related information that supports this fact is that *beach* (94) and *walking* (87) stand out among the most quoted individual terms in the chat.

Experiences of the development of apps in HIV have been published with the purpose of improving adherence [19], but perhaps, elderly HIV-infected patients represent a group in which this type of apps can promote stigma reduction and sharing experience between peers. The use of mobile apps, where anonymity is preserved, can help reduce the social barriers that these patients have to confront [20]. The presence of this stigma can be associated with worse ART adherence rates and less viral suppression rates [21-23]. However, in our patients, adherence to ART was very high, although it could be improved in non-ART medication. Comorbidity presence related to age translates into a higher use of these medications, and making this treatment easier (lower amounts of pills, and precise indications) must be another step in the reinforcement of this adherence.

Similar to other mobile phone–based interventions [24], ours has not demonstrated a significant increase in ART adherence, although the truth is that the initial situation was very positive in that parameter (almost 90% referred over 95% adherence).

Conclusions

Ours constitutes a preliminary experience that seems to confirm that our older adults with HIV infection find the utilization of a mobile app to be able to receive information about the infection and connect with individuals with their same problems to be useful. Studies larger than ours, and probably more extended in time, should confirm if some kind of benefit is obtained in this group of patients (older adults with HIV infection) through new technologies.

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Conflicts of Interest

None declared.

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Abbreviations

ART: antiretroviral treatment
IPAQ: International Physical Activity Questionnaire
ICT: Information and Communication Technology
6MWT: 6-min walking test
WHOQOL-BREF: World Health Organization Quality of Life Questionnaire (short version)

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Original Paper

Get Healthy, Stay Healthy: Evaluation of the Maintenance of Lifestyle Changes Six Months After an Extended Contact Intervention

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Abstract

Background: Extended intervention contact after an initial, intensive intervention is becoming accepted as best practice in behavioral weight control interventions. Whether extended contact mitigates weight regain in the longer term or it simply delays weight regain until after the extended intervention contact ceases is not clear.

Objective: This study aimed to evaluate, in multiple ways, maintenance of weight, diet, and physical activity outcomes following Get Healthy, Stay Healthy (GHSH), a text message–delivered extended contact intervention.

Methods: Clients completing the Get Healthy Service (GHS) lifestyle telephone coaching program were randomized to receive GHSH (n=114) or standard care (no additional contact, n=114) and were assessed at baseline (following completion of GHS), 6 months (following completion of GHSH), and 12 months (noncontact maintenance follow-up). At all 3 assessments, participants self-reported their body weight, waist circumference, physical activity (walking and moderate and vigorous sessions/week), and dietary behaviors (fruit and vegetable serves/day, cups of sweetened drinks per day, takeaway meals per week; fat, fiber, and total indices from the Fat and Fiber Behavior Questionnaire). Moderate-to-vigorous physical activity (MVPA) was also assessed via accelerometry. Maintenance was examined multiple ways: (1) using traditional methods to assess and compare group averages after some period of noncontact (ie, at 12 months), (2) using a novel approach to assess and compare group average changes over the first 6 months of noncontact, and (3) exploring individual participant changes (increase/decrease/no change) over the first 6 months of noncontact.

Results: Retention over the 12-month trial was high (92.5%, 211/228). Participants had a mean (SD) age of 53.4 (SD 12.3) years and a baseline body mass index of 29.2 (SD 5.9) kg/m^2. The between-group differences detected at 6 months were still present and statistically significant at 12 months for bodyweight (−1.33 kg [−2.61 to −0.05]) and accelerometer-assessed MVPA (24.9 min/week [5.8-44.0]). None of the other outcomes were significantly favored compared with the control group at 12 months. Changes over their first 6 months of noncontact for the GHSH group were significantly better than the control group in terms of accelerometer-measured MVPA and self-reported moderate activity (other differences between the groups were all nonsignificant). In addition to the maintenance seen in the group averages, most intervention participants had maintained their behavioral outcomes during the first 6 months of noncontact.

Conclusions: The GHSH participants were better off relative to where they were initially, and relative to their counterparts, not receiving extended contact in terms of MVPA. However, based on the between-group difference in bodyweight over the first 6

months of noncontact, GHSH does appear to simply delay the *inevitable* weight regain. However, this delay in weight regain, coupled with sustained improvements in MVPA, has public health benefits.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12613000949785; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=364821&isReview=true

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KEYWORDS

maintenance; mHealth; physical activity; exercise; diet; overweight; body mass index; text messages

Introduction

Background

A large body of evidence on the maintenance of weight loss and/or behavior change following the end of initial interventions resoundingly shows a *relapse effect*, characterized by weight regain and/or behavioral decline back toward baseline levels [1-3]. This has led to a concerted focus on weight loss maintenance interventions, defined in the current literature as "extended contact" interventions—the intervention that continues after initial weight loss intervention, typically at a comparatively lower intensity than the initial intensive phase of intervention. Extended contact interventions have been consistently shown to somewhat mitigate the relapse effect [4-6]. What is not known is whether extended contact helps mitigate weight regain in the longer-term or whether it simply delays weight regain until after the extended intervention contact ceases.

Moreover, 2 previous studies evaluating text message–delivered, extended contact interventions for weight loss maintenance have shown that 6 months after extended contact ceases, participants' body weight has remained, on average, significantly reduced compared with baseline [7,8]. However, another 2 studies that compared an extended contact intervention with a control condition after 2 months [9] or 6 months [10] of no contact found no between-group maintenance effects, although notably neither of these interventions achieved significant intervention effects at the end of text message–delivered extended contact. Research is needed to understand whether the improvements gained through extended contact behavioral interventions can be sustained following the end of such interventions, particularly in comparison with a control condition.

The "Get Healthy, Stay Healthy" (GHSH) intervention was an extended contact program delivered via text messages for 6 months following completion of an initial 6-month community-wide lifestyle telephone coaching program called "Get Healthy Service" (GHS) in Australia [11]. The GHSH intervention was evaluated in a randomized controlled trial (RCT) compared with normal practice following GHS (no ongoing intervention contact). Anthropometric (weight and waist circumference) and behavioral (physical activity and dietary) indicators were assessed at baseline (following completion of GHS), 6 months (following completion of GHSH), and 12 months (no-contact maintenance follow-up). We have previously reported that the GHSH intervention was feasible to deliver using semiautomated Web-based technology and was highly acceptable to participants [12]. Changes in body weight and physical activity (but not dietary outcomes) between baseline and 6 months were significantly better for the GHSH intervention group compared with the control group [12].

Objectives

This paper aims to evaluate maintenance beyond the period of the GHSH extended contact intervention in multiple ways. First, we used the traditional method of assessing and comparing changes from baseline contemporaneously after some period of noncontact (ie, at 12 months, which is after 6 months of noncontact for the intervention group and after 12 months of noncontact for the control group). This method establishes whether an intervention has a lasting effect, after allowing some time for intervention recipients to relapse. Second, we used a novel approach to directly assess and compare the degree of changes over the first 6 months of noncontact between the intervention group (between 6 and 12 months) and the control group (between baseline and 6 months). This method adds to the previous by determining whether the degree of changes after extended-contact intervention are any different to changes that naturally occur over the same amount of noncontact time without extended contact. Finally, both of these maintenance perspectives consider only changes at the group level. We, therefore, also examined individual-level changes (personal increase/decrease/no change) over the first 6 months of noncontact, to explore to what extent nonsubstantial changes in group averages reflect all or most participants making no changes or are due to large increases by some participants being offset by large decreases by other participants.

Methods

Study Design

A detailed description of this RCT is published elsewhere [11]. Eligible consenting participants were randomized in a 1:1 ratio to the GHSH intervention and control groups, via a randomization website, by a research assistant with no involvement in participant recruitment. Randomization was across 2 strata (≥ or < the median of 3 kg weight loss during GHS). Recruitment began in August 2012 and 12-month follow-up data were collected until August 2014. Ethical clearance was received from the Human Research Ethics Committee at The University of Sydney (Protocol number: 03-2011/13523).

Participant Recruitment

The GHS is available to adults (≥18 years and older) residing in New South Wales, Australia and is available for free via

self-referral and health professional referral. Participants completing GHS between August 2012 and February 2013 were eligible to join the GHSH trial if they had no intention of re-enrolling in GHS coaching, were not involved in other GHS evaluation substudies, and owned a mobile phone. All eligible clients completing the initial contact intervention (GHS) within the recruitment time frame were invited to participate in GHSH during their final coaching call. Interested participants were mailed an information sheet and consent form and then contacted via telephone to establish their eligibility and willingness to participate. Verbal consent to participate was audio recorded, and participants returned a signed consent form via reply-paid post.

The Extended Contact Intervention

The GHSH-extended contact intervention was delivered via individually tailored text messages. Tailoring data were collected during an initial and an interim telephone call (around 12 weeks), during which participants worked with a trained coach to set a 12-week weight goal (weight maintenance or further weight loss) and two 12-week goals for physical activity and/or dietary behavior change, with targets consistent with national guidelines [13,14]. For each behavioral goal (diet and/or physical activity), participants were asked to identify rewards for reaching their goal, expected benefits, preparatory behaviors for goal attainment, barriers and solutions, and a person who could support them to reach their goals. Participants selected their desired number of text messages (from 3-13 per fortnight), timing of texts (eg, 6 am), and type of texts. Overall, 4 types of texts targeted different behavior change strategies, each with different permitted frequencies: prompts to self-monitor weight (once per fortnight), goal checks for behavioral goals (from once per fortnight to once per week for each goal), real-time behavioral prompts (from none to 4 per fortnight for each goal), and goal resets for weight and behavioral goals (1 in week 6 and 1 in week 18). At 12 weeks, participants received a second telephone call from their coach to update their tailoring goals and preferences.

Control Group Treatment

To minimize trial attrition, control participants were posted brief written feedback of results following each assessment. The control group received no other contact.

Data Collection

Details of the data collection are reported elsewhere [11]. Briefly, data were collected at baseline, 6 months, and 12 months. Most outcomes were collected by computer-assisted telephone interviews (CATI), conducted by a research assistant, who was initially blinded to group allocation (information collected in the interviews limited this blinding at 6 and 12 months). The outcomes and measures were the same as those collected in the initial intervention, with the addition of an objective monitor of physical activity and a nutrition assessment tool, the Fat and Fiber Behavior Questionnaire (FFBQ) [15].

Anthropometric Outcomes

During the interviews, participants reported their body weight in kilograms (while wearing light clothes and no shoes) and waist circumference. Use of measurement aids during the interview was encouraged (scales and study-provided measuring tapes). Body mass index (BMI) was calculated based on self-reported height at GHS baseline and self-reported weight at each assessment point.

Physical Activity Outcomes

Self-reported physical activity included the number of weekly sessions spent: walking for 30 min or more, doing other moderate-intensity physical activity for 30 min or more (termed *moderate*), and doing vigorous-intensity physical activity for 20 min or more [16]. Further, objectively measured time spent engaged in moderate-to-vigorous physical activity (MVPA) was measured using the Actigraph GT1M—a dual-axis accelerometer. The protocol, published elsewhere [11], required participants to wear the accelerometer on the hip for 7 days during all waking hours. MVPA was assessed using a commonly implemented method [17] in which 60-second epochs with 1952 cpm or greater on the vertical axis were summed for each day of wear and averaged per wear day. Nonwear time, which was identified by an algorithm with published validity [18], was excluded along with nonwear days (<10 hours wear).

Dietary Behavior Outcomes

Dietary outcomes were recalled based on the participant's usual behavior in the past month and included daily servings of fruit and of vegetables [19], average daily consumption of sweetened drinks, and takeaway meals per week [20]. Additional outcomes were the FFBQ's 13-item fat index, 7-item fiber index, and 20-item total index, all of which were calculated as the average of the relevant items measured on a scale from 1 to 5 with higher values respectively indicating healthier habits concerning fat intake, fiber intake, or both.

Sample Size

As previously reported [11], the sample size had been chosen a priori to provide 90% or more power to detect the following expected differences between groups in primary outcomes with 5% 2-tailed significance: 2 sessions per week of self-reported MVPA, 1 daily serving each of fruit and vegetables, 2 kg body weight, and a 4 cm waist circumference. The study was not powered a priori for questions concerning within-groups changes. For the FFBQ indices, fruit intake, takeaways, and sweetened drinks only, power was adequate (≥80%) to detect differences between groups meeting the minimum differences of interest (MDI). The MDIs were set at 1 kg weight, 1 cm waist circumference, 30 min or 0.5 sessions/week physical activity, 0.5 servings per day of fruit and vegetables, 0.5 takeaway meals per week, 0.25 cups per day of sweetened drinks, and 0.2 units on the FFBQ indices [12].

Statistical Analysis

Maintenance is considered in three ways. First, whether anthropometric and behavioral outcomes are comparatively better after noncontact (at 12 months) for those who received the GHSH extended contact intervention than for those who had not (controls), second, comparing changes during the first 6 months of noncontact within the GHSH intervention group (ie, between 6 and 12 months) with changes in the control group (ie, between baseline and 6 months), and finally, considering

behavioral maintenance at the individual-level during the first 6 months of noncontact in the intervention group.

Statistical analyses were performed using SPSS Statistics version 22 (IBM, USA) and STATA version 13 (StataCorp LP, USA). Significance was set at $P<.05$, 2-tailed. Changes within groups were assessed using paired *t* tests. All differences between groups were estimated adjusting for the same potential confounders as per the main outcome evaluation of the GHSH intervention [12]. Differences between the groups in their changes (for all outcomes and all time frames) were assessed using separate linear regression models adjusting for baseline values of the outcome and confounders. When assessing change over the period from baseline to 12 months, baseline values were taken as the beginning of the GHSH evaluation. When assessing changes over the first 6 months of noncontact, baseline values were taken as the beginning of the GHSH evaluation for controls or at 6 months for the intervention group. Group differences in daily values of accelerometer MVPA (log-transformed) were assessed using generalized estimating equation models, which accounted for repeated measures (1-7 days per participant per assessment), adjusted for confounders, and controlled comparisons for baseline values via the method outlined by Twisk [21]. Marginal means of the appropriate back-transformed expression were used to obtain the contrasts in minutes per week. The absence of substantial changes in group averages can be suggestive of maintenance; however, this can be achieved by large worsening in some participants being offset by others' large improvements and does not necessarily show whether individuals maintained their personal outcomes. Accordingly, we further describe how many of the intervention participants maintained their outcomes during noncontact (ie, individual-level maintenance).

Results

Participants

Participants who remained in the study at 12 months had an average (mean [SD]) age of 53.4 (SD 12.3) years and baseline BMI of 29.2 (SD 5.9) kg/m^2 (Table 1). Approximately two-thirds of the participants were female. Retention over the 12-month trial was high overall (92.5%, 211/228), but slightly lower in the intervention group (86.8%, 99/114) than in the control group (98.2%, 112/114; $P=.002$). Those lost to follow-up at 12 months (n=17) had significantly heavier baseline BMI, were more likely to smoke at baseline, and reported consuming fewer vegetables and more sweetened drinks at baseline than those who participated in the 12-month follow-up CATI (n=211; see Table 1).

Sustained Improvement After Noncontact

Figure 1 shows changes from baseline to 12 months in study outcomes in the control group (12 months of noncontact after the initial GHS intervention) and in the GHSH intervention group (following 6 months of GHSH extended contact then 6 months of no contact). Results are described in units but plotted relative to a substantial decline or worsening (ie, MDI), to indicate whether the absence of a significant change was more consistent with maintenance (ie, a substantial worsening is unlikely) or an inconclusive result (ie, the error is too large to draw a conclusion). Over 12 months, the GHSH intervention group made significant improvements to waist circumference and the fiber index score, and the control group significantly improved their waist circumference and fat index score. The only significant declines between baseline and 12 months were self-reported walking, which declined in the intervention group, and self-reported vigorous activity, which declined in controls (Figure 1). Self-reported moderate physical activity and most of the dietary outcomes were maintained in both groups.

Although both groups had displayed a large degree of behavioral maintenance at 12 months, extended contact was still associated with a significant advantage over control treatment for body weight ($P=.04$) and accelerometer-assessed MVPA ($P=.01$), with differences between groups averaging approximately 1.3 kg and 25 min per week (Table 2). Only small and nonsignificant differences between groups were seen with the other outcomes; however, CI included meaningful differences in self-report physical activity and vegetable intake.

Changes During the Noncontact Period After Extended Care

Figure 2 shows the changes over the first 6 months of noncontact within each group. Statistically significant changes over the first 6 months of noncontact occurred only in the control group, not in the intervention group following extended contact. All of these changes were worsening of outcomes rather than improvements (Figure 2). Intervention changes (all nonsignificant) during this time frame were suggestive of maintenance for waist circumference, moderate activity, and all of the dietary outcomes, but margins of error precluded definitive conclusions concerning the other outcomes.

When compared with the control group changes over their first 6 months of noncontact, those receiving intervention fared significantly better than those receiving usual care in terms of accelerometer-measured MVPA and self-reported moderate activity (Table 2). Other differences between the groups were all nonsignificant. All were small (except for walking) and a substantial effect of extended contact was unlikely for weight, FFBQ indices, takeaways, sweetened drinks, and fruit intake (based on the CI). However, CI included potentially meaningful differences in waist circumference, walking, vigorous physical activity, and vegetable intake.

Individual-Level Maintenance of Outcomes During Noncontact

In addition to the maintenance seen in the group averages, many intervention participants had maintained their behavioral outcomes during 6 months of noncontact, whereas a minority of participants had worsened in their outcomes during that period. Figure 3 shows the percentage of intervention participants who had maintained their outcomes during noncontact. Nearly all outcomes were maintained (ie, no worsening of ≥ the MDI) by the majority of participants. The proportion of maintenance was lowest for weight (55.5% [56/101]) and highest for sweetened drinks (91.2% [93/102]), with a substantial proportion of maintenance coming in the form of further improvement for most outcomes. Notably, weight

regain was still reasonably common (44.5% [45/101]), despite this maintenance intervention and despite the overall intervention effects for weight outcomes.

Table 1. Baseline characteristics of participants by study group and for those who remained in the study at 12 months and those who dropped out by 12 months.

Characteristics	GHSH[a] intervention (n=114)[b]	Control (n=114)[b]	Retained at 12 months (n=211)[c]	Lost to follow-up (n=17)[c]	*P* value[d]
Health and demographics					
Age (years), mean (SD)	55.5 (12.3)	51.2 (11.9)	53.4 (12.3)	52.9 (12.6)	.87
Body mass index (kg/m^2), mean (SD)	29.3 (5.8)	29.6 (6.3)	*29.2 (5.9)*[e]	*32.6 (7.2)*	*.03*
Weight (kg), mean (SD)	82.8 (19.4)	83.6 (18.9)	82.6 (19.3)	89.9 (16.2)	.13
Waist circumference (cm), mean (SD)	98.9 (15.4)	99.6 (14.9)	99.0 (15.2)	103.1 (14.3)	.29
Gender (female), n (%)	74 (64.9)	78 (68.4)	140 (66.4)	12 (71)	.48
Paid employment (response: yes), n (%)	69 (61.1)	68 (59.6)	129 (61.1)	8 (50)	.43
Education (postschool qualification), n (%)	73 (64.0)	77 (67.5)	136 (64.5)	14 (82)	.19
English at home, n (%)	109 (96.5)	111 (97.4)	205 (97.2)	15 (94)	.41
Indigenous Australian, n (%)	1 (0.9)	5 (4.4)	6 (2.9)	0 (0)	__[f]
SEIFA[g] (percentage in most advantaged 3 quintiles), n (%)	86 (75.4)	78 (68.4)	151 (71.6)	13 (77)	.79
Region (percentage in major cities), n (%)	71 (62.3)	82 (71.9)	144 (68.2)	9 (53)	.28
Initial health (percentage ≤ “fair”), n (%)	25 (21.9)	30 (26.3)	49 (23.2)	6 (35)	.25
Current smoker, n (%)	5 (4.4)	7 (6.1)	*9 (4.3)*	*3 (18)*	*.05*
Physical activity (PA)					
Accelerometer PA (minutes/week), mean (SD)	196.9 (144.4)	196.2 (143.6)	195.1 (136.2)	214.4 (221.3)	.60
Vigorous PA (sessions/week), mean (SD)	1.56 (1.86)	2.33 (2.53)	1.9 (2.3)	2.1 (2.2)	.75
Moderate PA (sessions/week), mean (SD)	1.11 (1.78)	1.60 (1.97)	1.4 (1.9)	0.8 (1.4)	.13
Walking PA(sessions/week), mean (SD)	3.99 (3.04)	3.30 (2.44)	3.6 (2.7)	4.8 (3.7)	.20
Dietary behaviors					
Vegetable (servings/day), mean (SD)	3.1 (1.4)	3.4 (1.8)	*3.3 (1.7)*	*2.6 (0.8)*	*.005*
Fruit (servings/day), mean (SD)	2.0 (0.9)	2.0 (1.0)	2.0 (1.0)	2.0 (1.0)	.95
Sweetened drinks (cups/day), mean (SD)	0.2 (0.5)	0.4 (0.9)	*0.3 (0.8)*	*0.1 (0.3)*	*.04*
Takeaways (meals/week), mean (SD)	0.5 (0.8)	0.5 (0.9)	0.5 (0.8)	0.8 (1.3)	.38
FFBQ[h] total score (1-5), mean (SD)	3.3 (0.4)	3.3 (0.4)	3.3 (0.4)	3.2 (0.3)	.54
FFBQ fat score (1-5), mean (SD)	3.5 (0.5)	3.5 (0.5)	3.5 (0.5)	3.5 (0.4)	.89
FFBQ fiber score (1-5), mean (SD)	2.9 (0.5)	2.9 (0.5)	2.9 (0.5)	2.8 (0.4)	.44

[a]GHSH: Get Healthy, Stay Healthy.

[b]Figures exclude missing data; that is, 1 GHSH intervention participant (employment, English spoken at home, referral source, and accelerometer moderate-to-vigorous physical activity) and 1 control participant (waist circumference and indigenous status).

[c]Figures exclude missing data: n=1 lost to follow-up (employment, English at home, and waist circumference).

[d]*P* value for difference between those retained and those lost to follow-up determined by independent samples *t* test (continuous variables) or chi-square test (categories).

[e]A statistically significant difference between those lost to follow-up at 12 months (n=17) and those who participated in the 12-month follow-up computer-assisted telephone interview (n=211).

[f]Invalid chi-square test (not presented).

[g]Socioeconomic indices for areas (SEIFA), specifically the Index of Relative Socioeconomic Advantage and Disadvantage (IRSAD).

[h]FFBQ: Fat and Fiber Behavior Questionnaire.

Figure 1. Mean changes (95% CI) between baseline and 12 months in study outcomes plotted as multiples of the minimum difference of interest (MDI) in the Get Healthy, Stay Healthy (GHSH) intervention (n=114) and control (n=114) groups ("a" indicates significant change *P*<.05. Asterisk indicates that the x-axis values for the means and CI are displayed as the mean, upper limit, and lower limit divided by the MDI value. Missing data are excluded for the intervention group or control group: n=13/3 [weight], n=14/6 [waist circumference], n=12/3 [self-reported physical activity and diet outcomes], and n=16/9 [accelerometer moderate-to-vigorous physical activity, MVPA]). FFBQ: Fat and Fiber Behavior Questionnaire; PA: physical activity.

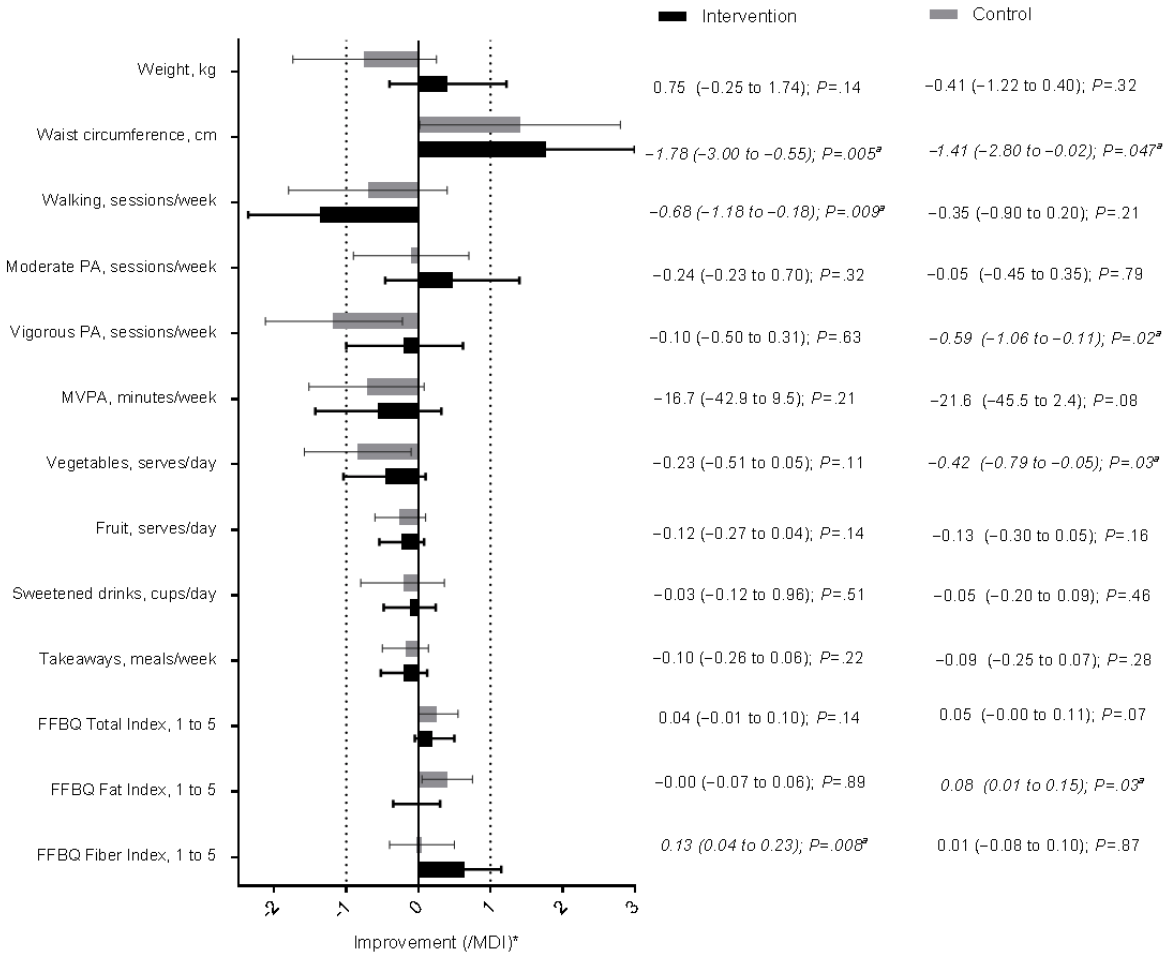


Table 2. Difference in study outcomes between the Get Healthy, Stay Healthy (GHSH) extended contact group (n=114) and control group (n=114) adjusted for baseline values of the outcome and potential confounders[a].

Outcome	Baseline to 12 months[b]		First 6 months of noncontact[c]	
	Mean difference (95% CI)	*P* value	Mean difference (95% CI)	*P* value
Anthropometry				
Weight (kg)	*− 1.33 (−2.61 to −0.05)*[d]	*.04*	0.01 (−0.94 to 0.95)	.99
Waist circumference (cm)	−0.60 (−2.33 to 1.12)[e]	.49	−0.72 (−2.13 to 0.69)[e]	.31
Physical activity (PA)				
Accelerometer PA, minutes/week	*24.9 (5.8 to 44.0)*	*.01*	*18.3 (0.8 to 35.7)*	*.04*
Walking PA, sessions/week	−0.07 (−0.69 to 0.55)[e]	.83	−0.51 (−1.34 to 0.32)[e]	.23
Moderate PA, sessions/week	−0.11 (−0.62 to 0.39)[e]	.66	*0.53 (0.07 to 0.99)*	*.03*
Vigorous PA, sessions/week	−0.12 (−0.64 to 0.40)[e]	.66	−0.32 (−0.84 to 0.21)[e]	.23
Dietary behaviors				
Vegetables, serves/day	0.10 (−0.32 to 0.53)[e]	.63	0.17 (−0.20 to 0.53)[e]	.36
Fruit, serves/day	−0.00 (−0.22 to 0.21)	.98	0.10 (−0.11 to 0.32)	.35
Sweetened drinks, cups/day	−0.06 (−0.19 to 0.06)	.32	−0.07 (−0.21 to 0.08)	.36
Takeaways, meals/week	−0.10 (−0.26 to 0.06)	.22	−0.02 (−0.18 to 0.13)	.77
FFBQ[f] total index, 1 to 5	−0.02 (−0.09 to 0.06)	.64	−0.02 (−0.10 to 0.05)	.51
FFBQ fat index, 1 to 5	−0.08 (−0.17 to 0.01)	.08	−0.08 (−0.17 to 0.01)	.08
FFBQ fiber index, 1 to 5	0.09 (−0.03 to 0.20)[d,e]	.13	0.08 (−0.04 to 0.19)	.19

[a]Mean differences (intervention−control) adjusting for confounders as per the main GHSH evaluation and baseline values of the outcome as estimated using linear regression, or generalized estimating equations for repeated measures for accelerometer data (1-7 days per assessment per participant).

[b]Missing data are excluded for intervention group/control group: n=13/3 (weight), n=14/6 (waist circumference), n=12/3 (self-reported physical activity and diet outcomes), and n=16/9 (accelerometer physical activity).

[c]With baseline values of the outcome taken as values at the beginning of the noncontact period (GHSH baseline in the usual care group and at 6 months upon cessation of extended care in the intervention group). Missing data were excluded for the intervention group/control group: n=13/2 (weight), n=15/2 (waist circumference), n=12/2 (self-reported physical activity and diet), and n=19/6 (accelerometer physical activity).

[d]Significant difference between control and intervention group favoring intervention.

[e]Inconclusive: nonsignificant comparison but meaningful differences contained within the 95% CI.

[f]FFBQ: Fat and Fiber Behavior Questionnaire.

Figure 2. Mean changes (95% CI) over first 6 months of noncontact in study outcomes plotted as multiples of the minimum differences of interest (MDI) in the Get Healthy, Stay Healthy (GHSH) intervention (n=114) and control (n=114) groups ("a" indicates significant change, $P<.05$. Asterisk indicates that the x-axis values for the means and CI are displayed as the mean, upper limit, and lower limit by the MDI value). FFBQ: Fat and Fiber Behavior Questionnaire; PA: physical activity.

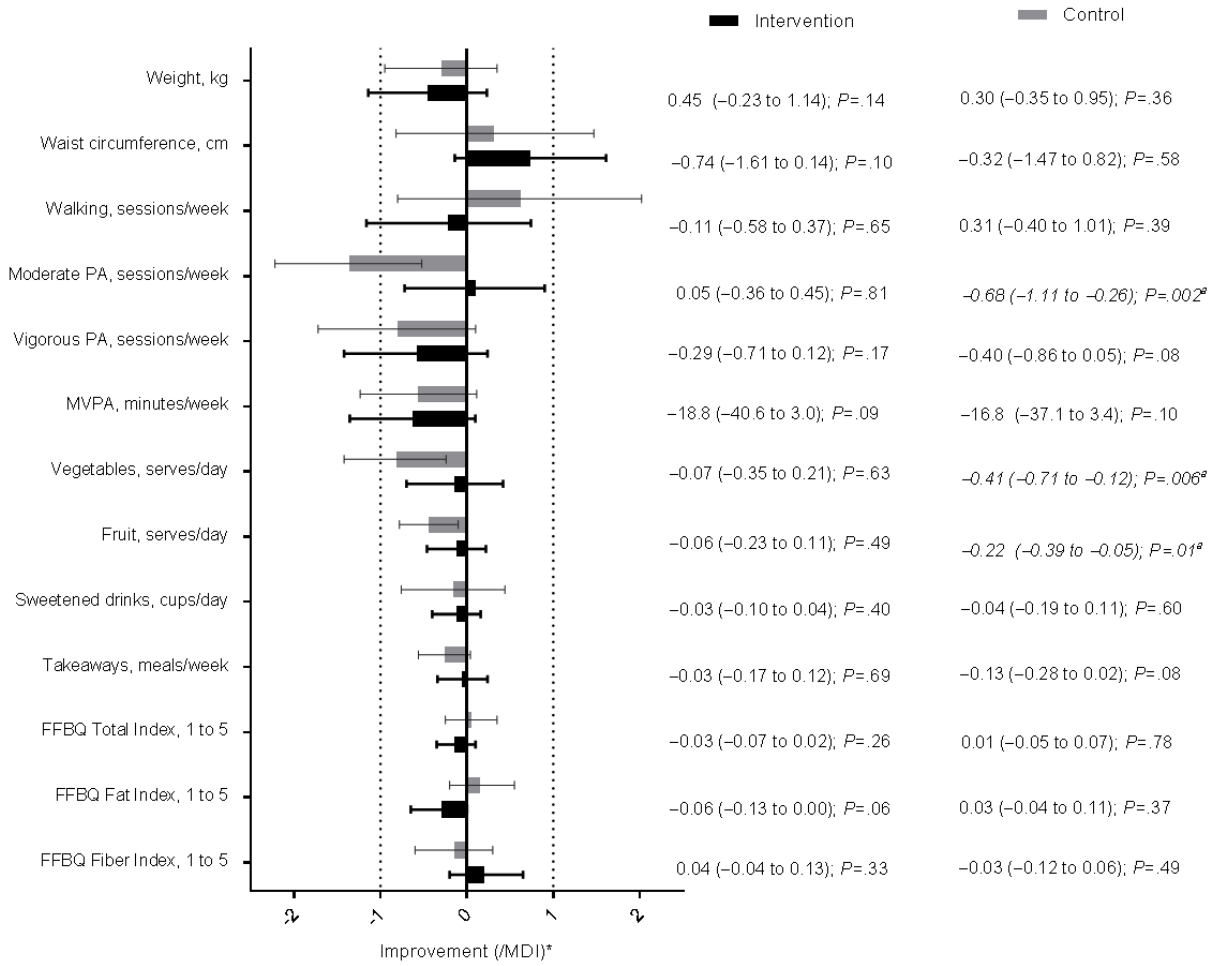
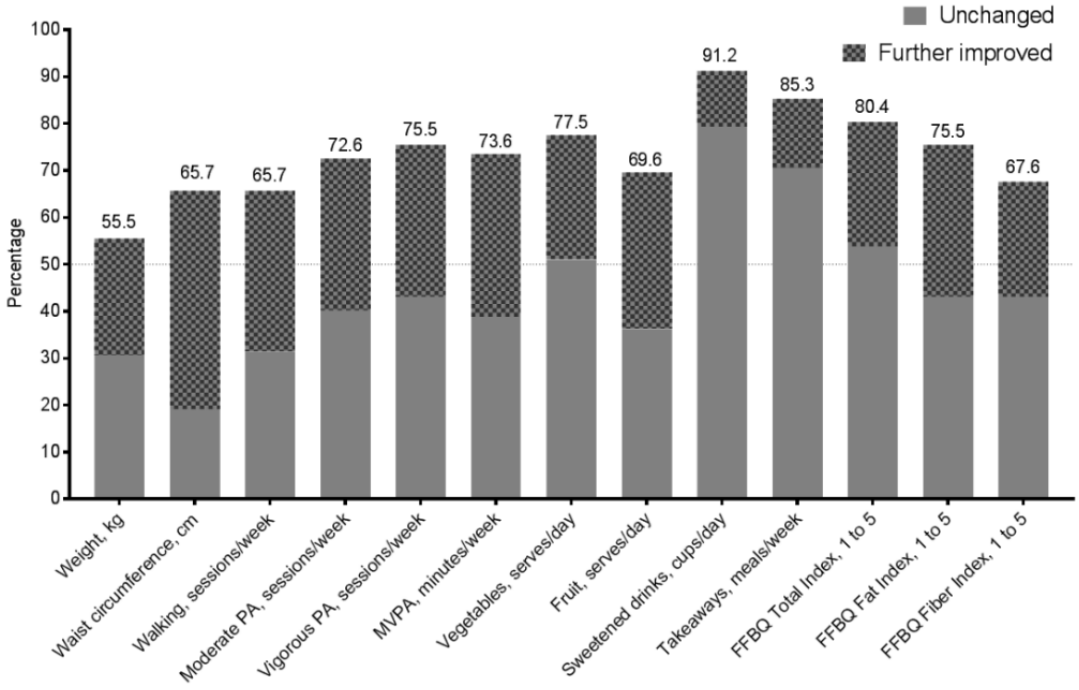


Figure 3. Percentage of the Get Healthy, Stay Healthy (GHSH) intervention participants (n=114) maintaining (by either no change or further improvement) their study outcomes during the first 6 months of noncontact. FFBQ: Fat and Fiber Behavior Questionnaire; MDI: minimum difference of interest MVPA: accelerometer moderate-to-vigorous physical activity; PA: physical activity.



Discussion

GHSH is an extended contact intervention offered after completion of a free, publicly available lifestyle telephone coaching program. Our evaluation [12] previously found that at the end of GHSH, both weight and accelerometer-measured MVPA were significantly better in the intervention group than in the control group, and the present evaluation showed that these between-group differences were still present and statistically significant at 12 months. None of the other outcomes, such as self-reported physical activity and dietary behaviors, were significantly favored compared with the control group at 12 months.

The presence of intervention effects following a noncontact period are commonly interpreted as indicators of maintenance of the intervention's effectiveness [22,23], but in isolation of other evidence (eg, the direction of change in individuals), this interpretation can be problematic. Therefore, in this study, we also considered the lack of substantial regression toward baseline levels as indicating outcomes were maintained. In GHSH, only self-reported walking declined significantly over 12 months in the group that received extended contact, with most other outcomes maintained or being further improved. Furthermore, during the noncontact period following extended contact (6-12 months), the intervention group did not significantly worsen in any outcomes, instead improving or maintaining outcomes. Over both of these time frames, there was some uncertainty around the maintenance of self-reported vigorous physical activity and vegetable intake, with wide margins of error failing to rule out worsening in these outcomes as being unlikely in general as opposed to just not observed in our sample.

These findings clearly indicate, relative to their counterparts not receiving extended contact, and relative to their initial levels, participants receiving extended care were "ahead of the game." Although useful, this perspective of maintenance fails to consider how extended care generates such gains. *Does it seem to mitigate the rate of behavioral decline upon withdrawal of intervention contact, or merely postpone behavioral decline (until after extended contact)?* Using a novel approach, we tested this question by comparing both groups in their changes over the same amount of noncontact time (6 months), beginning immediately after the intervention ceases (GHS or GHSH that involved extended care). This approach ensures that not just the amount of time (6 months) is consistent in comparing groups but also the timing relative to withdrawal of intervention contact. The changes over this key time frame significantly favored the intervention group in terms of accelerometer-measured MVPA and self-reported moderate activity, suggesting extended care helped to reduce the relapse effect for this behavior. However, there was no substantial or significant difference in body weight between groups over the first 6 months of noncontact. So, to some extent, the extended contact intervention promoted *maintenance* merely by delaying weight regain in the intervention group. This delay in weight regain meant that there was an extended period of continued or maintained weight loss, which, although not directly measured in this trial, should have public health benefits for participants' physical health [24]. Importantly, this extended period of continued or maintained weight loss is very promising, given that GHSH is a low resource, text message–delivered public health program offered free to participants. Furthermore, the extended contact did help participants to maintain their physical activity behaviors, which independent of changes in weight, should also bring public health benefit [25].

Individual-level maintenance is also important, but seldom considered [1], as average changes at the group level can be stable without individuals necessarily maintaining their personal changes. In GHSH, during the first 6 months of noncontact (whether following extended or initial contact), most of the outcomes were maintained by most individuals, with at least a two-thirds majority maintaining or further improving their outcomes over this time. The outcome for which most individuals had displayed a failure to maintain outcomes during noncontact (ie, worsening ≥MDI) was body weight, with just under half of the participants (intervention and controls) increasing weight by at least 1 kg.

Much has been written about the diversity of definitions applied to *maintenance* of behavior change [26-28]. Maintenance has been defined as being achieved when a significant intervention effect at the end of an intervention has been maintained after varying periods of no contact, which largely refers to the *success* of the intervention on group averages. Some authors have viewed maintenance as a criterion or threshold of amount of behavior change to be retained. Relatively few publications examine maintenance as individual trajectories. The findings of this evaluation, which examined maintenance from multiple perspectives, indicate researchers should similarly consider reporting maintenance of behavior change following interventions in multiple ways that help better understand how maintenance might occur, not just whether or not it occurred by some particular criterion for maintenance.

Evidence suggests need for ongoing support that people can access as required over long periods of time. Mobile technologies facilitate this type of ongoing monitoring and contact in cost-effective ways. There is international consensus that obesity is a chronic, relapsing disease process that requires continuous treatment [29]. Although it is important to point out that the participants in this study were not necessarily obese at baseline, the majority were working toward weight loss goals, and it is the mechanism of weight loss regain that needs ongoing treatment. Researchers and practitioners need to acknowledge that individuals will cycle in and out of multiple programs across a life span, and therefore, we should not be imagining a single intervention effect to be *maintained*. What we need to do instead is ensure that individuals have a positive experience in these programs so that they approach the next program with positive expectations and high self-efficacy.

This trial has tested the addition of tailored text messages to a telephone coaching program to extend the duration of care provided. It led to better outcomes for those receiving the texts, while the contact was maintained. As we move forward, we need to consider cost-effective mediums to maintain contact with people as they cycle in and out of weight loss and lifestyle support programs, and text messaging may be a feasible and affordable way to do this. Limitations of this trial include the

reliance on self-reported anthropometric outcomes (albeit validated and reliable tools were used) and that the trial was underpowered to detect within-group changes. The strengths of this trial include comprehensively examining maintenance in 3 different ways, conducting an RCT within partnership and in a service delivery context, and inclusion of high-quality behavioral measurement tools. These strengths and the positive maintained outcomes of the GHSH intervention have resulted in this evaluation directly informing the addition of an extended contact program in GHS. More pragmatic research trials such as, this one, need to be conducted to generate practice-based evidence to inform service delivery decisions. Finally, future evaluations of the maintenance of intervention impacts should consider reporting these in multiple ways, including a comparison of group averages when holding the period of noncontact equal and individual patterns of change.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 5MB - mhealth_v7i3e11070_fig.pdf]

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Abbreviations

BMI: body mass index
CATI: computer-assisted telephone interview
FFBQ: Fat and Fiber Behavior Questionnaire
GHS: Get Healthy Service
GHSH: Get Healthy, Stay Healthy
MDI: minimum differences of interest
MVPA: moderate-to-vigorous physical activity
RCT: randomized controlled trial

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Original Paper

A Mobile Health Contraception Decision Support Intervention for Latina Adolescents: Implementation Evaluation for Use in School-Based Health Centers

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Abstract

Background: Health care providers are a trusted and accurate source of sexual health information for most adolescents, and clinical guidelines recommend that all youth receive comprehensive, confidential sexual health information and services. However, these guidelines are followed inconsistently. Providers often lack the time, comfort, and skills to provide patient-centered comprehensive contraceptive counseling and services. There are significant disparities in the provision of sexual health services for Latino adolescents, which contribute to disproportionately higher rates of teenage pregnancy. To address this, we developed *Health-E You* or *Salud iTu* in Spanish, an evidence-informed mobile health (mHealth) app, to provide interactive, individually tailored sexual health information and contraception decision support for English and Spanish speakers. It is designed to be used in conjunction with a clinical encounter to increase access to patient-centered contraceptive information and services for adolescents at risk of pregnancy. Based on user input, the app provides tailored contraceptive recommendations and asks the youth to indicate what methods they are most interested in. This information is shared with the provider before the in-person visit. The app is designed to prepare youth for the visit and acts as a clinician extender to support the delivery of health education and enhance the quality of patient-centered sexual health care. Despite the promise of this app, there is limited research on the integration of such interventions into clinical practice.

Objective: This study described efforts used to support the successful adoption and implementation of the *Health-E You* app in clinical settings and described facilitators and barriers encountered to inform future efforts aimed at integrating mHealth interventions into clinical settings.

Methods: This study was part of a larger, cluster randomized control trial to evaluate the effectiveness of *Health-E You* on its ability to reduce health disparities in contraceptive knowledge, access to contraceptive services, and unintended pregnancies among sexually active Latina adolescents at 18 school-based health centers (SBHCs) across Los Angeles County, California. App development and implementation were informed by the theory of diffusion of innovation, the Patient-Centered Outcomes Research Institute's principles of engagement, and iterative pilot testing with adolescents and clinicians. Implementation facilitators and barriers were identified through monthly conference calls, site visits, and quarterly in-person collaborative meetings.

Results: Implementation approaches enhanced the development, adoption, and integration of *Health-E You* into SBHCs. Implementation challenges were also identified to improve the integration of mHealth interventions into clinical settings.

Conclusions: This study provides important insights that can inform and improve the implementation efforts for future mHealth interventions. In particular, an implementation approach founded in a strong theoretical framework and active engagement with patient and community partners can enhance the development, adoption, and integration of mHealth technologies into clinical practice.

Trial Registration: ClinicalTrials.gov NCT02847858; https://clinicaltrials.gov/ct2/show/NCT02847858 (Archived by WebCite at http://www.webcitation.org/761yVIRTp).

(JMIR Mhealth Uhealth 2019;7(3):e11163) doi:10.2196/11163

KEYWORDS

mobile health; adolescent health; pregnancy in adolescence

Introduction

Background

Despite the widespread use of mobile technologies (mobile phones, tablets, and computers) among adolescents and the rapid proliferation of mobile health (mHealth) apps, few studies have examined how to implement and integrate such technologies into clinical settings.

Mobile technologies are an especially attractive medium for adolescents and can be a powerful tool to promote health. Specifically, adolescents use computers and access the internet more than any other age group [1], and the use of computers to deliver behavioral health interventions is rapidly expanding [2-5]. Furthermore, computer-based sexual health risk assessments have been found to be acceptable to adolescents and to improve the disclosure of sexual health risk behaviors [3-7] and address psychological aspects of behavior in ways that teens perceive to be less judgmental than advice from a health educator or clinician [7].

Mobile technologies can also serve as a clinician extender and overcome barriers to promoting sexual and reproductive health services for adolescents. Although health care providers are a trusted and accurate source of sexual health information for adolescents [8] and clinical guidelines recommend that all adolescents receive comprehensive, confidential sexual health information and services [9,10], these guidelines are followed inconsistently [11,12]. Providers often lack the time, comfort, and skills to provide patient-centered comprehensive contraceptive counseling and services [13-15]. Many youth lack access to comprehensive, confidential contraceptive information and services, and racial disparities in teenage pregnancy rates persist despite overall declines across the United States [16,17]. A few Web-based contraceptive decision support tools have been developed to improve adolescents' and young adults' knowledge and use of contraceptives [18-20]; however, these are primarily Web-based programs that require a user to take the initiative to seek out these resources and are often aimed at young adults rather than adolescents [21]. In addition, most Latino and heterosexual adolescents do not actively seek out sexual health information online [22,23]. Furthermore, although youth find the privacy, anonymity, and ease of access to such information appealing, there is a vast amount of inaccurate sexual health information on the internet [24].

The Health-E You/Salud iTu App

To address this health care gap, we have developed an evidence-informed mHealth app, *Health-E You* or *Salud iTu* in Spanish, specifically for adolescent girls. This app is interactive, individually tailored, and provides patient-centered, contraceptive information and decision support in both English and Spanish. This is an internet-enabled app that can be used on a range of mobile devices (iPads, mobile phones, or computers). It is designed to be used in conjunction with a clinical encounter to support the contraceptive decision-making process; increase access to patient-centered, evidence-based contraceptive information and services; and ultimately reduce disparities in contraceptive knowledge, access to contraceptive information and services, and unintended pregnancies among Latina adolescents. The app was developed with significant input from Latina adolescents and health care providers. It is designed to individualize the educational experience by responding to a patient's unique needs, attitudes, experiences, and risk profiles. The app provides tailored health information based on the user's inputs and supports them in selecting a contraceptive method that is a good fit for them. When used in conjunction with a clinical visit, the app aims to (1) prepare adolescent patients for the visit and encourage them to ask about and, or, advocate for contraceptive services that are of interest to them and (2) act as a clinician extender to support the delivery of health education and enhance the quality of patient-centered care.

Objectives

To date, there is limited evidence on how to best utilize mHealth technologies, such as this app, to support effective interactions between adolescent patients and health care providers in a clinical setting [25]. To our knowledge, there are only 2 studies that designed and evaluated a contraceptive decision support tool for use in a clinical setting [26,27]. Although both these studies improved contraceptive knowledge and use, they were focused on outcomes and provided little detail on *how* the app was implemented. In addition, 1 study was relatively old (published in 1999) and was limited to oral contraceptives only [26]. With the rise of mHealth interventions aimed at enhancing the delivery of health education and services, there is a tremendous need to better understand processes to ensure effective implementation and integration into the clinical context [28].The purpose of this paper is to describe efforts to improve the successful adoption and implementation of the *Health-E You* app in clinical settings and to identify implementation facilitators and barriers that may be relevant to other types of computer apps being integrated across different clinical settings.

Methods

Study Context

This study is part of a larger, cluster randomized control trial (CRCT) conducted at 18 school-based health centers (SBHCs) across Los Angeles County, California, to evaluate the effectiveness of *Health-E You* on its ability to reduce health disparities in unintended pregnancies among sexually active

Latina adolescents [29]. All clinics are SBHCs that are operated and managed independently, cover a very large area of Los Angeles County, serve a large proportion of Latina students, and are centered in areas with high rates of sexual health morbidities according to the Los Angeles County Department of Public Health. The Institutional Review Board (IRB) for Protection of Human Subjects of the University of California, San Francisco, approved this study (IRB approval number: 10-02730). As this study is integrated into the delivery of sensitive, sexual health services provided in clinic, by the state law, these services are confidential and parental consent is not required. Parental consent to participate in the study was waived by the IRB to protect adolescent confidentiality and to comply with the state law.

App Development and Pilot Testing

A youth-centered design approach [30] was used to develop and test the app. In this approach, youth are engaged in all aspects of design, prototyping and pilot testing, and revision to achieve the final design of *Health-E You*. Several focus groups of youth from the SBHCs were conducted to gather input on the original design of the app. Youth provided feedback on design attributes that they felt would resonate with their peers, including content, images, font, and design layouts. The app was pilot tested in 3 SBHCs, which showed that Latina adolescents found it acceptable and it improved their knowledge and intentions to use effective contraception, and health care providers and staff agreed that it was feasible to implement [21]. Upon completion of the pilot study, again through an iterative process, additional feedback was gathered and incorporated into the revised app to further enhance the user experience, before implementing the CRCT. The result was a revised product that incorporated design features, content, and messages, which was relevant for Latina adolescents to increase their understanding of sexual health risk and support them in making informed decisions about contraceptive use.

Implementing the App Into Clinical Practice

The implementation of this app into clinical practice was informed by Rogers theory of diffusion of innovation [31,32]. This theory posits that an innovation is more likely to be adopted if it provides value or benefits to potential adopters, fits in well with existing systems, utilizes opinion leaders and champions who can influence others by spreading information about the innovation within and outside the organization, and addresses contextual and managerial factors within an organization [33]. In developing the app, these factors were taken into consideration. Specifically, The LA Trust research associates (RAs) observed the clinic operations and workflows before actual implementation and generated a draft *process map* that detailed how the app would be integrated into each individual clinic's unique workflow (see Figure 1). The draft process map was shared with each site so that clinic champions and staff could review and discuss the proposed implementation process. After this review, the process map was revised accordingly. This effort helped to ensure that the study team considered the individual needs and perspectives of providers and staff at each clinic with the goal of increasing the likelihood of successful integration and implementation of the app.

In addition, the implementation approaches used in this study were informed by the Patient-Centered Outcomes Research Institute's (PCORI) 6 principles of engagement: (1) reciprocal relationships between the roles and decision making between the development team, community, and clinical partners; (2) colearning between the research team, community liaisons, and clinical partners; (3) the time and contributions of patients and other stakeholder partners that are valued and demonstrated in fair financial compensation as well as in reasonable and thoughtful requests for their time commitment; (4) transparency; (5) honesty; and (6) trust [34]. As part of the PCORI funding application process, investigators are required to show that their project design adheres to the 6 PCORI principles of engagement. Throughout the life of the project, investigators are asked to self-assess their adherence and provide detailed descriptions of how this study criterion has been met in biannual progress reports. PCORI contract monitors subsequently review the information submitted.

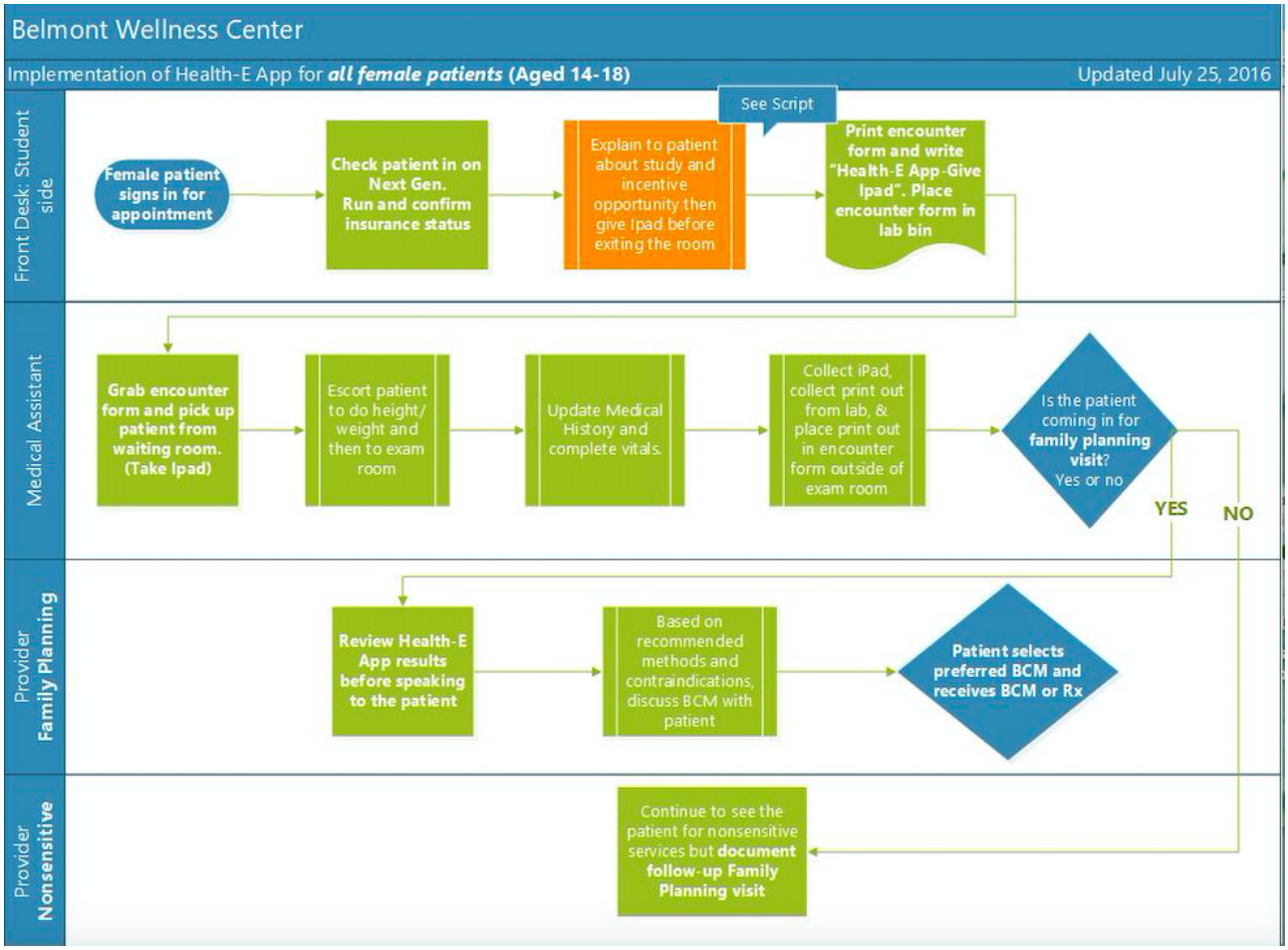
Data Collection to Assess Implementation of the App

This study used multiple sources of data to assess implementation facilitators and barriers including monthly conference calls, monthly in-person site visits, and quarterly in-person collaborative meetings.

The research team hosted monthly conference calls with The LA Trust and representatives and champions from each of the 9 SBHCs implementing the *Health-E You* app. Meeting notes were summarized and shared with all members of the call and used as a source of data for this study.

In total, 2 community-based, bilingual RAs from The LA Trust, both of whom had prior experience working for or with the various SBHCs, conducted in-person visits at each clinic at least once a month to assess app integration and implementation efforts and to identify technical assistance needs. Immediately after each visit, the RAs completed a data collection form to record implementation approaches, challenges, and technical assistance needs. The RAs provided a summary of each site visit during the research team meetings to identify and resolve any challenges that emerged. A Web-based platform was used to store, organize, and aggregate data for analyses. In addition, The LA Trust team gathered data from the quarterly collaborative quality improvement (QI) meetings to further assess implementation facilitators and barriers. Data were compiled across all 3 sources and analyzed by 2 independent Ras; key themes that emerged across all sites were identified across all sites. Any discrepancies were discussed and resolved by consensus of the research team.

Figure 1. Example of a clinic workflow that integrates the Health-E You app. BCM: birth control method; Rx: prescription.



Overview of App Implementation

Implementation of the app is described in our published study protocol [29]. In brief, clinic staff are to provide all adolescent girls who come into the clinic, for any reason, an iPad, which provides a brief explanation of the research study, obtains consent, and assesses eligibility. Pilot tests indicated that the app took approximately 10-15 min to complete, which could be done while adolescents were waiting to see their clinician.

When app users are done reviewing the various contraceptive methods, they are then asked to select the method(s) they are most interested in using. The app then provides a printout to the clinician before the face-to-face encounter with the patient, and the patient proceeds to the face-to-face encounter with the clinician.

Participants at the control clinics complete a computerized questionnaire to assess their baseline knowledge of contraception and their self-efficacy to obtain sexual health care and use, or nonuse, of contraception before proceeding to their visit to receive care as usual.

Results

The app was successfully integrated into the clinical workflows of SBHCs, and this study identified a number of factors that supported its integration into clinical workflows, which is described in the following section. In addition, there were a number of implementation challenges, which are also presented.

Successful Strategies

Engagement of Key Stakeholders in App Development

Youth engagement was essential, and youth have been engaged in all aspects of app development and implementation activities. Youth were engaged through the ongoing convenings of The LA Trust Youth Advisory Board (YAB), community advisory boards (CABs), and student advisory boards (SAB) at each clinic site. Specifically, youth guided both the content and design of the app to ensure that it would appeal to their peers. They also provided insights on the reading and comprehension level of the language used in the app. The youth helped develop scripts for video vignettes on each of the contraceptive options and served as actors in these videos. It was then pilot tested at several SBHCs to identify and address barriers to prepare for a larger scale implementation project. Youth, clinic providers, and staff champions were engaged as the project was scaled up and implemented at 9 SBHCs as part of the CRCT. Engaging both youth and clinicians in the app development and iterative pilot testing helped ensure that the ultimate product was developed in a way that was meaningful and of value to both youth and clinicians.

Engagement of Key Stakeholders in Implementation Efforts

The LA Trust YAB, CAB, and SABs provided feedback on a regular basis to inform outreach efforts to improve student utilization of the SBHCs and enrollment in the study. Although there were a number of site-specific engagement strategies (posters, student referral cards, lunch timetabling, clinic outreach, etc), the YAB also coordinated women's health presentations at each of the SBHCs to educate young girls on the services offered at the SBHCs and to stimulate conversations around reproductive health and life planning. On average, approximately 25 students attended each of these presentations. There was usually a clinic staff member present to schedule appointments for interested students.

The engagement of health care providers and clinic staff was equally critical. The RAs identified champions at each site who had a special interest in adolescent health and were excited about using the app. The RAs nurtured these relationships through monthly site visits and regular email and phone communications. They also worked to build relationships with the other providers and staff at each site by expressing a sincere desire to learn what was working well along with the challenges and implementation barriers they faced. The establishment of trust between clinicians, staff, RAs, and researchers enabled SBHC staff and clinicians to feel comfortable in expressing their challenges and concerns. The research team followed up on successes and challenges faced at individual sites through the group QI calls. During these calls, champions from each of the participating SBHCs described their implementation efforts and challenges encountered in a supportive, nonjudgmental context. This process enhanced the disclosure of barriers and allowed for collective problem solving and sharing of strategies that supported more effective implementation.

Partnership Structure, Compensation, and Reciprocity

Reciprocity between the university investigators, community partners at The LA Trust, YAB, and clinicians and staff further enhanced implementation efforts. The PCORI contract was awarded to University of California San Francisco (UCSF) but provided fiscal support for the partnerships through a formal subcontract with The LA Trust that supported The LA Trust staff, the YABs, the CABs, and their activities. As a *backbone organization* to support the Wellness Network, The LA Trust facilitates ongoing communications with the field. Learning collaborative meetings were convened quarterly, which brought all stakeholders together so that members could capitalize on each other's resources and skills and share best practices. These meetings identified topics that were considered important to increasing students' access to the SBHCs. A number of experts (including the study Principal investigator) were identified and presented on reducing stigma in SBHCs and understanding the state's minor consent and confidentiality laws. Immediately following each learning collaborative, we held special *strategy meetings* to allow for a more concentrated, site-specific problem-solving session with clinic champions and staff who reviewed study recruitment data and developed QI plans to increase recruitment of Latina patients.

Clinic administrators submitted letters of support articulating the need for and enthusiasm of such a project, strengthening the funding application and reinforcing their commitment to the project. In addition, formal memorandums of understanding (MOUs) were established with each SBHC at the onset of the project to formalize the relationship between the academic partner and community clinic agencies. The MOUs articulated the role of clinic staff members, recruitment goals, and specified the financial stipend each site would receive for their participation. Specifically, mentioning the recruitment goals in the MOU was helpful as a benchmark to discuss individual clinic's progress toward reaching those goals and as means of discussing implementation barriers and improvement strategies. It also served as a gentle reminder that the success of the project depended on collective efforts and a sense of ownership by all.

It is also important to note that beyond financial compensation, each partner (university and The LA Trust) was valued equally and shared their strengths and expertise with one another through formal presentations, manuscripts, and planning QI efforts to support implementation of the app.

The contributions of the Latina adolescents were also valued and acknowledged through financial stipends, gift cards, and formal acknowledgment of the participation through certificates of participation.

Colearning to Support Integration Into Clinical Workflows

To successfully implement a project of this size and scope within the *real-world* clinical setting, understanding the process and flow of the clinic operations was key. Each SBHC had its own unique clinical workflows, procedures, and protocols for serving adolescents, including the provision of reproductive health care. Members of The LA Trust met with the clinic leadership, clinicians, clinic managers, medical assistants, and frontline staff at each SBHC to obtain buy-in, understand the delivery of clinical services for adolescents, and to gather input from all levels of staff feedback on the best ways to integrate the app into each SBHC. As part of the QI process, the team modified the process map to address any unanticipated issues that arose during the initial implementation effort.

Although there was a desire to implement a universal workflow that would ask all female adolescents to participate in the study and for the providers to have a conversation with the student about birth control options, unique workflows had to be established. For instance, some SBHCs were designed to have 2 separate waiting rooms (1 for community patients and 1 for student patients), others had to share 1 congested waiting room for both types of patients. The RAs together with the clinic staff came up with solutions to address the privacy of the students while using the app. For example, 1 SBHC with a shared waiting room had a large health education room that was made available for patients to use the app in privacy, whereas another clinic allowed students to take the iPad with them so they could use the app during vitals.

Ongoing Quality Improvement

As noted previously, there were monthly group QI meetings held via WebEx with SBHC champions, The LA Trust team

and the UCSF principal investigator and project director. At each QI meeting, the study team provided the SBHCs with data that included the estimated number of youth who visited the clinic (where available), who used the *Health-E You* app, who were eligible to participate in the study, and who ultimately enrolled in the study by site. Using a Plan-Do-Study-Act QI approach [35,36], the study team and SBHCs identified and discussed implementation challenges, successful student engagement and recruitment strategies, and brainstormed ideas for overcoming the challenges. Having staff champions who represent various staff roles (ie, front desk, medical assistants, health educators, and clinic managers) contributed to a holistic discussion of the challenges and successes within and across sites. This approach contributed to increased buy-in and seamless continuity even in the face of staff turnover. Furthermore, this approach also empowered the staff that normally would not be given an opportunity to contribute to research projects of this scale.

Transparency, Honesty, and Trust

The UCSF, The LA Trust, and advisory boards worked together through a shared decision-making process. The UCSF and The LA Trust team met on a weekly basis through WebEx meetings to jointly develop the agendas for QI calls, teamwork plans, and action items. SABs met on a quarterly basis and more frequently if needed. There was a strong commitment to open and honest communication with one another, which was exemplified in the QI process.

Celebrating Success and Expressing Appreciation

The study team also provided an appreciation party for the youth who helped develop the videos used for the app and distributed participation certificates and *Oscar*-style awards. In addition, many clinicians and staff exceeded our engagement expectations and initiated strategies to improve clinic and app utilization. To express gratitude for this effort, staff was given additional thank-you gifts (eg, gift baskets, lunch for clinic staff, and other tokens of appreciation). These gifts were greatly appreciated and seemed to boost morale and engagement, especially in the context of under-resourced clinical settings where front-line staff and medical assistants may feel under-appreciated for their contributions to clinical operations.

Challenges

Despite the extensive efforts to support implementation, there were a number of noteworthy challenges.

Information Technology Infrastructure: Internet Access and Wireless Connectivity

Technology issues and staff capacity to troubleshoot problems related to technology were the most significant challenges. The amount of technical support and in-person engagement with clinic staff was greater than expected. The vast geographic distance between the SBHCs across Los Angeles made it difficult to identify individual clinic's ongoing needs or challenges and provide them with immediate support, regular communications, and updates. An online and telephone Technical Assistance support system was implemented to address the logistical challenge of in-person visits. However, this system was not widely used by clinic staff, and issues were more readily identified and addressed via in-person visits.

The app is a Web-based platform, which required Wi-Fi to transfer data captured electronically on the app to the secured back-end data storage system. Before implementing the app, The LA Trust RAs met with the clinic staff to assess technology infrastructure. All sites reported having Wi-Fi; however, the connectivity, reliability, and strength of the signal varied across all sites, and these issues did not come up during the pilot testing phase but emerged as the app was being used across more sites. To address this, the study team purchased mobile Wi-Fi devices (hotspots) to obtain internet access and set up the connection through a local internet service provider. In other cases, we purchased iPads with internet service and set up a data plan with a mobile phone company to access the internet. The specific approach had to be tailored to site-specific needs.

A key feature of the app, to enhance adoption and usability, was the ability for clinicians to see some of the user's input on the app before the scheduled face-to-face clinic visit. Clinicians prioritized 3 data points for the app to capture and share with them: the contraceptive method(s) the user was interested in, the method(s) the app recommended, and the potential contraindications. Another challenge was developing a system to share data captured from the app with clinicians. It was not possible to directly transmit information from the iPad to the patient's electronic health record (EHR). At the time of this study, that technology did not exist. Hence, there were multiple EHR systems and some SBHCs used paper charts, thereby, not allowing one uniform system for the transmission of information. In the pilot testing phase, clinicians requested to have this information emailed to them to avoid a paper trail and to move toward an electronic system. However, in developing the clinic workflows for the clinical trial, clinicians at each of these new study sites requested to have the app user's information printed instead of emails as originally designed, stating that they did not have time or it was not routine to check emails between patients or to use their personal mobile phone. The app had to be redesigned to accommodate this request and it added a new integration challenge. Printers compatible with the iPad were purchased, placed in a private area of the clinic, and set up so they could connect wirelessly to the iPads.

Again, site-specific solutions were necessary to ensure there was a reliable connection to the internet and between the iPad and printers. Even with these solutions in place, several clinics continued to report intermittent problems with connectivity to the internet and the printers' wireless connections. Few clinics had information technology staff available to address issues that arose; hence, The LA Trust RAs assumed this responsibility.

Protecting Patient Confidentiality and Data Security

There was a great deal of concern among providers about protecting patient confidentiality. The data system that stored users' input was housed on a secure network (encrypted, password-protected, and accessible to only essential research staff). The app informed users that their information was confidential; however, providers and clinic staff in turn needed to remind and assure patients that their information was confidential. In total, 2 sites expressed security concerns about

using clinic Wi-Fi for the app and thte protection of patient confidentiality. At 1 site, the MOU needed to be modified to articulate the measures taken to assure data privacy and security (eg, protocol for the protection of patient confidentiality, data encryption, and security of UCSF's back-end data system), at another we provided our approved protocol of the protection of human use in research.

Communication

Despite formal MOUs, monthly site visits, and QI calls, we identified communication barriers between clinic executives and staff that presented additional, unanticipated challenges to app implementation. For example, initially, information about the project was shared with clinic executives (eg, information from MOUs, site incentives, and initial QI data); however, upon conducting site visits, the RAs learned that this information was not universally shared with clinic providers or staff. The LA Trust team had to take extra efforts to ensure all stakeholders received necessary information. In addition, the vast distance between the clinic sites made it difficult to identify and address individual clinic's technical requirements. The distance did not allow a constant and *real-time* dialogue, even with the use of communication tools such as email and telephone. Often, the staff was too busy or the challenge was not as much a priority as other pressing clinic issues and responsibilities. Hence, these issues were not discovered or addressed until the in-person RA site visits occurred.

Staff Turnover

Many SBHCs struggled with high staff turnover, impacting their ability to implement the app. This is a problem not unique to this study and is common with many Federally Qualified Health Centers (FQHCs) who operate clinics in underserved and under-resourced communities [37].

FQHCs are the primary medical sponsors for most of the participating SBHCs in this study. Frequent in-person site visits helped identify staff changes and provide orientation to new staff. In addition, extensive time and effort invested in cultivating relationships with key staff at the clinics improved the extent to which the RAs were informed about staff changes. However, in many situations, staff vacancies remained in place for several months, which impacted the clinic's capacity to fully utilize the app.

Time to Complete App

The app was designed to be completed in approximately 15 min; yet at the same time, it allows for a user-driven educational experience. Actual time to complete the app ranged from 12 to 29 min, with an average completion time of 20 min. As the app is part of a research study, completion time included the time to obtain study consent and participation eligibility. Most clinics adapted their workflows to account for this variation and reported that extra completion time was acceptable because the app helped to *offset* some of the time a clinician would otherwise have to spend providing contraceptive education. Even so, a couple of clinics reported that the time patients needed to complete the app before seeing the clinician remained a challenge, especially during busy clinic hours when patients needed to see the clinician as soon as one became available. The research team with input from the CAB and YAB discussed the possibility of using the app before the clinic visit at home or school, but these approaches were not feasible to implement for a number of reasons. App use outside the clinic setting restricted the ability of providers to receive a printout summary. Providers also did not want to use an alternative form of communication to not disrupt the clinical flow and limit the risk of compromising patient confidentiality.

Discussion

Principal Findings

mHealth apps, such as *Health-E You*, have the potential to prepare youth for the clinic visit and act as a clinician extender to support the delivery of health education and enhance the quality of patient-centered sexual health care. Despite the proliferation of mHealth technologies, there is limited research on the integration of mHealth interventions into clinical practice. The purpose of this study was to describe and assess efforts to increase the successful adoption and implementation of the *Health-E You* app at 9 SBHCs that are participating in a larger CRCT.

Implementation of the app was informed by Rogers theory of diffusion of innovation [31,32], PCORI's principles of engagement, and previous pilot testing, which likely influenced the successful implementation of the app. In particular, engagement of both Latina adolescents and clinic providers helped to create a product (app) that addressed a shared health priority area and the needs of both stakeholders. In addition, other key factors that enhanced integration included significant engagement with clinic staff to meet clinical workflow needs and address technology-related barriers that arose during implementation; engagement with Latina adolescents to identify and address barriers to clinic utilization, promote app usage, and study participation; a strong partnership between university investigators, community partners at The LA Trust, and SBHCs that included formal subcontracts, fiscal support, and a sense of equity, trust, and mutual respect for each other's roles and expertise; a commitment to understanding local needs and adjusting protocols to fit with clinic specific workflows; an ongoing QI system; regular in-person technical assistance; and celebrating the successes and expressing appreciation for the commitment and effort of the partners, especially clinic staff and youth. We also found that developing strong, positive relationships with front-line clinic staff, medical assistants, and health educators and valuing them as equal partners in the research process was also key to our success.

Although these factors are included in the theory of diffusion of innovation and part of the PCORI principles of engagement, this study was not able to assess specific levels or rates of adoption of the technology. As this is a part of a larger study, there were formal MOUs along with financial incentives to support the participation of SBHCs in the research study, and it is possible that these factors also influenced the willingness of clinics to utilize this technology. As this trial ends and the app becomes available to a wider audience, there will be an opportunity to further assess dissemination, adoption, and diffusion beyond the SBHCs used in this study. There are

additional study limitations that should be noted. For instance, this study focused on an app aimed at addressing a specific and sensitive health need for sexually active adolescents who seek care at SBHCs. Thus, findings may not be generalizable to other mHealth apps on different topics or used in other clinic settings. Furthermore, SBHCs are inherently designed to support sexual and reproductive health needs of adolescents and may have been more receptive to the *Health-E You* app than other, less adolescent-friendly, clinical settings.

Despite the strong theoretical foundation and experienced clinical research team, there were a number of implementation challenges. The most significant challenges pertained to limitations with the technology infrastructure of SBHCs, which included intermittent internet access and reliable wireless or mobile phone service connectivity, assuring adolescent confidentiality and data security, communication across multiple levels within a clinic system, staff turnover, and time required for all youth to fully engage in and utilize the multiple features of the app.

Conclusions

Health-E You, an interactive, patient-centered, contraceptive decision support tool, was adopted and integrated into the clinical workflows of all 9 SBHCs. This app was developed to increase adolescents', who are at a risk of an unintended pregnancy, access to patient-centered contraceptive information and services and was designed to be used in conjunction with a clinical encounter to overcome clinician and individual barriers to comprehensive, patient-centered contraceptive care (including limited time, comfort, and knowledge).

Findings from this study provide important insights that can inform and improve implementation and integration efforts of future mHealth clinical interventions. In particular, this study found that an implementation approach founded in a strong theoretical framework and active engagement with patient and community partners enhanced the development, adoption, and integration of the app into clinical practice. In addition, in implementing mHealth interventions into clinical practice, it is important to consider the perspectives of multiple stakeholders (clinicians, managers, support staff, and patients) and the clinical context to identify strategies that will support the adoption and implementation of technology. It is also important to consider time restrictions, especially in busy clinical practices, and generate alternative ways of leveraging technology within and outside the clinical setting to improve access to health information and services to support health-promoting behaviors among adolescents. In addition, as technology evolves, developing solutions to improve the integration of mHealth technologies with EHR systems is critical.

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Conflicts of Interest

None declared.

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Abbreviations

BCM: birth control method
CAB: community advisory board
CRCT: cluster randomized control trial
EHR: electronic health record
FQHCs: Federally Qualified Health Centers
IRB: Institutional Review Board
mHealth: mobile health
MOUs: memorandums of understanding
PCORI: Patient-Centered Outcomes Research Institute
QI: quality improvement
RA: research associate
Rx: prescription
SABs: student advisory boards
SBHC: school-based health center
UCSF: University of California San Francisco
YAB: youth advisory board

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Original Paper

Theory-Based Predictors of Mindfulness Meditation Mobile App Usage: A Survey and Cohort Study

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Abstract

Background: Mindfulness meditation has become increasingly popular over the last few years, due in part to the increase in mobile apps incorporating the practice. Although studies have demonstrated the potential of mindfulness meditation to positively impact health, little has been uncovered about what predicts engagement in mindfulness meditation. Understanding the predictors of mindfulness meditation may help practitioners and phone app developers improve intervention strategies and app experience.

Objective: The purpose of this study was to use the Theory of Planned Behavior and Temporal Self-Regulation Theory to determine factors predicting mindfulness meditation mobile app use.

Methods: The sample consisted of 85 undergraduate students with no prior mindfulness meditation experience. During their first laboratory visit, participants completed tasks to measure their executive functioning and a survey to measure Theory of Planned Behavior constructs about mindfulness meditation. Over the following 2 weeks, participants logged the days and minutes that they practiced mindfulness meditation using a phone app. Hierarchical regression modeling was used to analyze the data.

Results: After controlling for demographic factors, participant subjective norms (beta=14.51, *P*=.001) and intentions (beta=36.12, *P*=.001) were predictive of the number of minutes practicing mindfulness. Participant executive functioning did not predict mindfulness meditation practice, nor did it moderate the link between intentions and mindfulness meditation practice. Participant attitudes (beta=0.44, *P*<.001) and perceived control (beta=0.42, *P*=.002) were positively associated with intentions to practice mindfulness.

Conclusions: These results suggest that among college student populations, the Theory of Planned Behavior may be useful in predicting the use of mindfulness meditation phone apps. However, participant executive functioning was not a predictor or moderator of mindfulness practice, and Temporal Self-Regulation Theory may be less useful for explaining mindfulness meditation behaviors using phone apps over a short period of time among college students. The results have implications for public health professionals, suggesting that a focus on subjective norms and intentions may promote mindfulness meditation practice using phone apps.

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KEYWORDS

executive function; intention; mindfulness; mobile apps; social theory

Introduction

Mindfulness is the practice of being aware of the present moment [1]. In recent years, mindfulness meditation has become especially popular in the Western world and is increasingly used as a form of medical and psychological therapy [2] due to its perceived benefits to mental and physical health. Although people can be mindful without meditating, mindfulness meditation guides can help people acquire the skill [3]. There are numerous ways to learn how to practice mindfulness, including mindfulness meditation retreats, small group classes, and audio-based training. More recently, several mindfulness

meditation phone apps (both paid and free versions) have been introduced on the market [4].

Prior studies have demonstrated several benefits of being mindful. The benefits to mental health are the most widely studied. For example, studies have found associations between mindfulness meditation and increased behavioral regulation and executive functioning [5,6], and decreased psychological symptoms and emotional reactivity [7]. Mindfulness meditation has also been associated with improved academic performance [8], improved well-being [7,9], and better quality of life [10,11]. Even more promising is that these changes may be sustained over time [11]. Benefits also extend to physical health [5], including that it may help to manage and treat chronic diseases [12-15] and improve immune function [16]. For example, a study conducted in a work environment of 41 employees examined the effectiveness of mindfulness meditation on immune function before receiving the flu vaccination [16]. Participants who practiced mindfulness meditation had increased levels of antibody titers to the influenza virus compared to those who did not practice mindfulness.

Mindfulness Phone Apps

Few clinical trials have been conducted assessing the effectiveness of mindfulness meditation mobile phone apps. However, the extant literature suggests that mindfulness mobile apps show promise in their ability to effectively increase mindfulness in university students, even compared to other tactics such as audio-based training [17]. Another study found that in an adult population a 5-week self-help intervention guided by a mindfulness app significantly improved quality of life and these gains were maintained for at least 3 months, demonstrating the possibility for mindfulness apps to achieve durable positive effects [11].

The potential of mindfulness phone apps remains largely unexplored [18]. A review of several mindfulness apps on the market found that few apps consistently performed well across areas of user engagement, functionality, visual esthetics, information quality, and subjective quality [4]. There is also limited research addressing what exactly predicts mindfulness app use and what will help make these apps a reliable tool for various populations moving forward.

Given the many perceived benefits of mindfulness meditation, it is important to know what encourages or predicts engagement in mindfulness meditation in the general population. Such information could help to inform intervention efforts. However, little is currently known about predictors of mindfulness meditation, particularly among those with limited exposure to the practice. Understanding predictors of mindfulness meditation and mindfulness phone app usage would aid in developing more effective health promotion interventions aimed at increasing mindfulness. Two theoretical frameworks, the Theory of Planned Behavior and Temporal Self-Regulation Theory, may be useful in predicting mindfulness meditation engagement.

Theoretical Framework

The purpose of this study was to examine the predictors of engaging in mindfulness meditation using phone apps among individuals with no prior exposure to mindfulness. The Theory of Planned Behavior [19] and Temporal Self-Regulation Theory [20] provided the theoretical framework for this study. The Theory of Planned Behavior is widely used across disciplines and in particular for understanding health behaviors [21,22]. Based on the Theory of Planned Behavior, intentions drive behavior. Intentions are formed from attitudes and beliefs about the behavior, perceptions of social norms regarding the behavior (ie, subjective norms), and perceived behavioral control. More recently, meta-analyses of studies that have used the Theory of Planned Behavior have demonstrated that intentions have a small-to-medium effect on behavior [21,22] and that the age of the participant and type of behavior being studied may affect the intention-behavior link [22]. Considering these factors, researchers increasingly are considering biological factors, including cognitive factors, which may influence the relationship between intentions and behavior [23].

Temporal Self-Regulation Theory may help to explain the modest association between intention and behavior. This theory posits that an individual's executive functioning capacity may directly predict behavior or moderate the association between intention and behavior [20]. Executive functions are goal-directed capacities including working memory, inhibitory control, and cognitive shifting [24]. These capacities allow the brain to exercise top-down control of behavior (eg, executive functioning may directly predict the health behavior). Furthermore, executive functions may also enable individuals to more easily act on their intentions due to their increased ability to inhibit prepotent responses in favor of a longer-term goal and to better focus their attention and motivation on achieving these goals.

Prior studies have used Temporal Self-Regulation Theory as the theoretical framework to predict physical health behaviors with mixed results. Hall and colleagues [25] found that executive functions added unique variance to models testing the relationship between intention and physical activity and between intention and dietary behaviors among undergraduate students. For both physical activity and dietary behaviors, they also found that the association between intentions and behaviors was stronger among participants with higher executive functioning [25]. Conversely, in an online sample, Evans and colleagues [26] examined whether self-control, an aspect of inhibitory control, predicted fruit and vegetable and unhealthy snack consumption. They found no relationship between self-control and these dietary behaviors, nor did self-control moderate the intention-to-behavior link.

Although the Theory of Planned Behavior and Temporal Self-Regulation Theory have not previously been linked with mindfulness meditation app usage, prior research has indicated a relationship between the Theory of Planned Behavior and other technology use. For example, in a study of university students, it was found that attitudes and subjective norms (but not perceived behavioral control) significantly predicted intentions to engage in high-level social networking websites, and intentions predicted actual behavior [27]. A study of junior and senior university students found that intentions to use information systems were predicted by attitudes and perceived behavioral control. Subjective norms did not predict intentions to use information systems [28].

Aims and Hypotheses

To our knowledge, no studies have examined theoretical constructs for why people practice mindfulness meditation. Furthermore, although Temporal Self-Regulation Theory has been associated with some physical health behaviors, it has not been tested on mental health behaviors such as mindfulness meditation. In this study, we hypothesized that (1) in accordance with the Theory of Planned Behavior, participant attitudes about mindfulness meditation practice, subjective norms, perceived behavioral control, and especially their intentions to practice mindfulness would predict the number of days and minutes of mindfulness meditation practice using a phone app, and (2) using Temporal Self-Regulation Theory, we hypothesized that individual executive functioning capacity would moderate the link between intentions and behaviors, such that the association between intentions and behaviors would be stronger among those with stronger executive functioning ability. We included measures of both days and minutes of mindfulness meditation app use to examine consistency of practicing mindfulness meditation (number of days) and the length of time spent practicing (number of minutes).

Methods

Recruitment and Procedures

The sample consisted of 85 undergraduate students at a university in the Intermountain West. Participants were recruited via in-class announcements and fliers posted around campus. Eligibility requirements were (1) participants must be currently enrolled as undergraduate students, and (2) participants must have had no prior or minimal exposure (less than 2 hours) to mindfulness meditation.

On enrolling in the study, two laboratory visits were scheduled with the participant. At the first laboratory visit, participants signed their consent to participate in the study. They were also introduced to mindfulness and mindfulness meditation using the Smiling Mind App. The Smiling Mind App was recommended to participants because it was free, compatible with Android and Apple products, and had been reviewed as one of the top mindfulness phone apps available [4,29]. Additionally, this app provides guided meditation for a variety of demographics and situations (eg, by age group, for work and sports, mindfulness for managing stress or improving relationships) and has flexibility in the length of each mindfulness meditation session (eg, from just over 1 minute to 30-60 minutes) [30]. Research personnel helped the participant download the app on their phone during the laboratory visit. Participants were told that they could use other mindfulness meditation apps should they choose and could also access these same programs online if they did not want to download the app on their phone. Participants then completed executive functioning and physiological tasks followed by a brief online survey on Qualtrics. At the end of the laboratory visit, research personnel instructed participants on how to complete a mindfulness meditation log. They were informed that if they filled out the mindfulness meditation log and brought it back to the next laboratory visit that they would be entered into a drawing for one of two US$100 e-gift cards. To be eligible for the draw, participants did not have to practice mindfulness, but they did have to enter the number of minutes that they practiced mindfulness each day (0 minutes for no mindfulness practice) during the 2 weeks between laboratory visits. Participants received a reminder text, email, or phone call (depending on their preference) 1 week after the first laboratory visit to remind them of the study and to fill out their log. Approximately 24 hours before the second laboratory visit, participants received a reminder text, email, or phone call. At the second laboratory visit, participants submitted their completed mindfulness meditation log, participated in the executive functioning tasks, and completed a follow-up survey. This study focuses on the tasks and survey responses from the first laboratory visit and the number of days and minutes that participants practiced mindfulness during the two weeks of the study. The study was approved by the Brigham Young University Institutional Review Board, Provo, Utah.

The sample size of 85 was selected based on a power analysis conducted in Stata 14 using the powerreg command, estimating a power of 0.80 and assuming a 10% dropout rate and a change in R^2 of .04 (based on a study using the Theory of Planned Behavior that examined health behaviors) [25]. We did not experience the expected 10% dropout and thus had higher power than 0.80.

Measures

Mindfulness Meditation

Mindfulness meditation was measured by participant self-report using their mindfulness meditation log. We measured the number of days that students practiced mindfulness meditation between laboratory visits and the total number of minutes of mindfulness practiced.

Theory of Planned Behavior Constructs

In the survey that participants completed during the first laboratory visit, participants reported on their attitudes about mindfulness meditation, subjective norms about mindfulness, perceived behavioral control to practice mindfulness, and their intentions to practice mindfulness. The Theory of Planned Behavior questions were created using methodology developed by Icek Ajzen [31] (see Table 1 for a complete listing of items).

Table 1. Theory of Planned Behavior items

Item	Response option range
Intentions	
1. I intend to practice mindfulness each day in the forthcoming 2 weeks.	Extremely unlikely to extremely likely
2. In the forthcoming 2 weeks, how often do you plan to practice mindfulness for at least 5 minutes?	Never to every day
3. I will try to practice mindfulness for at least 5 minutes each day in the forthcoming 2 weeks.	False to definitely true
4. I plan to practice mindfulness for at least 5 minutes each day in the forthcoming 2 weeks.	Strongly disagree to strongly agree
Attitudes	
5. For me, to practice mindfulness meditation each day in the forthcoming 2 weeks is:	Harmful to beneficial
6. For me, to practice mindfulness meditation each day in the forthcoming 2 weeks is:	Unpleasant to pleasant
7. For me, to practice mindfulness meditation each day in the forthcoming 2 weeks is:	Bad to good
8. For me, to practice mindfulness meditation each day in the forthcoming 2 weeks is:	Worthless to worthwhile
9. For me, to practice mindfulness meditation each day in the forthcoming 2 weeks is:[a]	Unenjoyable to enjoyable
10. For me, to practice mindfulness meditation each day in the forthcoming 2 weeks is:	A waste of time to an important use of my time
Subjective norms	
11. Most people who are important to me think that I should practice mindfulness meditation.[a]	Strongly disagree to agree
12. The people in my life whose opinions I value would approve of me practicing mindfulness meditation.[a]	Strongly disagree to agree
13. Most people who are important to me practice mindfulness meditation often.	Completely false to completely true
14. The people in my life whose opinions I value, practice mindfulness meditation often.	Completely false to completely true
Perceived behavioral control	
15. For me, to practice mindfulness meditation daily would be	Impossible to possible
16. If I wanted to, I could practice mindfulness meditation daily.	Definitely false to definitely true
17. How much control do you believe you have over practicing mindfulness meditation daily?	No control to complete control
18. It is mostly up to me whether or not I practice mindfulness meditation daily.	Strongly disagree to agree

[a]Item dropped during exploratory factor analysis.

Four items were used to measure intentions to practice mindfulness. For three questions, answer options were on a four-point scale; one question was on a seven-point scale ("In the forthcoming 2 weeks, how often do you plan to practice mindfulness for at least 5 minutes?" with answer options ranging from "never" to "every day") . Due to low response counts for practicing mindfulness on fewer than half of the days, and to be consistent with the other intentions questions, response options were combined for a four-point scale. There were six items in the attitudes subscale. Each item was measured on a five-point scale, with higher scores indicating more positive attitudes about engaging in mindfulness meditation. Due to low counts for negative or neutral perceptions about practicing mindfulness, we combined negative and neutral responses so that each item was analyzed on a three-point scale (0=negative or neutral attitudes; 1=somewhat positive attitudes; 2=strong agreement or strongly positive attitudes about practicing mindfulness). We asked four questions relating to subjective norms pertaining to practicing mindfulness meditation. Response options ranged from 1=strongly disagree/completely false to 5=agree/completely true. Perceived behavioral control about practicing mindfulness was measured through four items on a five-point scale.

Executive Functioning

Executive functioning was measured using three tasks from the NIH Toolbox (NIH-TB) [32]. We used the NIH-TB Dimensional Change Card Sort Test to measure cognitive shifting and the NIH-TB Flanker Inhibitory Control and Attention Test to measure inhibitory control and attention. We used the age-standardized scores and averaged participant scores across the two tasks. To assess working memory, we used the age-standardized score of the NIH-TB List Sorting Working Memory Test.

Demographic Controls

We controlled for participant gender (0=male; 1=female), age, employment status (0=not employed; 1=employed), and performance on the NIH-TB Picture Vocabulary Test [32] (age-standardized scores) to control for participant fluid intelligence (considered best practice when examining executive functioning [33]).

Statistical Analysis

We conducted exploratory factor analysis for one-, two-, three-, and four-factor models to examine whether the data fit the factor structure of the Theory of Planned Behavior constructs using Mplus Version 7. We assessed the factor loadings and two model fit indexes: the comparative fit index (CFI; >0.90 indicates adequate fit) and the root mean square error of approximation (RMSEA; <0.08 indicates adequate fit). Items with factor loadings <0.40 or with a cross-loading >0.30 on a second factor were dropped [34].

Descriptive statistics and hierarchical regression analyses were carried out using Stata Version 14. Using Stata's nestreg command, we used five blocks of data in a hierarchical linear regression process to test our hypotheses. In the first block, demographic factors were included. The second block included Theory of Planned Behavior constructs (attitudes, subjective norms, and perceived behavioral control). Participant intentions to practice mindfulness were added in the third block, and executive function (as a measure relating to Temporal Self-Regulation Theory) was added in the fourth block. The fifth block included interaction terms to examine whether executive functioning and working memory moderated the intention-behavior link.

Results

Sample Description

Approximately half of the participants were female (45 of 85 participants; 53%), 60 of 85 participants (80%) identified themselves as white or Caucasian, 20 (24%) were married, and 47 (56%) of participant's mothers had a bachelor's degree or higher. Table 2 contains the means and standard deviations of study variables.

Factor Analysis

Exploratory factor analysis demonstrated that a four-factor model fit the data best for the Theory of Planned Behavior items (RMSEA=0.040, CFI=0.997). Two items from the subjective norms subscale and one item from the attitudes subscale were below the minimum cutoff or had high cross-loadings on a second factor and were dropped. The remaining loadings were all above the minimum cutoff, with loadings >0.75 for factor 1 (intentions), >0.81 for factor 2 (attitudes), >0.75 for factor 3 (perceived behavioral control), and >0.91 for factor 4 (subjective norms). The Cronbach alpha for all subscales ranged from adequate to high (intentions: Cronbach alpha=.86; attitudes: Cronbach alpha=.90; subjective norms: Cronbach alpha=.70; perceived behavioral control: Cronbach alpha=.68).

Items were summed and averaged for each of the four constructs. Higher scores in each of the four constructs indicated greater intent to practice mindfulness, more positive attitudes about mindfulness meditation, higher perceived behavioral control to engage in mindfulness meditation, and stronger subjective norms to practice mindfulness, respectively.

Descriptive Results: Theory of Planned Behavior, Mindfulness, and Executive Functioning

On average, participants practiced mindfulness on 9.3 (SD 3.6) days and for 64.3 (SD 44.0) minutes over the 14 days, with a range from 0 minutes (two participants) to 210 minutes. In general, participants had very positive attitudes toward mindfulness (mean 1.54, SD 0.53; scale 0-2 points), but report of subjective norms was low (mean 1.03, SD 1.01; scale 0-4 points). Participants on average felt that they had very high control over practicing mindfulness (mean 3.73, SD 0.38; scale 0-4 points). Intentions to practice mindfulness were generally high, with an average score of 2.83 (SD 0.53; scale 0-4 points). The mean executive functioning score was 100.7 (SD 13.5) with 15 of 85 (18%) participants scoring below one standard deviation of the population age-standardized mean and 12 of 85 (14%) participants scoring one standard deviation or above the population mean. The mean score on the working memory task was 105.6 (SD 13.0) with 4 of 85 (5%) participants scoring below one standard deviation of the population age-standardized mean and 24 of 85 (28%) scoring one standard deviation or more above the population mean.

Correlations

Intentions to practice mindfulness were correlated with increased number of days (r=.43, P<.001) and minutes (r=.37, P<.001) practicing mindfulness. Neither executive functioning nor working memory were correlated with days (executive functioning: r=–.16, P=.15; working memory: r=–.04, P=.72) or minutes (executive functioning: r=–.19, P=.08; working memory: r=–.04, P=.70) of mindfulness meditation (see Table 3).

Table 2. Descriptive statistics of demographic and key study variables (N=85).

Study variable	Mean (SD)
Proportion female	0.53 (0.50)
Age	21.81 (2.60)
Proportion employed	0.74 (0.44)
NIH Toolbox Picture Vocabulary Test	117.39 (11.86)
Attitudes[a]	1.54 (0.53)
Subjective norms[b]	1.03 (1.01)
Perceived behavioral control[b]	3.73 (0.38)
Intentions[b]	2.83 (0.53)
Executive functioning	100.65 (13.49)
Working memory	105.60 (13.00)
Days of mindfulness	9.29 (3.56)
Minutes of mindfulness	64.31 (43.95)

[a]Attitude items were on a scale of 0-3 points.

[b]Subjective norms, perceived behavioral control, and intentions were on a scale of 0-4 points.

Table 3. Correlations (*r*) of demographic and key study variables (N=85).

Variable name	1	2	3	4	5	6	7	8	9	10	11	12
1. Gender[a]	1.00											
2. Age	–0.29[b]	1.00										
3. Employed[c]	–0.18	0.37[b]	1.00									
4. NIH Toolbox Picture Vocabulary Test	–0.08	–0.22[b]	–0.10	1.00								
5. Attitudes[d]	–0.03	0.14	0.14	–0.06	1.00							
6. Subjective norms[e]	0.02	0.23[b]	0.02	–0.07	0.23[b]	1.00						
7. Perceived behavioral control[e]	0.08	–0.17	0.03	–0.03	0.28[b]	0.05	1.00					
8. Intentions[e]	–0.06	0.06	0.12	–0.09	0.54[b]	0.15	0.43[b]	1.00				
9. Executive functioning	–0.10	0.10	0.08	–0.11	–0.10	0.05	0.07	–0.14	1.00			
10. Working memory	0.10	–0.18	0.09	0.38[b]	–0.19	0.06	0.20	–0.08	0.17	1.00		
11. # Days mindfulness	0.01	0.02	0.03	0.03	0.17	0.23[b]	0.10	0.44[b]	–0.16	–0.04	1.00	
12. # Minutes mindfulness	0.09	0.05	–0.08	0.02	0.22[b]	0.38[b]	0.01	0.37[b]	–0.19	–0.04	0.68[b]	1.00

[a]0=male, 1=female.

*These pairwise correlations are significant (*P*<.05).

[b]0=not employed, 1=employed.

[c]Attitude items were on a scale of 0-3 points.

[e]Subjective norms, perceived behavioral control, and intentions were on a scale of 0-4 points.

Hierarchical Regressions

In the hierarchical regressions (see Tables 4 and 5), participant demographic factors did not contribute significantly to the models ($F_{4,80}$= 0.05, R^2=.003, *P*=.99). For number of days practicing mindfulness (Table 4), participant attitudes, subjective norms, and perceived behavioral control did not significantly explain the variance in the model ($F_{3,77}$=2.00, Δ R^2=.07, *P*=.12), but the addition of behavioral intentions (beta=3.52, *P*<.001) in step 3 was significant ($F_{1,76}$= 17.29 , Δ R^2=.17, *P*<.001). The addition of executive functioning and working memory in step 4 ($F_{2,74}$= 0.46, Δ R^2=.01, *P*=.63) and the inclusion of interaction terms in step 5 ($F_{2,72}$ =0.08, Δ R^2=.002, *P*=.92) did not significantly contribute to the model.

For number of minutes practicing mindfulness (Table 5), demographic variables did not contribute significantly to the model ($F_{4,80}$=0.57, R^2=.03, P=.68). The addition of attitudes, subjective norms, and perceived behavioral control to the model significantly improved the variance explained by the model ($F_{3,77}$=5.13, ΔR^2=.16, P=.003), with subjective norms significantly associated with more minutes practicing mindfulness (beta=15.19, P=.002). The addition of intentions (beta=36.12, P=.001) in step 3 also significantly explained the variance of the model ($F_{1,76}$= 13.07, ΔR^2=0.12, P<.001) and subjective norms also remained significant (beta=14.51, P=.001). As with the model illustrating the number of days, executive functioning and working memory did not contribute significantly to the model for number of minutes practicing mindfulness ($F_{2,74}$=0.64, ΔR^2=.01, P=.53), nor did executive functioning and working memory significantly moderate the intention-to-behavior link ($F_{2,72}$=0.14, ΔR^2=.003, P=.87).

Sensitivity Analysis

Adding interaction terms to a model may result in multicollinearity; therefore, we next z-score standardized the variables to examine if results changed [35]. Results were substantively the same as the models reported in Tables 3 and 4.

Table 4. Hierarchical regression analyses: Theory of Planned Behavior constructs and executive function as predictors of number of days using a mindfulness meditation phone app (N=85).

Variable	Step 1		Step 2		Step 3		Step 4		Step 5	
	Beta	*P* value	Beta	*P* value	Beta	*P* value	Beta	*P* value	Beta	*P* value
Gender	0.19	.82	0.04	.96	0.32	.67	0.30	.70	0.38	.64
Age	0.03	.85	–0.05	.80	–0.04	.81	–0.04	.81	–0.06	.76
Employed	0.21	.83	0.20	.84	0.04	.96	0.18	.84	0.24	.80
NIH Toolbox Picture Vocabulary Test	0.01	.74	0.01	.69	0.02	.46	0.03	.43	0.03	.45
Attitudes			0.70	.38	–0.83	.31	–0.97	.26	–0.93	.29
Subjective norms			0.76	.07	0.70	.07	0.75	.05	0.76	.05
Perceived behavioral control			0.52	.64	–0.96	.37	–0.67	.55	–0.76	.55
Intentions					3.52	<.001	3.37	<.001	3.29	.65
Executive functioning							–0.02	.47	0.03	.82
Working memory							–0.02	.64	–0.07	.71
Intentions × executive functioning									–0.02	.71
Intentions × working memory									0.02	.77

Table 5. Hierarchical regression analyses: Theory of Planned Behavior constructs and executive function as predictors of number of minutes using a mindfulness meditation phone app (N=85).

Variable	Step 1		Step 2		Step 3		Step 4		Step 5	
	Beta	*P* value	Beta	*P* value	Beta	*P* value	Beta	*P* value	Beta	*P* value
Gender	9.92	.34	7.35	.44	10.24	.25	9.25	.31	10.08	.29
Age	2.35	.27	0.20	.93	0.26	.89	0.36	.86	0.02	.99
Employed	–10.89	.36	–9.61	.39	–11.22	.29	–10.34	.34	–9.62	.39
NIH Toolbox Picture Vocabulary Test	0.20	.64	0.20	.61	0.30	.41	0.27	.52	0.28	.50
Attitudes			14.58	.12	–1.16	.91	–2.04	.84	–1.58	.88
Subjective norms			15.19	.002	14.51	.001	14.90	.001	15.07	.002
Perceived behavioral control			–6.77	.59	–21.98	.08	–19.10	.15	–22.55	.13
Intentions					36.12	.001	33.97	.001	69.52	.42
Executive Functioning							–0.37	.28	0.43	.81
Working memory							–0.03	.94	0.11	.96
Intentions × executive functioning									–0.29	.65
Intentions × working memory									–0.05	.95

Given the importance of intentions to predicting days and minutes of mindfulness meditation practice, we conducted a hierarchical analysis with intentions at the outcome to examine the key predictors of intention to practice mindfulness. After entering participant demographic factors in step 1 ($F_{4,80}$=0.51, ΔR^2=.02, P=.73), in step 2 we found that participant attitudes (beta=0.44, P<.001) and perceived behavioral control (beta=0.42, P=.002) were both positively associated with their intentions. Subjective norms were not associated with intentions (beta=0.02, P=.71) nor were participant demographics ($F_{3,77}$=14.74, ΔR^2=.36, P<.001).

Discussion

Principal Results

The results of this study indicate that among individuals with no prior experience with mindfulness meditation, participant reports of their intentions to practice mindfulness meditation and subjective norms were the best predictors of the number of days and minutes spent practicing mindfulness using a phone app over a 2-week period. These results are generally consistent with the Theory of Planned Behavior (hypothesis 1), although subjective norms appeared to affect the number of minutes practicing mindfulness directly and not through intentions. Participant attitudes and perceived behavioral control were not associated with app usage in this study. Contrary to Temporal Self-Regulation Theory and our second hypothesis, executive functioning was not a predictor of app usage or a moderator of the intention-to-behavior link.

These results have implications that are particularly relevant for public health and medical practice. Among populations with limited experience with mindfulness meditation, creating more favorable subjective norms may be an important intervention focus to increase the amount of time that individuals spend practicing mindfulness (eg, number of minutes spent practicing mindfulness). This may be particularly true in younger populations where rational considerations such as knowledge and attitudes may play less of a role than affective considerations such as subjective norms [23]. Although subjective norms predicted practicing mindfulness in this study, the subjective norm-intention relationship was nonsignificant, which is consistent with other studies that have found that the link is not always strong [28]. For example, prior research has demonstrated a weaker association between subjective norms and intentions when measuring physical activity compared to studies measuring sexual and reproductive health behaviors [22].

Practitioners may be most successful at increasing intentions to practice mindfulness by targeting participant attitudes and perceived behavioral control. In this study, participant attitudes and perceived behavioral control were both positively associated with intentions, which led to increased consistency and time practicing mindfulness. Participants in our sample overwhelmingly held positive attitudes and reported high perceived behavioral control about mindfulness meditation. Thus, a little time spent in an intervention showing participants how to access mindfulness meditation apps and educating them on the benefits of mindfulness may go a long way in helping to increase their intentions to engage in mindfulness meditation.

Prior studies have demonstrated that executive functioning deficits have been associated with decreased adherence to treatment plans [36]. In this study, however, executive functioning performance (including working memory, inhibitory control, and cognitive shifting) explained almost no variance in the models and did not appear to interfere either positively or negatively with mindfulness meditation using a phone app. This finding may be particularly relevant for practitioners who use mindfulness meditation as a treatment or prevention option in their work in populations with suspected or known executive functioning deficits, such as among populations with mental health disorders or in communities with high stress and poverty [37-39]. Thus, an intriguing consideration is that phone apps might be an effective strategy to circumventing some of the challenges to adherence in populations with suspected executive functioning deficits.

Although the initial results are encouraging that executive functioning deficits may not undermine participant intention to practice mindfulness meditation, more research is needed. Examining the maintenance of mindfulness meditation practice over a longer period of time would be an important next research step because the mindfulness meditation practice in this study was only studied over 2 weeks. Furthermore, more randomized controlled trials to assess the effectiveness of mindfulness meditation phone apps are needed to examine their efficacy given the paucity of studies on this topic.

Study Limitations and Strengths

This study was based on a convenience sample of undergraduate students attending a university with high admissions standards. Although a small subset of the sample scored below one standard deviation of the age-standardized mean for executive functioning ability, this was still a relatively high functioning, homogenous sample. As such, these results may not be generalizable to other young adult populations. Future studies using a more diverse, random sample would be beneficial. A second limitation of the study was the length between time points, which was only 2 weeks. It is possible that results may vary over time as the experience of practicing mindfulness becomes less novel. Thus, the study should be replicated over several weeks or months to see if executive functioning skills would play a bigger role.

Although there are limitations to the diversity of the sample, these results do provide novel data that future studies can build on. Specific strengths of the study included that we had a longitudinal design and used task measures of executive functioning. Further, the study provides one method for a way to collect engagement data from participants (eg, the use of a mindfulness log). Future studies may also investigate other methods such as built-in app usage data. Finally, this is the first study, to our knowledge, that examined theoretical predictors of mindfulness meditation using mobile phone apps. As such, the results may be particularly relevant to those developing health promotion and psychotherapy interventions using phone apps.

Conclusions

The Theory of Planned Behavior appears to be a good theoretical framework for predicting mindfulness meditation app usage among participants with no prior experience with mindfulness. In particular, intentions to practice mindfulness and subjective norms directly predict both the number of days and number of minutes practicing mindfulness using a phone app. Participant attitudes and perceived behavioral control were associated with participant intentions to practice mindfulness. Participant executive functioning does not appear to influence mindfulness meditation app usage, either directly or as a moderator, suggesting that participant limitations in cognitive control capacity might not undermine mindfulness meditation interventions using phone apps.

Conflicts of Interest

None declared.

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Abbreviations

CFI: comparative fit index
NIH-TB: NIH Toolbox
RMSEA: root mean square error of approximation

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Original Paper

Mobile Phone App for Self-Monitoring of Eating Rhythm: Field Experiment

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Abstract

Background: Temporal aspects of eating are an integral part of healthy eating, and regular eating has been associated with good diet quality and more successful weight control. Unfortunately, irregular eating is becoming more common. Self-monitoring of behavior has been found to be an efficient behavioral change technique, but the solution should be simple enough to ensure long-lasting adherence.

Objective: This study aimed to explore the influence of self-monitoring of daily eating pattern with mobile phone app on eating rhythm, eating behavior tendencies, and the underlying motives and attitudes related to eating.

Methods: A mobile phone app, *Button*, was developed for effortless self-monitoring of eating rhythm. The feasibility of the app was tested in a 30-day intervention. The participants (N=74) recorded their eating occasions during the intervention by pressing a button in the app widget.

Results: The average interval between meals increased (96 [SD 24] min during the first 10 days vs 109.1[SD 36.4] during the last 10 days) and the number of daily eating occasions decreased (4.9 [SD 0.9] during the first 10 days vs 4.4 [SD 0.9] during the last 10 days). The tendencies for cognitive restraint, emotional eating, and uncontrolled eating increased. Eating-related attitudes and motives remained largely unchanged.

Conclusions: These results indicate that a simple self-monitoring tool is able to draw a user's attention to eating and is a potential tool to aid people to change their eating rhythm.

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KEYWORDS

mHealth; behavior observation; self-regulation; eating; ecological momentary assessment

Introduction

Eating rhythm is an integral part of healthy eating. A regular eating pattern including breakfast, lunch, dinner, and 1 to 2 snacks has been found to be associated with good diet quality [1], whereas skipping breakfast has been consistently found to associate with poor overall diet quality and exposure to weight gain [2,3]. In addition, eating less than 3 times a day negatively influences appetite control, and unplanned snacking and consumption of the major part of the energy at the end of the day seem unfavorable for weight balance [4,5]. On the other hand, a recent review was not able to confirm associations between eating frequency and body weight [6]. Nevertheless, irregular eating has been associated with various adverse health effects [7] as it may complicate weight regulation via hindered circadian system [8]. A recent review also found irregular eating habits to be associated with increased risk of metabolic syndrome and cardiometabolic risk factors [9].

Reports from different parts of the world suggest that irregular eating is becoming more common. Irregular eating patterns that

manifest as a tendency to skip conventional meals (*unsynchronized eating patterns*) have increased in Nordic countries; approximately one-fifth of Danish, Finnish, Norwegian, and Swedish people have been found to possess unsynchronized eating patterns during weekdays and about one-third during weekends [10]. The prevalence is specifically high among young and singles. Similarly, a meal pattern with obscured meal times was found to be more common in young German adults than in older adults [11]. Irregular eating patterns and vast differences between weekdays and weekends have also been observed in US adults; breakfast-lunch-dinner pattern has been found to be largely absent and the fasting period (night fast) has been found to be relatively short [12]. In addition, snacking has increased [13]. Moreover, approximately one-fourth of Australian adults have been found to follow a *grazing* pattern in which there are no clear meal times but frequent peaks of eating occasions during the day [14]. Therefore, actions are needed to change the course toward a more regular, health-supporting eating rhythm.

Changing habits requires well-developed self-regulation, which in turn is enabled by self-monitoring and self-evaluation of progress [15]. Self-monitoring, which assists individuals to become aware of their current behavior, has been successfully applied in weight-loss interventions using both traditional methods as well as self-monitoring with mobile apps [16]. Moreover, adherence to weight management intervention has been found to be better with mobile phone-based intervention compared with website or paper food diary based–interventions [17]. An array of mobile apps related to nutrition are launched yearly and installed by millions of people [18]. A majority of the apps are food diaries that provide detailed dietary information when they are consistently filled in. However, food diaries are laborious for the user and they might suffer from problems with memory and interpretation of the data. Therefore, an ecological momentary assessment (EMA) where events are recorded in real time in the natural environment has also been suggested as a tool for nutrition research to collect more accurate information about dietary behavior and underlying reasons for the behaviors [19]. EMA builds a picture of an individual's habits by recording multiple days. For example, EMA has been recently used to evaluate how fasting influences disordered eating behaviors [20] and if the meal and snack-time eating disorder cognitions predict eating disorder behavior [21]. The previous apps utilized EMA as a methodological tool to collect data on a moment of the behavior or occurrence, which was the focus of a study. EMA approaches could also be applied in the context of behavior change, as is the case of this study. Self-monitoring of eating rhythm offers a possibility to direct users' attention to their own eating patterns and push them toward positive behavioral changes with low burden on the user.

The EMA tool (mobile app *Button*) was developed for the self-monitoring of eating rhythm in real time. At present, there are apps available (eg, in Google Play) reminding about eating times (eg, Meal Reminder) or coaching fasting (eg, BodyFast Intermittent Fasting) for certain time periods. Unlike the current apps, the *Button* app does not remind or coach the user to eat but makes eating rhythm visible and thus grants the ownership of eating rhythm to the user. The idea of the app is to offer the user a simple tool to become aware of his or her temporal eating pattern, which might act as a stimulus to regularize eating.

The aim of the study was to explore the influence of self-monitoring of daily eating pattern with an EMA mobile app on eating rhythm, eating behavior tendencies, and underlying motives and attitudes related to eating. A further aim was to study whether 1 of the 2 app versions (healthy-unhealthy dichotomy or content-discontent dichotomy) is more influential.

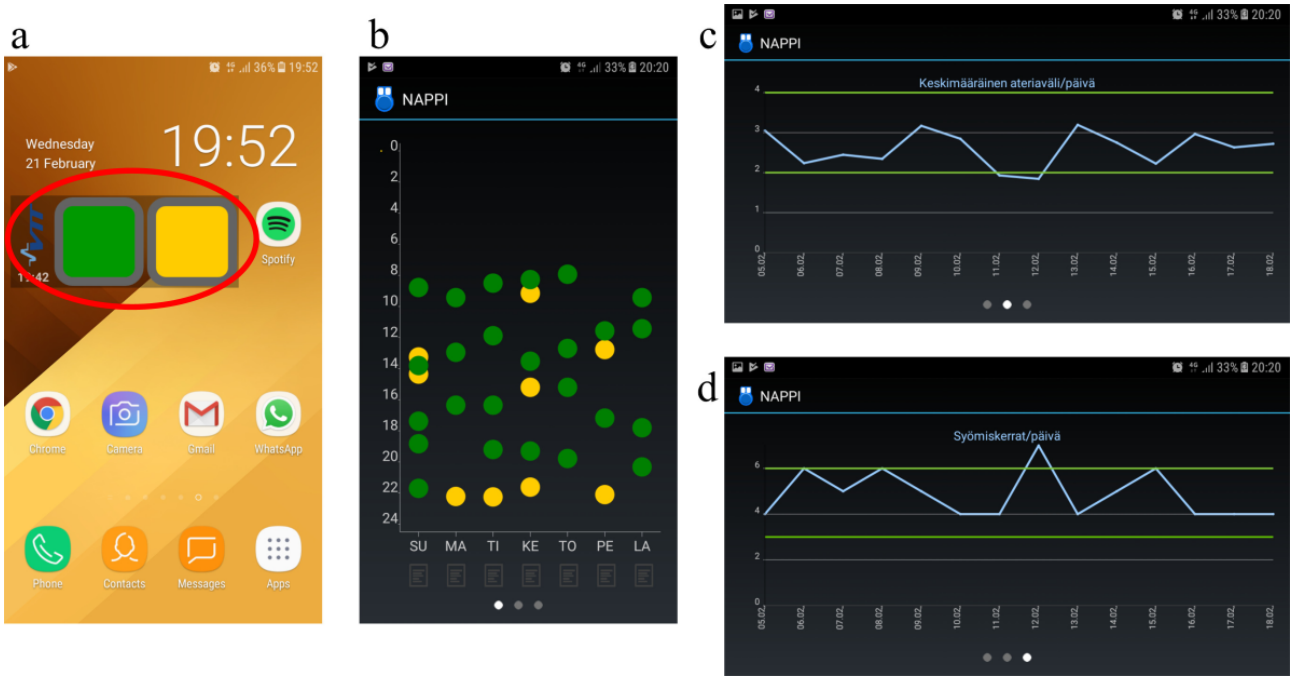
Methods

Ecological Momentary Assessment Mobile App Development

The Button comprises 2 components: the desktop widget and the actual app. The user presses 1 of the 2 buttons reflecting different types of eating occasions (healthy or unhealthy or content or discontent) in the Button widget after each eating occasion to record the time stamp and type of the eating occasion. The Button app visualizes the user's eating pattern with 3 summary screens (Figure 1). The data on the user's eating occasions are automatically transferred to a research database, where user data are protected using identification codes and encryption. The app frontend was implemented for Android mobile devices using Java, whereas the server backend utilizes Spring framework.

The app development was an iterative process including 2 real-life user trials in January 2017 and April 2017. The aim of the user trials was to find a feasible way to record the eating occasions to guarantee the technical functionality of the Button app and easiness to use. Volunteers (trial 1:9 and trial 2:8) used the app for a 2-week period, which was followed by a focus group discussion about the usability aspects and recommendations for further development. The participants of the first trial found it nebulous to interpret the graphs related to the optimal interval between meals and number of eating occasions per day. Therefore, green horizontal lines depicting the recommendations (2- to 4-hour intervals among meals, 3-6 meals per day) were included in the app after the first trial. This change increased the easiness of the data interpretation in the second trial.

Figure 1. The Button widget with green and yellow buttons (circled) on mobile phone desktop (a) and visual summaries shown in the Button application (b-d). The user presses either green (content with eating occasion) or yellow (discontent with eating occasion) button of the widget after every eating occasion. The first visualization (b) in the application shows the eating occasions during the past seven days (weekdays on x-axis, time on y-axis), the second screen (c) shows the average interval between eating occasions per day during the past 14 days and, the third screen (d) shows the average number of eating occasions per day during the past 14 days. Green horizontal lines in c and d indicate the shortest (2 h) and longest (4 h) recommended interval between eating occasions and the smallest (3) and the highest (6) recommended number of eating occasions per day.



Two App Versions

The user trial participants found color coding in the Button widget as the most feasible option to differentiate eating occasions. They also preferred the healthy (green)-unhealthy (red) dichotomy for the buttons. Considering that healthiness is not the only viewpoint when evaluating eating and food choices, a version with content (green)-discontent (yellow) dichotomy was also developed. It was considered that the possibility to make a subjective judgment about whether the eating episode is subjectively good or bad versus normative healthy-unhealthy logic might provide the user with a stronger feeling of autonomy and commitment and therefore motivate the user to change eating habits [22-25]. Thus, 2 app versions (*Healthiness* version and *Contentment* version) were developed. The *Healthiness* version had green and red buttons, the green button meaning an eating occasion that the user perceived as healthy and the red button meaning an occasion that was perceived as unhealthy. The *Contentment* version had green and yellow buttons. The green button reflected an eating occasion that the user was content with and the yellow button reflected an eating occasion the user was not fully content with. Only the meanings for the 2 buttons of the widget varied, but the functionalities of the 2 app versions were the same.

Self-Monitoring Study

Participants (n=74) were recruited through public advertisements, email advertisements, and institutions' intranets in 2 university campus areas in Finland. The participants had to be over 18 years of age and interested in well-being. In addition, an updated Android phone (Version 4.3 or newer) was a prerequisite for the attendance. The volunteers with red-green color blindness (self-reported) were excluded from the study.

The eligible volunteers were invited to the study location where the details of the study were explained, and they had a chance to ask questions. After receiving both written and verbal information about the study (voluntariness, purpose, content, and confidentiality), the volunteers signed an informed consent form. The Button app was installed in the participants' personal mobile phones, and they were instructed on how to use the app. The participants were given 4 movie tickets worth 52 euros to compensate their time and effort. Data collection was conducted in May and June 2017. The study protocol was approved by the Coordinating Research Ethics Committee of the Helsinki and Uusimaa Hospital District. The study was conducted according to the ethical principles of good research and clinical practice described in the Declaration of Helsinki.

The participants were randomly distributed to *Healthiness* group or *Contentment* group. Background information about the participants is given in Table 1. The members of the Healthiness and Contentment groups were alike regarding gender distribution, age, body mass index (BMI), and perceived importance of new technologies. The share of participants currently working was higher in the Healthiness group than in the Contentment group. There were 20 normal weight, 13 overweight, and 4 obese in the Healthiness group and 14 normal weight, 15 overweight, and 8 obese in the Contentment group.

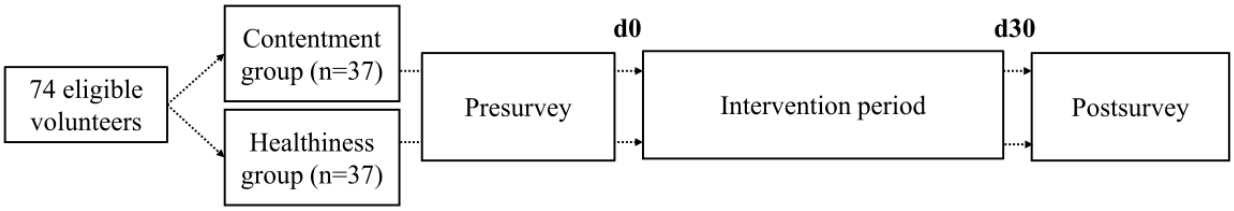
Table 1. Background information about the participants.

Variables	All participants (N=74)	Healthiness group (n=37)	Contentment group (n=37)	t test (df)	Chi-square test (df)	P value
Gender, number of females, n (%)	45 (61)	24 (65)	21 (57)	—[a]	0.5 (1)	.48
Age (years), mean (SD)	36.2 (12.5)	35.4 (11.2)	36.9 (13.8)	0.518 (72)	—	.14
Body mass index (kg/m^2), mean (SD)	26.1 (4.9)	25.5 (4.9)	26.7 (4.8)	1.026 (72)	—	.99
Work situation, number of participants working currently, n (%)	67 (91)	36 (97)	31 (84)	—	3.9 (1)	.05
Personal importance of new technologies[b], mean (SD)	5.2 (1.4)	5.1 (1.4)	5.2 (1.3)	0.294 (72)	—	.70

[a]Not applicable.

[b]measured on a 7-point scale in which 1=not important at all and 7=extremely important.

Figure 2. Study design.



Study Design and Experimental Procedure

The study adopted within- and between-subject design with 2 independent study groups using 1 of the 2 app versions (*Healthiness* group and *Contentment* group, Figure 2).

The participants were instructed to record the eating occasions (excluding eating occasions with calorie-free drinks only) by pressing either green or red (*Healthiness* group) or green or yellow (*Contentment* group) buttons after eating according to their own evaluation about the eating occasion. No instructions were given about eating rhythm or dietary choices. The participants were also instructed that they could freely open the Button app and observe the visual summaries of their eating rhythm and add comments. The intervention lasted for 30 days. Surveys measuring participants' self-reported daily meals, attitudinal constructs, food choice motives, and eating behavior tendencies were administered before and after the intervention period to detect potential changes caused by the Button usage.

Independent Variables

Table 2 presents the independent variables used in this study, their reliability, and sources variables (Cronbach alpha values higher than .70 are considered sufficient [26]). The main interest was in the changes in the eating rhythm during the intervention period. Therefore, the main independent variables were derived from the Button press data. The data were sent automatically from the Button app in the participants' mobile phone to the research database. The surveys before (presurvey) and after the intervention (postsurvey) comprised variables related to the eating rhythm (daily consumed meals), of eating behavior tendencies—the three-factor eating questionnaire (TFEQ)—, discontent with eating, attitudes toward health (general health interest), and relevant food choice-related motives (health, mood, and weight control). Daily consumed meals were measured by asking the respondent to mark down the meals that he or she consumes daily. The meal options included breakfast, lunch, afternoon snack, dinner or such, evening snack, and 5 unspecified options. The number of daily consumed meals was calculated as a sum of the marked meals. The TFEQ was administered to assess the potential effects of self-monitoring of eating pattern on the eating behavior tendencies [27]. A recently modified version (TFEQ-R15) of the questionnaire was used [28]. All items were measured with 4-point scales. The raw scale scores were transformed to a 0 to 100 scale ([raw score–lowest possible raw score]/highest possible raw score×100) [29]. The higher raw scale scores mean greater tendency toward the measured subscale. Discontent with eating at different meal times was measured by asking the respondents to rate the frequency of discontent at different meal times (breakfast, lunch time, afternoon, dinner time, late evening or in the night, and some other time) on a scale of 1=never to 5=very often. The mean value for discontent in each meal time was calculated.

Table 2. Reliability and sources of independent variables (Cronbach alpha values higher than .70 are considered sufficient).

Category	Content	Cronbach alpha presurvey	Cronbach alpha postsurvey	Source
Button data				
Eating rhythm	Interval between eating occasions per day	—[a]	—	Button app
	Eating occasions per day	—	—	Button app
Adherence to use the app	App openings per day to observe visual summaries about eating rhythm	—	—	Button app
Survey data				
Eating rhythm	Daily consumed meals	—	—	List of meals types
Eating behavior tendencies	Three-factor eating questionnaire (R-15) (scale 0-100)	uncontrolled eating: .77; cognitive restraint: .76; emotional eating: .77	uncontrolled eating: .81; cognitive restraint: .71; emotional eating: .89	[27,28]
Discontent with eating	Discontent with eating in different meal times (scale 1=never, 5=very often)	—	—	modified from [28]
Attitudes	General health interest (scale: 1=completely disagree, 7=completely agree)	.81	.80	[30]
Food-related motives	Food choice motives regarding health, mood, weight control (subscales of food choice questionnaire (scale: 1=not important at all, 4=very important)	health: .75; mood: .80; weight control: .76	health: .74; mood: .88; weight control: .79	[31]

[a]Not applicable.

Postsurvey also included an open-ended question about gained insights related to one's personal eating rhythm, eating behavior, and factors affecting these. First, participants were asked if they gained insights about their eating habits during the intervention period. In a positive case, the participant was asked to describe those insights in writing.

Data Analysis

Complete case analysis was conducted. The analysis included those participants (n=59) who completed the 30-day intervention successfully. Those participants (n=15) who had more than 4 days per 1 of the 3 10-day periods without any stamps because of technical difficulties or incompliance were removed from the Button data. The analytical approach was chosen as the Button app is intended to be used voluntarily and thus those participants who continued to use the app during the entire study were deemed to represent the real-life user. Pre and postsurvey data were analyzed on an intention-to-treat basis including all the 74 participants in the analyses. A different analytical approach was applied as all users had been exposed to Button usage at least to some extent during the entire 30-day period. Therefore, the survey data from the participants with and without valid Button data were deemed comparable.

The collected Button data were preprocessed to screen out faulty data and to prepare them for the actual analysis. Records deemed as duplicate values (more than 1 timestamp within 5 min) were removed, and timestamp values were converted from server time to actual local time. To determine the actual number of eating occasions per day, it was decided that the day begins and ends at 4 am instead of midnight, and the data were handled accordingly. Before the analysis, data were treated in the following manner: (1) for the evaluation of the changes in eating rhythm, the 30-day intervention period was divided into 3 10-day periods, (2) all days with less than an average of 1,000 seconds (<17 min) interval between the meals were removed (197/1770 days, 11%) as this was considered as an indication of multiple miss-presses or a technical flaw; moreover, evident outlier days with only 1 or 2 stamps per day were removed, (3) after suspicious data were removed, an average was calculated for each participant for each 10-day period, and the average was applied for the days with missing data.

SPSS Statistics (Version 24, IBM Corp, Chicago, IL, USA) was used for the statistical analysis. Repeated measures analysis of variance (ANOVA) with Bonferroni adjustment for multiple comparisons was used to analyze the within-group changes in eating rhythm (interval between meals, number of eating occasions per day) and adherence (number of app openings per day; n=59). A 1-way ANOVA was carried out to study between-group differences in data derived from the Button app (interval between eating occasions, number of eating occasions per day, and adherence to use the app). False discovery rate (FDR) was controlled by using the Benjamini-Hochberg method. The survey data analyses were conducted for all the participants (N=74) and separately for the subgroups. Repeated-measure ANOVA with Bonferroni adjustment for multiple comparisons were conducted to analyze within-group changes between presurvey and postsurvey. A 1-way ANOVA was used to analyze between-group differences in the self-reported number of daily meals, eating behavior tendencies (TFEQ-R15), discontent with eating habits, general health interest, and food-related motives. Benjamini-Hochberg method was used to control the FDR.

Responses to the open-ended question about insights gained during the intervention period were analyzed following the standard content analysis procedures. Reported individual

insights were categorized on the basis of their content in appropriate higher-order subcategories and finally in main categories.

Results

Eating Rhythm

Interval Between Eating Occasions

The average interval between eating occasions (on the basis of button presses) was 96±24 min in all participants during the first 10 days of intervention, and it increased to 109.1±36.4 min ($F_{1,694}$=6.241, P=.003) during the last 10 days of the intervention (Figure 3). This was mainly because of the increased interval between eating occasions in the Healthiness group between the last 2 study periods (P=.03). The average interval between eating occasions did not vary in the Contentment group. Between-group analyses revealed no statistically significant differences in any of the periods (Period 1: F_1=.549, P=.46; Period 2: F_1=.389, P=.54; Period 3: F_1=1.734, P=.19).

Number of Meals Per Day

In the presurvey, participants reported to consume approximately 4.5±0.9 meals per day (Table 3). There were no differences between the groups (F_1=.825, P=.37). The number of the reported daily meals was significantly lower after the intervention in all participants (4.2[SD 1.0] meals; t_{73}=2.591, P=.01) and again mainly caused by the change in Healthiness group. There were no statistically significant differences in the number of daily meals between the groups after the intervention (F_1=.015, P=.90).

The number of reported eating occasions (button presses) reduced during the 4-week intervention among all participants (Figure 4). The trend was similar in both the Healthiness group and Contentment group, and the groups did not differ from each other (Period 1: F_1=.333, P=.57; Period 2: F_1=.289, P=.59; and Period 3: F_1=.007, P=.93). On average, 77% of the eating occasions of the Healthiness group were classified as *healthy* and 86% of the eating occasions of the Contentment group were classified as *content*.

Figure 3. Average intervals between eating occasions (Button presses) (mean ± SD) in the three periods (Period 1 = days 1-10, Period 2 = days 11-20, Period 3 = days 21-30) in a) all participants (n=59) and members of b) Healthiness group (n=29) and c) Contentment group (n=30). Different superscript letters indicate a statistically significant difference (P≤.05) between study periods.

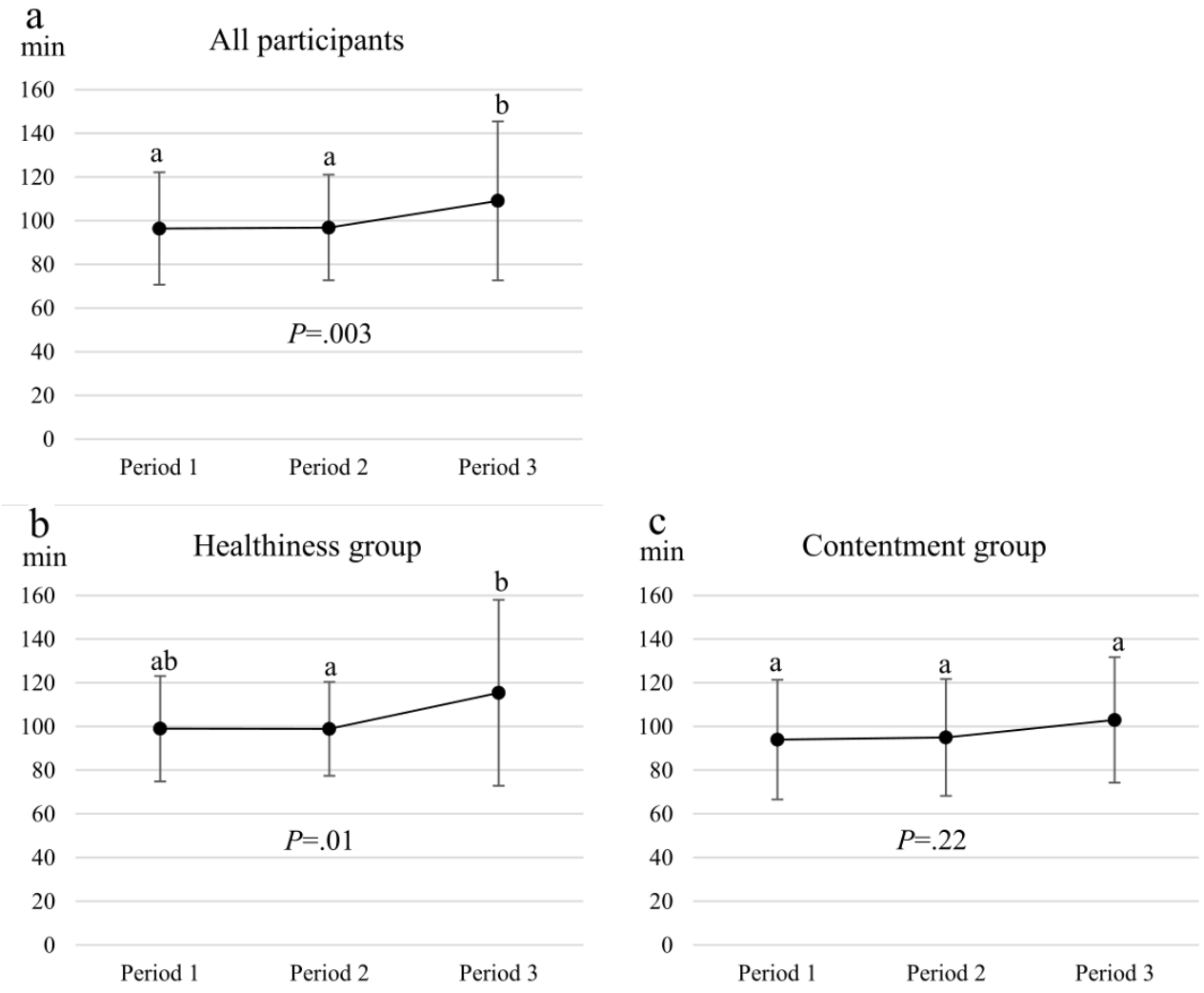
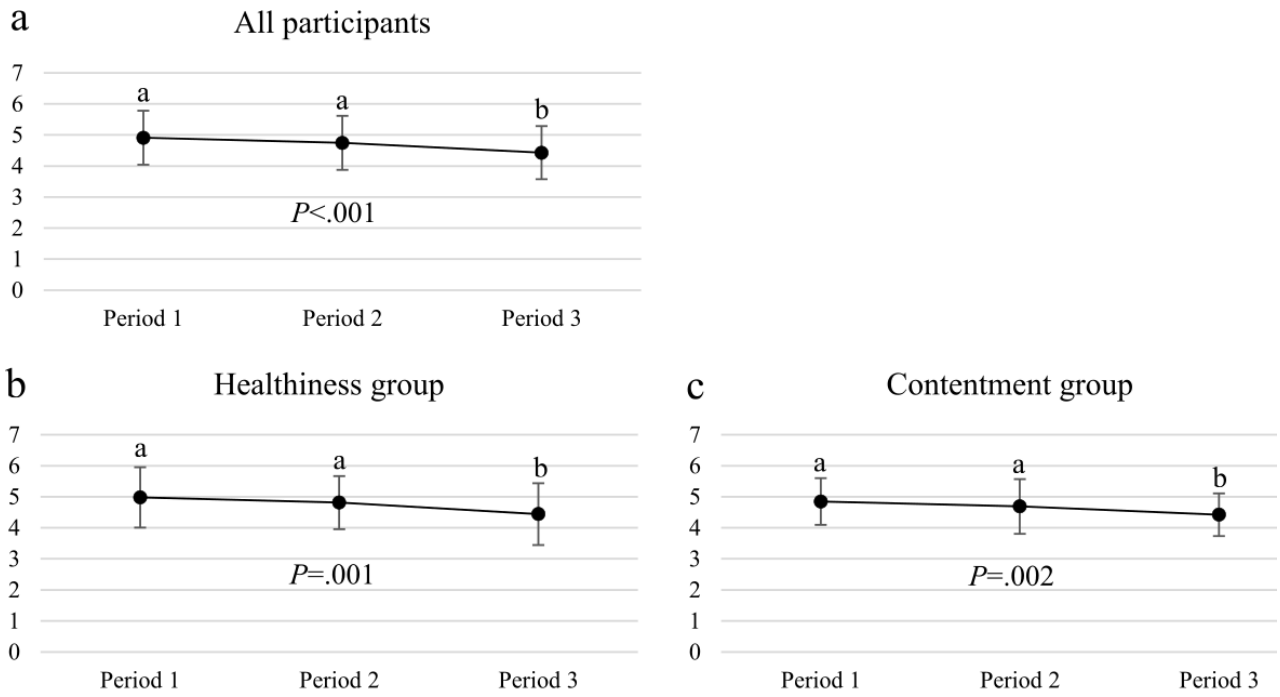


Table 3. The number of reported meals (breakfast, lunch, afternoon snack, dinner, evening snack, and other snacks) per day (mean [SD]) before and after the intervention in (1) all participants (N=74) and members of (2) Healthiness group (n=37), and (3) Contentment group (n=37).

Meals per day	Mean (SD)		*F* test (*df*)	*P* value
	Before	After		
All participants (N=74)	4.5 (0.9)	4.2 (1.0)	6.712 (1)	.01
Healthiness group (n=37)	4.6 (0.8)	4.2 (1.1)	4.776 (1)	.04
Contentment group (n=37)	4.4 (1.0)	4.2 (0.9)	1.974 (1)	.17

Figure 4. Average number of reported eating occasions per day (mean ± SD) in the three periods (Period 1 = days 1-10, Period 2 = days 11-20, Period 3 = days 21-30) in a) all participants (n=59) and members of b) Healthiness group (n=29) and c) Contentment group (n=30). Different superscript letters indicate a statistically significant difference between study periods.



Adherence to Use the App

Adherence to use the Button app decreased during the study among all participants. They opened the app to observe the visual summaries related to eating rhythm on average 2.6±1.2 (Period 1); 2.2±1.4 (Period 2), and 1.8±1.3 (Period 3) times per day (Figure 5). Within study groups, the trend was similar, but significant differences were observed only between Period 1 and Period 3. Between-group analysis showed no significant differences between the groups (Period 1: F_1=2.042, P=.16; Period 2: F_1=1.126, P=.29; and Period 3: F_1=1.207, P=.28).

Eating Behavior Tendencies

There were no differences between groups regarding cognitive restraint, uncontrolled eating, or emotional eating before the intervention (F_1=.039, P=.85; F_1=.177, P=.68; and F_1=.900, P=.35, respectively). The reported tendencies of emotional eating, uncontrolled eating, and cognitive restraint were higher after the intervention than before the intervention in both the intervention groups (Table 4). The changes were statistically significant except that of uncontrolled eating among the members of Healthiness group. There were no differences between the groups in any of the measured eating behavior tendencies after the intervention (cognitive restraint: F_1=.004, P=.95; uncontrolled eating: F_1=.255, P=.62; emotional eating: F_1=.493, P=.49).

Figure 5. Adherence to usage of the Button application. The average number of times the application was opened per day during the three periods in a) all participants (n=59) and members of b) Healthiness group (n=29) and c) Contentment group (n=30).

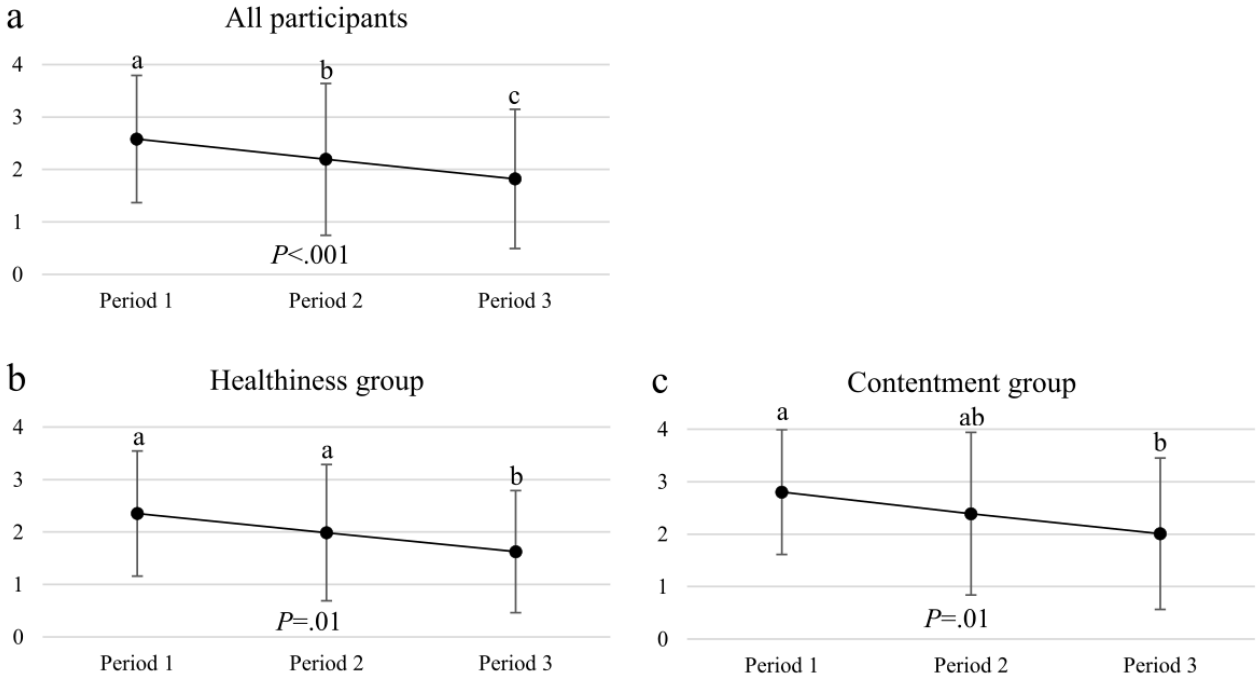


Table 4. Participants' (all participants and subgroups) responses to the three-factor eating questionnaire R15 (mean, SD, scale 0-100, in which higher score means greater tendency toward the measured subscale) before the intervention and after the intervention.

Eating behavior tendency	Mean (SD)		*F* test (*df*)	*P* value
	Before	After		
Cognitive restraint				
All participants (N=74)	29.1 (23.5)	37.4 (20.9)	12.641 (*1*)	.001
Healthiness group (n=37)	29.7 (28.5)	37.2 (24.2)	4.954 (*1*)	.03
Contentment group (n=37)	28.6 (17.4)	37.5 (17.3)	7.781 (*1*)	.01
Uncontrolled eating				
All participants	24.5 (13.2)	28.7 (13.6)	10.847 (*1*)	.002
Healthiness group	25.2 (12.9)	27.9 (12.3)	1.912 (*1*)	.18
Contentment group	23.9 (13.6)	29.5 (14.9)	12.532 (*1*)	.001
Emotional eating				
All participants	20.7 (21.5)	29.7 (25.7)	20.785 (*1*)	<.001
Healthiness group	18.3 (21.3)	27.6 (26.8)	11.833 (*1*)	.001
Contentment group	23.5 (21.9)	31.8 (24.7)	8.925 (*1*)	.01

Discontent With Eating

The participants were asked to evaluate how often they were discontent with their eating habits (1=never to 5=very often), and the average value for discontent was calculated for each meal time. In general, the participants were content with their eating habits (1.6-2.8, Table 5). The 2 groups did not differ regarding the frequency of discontent before the intervention (F_1=1.303, *P*=.26; F_1=.215, *P*=.64; F_1=1.435, *P*=.24; F_1=.889, *P*=.35; F_1=.136, *P*=.71; F_1=.014, *P*=.91 during breakfast time, lunch time, afternoon, dinner time, late evening or in the night, or some other time, respectively). More frequent discontent with eating habits during lunch time was reported after the intervention than before the intervention among all participants and among the members of the Healthiness group. There were no differences between the groups regarding the frequency of discontent after the intervention (F_1=1.323, *P*=.25; F_1=1.432, *P*=.24; F_1=1.462, *P*=.23; F_1=.543, *P*=.46; F_1=.809, *P*=.37; F_1=1.889, *P*=.17) during breakfast time, lunch time, afternoon, dinner time, late evening or in the night, or some other time, respectively.

Table 5. Participants' (all participants and subgroups) evaluations of discontent with their eating habits (scale 1-5, in which 1=never, 5=very often; mean, SD) in different meal times before and after the intervention.

Meal times	Mean (SD)		*F* test (*df*)	*P* value
	Before	After		
Breakfast				
All participants (N=74)	2.0 (1.0)	2.1 (0.9)	.451 (1)	.50
Healthiness group (n=37)	2.1 (1.2)	2.2 (1.0)	.130 (1)	.72
Contentment group (n=37)	1.9 (0.9)	2.0 (0.8)	.354 (1)	.56
Lunch time				
All participants	2.0 (0.7)	2.2 (0.7)	10.790 (1)	.002
Healthiness group	2.0 (0.8)	2.3 (0.8)	6.640 (1)	.01
Contentment group	1.9 (0.7)	2.1 (0.6)	4.083 (1)	.05
Afternoon				
All participants	2.6 (0.9)	2.7 (0.8)	1.820 (1)	.18
Healthiness group	2.7 (0.9)	2.8 (0.8)	.722 (1)	.40
Contentment group	2.5 (0.8)	2.6 (0.7)	1.090 (1)	.30
Dinner time				
All participants	2.6 (0.9)	2.6 (0.8)	.899 (1)	.35
Healthiness group	2.7 (0.9)	2.7 (0.7)	.163 (1)	.69
Contentment group	2.5 (0.8)	2.6 (0.9)	1.000 (1)	.32
Late evening or night				
All participants	2.6 (0.9)	2.6 (1.0)	.102 (1)	.75
Healthiness group	2.6 (1.0)	2.5 (1.1)	.342 (1)	.56
Contentment group	2.5 (0.9)	2.7 (1.0)	1.202 (1)	.28
Some other time				
All participants	1.6 (1.0)	1.8 (0.9)	1.392 (1)	.24
Healthiness group	1.6 (1.0)	2.0 (1.0)	1.891 (1)	.18
Contentment group	1.7 (1.0)	1.7 (0.8)	.000 (1)	>.99

Insights Into Eating Patterns

The participants reported that they had obtained insights into their eating patterns during the intervention period. These were related to eating rhythm, variation in eating rhythm, and healthiness of eating habits (Table 6).

Attitudes and Motives

The measured attitudes toward health (General Health Interest) did not differ between the groups before the intervention (F_1=.571, P=.45), and they did not change during the intervention (Table 7). The groups did not differ regarding attitudes toward health after the intervention either (F_1=.406, P=.53).

The groups were similar regarding motives related to food choices before the intervention (Health: F_1=.002, P=.97; Mood: F_1=.000, P>.99; Weight Control: F_1=.975, P=.33). Motives related to food choices remained unchanged within all the participants and subgroups except the increase in weight control motive in the Contentment group. No differences between the groups were identified after the intervention (Health: F_1=.017, P=.90; Mood: F_1=.426, P=.52; Weight Control: F_1=2.629, P=.11).

Table 6. Examples of comments of the participants after Button usage in 3 main categories: eating rhythm, variation in eating rhythm, healthiness of eating habits, and their subcategories.

Main category	Subcategories and examples of comments (in brackets)
Eating rhythm	Observations on eating rhythm in relation to own preconceptions: "My eating rhythm was surprisingly regular even though I felt that I eat very irregularly"; Attention paid and observations made on one's own eating rhythm: "Irregularity of my eating rhythm was shaped"; Observation of a relationship between eating rhythm, food choices, and wellbeing: "Regular eating maintains blood glucose levels (which I already knew) and I was more alert during the day (which I finally experienced concretely)"; Recognition of a need to change eating rhythm: "I am planning to reduce snacking"
Variation in eating rhythm	Observation of variation in eating rhythm because of the day of the week: "Eating rhythm is more irregular in weekends"; Observation of variation in eating rhythm because of time of the day: "I noticed that often during forenoon my eating rhythm is regular. Often, towards evening I either forget to eat or increase eating, depending on the day"; Observation of variation because of external factors: "There are workdays and travels during which I cannot ensure short enough gaps between meals without planning"
Healthiness of eating habits	Observation of healthiness of one's own eating habits "In many days I eat some unhealthy snack"; Recognition of a need to improve eating habits: "I decided not to buy some ice cream and candy when I still saw the last red mark on the screen"

Table 7. Participants' (all participants and subgroups) attitudes toward health (General Health Interest questionnaire, scale 1-7, in which 1=completely disagree, 7=completely agree) and motives related to food choices (Food Choice questionnaire, scale 1-4, in which 1=not important at all, 4=very important; mean, SD) before the intervention and after the intervention.

Participants' attitudes and motives	Mean (SD)		*F* test (*df*)	*P* value
	Before	After		
General Health Interest				
All participants (N=74)	5.0 (1.0)	4.9 (1.0)	1.039 (1)	.31
Healthiness group (n=37)	4.9 (1.0)	4.9 (0.8)	.311 (1)	.58
Contentment group (n=37)	5.1 (1.0)	5.0 (1.1)	.792 (1)	.38
Health motive				
All participants	3.3 (0.4)	3.3 (0.4)	.047 (1)	.83
Healthiness group	3.3 (0.4)	3.3 (0.5)	.004 (1)	.95
Contentment group	3.3 (0.5)	3.3 (0.5)	.084 (1)	.77
Mood motive				
All participants	3.1 (0.5)	3.1 (0.6)	1.578 (1)	.21
Healthiness group	3.1 (0.5)	3.1 (0.5)	.079 (1)	.78
Contentment group	3.1 (0.5)	3.1 (0.5)	2.614 (1)	.15
Weight control motive				
All participants	2.5 (0.6)	2.6 (0.7)	2.807 (1)	.10
Healthiness group	2.4 (0.7)	2.4 (0.7)	.111 (1)	.74
Contentment group	2.5 (0.5)	2.7 (0.7)	4.751 (1)	.04

Discussion

Principal Findings

The 30-day self-monitoring of eating occasions with an EMA mobile phone app, *Button*, changed the eating patterns: the average interval between meal occasions lengthened and the number of daily-consumed meals decreased. The effectiveness of the app varied in the 2 study groups: the changes were statistically significant mainly among all the participants and among the members of Healthiness group. The participants reported higher tendencies of emotional eating, uncontrolled eating, and cognitive restraint after the intervention than before the intervention, and the discontent with eating slightly increased regarding eating at lunch time. Participants also reported having gained insights into the eating rhythm or eating habits during the intervention period, which indicates that the awareness on their eating patterns increased. The measured attitudes and motives remained unchanged except for a small increase in weight control motive among the participants of Contentment group. To sum up, the study results indicate that self-monitoring of eating occasions with an EMA tool might assist in battling against the growing tendency of irregular eating [9-13] and harms related to it [2,3,6-8]. The tool might be useful especially for people who follow a *grazing* eating pattern with no clear meal times but frequent peaks of eating occasions during the

day. However, the underlying reasons for the more pronounced tendencies of emotional eating and uncontrolled eating after the intervention require further investigations.

The 2 Button versions were developed and studied among 2 similar study groups. The only difference between the versions was the logic of the 2 buttons (healthy-unhealthy, content-discontent), indicated by different button colors. The content-discontent version was intended to provide the users freedom and feeling of autonomy to choose whether they are content with the eating occasion regardless of its healthiness and therefore to motivate the users toward behavior change [20-23]. However, the observed changes in eating rhythm were statistically significant only in the Healthiness group, as opposed to the expectation. A possible reason for the result could be in the familiarity and more normative nature of the healthy-unhealthy concept, which might have made it easier to evaluate eating. Some indications about this were received during the usability studies carried out during the Button development in which healthy-unhealthy dichotomy was preferred by the participants because of its logical and easy-to-interpret nature. Both of the groups classified the majority of the eating occasions as *green* (healthy in Healthiness group, content in Contentment group). However, the proportion of red button presses (unhealthy) was larger than that of yellow button presses (discontent).

In both the study groups, the intensities of the 3 measured eating behavior tendencies (emotional eating, uncontrolled eating, and cognitive restraint) were elevated in postsurvey compared with presurvey. Cognitive restraint has been found to increase because of weight-loss interventions [32,33], whereas uncontrolled eating has been found to decrease among successful dieters [33,34]. Moreover, in a Web-based weight loss program, cognitive restraint increased and uncontrolled eating decreased among the participants who completed (620 out of 22,800 enrolled participants) the 6 months intervention [35]. However, eating behavior tendencies have found to change not only among intervention groups but also among control groups, indicating that they are not stable constructs [32,33].

High tendencies for cognitive restraint, emotional eating, and uncontrolled eating are considered to associate with generally negative phenomena such as high BMI and stress [36-38]. Therefore, the potentially adverse effects of self-monitoring of eating rhythm on these eating behavior tendencies cannot be ruled out. The increase in cognitive restraint could be regarded as a natural consequence of increased attention to eating, in accordance with earlier studies investigating the effects of dietary interventions on eating behavior tendencies [32,33]. However, the increases in emotional eating and uncontrolled eating are more cumbersome phenomena. In the case of cognitive restraint, it could be hypothesized that marking down the eating occasions might have strengthened the role of reflective cognitive processes instead of automatic processes that generally dominate dietary choices, meaning that increased attention and awareness of these tendencies might have influenced the evaluation [15]. After completing the questionnaire in the presurvey and paying attention to the eating pattern for 30 days, the participants might have had better capabilities to evaluate eating behavior tendencies in the postsurvey. This interpretation is supported by the open-ended responses related to insights into eating pattern during the intervention period. The majority of the participants reported that they had paid attention to their eating habits, and many of those insights were related to contrast between participants' earlier beliefs and actual behavior illustrated by the app. These insights might have made participants more susceptible, precise, and realistic in their evaluations of eating tendencies in the postsurvey. However, as it is not clear if the increase in emotional eating and uncontrolled eating reflected actual changes in the eating behavior tendencies or just improved the ability to evaluate these tendencies, the potential adverse effects cannot be ruled out. Therefore, the evolvement of the eating behavior tendencies should be evaluated in future interventions.

The participants of both the intervention groups reported being more discontent with their eating during lunch time, after the intervention. This finding indicates that Button use made them more aware of lunch-time eating and the downsides of it (eg, inability to enjoy lunch break because of the hectic working pace or lack of good lunch options). In the open-ended questions, some participants shared this view. In a best-case scenario, the increased discontent might trigger changes in the lunch-time eating habits: more time could be preserved for lunch, or better lunch options could be sought. However, unless some changes can be made, the increased discontent can be interpreted as a negative effect of using the app.

A small increase in the weight-control motive was seen among the participants of the Contentment group, but there were no other changes in the food choice motives or attitudes. This is not surprising as attitudes are especially stable psychological constructs and difficult to be altered [39,40]. However, alteration of occasionally misrepresented beliefs behind the attitudes might be worthwhile as a change in those might in time lead to attitude change and eventually lead to behavior change [41,42]. In the case of this study, the responses to the open-ended questions suggested that the use of app was able to reveal to the participants some of their misrepresented beliefs related to eating behavior. Although this effect was not visible in attitude and motive measurements, it could be suggested that an app with more features, focusing on revealing incorrect beliefs might be powerful enough in time to alter even attitudes and thus result in long-lasting changes in eating patterns.

Self-monitoring of daily behavior is 1 way to become more aware of behavior, which in turn facilitates changes in behavior [15]. A majority of the apps for monitoring eating have been laborious to use, and adherence does not last long [43]. In this study, the participants opened the Button app to observe the summaries almost twice a day, even during the last 10 days of intervention. This indicates that adherence was relatively good, making the Button a feasible tool to monitor eating pattern.

Limitations

The study has limitations. First, there was no control group without the Button app, which limits the interpretation of the results. Part of the observed changes might have occurred because of study participation rather than the use of the app itself. Moreover, we cannot rule out the possibility that some external factors, such as season of the year, could have

contributed to the observed changes in the study. Control would have also been useful for evaluating how the repetition of TFEQ after a relatively short period (30 days) influences the results (ie, do the participants evaluate their tendencies differently after the first exposure to the questionnaire?). Second, the charm of the novelty of the app might have diminished toward the end of the intervention; therefore, the ease of remembering to mark every eating occasion might have weakened, influencing the number of daily presses. However, importantly, the reduction of daily consumed meals was observed in both survey data and data derived from the Button. Third, the intervention period of 30 days was relatively short. Engagement to the app use would have likely decreased over a longer period. However, we consider Button as a tool to become aware of temporal eating patterns rather than a tool for sustained use. Therefore, the period of 30 days is justified. However, a follow-up study would be especially useful to evaluate the long-term effects on eating behavior tendencies. Finally, Button data of 15 participants had to be excluded from the analyses. Complete case analysis was perceived as a more suitable approach than intention to treat with regard to Button data. The reasoning lies in the nature of the Button app, which is intended for voluntary use for those who are motivated to monitor their eating behavior. Therefore, including those who discontinued the app use might have led to very pessimistic results. On the other hand, complete case approach along with limited convenience sample might bias the results toward unjustified optimism. This bias is alleviated by the results derived from the survey data, which were based on the full sample. These results are in line with the observations from Button data. Considering the identified limitations, the future studies should include a control group, and there should be follow-up points to observe if the observed changes will sustain. The reported number of daily meals of the participants (4.5) was already as recommended in the Finnish nutrition recommendations—4 to 5 meals per day [44]—before the intervention. In future studies, it would be interesting to test the app among user groups who have a *grazing* meal pattern.

Conclusions

The Button app was easy to use, and adherence was good. The results indicate that self-monitoring of eating with a simple mobile app may hold promise in promoting regular eating patterns. However, the suitability of the app for users with different meal patterns and eating behavior tendencies needs further studies.

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Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
BMI: body mass index
EMA: ecological momentary assessment
FDR: false discovery rate
TFEQ: three-factor eating questionnaire

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Original Paper

Diagnostic Performance of a Smart Device With Photoplethysmography Technology for Atrial Fibrillation Detection: Pilot Study (Pre-mAFA II Registry)

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Abstract

Background: Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. The asymptomatic nature and paroxysmal frequency of AF lead to suboptimal early detection. A novel technology, photoplethysmography (PPG), has been developed for AF screening. However, there has been limited validation of mobile phone and smart band apps with PPG compared to 12-lead electrocardiograms (ECG).

Objective: We investigated the feasibility and accuracy of a mobile phone and smart band for AF detection using pulse data measured by PPG.

Methods: A total of 112 consecutive inpatients were recruited from the Chinese PLA General Hospital from March 15 to April 1, 2018. Participants were simultaneously tested with mobile phones (HUAWEI Mate 9, HUAWEI Honor 7X), smart bands (HUAWEI Band 2), and 12-lead ECG for 3 minutes.

Results: In all, 108 patients (56 with normal sinus rhythm, 52 with persistent AF) were enrolled in the final analysis after excluding four patients with unclear cardiac rhythms. The corresponding sensitivity and specificity of the smart band PPG were 95.36% (95% CI 92.00%-97.40%) and 99.70% (95% CI 98.08%-99.98%), respectively. The positive predictive value of the smart band PPG was 99.63% (95% CI 97.61%-99.98%), the negative predictive value was 96.24% (95% CI 93.50%-97.90%), and the accuracy was 97.72% (95% CI 96.11%-98.70%). Moreover, the diagnostic sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of mobile phones with PPG for AF detection were over 94%. There was no significant difference after further statistical analysis of the results from the different smart devices compared with the gold-standard ECG (P>.99).

Conclusions: The algorithm based on mobile phones and smart bands with PPG demonstrated good performance in detecting AF and may represent a convenient tool for AF detection in at-risk individuals, allowing widespread screening of AF in the population.

Trial Registration: Chinese Clinical Trial Registry ChiCTR-OOC-17014138; http://www.chictr.org.cn/showproj.aspx?proj=24191 (Archived by WebCite at http://www.webcitation/76WXknvE6)

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KEYWORDS

atrial fibrillation; photoplethysmography; detection; accuracy; mobile phone; smart band; algorithm

Introduction

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia encountered in clinical practice and is associated with increased risk of stroke, systemic embolism, heart failure, hospitalization, and death [1-3]. At least one-third of patients with AF are asymptomatic [4]. Due to the asymptomatic nature and paroxysmal frequency of this arrhythmia, early detection is challenging and often unsuccessful [5]. Strikingly, acute stroke or heart failure is often the first sign of AF [6,7]. Asymptomatic AF is also related with worse outcomes compared with symptomatic AF [8]. However, approximately 70% of AF-related strokes could be avoided with early detection and early management, such as initiation of oral anticoagulants [9]. The European Society of Cardiology now recommends screening of AF in the primary care of high-risk patients, including those aged 65 years and older, which is important for the prevention of stroke [10].

Although studies have shown that more frequent monitoring can improve AF detection [11-13], population-based screening remains suboptimal because of the inconvenience and high expense of current screening approaches, such as Holter monitoring with different time durations (24 hours and 7 days) [14,15]. In addition, the diagnostic value of the standard 12-lead electrocardiogram (ECG) is limited by the need for patients to obtain ECG diagnostic equipment, as well as the requirement that AF be present at the time of the ECG recording. As such, we need a more convenient heart rhythm screening or detection approach to identify AF and initiate early treatment.

Technical options to detect AF have significantly improved within the past decade. Different technologies such as blood pressure monitors [16], single-lead cardiac event monitors (Kardia Mobile case or card) [17], and mobile phone apps using photoplethysmographic signals have emerged for this purpose [18,19]. Taggar et al [20] analyzed 21 studies that investigated 39 interventions for detecting AF before March 16, 2015. Their meta-analysis found that the most accurate methods for detecting AF were blood pressure monitors, which had a sensitivity of 98% and a specificity of 92%, and non-12-lead ECG, which had a sensitivity of 91% and a specificity of 95%. Although blood pressure monitors and non-12-lead ECG both had relatively high diagnostic accuracies, the need for a blood pressure monitor and a clinical specialist to analyze the non-12-lead ECG pose a challenge for wide-scale implementation of AF screening. ECG hand-held devices usually provided a single-lead ECG for detecting AF, which including two different types: on-device diagnostic algorithm and transmitted data devices. According to the data from the sixth Atrial Fibrillation NETwork (AFNET) and the European Heart Rhythm Association (EHRA) Consensus Conference [21], the sensitivity of an on-device diagnostic algorithm was 94% to 98%, and the specificity was 76% to 97%. Transmitted data devices achieved a sensitivity and specificity of 94% to 96% and 90% to 95% for AF detection, respectively [21]. However, the diagnostic sensitivity of photoplethysmography (PPG) for AF detection was 97% to 100%, and the specificity was 92% to 94% [21]. The potential of PPG technology for AF detection has been confirmed in some small sample studies, but it is still necessary to verify the diagnostic accuracy of PPG technology for AF detection with a larger sample size study in the real world.

Available studies have indicated that PPG technology is a promising technology for AF screening. PPG is an optical method measuring changes in tissue blood volume through the skin capillary bed, which can be performed by using a mobile phone without any additional peripheral equipment [22,23]. The PPG waveform is generally acquired by the built-in camera of a mobile phone to measure pulsatile changes in light absorption reflected from a fingertip illuminated by the light-emitting diode (LED) flash [19]. Most smart bands currently on the market use PPG technology, and heart rate sensors on most smart bands work via PPG [24]. Detecting AF using easily accessible devices, such as mobile phones and smart bands, may represent a novel opportunity to passively and automatically detect asymptomatic AF that does not require additional hardware and is simple to operate. However, there has been limited validation of mobile phone and smart band PPG compared to 12-lead ECG, and the consistency and stability of PPG technology in AF screening with different smart devices still lack accurate data.

In this study, we tested the hypothesis that pulse waveform signals recorded using smart devices, including mobile phones and smart bands, can be analyzed by a realizable algorithm and can distinguish AF from normal sinus rhythm. This study also provides data on AF screening technology for the Chinese population.

Methods

Study Population

A total of 112 consecutive inpatients were recruited from the Chinese People's Liberation Army General Hospital (Beijing, China) from March 15 to April 1, 2018. Information regarding demographic characteristics, medical history, blood test results, and medications were recorded.

Patients aged 18 years and older were included in the study. Exclusion criteria included patients unable to use mobile phones and smart bands, with mental or memory problems, or with a pacemaker or implantable cardioverter defibrillator. Written informed consent was obtained and signed by each individual willing to take part in the study.

The mobile atrial fibrillation apps (mAFA) II registry is mobile health (mHealth) technology for improved screening, patient involvement, and optimizing integrated care of AF. Ours was a single-center pilot study of AF screening that was pre-mAFA II registry. The Medical Ethics Committee of the Chinese PLA General Hospital and the China Food and Drug Administration approved the study protocol (no: S2017-105-02). The study is registered in the Chinese Clinical Trial Registry, International Clinical Trials Registry Platform of the World Health Organization (ChiCTR-OOC-17014138).

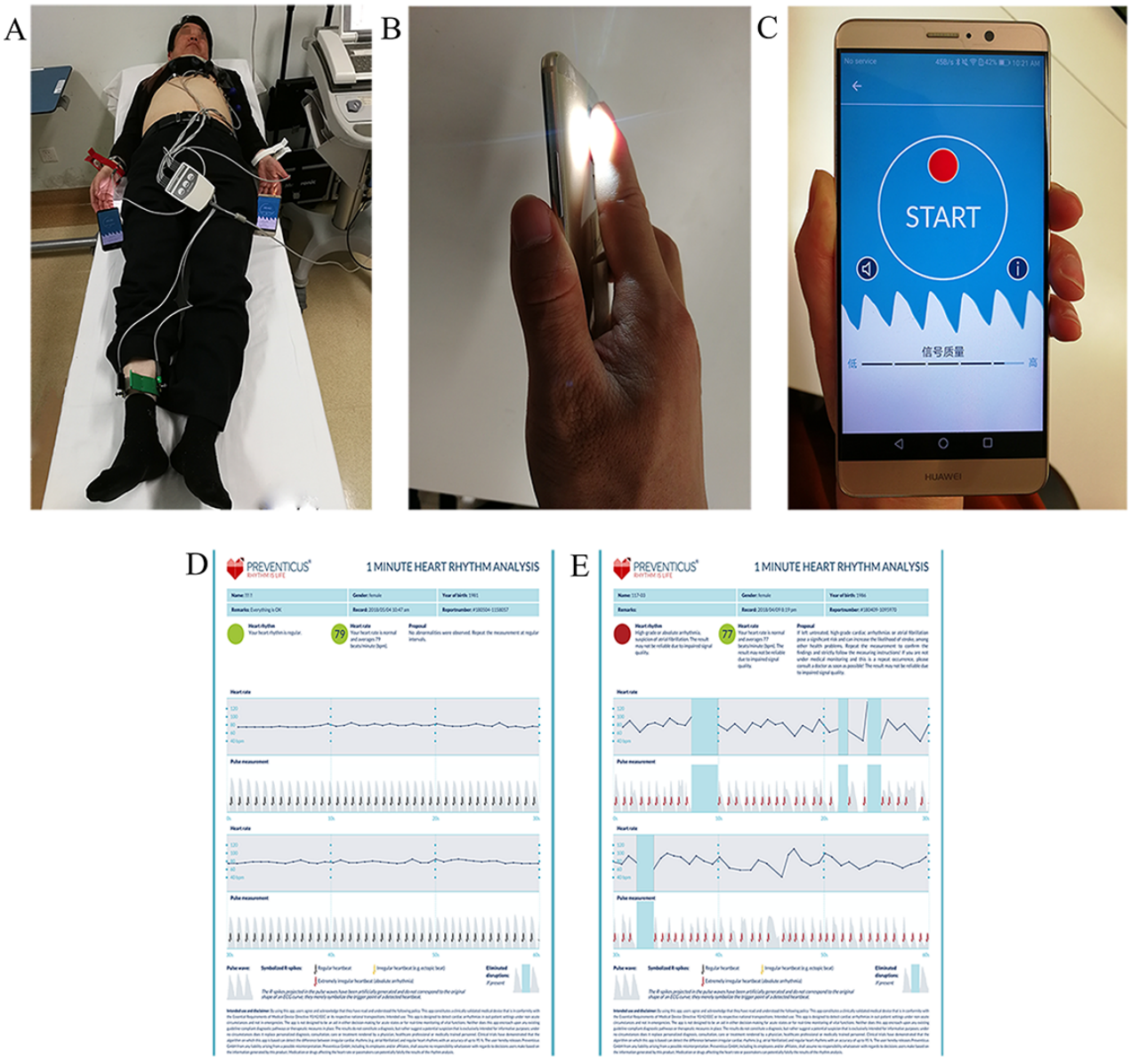
Signal Acquisition and Processing

Mobile phones (HUAWEI Mate 9, HUAWEI Honor 7X; Huawei Technologies Co, Ltd, Shenzhen, China) and smart bands

(HUAWEI Band 2) were used for collecting pulse waveform signals. Pulse waveform recordings were performed by the participants under the supervision of trained study personnel. A dedicated data collection app, Heartbeats (Preventicus GmbH, Jena, Germany), was responsible for the pulse waveform signal acquisition and was installed in the HUAWEI mobile phones.

Participants were simultaneously tested with mobile phones (HUAWEI Mate 9, HUAWEI Honor 7X), smart bands (HUAWEI Band 2), and 12-lead ECG for 3 minutes. Participants were advised to lie down in a supine position and breathe spontaneously. A HUAWEI Mate 9 (mobile phone 1) was positioned on the left-hand finger (either the index or middle finger) with the camera lens and LED light placed on the fingertip of the participant. Similarly, a HUAWEI Honor 7X (mobile phone 2) was positioned on the finger of the right hand. PPG measurements were performed by using the Heartbeats mobile phone app. The participant was asked to wear two smart bands, one each on the left and right hand. A 3-minute pulse waveform recording was obtained from each participant using the smart devices and a formal 12-lead ECG simultaneously. The PRO AF PPG was not running on the mobile devices in real time but remotely in the cloud. Then all 3-minute pulse waveform recordings using the smart devices were uploaded to the online cloud center and analyzed by a realizable algorithm (PRO AF PPG) provided by Preventicus (Preventicus GmbH, Jena, Germany). Figure 1 shows a prototype for AF detection using HUAWEI mobile phones and smart bands.

Figure 1. A prototype for atrial fibrillation detection using HUAWEI mobile phones and smart bands. A: A patient is simultaneously checked with HUAWEI mobile phones (Mate 9, Honor 7X), HUAWEI smart bands (Band 2), and 12-lead ECG. B: A fingertip is placed in contact with the built-in camera lens of a HUAWEI Mate 9 mobile phone and is illuminated by the adjacent LED flash. C: A screenshot of the pulse waveform data collection app (Heartbeats) running on a HUAWEI Mate 9 mobile phone. D: Representative pulse waveform recording from a patient with normal sinus rhythm. E: Representative pulse waveform recording from a patient with persistent atrial fibrillation.



Rhythm Diagnosis

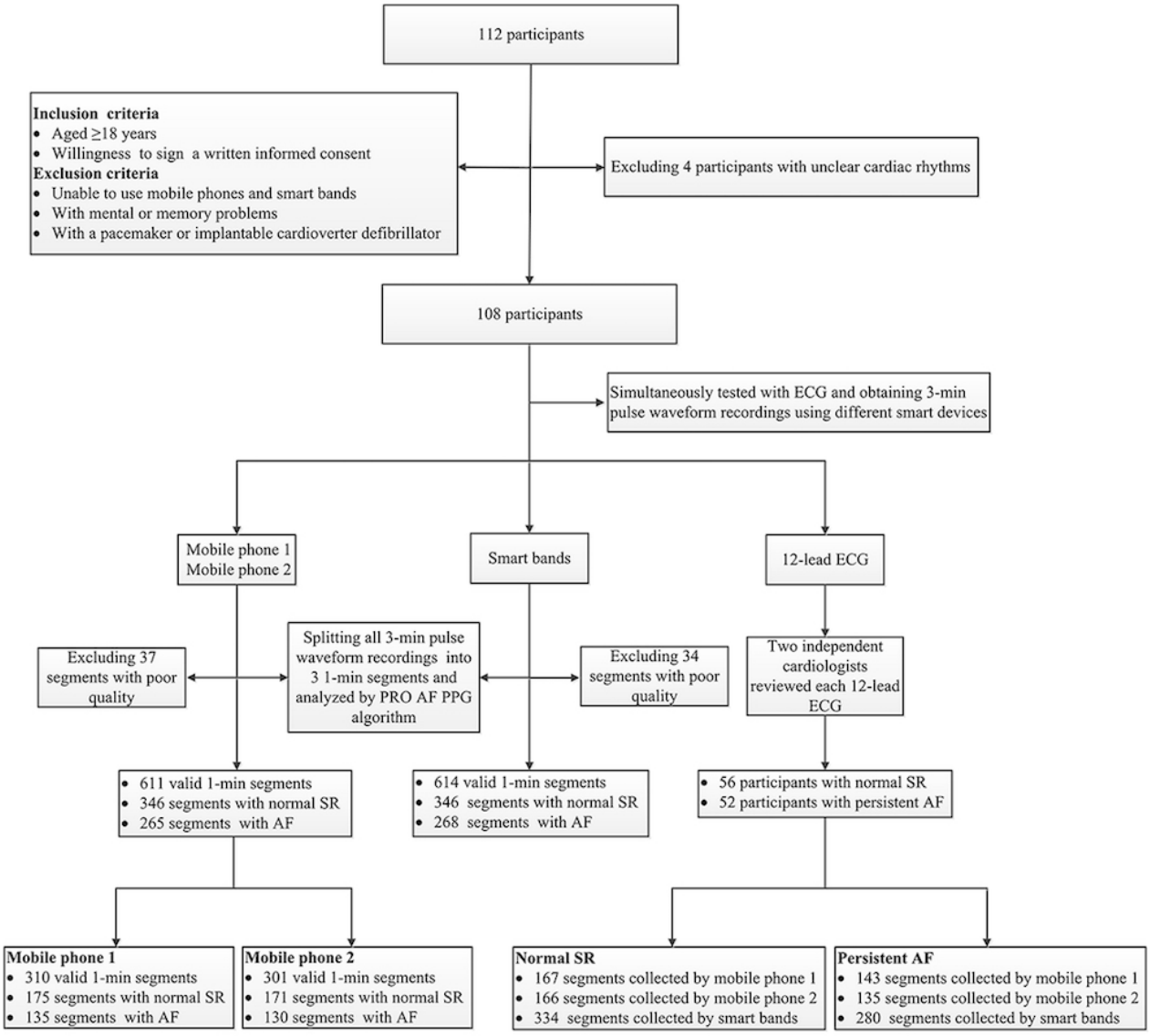
Results from an ECG remain the gold standard for the measurement of heart rhythms, and they were confirmed by two independent cardiologists who were blinded to the baseline information of participants. The results of the algorithm were independently reviewed for each 12-lead ECG. For participants whose ECGs were initially affected by artifacts, trained study personnel instructed them to repeat the recordings to provide an optimal tracing for subsequent reading by the cardiologists. The Heartbeats app added a pulse waveform quality assessment step to reject recordings that were corrupted or too noisy and to prompt the user to retake a measurement.

After data collection, the novel heartbeat detection algorithm (PRO AF PPG), based on a combination of morphology and frequency analysis of the pulse waveform, was applied to perform beat-to-beat rhythm analysis and determine whether or not the participant suffered from AF. The diagnostic performance of the algorithm in detecting AF was then evaluated using the 12-lead ECG interpretation as the standard. Figure 2 shows a flowchart of the study.

Statistical Analysis

Continuous variables were tested for normality by the Kolmogorov-Smirnov test. Data with a normal distribution are presented as means and standard deviations and were analyzed using the *t* test for two independent samples. Data with a nonnormal distribution are presented as medians and interquartile ranges (IQRs) and were analyzed using the Mann-Whitney *U* test. Data with discrete variables are presented as percentages and were analyzed using the Pearson chi-square test or Fisher exact test.

Figure 2. A flowchart of the study. AF: atrial fibrillation; ECG: electrocardiogram; SR: sinus rhythm.



Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy with 95% CI were used to measure the performance of our AF screening algorithm in the smart devices. The diagnostic performance of the algorithm in different devices was evaluated against reference ECG recordings, from which was calculated the number of true positives (TP), true negatives (TN), false positives (FP), and false negatives (FN). Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy for AF diagnosis were calculated as simple proportions for the PRO AF PPG algorithm. The sensitivity was calculated as TP/(TP+FN) (true positives divided by all positives) and specificity as 1–FP/(TN+FP) (true negatives divided by all negatives). The corresponding positive predictive value was defined as TP/(TP+FP), and the negative predictive value as TN/(FN+TN). The corresponding accuracy was calculated as (TP+TN)/(TP+TN+FP+FN). Statistical evaluation was performed with SPSS 19.0 (SPSS Inc, Chicago, IL, USA). A value of $P<.05$ was considered statistically significant.

Results

Among the 112 participants who fulfilled the inclusion criteria for the study, four participants were excluded because the ECG recordings showed unclear cardiac rhythms. As a result, 108 patients (56 with normal sinus rhythm, 52 with persistent AF) were enrolled in the final analysis. Table 1 summarizes the clinical characteristics of the study population. Participants with persistent AF were significantly older ($P=.002$), had a higher body mass index ($P=.02$), and had more prevalent heart failure ($P=.006$). Thromboembolic risk and bleeding risk were higher in participants with persistent AF compared to those with normal sinus rhythm based on CHA_2 DS_2-VASc score (median 3, IQR 2-5 vs median 2, IQR 1.3-3.75, $P=.003$) and HAS-BLED score (median 2, IQR 1-2 vs median 1, IQR 0-2, $P=.005$), respectively. The use of oral anticoagulants for preventing stroke was 77% (40/52) in participants with persistent AF and 18% (10/56) in participants with normal sinus rhythm ($P<.001$). The use of diuretics and digoxin were significantly higher in participants with persistent AF compared to those with normal sinus rhythm ($P=.03$ and $P=.02$, respectively), as well as the use of class III antiarrhythmic drugs ($P<.001$).

We split the 3-minute pulse waveform recordings of each participant obtained from mobile phones and smart bands into three 1-minute segments for further analysis with results from the 12-lead ECG. After splitting, there were 614 valid 1-minute segments of pulse waveform recordings in total obtained from smart bands, divided into 280 for AF and 334 for normal sinus rhythm based on ECG. Thirty-four 1-minute segments of signal recordings were deemed poor quality and were disregarded. The diagnostic performance of the PRO AF PPG AF screening algorithm in smart bands was evaluated against reference ECG recordings and demonstrated a sensitivity of 95.36% (95% CI 92.00%-97.40%) and a specificity of 99.70% (95% CI 98.08%-99.98%) for the detection of AF. The corresponding positive predictive value of the PRO AF PPG algorithm for AF screening was 99.63% (95% CI 97.61%-99.98%), the negative predictive value was 96.24% (95% CI 93.50%-97.90%), and the accuracy was 97.72% (95% CI 96.11%-98.70%).

For mobile phones, we obtained 611 valid 1-minute segments of pulse waveform recordings in total, of which 310 were obtained from mobile phone 1 and 301 from mobile phone 2, divided into 278 for AF and 333 for normal sinus rhythm based on standard ECG recordings. Thirty-seven 1-minute segments of signal recordings were omitted because of poor quality, of which 14 were recorded by mobile phone 1 and 23 by mobile phone 2. The diagnostic sensitivity and specificity of the PRO AF PPG algorithm for AF detection using mobile phone 1 and mobile phone 2 were 94.96% (95% CI 91.51%-97.11%) and 99.70% (95% CI 98.07%-99.98%), respectively. The positive predictive value was 99.62% (95% CI 97.59%-99.98%), the negative predictive value was 95.95% (95% CI 93.15%-97.68%), and the accuracy of the algorithm for AF detection was 97.55% (95% CI% 95.89%-98.57%). Moreover, the diagnostic sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of mobile phone 1 alone or mobile phone 2 alone with PPG for AF detection were over 94%. Detailed diagnostic performance of the PPG technology for AF screening in different smart devices is summarized in Table 2. There was no significant difference in further statistical analysis of the results from different smart devices compared with ECG ($P>.99$).

Table 3 lists data from the literature on AF detection with different technologies. Compared with recent studies on AF detection, the PRO AF PPG algorithm showed good diagnostic performance from each smart device.

Table 1. Baseline characteristics of participants (N=108).

Characteristics	Sinus rhythm (n=56)	Persistent AF[a] (n=52)	*P* value
Demographics			
Age (years), mean (SD)	58 (14.78)	66.56 (13.17)	.002
Female, n (%)	26 (46)	19 (37)	.30
Body mass index (kg/m^2), mean (SD)	24.44 (2.88)	25.98 (3.97)	.02
Medical history			
Heart failure, n (%)	2 (4)	12 (23)	.006
Hypertension, n (%)	29 (52)	35 (67)	.10
Diabetes mellitus, n (%)	15 (27)	17 (33)	.50
Previous stroke/SE[b]/TIA[c], n (%)	4 (7)	9 (17)	.19
Coronary artery disease, n (%)	25 (45)	19 (37)	.39
Vascular disease, n (%)	31 (55)	37 (71)	.09
COPD[d], n (%)	1 (2)	3 (6)	.56
Renal dysfunction, n (%)	2(4)	8 (15)	.07
Hepatic dysfunction, n (%)	0	2 (4)	.23
Sleep apnea, n (%)	2 (4)	6 (12)	.22
Hyperthyroidism, n (%)	1 (2)	4 (8)	.32
Current smoking, n (%)	16 (29)	17 (33)	.64
Current drinking, n (%)	13 (21)	11 (23)	.80
CHA_2DS_2-VASc[e] score, median (IQR[f])	2 (1-3.75)	3 (2-5)	.003
HAS-BLED[g] score, median (IQR)	1 (0-2)	2 (1-2)	.005
Medications, n (%)			
Oral anticoagulant	10 (18)	40 (77)	<.001
Antiplatelet drug	15 (27)	23 (44)	.06
Calcium channel blockers	17 (30)	13 (25)	.54
ACEI/ARB[h]	21 (38)	16 (31)	.46
Diuretic	5 (9)	13 (25)	.03
Digoxin	3 (5)	11 (21)	.02
Antiarrhythmic drug, n (%)			
Class I	6 (11)	2 (4)	.32
Beta blocker	27 (48)	34 (65)	.07
Class III	3 (5)	20 (38)	<.001
Class IV	3 (5)	3 (6)	>.99

[a]AF: atrial fibrillation.

[b]SE: systemic arterial embolism.

[c]TIA: transient ischemic attack.

[d]COPD: chronic obstructive pulmonary disease.

[e]CHA_2DS_2-VASc: congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke (doubled), vascular disease, age 65-74, female sex.

[f]IQR: interquartile range.

[g]HAS-BLED: hypertension, abnormal renal function, abnormal liver function, stroke, bleeding, labile INR, age >65 years, drugs or alcohol.

[h]ACEI/ARB: angiotensin-converting-enzyme inhibitor, angiotensin receptor blockers.

Table 2. Detailed diagnostic performance of the photoplethysmography technology for atrial fibrillation screening in different smart devices.

Index	Smart bands	Mobile phones	Mobile phone 1	Mobile phone 2
Sensitivity, % (95% CI)	95.36 (92.00-97.40)	94.96 (91.51-97.11)	94.41 (88.91-97.38)	95.56 (90.16-98.18)
Specificity, % (95% CI)	99.70 (98.08-99.98)	99.70 (98.07-99.98)	100 (97.20-100)	99.40 (96.18-99.97)
PPV[a], % (95% CI)	99.63 (97.61-99.98)	99.62 (97.59-99.98)	100 (96.55-100)	99.23 (95.16-99.96)
NPV[b], % (95% CI)	96.24 (93.50-97.90)	95.95 (93.15-97.68)	95.43 (90.88-97.86)	96.49 (92.17-98.57)
Accuracy, % (95% CI)	97.72 (96.11-98.70)	97.55 (95.89-98.57)	97.42 (94.78-98.80)	97.67 (95.05-98.97)

[a]PPV: positive predictive value.

[b]NPV: negative predictive value.

Table 3. Data from the literature on atrial fibrillation (AF) detection with different technologies.

Study, year, and population studied	AF detection protocol	Sensitivity, %	Specificity, %	PPV[a], %	NPV[b], %
McManuset al, 2013 [25]					
76 patients before and after cardioversion	An iPhone 4S, an algorithm combining RMSSD[c] and ShE[d]	96.2	97.5	__[e]	—
Chan et al, 2016 [22]					
1013 patients	Cardiio Rhythm mobile phone app	92.9	97.7	53.1	99.8
1013 patients	AliveCor automated algorithm	71.4	99.4	76.9	99.2
Krivoshei et al, 2017 [19]					
80 consecutive patients	An iPhone 4S, an algorithm combining RMSSD and ShE	80	95	—	—
80 consecutive patients	An iPhone 4S, an algorithm combining RMSSD and PPA[f]	95	95	—	—
80 consecutive patients	An iPhone 4S, an algorithm combining ShE and PPA	50	95	—	—
Rozen et al, 2018 [26]					
97 patients before and after electrical cardioversion	An iPhone, Cardiio Rhythm mobile app	93.1	90.9	92.2	92.0
Bumgarner et al, 2018 [27]					
100 patients before and after cardioversion	Kardia Band from AliveCor paired with an Apple Smartwatch, AliveCor automated algorithm	93	84	—	—
Tisonet al, 2018 [28]					
51 sedentary participants undergoing cardioversion	Smartwatch PPG[g] coupled with a deep neural network	98	90.2	90.9	97.8
1617 ambulatory participants	Smartwatch PPG coupled with a deep neural network	67.7	67.6	7.9	98.1

[a]NPV: negative predictive value.

[b]PPV: positive predictive value.

[c]RMSSD: root mean square of successive difference of RR intervals.

[d]ShE=Shannon entropy.

[e]Missing data.

[f]PPA: Poincaré plot analysis.

[g]PPG: photoplethysmography.

Discussion

Principal Findings

In this study, we demonstrated good diagnostic performance of the smart devices for AF detection using pulse waveform data measured by PPG. To the best of our knowledge, this is the first study on AF screening technology in a Chinese population. The main findings were (1) the PRO AF PPG algorithm demonstrated promising potential for accurate detection and discrimination of AF from normal sinus rhythm in a trial setting and may be applied to any mobile phone or smart band for AF screening, and (2) there was no significant difference in the results from different smart devices compared with ECG, and the tested models of mobile phone had no impact on the diagnostic performance of the algorithm.

In this study, HUAWEI mobile phones and smart bands showed higher consistency and stability of PPG technology in AF screening with PRO AF PPG algorithm and performed better with higher sensitivity and specificity. Prior to the development of the PRO AF PPG algorithm, several algorithms were validated for the detection of AF based on mobile phones and wearable devices (Table 3). Root mean square of successive difference of RR intervals (RMSSD), Shannon entropy (ShE), Poincaré plot analysis, and the AliveCor automated algorithm have been used to discriminate between AF and sinus rhythm by analyzing pulse waveform signals recorded using smart devices in several recent studies [19,22,25,27]. McManus et al [25] described an app using a camera and LED light of an iPhone 4S to record pulse waves obtained from the fingertips of patients. The signal recorded was processed through an algorithm combining RMSSD and ShE. They evaluated the algorithm in 76 patients before and after cardioversion, effectively using each patient as their own control, and reported a sensitivity of 96.2%, specificity of 97.5%, and accuracy of 96.8%. Krivoshei et al [19] applied the same published algorithm as McManus et al to detect AF with 80 consecutive patients. They demonstrated that the algorithm reliably discriminated between normal sinus rhythm and AF based on pulse wave signals from an iPhone 4S camera only and achieved a sensitivity and specificity of 80% and 95%, respectively. Rozen et al [26] conducted a study to assess the Cardiio Rhythm mobile phone app as a diagnostic tool in 97 patients before and after electrical cardioversion, and achieved a sensitivity of 93.1%, a specificity of 90.9%, a positive predictive value of 92.2%, and a negative predictive value of 92.0% for AF detection. Bumgarner et al [27] reported that the Kardia Band algorithm from AliveCor paired with an Apple Smartwatch accurately differentiated AF from sinus rhythm in 100 patients before and after cardioversion, and demonstrated 93% sensitivity and 84% specificity. Tison et al [28] demonstrated that smartwatch PPG coupled with a deep neural network can passively detect AF compared to standard 12-lead ECG among 51 sedentary participants undergoing cardioversion with a sensitivity of 98.0% and specificity of 90.2%, but with some loss of sensitivity (67.7%) and specificity (67.6%) in 1617 ambulatory participants.

Compared with other algorithms reported in previous studies, the PRO AF PPG algorithm performed better for AF screening in different smart devices with generally higher sensitivity, specificity, positive predictive value, negative predictive value, and accuracy. The majority of false positives originated from pulse waveforms that were corrupted by finger movement artifacts that may have affected the detection algorithm [22]. In fact, AF detection with single-lead ECG and PPG technology both should avoid the interference caused by movement to improve the accuracy. In this case, a 12-lead ECG was less affected by movement artifacts and may overall compare favorably in terms of inherent technical limitations compared to PPG. Although the diagnostic sensitivity of the PRO AF PPG algorithm was numerically lower compared to that from McManus et al [25] (95.56% vs 96.20%), this may be due to our different study design. In this study, we analyzed heart rhythm data from 108 consecutive inpatients, whereas McManus et al performed repeated measurements in the same individual patients before and after cardioversion. We consider our study design more reasonable and closer to the intended use of AF detection in a large-scale, high-risk population.

Although short-term pulse waveform recordings with mobile phones for AF screening are superior to single spot-checks in the clinic, they are vulnerable to misdiagnosis in many patients with paroxysmal AF. We attempted to partially address this limitation by using smart bands, which can be worn on the wrist for 24 to 48 hours or even longer to obtain long-term pulsatile PPG signals. Therefore, mobile devices, either mobile phones or smart bands, may provide at-risk patients with important tools for screening AF in a single shot or over a long duration, which may help facilitate the early detection and early management of asymptomatic AF before a devastating outcome such as ischemic stroke occurs.

Strengths and Limitations

This is the first study on AF screening technology in China, and it demonstrates an easy AF screening approach using an algorithm based on smart devices with PPG and shows optimal diagnostic accuracy for heart rhythm readings. The advantage of AF screening with mobile phones is that it does not require additional hardware because optical video monitoring of the fingertip with a camera provides an accurate pulsatile time series related to variability in heart rate signals, making it more accessible and appealing to patients.

Some limitations of this study need to be addressed. First, we only focused on discriminating between AF and sinus rhythm in this study. However, the effect of sinus arrhythmia and other forms of ectopics, such as premature atrial beats, premature ventricular beats, and atrial flutter, on the performance of the algorithm should be evaluated, as these are common in the general population and might be similar in appearance to AF. In addition, the algorithm is unable to detect atrial flutter with a fixed atrioventricular conduction proportion that may also confer some risk of stroke and that frequently accompanies AF. Single-lead ECG may be used to detect AF and other arrhythmias. In our next study, new algorithms will be further developed to identify and differentiate sinus arrhythmia and various forms of ectopics. Second, although we reported the feasibility of using pulsatile PPG signals acquired from mobile phones and smart bands to detect AF in a group of participants

preselected for their heart rhythm status, the ability to diagnose or screen AF with ambulatory outpatients has not been adequately investigated. Third, in this study, the data was collected in a supine position which could acquire stable pulse waveform signals and achieve reliable detection. However, the supine position is not common for home screening and creates inherent "not real world" rest conditions; therefore, it overestimates the results. Fourth, when we collected pulse waveform signals, we used the index or middle finger, not the pinky, which could have some effect on the results. However, it has been confirmed in several studies that using other fingers to collect pulse wave signals can also achieve good results [19,25,29]. Finally, although this was a pilot study, the sample size was relatively small, and more extensive clinical studies will need to be performed in the future.

Conclusions

Atrial fibrillation can be detected and heart rhythms analyzed using the broadly accessible smart devices with PPG technology. It provides an accurate and easy method of discriminating AF form sinus rhythm and may be used to detect asymptomatic patients with AF. Although PPG technology can be used to detect AF with good performance, the final diagnosis of AF must still be based on ECG according to current guidelines. Further studies are needed to assess the efficacy of this approach in detecting, screening, and diagnosing AF early, which we are currently performing.

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Authors' Contributions

YYF conducted data collection and analysis and wrote the initial draft of the manuscript. YTG and YTW were the supervisors of this project as well as joint senior authors. YGL, JL, WKC, and ZLS provided guidance concerning statistical analysis. All coauthors contributed revisions to the manuscript and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Baseline characteristics of participants.

[PDF File (Adobe PDF File), 228KB - mhealth_v7i3e11437_app1.pdf]

Multimedia Appendix 2

Detailed diagnostic performance of the PPG technology for AF screening in different smart devices.

[PDF File (Adobe PDF File), 91KB - mhealth_v7i3e11437_app2.pdf]

Multimedia Appendix 3

Data from the literature on atrial fibrillation detection with different technologies.

[PDF File (Adobe PDF File), 176KB - mhealth_v7i3e11437_app3.pdf]

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Abbreviations

ACEI: angiotensin-converting-enzyme inhibitor
AF: atrial fibrillation
ARB: angiotensin receptor blockers
CHA_2DS_2-VASc: congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, stroke (doubled), vascular disease, age 65-74, female sex
COPD: chronic obstructive pulmonary disease
ECG: electrocardiogram
FP: false positives
FN: false negatives
HAS-BLED: hypertension, abnormal renal function, abnormal liver function, stroke, bleeding, labile INR, age >65 years, drugs or alcohol
IQR: interquartile range
NPV: negative predictive value
PPA: Poincaré plot analysis
PPG: photoplethysmography
PPV: positive predictive value
RMSSD: root mean square of successive difference of RR intervals
SE: systemic arterial embolism
ShE: Shannon entropy
TIA: transient ischemic attack
TP: true positives
TN: true negatives

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Original Paper

Mobile Phone–Based Use of the Photoplethysmography Technique to Detect Atrial Fibrillation in Primary Care: Diagnostic Accuracy Study of the FibriCheck App

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Abstract

Background: Mobile phone apps using photoplethysmography (PPG) technology through their built-in camera are becoming an attractive alternative for atrial fibrillation (AF) screening because of their low cost, convenience, and broad accessibility. However, some important questions concerning their diagnostic accuracy remain to be answered.

Objective: This study tested the diagnostic accuracy of the FibriCheck AF algorithm for the detection of AF on the basis of mobile phone PPG and single-lead electrocardiography (ECG) signals.

Methods: A convenience sample of patients aged 65 years and above, with or without a known history of AF, was recruited from 17 primary care facilities. Patients with an active pacemaker rhythm were excluded. A PPG signal was obtained with the rear camera of an iPhone 5S. Simultaneously, a single-lead ECG was registered using a dermal patch with a wireless connection to the same mobile phone. PPG and single-lead ECG signals were analyzed using the FibriCheck AF algorithm. At the same time, a 12-lead ECG was obtained and interpreted offline by independent cardiologists to determine the presence of AF.

Results: A total of 45.7% (102/223) subjects were having AF. PPG signal quality was sufficient for analysis in 93% and single-lead ECG quality was sufficient in 94% of the participants. After removing insufficient quality measurements, the sensitivity and specificity were 96% (95% CI 89%-99%) and 97% (95% CI 91%-99%) for the PPG signal versus 95% (95% CI 88%-98%) and 97% (95% CI 91%-99%) for the single-lead ECG, respectively. False-positive results were mainly because of premature ectopic beats. PPG and single-lead ECG techniques yielded adequate signal quality in 196 subjects and a similar diagnosis in 98.0% (192/196) subjects.

Conclusions: The FibriCheck AF algorithm can accurately detect AF on the basis of mobile phone PPG and single-lead ECG signals in a primary care convenience sample.

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KEYWORDS

atrial fibrillation; electrocardiography; photoplethysmography; mobile phone; algorithm

Introduction

Background

Atrial fibrillation (AF) is the most common cardiac arrhythmia affecting approximately 33.5 million people worldwide [1]. AF prevalence is estimated at 3% in adults aged over 20 years, increasing in the elderly and patients with comorbid conditions such as hypertension, heart failure, coronary artery disease, heart valve disease, obesity, diabetes, and chronic kidney disease [2]. Stroke remains the most fearsome complication of AF; its risk after a diagnosis of AF is increased 5-fold [1]. Although effective anticoagulation therapy reduces this risk dramatically by 60%, initial AF episodes may frequently go undetected [3]. Indeed, contemporary studies on ischemic stroke demonstrate that AF is regularly diagnosed during or immediately after an event [4]. Importantly, AF incidence is markedly influenced by the intensity of screening efforts [5]. At the time of this study, the guidelines of the European Society of Cardiology recommended opportunistic screening in people aged 65 years and above by pulse palpation and, if irregular, by a 12-lead electrocardiogram (ECG) [6].

Objectives

Evolving technology may offer scalability to reach a general population at relatively low cost and with minimal logistic efforts, which may further lower the threshold for screening. Mobile phones may offer an interesting modality to aid AF diagnosis as their use has exponentially increased in recent years and is continuing to grow. By applying the photoplethysmography (PPG) technique through the mobile phone camera, rhythm registration from the fingertip of a subject becomes a real possibility. A software has been developed to acquire PPG measurements with the most common mobile phones and use these signals to analyze the heart rhythm. The aim of this study was to test the diagnostic accuracy of such an approach using the FibriCheck mobile phone app (Qompium) in comparison with the gold standard method of AF diagnosis, the 12-lead ECG.

Methods

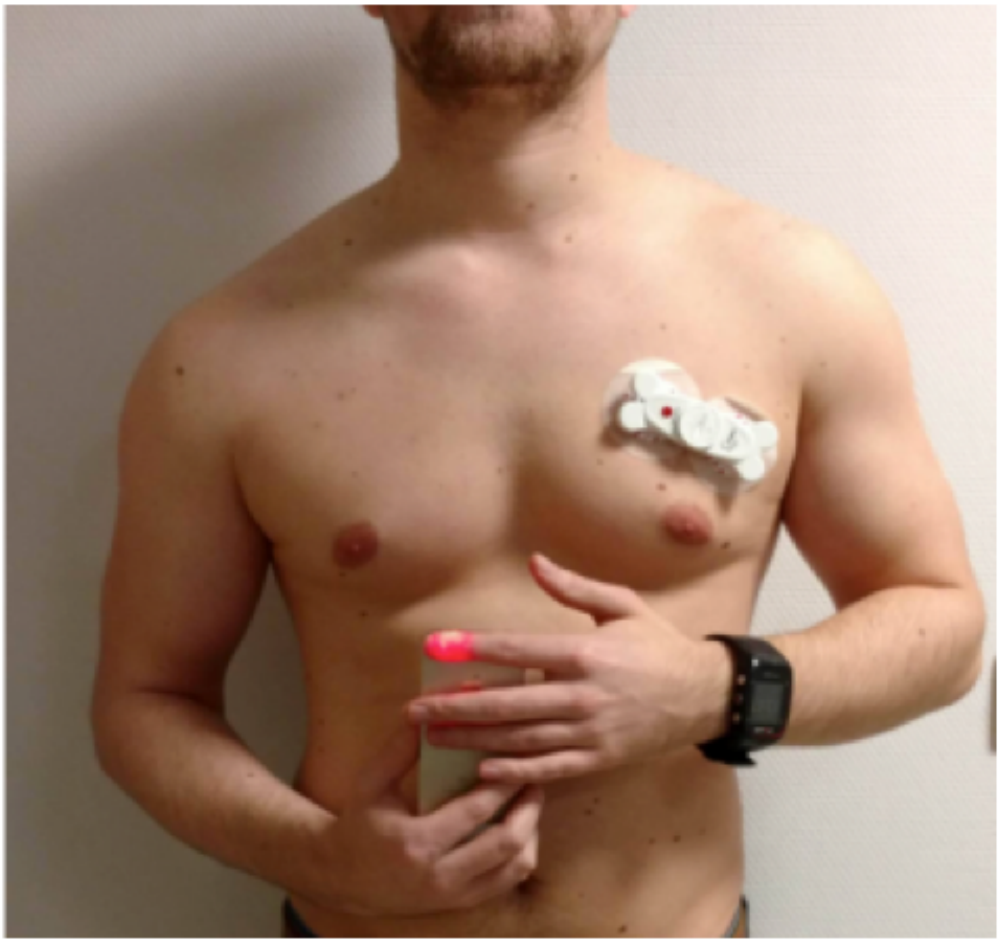
Study Design

This diagnostic accuracy study was performed between October 2015 and March 2016 in 17 general practitioner (GP) centers in Belgium. Participating GPs were asked to invite patients with known paroxysmal or persistent AF to participate in the study. By searching electronic medical records, patients aged 65 years and above with a diagnosis of AF were identified. This convenience sample was supplemented with subjects without a history of AF. The presence of an active pacemaker rhythm was an exclusion criterion, as this could impact the diagnostic results obtained during the subsequent measurements. With a probability of finding a false-positive result of 5% or less (alpha=.05), an estimated AF prevalence of 50% in the study population, an expected sensitivity and specificity of 95%, and a CI of 4%, a sample size of 160 subjects was calculated. The study complies with the Declaration of Helsinki and was approved by the ethical review board of the medical faculty of the Katholieke Universiteit Leuven, Belgium (Number MP 05256). All study subjects provided written informed consent before participation. For all participants, researchers (CM, RVH) registered the demographics, vital parameters, medication use, and components of the CHA_2 DS_2-VASc score to determine the stroke risk (ie, congestive heart failure, hypertension, age, diabetes mellitus, previous stroke, vascular disease, and sex category).

Photoplethysmography and the FibriCheck App

In every subject, a mobile phone-based assessment of the cardiac rhythm using the Conformité Européenne–approved FibriCheck app was performed by a single researcher (CM or RVH) who was not blinded for the medical history of the patient. For this purpose, a PPG signal was acquired with the rear camera of an iPhone 5S (Apple Inc). PPG is a technique whereby a volumetric measurement is optically obtained. A classic application of the PPG technique is the pulse oximeter, which illuminates the skin and measures changes in light intensity with blood volume pulse variation in the local arterioles and uses this information to determine arterial oxygen saturation and pulse frequency. The same principle can be applied by using the camera of a mobile phone and measuring the amount of reflected light. In this way, each heartbeat is recorded, and the rhythm can be determined on the basis of the intervals between heartbeats (ie, RR-intervals). The FibriCheck app provides software to obtain and analyze such measurements with most common mobile phones. To obtain a high-quality PPG signal, subjects were asked to adopt a sitting position with both arms resting on a table, holding the iPhone 5S in a vertical position with their right hand. Subsequently, they were asked to cover the flashlight and the rear camera horizontally with their left index finger (Figure 1). The measurement time to acquire the PPG signal with the FibriCheck app is 1 min, visualized by a countdown clock on the mobile phone screen. To minimalize motion artifacts, subjects were instructed not to speak or move during the registration process. Subjects were asked to independently perform 3 consecutive measurements. To avoid evoking a reaction following the result of a measurement, researchers and participants were blinded for the PPG signal during the measurements and the automated interpretations after the measurements. The researchers performing the measurements scored every study subject on a scale from 1 to 4 according to their experience with and handling of the mobile phone (1, optimal handling; 2, subject has good knowledge of the mobile phone and only requires minor input or corrections on handling; 3, subject has some knowledge of the mobile phone but needs substantial corrections on handling; 4, subject has never held a mobile phone before or has many issues in holding and handling it correctly).

Figure 1. Smartphone-based assessment of the cardiac rhythm using the FibriCheck® application. The ECG-bone, attached to a subject's chest, for obtaining a single-lead electrocardiogram wirelessly connected to the smartphone by the FibriCheck® application.



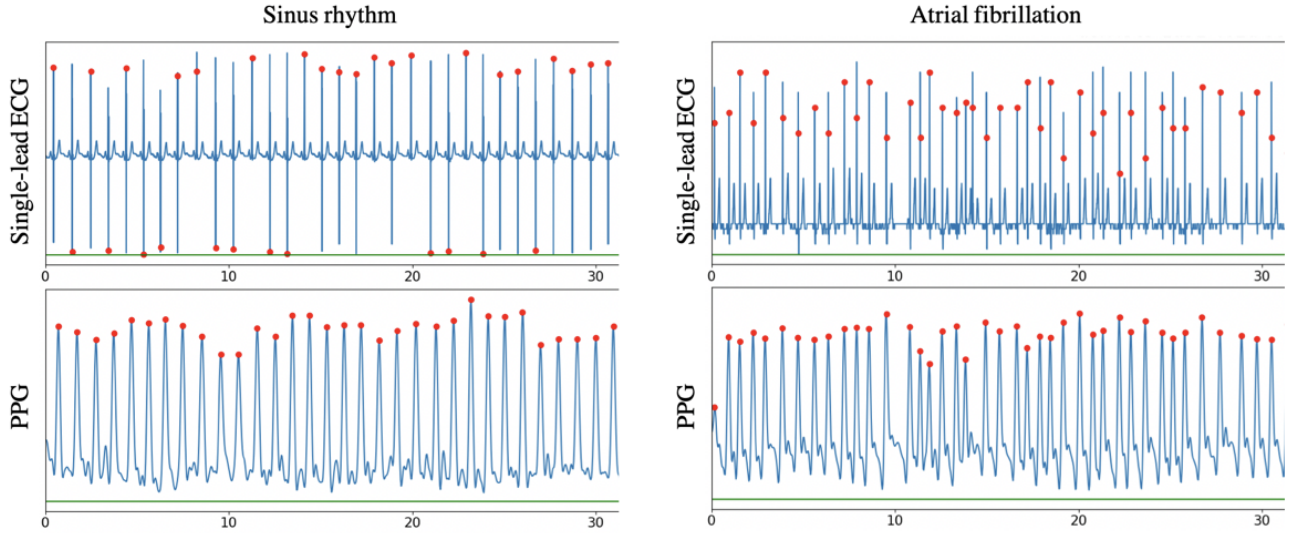
Single-Lead Electrocardiogram Using the Electrocardiogram-Bone

Simultaneously with the PPG measurement, a synchronized single-lead ECG was obtained using the ECG-bone (Interuniversity Micro-Electronics Center, IMEC) [7]. This module was attached with a patch on the left side of the subject's chest above ribs 2 and 3 (Figure 1) and was wirelessly connected to the iPhone 5S with the help of the FibriCheck app. This procedure was performed by the same researcher who helped with the operation of the FibriCheck app.

Data Processing

After simultaneous collection of both the PPG and single-lead ECG signal, data were transferred to a secured Web-based data platform for analysis. First, raw signals were analyzed by a recurrent neural network algorithm to classify them on the basis of quality metrics. The PPG signal quality judgement was based on the capacity to detect and differentiate heartbeats. If heartbeat detection was compromised with noise or if heartbeats were absent, these measurements were filtered out as insufficient quality. QRS complexes in the single-lead ECG signals were detected using the Pan-Tompkins algorithm based on slope, amplitude, and width analysis of the waveform [8]. The reliable measurements were evaluated by the FibriCheck AF algorithm on the basis of RR-interval variability analysis (Figure 2).

Figure 2. A snapshot of a synchronized photoplethysmography signal and single-lead electrocardiogram in patient with sinus rhythm (left) and atrial fibrillation (right). The red dots indicate a detected heart beat. ECG: electrocardiogram; PPG: photoplethysmography.



Twelve-Lead Electrocardiogram

The same researcher obtained a 12-lead ECG (gold standard). The ECGs were taken using digital machines CardiMax FCP-7101 (Fukuda Denshi), CP 50 (Welch Allyn), Universal ECG (QRS Diagnostic), and ECG-1150 (Nihon Kohden Corporation) and the data were immediately printed. All 12-lead ECGs were analyzed offline on the basis of the Minnesota Code Classification System for Electrocardiographic Findings (code 8-3-1) by 2 experienced, independent cardiologists blinded to all other data. In case of a disagreement, a third cardiologist was consulted to interpret the rhythm.

Statistical Analysis

Continuous variables are expressed as the means (SDs) if normally distributed or otherwise by medians (interquartile ranges, IQR). Categorical variables are expressed as percentages. A Mann-Whitney *U* test was used to compare mobile phone handling between patients with AF versus without AF. The levels of diagnostic accuracy of the PPG and single-lead ECG signals analyzed by the FibriCheck AF algorithm were tested against the gold standard using 2×2 tables (MedCalc Software). Data analysis was performed both on measurement level, including the results of all 3 measurements, and on participant level, using a majority rule to determine the overall result. For both approaches, data analysis was performed (1) after exclusion of insufficient quality measurements, (2) with insufficient quality measurements categorized as *sinus rhythm*, and (3) with insufficient quality measurements categorized as *possible AF*. If 2 insufficient quality measurements were present, the majority rule did not uphold, and a decision was made on the basis of severity. The positive and negative predictive values (PPV and NPV) were also estimated on the basis of an expected AF prevalence of 6% in the population aged 65 years and above [2]. Finally, the results of PPG versus single-lead ECG were compared case by case for inconsistencies, with beat-to-beat analysis of the raw data to reveal the underlying reasons for any differences.

Results

Study Population

A total of 241 patients participated in the study. The study flowchart is presented in Figure 3. In total, 18 pacemaker patients had to be excluded because of active pacing during the measurements. Therefore, the final study population comprised 223 subjects. Their characteristics are presented in Table 1. Overall, the mean age was 77 (SD 8) years (range: 59 to 95 years), with 46.6% (104/223) males. AF was present in 45.7% (102/223) patients. Patients with AF had a mean CHA_2DS_2-VASc score of 5 (SD 2). Mobile phone handling was significantly different between patients with AF (median=4, IQR 3-4) versus without AF (median=3, IQR 2-4; *P*=.001).

Photoplethysmography Measurements

On Participant Level

PPG measurements were recorded for a total of 223 participants. After exclusion of measurements of insufficient quality, 7% (16/223), a PPG signal suitable for analysis was obtained for 92.8% (207/223) subjects. Positive results were found in 91 subjects and negative results were found in 116 subjects. PPG results matched the diagnosis made by cardiologists on the basis of the 12-lead ECG in 96.1% (199/207) subjects, resulting in an overall sensitivity of 95.6% (95% CI 89.1%-98.8%) and a specificity of 96.6% (95% CI 91.4%-99.1%; Table 2). From the 8 inconsistent results, 4 were false-positive and 4 false-negative. False-positive results were caused by atrial premature beats (n=4). False-negative results were caused by peak wave undersensing (n=1) and misinterpretation of an atrial flutter as sinus rhythm (n=3). On the basis of an expected prevalence of 6% in the population aged 65 years and above, a PPV of 63% (95% CI 61.3%-64.8%) and an NPV of 99.7% (95% CI 99.6%-99.8%) were estimated.

Figure 3. Study flowchart. AF: atrial fibrillation.

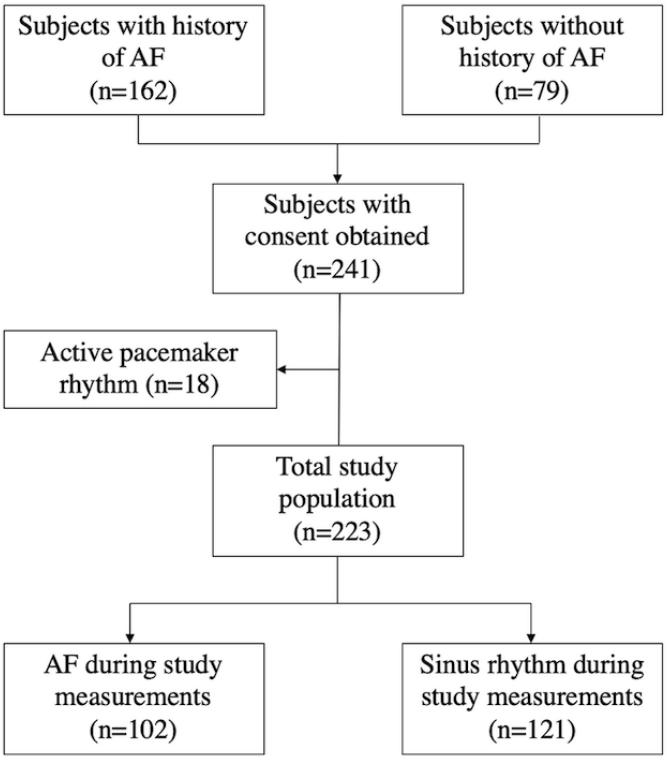


Table 1. Characteristics of the study population (N=223).

Characteristics	Healthy patients (n=79)	AF[a] patients with sinus rhythm (n=42)	AF patients with AF (n=102)	Total population (N=223)
Age (years), mean (SD)	75 (8)	78 (8)	79 (8)	77 (8)
Male, n (%)	32 (41)	21 (50)	51 (49.0)	104 (46.6)
Resting heart rate, bpm[b], mean (SD)	71 (14)	70 (18)	83 (20)	77 (19)
Systolic BP[c], mm Hg, mean (SD)	130 (16)	129 (14)	129 (17)	129 (16)
Diastolic BP, mm Hg, mean (SD)	73 (8)	74 (7)	74(11)	74 (9)
Risk factors				
CHA_2 DS_2-VASc[d]-score, median (IQR[e])	3 (2-4)	4 (3-5)	5 (3-6)	4 (3-6)
Congestive heart failure, n (%)	12 (15)	10 (24)	42 (41.2)	64 (28.7)
Diabetes, n (%)	9 (11)	9 (21)	27 (26.5)	45 (20.2)
Stroke or transient ischemic attack, n (%)	9 (11)	9 (21)	32 (31.4)	50 (22.4)
Atherosclerotic disease, n (%)	19 (24)	22 (52)	48 (47.1)	89 (40.0)
Medication use				
Anticoagulation, n (%)	2 (3)	30 (71)	92 (90.2)	124 (55.6)
ACE[f] inhibitor, n (%)	11 (14)	13 (31)	32 (31.4)	56 (25.1)
Angiotensin receptor blocker, n (%)	11 (14)	10 (24)	21 (20.6)	42 (18.8)
Beta blocker, n (%)	33 (42)	22 (52)	71 (69.6)	126 (56.5)
Diuretics, n (%)	16 (20)	11 (26)	53 (52.0)	80 (35.9)
Mobile phone handling				
Mobile phone ownership, n (%)	19 (24)	6 (14)	11 (10.8)	36 (16.1)
Mobile phone handling, median (IQR)	3 (2-4)	4 (2-4)	4 (3-4)	4 (2-4)

[a]AF: atrial fibrillation.

[b]bpm: beats per minute.

[c]BP: blood pressure.

[d]CHA_2 DS_2-VASc: congestive heart failure, hypertension, age, diabetes mellitus, previous stroke, vascular disease, and sex category.

[e]IQR: interquartile range.

[f]ACE: angiotensin-converting enzyme.

Table 2. Diagnostic accuracy of photoplethysmography and single-lead electrocardiography signal analysis on participant level, based on a majority rule, compared with the reference gold standard 12-lead electrocardiography.

Diagnostic metrics	Insufficient quality excluded		Insufficient quality categorized as *sinus rhythm*[a]		Insufficient quality categorized as *possible AF*[b]	
Diagnostic test	PPG[c] (n=207)	ECG[d] (n=210)	PPG (n=223)	ECG (n=223)	PPG (n=223)	ECG (n=223)
Prevalence, n (%)	91 (44.0)	95 (45.2)	100 (44.8)	100 (44.8)	100 (44.8)	100 (44.8)
Sensitivity (%)	95.6	94.7	87	90	96	95
Specificity (%)	96.6	96.6	96.8	96.8	91.1	91.1
PPV[e] (%)	95.6	95.7	95.6	95.7	89.7	89.6
NPV[f] (%)	96.6	95.7	90.2	92.3	96.6	95.7
Accuracy (%)	96.1	95.7	92.4	93.7	93.3	92.8

[a]The rhythm categories *sinus rhythm* and *possible AF* were made by separating the measurements indicative for sinus rhythm and AF, and by adding to them insufficient quality measurements as stated in the column headings.

[b]AF: atrial fibrillation.

[c]PPG: photoplethysmography.

[d]ECG: electrocardiogram.

[e]PPV: positive predictive value.

[f]NPV: negative predictive value.

Using the same approach but classifying insufficient quality measurements as *sinus rhythm*, a sensitivity of 87% (95% CI 78.80%-92.89%) and a specificity of 96.75% (95% CI 91.88%-99.11%) were obtained (Table 2). In this scenario, PPG results matched the cardiologists' interpretation of the 12-lead ECG in 92.4% (206/223) subjects. The amount of false-negatives in this scenario increased to 13. Classifying insufficient quality measurements as *possible AF* yielded a sensitivity of 96% (95% CI 90.07%-98.90%) and a specificity of 91.06% (95% CI 84.56%-95.45%; Table 2). Here, PPG results matched the diagnosis of 12-lead ECG in 93.2% (208/223) subjects and the number of false-positives increased to 11.

On Measurement Level

A total of 657 PPG measurements were recorded, 16.7% (110/657) were labelled as *insufficient quality* by the algorithm quality filter. Analyzing solely high-quality PPG measurements resulted in a sensitivity of 95.28% (95% CI 91.71%-97.62%) and a specificity of 96.18% (95% CI 93.42%-98.01%; Table 3). For 95.8% (524/547) PPG measurements, the diagnosis matched the diagnosis on the basis of the 12-lead ECG. The 23 inconsistent results were caused by 12 false-positives and 11 false-negatives. When categorizing insufficient quality as *sinus rhythm*, the sensitivity dropped to 76.03% (95% CI 70.71%-80.81%) with a specificity of 96.71% (95% CI 94.33%-98.29%; Table 3). This resulted in an agreement between PPG and 12-lead ECG for 87.5% (575/657) measurements and an increase of false-negatives to 70. Interpreting insufficient quality as *possible AF* resulted in a sensitivity and specificity of 96.23% (95% CI 93.36%-98.10%) and 82.74% (95% CI 78.46%-86.47%), respectively (Table 3). Overall, 88.7% (583/657) PPG measurements had the same diagnosis compared with 12-lead ECG. Here 11 measurements were false-negative, and 63 measurements were false-positive.

Insufficient Quality

The Chi-square test was used to identify causes or correlations between comorbidities and insufficient PPG measurements (Table 4).

In addition, on the basis of the Chi-square test, there is no association between mobile phone handling and insufficient quality (P=.43).

Single-Lead Electrocardiogram by the Electrocardiogram-Bone

On Participant Level

Single-lead ECG recordings were collected from a total of 223 participants. After eliminating insufficient quality measurements, a single-lead ECG signal suitable for analysis was obtained for 94.2% (210/223) subjects. Positive results were found in 90 subjects and negative results were found in 111 subjects. Single-lead ECG results matched the diagnosis made by cardiologists on the basis of the 12-lead ECG in 95.7% (201/210) cases, yielding a sensitivity and specificity of 94.74% (95% CI 88.14%-98.27%) and 96.55% (95% CI 91.33%-99.04%), respectively (Table 2). Among the 9 inconsistent results, 4 were false-positive and 5 were false-negative. False-positive results were caused by atrial (n=3) and ventricular (n=1) premature beats. False-negative results were caused by misinterpretation of an atrial flutter as sinus rhythm (n=5).

Including the insufficient quality measurements as *sinus rhythm* resulted in a sensitivity of 90% (95% CI 82.38%-95.10%) and a specificity of 96.75% (95% CI 91.88%-99.11%), whereas including these measurements as *possible AF* resulted in a sensitivity of 95% (95% CI 88.72%-98.36%) and a specificity of 91.06% (95% CI 83.58%-94.86%; Table 2). In the first scenario, the amount of false-negatives increased to 10. In the latter, the amount of false-positives increased to 12.

Table 3. Diagnostic accuracy of photoplethysmography and single-lead electrocardiography signal analysis on measurement level compared with reference gold standard 12-lead electrocardiography.

Diagnostic metrics	Insufficient quality excluded		Insufficient quality categorized as *sinus rhythm*[a]		Insufficient quality categorized as *possible AF*[b]	
Diagnostic test	PPG[c] (n=547)	ECG[d] (n=612)	PPG (n=657)	ECG (n=657)	PPG (n=657)	ECG (n=584)
Prevalence n (%)	233 (42.6)	274 (44.8)	292 (44.4)	291 (44.3)	292 (44.4)	291 (44.3)
Sensitivity (%)	95.30	92.00	76.00	86.60	96.20	92.40
Specificity (%)	96.20	96.50	96.70	96.70	82.70	89.10
PPV[e] (%)	94.90	95.50	94.90	95.50	81.70	87.10
NPV[f] (%)	96.50	93.70	83.50	90.10	96.50	93.70
Accuracy (%)	95.80	94.40	87.50	92.20	88.70	90.60

[a]The rhythm categories *sinus rhythm* and *possible AF* were made by separating the measurements indicative for sinus rhythm and AF, and by adding to them insufficient quality measurements as stated in the column headings.

[b]AF: atrial fibrillation.

[c]PPG: photoplethysmography.

[d]ECG: electrocardiogram.

[e]PPV: positive predictive value.

[f]NPV: negative predictive value.

Table 4. The effect of comorbidities on the signal quality of photoplethysmography measurements.

Comorbidity	*P* value on measurement level	*P* value on subject level
Diabetes	.18	.15
Heart failure	.32	.73
Gender	.02	.44
Body mass index (>25)	.02	.41
Age >75 years	.06	.58
Vascular disease	<.001	.86

On Measurements Level

A total of 657 single-lead ECG measurements were recorded, out of which 7% (45/657) were identified as insufficient quality. Analysis of solely high-quality measurements yielded a sensitivity and specificity of 91.97% (95% CI 88.10%-94.90%) and 96.45% (95% CI 93.88%-98.15%), respectively (Table 3). There was an agreement between the diagnosis based on single- and 12-lead ECG for 94.4% (578/612) measurements. Here 12 measurements were false-positive and 22 measurements were false-negative. Categorizing the insufficient quality measurements as *sinus rhythm* resulted in 86.60% (95% CI 82.14%-90.29%) sensitivity and 96.72% (95% CI 94.34%-98.29%) specificity (Table 3). The diagnosis based on single-lead ECG matched the diagnosis based on 12-lead ECG for 92.2% (606/657) measurements. The amount of false-negative measurements increased to 39. Interpreting insufficient quality as *possible AF* resulted in a sensitivity of 92.44% (95% CI 88.87%-95.20%) and a specificity of 89.07% (95% CI 85.42%-92.08%; Table 3). Here, there was an agreement for 90.6% (595/657) measurements. The amount of false-positives increased to 40.

Consistency Between Photoplethysmography and the Single-Lead Electrocardiogram Signals

In 87.9% (196/223) subjects, the quality of both the PPG and single-lead ECG signals were reliable for analysis. Both signals resulted in similar diagnoses in 98.0% (192/196) subjects. On measurement level, 78.7% (516/656) PPG and single-lead ECG paired measurements had a sufficient quality of reliable analysis. This resulted in similar diagnosis in 98.1% (506/516) measurements.

Discussion

Principal Findings

This diagnostic accuracy study in a primary care convenience sample revealed that cardiac rhythm analysis through a mobile phone–based PPG signal with the FibriCheck AF algorithm had very good sensitivity and specificity to detect AF. False-positive results were mainly because of the presence of extrasystoles. Furthermore, the FibriCheck AF algorithm accurately diagnosed AF on the basis of a single-lead ECG, with a similar sensitivity and specificity compared with the PPG signal. Both sensitivity and specificity were affected when insufficient quality measurements were included as either *sinus rhythm* or *possible*

AF, leading to a decrease in accuracy to 92.38% and 93.27%, respectively, from 96.14%. Beat-to-beat analysis showed a strong agreement between the PPG and the single-lead ECG signal.

The diagnostic accuracy of the FibriCheck AF algorithm was comparable with other screening methods and devices. A recent systematic review and meta-analysis found the greatest accuracy for blood pressure monitors and non-12-lead ECGs [9]. The modified sphygmomanometers had a pooled sensitivity of 98% and a specificity of 92%. Non-12-lead ECGs scored a sensitivity of 91% and a specificity of 95%. However, when focusing on the primary care setting, a lower specificity of 89% was obtained. Mobile phone apps also showed a good pooled accuracy, with 97% sensitivity and 95% specificity. The AliveCor, a handheld single-lead ECG device, showed a sensitivity of 94% and a specificity of 99% in cardiology clinic patients [10], but AliveCor showed a low sensitivity ranging from 55% to 79% and a specificity between 97.5% and 97.9% in hospitalized patients [11]. This was later attributed to several defects, which impaired diagnostic accuracy and necessitated a product recall in the United States during the course of the study. The commercial algorithm has been biased for enhanced specificity, whereas the version of the AF detection algorithm used in published screening studies was biased for enhanced sensitivity. The defects, together with the enhanced specificity biasing, resulted in the reported low sensitivity [12].

A mobile phone app is quick, inexpensive, and practical without the need for special infrastructure or external hardware. The patient does not require any experience or medical education and can be easily trained to use the app. Physicians can remotely review the transferred data, which enable optimal patient follow-up in a less time-consuming manner. Furthermore, the high accessibility of mobile phone apps and the increasing mobile phone usage among the elderly are important assets [13,14]. However, only 17% of our study population owned a mobile phone compared with the 27% reported in recent Austrian [12] and American [14] senior surveys. Recent Belgian and Dutch surveys reported mobile phone use in 54% of the population aged between 65 and 75 years and 29% in the population aged 75 years and above [15]. Furthermore, a relatively high difficulty in mobile phone handling was observed (Table 1). However, it is expected that, together with AF prevalence, the mobile phone usage in the senior population will continue to rise and the lack of familiarity will partially fade. Moreover, a recent study demonstrated an increasing willingness and capacity to use mobile health devices by older persons [16].

This phase 2 diagnostic study demonstrates that great opportunities lie in AF screening through PPG measurements. However, the place of the FibriCheck app in future screening or case-finding programs for AF remains to be determined. The FibriCheck app could be a good candidate for implementation as a case-finding or event-recording solution for paroxysmal AF in high-risk patients in primary care or patients with paroxysmal palpitations without a clear diagnosis. Furthermore, this mobile technology also allows follow-up of patients after resynchronization or ablation. Indeed, it has been demonstrated that intermittent measurements over a longer time period, as made possible by a mobile phone app, have a great chance of increasing the diagnostic yield.

Further research, such as validation studies and cluster randomized trials, is needed to investigate the effects of these implementation strategies and the performance in a population with a lower incidence of AF.

Limitations

This is the first study investigating the diagnostic accuracy of the FibriCheck app in a realistic primary care population. The simultaneous measurement of PPG and single-lead ECG offered the opportunity for beat-to-beat comparisons of the 2 measurement methods to reveal the underlying reasons for inconsistencies in diagnosis using the FibriCheck AF algorithm. However, a few limitations should be noted. First, different digital 12-lead ECG devices were used as the reference standard instead of 1 standardized device. Second, there was a gap of a few minutes between the simultaneous PPG and single-lead ECG measurements and the subsequent 12-lead ECG measurement, and the subject's heart rhythm might have changed in that short time period. Third, to calculate the PPV and the NPV in a population aged over 65 years, we assumed an AF prevalence of 6%. However, because of the heterogeneity between conducted studies, various values were found for AF prevalence in the literature [2,17]. Fourth, as the study population was a convenience sample, extrapolation of these results to the general population should be made with caution. In addition, all measurements were performed under medical supervision. Although participants and researches were blinded for all notifications and results and were thereby prevented to attempt to improve the measurement results, it remains unclear whether such apps would achieve the same accuracy in an unsupervised (real-world) situation. Another important aspect that should be considered is the accuracy of the algorithm to screen patients who may have uncontrolled high heart rates. As this study was positioned as a validation study and not as a screening study, further research to assess real-life accuracy is warranted. Finally, some false-positive results with the FibriCheck AF algorithm were caused by atrial or ventricular extrasystoles, which is a known issue in AF screening using RR-interval variability analysis. However, as confirmation with 12-lead ECG or single-lead ECG documenting P-waves is required and recommended by several guidelines [7,18,19], this limitation does not jeopardize the potential of FibriCheck as screening tool.

Conclusions

To conclude, the FibriCheck app is an accessible standalone mobile phone app that showed promising results for AF detection in a primary care convenience sample. The FibriCheck AF algorithm showed a very good sensitivity and specificity. These findings confirm the FibriCheck app to be a possible candidate to implement in future screening, case-finding programs for AF, or monitoring programs in a home setting. However, further research is needed to determine the place of the FibriCheck app in such a strategy.

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Conflicts of Interest

None declared.

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Abbreviations

AF: atrial fibrillation
ECG: electrocardiogram
GP: general practitioner
IMEC: Interuniversity Micro-Electronics Center
IQR: interquartile range
NPV: negative predictive value
PPG: photoplethysmography
PPV: positive predictive value
RR-interval: intervals between heartbeats

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Original Paper

Child Maltreatment Disclosure to a Text Messaging–Based Crisis Service: Content Analysis

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Abstract

Background: Disclosure is a difficult but important process for victims of child maltreatment. There is limited research on child maltreatment disclosure. Young people have been reluctant to disclose victimization to adults, but short message service (SMS) crisis services may represent one novel method of engaging young people around sensitive topics.

Objective: The purpose of this study was to determine characteristics of child maltreatment disclosure to an SMS-based crisis service.

Methods: We conducted a content analysis of all conversations (N=244) that resulted in a mandatory report by an SMS-based crisis service between October 2015 and July 2017. We coded characteristics of the disclosure process, including the reason for initial contact, phrase used to disclose abuse, perpetrator, type of abuse, and length of victimization. After identifying terms used by young people to disclose child abuse, we randomly selected and analyzed 50 conversations using those terms to determine if use of the terms differed between conversations that did and did not result in mandatory report.

Results: Parents were the most common perpetrator. Physical abuse was the most common form of abuse discussed in the initial abuse disclosure (106/244, 43.4%), followed by psychological abuse (83/244, 34.0%), sexual abuse (38/244, 15.6%), and neglect (15/244, 6.1%). More than half of the texters discussed abuse or other significant family issues in the first message. An explicit description of the experience or definite language, such as abuse, rape, and molested, was common in disclosures.

Conclusions: Early disclosure, combined with explicit language, may suggest at least a portion of young victims are actively seeking safe ways to talk about their experiences with abuse, rather than incidentally sharing experiences while seeking support for other issues. SMS text messaging may be a valuable way to engage with young people around sensitive topics, but these approaches will require careful consideration in their development, implementation, and evaluation to ensure a positive experience for young people.

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KEYWORDS

child maltreatment; disclosure; SMS; text message

Introduction

Disclosure of child maltreatment is often a grueling experience for children and may result in the young victim re-experiencing the trauma [1]. Children and young people who disclose their experiences risk inadequate support through the disclosure process, social stigmatization associated with maltreatment victimization, retribution by the perpetrator, and removal of the

victim or perpetrator from the home [1,2]. Relatively few victims disclose their maltreatment experiences to adults due to these risks [3-5]; however, disclosure is often necessary to end the abuse and connect children with resources to support their physical and psychological health [6,7]. Despite the importance of disclosure, research on children's disclosure of physical or emotional abuse and neglect is limited [3].

Phone-based crisis lines have historically been available for young people to discretely seek support and referral to resources, but these services have not been well-adopted by young people [8]. As a result, some organizations have explored other approaches, such as short message service (SMS) text messaging, to provide crisis services to young people through their preferred methods of communication [9]. Crisis Text Line (CTL) was among the first to provide a free, 24/7 SMS line for people in crisis in the United States [10]. Since launching in August 2013, CTL's volunteer crisis counselors have served hundreds of thousands of texters seeking help for suicidal behavior, bullying, abuse, and other crises. Other services, such as the 24/7/365 Crisis Hotline, Teens Helping Teens, and Mind Infoline, also provide SMS-based crisis services, although most provide service during limited hours or about limited topics [11-13].

Considering the significant mental health consequences of maltreatment [14], it is likely that many users of crisis services have experienced child maltreatment. To date, there have been no studies of child maltreatment disclosure using SMS-based technology. To address this gap, we conducted a content analysis of conversations between crisis counselors and texters to determine characteristics of child maltreatment disclosure to an SMS-based crisis service. The findings of this study have important implications for the use of technology to support disclosure of child maltreatment.

Methods

Procedures and Sample

The SMS-based crisis service provided deidentified transcripts of all conversations that resulted in a mandatory report between October 2015 and July 2017. Within this crisis service platform, conversations began when texters initiated contact and ended when texters actively ended the conversation or did not respond for an extended period. Because millions of messages have been exchanged through this service, it was not feasible to conduct content analysis with the full sample. Limiting the content analysis to conversations that resulted in mandatory report created a sample of conversations that were confirmed by crisis counselors to be about child maltreatment. Mandatory reporting is the legal requirement in the United States for professionals to report suspected child abuse or neglect to the authorities. The guidelines for mandatory reporting vary from state to state, but in most states "a report must be made when the child is known or suspected of being a victim of abuse or neglect" [15], meaning situations where the child is suspected to be in danger are required to be reported. Mandatory reporters are not required to report cases where the child has permanently left the dangerous situation or cases where adults report past childhood abuse or neglect.

However, mandatory reporting in this crisis service is complicated because user information is anonymized by the system. After disclosure of experiences consistent with maltreatment, crisis counselors are trained to disclose their status as mandatory reporters and to explicitly state that they must make a report to authorities if they know about abuse or neglect of a minor and have sufficient identifiable information (eg, name and address) to make a report. As a result, the sample does not include all instances of child maltreatment disclosure.

The Colorado Multiple Institutional Review Board determined that the study was exempt from review because no identifiable information of texters was available to researchers.

Coding and Analysis

The research team conducted an inductive content analysis. One member of the research team read through the 244 mandatory report conversations twice to achieve immersion. During the second read, she took notes on emerging themes. Based on this process, she developed the content analysis coding framework that was revised by the research team and employees of the crisis service. Once the coding framework and data dictionary were complete, a research team member applied the coding framework (see Table 1) to the 24,730 text messages. She recoded five conversations at the mid- and endpoint of data coding—10 total—to assess coding reliability, which was greater than 95%.

All open-response sections of the coding framework (eg, language used in disclosure) were recorded verbatim, including all spelling and grammatical errors, and analyzed qualitatively following established content methods and reflexive team analysis [16-18]. Through multiple readings, the team identified themes and codes for each open-response section of the conversation. After discussing the themes and codes with the team, a research team member applied the final coding schema, which is reported in the Results section, to the open-response section of the conversations.

During the coding process, the research team recognized that several terms were frequently used to disclose maltreatment experiences. To determine if this type of language was commonly used by texters to describe experiences that was not child abuse, the team repeated the content analysis with 50 randomly selected conversations that included any of the terms commonly used during disclosure (ie, *abuse*, *abused*, *abusive*, and *molested*) from the overall pool of messages exchanged within the platform.

Table 1. Coding scheme of conversations that resulted in a mandatory report.

Variable	Definition	Coding approach
Year	Year of conversation from administrative system	Numerical
Month	Month of conversation from administrative system	Numerical
Age	Self-reported age of texter	Numerical
Sex or gender	Self-reported sex or gender of the texter	Categorical (*male; female; other*)
First contact	Initial text from texter	Open response
Disclosure text	First phrase and/or sentence disclosing abuse by texter	Open response
Perpetrator	Identification of perpetrator by texter	Multiple-selection categorical (*mother; father; brother; sister; stepfather/mother's partner; stepmother/father's partner; aunt/uncle/cousin; grandparent; other extended family; other*)
First abuse type	Type of abuse first disclosed by texter	Categorical (*physical; sexual; emotional/psychological; neglect*)
All abuse types	All abuse types disclosed by texter	Multiple-selection categorical (*physical; sexual; emotional/psychological; neglect*)
Length of victimization	Length of abuse victimization reported by youth	Categorical (*acute: first time/only time; chronic: multiple times*)
Help-seeking	Text of reason why youth reached out at this point rather than previously or at a point in the future	Open response
Other issues	Other nonabuse issues disclosed by the texter	Multiple-selection categorical (*bullying; eating disorder; friend issues; sexual or gender-identity issues; mental health; school problems; self-harm; substance abuse; suicidal thoughts/ideation; suicide attempt*)
Other interactions	Text of other interactions that were particularly representative of themes	Open response

Results

Overview

A total of 244 conversations from 236 individuals resulted in a mandatory report. The average age of texters was 14.3 years (SD 1.8, range 7-17). In 29 out of 244 conversations (11.9%), the specific age of the user was not confirmed, but the texter was a minor (eg, reported they were under 18). Gender identity was rarely explicitly discussed by the crisis counselor or the user.

The texters often discussed other psychosocial issues beyond the maltreatment and many reported concurrent issues. Nearly a quarter of conversations (55/244, 22.5%) reported suicidal desire, 16.4% (40/244) reported having access to the intended lethal means for suicide, and 10.2% (25/244) reported having a timeline for the suicide. Mental health issues, including depression (29/244, 11.9%), self-harm (29/244, 11.9%), anxiety (22/244, 9.0%), and stress (21/244, 8.6%) were also commonly reported by texters.

Focus of Initial Texts With the Crisis Counselor

Upon receiving a message from a texter, the crisis service platform automatically issues a text asking for additional information. In response to the initial query, nearly half of texters discussed abuse (see Table 2). Many of these initial disclosures included a variant of the word *abuse*, such as "I think my parents are abusive..." or "I've been having problems with my mom with abuse and neglect." Other initial disclosures included a description of the situation, for example, "...he [father] tried to swing a broken bottle at my head !!" and "My brother just beat me. he's 18."

Other responses to the initial, automated query focused on a range of other issues. General family issues, such as "I hate my dad," "I dont want to be with my family no more...," and "My dad is freaking me the hell out...," were the most common initial responses. Disclosures of suicide and self-harm (eg, "I feel like not living anymore") or advice and support-seeking (eg, "I need help") were also common in these initial texts. A few other responses focused on mental health, running away, or other topics.

Characteristics of Disclosed Abuse

The most common perpetrator of abuse disclosed by texters were parents (mom, 121/244, 49.6%; dad, 113/244, 46.3%). Stepfathers/mother's partners (18/244, 7.4%), brothers (16/244, 6.6%), and grandparents (14/244, 5.7%) were also frequently mentioned. Physical abuse was the most common form of abuse discussed in the initial abuse disclosure (106/244, 43.4%). Emotional or psychological abuse (83/244, 34.0%), sexual abuse (38/244, 15.6%), and neglect (15/244, 6.1%) were also included. Many texters discussed multiple types of abuse. Nearly three-quarters of texters talked about physical abuse (173/244, 70.9%) and more than half discussed emotional or psychological abuse (138/244, 56.6%). Sexual abuse (51/244, 20.9%) and neglect (26/244, 10.7%) were less common. Texters reported, on average, 1.59 (SD 0.6) types of abuse victimization.

Table 2. Distribution of content of initial message and first maltreatment disclosure (N=244).

Theme	n (%)	Example quote
Initial message		
Disclosure of abuse	108 (44.3)	"My dads abusing me and I have no escape"
Family issues	33 (13.5)	"I dont want to be with my family no more im tired of being in this family"
Suicide/self-harm	25 (10.2)	"i feel extremely alone and I honestly want to die"
General support-seeking	15 (6.1)	"I need someone to talk to"
Limited information	15 (6.1)	"A lot of things"
Other mental health	5 (2.0)	"Just really depressed is all"
Running away	5 (2.0)	"i am thinking about running away. i think i will run away..."
Other	38 (15.6)	"I want to stop being hurt"
First maltreatment disclosure		
Description of event consistent with abuse	119 (48.8)	"touched me in a place I didn't want to be touched"
Abuse	99 (40.6)	"my parents are abusive"
Other definite language	16 (6.6)	"father rapes me..."
Other	6 (2.5)	"my mom enjoys punishing me"
No identifiable child maltreatment disclosure	4 (1.6)	N/A[a]

[a]N/A: not applicable.

For many texters, their abuse experiences were chronic. Of the 221 conversations where chronicity of abuse was discussed, 92.8% (205/221) of texters discussed recurrent abuse. A recent crisis or escalation in the abuse was a common reason for texters to initiate contact. Several texters discussed issues with divorce or custody arrangements involving an impending visit with the noncustodial, abusive parent. Some texters discussed an increase in the frequency or severity of the abuse prior to reaching out for help. Other texters disclosed they had recently unsuccessfully attempted to reach out for help from extended family or adults in the community and were seeking support in managing the trauma associated with the abuse or assistance reporting the abuse.

Language Used in Maltreatment Disclosure

In their initial maltreatment disclosures, texters most commonly described experiences consistent with abuse without explicitly naming it as such (see Table 2). However, nearly half of texters included a variant of the word *abuse* in their initial disclosure of child maltreatment (eg, *abusive*, *abused*, or *abuse*) or other definite language (eg, *raped*, *molested*, or *assaulted*). Phrases related to hitting (eg, "mom hit me" or "he hits me") were frequently used, as was language related to being beaten (eg, "beat me" or "get beat up") and being forced to engage in sexual touching (eg, "forced me to have sex" or "touched me in my sleep"). Other participants described very specific incidents (eg, "say she will burn the house down with me in it" or "threatened to pull a gun on me"). In a few instances, crisis counselors asked participants if they were being abused or clarified the seriousness of the issues, as it was not clear if the user perceived the behavior to be irritating or truly harmful.

Language Used in Comparison Cases

In the 50 randomly selected conversations that included any of the terms commonly used during disclosure (ie, *abuse*, *abused*, *abusive*, or *molested*) from the overall pool of messages exchanged within the platform, the research team found no indication that texters use the word *abuse* to describe nonabuse situations; however, these words did not always indicate recent child abuse where mandatory reporting would have been appropriate. In some instances, texters were referring to intimate partner violence or substance abuse, which do not fall under the jurisdiction of child maltreatment mandatory reporting. In others, the texters inquired about the confidentiality policy of the crisis service and the crisis counselors detailed the instances, including abuse, when confidentiality could be broken.

In the conversations in which the abuse-related words were used to describe child maltreatment, the disclosure and details about child maltreatment in this additional sample were quite like the disclosures that resulted in a mandatory report. They included vivid descriptions of the abuse, such as "My stepdad beat the shit out of me...," "He held a knife to my stomach. He told me if he wanted he could kill me in an instant...," and "She [sister] pushed me then proceeded to grab my hair, and throaty then attempt to punch me." There were two main reasons why these conversations were not reported through the mandatory reporting process. First, more than half of the texters were discussing historical events, such as an adult saying, "I was sexually abused when I was 14-15 years old..." or a child saying, "I got molested by my dad for four years, TWO YEARS AGO." In other instances, the texter withheld key information necessary to make a report (eg, name and location). The crisis service does not retain identifiable information of the texter; it is only available if the texter agrees to provide it.

In other conversations, texters withheld their identifying information because they were concerned about the consequences of mandatory reporting. In some situations, texters had prior experience with child protective services and decided the costs of re-engaging with the system (eg, "and the caseworker hasn't done anything about it yet...") were outweighed by the potential benefits. Some texters had fears related to parents finding out about the disclosure (eg, "My parents can't kbiw about this" or "No That [stepfather finding out about disclosure] would be worse").

Discussion

Principal Findings

Disclosure of child maltreatment is a complex and difficult process for many young victims but is a critical step to receiving support that would ideally end the maltreatment. Technology-based approaches may represent a novel method for young people to seek support [9], and this study suggests young people disclose their experiences through SMS-based services. More than half of texters whose conversation resulted in a mandatory report discussed abuse or other significant family issues in the first response. Texters were also explicit in their initial disclosure language, with almost all cases including the word *abuse*, other definite language indicating assault, or an explicit description of the experience. Early disclosure, combined with explicit language, may suggest at least a portion of young victims are actively seeking safe ways to talk about their experiences, rather than incidentally sharing experiences while seeking support for other issues.

As SMS-based and other brief written communication-based crisis services (eg, online chat and forums) expand, it will be vital to collaboratively develop and expand evidence-based best practices and trainings with providers to ensure texters have a positive disclosure experience. Although there is limited research focused on disclosure of physical and emotional child abuse and neglect [3], there is considerable research on disclosure of sexual abuse and assault in both children and adults. Sexual assault experiences are unlikely to be directly analogous to child maltreatment experience but may share some similarities in the disclosure process; therefore, the sexual assault research literature may provide guidance on easing the disclosure process for young people who have experienced child maltreatment [1,2,19]. Authors of a study on sexual assault disclosure in an online forum found that individuals were often directly seeking information, network, or emotional support [20]. In general, people seeking informational and emotional support were more likely to post these requests anonymously, which the authors theorized was due to fear of unsupportive responses [20]. These fears may be justified, as another study found that while most disclosures in an online forum received positive responses, several responses were categorized as blaming, doubting, or being generally unsupportive [21]. Social responses to sexual assault disclosure have been strongly associated with postassault mental health and well-being [22,23], and it is likely the relationship between social responses to disclosure and well-being persist for child maltreatment victims. As a result, organizations providing this type of service may need to have a moderation process for interactions between users, if applicable, and train affiliated staff or volunteers to appropriately respond to disclosure to ensure young people receive an appropriate response.

Implications

There is considerable evidence to suggest that adolescents and young adults prefer brief written communication to verbal communication [9]. Since young people have readily adopted SMS-based communication, it may be prudent for other social and health services who engage young users around sensitive information to implement brief written communication options. For example, child welfare services could explore adding an SMS or online chat reporting option, which could encourage young people to disclose their own experiences and connect them to individuals specifically trained in child maltreatment. However, additional research must be conducted to determine the feasibility, acceptability, and effectiveness of use. If acceptable and effective, these strategies must be judiciously and deliberately implemented to ensure a positive experience for the user.

Additional research in this area must continue to carefully consider the ethical implications of using technology-based data created for purposes other than research. The platform used in this study disclosed on their website that data may be shared with external research partners to support research, policy, and community organizing. In addition, users may request to have their data removed from the database. The platform also created an independent data ethics committee, based their research vetting practices on other established data warehouses; they auto-scrubbed data of identifying information and required researchers to work in a restricted data enclave.

However, recent controversies surrounding Internet privacy may necessitate that researchers take additional precautions when conducting research using technology-based data created for purposes other than research [24]. The Association of Internet Researchers suggests that researchers carefully consider several guidelines prior to using technology-based data, including the users' expectations around privacy and who may benefit or be harmed from the study [25,26]. Due to the sensitive nature of this data, users would likely be embarrassed, hurt, or angry if their expectations of data privacy did not match those of the service and the researchers. In partnership with the platform used in this study, we took precautions to ensure that users could not be indirectly identified through our research outputs. We carefully selected quotes that were general enough to apply to many situations and would not be recognizable as uniquely attributable to a specific user or situation. We, and other researchers in this area, will need to continue to critically consider ethical approaches to Internet and technology-driven research as technology, data management, and privacy standards evolve.

Limitations

Given the scale of the crisis service data, it was necessary to focus on a segment of the data for this first research study. As a result, the primary dataset was restricted to conversations resulting in mandatory report with limited exploration of other

conversations for sensitivity analysis. The results may not generalize to other types of conversations, as they represent the users willing to allow crisis counselors to seek services on their behalf. Users most fearful of the perpetrator and users least troubled by their victimization may be less willing to take that step. It may be beneficial to engage with computer scientists to develop machine learning algorithms that would allow processing of the entire dataset and that may improve the sensitivity and specificity of screening.

In addition, only one researcher had access to the raw conversation files as part of the data-sharing agreement, so only she could code the conversations. Her training and experience in child maltreatment research likely influenced some aspects of the research, such as which segment of the conversation constituted the initial disclosure of abuse. However, the researcher also has training in qualitative methods and was intentionally mindful of how this training may influence her coding.

The crisis service may also represent a unique environment for disclosure, as it is user-directed and anonymous. Users may feel more secure sharing explicit details of their experiences because they are able to disengage at any point and are not personally identifiable. Additional evaluation of the suitability of SMS approaches in personally identifiable situations is necessary.

Conclusions

This study found that young people are seeking support related to child abuse in an SMS-based crisis service. As additional SMS- and technology-based approaches develop, it may be beneficial to evaluate how these methods of communication may be built into systems that regularly engage with young people. However, it will be necessary to explicitly consider how to address child maltreatment disclosures within the systems. In addition, careful consideration of evaluation methods for these approaches and the ethical use of data created by these systems will be necessary. If feasible and acceptable methods are developed and evaluated, SMS or other brief written communication platforms may improve the communication between young people and health and human service organizations.

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Conflicts of Interest

None declared.

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Abbreviations

CTL: Crisis Text Line
SMS: short message service

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Original Paper

Combining Real-Time Ratings With Qualitative Interviews to Develop a Smoking Cessation Text Messaging Program for Primary Care Patients

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Abstract

Background: Text messaging (short message service, SMS) interventions show promise as a way to help cigarette smokers quit. Few studies have examined the effectiveness of text messaging (SMS) programs targeting smokers associated with primary care or hospital settings.

Objective: This study aimed to develop a text messaging (SMS) program targeting primary care smokers.

Methods: Adult smokers in primary care were recruited from February 2017 to April 2017. We sent patients 10 to 11 draft text messages (SMS) over 2 days and asked them to rate each message in real time. Patients were interviewed daily by telephone to discuss ratings, message preferences, and previous experiences with nicotine replacement therapy (NRT). Content analysis of interviews was directed by a step-wise text messaging (SMS) intervention development process and the Information-Motivation-Behavioral Skills model of medication adherence.

Results: We sent 149 text messages (SMS) to 15 patients. They replied with ratings for 93% (139/149) of the messages: 134 (96%, 134/139) were rated as clear or useful and 5 (4%, 5/139) as unclear or not useful. Patients' preferences included the addition of graphics, electronic cigarette (e-cigarette) content, and use of first names. Regarding NRT, patients identified informational gaps around safety and effectiveness, preferred positively framed motivational messages, and needed behavioral skills to dose and dispose of NRT.

Conclusions: Patients recommended text message (SMS) personalization, inclusion of e-cigarette information and graphics, and identified barriers to NRT use. Combining real-time ratings with telephone interviews is a feasible method for incorporating primary care patients' preferences into a behavioral text messaging (SMS) program.

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KEYWORDS

text messaging; smoking cessation; primary care

Introduction

Background

There is growing evidence that smoking cessation interventions delivered by mobile phone are effective at helping smokers quit [1]. Smartphone apps have been developed for smokers that deliver evidence-based behavioral advice, acceptance and commitment therapy, mindfulness training, digital photo aging, contextually tailored messages using geoposition and social context, medication adherence support, and positive psychology interventions to name just a few [2-10]. However, so far, no smartphone apps have demonstrated improved long-term cessation outcomes at 6 months or longer.

In contrast, short message service (SMS) text messaging interventions have demonstrated improved long-term cessation among cigarette smokers [1,11-13]. SMS text messaging programs for smokers deliver behavioral advice on the basis of several behavior change theories [14] to increase self-efficacy [15]. Further, they have been shown to improve quit chances by 30% to 70% compared with self-help material or usual care [1,11-13]. Most of the previous mobile health interventions for smokers, both SMS text messaging– and smartphone-delivered interventions, have examined community-based samples recruited from schools or internet advertisements [16-21].

Mobile health interventions for smokers have not been well studied in health care settings. Studies examining mobile apps for smokers in health care settings have not tested long-term outcomes [10,22-24]. Studies of SMS text messaging in health care settings have measured long-term abstinence but have found mixed results. There were 2 studies that examined smoking outcomes among patients and offered varenicline or varenicline plus SMS text messaging and found no effect from adding SMS text messaging [25,26]. Another study found no effect of SMS text messaging for hospitalized smokers [27]. Furthermore, 1 study found no significant effect of SMS text messaging for pregnant smokers [28]. In contrast, 2 primary care–based studies and 1 study among cardiac rehabilitation patients examined SMS text messaging versus usual care or a brief behavioral intervention and found improved smoking outcomes [29,30]. These mixed results highlight the need to better understand how to integrate SMS text messaging in health care settings with other smoking cessation treatments.

All these previous studies targeted motivated or treatment-seeking smokers, yet 80% to 90% of smokers did not meet these criteria [31]. Interventions that actively seek smokers could have a much wider population impact [32]. We have previously examined the feasibility of proactively offering an SMS text messaging intervention to smokers identified from the electronic health record (EHR) of 2 primary care practices [33]. In that study, 10% of the patients including both motivated and unmotivated smokers accepted an SMS text messaging intervention tailored to readiness to quit from their health care system.

Primary care is an important site for delivering tobacco cessation interventions with 84% of US smokers being screened for tobacco use by a physician each year [34]. Receiving digital messages from a trusted source, such as a local health care system [35], may boost their behavioral impact. We also do not know how patients' expectations for communications from their health care provider affects their preferences for SMS text message content or what literacy level is appropriate for SMS text messages targeting patients.

Integrating SMS text messaging programs within primary care also presents an opportunity to support other treatments including pharmacotherapy. Adherence to smoking cessation medications is suboptimal with nicotine replacement therapy (NRT) users continuing treatment for less than half the recommended duration [36-40]. SMS text messaging programs have been used to improve medication adherence in chronic conditions including HIV, diabetes, and schizophrenia [41-44], but there is only 1 previous study examining an SMS text messaging intervention addressing medication adherence among smokers [25]. In that study, SMS text messages promoting varenicline use among people with HIV did not increase adherence, but abstinence was higher at 8 weeks among patients receiving SMS text messages plus telephone counseling compared with standard care [25].

There are few published studies describing the development and adaptation of smoking cessation mobile health interventions for health care settings [4,22,45-47]. To our knowledge, none have included both behavioral advice and content encouraging NRT adherence for primary care patients. In this paper, we present a step-wise process for message development. Our process followed other published processes for SMS text message intervention design with the unique aspect of combining real-time ratings of messages with daily qualitative interviews with target users [48-50]. This use of real-time ratings is similar to previous work combining behavioral smoking data from ecological momentary assessments with qualitative data to understand substance use behaviors [51].

Objectives

We aimed to gather insights into primary care patients' reactions to messages in the context of their daily lives and to understand their experiences with and barriers to using NRT. Specifically, we examined 3 SMS text messaging intervention components: (1) new content for smokers not ready to quit, comprising motivational advice and encouragement to practice quitting, (2) new content promoting NRT use, and (3) content included in an existing national SMS text messaging campaign. The national campaign content is SmokefreeTXT. This content was developed for the US public [14] and was not targeted to patients in primary care settings who may have different expectations for content coming from their health care provider and access to different resources in the primary care context. Our objective was to develop an SMS text messaging program tailored to the needs of smokers in primary care by adapting established SMS text message content and developing new theory-based medication messages, incorporating patients' preferences for communication from their health care provider, and preferences for language around smoking cessation. Patient interviews and SMS text message assessments were designed to improve our understanding of patient preferences for SMS text messaging and experiences using NRT. These results inform the adaptation

of SMS text messages offering behavioral advice to smokers during a quit attempt and the development of novel motivational and medication-focused messages targeting smokers in primary care.

Methods

Our overall step-wise approach to SMS text messaging intervention development for primary care patients who smoke is shown in Figure 1.

In Step 1, we compiled a preliminary set of programmatic messages for primary care patients who smoke from established sources [33,52]. In Step 2, we asked a sample of primary care patients to rate messages in real time. We measured the time to respond to the rating message to understand when patients were reading and responding to messages. The ratings also measured usefulness or clarity of draft content. We also measured URL links clicked as proportion of URL links clicked out of all URL links sent to a patient to understand engagement with the program and accessibility of Web-based content. The patients simultaneously participated in daily qualitative telephone interviews to explain their ratings, their use of Web-based content, and their preferences for smoking cessation SMS text messaging content. In Step 3, the findings were used to design a set of modifications to the preliminary message set.

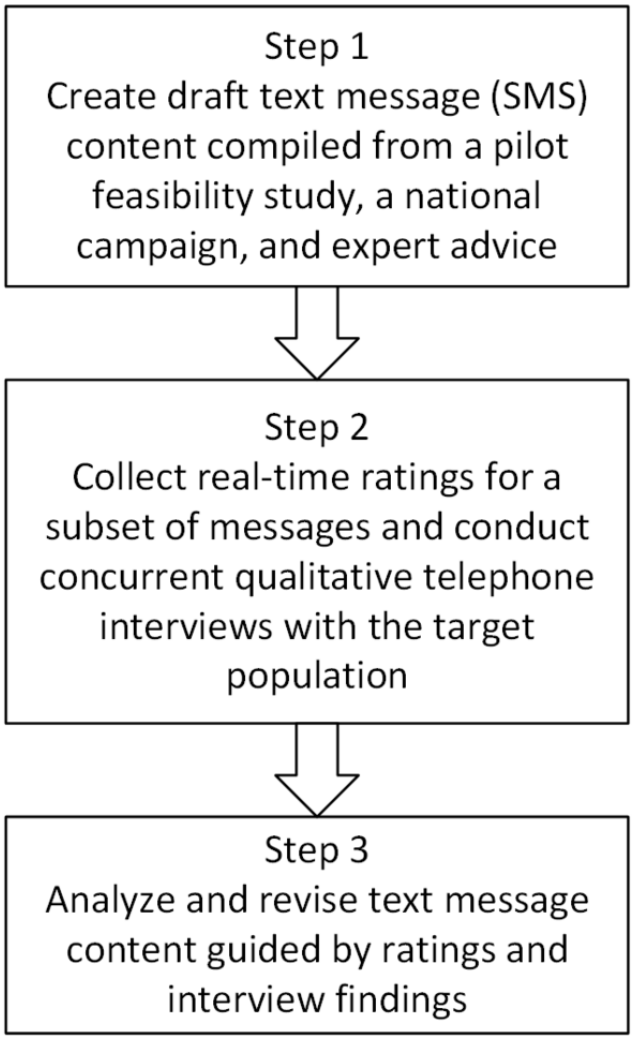
Participants

From February 2017 through April 2017, we recruited smokers from 2 Boston-area community health centers affiliated with a large academic medical center. We recruited patients who participated in a previous feasibility study of SMS text messaging for smokers in primary care [33]. These patients were approved by their primary care providers to be contacted about SMS text messaging research studies for smokers so that we were not required to seek additional provider approval before contacting them. Eligibility criteria included the following: aged 18 years or older, current or former smoker, able to speak and read English, visited their primary care physician in the last 2 years, had a mobile number in their electronic health record, not pregnant, and able to provide informed consent.

Ethics

The project was approved by the Partners Healthcare Institutional Review Board. Participants provided verbal informed consent to participate and received a US $40 gift card.

Figure 1. Steps of short message service (SMS) text message development and testing.



Preliminary Text Messaging Set

A preliminary set of "programmatic messages" comprised messages from 3 sources: (1) the National Cancer Institute's SmokefreeTXT [52], (2) the novel content we developed for smokers not ready to quit [33], and (3) the novel messages promoting use of NRT based on the Information-Motivation-Behavioral Skills (IMB) model of adherence [53].

SmokefreeTXT

Messages from a 2013 version of SmokefreeTXT were used [52]. SmokefreeTXT targets smokers who are ready to quit in the next 30 days. The program invites users to enter a quit date in the next 30 days and sends messages to support them through the quit attempt by addressing motivation, self-regulatory capacity, and other behavioral skills [14]. It includes periodic assessments that query smoking status and other self-reported outcomes and offers real-time support through keywords, which the users can type and send to request specific help with cravings, mood symptoms, or if they *slip* and have a cigarette.

Content for Smokers Not Ready to Quit

The content for smokers not ready to quit included motivational and quit induction messages developed for our previous pilot study that aimed to test the feasibility of sending proactive SMS text messages to smokers in primary care [33]. Motivational messages encouraged users to identify personal reasons for change and internal motivations to quit [54,55]. Quit induction messages are used on smokefree.gov and have been studied in randomized trials [52,56]. These messages encourage smokers to try a practice quit attempt (PQA) explained as an attempt to not smoke for hours or days without commitment to increase motivation and self-efficacy [57].

Smoking Cessation Medication Adherence Content

Medication-promoting messages were based on the IMB model of medication adherence [53]. This novel content was not included in the previous feasibility study. In the IMB model, information relevant to medication adherence may be accurate or inaccurate and facilitate or hinder adherence and may include how to take medications, medication effectiveness, drug interactions, or side effects. Motivation to adhere to medications encompasses both personal and social motivations and may include the individual's attitudes toward adherence, beliefs about the effects of adherence, perceived social support to adhere to medication, and interest in complying with the wishes of others. Behavioral skills include the self-efficacy and actual abilities to take medications including acquiring and using medication, dealing with adverse effects, communicating with health care providers, and calling up social support. Preliminary medication-promoting messages included informational messages about the mechanism of action and effectiveness of NRT, motivational reminders highlighting social factors, and behavioral tips about how to use NRT *ad lib* or after a slip.

Phase 1: Real-Time Message Ratings

From our programmatic message set, we purposively selected subsets of messages with potential challenges for users. First, we selected messages with a high literacy level based on a Flesch-Kincaid score greater than eighth-grade level. Second, we selected messages with URLs. Third, we selected messages describing the PQA and novel medication adherence messages. Using an internet-based mobile messaging platform (Upland Mobile Messaging, Austin, TX), we created 4 sets of 10 to 11 messages scheduled for delivery over a 2-day span between the hours of 9:00 am and 5:00 pm. Each programmatic message was followed by a *rating message* that asked the participant to rate the message's usefulness or clarity depending on the message content. Each participant was assigned to receive 1 of the 4 sets of programmatic messages and ratings. Assignment to message subsets was sequential, with each message set being rated by 3 to 4 participants.

Quantitative Analysis

We compared the characteristics of the participants in this study with those who were unreachable or declined participation using Chi-square and student's *t* tests. We calculated the proportion of messages rated as clear or useful, the proportion of URL links clicked, and the median and distribution of response times to ratings. Analyses were conducted in Stata version 13 (StataCorp).

Phase 2: Semistructured Interviews

Each day of messages was accompanied by a qualitative telephone interview. Interviews were conducted by a clinical research coordinator (NS) and a physician-researcher (GK) with qualitative interview experience. Interview topics included structured data on participants' smoking status, readiness to quit, and use of NRT; they also included open-ended inductive inquiries exploring the day's real-time message ratings and message content, *a priori* inquiries about preferences for message timing and frequency, personalization, privacy concerns, previous experiences with cessation medications, and *a priori* inquires asking about preferences among sample message types (eg, preference for informational or motivational medication messages, spiritual content, inspirational stories, or games). Interviews were audio recorded and transcribed for content analysis. After every 3 to 4 patients, we iteratively reviewed the transcripts to assess for new content. We stopped recruitment when saturation was reached, defined as the point at which we heard no more new topics or ideas in response to interview questions [58].

Qualitative Analysis

Qualitative interview transcripts were content analyzed using NVivo version 11 (QSR International) by 2 coders (GK and NS). The unit of analysis was the patient. Coders first read the transcripts and identified the key concepts. These key concepts were used to develop a preliminary coding framework. Furthermore, the coders reviewed each transcript using the preliminary framework to refine *a priori* themes and add emergent themes [59]. Coding was at the sentence level. All content was analyzed and could be coded with multiple themes. After iteratively analyzing all transcripts and reconciling discrepancies, the final coding structure was reviewed with a third researcher (EP). All interviews were double coded with the final coding structure that included 4 domains, 17 major themes, and 4 subthemes. We used kappa statistics to measure intercoder agreement with the final coding structure. The overall

kappa, calculated by averaging across all themes and weighting patients equally, was 80% (individual kappa scores are indicated in Multimedia Appendix 1).

Phase 3: Modifications to Text Messaging Intervention

In the final phase of this message development process, the qualitative interview findings and ratings informed changes to the SMS text messaging program. To define the message modifications, the study team reviewed the final qualitative themes and, through in-person and written discussion, came to a consensus on the planned message changes.

Results

Study Sample

Of 76 participants in the previous feasibility study, 57 (75%, 57/76) were reached and 15 (20%, 15/76) enrolled in this study. Characteristics of the 15 participants are shown in Table 1. Compared with patients who did not participate, participants who enrolled in this study were more often non-Hispanic white (*P*=.04). In all, 9 participants (60%, 9/15) were daily smokers, 4 (26.7%, 4/15) less-than-daily smokers, and 2 (13.3%, 2/15) former smokers who quit after the previous pilot study. A total of 10 (66.7%, 10/15) reported using NRT in a previous quit attempt.

Phase 1: Real-Time Message Ratings

We sent 149 programmatic messages and 149 rating messages. Of the 24 unique messages with URL links, none were clicked. Participants replied with ratings for 93.2% (139/149) of messages sent. The median time from rating message to reply was 7.0 min (interquartile range 1.0-29.0; Multimedia Appendix 2). Each message was rated by 3.6 participants on average with 1 message receiving only 2 ratings. The 10 missing ratings came from 5 participants. Of the 139 ratings, 96.4% (134/139) rated messages as useful or clear. Messages rated as unclear or not useful included 2 messages describing PQAs, 1 informational message about NRT, 1 motivational message, and 1 high literacy-level message (Multimedia Appendix 3).

Phase 2: Semistructured Interviews

All 15 participants completed the first qualitative interview, 87% (13/15) completed the second and 2 people were unreachable for the interview despite completing the message ratings. Our interviews produced 17 themes and 4 subthemes across 4 domains (Multimedia Appendix 1).

Program Framework

Message Frequency and Timing

Participants recommended from 1 to 5 messages per day and some recommended sending messages before bed, in the evening. When asked whether sample messages would be more effective if sent at other times, all participants thought the message's effectiveness would not be altered if received at a different time. When asked separately about URL links, some participants reported being at work as a reason for not clicking at the time of receipt.

Personalization

Most participants liked personalization with their first name and described it as humanizing and comforting. However, several participants had concerns about other types of personalization such as including their doctor's name:

> *[Use of first names] makes it sound like it's not coming from a robot caller.* [Daily smoker, female]
>
> *Yeah, I think [Using your doctor's name] would feel invasive like, "Whoa, they-- what else do they know about me?"* [Former smoker, male]

Table 1. Characteristics of participants.

Demographic characteristics	Participants (N=15)	Declined or unreachable (N=61)	*P* value[a]
Age (years), mean (range)	46 (28-61)	52 (23-70)	.10
Female, n (%)	6 (40)	41 (67)	.08
Race and ethnicity, n (%)			**.04**
White	12 (80)	58 (95)	
African American	1 (7)	2 (3)	
Latino	2 (13)	0 (0)	
Other	0 (0)	1 (2)	
Medical comorbidities[b]	5 (33)	19 (31)	>.99
Insurance status, n (%)			**.51**
Medicare	4 (27)	9 (15)	
Medicaid	4 (27)	12 (20)	
Commercial payer	7 (47)	39 (64)	
Self-pay	0 (0)	1 (2)	

[a]On the basis of student *t* test or Fisher exact test.

[b]Includes diabetes, hypertension, and coronary artery disease.

Privacy Concerns

Participants reported no issues with privacy of the messages they received. They also reported no concerns for privacy with an SMS text messaging program about smoking and no concerns about other people seeing their messages about smoking.

Message Content

Electronic Cigarette Content

Participants expected electronic cigarette (e-cigarette) content in messages about other tobacco products or treatments:

> *The one thing it doesn't include that they may want to include is the electronic cigarettes. Because that's what I used to help me quit and I quit for almost six months...* [Daily smoker, female]

Features-Graphic Content

A few participants recommended adding emoji-style images to attract interest:

> *Suppose so if you have no time and you look at it and you see a picture, you'll be more apt to look at it ... make it look fun, have some balloons or something.* [Nondaily smoker, female]

Moreover, 2 participants recommended adding graphic images of lungs to enhance message effectiveness:

> *Nobody shows pictures of lungs…They don't show family members sitting next to the people in bed...I think the shock value of things would really help with people too.* [Former smoker, male]

Specific Facts Versus General Statements About Quitting Tobacco

Participants reported that they found specific statements of the effects of quitting to be more impactful than more general statements:

> *If there are more specifics on what they're going to gain out of it and then more specifics on what they're going to expect doing it, people more likely want to take those steps, knowing what could happen to them.* [Daily smoker, female]

Encouragement and Message Framing

Participants reported that messages offering encouragement and praise would be more effective than negatively-framed messages:

> *Every couple days you could say, "Well if you didn't smoke, know you can pat yourself on the back." And just kind of encourage the person and give them good feedback as to, "Good job if you didn't smoke today." You know give yourself a high-five. As opposed to like, "Don't smoke, this will happen," and "Don't do that."* [Nondaily smoker, female]

Language Clarity

Participants did not understand some terminology in the messages including slip, lozenge, trigger, and the PQA:

> *Oh, those [lozenges] are the hard candy things?* [Nondaily smoker, male].

Language Counseling Versus Coaching

Participants reported counseling for tobacco use had a negative connotation and made it seem more like an illness. Participants were interested in coaching:

> *I think coaches and-things like are better off because people think of counseling and they think like, "I have mental issue. Oh, I have a drug problem," or-- "people don't think of cigarettes as heroin or opiates or something like that."* [Former smoker, male]

URL Links

Participants reported not clicking URL links as they did not have time, were not looking for or needing the information offered, were at work, had no internet access, or lacked computer skills. Participants recommended use of a visual link rather than a URL to increase the appeal. Participants also made suggestions for how to improve messages with URL links such as offering a telephone number for local smoking-cessation programs to learn about available treatment and services in addition to a link to the local program website for those without internet access:

> *Maybe you could leave a phone number too, something like that...because like I said, I don't have all them fancy phones that can go on the computer.* [Nondaily smoker, male]

Features Games for Distraction

Participants were asked *a priori* questions about preferences for message content from a list of options. Nearly all participants preferred games for distraction:

> *Progressive things where today you do this, and then tomorrow, you're going to add to your score for this. And then it leads up to you get a silver cup, and then next week, you go for a gold cup...You know how games grab you and bring you in.* [Former smoker, male]

Barriers to Nicotine Replacement Therapy Use

Cost

Participants identified several barriers to starting or continuing NRT use including cost, side effects and safety, effectiveness, forgetting, and difficulties or dislikes. Cost was a commonly-cited barrier to using NRT and something participants wanted to receive information about, by SMS text message:

> *I don't know if they give them free in places. So maybe more information on how you can get them if you don't have money. Because they are pretty pricey.* [Nondaily smoker, female]

Side Effects and Safety

Concerns about NRT side effects and safety included cancer-risk beliefs, risks of smoking when using NRT, and potential for addiction to NRT. These concerns were a source of stress:

> *I was just like, "Oh my God. If I do smoke with this on, I'm going to like, blow up or something." So, I just felt like there was a lot of pressure. So, I wanted to smoke more.* [Nondaily smoker, female]
>
> *All these things to help you quit smoking, it's still nicotine going into your body. Can't that still cause you to get cancer?* [Nondaily smoker, female]

Perceived Effectiveness

Some participants reported NRT was ineffective in their previous attempts, and this was a barrier to subsequent use:

> *[The patches] they're not really great for-- if you smoke a lot and you've been smoking a long time, the patches don't help all that much.* [Daily smoker, male]

Difficulties and Dislikes

Participants described disliking the taste of lozenges and the difficult process of patch disposal:

> *I mean it's not a real pain in the neck, but they talk about it [the patch] like you got to get rid of it like it's a contaminant. Like it's medical waste or something.* [Nondaily smoker, male]

Forgetting

Few participants reported forgetting medications and some reported feeling aware of having the patch on:

> *I'm pretty much like "oh my gosh it's on me."* [Nondaily smoker, female]

Facilitators of Nicotine Replacement Therapy Use

Information

Queries about facilitators of medication use were organized around information, motivation, and behavioral skills constructs. People identified informational needs about side effects, safety, and dosing of medications and recommended providing this in simple, short formats:

> *Maybe, I don't understand how they say if you smoke less than ten cigarettes a day, start on a number two patch. If they explain that a little more.* [Nondaily smoker, male]

Motivation

When asked *a priori* questions about their preferences for informational, motivational, or behavioral skills medication messages, participants who preferred motivational messages described them as caring and conversational:

> *It's more personal, I don't know. More like let's get to it, it just seemed to me more normal.* [Daily smoker, female]

Behavioral Skills

Participants who liked the behavioral skills messages described them as straightforward and useful. Participants identified needed skills to take NRT such as how to manage slips, *ad lib* use, side effects, and getting refills:

> *In order not to slip up, take a couple of more-- of the lozenge or the patch. You know what I mean?* [Nondaily smoker, male]

When asked about tips or skills for remembering to take medications, participants thought reminders by SMS text message could be helpful:

> *Well, probably if I got a reminder on my phone, a text message or something.* [Daily smoker, female]

Phase 3: Modifications to Text Messaging Intervention

On the basis of the interview findings, we modified the existing messages including delivery timing, message text, and pictorial content and added new medication-focused messages for a final program of 244 scheduled messages. We adjusted message timing to add evening messages on some days for a total of 3 to 5 messages per day. Sample messages that were modified or developed based on qualitative data are shown in Table 2. In addition to these changes, we tried to leverage the users' relationship with their health care system by referencing local tobacco-cessation resources. Given the preferences for normal or conversational messages, we added a feature to respond with, "You are welcome" whenever someone texts "Thank you."

Table 2. Description of text message modifications and examples by theme.

Theme	Modification	Example
Program framework and content		
Personalization	We personalized 17 messages to the user's first name. Other types of personalization were not used, such as referencing the user's primary care provider.	You are getting closer to the big day [first_name]. It may help to cut back on the number of cigarettes you smoke. Give it a try.
Electronic cigarette (e-cigarette) content	We added messages that acknowledged that people are using electronic nicotine delivery systems.	Using e-cigs or vaping? We don't know if these help people quit cigarettes. Keep your smokefree goal in mind--to quit cigarettes completely.
Graphic content	We added emoji icons to 7 messages. We added links to personal stories from the Center for Disease Control's "Tips from former smokers" public health campaign and links to the World Health Organization's library of graphic warning labels.	Wow, 3 weeks smokefree. [balloon emoji] Give yourself a pat on the back! Just don't light up to celebrate; that is a slippery slope.
Specific facts versus general statements	We added messages with facts about the effects of quitting smoking.	Quitting smoking improves your health immediately, it lowers your blood pressure in the first 20 minutes.
Encouragement and framing of messages	We used participants' own language to replace negatively-framed messages with encouraging messages.	Wow, 2 weeks smokefree! Ask the person next to you for a high five! You did well! You deserve it.
Language clarity	We added definitions of triggers, lozenges, and slips and modified our description of the practice quit attempt.	You might slip by having a puff or even 1 or 2 cigarettes after you quit. Don't let 1 slip be an excuse to start smoking again. Learn from the situation ASAP and move on.
Language counseling versus coaching	We edited all messages to use the words "coach" or "coaching" instead of "counseling."	Quit-Tobacco coaches & medication can increase your chances of quitting. Free 1-on-1 coaching is available at MGH Community Health Centers. Call XXX-XXX-XXXX for more info.
Features: URL links	We modified the link content to reflect requested information such as information about e-cigarettes or patch dosing. We added telephone numbers together with URL links to additional tobacco treatment resources.	Using e-cigs or vaping? We don't yet know if vaping is safe or if it helps to quit smoking. Nicotine patches are safe & effective. Learn more: URL.
Features: games for distraction	We created a trivia game prompted by a keyword TRIVIA.	Distract yourself with trivia for a few minutes. When did MGH open its doors? Text A for 1801, B for 1821 or C for 1905; <B response> That's right! [gold cup emoji] MGH opened in 1821. It is the 3rd oldest general hospital in the US.
Medication information, motivation, and behavioral skills		
Information: dosing	We added messages with simple dosing instructions.	Patch users, if you smoke 10 or more cigs per day start with step 1. If you smoke less than 10 cigs start with step 2: URL.
Information: safety and side effects	We added messages with information about the maximum daily dose to reassure participants concerned about overuse and describing the low risk of addiction to nicotine medications. We also added messages with advice for dealing with common side effects of skin irritation or sleep disturbance.	The nicotine patch and lozenge have less nicotine than cigarettes. You are not likely to become addicted to the patch or lozenges.
Information: medication effectiveness	We added messages encouraging users to consider combination therapy in consultation with their doctor to address concerns of ineffectiveness and advice on correct medication use to maximize effectiveness.	Consider using the patch and gum or lozenge together if you've been unable to quit with medication in the past. Ask your doctor for advice.
Motivation: forgetting	We added weekly reminder messages offering conversational encouragement and asking users if they used medications that day.	We hope you are doing well. Did you use your nicotine patch or lozenge today? Reply with USED or NOT USED.

Theme	Modification	Example
Motivation: social support	We added motivational messages highlighting social motivations.	Nicotine patches and lozenges increase your chance of quitting, which will protect your health and help you to be there for your family.
Behavioral skills: cost	We added messages describing behavioral skills including checking on insurance coverage and contacting the local quit-line which has free medication opportunities.	Your insurance may cover quit smoking medications. To learn more about your options, speak with your doctor & visit: URL.
Behavioral skills: difficulties and dislikes	We added a message about safe disposal, labeled as a tip instead of a rule or regulation.	Tip: Save the pouch your nicotine patch came in. Fold used patches sticky sides together and throw them out in the pouch safely away from kids & pets.

Discussion

This study aimed to develop an SMS text messaging program tailored to readiness to quit using preferences of primary care patients who smoke cigarettes and to explore patients' previous experiences with NRT with the purpose of developing messages promoting NRT use.

Principal Findings

By combining real-time message ratings with daily interviews, we identified SMS text message modifications including preferences for the inclusion of graphics, expectations around e-cigarette content, preferences for the inclusion of personalization by user's name, and recommendations to make URL links more impactful by using pictures or adding telephone numbers for those without internet access. Real-time ratings provided feedback, in most cases, within 30 min of receiving the message. We also identified preferences for message style such as a conversational tone and use of emoji graphics. Participants described barriers to taking smoking-cessation medications including costs, side effects and safety concerns, and perceived effectiveness.

Comparison With Previous Work

Many previous mobile health apps and SMS text messaging interventions used focus groups, interviews with individuals in the target population, or professional input to develop message content [4,46,47,49,50,60]. Our work used a hybrid approach on the basis of recommended steps for SMS text messaging program development [61]. Few previous studies have combined real-time assessments of SMS text messages with daily interviews [60]. Our interviews provided insight about what patients were doing when they received messages and their reaction in that setting. Although we used this real-time rating for intervention development, it has also been used within interventions through machine-learning and 5-item real-time user ratings to select messages that influence smoking cessation behaviors [62].

In this study, when presented with different options for personalizing messages, participants liked personalizing SMS text messages with their first names, but the use of the physician's name was viewed as intrusive by some. Previous work examining preferences for SMS text messages about health topics has produced conflicting results, with some participants expressing concerns about privacy of message content about health screening tests, whereas others expressed no concern despite the inclusion of sensitive material such as HIV status [63,64]. We tried to balance privacy concerns by using first names but excluding personal information described as intrusive. For example, instead of referencing the individual physician, we included the name of the local health care system [65].

Previous work has explored the effectiveness of graphic images or emoticons in nutrition campaigns [66,67]. Previous work has also shown that individuals communicate about tobacco products via social media using emoticons or images [68]. To our knowledge, this is the first study describing user preferences for graphic images or emoticons in an SMS text messaging program for smokers. It is possible that proactively sending SMS text messages with a link to graphic images may confer some of the benefits graphic warning labels confer on smoking cessation [69].

Limitations

Our sample recruited participants from an earlier SMS text messaging feasibility study. All of them had previously seen a smoking cessation SMS text messaging program; this experience may have introduced bias. Several were former smokers. We tested only a subset of messages over 2 days and did not gather participants' reactions to the entire SMS text messaging program. We used a 2-item rating scale for simplicity and with this scale, most of the messages were rated positively. Use of a nonbinary rating instrument, changing the rating system to reflect the targeted behavioral constructs such as self-efficacy, or rating usability [50] may produce greater insight into message preferences and impact.

Conclusions

This message development method of combining message ratings with daily telephone interviews is novel and was feasible among a sample of smokers in primary care. This method produced insights and modifications to the SMS text messaging intervention, including edits to the message style such as addition of graphics, conversational tone, editing of URL links, and clarifying the language. User-reported barriers and facilitators of NRT use were used to generate informational messages about medication safety, use and effectiveness, motivational messages in a conversational style, and messages describing behavioral skills such as dealing with slips when on NRT.

Combining real-time SMS text message ratings with qualitative data was feasible among primary care patients who smoke, directed modifications to SMS text message content to better tailor it to primary care patient preferences, and was used to produce novel medication-adherence messages. The final SMS text messaging program is being tested in a pilot randomized trial of SMS text messaging and mailed NRT among primary care patients who smoke (NCT03174158).

Acknowledgments

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Conflicts of Interest

GK has a family financial interest in Dimagi, Inc, and is a paid consultant for Click Therapeutics, Inc. NAR has consulted without pay for Pfizer, is a paid consultant for Achieve Life Sciences, and received royalties from UpToDate for chapters on smoking cessation. ERP received royalties from UpToDate for chapters on smoking cessation. JEH has been a paid consultant for Merck and Natera. LA has stock in Welltok, Inc, and receives royalties from the licensing of Text2Quit to Welltok, Inc.

Multimedia Appendix 1

Qualitative themes and kappa statistics.

[DOCX File, 14KB - mhealth_v7i3e11498_app1.docx]

Multimedia Appendix 2

Distribution of response time to message rating queries.

[PNG File, 65KB - mhealth_v7i3e11498_app2.png]

Multimedia Appendix 3

Rating message responses (N=149).

[DOCX File, 12KB - mhealth_v7i3e11498_app3.docx]

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Abbreviations

e-cigarette: electronic cigarette
EHR: electronic health record
IMB: Information-Motivation-Behavioral Skills
NRT: nicotine replacement therapy
PQA: practice quit attempt
SMS: short message service

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Review

Examining Development Processes for Text Messaging Interventions to Prevent Cardiovascular Disease: Systematic Literature Review

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Abstract

Background: Interventions delivered by mobile phones have the potential to prevent cardiovascular disease (CVD) by supporting behavior change toward healthier lifestyles and treatment adherence. To allow replication and adaptation of these interventions across settings, it is important to fully understand how they have been developed. However, the development processes of these interventions have not previously been systematically examined.

Objective: This study aimed to systematically describe and compare the development process of text messaging interventions identified in the Text2PreventCVD systematic review.

Methods: We extracted data about the development process of the 9 interventions identified in the Text2PreventCVD systematic review. Data extraction, which was guided by frameworks for the development of complex interventions, considered the following development stages: intervention planning, design, development, and pretesting. Following data extraction, we invited the developers of the interventions to contribute to our study by reviewing the accuracy of the extracted data and providing additional data not reported in the available publications.

Results: A comprehensive description of the development process was available for 5 interventions. Multiple methodologies were used for the development of each intervention. Intervention planning involved gathering information from stakeholder consultations, literature reviews, examination of relevant theory, and preliminary qualitative research. Intervention design involved the use of behavior change theories and behavior change techniques. Intervention development involved (1) generating message content based on clinical guidelines and expert opinions; (2) conducting literature reviews and primary qualitative research to inform decisions about message frequency, timing, and level of tailoring; and (3) gathering end-user feedback concerning message

readability, intervention acceptability, and perceived utility. Intervention pretesting involved pilot studies with samples of 10 to 30 participants receiving messages for a period ranging from 1 to 4 weeks.

Conclusions: The development process of the text messaging interventions examined was complex and comprehensive, involving multiple studies to guide decisions about the scope, content, and structure of the interventions. Additional research is needed to establish whether effective messaging systems can be adapted from work already done or whether this level of development is needed for application in other conditions and settings.

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KEYWORDS

systematic review; cardiovascular disease; telemedicine; text messaging; methods

Introduction

Background

Worldwide, cardiovascular disease (CVD) is a major cause of premature morbidity and mortality [1]. Observational studies have shown that a few potentially modifiable risk factors account for most of the risk of CVD outcomes [2,3]. These risk factors, which include abnormal blood lipids, smoking, diabetes, and high blood pressure, are common and often occur together in the same individual. For example, more than two-thirds of people with diabetes also have high blood pressure [4]. There is good evidence now that low-cost medications and changes in lifestyle can improve risk profiles for individuals [5]. However, suboptimal adherence to prescribed medication and lifestyle modification is a major barrier to the health benefits of these evidence-based treatments [6].

Mobile communications technology has the potential to support behavior change and treatment adherence by facilitating remote, interactive, and timely access to relevant information and providing context-specific support and prompts to action [7]. The simplest and most widely available mobile communications standard is the short message service (SMS) text message. Results from some but not all trials suggest that SMS text message interventions may be a useful adjunct to usual care for the prevention and management of CVD [8-10]. The quality and success of these interventions partially depend on how they have been developed. Guidelines for the development of digital [11] and mobile Health (mHealth) behavior change interventions [12,13] now exist. They propose a number of steps to follow to maximize intervention benefit, including formative research for insights into the target audience and health behavior, designing the text messaging program, pretesting the text messaging program concept and messages, and revising the text messaging program.

However, the development process of mHealth interventions is frequently underreported and not well understood, having been described as “hidden within a black box” [14]. Understanding how mHealth interventions are developed is crucial to allow replication and adaptation of successful interventions across settings—a necessary step to accumulating evidence around the effectiveness of these interventions. In 2016, the *International Consortium of Text2PreventCVD Trial Collaborators Group* was established as part of an initiative to gather and analyze individual participant data from randomized clinical trials identified as part of a systematic literature review of text messaging interventions to prevent CVDs [15]. This international consortium offered a unique opportunity for an in-depth examination of the development processes of these interventions, based on information directly supplied by the developers of the interventions (rather than merely relying on data reported in available publications, as commonly done in conventional systematic literature reviews).

Objective

The aim of this study was to systematically describe and compare the processes followed to develop the text messaging interventions for the prevention and management of CVD that were included in the Text2PreventCVD meta-analysis.

Methods

Design

We undertook a systematic description and comparison of the development processes of the interventions included in the Text2PreventCVD systematic review (the results from the individual participant data meta-analysis examining the effectiveness of the interventions in the prevention of CVD will be published elsewhere).

Identification of Studies

The protocol including the methods for the identification of trials included in the Text2PreventCVD systematic review is available elsewhere [15]. In short, 4 electronic databases of published studies (MEDLINE, EMBASE, PsycINFO, and Cochrane Library) and international trial registries were searched to identify potentially relevant studies. The eligibility of the retrieved references was assessed by 2 independent reviewers based on the following inclusion criteria: (1) randomized clinical trials of mobile phone SMS or text message intervention with a control group receiving standard care (no messages or some form of control message), (2) follow-up period of at least 6 months, (3) with a minimum 70% of completed follow-up of patients, (4) focusing on CVD primary and secondary prevention in men and women aged 18 years and older, (5) evaluating interventions applying at least 2 behavioral techniques to support behavior change (as an indicator of a comprehensive CVD prevention program rather than a single focus, eg, medication adherence reminders), and (6) with a minimum total sample size of 30 participants (as sample size was perceived to be a surrogate marker of study quality).

The principal investigators of the 9 selected trials [8,9,16-34] meeting the inclusion criteria described above were invited by

email to join the International Consortium of Text2PreventCVD Trial Collaborators Group. Reminders were sent after a week to nonresponders, followed by approaching other investigators by email, phone calls, and fax. Investigators were requested to share their data after obtaining a signed agreement. Authors of 5 of the trials (Tobacco, Exercise and Diet Messages [TEXT ME] [9,19,32], Islam et al [22,33], Heart Exercise And Remote Technologies [Heart] [24-26,30], Mobile Phone Text Messages to Support Treatment Adherence in Adults With High Blood Pressure [StAR[[8,18], and Text message and Internet-based comprehensive cardiac rehabilitation intervention [Text4Heart] [21,29]) agreed to participate by providing data on the development of their interventions.

Data Collection

Before data extraction, 3 researchers (IRC, AF, and KB) designed a data extraction form in an iterative process. The Medical Research Council framework for the development of complex interventions [35] and other available frameworks [11,12,36,37] were used to ensure the data extraction form covered all relevant areas in the development of mHealth interventions. The resulting data extraction form covered the following 4 domains: intervention planning, intervention design, intervention development, and intervention pretesting. The final form was reviewed and approved by the senior authors of the 5 trials included in this study. One researcher (IRC) then used the final form to extract all the relevant data available in the full texts and appendices of the manuscripts previously identified. Subsequently, the extracted information was sent by email to the authors of the 5 trials that agreed to take part in this study. They were requested to cross-check the accuracy of the extracted information and to provide additional details not reported in the available publications. When needed, we recontacted the authors for additional details or clarifications about the methods used to develop their intervention.

Data Analysis

We carried out a narrative synthesis of the results, describing the different methods identified for developing the interventions. We classified the methods according to the 4 development stages considered (intervention planning, design, development, and pretesting). We calculated, in terms of frequency, the number of interventions that applied each of the methods identified and tabulated this information (Table 1). To allow head-to-head comparisons across interventions, we present in tables (Tables 2-4), and describe narratively, more detailed information about the methods used for the development of each intervention.

Results

Intervention Characteristics

We extracted information about the main characteristics of the selected mHealth interventions, including the level of customization of the messages, timing and frequency of delivering the messages, content (degree of personalization, readability, length, and presence of sender´s signature), directionality (unidirectional or bidirectional), and type of platform used to deliver the messages (see Multimedia Appendices 1 and 2). All the interventions were based on text messages containing less than 160 characters, which included the sender's signature, and which were sent free of charge to participants. Most interventions included some degree of customization either in the content of the message (TEXT ME [9,19,32] and Heart [24-26,30]), preferred timing (Text4Heart [21,29] and StAR [8,18]), or language (StAR [8,18]). The number of messages sent per week ranged from 1 (StAR [8,18]) to 7 (Text4Heart [21,29]). Furthermore, 3 interventions (TEXT ME [9,19,32], Islam [22,33], and Heart [24-26,30]) used unidirectional messages, whereas 2 interventions (Text4Heart [21,29] and StAR [8,18]) used bidirectional messages (ie, allowing the participants to not only receive but also send messages).

Although the interventions generally aimed at preventing CVD, they varied in terms of their specific goal and population targeted. The TEXT ME intervention aimed at decreasing cardiovascular risk by encouraging lifestyle change in people with coronary heart disease in Australia [9,19,32]. The Text4Heart intervention aimed to support adherence to healthy lifestyle behaviors in adults with coronary heart disease in New Zealand [21,29]. The intervention developed by Islam et al [22,33] aimed to improve glycemic control in patients with type 2 diabetes in Bangladesh. The Heart intervention aimed to promote exercise capacity and physical activity behavior in people with ischemic heart disease in New Zealand [24-26,30]. The StAR intervention aimed to support treatment adherence and blood pressure control in adults with hypertension in South Africa [8,18].

Intervention Development Process

All the interventions followed a comprehensive development process (or framework) that involved 1 or more studies to inform each development stage, including the planning, design, development, and pretesting of the interventions (Table 1).

Intervention Planning

A number of different information sources were used to identify the key behavioral issues, needs, and challenges the intervention was planned to address (Multimedia Appendix 3). These included stakeholder consultations (used in all interventions), literature reviews (TEXT ME [9,19,32], Text4Heart [21,29], Islam [22,33], and StAR [8,18]), examination of relevant theory (TEXT ME [9,19,32], Text4Heart [21,29], and Heart [24-26,30]), and preliminary qualitative research (StAR [8,18] and Heart [24-26,30]).

Intervention Design

Interventions were designed according to a wide range of behavior change theories (Table 2). Overall, 3 interventions (TEXT ME [9,19,32], Text4Heart [21,29], and Islam [22,33]) were based on multiple theories, whereas 2 interventions (Heart [24-26,30] and StAR [8,18]) relied on a single theory. All interventions were designed following multiple behavior change techniques (mean number of techniques per intervention=8, range=2 to 17). Most common techniques included general encouragement (used in 4 interventions), information about behavior-health link (3 interventions), information on consequences (3 interventions), time management advice (3 interventions), and goal setting (3 interventions).

Table 1. Frequency of the different methods used to inform the development process of the interventions identified.

Methods used to inform the development process of the interventions identified	Number of trials (trial name)
Intervention planning	
Information sources consulted to identify the key behavioral issues, needs, and challenges that the planned intervention was intended to address	
Consultation with experts, users, or other stakeholders	5 (TEXT ME[a] [9,19,32], Text4Heart[b] [21,29], Islam [22,33], Heart[c] [24-26,30], and StAR[d] [8,18])
Literature reviews	4 (TEXT ME [9,19,32], Text4Heart [21,29], Islam [22,33], and StAR [8,18])
Primary research with users	4 (TEXT ME [9,19,32], Text4Heart [21,29], Heart [24-26,30], and StAR [8,18])
Examination of relevant theory	3 (TEXT ME [9,19,32], Text4Heart [21,29], and Heart [24-26,30])
Intervention design	
Theories used	
Social-cognitive theory [38]	2 (Text4Heart [21,29] and TEXT ME [9,19,32])
Control theory [39]	1 (TEXT ME [9,19,32])
Information-motivation-behavioral skills model [40]	1 (TEXT ME [9,19,32])
Operant conditioning [41]	1 (TEXT ME [9,19,32])
Theory of planned behavior [42]	1 (TEXT ME [9,19,32])
Theory of reasoned action [43]	1 (TEXT ME [9,19,32])
Common sense model [44]	1 (Text4Heart [21,29])
Behavioral learning theory [45]	1 (Islam [22,33])
Transtheoretical model of behavioral change [46]	1 (Islam [22,33])
Self-efficacy theory framework [47]	1 (Heart [24-26,30])
Integrated theory of behavior change [48]	1 (StAR [8,18])
No theory used	0
Behavior change techniques used	
Provide general encouragement	4 (TEXT ME [9,19,32], Text4Heart [21,29], Heart [24-26,30], and StAR [8,18])
Provide information about behavior-health link	3 (TEXT ME [9,19,32], Text4Heart [21,29], and StAR [8,18])
Provide information on consequences	3 (TEXT ME [9,19,32], Text4Heart [21,29], and StAR [8,18])
Prompt specific goal setting	3 (Text4Heart [21,29], Heart [24-26,30], and StAR [8,18])
Time management	3 (TEXT ME [9,19,32], Text4Heart [21,29], and Heart [24-26,30])
Prompt barrier identification	3 (TEXT ME [9,19,32], Text4Heart [21,29], and Heart [24-26,30])
Set graded tasks	2 (TEXT ME [9,19,32] and Text4Heart [21,29])
Provide instruction	2 (TEXT ME [9,19,32] and Text4Heart [21,29])
Model or demonstrate the behavior	2 (Text4Heart [21,29] and Heart [24-26,30])
Prompt self-monitoring of behavior	2 (Text4Heart [21,29] and TEXT ME [9,19,32])
Provide information about others' approval	1 (StAR [8,19])
Prompt intention formation	1 (Text4Heart [21,29])
Prompt review of behavioral goals	1 (Text4Heart [21,29])
Provide feedback on performance	1 (Text4Heart [21,29])
Teach to use prompts or cues	1 (TEXT ME [9,19,32])
Provide opportunities for social comparison	1 (Text4Heart [21,29])
Plan social support or social change	1 (Text4Heart [21,29])
Relapse prevention	1 (TEXT ME [9,19,32])
Stress management	1 (Text4Heart [21,29])

Methods used to inform the development process of the interventions identified	Number of trials (trial name)
Intervention development	
Message content based on	
Clinical guidelines	5 (TEXT ME [9,19,32], Text4Heart [21,29], Islam [22,33], Heart [24-26,30], and StAR [8,18])
Expert opinion	2 (Islam [22,33] and StAR [8,18])
Qualitative patient interviews	1 (Heart [24-26,30])
Other intervention characteristics (timing, frequency, directionality, etc) based on	
Literature reviews	3 (TEXT ME [9,19,32], Text4Heart [21,29], and StAR [8,18])
Primary research	2 (Heart [24-26,30] and StAR [8,18])
End-user feedback gathered	
Yes (questionnaires)	4 (Heart [24-26,30], Text4Heart [21,29], TEXT ME [9,19,32], and StAR [8,18])
Yes (semistructured interviews)	2 (Text4Heart [21,29] and Islam [22,33])
Yes (focus groups)	1 (StAR [8,18])
No	0
Intervention pretesting	
Yes	5 (TEXT ME [9,19,32], Text4Heart [21,29], Islam [22,33], Heart [24-26,30], and StAR [8,18])
No	0

[a]TEXT ME: Tobacco, Exercise and Diet Messages.

[b]Text4Heart: Text message and Internet-based comprehensive cardiac rehabilitation intervention.

[c]Heart: Heart Exercise And Remote Technologies.

[d]StAR: Mobile Phone Text Messages to Support Treatment Adherence in Adults With High Blood Pressure.

Intervention Development

A number of different sources were used to inform the content of the messages, namely, clinical guidelines (all interventions), expert opinion (Islam [22,33], StAR [8,18], and (Heart [24-26,30]), and feedback from qualitative formative work (Heart [24-26,30]; see Multimedia Appendix 4). A number of different professionals were involved in the development of the messages, including clinicians (all interventions), academics (TEXT ME [9,19,32], Islam [22,33], Heart [24-26,30], and StAR [8,18]), health psychologists (Text4Heart [21,29]), exercise physiologists and cardiologists (Heart [24-26,30]), and patient and public representatives (TEXT ME [9,19,32], StAR [8,18], and Text4Heart [21,29]). The frequency and timing of the messages, intervention duration, directionality, and level of tailoring were determined based on literature reviews (TEXT ME [9,19,32], StAR [8,18], and Text4Heart [21,29]), qualitative research (Heart [24-26,30] and StAR [8,18]), and previous similar studies undertaken by the authors (Text4Heart [21,29] and Heart [24-26,30]).

End-user feedback was gathered to inform the development of all the interventions (Table 3). Feedback was most frequently gathered through structured questionnaires (TEXT ME [9,19,32], Text4Heart [21,29], Islam [22,33], and Heart [24-26,30]). Some studies also used qualitative methods, namely, semistructured interviews (Text4Heart [21,29] and StAR [8,18]) and focus groups (StAR [8,18]). Readability, acceptability, and perceived utility were the aspects more frequently examined. End users' feedback contributed to the refinement of all the interventions (simplifying the content of the messages, changing their tone, and increasing the level of tailoring, among others).

Intervention Pretesting

All the interventions were pretested before being formally evaluated in a clinical trial. Pretesting activities involved pilot studies with a purposive or convenience sample of 10 to 30 participants who received the text messages for a period ranging from 1 to 4 weeks (Table 4). A number of modifications were introduced in all interventions as a result of the pilot studies. They included the refinement of the message bank and software system to deliver them (TEXT ME [9,19,32]), increasing the level of tailoring and modifying the website system (Text4Heart [21,29]), changing the timing of the messages (Islam [22,33] and StAR [8,18]), including all SMS messages on a website for the participants to review retrospectively if they chose (Heart [24-26,30]), and allowing the participants to change the language of the messages (StAR [8,18]).

Table 2. Intervention design: use of theory and behavior change techniques.

Trial	Theoretical approach adopted for intervention	In what way were theories used to develop the intervention	Behavior change techniques used
TEXT ME[a] [9,19,32]	Control theory, information-motivation-behavioral skills model, operant conditioning, social-cognitive theory, theory of planned behavior, and theory of reasoned action	Select intervention techniques	Provide information about behavior-health link, provide information on consequences, prompt barrier identification, provide general encouragement, set graded tasks, provide instruction, prompt self-monitoring of behavior, teach to use prompts or cues, relapse prevention, and time management
Text4Heart[b] [21,29]	Social-cognitive theory and common sense model	Select and develop intervention techniques	Provide information about behavior-health link, provide information on consequences, prompt intention formation, prompt barrier identification, provide general encouragement, set graded tasks, provide instruction, model or demonstrate the behavior, prompt specific goal setting, prompt review of behavioral goals, prompt self-monitoring of behavior, provide feedback on performance, provide opportunities for social comparison, plan social support or social change, stress management, time management, and interpretation and normalizing of physical or emotional symptoms when changing behavior
Islam [22,33]	Behavioral learning theory and transtheoretical model of behavioral change	Select and develop intervention techniques	Reinforce and encourage healthy behavior and lifestyle modification, stimuli for medication adherence—using behavior learning techniques—and inform, motivate, and provide psychological support—using transtheoretical model of behavior change techniques
Heart[c] [24-26,30]	Self-efficacy theory framework	Select and develop intervention techniques	Prompt barrier identification; provide general encouragement; model or demonstrate the behavior; prompt specific goal setting; time management; coping efficacy, self-regulation, social support; scheduling efficacy; interpreting physiology, including somatic and emotional states; and exercise prescription
StAR[d] [8,18]	Integrated theory of behavior change	Select intervention techniques and tailor intervention techniques to recipients	Provide information about behavior-health link, provide information on consequences, provide information about others' approval, provide general encouragement, and prompt specific goal setting

[a]TEXT ME: Tobacco, Exercise and Diet Messages.

[b]Text4Heart: Text message and Internet-based comprehensive cardiac rehabilitation intervention.

[c]Heart: Heart Exercise And Remote Technologies.

[d]StAR: Mobile Phone Text Messages to Support Treatment Adherence in Adults With High Blood Pressure.

Interventions With Development Details Not Available

Additional information about intervention development was not available from authors for 4 of the 9 trials identified in the Text2PreventCVD systematic review [16,17,23,31,34]. Only 1 of them replied to our invitations, but they were unable to share data in the time specified for the analysis. These interventions were heterogeneous in scope (targeting diabetes prevention [31] and control [16,17], hypertension [23], and adherence to cardiovascular preventive treatment [34]) and setting (inner city emergency department in the United States [16,17], ambulatory care in Russia [23], community of working men in India [31], and primary care general practices in England [34]). The intervention planning was only reported in 1 of the interventions (Text-Med intervention [16,17], which used qualitative research methods to elicit user views of the planned behavior changes. The process of designing the intervention was reported only in 1 of the studies [31], which used the transtheoretical model of behavioral change. Intervention development and pretesting was only reported by 1 intervention (Text-Med intervention [16,17], which used clinical guidelines, expert opinions, and qualitative research with patients to develop the intervention, pretesting it in a 1-week pilot trial with 23 participants). Additional details about the development process of the rest of the interventions were not identified in the available publications.

Table 3. Intervention development: end-user feedback.

Trial	Methods used to gather end-user feedback	Aspects intended to be examined through end-user feedback	Changes in the intervention implemented as a result of end users' feedback
TEXT ME[a] [9,19,32]	Data collection: questionnaires (n: 53); sampling: opportunistic	Readability and perceived utility	Stop sending messages about eating meat products to vegetarians and grammatical suggestions
Text4Heart[b] [21,29]	Data collection: website usage statistics (n=85), mobile phone usage survey (n=74), intervention feedback surveys (n=85), and intervention feedback semistructured interviews (n=17); sampling: opportunistic	Choice of technology to deliver the messages, acceptability of physical activity messages, level of tailoring, and directionality of messages	Intervention delivered by short message service only (too few end users had smartphones at the time), changes made to content of exercise prescription messages, higher level of tailoring (messages personalized with name, time of day to receive messages, and primary behavior targeted), and 2-way messaging (participants could text in questions and receive a personal reply)
Islam [22,33]	Data collection: face-to-face interviews using structured questionnaires (n=50); sampling: purposive	Readability, acceptability, and perceived	Messages made simpler (only 1 content per message)
Heart[c] [24-26,30]	Data collection: Web-based survey (n=20); sampling: purposive	Readability, acceptability, perceived utility, and persuasiveness	Actions taken to resolve technical difficulties encountered by participants (eg, written instructions about how to log on to the study website)
StAR[d] [8,18]	Data collection: semistructured interviews and focus groups with patients (n=35), primary care providers (n=12), health systems managers (n=5), and chronic dispensing service providers (n=3); sampling: purposive	Readability, acceptability, perceived utility, and persuasiveness	Tone, use of abbreviations, and addition of named provider to sign off message

[a]TEXT ME: Tobacco, Exercise and Diet Messages.

[b]Text4Heart: Text message and Internet-based comprehensive cardiac rehabilitation intervention.

[c]Heart: Heart Exercise And Remote Technologies.

[d]StAR: Mobile Phone Text Messages to Support Treatment Adherence in Adults With High Blood Pressure.

Table 4. Intervention pretesting.

Trial	Pretesting methods	Changes in the intervention implemented as a result of the pretesting exercise
TEXT ME[a] [9,19,32]	n=16; sampling: convenient; additional details: The aim of the pilot testing was to evaluate the messages and the system to deliver them. Participants received the relevant messages for 1 week. At the conclusion of the pilot study, participants received a questionnaire asking for the potential impact of the messages to change behavior, the process of receiving messages (eg, timing, personalization, and frequency), and for any further feedback	Refinement of the message bank and software system
Text4Heart[b] [21,29]	n=20; sampling: convenient; additional details: The aim of the pilot testing was to test the healthy eating messages. Participants received 1 text message per day (28 in total) and had access to the supporting website; 4 weeks later, participants were contacted by text and email to complete a follow-up Web-based survey. Website usage statistics including the frequency, login period, and page views were also tracked	No changes made to healthy eating message content or tone (viewed as acceptable), self-efficacy included as underlying theoretical construct; higher level of tailoring (messages personalized with name, time of day to receive messages, and primary behavior targeted), website log-on system simplified
Islam [22,33]	n=30; sampling: purposive; additional details: intervention pretested in patients with type 2 diabetes selected from a diabetes clinic of a tertiary hospital	Timing of text messages was set to be delivered from 10 am to 5 pm
Heart[c] [24-26,30]	n=10; sampling: convenience; additional details: Pilot testing of the intervention was integrated into the full randomized controlled trial (during the study, the first 10 study participants were closely monitored for 6 weeks to ensure that they received the messages and to resolve technical issues)	All SMS[d] messages were made available on a website for participants to review retrospectively if they chose and correction of grammatical errors identified by participants
StAR[e] [8,18]	n=19; sampling: purposive; additional details: The full intervention package was tested in the 3 languages most commonly used in Cape Town (English, Afrikaans, and isiXhosa). Participants were contacted on a weekly basis by a researcher for a semi-structured interview on their experience of the intervention and the SMS text message delivery system	Change timing of the message and allowing users to change language

[a]TEXT ME: Tobacco, Exercise and Diet Messages.

[b]Text4Heart: Text message and Internet-based comprehensive cardiac rehabilitation intervention.

[c]Heart: Heart Exercise And Remote Technologies.

[d]SMS: short message service.

[e]StAR: Mobile Phone Text Messages to Support Treatment Adherence in Adults With High Blood Pressure.

Discussion

Summary of Findings

In this study, we conducted an in-depth examination of the development process for 5 of the 9 mHealth interventions identified as a part of the Text2PreventCVD meta-analysis. We observed that the development process of these interventions was complex and comprehensive, involving formative work with multiple studies using both quantitative and qualitative designs to gather evidence to inform decisions about the scope, content, and structure of the intended interventions. Although formative studies varied in terms of the way the interventions were developed, the following processes were identified in all the interventions: use of theory and behavior change techniques for intervention design, use of end-user feedback for intervention development, and pilot studies for intervention pretesting.

Comparison of Findings With Previous Literature

It has been argued that, as in any health promotion practice, quality, rigor, and careful development of mHealth interventions remain essential [49]. However, a number of recent systematic reviews highlight that a significant proportion of health behavior interventions are not based on theory [50-52], do not follow a user-centered approach [11,53], and lack adequate pretesting procedures [54,55]. Indeed, it has been argued that the SMS text message development is commonly hidden within a black box, lacking deconstruction of the steps involved in creating messages as well as rigorous evaluations of the quality of the health communication messages [14]. None of this is supported by findings from our study, which showed that the development process of the interventions contributing to the Text2PreventCVD meta-analysis included those elements. At least 3 factors could contribute to explaining this apparent discrepancy. First, as opposed to previous reviews, our findings are mostly based on data supplied by the authors of the studies themselves rather than merely by information in published manuscripts. Therefore, it is plausible that some interventions were not underdeveloped but rather underreported. Previous studies have already noted that the documentation and critical analysis of the formative research process required in the development and refinement of messages is a neglected area in the published literature [56]. For quality assessment purposes and to improve future research and program implementation, this research should be accessible for scientific scrutiny. This

should include a description of the development of the SMS content (and quality of the evidence on which the messages are based), the theoretical basis of the messages (and the rationale for choosing it), cultural adaptation to the target population, and context along with an analysis of how the content is received by users [54,57,58]. This would enable translation and assessment of generalizability of findings of the research. Second, although all the examined interventions included as part of their development the use of theory, user feedback, and pretesting activities, it could be argued that these elements were not rigorously applied, a common criticism in the current literature [11,37,52]. This may be particularly relevant with the use of theory; superficial use of theory in the development of health behavior interventions has been identified as one of the main barriers hindering progress in quantifying its impact on behavior change [52]. Third, almost half of the interventions initially identified were not able to be included, and this could have resulted in a selection bias (leading to an overrepresentation of more comprehensively developed interventions), as discussed as part of the limitations below.

Implications for Future Research

Future studies are needed to explore the extent to which the development process is associated with intervention success and to identify *activeingredients* in the development process. To do so, valid and reliable measures of intervention development complexity are very much needed as well as data from a larger number of more heterogeneously developed interventions. Publication bias (a common source of potential bias in systematic reviews [59]) should also be adequately accounted for in such studies, as less successful interventions may be less likely to be published and may be less likely to have followed a thorough development process. Intervention success should not only be evaluated in terms of clinical effectiveness observed within the context of a clinical trial but also in terms of research translation capacity, that is, the extent to which the interventions are successfully implemented at the population level and are acceptable and perceived as useful by the target populations.

Strengths and Weaknesses

This study provides for the first time a detailed and systematic description of the development process of mHealth interventions to support behavior change in people with CVD. The data described in our study were initially extracted from available publications and subsequently reviewed by the authors of the relevant trials to maximize their accuracy and completeness. Our study has some limitations. First, although 9 trials were identified in the Text2PreventCVD meta-analysis, there was no contribution beyond published data for 4 of them (ie, the information we initially extracted from the publications was not reviewed and added by the developers). This could bias our results if the reason for not providing further data was related to the methods used to develop those interventions. Second, in our study, we could not examine the important question of whether more comprehensive development processes lead to more successful interventions. The main reason for not being able to explore this was the lack of sufficient variability across intervention development methods. As shown in Table 1, all the interventions included in this study were developed using complex and comprehensive methods: all of them carried out studies to identify the key behavioral issues, needs, and challenges that the planned intervention was intended to address; all of them used 1 or more theory and behavior change techniques to design the intervention; all developed the messages based on a number of different information sources; all gathered end-user feedback; and all conducted feasibility studies to pretest the interventions.

Conclusions

A detailed examination of the development of SMS interventions to improve CVD showed the processes used were complex and comprehensive. Our study identified a wide range of different methodologies to inform intervention planning, intervention design, intervention development, and intervention pretesting. Literature review and stakeholder consultations were the most frequently used methods to guide intervention planning and design. Regarding the development of the interventions, clinical guidelines and expert consultations were the main information sources for message content, whereas literature reviews and end-user feedback were the main source to inform decisions about other components of the interventions such as timing, directionality, or level of tailoring. Pilot studies with relatively small sample sizes were frequently used for intervention pretesting. Further work is needed to establish whether effective messaging systems can be adapted from work already done or whether this level of development is always needed for application in other conditions and settings. Additional research is also needed to examine the potential association between development methods and intervention success as well as to identify *activeingredients* in the development methods.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Characteristics of the interventions (message customization, personalization, delivery timing, frequency, message content, directionality, character set).

[PDF File (Adobe PDF File), 258KB - mhealth_v7i3e12191_app1.pdf]

Multimedia Appendix 2

Platform characteristics.

[PDF File (Adobe PDF File), 233KB - mhealth_v7i3e12191_app2.pdf]

Multimedia Appendix 3

Intervention planning: information sources used to identify the key behavioral issues, needs, and challenges that the planned intervention was intended to address.

[PDF File (Adobe PDF File), 143KB - mhealth_v7i3e12191_app3.pdf]

Multimedia Appendix 4

Intervention development: sources used to inform the development of the intervention.

[PDF File (Adobe PDF File), 139KB - mhealth_v7i3e12191_app4.pdf]

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Abbreviations

CVD: cardiovascular disease
Heart: Heart Exercise And Remote Technologies
mHealth: mobile health
NIHR: National Institute for Health Research
SMS: short message service
StAR: Mobile Phone Text Messages to Support Treatment Adherence in Adults With High Blood Pressure
Text4Heart: Text message and Internet-based comprehensive cardiac rehabilitation intervention
TEXT ME: Tobacco, Exercise and Diet Messages

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Original Paper

Comparison of Developers' and End-Users' Perspectives About Smoking Cessation Support Through the Crush the Crave App

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Abstract

Background: High smoking rates among end-users, combined with their high rates of app use, render this age group as a particularly captive audience for quit smoking apps. There is emerging evidence that apps are an effective way to support smoking cessation among end-users. How the expectations behind the design of apps align with the needs and preferences of end-users, and if this differs by gender, is poorly understood, limiting the ability to evaluate and scale these interventions.

Objective: The objective of this qualitative case study was to detail how the overall design approach of Crush the Crave (CTC), a quit smoking app that targets end-users, compares with young adult women's and men's perspectives and experiences, with consideration for the influence of gender.

Methods: Semistructured interviews were conducted with 15 developers involved in the development of CTC and 31 young adult CTC users. Data were analyzed inductively to derive thematic findings of the perceived pros and cons of CTC by both developers and end-users. Findings were grouped under 4 categories (1) technology and platforms utilized for the app, (2) foundation of app content, (3) underlying focus of the app, and (4) look, feel and functionality of the app.

Results: Under the category, technology and platforms utilized for the app, it was found that both developers and end-users agreed that apps aligned with the needs and preferences of young adult smokers. Major limitations with the technology identified by end-users were the frequent "glitches" and requirement for internet or data. For the category, foundation of app content,developers agreed that the strength of CTC was in its strong evidence-base. What mattered to end-users, however, was that the content was packaged positively, focusing on the benefits of quitting versus the consequences of smoking. It was found under the category, underlying focus of the app, that the individually-led focus of the app resonated with both developers and end-users, especially young men. Under the final category, look, feel and functionality of the app, it was found that developers were very positive about the app's aesthetics but end-users thought that the aesthetics incited a negative effect. Also, while end-users found it easy to use, they did not find the app intuitive. Finally, end-users thought that, because the app functions were largely based on a user's quit date versus their ongoing efforts, this often lent to unmeaningful data.

Conclusions: The current study findings highlight the importance of understanding multiple perspectives of stakeholders involved in a mobile-based intervention. By gathering the viewpoints of developers and end-users, both problematic and effective approaches that underlie development goals were revealed as a means of informing the development, implementation, and evaluation of future electronic health (eHealth) interventions.

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KEYWORDS

mobile app; smoking cessation; tobacco control; young adult; qualitative research

Introduction

Smoking remains the number one public health concern, especially among young adults because they continue to maintain the highest smoking rates [1]. Despite comprehensive evidence that the younger a smoker quits (before 34 years of age), the greater the health benefits, a significant number of smokers don't successfully quit until after the age of 45 [2,3], when the adverse health impacts of smoking are not completely reversible. This is due, in part, to low uptake of cessation interventions by the young adult population [4-6]. This evidence underscores the urgent need to reach young adults with effective smoking cessation interventions, and mobile phone apps present as an attractive means to do so, with young adults representing a particularly receptive audience for quit smoking apps [7,8].

The benefits of mobile phone apps over traditional cessation interventions include the ability to access support anytime, anywhere, via complex functions, including interactive self-monitoring activities, diverse multimedia, and tailored support via context sensors [9,10]. As a result, the quit smoking app market has exploded, with hundreds (over 500) of smoking cessation apps now available on the Apple and Android platforms [11,12]. Despite the plethora of quit smoking apps, few are evidence-informed, theoretically-based, or include the perspectives of end-users [13-15]. Regardless, consumers are downloading these apps to help them quit smoking, with popularity especially high among the young adult population [8]. While emerging evidence indicates that apps may be an effective way to assist individuals with quitting smoking [16-20], and young adults in particular [18], little is known about which aspects of these apps are well designed and address the needs and preferences of young adults.

Researchers have expressed concern about how little detail is provided in relation to the underlying principles of development and design processes of mobile health (mHealth) smoking cessation interventions [10,21,22]. Tomlinson and colleagues [21] have described the current influx of mHealth interventions as a wave of "black boxes" because there is a lack of research detailing the developmental processes of and subsequent expectations for these interventions. The paucity of research on the development of these initiatives reflects a primary concern for health outcomes in the mHealth intervention literature despite the fact that the processes of development are essential to the establishment of optimal and scalable interventions [21].

In addition to the lack of research in relation to the design and development of cessation apps, there is also a lack of research on end-user (those who actually use the apps) perspectives and experiences and if they align with the expectations of development. While some studies have harnessed end-user input during the development of an app [23], the actual experiences of end-users after app roll-out has yet to be interrogated. We don't know if users' actual experiences align with the design expectations of the developers. This is a critical step toward enhancing uptake and engagement with interventions. For example, while Ploderer and colleagues [24] did not make explicit the underlying development principles of the DistractMe app, they did describe which end-user experiences aligned with the design intentions of the app. As a result, the authors were able to draw conclusions about which aspects of the app worked well and how development practices can be improved to optimize its effectiveness.

Furthermore, it is well established in the literature that there are significant gender influences on smoking behavior, and that gender-sensitive approaches to quitting smoking have been found to positively influence receptivity to and use of the interventions, as well as mobilize smoking cessation [25-27]. Yet, no efforts to investigate the influence of gender and ways to incorporate a gender-sensitive approach into mobile-based smoking cessation interventions specifically have been found. Because the ways in which young women and men use and benefit from smoking cessation interventions as they engage in quitting smoking may differ, attention should be paid to potential gender-related influences in the ways that an app is developed, as well as how women and men perceive and experience these interventions.

To our knowledge, no studies to date have explicitly aligned developers' perspectives and end-user perspectives on using an app for cessation. Juxtaposing the processes of development and design that underpin an app against user perspectives and experiences is essential to exposing misalignments and optimizing design practices. The aim of this study was to address an important knowledge gap by comparing the overall design approach of Crush the Crave (CTC), a quit smoking app that targets young adults motivated to quit smoking, with young adult women's and men's perspectives. As described in Baskerville and colleagues [23], the features and functions in the app are underpinned by principles of persuasive technology for behavior change and the US Clinical Practice Guidelines on what works to support quitting smoking. This study specifically compares the pros and cons of the app as perceived by the developers of CTC with the perceptions and experiences of young adult smokers who have used the app.

Methods

Design

The CTC app was being evaluated through a randomized controlled trial (RCT) [28] at the time of the current study. In the RCT, baseline, 3-month, and 6-month follow-up surveys were collected to assess the effect of CTC on smoking cessation compared to the quit guide. The present study served as a companion study to this RCT. Young adult participants for the present study were drawn from the individuals in the intervention group that completed all 3 surveys (n=307).

Through a qualitative case study design [29], the processes of development that underpin CTC were juxtaposed with end-users' perspectives and experiences in using the app, a knowledge area that we know little about. A qualitative case study is ideal for engaging in a holistic investigation of a phenomenon on which little is known [29]. Congruent with this methodology, data collection and analysis were qualitative in nature.

Ethics approval for this study was obtained from the University of British Columbia (Okanagan campus) Behavioral Research Ethics Board (Certificate H15-00466).

Participants

Developers

Using a purposive sampling strategy, developers were derived from those who were directly involved in the decision making in relation to the development, design, and implementation of CTC. Developers were put in touch with the principal investigator via an introductory email sent by the senior scientist of CTC and subsequently recruited via email. Altogether, 15 developers provided informed consent and participated in the study. Table 1 provides a description of the key informant sample.

Using a purposive sampling strategy, young adults (ages 19-29) who had been assigned to the RCT intervention group and were either recent quits or still smoking were recruited into the current study. Participants recruited were those who completed the 6-month questionnaire in the RCT and selected "yes" to receiving information about this qualitative companion study. These participants provided their contact information (email and phone number) and, therefore, recruitment was conducted via email, phone calls, and texting. Altogether, 31 young adult end-users provided informed consent and participated in this study. Table 2 provides demographic and smoking behavior data for young adult participants.

Data Collection

Semistructured interviews were held with developers and end-users, which are less directive and more open-ended [29] to ensure that the perspectives of each sample were captured. Except for one Skype interview with a developer, all interviews were conducted via telephone. Interview questions for developers focused on perceived strengths and limitations in the design of the app, while interview questions for end-users focused on their likes and dislikes related to app design. These conversations were about the overall features and functions of the app rather than the specific content (eg, for developers: "In your opinion, what are some of the best things about the app?" and for end-users: "Looking back over the time you have used the app, what were some of the things you liked best about using CTC?").

All interviews were audio-recorded and lasted between 30 and 80 minutes. Young adult participants received an honorarium (Can $50/interview) to acknowledge time spent on the study.

Table 1. Key informant sample.

Job role	Time of involvement in Crush the Crave development	Involvement with the app
Men (n=8)		
Academic	During	Design
Academic	During	Design
Academic	During and after	Design and evaluation
Clinician scientist	During	Design
Data systems specialist	During	Branding
Media developer	During and after	Design and marketing
Academic	During and after	Design and evaluation
Senior scientist	During and after	Design and evaluation
Women (n=7)		
First project manager	During	Study management
Second project manager	After	Study management
Academic	After	Evaluation
Academic	During	Literature review
Academic	After	Evaluation
Partner organization	During	Design and marketing
Research coordinator	During and after	Management of social media

Table 2. Young adult study population (N=31).

Characteristics	Value
Age (years), mean (SD), range	24.7 (2.7), 20-29
Gender, n (%)	
Female	13 (41.9)
Male	18 (58.1)
Education, n (%)	
<High school	3 (9.7)
High school	4 (12.9)
Some postsecondary	9 (29.0)
Trade	1 (3.2)
College	11 (35.5)
University degree	3 (9.7)
Income (Can $), n (%)	
<15,000	4 (12.9)
15,000-29,000	4 (12.9)
30,000-44,999	4 (12.9)
45,000-59,999	5 (16.1)
60,000-79,999	3 (9.7)
≥80,000	3 (9.7)
Don’t know/refused	8 (25.8)
Population group, n (%)	
Aboriginal	3 (9.7)
White	22 (70.9)
South Asian	2 (6.5)
Other	4 (12.9)
Home province, n (%)	
British Columbia	2 (6.5)
Alberta	3 (9.7)
Saskatchewan	4 (12.9)
Ontario	15 (48.3)
Quebec	1 (3.2)
New Brunswick	2 (6.5)
Nova Scotia	3 (9.7)
Newfoundland	1 (3.2)
Smoking status at 6 months, n (%)	
Quit smoking	7 (22.6)
Currently smoking	24 (77.4)

Data Analysis

Data analysis was conducted simultaneously with data collection, with a minimum requirement of six interviews for saturation [30]. Saturation was ultimately driven by saturation of themes within the overall framework of the study. All interviews were transcribed verbatim. Transcripts and documents were uploaded onto NVivo(QSR International (Americas) Inc.). An analysis was then guided by the framework approach, which consisted of a series of interconnected stages (familiarization, identifying an analytic framework, indexing, charting, and mapping and interpretation), enabling a coherent and transparent account of the analysis [31].

Data from interviews with young women were kept as a separate dataset from those with young men to enable the lead author to compare and contrast young women's and men's experiences and identify notable gender-related influences in the datasets and findings. After the first four interviews with developers, young women, and young men, a coding framework was developed, identifying key themes in relation to their overall perspectives on the app. The thematic frameworks for each dataset were then reviewed and approved by all authors. The frameworks were subsequently used to code the remaining transcripts and revised as added to as new data emerged. The frameworks for young women and men were compared and then combined with important similarities and differences noted. The final frameworks were then transferred to tables. Representative quotes were selected to illustrate key themes and subthemes.

Results

The perceived pros and cons of CTC fell into 4 categories: (1) technology and platforms utilized for the intervention (relates to perspectives on delivering a cessation intervention via a mobile app, with the additional support of social media, (2) foundation of app content (relates to perspectives on the principles that underpin the app design), (3) underlying focus of the app (relates to perspectives on the implied focus of the app design based on the technology used and the dominant features and functions that were built into the app), and (4) look, feel and functionality of the app (relates to perspectives on the overall design of the app and how it is packaged for young adults).

Technology and Platforms Utilized in the Intervention

Developers described the use of mobile technology as a natural evolution of tobacco control efforts—that it was necessary to keep up with current trends of using digital media in tobacco control, and health care more broadly. Along with this vein, there was often a sense of urgency to take tobacco control efforts into the realm of electronic health (eHealth). Notably, this urgency was underpinned by a desire to get it right and to not just put something out there that wasn't given much thought. It was clear that the developers were invested in designing an eHealth approach that would work rather than something that was simply novel:

> *This is going to be the app or some version of something like that—some portable, accessible, customizable, personalized thing. Every trend is going to that; this is the future…We need to understand how to get this right because if we don't, the tobacco companies will and other people will, and we [will be] competing against all kinds of other things. If we can get this right, this [will become] a frontline for public health…If we don't go there, we're losing an enormous opportunity to make a big difference in people's lives.* [Informant #9, male]

Both developers and end-users thought that a cessation app has an edge on other cessation intervention formats because an app would meet diverse populations of young adults where they are at, both in terms of being ready at hand and in terms of the type of support they'd want to receive. For example, a key informant reflected on how young adult smokers have been neglected in relation to tobacco control efforts, mainly because the health-seeking behaviors of young adults are diverse and can differ from their older counterparts, with whom young adults are often grouped together in cessation initiatives (eg, going to a physician, counseling). She described CTC as an intervention that was designed to align with how young adults seek health information and support, saying that CTC "is a place that they can go to get that kind of support that is not totally out of their comfort zone". End-users agreed that the use of mobile technologies for a smoking cessation intervention fit with the needs and preferences of their age group. They particularly described the portability of CTC, since it is delivered via an app, as one of the most liked aspects of using the CTC app:

> *Just the fact that it is an app and I can bring it with me instead of like having a chart at home or something like that where it's not very portable. The app you can bring with you wherever you go 'cause chances are you're gonna have your phone on you.* [Participant #2, female smoker]

Developers and end-users agreed that integrating the app with social media platforms enabled easier access and opened opportunities to reach young adults with cessation support. While end-users did not perceive any downfalls to delivering cessation support via an app, developers were concerned about the ever-changing nature of technologies and platforms, and user preferences and implications this had for keeping interventions relevant:

> *Things go by the wayside so fast that by the time we probably tried to work something out, Snapchat would be no longer the thing that young adults are using. They would be on to the next thing. So, it's so hard to keep up with technology just because it's such a quick pace nowadays. Like phones—new phones come out every six months now…similar to apps and similar to the different platforms that people are using.* [Informant 11, male]

While developers didn't anticipate technical problems, this was a frequent problem encountered by end-users (eg, freezing), leaving them feeling empty-handed in trying to get help with quitting smoking. These glitches frequently drove users away from the app. A few end-users also lamented the fact that the app could only be used if they had an internet or data connection. This often resulted in limited use of the app, as well as disappointment in not being able to access the app and its features during times that they needed it (eg, during a craving).

Foundation of App Content

The most talked about strength underlying the design of the app among developers was that its content and development was informed by evidence and theory. In particular, developers described the inclusion of end-users via focus groups during the development of the design concept, as well as to test the app prototype, as a key strength. This led many developers to suggest that the app would be relevant to various subpopulations of young adults, and it was often described as a "one-stop shop" or a "Cadillac" design because it included so many

evidence-informed features. As demonstrated in the statement below, developers thought that the evidence-informed nature of the app gave CTC an edge on the growing number of quit smoking apps available:

> *There were plenty of stop smoking apps out there but they weren't particularly good ones. They weren't…[based] on the evidence of what we know works, and they weren't based on good theory around behavior change…There was an obvious gap there and we wanted to try and make sure there was something good available for young people who would be looking for apps.* [Informant #14, male]

A few developers, however, had counterviews about the staying power and transferability of clinical practice guidelines and long-standing theories related to behavior change in the eHealth context. Developers were cautious about taking guidelines that were designed for a clinician in a clinic and putting them into an app for users to support self-management of health behavior. Some developers were also concerned that the app was built upon the notion of a successful quit trajectory. Rather than making room for the relapses that frequently occur during quitting, the app implies that quitting is straightforward (eg, that end-users can expect to be smoke-free by the time they reach their quit date). A challenge during development was balancing an idealized notion of quitting with the reality of a quitting trajectory:

> *The biggest limitation that I see is that they [the features of the app] are based on a generalized model of quitting smoking, even if you think about the theoretical model, it just kind of goes forward right? And they will acknowledge that yes people go back and forth…[But] the reason you don't draw…anything other than an arrow, aside from maybe something going backward occasionally, is that it looks like spaghetti when you actually think about how people change...It's a complete mess...people go forward, backward, sideways...But that's almost impossible to put on a program. And so, we run this risk of creating a bit of a fiction, an evidence-informed fiction, if we may.* [Informant #9, male]

When asked about how gender was considered during the development of the app, key informants explained that the app was designed to be "gender neutral" and therefore, was not underpinned by consideration for gender. Some key informants thought that this led to them defaulting to a rather male-centric app:

> *Definitely, the app is very much branded to your white male. Especially with the default images at the front with the rock climbing and that sort of thing so—that initial white male [feel] is unfortunately very prominent when you look at it through that lens.* [Informant #10, female]

What end-users liked about the foundation of the app content was that, despite it being developed and informed by evidence and scientific institutions, the content was delivered in a fun and positive way. Many end-users described how they typically expect to receive messages about the negative consequence of smoking versus the positives of quitting. Because the app focused on the latter, end-users were more receptive to it. One young woman who still smoked provided a detailed description of why the ways in which the content was delivered was appealing to those her age:

> *[The app] is not just pure scientific, "this is what you have to do, this is why you need to quit smoking, these are all the chemicals that are in it," you know what I mean? There was more of a fun aspect to it. Where it seemed like it wasn't so serious…And so I liked that about it, right? 'Cause it wasn't so stuffy, it wasn't so clinical. It was more like, "okay, we know that you wanna quit, but we're not gonna judge you too severely if you don't," right? I don't wanna say that it didn't seem as serious, it just didn't seem as clinical.* [Participant #22, female smoker]

The Underlying Focus of the App

A strength of the underlying focus in the design of CTC according to both developers and end-users was the individually-led nature of the intervention. In this respect, the CTC app was designed to enable end-users to quit on their own and track and modify their smoking behaviors without consultation with others, health professionals and personal networks alike. It was agreed by both developers and end-users that this individually-led focus was compatible with how young adults generally approach quitting smoking, which is on their own. In particular, this design feature was viewed as a strength for reaching young men. One female key informant described how the self-driven nature of the app played to many men's preferences for self-management when it comes to their health:

> *I mean, men like tools…it's like a tool, it's a do it yourself, I don't have to tell anybody, I don't have to ask anyone [thing]…Yeah, I think the fact that it's a do it myself; [I don't have to] ask for help sort of thing, and it's like one-stop shop.* [Informant #5, female]

In keeping with these sentiments, young men were particularly vocal about liking the self-led design of CTC, explaining that they are very private and like to take on quitting smoking independently. Young men frequently stated that they did not like to share personal things, such as the decision to quit smoking, with anyone—friends and family alike. Young women, on the other hand, were more inclined to draw on social support options within the app (eg, the quit buddy).

An aspect that women liked, but men were not keen about, was the "give and take" focus in the app. While men wanted to be less engaged with data entry, women appreciated the need to be engaged throughout the process because it provided them with opportunities to reflect on their smoking and to develop new ways of coping:

> *Yeah, so it's not just like documenting data, it's giving you something to do…And, it's like—it also takes and gives to you… it's like, "what are you doing when you crave or when you do have a cigarette…what you're feeling then,"…Some of the other apps, most of them, you have to buy that information. Like you*

have to pay, God only knows how much, and this app, it's just like, okay it's there for you. [Participant #12, female, smoker]

Look, Feel, and Functionality of the App

In relation to the app's aesthetics, developers thought that they were done well:

There is something that has to catch their eye, and we talked a lot about the design of it—like literally the design, like the logo, that sort of stuff because that sort of stuff does matter...It's a nice logo, it's different, it's a cool name…I think this team got it. [Informant #9, male]

Interestingly, almost all end-users, women and men alike, did not like the way the app was aesthetically packaged. In keeping with the one key informant's thoughts, they described the app as too dark, espousing a negative effect, which contradicts the otherwise positive orientation of the app. This is captured in the following statement:

One thing that I did notice is that the background colors; they're a little dreary. Like the black and the orange and like when you first click on it….it could be a little more like brighter and happier….A different color scheme I think would work a lot better…And like black, from a psychological standpoint, black and red, they're like angry negative colors…So if you put more like blues and greens and like yellows and like summer colors and things like that in it, it might change people's you know mood a little bit more, psychologically without them even knowing. [Participant #2, female smoker]

One thing that end-users stated that they liked about the look and feel of the app was that it was easy to use. This is demonstrated in the following quote by a young woman:

It was easy to get to, easy to use. Especially like being a mom…it was easy and simple. It wasn't overly complicated—like to start, like the start-up was [easy to] enter stuff…it wasn't overly long…[My son] only lets me use my phone for like two seconds at a time. [Participant #25, female smoker]

Despite that the app was often described as easy to use, end-users agreed that navigating the app was not very intuitive. They often questioned why there were so many subpages of pages, which led to "hidden" features they were unaware of, or found out about late in their quit smoking journey. They also expressed frustration with being sent out of the app to access certain tools (eg, craving distractions).

A limitation identified by end-users in relation to the functionality of the app was that the functions (awards, leaderboard, health calculators) were based on a point in time—the user's quit date. One young woman described how the calculators (money saved, health regained) could be very powerful for quitting smoking but that the glitches in the app prevented her from logging her smoking and cravings, which lent to inaccurate statistics displayed on the app:

I couldn't actually log how many cigarettes and stuff I had …[so] it's not accurate. But if it was accurate it [would be] cool to see like, you know, money saved, like, oh hey, I saved $100 smoking so far. Like you know, it's something to be proud of. [Participant #30, female smoker]

Discussion

Principal Findings and Implications

To date, there has been a primary reliance on quantitative research evidence for evaluating eHealth interventions. The rich findings as a result of harnessing perspectives of both developers involved in app design and end-users using CTC hold potential for contextualizing why certain aspects of the app worked well and others did not work well, and in doing so extend the results of the quantitatively focused evaluations of CTC [28]. The importance of gaining knowledge about the implementation processes and experiences associated with interventions has been recognized [32-34] and is supported by the findings in the present study.

This qualitative study is novel in that it provides a formal comparison of the developers' and end-users' perspectives providing much needed empirical evidence to the eHealth literature. By gathering the viewpoints of developers, both problematic and effective approaches that underlie development goals were revealed. Indeed, developers and end-users in the current study findings can advance the development and implementation of eHealth interventions, holding great promise to improve their uptake and impact compared to their current overall status, which is often poor or undecided [35-37].

The positive feedback by both sample groups on entering the mobile market for supporting smoking cessation demonstrates that the use of mobile phone technology is a much-needed and relevant approach for supporting quitting smoking among young adults. Emerging evidence of the efficacy of some evidence-informed apps for quitting smoking [11,18,19,38] confirms that smoking cessation interventions are appropriately positioned in the mobile context. In the recent RCT of CTC (Baskerville et al in press), it was found that, while CTC was not superior to the control condition, the prolonged abstinent rate and thirty-day abstinent rate for CTC was comparable to other research on smoking cessation smartphone apps [11,38]. The widespread support by end-users in this study confirms support for entering the mobile space to reach young adult smokers specifically.

While it is established that we are on the right track with using mobile technology, the differential and sometimes problematic experiences with CTC among end-users bring forward questions about how and when the target end-users are appropriately engaged in intervention research. Although CTC was designed and developed with input from young adult focus groups, the findings of the study revealed gaps between the developers' perspectives and the perspectives and experiences of the end-users. As previously described [23], apart from one pilot test run with end-users, engagement with end-users primarily consisted of preintervention focus groups. This raises questions about the value in relying primarily on preintervention focus

groups in the development of mHealth interventions. Recent research has detailed the problematic position of end-users in the development of eHealth interventions—they are often peripheral stakeholders that have marginal engagement during the development [37], which was the case for CTC. Others have argued that positioning end-users in this way have the potential to lead to a mismatch between technologies and end-users' daily lives, habits, and rituals [37], lending to usability problems and high attrition rates [35,39,40]. The findings of this study provide further support for these concerns. For example, many end-users complained about technology glitches (eg, freezing) and the lack of intuitive design (eg, features and functions were not easily accessed or located). Users often cited these issues as contributing to their disinterest and eventual disengagement with the app.

Researchers in eHealth have highlighted the need for and benefits of harnessing end-user perspectives during the design and development of eHealth behavior interventions. For example, involving end-users has been shown to improve usability [41], prevents the inclusion of superfluous features [42], and can be more economical in that money is not put into bad design aspects [41]. However, what is lacking in the literature is how and when to engage end-users in eHealth intervention research. This raises questions about the appropriateness and effectiveness of the ways in which end-users were engaged during the development of the app. Recently, eHealth researchers have begun to pay close attention to the developmental requirements of health behavior interventions so that these interventions can be more effectively developed and subsequently scaled up. In this vein, it has been suggested that multiple formative evaluations be conducted with end-users to test design assumptions and prototypes [37,43]. One way to address this need would be the inclusion of end-users on the development team in addition to conducting feature-level analyses based on log data (eg, google analytics), such as that used by Heffner and colleagues [44]. These practical strategies may help address the need for more comprehensive and frequent end-user input, while also addressing issues in relation to time, resources and funding that are commonly associated with evaluating eHealth interventions.

A recently published qualitative investigation of CTC found that end-users did not engage with the social support aspects of CTC due to fear of judgment, failure in quitting, and shame in smoking [16]. Considering the current study finding in relation to end-users' preference for an individually-led intervention, it can be reasonably argued that the social support features were not designed in a way that aligned with the nature of the intervention. This highlights the need to pay attention to how content is presented and if it aligns with the overall focus of the intervention (eg, an app-based forum versus a public social media page).

Furthermore, while developers focused on the scientific background of the app content, end-users focused, again, on how this content was presented. Positive framing of the app and its content appeared to play an important role in uptake and use of the app. Despite some developers concerns about uptake, end-users described how the apps focus on the benefits of quitting versus the consequences of smoking largely influenced their desire to download and use the app. Given traditional approaches that frequently played on fear (eg, pictures of negative health consequences on cigarette packs), guilt (eg, neonatal health consequences), or judgment [45], end-users welcomed the positive and encouraging nature of the app. In the debate between positive and negative framing of content for tobacco control efforts, the findings of this study extend existing evidence that positive message framing resonates with smokers [45,46] and specifically resonates with the young adult population [47].

CTC was designed to be "gender-neutral." A gender-neutral approach in cessation interventions can be understood as gender-blind, running counter to best practice frameworks and guidelines for treating tobacco dependence [48,49]. Researchers have raised concerns about the lack of attention to gender in cessation interventions given evidence that gender-related factors play a significant role in tobacco use [50,51]. For example, men have a long history with tobacco use and dependence that has been linked to masculinities and gender roles. Similarly, gender-related factors have been implicated in women's smoking, with femininities and attractiveness associated with women's smoking and gendered factors such as concern for weight gain contributing to smoking maintenance [52]. Furthermore, a gender-neutral approach puts emphasis on the end-goal (quitting among end-users), ignoring gender-related factors that may limit ones' ability to quit smoking. For example, oftentimes, young women have been reported to take up and maintain smoking/substance use to cope with current trauma or past trauma (eg, domestic violence) [53]. Given reports that 1 in 3 women experience trauma [54], a gender-neutral approach fails to account for and address this issue. Along with this vein, discourses in relation to gender roles and norms (eg, women are responsible for their personal and familial health) may be reinforced through a gender-neutral approach because gender-related diversity and differences are ignored and unaddressed. It is naïve to focus on the end-goal (in this case, smoking cessation) and not account for established factors that may prevent one from achieving important health behavior changes, like quitting smoking. Indeed, in keeping with the positive impacts of gender-sensitive interventions [25-27,55], it is strongly recommended that mobile-based smoking cessation interventions be designed to address gender-related factors influencing smoking and quit efforts.

That end-users did not like the aesthetics of the app because it stimulated negative emotions, brings attention to the emotional side of end-user experiences, something that has been neglected by researchers investigating human-technology interactions [56]. Thuring and Mahlke [56] assert that researchers are primarily focused on effectiveness, efficiency, and satisfaction at the neglect of other aspects, such as the aesthetics of system design and emotional experiences during system usage. In addition, researchers have found that the visual attractiveness of an app also influences perceived usability [56,57]. It is urged, therefore, that future development practices in the area of mHealth foreground consideration of the aesthetics of apps alongside effectiveness and efficiency.

Limitations

There are several limitations to this study. As with all self-report research, there may be perspectives and experiences that were not captured during the interviews. Also, interviews with developers were conducted a couple of years after the app was developed between 2012 and 2014. In this regard, perspectives of developers may have been influenced by current advancements in technologies, as well as their knowledge of what aspects of the app worked well and which ones did not work well. In the same way, some end-users were interviewed up to a year after they entered the RCT study, potentially limiting their ability to recall their experiences. To address this potential limitation, reflective questions were posed during interviews with both samples to assist participants in recalling events and experiences, and when necessary follow-up questions and probes were used to capture additional details. Also, the young adult sample largely consisted of those who continued to smoke and were primarily Caucasian, thus affecting the generalizability of the findings. Finally, evolutions in technology inherently challenge the transferability of eHealth research.

Conclusion

Given the rich findings of this study, particularly in relation to some of the stark differences found between developers and end-users, the inclusion of multiple perspectives is a much-needed addition to the eHealth literature. By gathering the viewpoints of developers, both problematic and effective approaches that underlie development goals were revealed. Incorporating a gender-based lens in this study brought forward nuances between young women's and men's perspectives and experiences with the app. Indeed, by harnessing data from both developers and end-users, the current study findings can advance the development and implementation of eHealth interventions.

Conflicts of Interest

None declared.

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Abbreviations

CTC: Crush the Crave
eHealth: electronic health
mHealth: mobile health
RCT: randomized controlled trial

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Original Paper

A Mobile-Based Mindfulness and Social Support Program for Adolescents and Young Adults With Sarcoma: Development and Pilot Testing

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Abstract

Background: Approximately 70,000 adolescents and young adults (AYA) are diagnosed with cancer each year in the United States. Sarcomas carry a particularly high symptom burden and are some of the most common cancers among AYA. Recent work has documented significant levels of unmet needs among AYA with cancer, particularly the need for psychosocial support. Mobile technology may be a cost-effective and efficient way to deliver a psychosocial intervention to AYA with cancer and cancer survivors.

Objective: The two aims of this study were to (1) develop a pilot version of a mobile-based mindfulness and social support program and (2) evaluate program usage and acceptability. An exploratory aim was to examine change in psychosocial outcomes.

Methods: Thirty-seven AYA with sarcoma or sarcoma survivors, parents, and health care providers participated in the study. Semistructured interviews were conducted with 10 AYA, parents of five of the adolescents, and six health care providers. Themes from the interviews helped to inform the development of a mobile-based mindfulness pilot program and a companion Facebook-based social support group. Twenty AYA consented to participate in a single-arm pre-post evaluation of the program; 17 downloaded the app and joined the Facebook group. Seven of these participants had participated in the semistructured interviews. Six additional health care providers consented to participate in the evaluation stage.

Results: On average, participants completed 16.9 of the 28 unique sessions and used the mindfulness app for a mean 10.2 (SD 8.2) days during the 28-day evaluation period. The majority of participants (16/17) engaged in the social group and posted at least one reply to the moderator's prompts. The mean number of responses per person to the moderator of the social group was 15.2 of 31 (49%, range 0%-97%). Both AYA and health care providers responded positively to the Mindfulness for Resilience in Illness program and offered useful recommendations for improvements. Exploratory psychosocial analyses indicated there were no significant differences from pretest to posttest on measures of perceived social support, mindfulness, body image, or psychological functioning.

Conclusions: This study offers preliminary support for the feasibility and acceptability of a mobile-based mindfulness and Facebook-based social support program for AYA with sarcoma. The feedback from AYA and health care providers will assist in creating a fully developed intervention.

Trial Registration: ClinicalTrials.gov NCT03130751; https://clinicaltrials.gov/ct2/show/NCT03130751

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KEYWORDS

cancer; mindfulness; social support; mobile app; adolescents; young adults

Introduction

The past decade has seen an emerging interest in identifying and meeting the unique needs of adolescents and young adults (AYA) with cancer [1,2]. Approximately 70,000 AYA are diagnosed with cancer each year in the United States, with the incidence of cancer in this cohort increasing steadily over the past 30 years [3]. Sarcomas are some of the most common cancers in AYA and are particularly difficult to cope with given the high symptom burden (eg, amputation, limb-salvage surgery) [4].

Those AYA diagnosed with cancer have a number of unmet psychosocial needs [2,5,6]. Living with uncertainty about the future can be an ongoing source of stress and anxiety during and after cancer treatment [7-9]. In addition, problems with maintaining or making new social relationships have often been cited as pressing issues for AYA with cancer [10-12]. Given the psychosocial challenges evident in this patient population, the Institute of Medicine National Cancer Policy Forum Workshop emphasized the need to address the unique developmental needs and quality of life in AYA with cancer [2]. Unfortunately, very few studies of psychosocial interventions for AYA with cancer have been conducted [13].

Two approaches that show promise for helping AYA to cope with the daily psychosocial challenges of cancer treatment are mindfulness and peer social support. Mindfulness-based interventions (MBIs) teach individuals how to observe thoughts and emotions in a nonjudgmental and compassionate manner and redirect attention to the present moment [14]. Mindfulness skills training may help AYA cope with thoughts and feelings rooted in the uncertainty of their prognosis [15] and distress surrounding treatment, adverse effects, and body image concerns. Indeed, among AYA who have finished cancer treatment, those who report higher mindfulness report significantly less distress and uncertainty than those who report lower mindfulness [16]. To date, very few studies have focused on the effect of MBIs in AYA with cancer. However, AYA cancer survivors who completed an 8-week MBI showed a significant reduction in emotional distress and improvement in quality of life, a significant reduction in negative attitudes toward self, and a significant improvement in mindfulness skills at a 3-month follow-up [17].

Given the lack of peer social support experienced by AYA with cancer, interventions that seek to connect patients or survivors with other AYA who have experienced cancer also show promise [18] because they give AYA the opportunity to receive support from someone who can understand their unique life-changing experience. Despite the documented need for social support in AYA with cancer, research on social support interventions are lacking in this population [18,19]. Olsen and Harger [20] examined the feasibility of implementing a nurse-led supportive social networking group for AYA with cancer; participants reported experiencing an increased sense of support following the intervention.

Young adult cancer survivors have expressed the need for interventions that are delivered remotely and provide social support [21]. MBIs are increasingly being delivered through mobile phones. A meta-analysis designed to estimate the overall effects of online MBIs (including mobile app-based MBIs) on mental health for a range of populations found that they had a moderate effect on stress and a small but significant beneficial impact on depression, anxiety, well-being, and mindfulness [22]. In addition, social media channels such as Facebook have been explored as a way to connect patients managing health conditions with one another. Key recommendations include iterative content development with input from the target patient population, exploring the role of group "champions," complying with social media policies of health care institutions, and using comprehensive evaluation strategies [23].

This study had two aims: (1) develop a pilot version of the Mindfulness for Resilience in Illness intervention, a mobile-based mindfulness program and a companion Facebook-based social support program for AYA with sarcoma and survivors, informed by interviews with AYA who have experienced sarcoma, parents, and health care providers; and (2) conduct a single-arm 28-day pilot study to examine program usage and acceptability. An exploratory aim was to examine the effect of the Mindfulness for Resilience in Illness intervention on psychosocial outcomes (ie, mindfulness, social support, psychological functioning, and body image).

Methods

Aim 1: Development of the Pilot Program

The objective of this aim was to conduct semistructured interviews to inform the development of the Mindfulness for Resilience in Illness program.

Design

Our overall qualitative approach was deductive, informed by a preexisting Resilience in Illness Model that described factors associated with resilience in illness [24,25] in AYA with cancer.

Participants

Those AYA aged 13 to 25 years, previously diagnosed with sarcoma and either undergoing active treatment or within 5 years of transitioning to survivorship care, were eligible to participate. To capture a range of perspectives, we purposefully sought a representative sample of AYA in terms of age, gender, and treatment history (eg, on and off treatment, limb-salvage procedure, amputation). Inclusion criteria for parents were having an adolescent (aged 13-17 years) son or daughter enrolled in the study and being fluent in English. Given that there was likely to be variability in the living situation of young adults (eg, living independently or at college), we limited our parent interviews to parents of adolescents aged 13 to 17 years. For these interviews, we sought parents' perspectives surrounding their adolescent's day-to-day challenges. Health care providers currently providing clinical services to AYA with sarcoma were eligible to participate. Health care providers were purposefully recruited to represent the range of roles in a treatment team (eg, oncologists, nurses, and social workers).

Recruitment

The AYA and adolescents' parents were recruited from a pediatric sarcoma clinic in Los Angeles, California. Research team personnel distributed research flyers to families waiting for clinic appointments and screened interested patients or parents over the phone. Eligible AYA and parent participants provided online assent and consent prior to beginning study procedures. Potential health care provider participants were identified from author NF's network of providers. Author NF emailed study invitations to providers, and interested providers were contacted by research personnel. Providers gave oral consent over the phone prior to beginning study procedures.

Development of Interview Guides

We developed semistructured interview guides to explore ways in which a mobile-based mindfulness and social support program can address the psychosocial needs of AYAs with cancer during and posttreatment. Three separate interview guides were created for AYA, parents, and health care providers. The first section of the interview guides was informed by the Resilience in Illness Model (RIM) [24,25], which identified psychosocial factors associated with resilience in AYA with cancer (ie, spiritual perspective, social integration, family environment, coping skills, and hope-derived meaning). This model was chosen to help identify potential resilience-enhancing program components. The second section of the interview guides focused on the use of mobile technology and preferences surrounding potential program content (ie, mindfulness and Facebook social support component). First drafts of the semistructured interview guides were created by author ED and were revised with significant input from the research team. To facilitate the comparison of multiple perspectives on the same topics, the parent and provider interview guides mirrored the patient interview guide and included queries about their beliefs about AYAs' needs for a mobile-based psychosocial intervention. Interview guides are available on request.

Procedure

Two female research team members with qualitative research experience conducted the interviews. No interviewer and interviewee had a prior relationship. Patient and parent interviews were conducted in-person (at the research study's hospital-based offices) or by phone. Health care provider interviews were conducted by phone. All interviews lasted between 45 and 90 minutes. Interviewees were offered Amazon gift cards of US$25 (AYA and parents) or US$100 (providers) as compensation for participating in the study. The research team continued to collect interview data until 10 AYA, five parents of adolescents, and six providers had been interviewed. This coincided with when the team reached a consensus regarding thematic saturation. All interviews were audio recorded, transcribed verbatim, and deidentified for analysis. Interviews were conducted from December 2016 to March 2017. The study was approved by the University of California, Los Angeles Institutional Review Board (IRB).

Data Analysis

The coding scheme was created by the research team. We used deductive coding, informed by the RIM model [24,25]. As such, author ED created an initial coding structure based on the interview guide, with each factor in the RIM model represented. In addition, codes were created to capture beliefs about the proposed program delivery method (mobile device) and program content (mindfulness and social support). Three research team members trained in qualitative analysis coded the interview transcripts in duplicate and discrepancies were resolved with discussion. Coded interview transcripts were entered into NVivo software (version 10) [26]. Two members of the team independently reviewed data associated with each code and met weekly to discuss emerging themes, ending the discussion when three to five themes were agreed upon. Themes, supporting quotes, and exceptions to the themes were entered into an Excel sheet.

Aim 2: Pilot Test of the Mindfulness for Resilience in Illness Program

The aim of the pilot study was to evaluate the Mindfulness for Resilience in Illness mobile-based mindfulness and Facebook social support program for AYA with sarcoma by assessing usage and acceptance and exploring psychosocial outcomes.

Design

The study consisted of a single-arm, pre-post evaluation of the pilot program.

Participants

The inclusion criteria for AYAs and providers used for the formative interview phase were also used for the pilot test. Parents were not included in the pilot phase of the study. Participants included 17 AYA, seven of whom had participated in the qualitative interviews, and six health care providers.

Recruitment

The AYA were recruited from the same sarcoma clinic from aim 1. The same recruitment method used during the formative

interview stage was used to recruit AYA and provider participants for the pilot study.

Mindfulness for Resilience in Illness Intervention Program

The 4-week Mindfulness for Resilience in Illness program consisted of a mindfulness mobile app, a private Facebook group, and a provider guide. The mindfulness mobile app was delivered although a customized version of an existing mindfulness mobile app (Whil Concepts, Inc) available through the Apple iOS App Store and Android Google Play Store. A total of 28 mindfulness audio exercises were selected from the Whil library for the 4-week program. The Learning to BREATHE framework [27] and themes from the qualitative interviews informed the selection of mindfulness meditations for the four weekly program themes: (1) breathe and listen to your body, (2) dealing with difficult emotions, (3) dealing with negative thoughts, and (4) being kind to yourself through challenging times (Textbox 1). Program host videos featuring two sarcoma survivors were also included in the app. The videos were used to familiarize AYA with mindfulness terms and introduce and conclude the weekly program exercises. Four weekly blog posts designed to reinforce the weekly mindfulness concepts were also created for the app and posted on the Facebook group.

The goals of the private Facebook group were to (1) solicit feedback about the app and (2) promote social support among group members. A sarcoma survivor was recruited to moderate the Facebook group, which included posting daily content and facilitating conversation among participants by responding to posts. A total of 38 messages were created for the moderator to post daily (one or two per day).

The provider guide (e-book) was developed to help providers support patients using the Mindfulness for Resilience in Illness program. The 12-page guide provided information about the rationale for teaching mindfulness skills to AYA with cancer and encouraging peer-to-peer social support, with specific strategies for supporting patients through each of the 4 weeks of the program.

Procedure

Both AYA participants and parents (if the AYA was younger than 18 years) completed online assent or consent forms via a secure online survey platform. Following assent or consent, participants also completed demographic questions and psychosocial measures (described subsequently) via the online survey platform. Before beginning the program, AYA participants were invited to attend a 20-minute webinar that provided (1) an overview of how to use the mobile app and the Facebook group and (2) an outline of the 4-week program components (eg, meditations, Facebook posts) and expectations (ie, one meditation per day for 28 days and responding to daily Facebook posts). All AYA participants began the 4-week study on the Monday after the week that the webinars were held. Psychosocial measures and an acceptance test were completed immediately following the completion of the program. The AYA were compensated with a US$75 Amazon gift card.

Three people were involved in the daily administration of the Facebook group: the moderator and two monitors. The moderator was paid US$25 per day for a total of US$750. In addition, two members of the hospital-based research team (authors SRM and LCS) served as monitors for the Facebook group. They were trained by authors LKZ and LAP, a pediatrician and clinical psychologist, to review posts on the Facebook group and to follow the emergency protocol in the case of code of conduct violations (eg, bullying) or signs of self-harm. No such incidents occurred during the study period.

After indicating interest in participating, health care providers were emailed the IRB-approved information sheet serving as informed consent. Providers were emailed the Mindfulness for Resilience in Illness provider guide e-book, instructions for downloading the app, and a link to the online acceptance test. Providers were compensated with a US$100 Amazon gift card. This pilot study was approved by the University of California, Los Angeles IRB and registered on ClinicalTrials.gov (NCT03130751).

Textbox 1. Description of the weekly sessions of the mindfulness program.

Week 1: Breathe and Listen to Your Body

- Focus Your Attention
- Belly Breathing
- Finding an Anchor
- Fuller Deeper Breath
- 1, 2, 3 Breath
- Sense the Body
- Happy Breath

Week 2: Dealing With Difficult Emotions

- Welcome Emotions
- Feel to Heal
- Recognize Challenge
- Present With Anger
- Name It and Tame It
- This Too Shall Pass
- Discover A Safe Place

Week 3: Dealing With Negative Thoughts

- Recognize and Release Thoughts
- Unfuse our Beliefs
- Attention to Change
- Reflect and Redirect
- Dealing with Parents
- Paradox of Letting Go
- Skillful distraction (Exercise)

Week 4: Being Kind to Yourself Through Challenging Times

- Understanding Compassion
- Inward Compassion
- I Heart My Body
- Wishing Well
- Like Floating
- Simple Gratitude (Exercise)
- Circle of Kindness

Measures

Demographics

The AYA participants were asked about demographic characteristics during study enrollment, including age in years, race and ethnicity, and treatment status. Providers were asked their clinical specialty.

Usage

Use of the mindfulness app was assessed with (1) number of unique sessions completed (out of 28), (2) number of days using the mindfulness app, and (3) total minutes of engagement with the mindfulness app. Use of the Facebook group was assessed with the response rate to the daily posts.

Acceptance

The acceptance test included questions about general impressions of the mindfulness app, as well as the app's features. Participants were also asked about the helpfulness of the app features and the Facebook group, using both Likert scales and optional open-text fields.

Providers were asked about the usefulness of the program for AYA, the usefulness of the provider guide, and whether they would recommend it to another health provider.

Psychosocial Measures

Mindfulness was measured with the 10-item Child and Adolescent Mindfulness Measure (CAMM) [28]. Items are rated on a 0 (never true) to 4 (always true) scale. The CAMM is scored by reverse scoring all items and calculating a sum. Total scores can range from 0 to 40 with higher scores indicating higher levels of mindfulness. The CAMM has demonstrated validity and reliability [28].

Social support was measured with the 20-item Perceived Social Support, Friends (PSS-Fr) scale, which assesses social functioning and peer support [29]. Answer choices for the PSS-FR are "yes," "no," and "don't know." Responses indicating positive perceived social support are scored as 1 (other responses scored as 0). Total scores range from 0 to 20 with higher scores indicating more perceived social support. The PSS-Fr scale has demonstrated validity and reliability [29] and has been used in AYA with cancer [30].

Psychological functioning was measured with the six-item Pediatric Cancer Quality of Life Inventory 32-Psychological Functioning subscale (PCQL-32-PF) assessing levels of fear, sadness, and worry, including those related to cancer symptoms and relapse [31,32]. Items are scored on a 0 (never a problem) to 3 (always a problem) scale, and answer choices are summed to create the subscale score. The PF subscale scores range from 0 to 18 with higher scores indicating higher impairment (ie, lower psychological functioning).

Body image was measured using three items from the Body Image Scale (BIS) [33]. This subscale was created from items 1, 8, and 9 from the original measure, which was developed for use with cancer patients. These three items were selected by the clinical team as a brief but representative measure of body image issues faced by AYA sarcoma patients. The items were "Have you been feeling self-conscious about your appearance?" "Have you been feeling the treatment has left your body less whole?" and "Have you felt dissatisfied with your body?" Items are scored on a 0 (not at all) to 3 (very much) scale, and answer choices are summed to create the subscale score. Scores for this subscale range from 0 to 9 with higher scores indicating higher levels of body image distress.

Data Analysis

Usage

Descriptive analyses (means and standard deviations) characterized session completion, daily app usage, app engagement time, and Facebook responses.

Acceptance

Means and standard deviations or proportions were calculated for the quantitative acceptance test responses. Qualitative acceptance test responses were reviewed several times by members of the research team, and main themes were discussed and recorded.

Psychosocial Measures

Change in psychosocial outcomes from pretest to posttest were analyzed using paired sample *t* tests.

Results

Aim 1: Development of the Pilot Program

Characteristics of Participants

Five adolescents and their parents and six young adults (>18 years) were approached and screened. Of the five adolescents and their parents screened, all were eligible and enrolled. Of the six young adults screened, six were eligible and five enrolled. One patient indicated interest but was lost to follow-up. Seven providers were approached and six were screened. One provider declined indicating they were too busy. In total, 21 participants were interviewed. The AYA (n=10) ranged in age from 14 to 23 years (mean 19.3, SD 3.4 years; 50%, 5/10 female). All AYA reported a current or past diagnosis of sarcoma, except for one patient who had another cancer diagnosis but was receiving treatment through the sarcoma clinic. Four of the five parent participants and three of the six providers were female. Participant demographic data are presented in Table 1.

Main Themes

Our exploration of the ways in which a mobile-based mindfulness and social support program can address the psychosocial needs of AYAs with sarcoma yielded three main themes: anxiety about reoccurrence, openness to mindfulness, and desire to connect with other patients.

Main Theme 1: Anxiety About Reoccurrence

Most parents, providers, and patients described that patients are often consumed with worry about the future. Patients described how they feared medical scans or became overly focused on symptoms because of underlying fears about an uncertain future. For example, one participant described:

> *Well, there's always that impending doom feeling, you know, it's like a hypochondriac, you become a hypochondriac because you know the implications. For someone having a stabbing pain in their abdomen might be like, "Oh, I probably, I wasn't breathing correctly while I was doing this or I was, I don't know, I ate something bad." For a former cancer patient, it's like, "Oh, my God. Maybe my kidney suddenly decided this is the time to go," you know?* [patient 07]

Table 1. Characteristics of the adolescents and young adults (AYA), parents, and providers participating in the qualitative interviews (aim 1).

Characteristic	AYA (n=10)	Parents (n=5)	Providers (n=6)	Total (N=21)
Age (years), mean (SD)	19.3 (3.4)			
Age range (years), n (%)				
13-17	5 (50)			
18-25	5 (50)			
Sex, n (%)				
Male	5 (50)	1 (20)	3 (50)	9 (43)
Female	5 (50)	4 (80)	3 (50)	12 (57)
Ethnicity, n (%)				
Hispanic/Latino	4 (40)	1 (20)	1 (17)	6 (29)
Non-Hispanic/Non-Latino	5 (50)	4 (80)	5 (83)	14 (67)
Unknown	1 (10)	0 (0)	0 (0)	1 (5)
Race, n (%)				
White	6 (60)	3 (60)	5 (83)	14 (67)
Black/African American	1 (10)	1(20)	0 (0)	2 (10)
Asian	0 (0)	0 (0)	1 (17)	1 (5)
Multiracial	2 (20)	1 (20)	0 (0)	3(14)
Unknown	1 (10)	0 (0)	0 (0)	1 (5)
Treatment status, n (%)				
On treatment	2 (20)			
1-3 months posttreatment	2 (20)			
4-8 months posttreatment	1 (10)			
1-2 years posttreatment	3 (30)			
3-6 years posttreatment	2 (20)			
Off treatment for unknown duration	0 (0)			
Providers' specialties, n (%)				
Oncologist			3 (50)	
Nurse or medical assistant			2 (33)	
Child life, psychology			1 (17)	

Main Theme 2: Openness to Mindfulness

When asked about interest in mindfulness to cope with anxiety, most AYA expressed being open to mindfulness but were generally unfamiliar with mindfulness skill-building strategies. A young participant described her interest in learning more about mindfulness skills (eg, present moment awareness, breath work, self-compassion):

> *Oh no, I could definitely see it being helpful to a lot of them [AYA patients with cancer]. I was never told the ideas, so I don't think that's the reason why...I think that's why I never did it. I didn't have the option. No one told me about that, so to me, as a kid, my always escape was TV and sleep. So that was my go-to thing.* [patient 09]

Parents also described being open to mindfulness:

> *That would be the best thing you have to give these children is lessons in meditation because from what I've witnessed with my son, even the nurses at [hospital name], they were to a point just where everything they gave him wasn't working.* [parent 06]

Health care providers also overwhelming endorsed the idea of a mindfulness-based program, stating that they believed it could equip AYA with new coping skills. One provider described how an app could be a valuable delivery method for mindfulness content:

> *Yes, I think that I'm personally a huge believer in meditation and mindfulness as a way of coping and I think that it would be really helpful. I have found that ways that are easy and accessible that are already being used, so say if a patient really likes an app or likes the format and goes on it anyway as a*

way to get support, to also have meditation in that can help to get that by. [provider 02]

Main Theme 3: Desire to Connect With Other Cancer Patients

Almost all AYA participants described a desire to connect with other AYA with cancer. Many AYA described their belief that only other patients who had gone through the life-changing experience of cancer could understand them.

Well, there's a level of camaraderie that you can't get anywhere else. It's like you know exactly what the other person went through without having to talk about it. It's so much less energy and effort to spend time with a person like that. [patient 07]

Most patients described how changes in their body had led them to feel differently about themselves, and many expressed enthusiasm for connecting with other AYAs to discuss these changes. For example, one young woman described interest in meeting other AYA through Facebook:

You know, [if I] met these girls, like, through the Facebook page, and I can ask them, like, oh, has your menstrual cycle came back? Like, oh, no, my menstrual cycle hasn't come back. You know, stuff like that, because it's like as a girl you ask yourself, like, is my menstrual cycle ever going to come back again? [patient 02]

In fact, patients, parents, and providers were enthusiastic about the internet as a tool for facilitating peer-to-peer support. As one mother described:

Yes, and that has been one of the most incredibly beneficial things about it. If you had asked me before my daughter had cancer that my kid would be on the computer talking with people I don't know at midnight, I would have flipped out. I would have never thought that would be the case, but I will tell you with her having continual setbacks with her situation drawing her away from her real friends in real life, this has been a way for her to communicate with people, and it has been amazing. [parent 05]

One provider described her interest in social media as a tool for promoting social support:

There are a large percentage of these patients who will require multiple rounds of therapy and many of these patients will not be cured and they will succumb to their disease. I think that this population would benefit from a social networking or peer-to-peer type of outreach to help them sustain them through this journey. [provider 01]

Main themes associated with AYA intervention preferences are presented in Table 2.

Integration of Framework and Key Interview Themes into Development of the Program

Examination of the RIM-based [24,25] interview themes guided the development of the Mindfulness for Resilience in Illness program content. Specifically, a persistent theme of anxiety related to uncertainty surrounding reoccurrence and treatment adverse effects confirmed the utilization of a mindfulness-based program. Qualitative data revealed that imaging scans are a source of anxiety, and one participant expressed concern about using the term "body scan" to describe a mindfulness activity. As such, we did not use this specific exercise and reviewed program content for other potential procedure-related terminology. In addition, discussion of self-image concerns informed our decision to end the program with an emphasis on self-compassion.

The strong interest of the AYA in connecting with and learning from other AYA who have experienced cancer guided the content development for both the mindfulness app and the Facebook-based social support group. Given that AYA were interested in—but mostly unfamiliar with—mindfulness, we decided to create videos featuring two sarcoma survivors as program hosts. Facebook group refinement included tailoring activities to promote group interaction and ensuring that group participation would be private.

Building on the interview results, the Learning to BREATHE program [27] informed the structure of the mindfulness app portion of the program. The Learning to BREATHE [27] program was chosen because it is a sequenced mindfulness program appropriate for introducing AYA to mindfulness. Learning to BREATHE has been shown to affect positive outcomes in high school [27,34] and college-aged students [35].

Provider interviews indicated that providers wanted to support their patients' use of a mindfulness-based program. Providers also indicated that providers focused on addressing psychosocial needs of AYA (eg, psychologists, social workers, and child life specialists) would be most likely to implement the program. Collectively, these findings guided the development of a provider e-book guide.

All program content was reviewed by the study team to ensure that the content would be developmentally and cognitively appropriate for the intended participant sample. Intervention components are described in the aim 2 section; Textbox 1 and Table 3 present the app program content and a description of the Facebook group content, respectively.

Table 2. Suggestions from adolescents and young adults for the intervention.

Theme	Example quote
Positive tone	"I think that, and just like spreading positivity on that page is obviously going to be a huge plus".
Privacy	"I don't necessarily need this friend that I knew in elementary school to know that I am part of this sarcoma support group. Having that either be secret or specifically just within the app, I think that make some people feel more comfortable."
Space to exchange practical tips for dealing with sarcoma	"Different sections dedicated to patients going through what they're going through...What do you guys do when it's scan time? How do you guys relax."
Bright, appealing visuals	"I would say, go kind of colorful. Not over the top, but definitely a lot of colors are always fun to see. Appealing to the eye."

Table 3. Description of Facebook content, average response rates by AYA participants, and sample posts and responses from among the 38 total Facebook posts.

Post type and sample post	n (%)	Response rate, n (%)	Sample reply
Informational	**7 (18)**	**N/A**	
At the beginning of each week I'll post a link to the weekly blog posted on the app. Check out this week's blog post! [link to blog post URL]			
App feedback	**12 (32)**	**8 (47)**	
Which relaxation from the program have you enjoyed the most, and why? (1) Focus your Attention, (2) Belly Breathing, (3) Finding an Anchor, (4) Fuller, Deeper Breath, (5) 1.2.3. Breathe (6) Sense the Body, (7) Happy Breath			"Belly breathing was my favorite because it really helped me calm down"; "I liked the finding an anchor because it focused on different ways to relax other than breathing (even though breathing relaxes me)"
What did you think about today's "Reflect and Redirect" exercise?			"It was very interesting, definitely going to try it when I need to next"; "I liked this one but I preferred the other two where we would name the emotion a bit more. The others where a bit more helpful to me since the reflection often caused me to start over analyzing and I wasn't really able to get out of it."
It's the final day of the program. List 4 words that describe how you feel about the program. What have you learned? Post a word, picture or image that helps to summarize what you have learned.			"I have learned to be calm and 4 words are calm passion thankful and nature"; "Introspection, breathing, calm, and accepting. I've learned that this is something that truly helps and that I should continue doing in some way, even if it's only 5-10 minutes a day."
Interaction and reflection	**19 (50)**	**9 (53)**	
What is your spirit animal and why? (It doesn't have to be an actual animal, you can channel your favorite singer/artist, etc) Give us a visual! Post a photo to illustrate!			"My spirit animal would be a lion. The lion is my spirit animal because it is stronger, courage(ous) and a leader. I'm very much like a lion…and they are also my favorite animal"; "Batman is my spirit animal. I believe Batman is someone that represents the good and bad in everyone, He transcends the limits of man. I believe that in battling cancer we all find ourselves becoming Batman!"
You have $500 and you can shop for anything that affects your self-image. Post a picture of what you would buy.			"The $500 would go into my cosplay fund. I can buy fabric and wigs for characters I want to become"; "I think I would save it for my college fund. I feel like that would help my self-image in that it makes me more secure in my future and gives me more power and choice over it."
This is the last week of relaxation exercises, and the theme is positivity. For what in your life do you feel most grateful?			"I'm so grateful for my family, as cliche as that sounds"; "I'm most grateful for my life because after battling cancer and not knowing whether I would win or lose I'm grateful for every moment!"

Aim 2: Pilot Test of the Mindfulness for Resilience in Illness Program

Characteristics of Participants

Of the 26 patients approached, 22 patients were screened. Of those not screened, two were lost to follow-up, one was not interested, and one was not available during the intervention period. Of the 22 AYAs screened, 22 were eligible and 20 enrolled in the study. One patient indicated interest and was invited to enroll but did not complete online consent forms. The other patient declined because of disinterest. Six providers were screened, found to be eligible, and enrolled. In total, 26 people participated in the pilot study. Twenty AYA participants consented to be in the study. Seventeen of these participants (mean age 19.1, SD 3.7 years; 41%, 7/17 female) downloaded the app and joined the Facebook group (seven of these participants participated in the aim 1 interviews). Of the remaining three participants, one formally withdrew, and two did not participate in the study after completing the online consent and prestudy questionnaires. Data presented throughout this report exclude these three individuals who withdrew from the study. Six additional health care providers consented to participate in the pilot study stage; all six were female. Based on information gathered in the earlier interviews about who would be most likely to offer a psychosocial intervention to patients, we purposefully recruited three child life specialists: two nurses and one psychologist. See Table 4 for details about participant characteristics.

Table 4. Characteristics of the adolescents and young adults (AYA) and providers participating in the pilot test (aim 2).

Characteristic	AYA (n=17)	Providers (n=6)	Total (N=23)
Age (years), mean (SD)	19.1 (3.7)		
Age range (years), n (%)			
13-17	7 (41)		
18-25	10 (59)		
Sex, n (%)			
Male	10 (59)	0 (0)	10 (44)
Female	7 (41)	6 (100)	13 (57)
Ethnicity, n (%)			
Hispanic/Latino	8 (47)	0 (0)	8 (35)
Non-Hispanic/Non-Latino	8 (47)	6 (100)	14 (61)
Unknown	1 (6)	0 (0)	1 (4)
Race, n (%)			
White	9 (53)	6 (100)	15 (65)
Black/African American	1 (6)	0 (0)	1 (4)
Asian	1 (6)	0 (0)	1 (4)
Multiracial	6 (35)	0 (0)	6 (26)
Unknown	0 (0)	0 (0)	0 (0)
Treatment status, n (%)			
On treatment	1 (6)		
1-3 months posttreatment	1 (6)		
4-8 months posttreatment	4 (24)		
1-2 years posttreatment	4 (24)		
3-6 years posttreatment	6 (35)		
Off treatment for unknown duration	1 (6)		
Providers' specialties, n (%)			
Oncologist		0 (0)	
Nurse or medical assistant		2 (33)	
Child life, psychology		4 (67)	

Mindfulness App Usage

On average, participants completed a mean 16.9 (SD 11.9, range 0-28) of the 28 unique sessions, used the app for a mean 10.2 (SD 8.2, range 1-23) days during the evaluation period, and engaged with the app for a mean 112.5 (SD 79.4, range 1-208) minutes.

Facebook Social Support Group Usage

All but one person (16/17) in the Facebook group posted at least one reply to the moderator's prompts. The mean number of responses was 15.2 of 31 (49.0%, range 0%-96.8%); therefore, participants responded to approximately half the moderator's posts. The daily response rate ranged from 23.5% to 75.0% (mean 49.9%); which means on any given day approximately half the participants responded to the moderator's post. See Table 3 for a sample of the daily moderator prompts, example responses, and the mean response rates for each category of post.

Mindfulness App Acceptance

Overall, participants responded that they enjoyed using the app (mean 5.69, SD 1.12; 1=not at all to 7=very much so), would be likely to continue using the app (mean 5.13, SD 1.54; 1=definitely no to 7=definitely yes), and would be very likely to recommend it to others (mean 6.19, SD 1.05; 1=definitely no to 7=definitely yes). See Table 5 for the ratings of specific features.

Table 5. Results of acceptance tests completed by adolescents and young adults (AYA) and providers.

Question	Mean (SD)	Rated ≥5, n (%)
AYA[a]		
How much did you enjoy using the prototype mindfulness mobile app?	5.69 (1.20)	13 (81)
Overall, how easy or difficult did you find it to navigate through the mobile app?	5.50 (1.27)	12 (75)
How much did you like or not like the seven audio relaxations offered during...		
Week 1	5.19 (1.64)	12 (75)
Week 2 (n=14)	5.00 (1.30)	9 (64)
Week 3 (n=15)	5.07 (1.71)	8 (53)
Week 4 (n=14)	5.14 (1.29)	8 (57)
Recalling the weekly video introductions and conclusions, how much did you like or not like the videos of the program hosts?	4.56 (2.22)	9 (56)
How helpful were the following features ...		
Facebook group	4.56 (1.75)	11 (69)
Blog posts (n=13)	4.15 (1.46)	6 (46)
Sleep meditations (n=13)	5.46 (1.76)	11 (85)
Host videos (n=15)	3.80 (2.04)	8 (53)
Did the mobile app help you to relax?	5.75 (1.39)	12 (75)
Did the mobile app help you to learn about managing difficult thoughts and feelings? (n=15)	4.13 (1.64)	4 (27)
Did the mobile app help you to learn about practicing self-kindness? (n=15)	4.93 (1.83)	7 (47)
Did the Facebook group help you to connect with other people?	3.50 (1.97)	5 (31)
If it was available to you, would you continue to use the mobile app?	5.13 (1.54)	10 (63)
Would you recommend the mobile app to someone you know with cancer?	6.19 (1.05)	14 (88)
Provider (n=6)		
How helpful do you believe the app may be for AYA with cancer?	6.67 (0.52)	6 (100)
How likely would you be to recommend the mindfulness app to a family with an adolescent or young adult managing cancer?	6.83 (0.41)	6 (100)
Overall, do you believe the sample Provider Guide would be a helpful resource for providers, or members of their teams, working with AYA with cancer?	6.50 (0.84)	6 (100)
How useful do you think mindfulness-based stress reduction strategies are for AYA with cancer?	6.50 (0.55)	6 (100)
How likely would you be to recommend the Mindfulness for Resilience in Illness program to another health provider?	6.67 (0.82)	6 (100)

[a]For AYA, n=16 unless otherwise noted.

Textbox 2. Participants' recommendations for improving the mindfulness app.

Adolescents and young adults

- Additional features: search bar, chat forum/support group, relaxing music, a place to write down thoughts, other activities (brain quizzes, etc)
- An online counselor or someone to talk to
- Making the videos a little shorter
- Improved navigation
- Change the audio narration to include fewer pauses
- Talking more about cancer throughout the app content, not just during the introductions and takeaway videos
- Decrease the number of passive activities (eg, audio/video) and increase the number of active activities (eg, journal)
- Integrate the social support group into the app; including more group conversations
- Meditations should keep running, even if the phone was in sleep mode; or add a sleep timer
- Enable commenting on specific exercises within the app

Providers

- Remove the dashboard feature for tracking progress
- More easily separate app into its different components (blog, video, mindfulness activities)
- More content featuring peers
- Add pre and post mood assessments into each exercise to help the youth notice benefits
- Continue to receive feedback from the patients
- Interactive chat rooms; someone available to respond in times of crisis; hotline link
- Add mood and sleep tracking

Open-ended responses about the experience of AYA with the mindfulness app revealed that some participants found the audio meditations to be relaxing, and in some cases detailed how they were helpful. As one male explained, "I loved that it helped remind me to be mindful of my actions that contribute to battling my anxiety" (patient 205). Others explained that the audios helped with sleep; one female said, "I sometimes have [a difficult time] time sleeping or getting a full night rest but after listening to the voices I slept through the whole night" (patient 206). Participants also offered a range of suggestions for improving the mindfulness app, which centered around improving navigation, more opportunities for active participation, and more references to the cancer experience. Recommendations are listed in Textbox 2.

Facebook Social Support Group Acceptance

Participants responded that they found the Facebook group somewhat helpful (mean 4.56, SD=1.75; 1=not at all helpful to 7=very helpful). All 16 participants who completed the acceptance test replied "yes" when asked, "Would you recommend that this type of online social group be part of a future support program for youth with cancer?"

Participants described their experience with the Facebook group in open-ended responses. Participants felt strongly that online social support was a crucial and absent component of their cancer experience. As one young female described, "A social group for young people affected by cancer is something major that is missing for the emotional side of treatment" (patient 215). Some participants stated appreciation for the group; for example, "I liked that it was a safe place to expose your own thoughts/anxieties" (patient 205). In addition, they appreciated that the questions posed by the moderator were not only direct questions about the app program; for example, "I liked that there were not just questions referring to the meditations" (patient 213). Some responded that being expected to respond daily was too much; for example, "That there were questions every day, it was a little hard to keep up with responding" (patient 209).

Participants also offered several useful suggestions for future iterations of the online social support group. To enrich the experience, a few participants suggested facilitating more meaningful relationship-building conversations. For example, a young female said:

> *I would recommend it, but also something slightly less faceless if that makes sense. It was difficult to actually get to know people since most of the questions or discussion topics were more "fun fact" than really getting to know. Maybe having some more personalized chat features or encouragement to post not just on prompts but on our own would also be good.* [patient 213]

Textbox 3. Recommendations from adolescents and young adults for improving the Facebook group.

- Increase interaction among participants, including sharing diagnoses and situations, more personal conversations, talking about being in the hospital
- Opportunities to meet up with people
- Expand to other hospital patients
- Add inspirational quotes
- Pair up someone in remission with someone currently going through treatment
- Talking more about cancer and treatment instead of just emotions and exercises
- Asking people in the group to do things that take their mind off their issues (more talking to people, exercising, new hobbies, etc); education/advice about these types of things you can do to feel better
- Combining the questions with optional writing exercises
- Include some articles that don't just pertain to emotional dealings but pragmatic tips for dealing with nausea or hair loss (like those found in magazines)
- Make the group easier to access within Facebook
- Extension of the blog posts, including having teens and young adults submit questions, topics, writing pieces, etc

Another female suggested that content could be more cancer-specific:

> *Articles that don't just pertain to emotional dealings but pragmatic tips for dealing with nausea or hair loss. Something similar to how magazines give tips and tricks since that is a very palatable format to many people that I know, and something that I really missed from a lot of coping and support forums that I've encountered for cancer. It also makes the situation feel less momentous and alien since if it's presented in such a way, ultimately leading to a certain amount of normalization that I know that I often seek out.* [patient 213]

Suggestions for future enhancements are summarized in Textbox 3.

Psychosocial Measures

Results of paired samples *t* tests indicated there were no significant differences from pretest to post test on measures of perceived social support, mindfulness, body image, or quality of life. Means are presented in Table 6.

Provider Acceptance of the Mindfulness App and Facebook Social Support Group

Providers were enthusiastic about the program. Asked if the mindfulness app would be very helpful for AYA with cancer, four of six responded 7, and two of six responded 6 (where 1=not at all helpful to 7=very helpful). Five of six responded 7, and one of six responded 6 when asked if they would be very likely to recommend it to a family with an adolescent or young adult managing cancer. Please see Table 5 for other quantitative responses.

Providers' open-ended responses about the mindfulness app and the Facebook social support group also revealed enthusiasm for the approach. One provider reported that the peer-to-peer resources were important (eg, "Peer videos were great! I think you get the most buy in from teenagers when they can hear directly from others who have similar experiences"). Others described the importance of helping AYA to identify and regulate emotions, for example, "I also specifically liked the information about the temporary state of emotions" (provider 02) and "Love the ride the waves quote. This is so true. We cannot take away our emotions, but we can learn to deal with them" (provider 03).

Provider Acceptance of Provider Guide

Providers also reported that the provider guide would be a helpful resource (four of six chose 7, one of six chose 6, one of six chose 5; 1=not at all helpful to 7=very helpful), and that the program overall was something that they would be very likely to recommend to another health care provider (five of six chose 7, one of six chose 5; 1=not at all likely to 7=very likely).

Table 6. Psychosocial measures completed by adolescent and young adult participants.[a]

Measure	Preintervention, mean (SD)	Postintervention, mean (SD)
Social support	14.4 (3.9)	13.6 (3.4)
Mindfulness	24.9 (7.1)	23.7 (6.6)
Psychological functioning	6.1 (3.1)	6.6 (3.8)
Body image	3.9 (2.9)	3.0 (2.9)

[a]Data presented are for the 16 participants who completed pre- and poststudy questionnaires.

Textbox 4. Providers' recommendations for improving the provider guide.

- Additional resources; links with local resources
- Written and visual instructions for navigating the app (for providers who are less tech savvy)
- Make it available as an app for reference; have it available to parents as a resource

To aid with future efforts, providers were asked what information they would find most useful for introducing the mindfulness app to patients. Most (four of six) responded that they would like to receive the provider guide paired with video training on relaxation and mindfulness basic practice. Three providers responded that they would like to receive the provider guide paired with a live webinar run by an expert in mindfulness; two responded that they would like to receive the provider guide paired with a list of practitioners who could use it to help support patients. Suggestions for improvement are summarized in Textbox 4.

Discussion

The aim of this study was to use a patient-centered approach to develop and pilot-test the Mindfulness for Resilience in Illness program, a mobile-based mindfulness and social support program for AYA with sarcoma and survivors. Overall, AYA used the program and responded positively to it, offering useful suggestions for improvement. This study extends the small body of research on the use of mindfulness-based programs for AYA with cancer [17], offers further support for the use of Facebook as a tool to offer social support to young people managing a health condition [36], and suggests that it may be acceptable to deliver this content through a mobile device to AYA who have experienced sarcoma.

Participants in our study were encouraged to complete one meditation per day for 28 days. On average, participants completed 17 unique meditations and used the app for 112 minutes over 10 of the 28 days, which suggests that AYA users may prefer informal use of mindfulness and resiliency skills rather than directed daily use. Limited data exist on how much time participants need to practice mindfulness meditations to experience meaningful change. Although many mindfulness apps exist, the quality and systematic examination of these apps vary. A recent review and evaluation of mindfulness-based iPhone apps [37] identified five apps that provided progressive/program-based mindfulness training with recommendations for daily practice. Of these, the Headspace app received the highest average quality score. In a recent study [38] of the effectiveness of the Headspace app, completion of 10 approximately 10-minute sessions, was found to be sufficient to positively impact stress, affect, and irritability. These 10 sessions were completed over 15.8 days. Although these app engagement data are comparable to the results from this study, the Headspace intervention was conducted with healthy adults so these findings may not generalize to a clinical AYA population. More research is needed to determine the appropriate mindfulness app treatment engagement dosage necessary to affect meaningful clinical change.

Acceptance data suggested that most participants enjoyed using the program and that it helped them to relax. Participants also suggested modifications that could improve the experience, such as including music in the app or including a timer so that the app could turn off after the user had likely fallen asleep. Practical suggestions such as these could help increase engagement in a program. Sleep difficulties are common among AYA with cancer [39], so it is important to get feedback on modifications to the app that might help with sleep. Given that others have reported that mindfulness may be helpful for AYA dealing with the experience of cancer [17], the main implication from our study is that it may be feasible to deliver an MBI to AYA with sarcoma using mobile technology. Mobile-based interventions can be used to complement or extend the benefits of in-person programs. As such, a program such as the one described in this paper may be a valuable complement to a hospital-based mindfulness program for AYA dealing with sarcoma.

Participants in the study were also encouraged to participate in a Facebook group with daily prompts to answer questions about the mindfulness app, or questions designed to promote positivity and social interaction. Participants responded to approximately half of the prompts, and approximately half of the participants joined the conversation on any given day. Quantitative acceptance data revealed that most participants did not agree that the Facebook group helped them connect with other patients. The qualitative feedback helped to explain this finding; AYA reported that they wanted more of the conversation to be about the cancer experience and they wanted more opportunities to get to know the other participants. These qualitative findings are consistent with results from surveys suggesting that AYA with cancer have unmet social needs [12] and suggest that improvements to a future Facebook-based social support group could be to facilitate more opportunities for relationship building among participants. Possibilities include crafting daily prompts specifically around the experience of living with cancer as a way to facilitate more meaningful conversation and deeper connections, and asking participants to participate in "buddy" exercises with another member of the group. In addition, guidelines for using Facebook groups in the management of disease include understanding the potential role of group "champions" [23]. In our experience, it was important to recruit a group moderator who was enthusiastic about the goals of the group and who had also experienced cancer. The daily presence of the moderator and the moderator's willingness to respond to participants' comments appeared to encourage conversation.

Finally, health care providers were asked to review a provider guide and comment on the program overall. The response was positive, and providers gave practical suggestions for improvement. Specifically, providers reported that including resources to help them learn mindfulness skills would be useful.

For the pilot study, we purposefully recruited providers who would be likely to offer the program to AYA (based on findings from the preliminary interviews). As such, we are encouraged that this group of six providers saw value in the program.

We did not see a significant change in the psychosocial measures of mindfulness, social support, psychological functioning, and body image. The main goals of the study were to develop and evaluate the use and acceptance of a pilot program. Given that the examination of psychosocial outcomes was exploratory in nature, this sample may not have been adequately powered to detect significant changes in these outcomes. The pilot study also did not include an assessment of factors that may have affected psychosocial outcomes. For example, it was beyond the scope of this pilot study to assess whether treatment engagement factors (eg, adherence, type of sessions completed, mindfulness practice, Facebook engagement) affected outcomes. In addition, the intervention improvement recommendations may provide some insight into intervention-related factors that may have contributed to psychosocial outcome results. Specifically, the program content may not have included enough opportunities for social interaction and social discussions surrounding different aspects of cancer treatment. Collectively, given these findings and methodological considerations, more work is needed to determine the effects of this intervention on psychosocial outcomes.

There are several limitations to our study. Our sample included patients with sarcoma, and most patients were off treatment, which may limit the generalizability of our findings to AYA patients with other cancer diagnoses and at different phases of treatment. In addition, it was beyond the scope of this study to examine how gender or age may affect intervention outcomes. Although qualitative themes were consistent across participants and participants expressed a desire for advice from teens and young adults, future work would benefit from examining whether developmental stage and gender affect psychosocial treatment needs and outcomes. Feedback from this sample will inform future program refinement, and future studies will utilize randomized controlled trials to examine the effects of this intervention on psychosocial outcomes in more diverse samples of AYA with cancer.

This study used a patient-centered approach to evaluate the unique needs of AYA with sarcoma and develop a mobile-based mindfulness and social support program for this AYA patient population. Mobile-based programs are cost-efficient, easy to disseminate, and have wide reach. These findings provide preliminary evidence of the feasibility and acceptability of a mobile-based mindfulness and social support program for AYA with sarcoma.

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Conflicts of Interest

At the time this study was conducted, ED was Chief Science Officer at BodiMojo, Inc, and TMC was Chief Executive Officer at BodiMojo, Inc, a company that collaborated with Whil Concepts Inc to create the Mindfulness for Resilience in Illness program.

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Abbreviations

AYA: adolescents and young adults
CAMM: Child and Adolescent Mindfulness Measure
IRB: Institutional Review Board
MBI: mindfulness-based interventions
RIM: Resilience in Illness Model

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Original Paper

Mobile Health Systems for Community-Based Primary Care: Identifying Controls and Mitigating Privacy Threats

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Abstract

Background: Community-based primary care focuses on health promotion, awareness raising, and illnesses treatment and prevention in individuals, groups, and communities. Community Health Workers (CHWs) are the leading actors in such programs, helping to bridge the gap between the population and the health system. Many mobile health (mHealth) initiatives have been undertaken to empower CHWs and improve the data collection process in the primary care, replacing archaic paper-based approaches. A special category of mHealth apps, known as mHealth Data Collection Systems (MDCSs), is often used for such tasks. These systems process highly sensitive personal health data of entire communities so that a careful consideration about privacy is paramount for any successful deployment. However, the mHealth literature still lacks methodologically rigorous analyses for privacy and data protection.

Objective: In this paper, a Privacy Impact Assessment (PIA) for MDCSs is presented, providing a systematic identification and evaluation of potential privacy risks, particularly emphasizing controls and mitigation strategies to handle negative privacy impacts.

Methods: The privacy analysis follows a systematic methodology for PIAs. As a case study, we adopt the GeoHealth system, a large-scale MDCS used by CHWs in the Family Health Strategy, the Brazilian program for delivering community-based primary care. All the PIA steps were taken on the basis of discussions among the researchers (privacy and security experts). The identification of threats and controls was decided particularly on the basis of literature reviews and working group meetings among the group. Moreover, we also received feedback from specialists in primary care and software developers of other similar MDCSs in Brazil.

Results: The GeoHealth PIA is based on 8 Privacy Principles and 26 Privacy Targets derived from the European General Data Protection Regulation. Associated with that, 22 threat groups with a total of 97 subthreats and 41 recommended controls were identified. Among the main findings, we observed that privacy principles can be enhanced on existing MDCSs with controls for managing consent, transparency, intervenability, and data minimization.

Conclusions: Although there has been significant research that deals with data security issues, attention to privacy in its multiple dimensions is still lacking for MDCSs in general. New systems have the opportunity to incorporate privacy and data protection by design. Existing systems will have to address their privacy issues to comply with new and upcoming data protection regulations. However, further research is still needed to identify feasible and cost-effective solutions.

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KEYWORDS

mobile health; mHealth; data security; privacy; data protection; privacy impact assessment; public health

Introduction

Background

Mobile health (mHealth) apps for *health surveys and surveillance* play a crucial role in creating rich data repositories for public health decision-making [1,2]. Apps for health surveys are usually known as mHealth Data Collection Systems (MDCSs), used by Community Health Workers (CHWs), replacing less efficient and less reliable paper-based approaches [3,4]. The CHWs' main task is to visit families at their homes to provide primary care, but they also carry out surveys, collect the family's data, and report it to the government. Instead of using paper forms, the CHWs can now use smartphones or tablets for the data collection process.

It is a problem that although mHealth initiatives are developed with a positive and optimistic outlook, there is often little concern for the privacy implications of the app [5]. The existing solutions do not carefully consider privacy and it remains unclear how to deal with the issues inherent to systems of health surveillance. MDCSs are used to collect, process, and share sensitive data (ie, personal health data), making *privacy and security* of paramount importance.

In recent years, much research has focused on the information security aspects of MDCSs [6-9], that is, dealing with the concepts of confidentiality, integrity, and availability, which are commonly addressed by means of security mechanisms for encryption, authentication, secure storage, and access control. Privacy, in turn, stands for the respect of fundamental rights and freedoms of individuals with regard to the processing of personal data. It overlaps with security, especially regarding confidentiality, but many other privacy principles should be addressed (eg, purpose binding, transparency, data minimization, unlikability, intervenability, accountability, and consent)—fundamental differences that are further discussed in this paper. It means that although privacy-preserving systems require strong security, security by itself is not enough.

There are many reasons for enforcing privacy in the primary care context. Privacy is *sine qua non* for achieving high-quality health care [10]. Personal data are collected, processed, and shared in the delivering of health services. Patients (ie, the data subjects) want their information to be used for meaningful purposes, and they want to provide personal data access to health workers so that they can receive proper care. If privacy is not enforced, patients may refrain using the service and/or hold back information, thus preventing health care workers from providing efficient and effective care. The result is inferior quality of health care.

MDCSs are inherently mass surveillance tools. Health care workers may have access to health data of entire communities, so that the privacy impact is amplified. There is a great power imbalance between individuals and the health agencies. Members of underserved communities, typically with less power, face greater risk because of privacy violations [11]. Therefore, it is important to follow *privacy principles* during the design of such systems. Privacy principles have been vastly discussed in the scientific literature and embodied in legal frameworks in various jurisdictions, for example, European General Data Protection Regulation (EU GDPR) [12] and the Brazilian general Bill on the Protection of Personal Data (PLC 53/2018) [13]. Legal frameworks entail compliance, and thus project managers and developers should be prepared to follow such regulations.

Given that, our main research question is the following: *How to design a privacy-aware and secure MDCS?* To answer this question, a Privacy Impact Assessment (PIA) framework is chosen as a strategy for realizing privacy by design. [PIA] *is a systematic process that identifies and evaluates, from the perspectives of all stakeholders, the potential effects on privacy of a project, initiative or proposed system or scheme, and includes a search for ways to avoid or mitigate negative privacy impacts* [14]. PIA comes from the notion of *impact assessment*, defined as *the identification of future consequences of a current or proposed action* [15]. PIAs support a stricter analysis of privacy risks, that is, *effect of uncertainty on privacy* [16]. Each stage of the PIA process builds up on each other, offering not only the risk assessment but also a solid strategy for risk management regarding privacy. In this paper, a PIA is presented using the GeoHealth MDCS [3] as a case study to ground our analysis. As our methodology, the PIA framework proposed by Oetzel et al [17,18] is adopted in this study.

As a result, this paper brings the following contributions: (1) it provides a comprehensive privacy analysis for an MDCS, identifying threats and controls that help project managers and developers solve privacy and data protection issues in their systems, and (2) it shares the experience on how to carry out a PIA for a large-scale mHealth system, as advocated in previous studies [5,19], and it can be seen as an example to other mHealth initiatives. To the best of our knowledge, this is the first thorough privacy analysis for an MDCS. In fact, most mHealth systems neither mention nor appropriately discuss security issues in their systems [20], including privacy.

Previous Work

This section presents an overview of the previous work in regard to (1) MDCSs, (2) PIA frameworks, and (3) security and privacy of MDCSs. In the sections that follow, various contributions in the area that precedes the current research are described.

Mobile Health Data Collection Systems Worldwide and in Brazil

Initiatives for replacing paper-based solutions by MDCSs have been increasingly and especially adopted in developing countries [21]. A more recent example is MoTeCH [22,23], employed in Ghana, which empowers nurses and CHWs with a simple mobile app for recording and tracking the care delivered to women and newborns, and it generates management reports mandated by the country's health authorities. There are also standardized, general purpose tools that help in the task of designing forms and sending them to mobile devices, such as the Magpi framework [24] and the Open Data Kit [25]. Moreover, the World Health Organization together with a group of academic and research institutions and technology partners is developing the Open Smart Register Platform [26], which has been used

to empower frontline health workers to electronically register and track the health of their entire client population.

Similarly, many MDCSs have been developed and tested in Brazil. Given the importance of Brazil's Family Health Strategy (FHS) program for community-based primary care [27], it is natural that various MDCSs focus on the data gathering for the Health Information System for Primary Care (SISAB) database. FHS is one of the most important programs of the Brazilian public health service, *Sistema Único de Saúde*. In the past, the research on MDCSs was mainly developed by research groups inside universities, as it was the case with projects Borboleta [28] and GeoHealth [3].

In this paper, the privacy analysis is particularly grounded on the GeoHealth system. GeoHealth has been targeted in various scientific publications over the years, including work about the design process [8,29], large-scale deployment [3], and CHWs' experience with the technology [4], which enables us to perform the PIA on the basis of published material, as well as previous first-hand experience with the system.

Privacy Impact Assessment Frameworks

Many PIA frameworks exist. Some are recommended to a specific jurisdiction and legal framework, whereas others aim for a specific industry sector or for a general methodology. The PIA for Radio Frequency Identification (known as PIA RFID) [18,30] and PIA Smart Grids [31] are examples of sector-specific frameworks. However, the PIA RFID was later generalized in a systematic methodology [17] and it is no longer limited to RFID applications. Other well-known PIA frameworks were proposed by data protection authorities in various countries, such as the British Information Commissioner's Office (ICO) PIA [32], the Australian Office of the Australian Information Commissioner's (OAIC) PIA [33], and the French Commission nationale de l'informatique et des libertés' (CNIL) PIA [34].

More recently, International Organization for Standardization/International Electrotechnical Commission released a standard for PIAs numbered ISO/IEC 29134:2017 [35]. This PIA framework offers as sound methodology with well-defined privacy principles (ISO/IEC 29100), risk identification and evaluation (ISO/IEC 31000 and ISO/IEC 29134), and privacy controls (ISO/IEC 27001 and ISO/IEC 29151). However, it is worth mentioning, that at the ISO/IEC, standards, for example, ISO/IEC 29134 and ISO/IEC 29151, had only been published when this study was already well underway, so they were not chosen as main PIA framework.

In recent years, the systematic PIA methodology [17] also gained more maturity and was endorsed by the Article 29 Data Protection Working Party [36], leading to its adoption for GeoHealth's PIA. Furthermore, the PIA RFID framework not only provides a robust methodology but it is also accompanied with extensive supplementary material [18,30], openly published and freely accessible since 2011. As far as possible, a parallel among existing PIA frameworks is drawn throughout the paper, given that methods from different PIA frameworks can be combined to better suit the analysis.

Security and Privacy of Mobile Health Data Collection Systems

Issues regarding *information security* in MDCSs (ie, confidentiality, integrity, and availability) have already been addressed by different authors. For instance, in a study by Cobb et al [9], a range of security threats to MDCSs, that is, Open Data Kit [37], have been identified. In the study [9], the authors detailed a threat modeling exercise on the basis of surveys and interviews with technology experts. Other examples on information security are the works of Gejibo at al [7] and Simplício et al [8] that propose 2 distinct security frameworks for MDCSs. These frameworks are designed to cope with the networking and processing constraints that are inherent to mobile computing. However, both frameworks considerably converge to the same security issues identified in the study by Cobb et al [9].

In addition, regarding mHealth privacy in general, the work of Avancha et al [6] proposes *threat taxonomy* that organizes threats into 3 categories: (1) identity threats, (2) access threats, and (3) disclosure threats. However, privacy is addressed in the study [6] in a rather narrow way. The taxonomy is composed by privacy-related threats, but it essentially overlaps with classical security properties (ie, threats to confidentiality, integrity, and availability). Therefore, if privacy should be considered in a broader dimension, the mHealth threat taxonomy [6] does not contemplate many important Privacy Principles (such as the ones listed in the section "Definition of Privacy Targets").

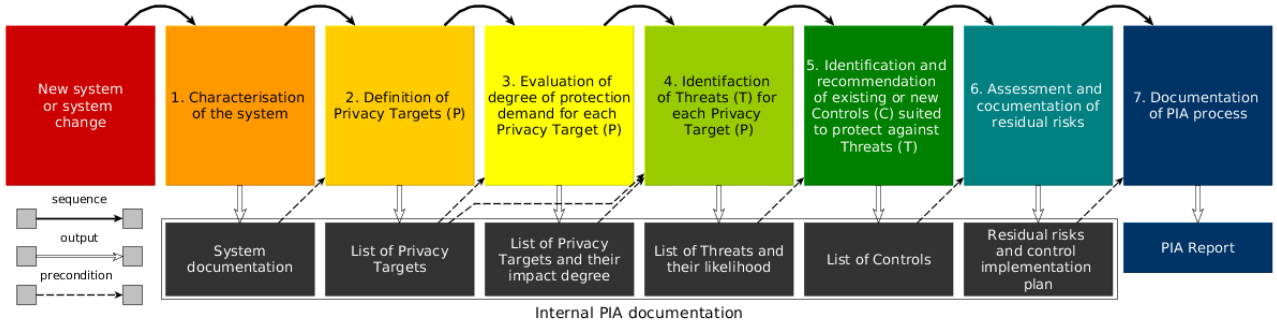
Finally, this paper also expands our previous work on GeoHealth's privacy threat analysis presented in a study by Iwaya et al [38]. On the basis of that, controls are identified and recommended in this paper to mitigate the previously identified threats. In addition, an extensive documentation is provided, enabling research reproducibility of GeoHealth's PIA and therefore contributing to bridge the knowledge gap between mHealth practitioners and privacy engineers.

Methods

This privacy threat analysis follows the PIA framework defined by Oetzel and Spiekermann [17]. In brief, this PIA framework supports project managers and developers to integrate privacy by design in their system development life cycle. The methodology comprises 7 steps, as shown in Figure 1.

Starting with the system characterization in Step 1, the Brazilian GeoHealth MDCS [3,4] is analyzed in the context of previous work on similar solutions [7].

Figure 1. Privacy Impact Assessment (PIA) methodology overview.



In Step 2, the Privacy Principles and Privacy Targets are defined on the basis of a legal framework. This PIA follows the EU GDPR [12] (enacted in May 2018). This choice is based on 2 reasons: (1) scientifically, the EU GDPR can be considered as state of the art in privacy regulations, and it can be also mapped to the work "A Taxonomy of Privacy [39]," regarded as "*the most complete list of privacy threats* [17]." (2) The current draft of the Brazilian data protection regulation, in a broad way, is akin to the EU GDPR. Even though the health and medical fields often have their own privacy-related regulations, GDPR compliance addresses the privacy problems to a great extent.

In Step 3, the Privacy Targets are evaluated using a degree of protection demand, similar to an impact level (eg, low, medium, and high). During the threat analysis in Step 4, stakeholders identify threats associated to each of the Privacy Targets. All threats are addressed in Step 5 with respective technical and/or nontechnical control measures; residual risk is analyzed, and an implementation plan is specified.

In Step 6, the plan for implementing controls and the remaining residual risk is documented. However, given that GeoHealth has been discontinued and controls cannot be implemented, this step is not performed. For this reason, this PIA can be considered as an *after-the-fact* review, which is still helpful to mHealth practitioners, who might not be particularly keen to publish in-depth public PIA reports about on-going deployments.

As a final outcome of Step 7, this paper can be considered as a "PIA Report" describing the whole analysis, with emphasis on Step 5, "Identification and Recommendation of Controls." Nonetheless, extensive documentation generated during the PIA process for Steps 1 to 4 is also provided in the form of Appendices.

GeoHealth's PIA was carried out by our group of researchers with expertise in information security, privacy, and health informatics. Particularly for Steps 3 to 5, the working group meetings were based on evidence from the scientific literature (presented in Section 1). Moreover, 1 of the members participated in the design and development of GeoHealth. Contributions from software developers of other MDCSs as well as specialists in public health and primary care were also received. During the interaction with partners, feedback on our reports and documentation were collected, so that the analysis could be refined.

Results

This section describes the intermediate results of the PIA process. As explained, Step 5, "Identification and Recommendation of existing or new Controls," is emphasized in this paper to offer the reader a minimum background. The preceding Steps 1 to 4 are nonetheless summarized, and complete documentation is provided in Multimedia Appendices 1 to 4.

Characterization of the System

GeoHealth is an MDCS tailored for Brazil's FHS program. It is composed by the GeoHealth-Mobile and the GeoHealth-Web. At the client side, the GeoHealth-Mobile is the Android app that implements all forms used for data collection. At the server side, the GeoHealth-Web implements Web services for receiving and consolidating data as well as for generating reports and exporting data to the national-level system (ie, SISAB/Department of Informatics of the Unified Health System). Figure 2 presents the system architecture, main actors (CHWs, families, physicians, and health managers), and system components.

The GeoHealth has been the target of many studies over the last years, so that further information can be found in the original material [3,4,8,29], as well as in a comprehensive description in Multimedia Appendix 1 [40,41]. For the readers' convenience, the data flow diagram presented in Figure 3 shows how personal information is handled by the different subprocesses.

Figure 2. Overview of the GeoHealth actors and their interaction with the system's components.

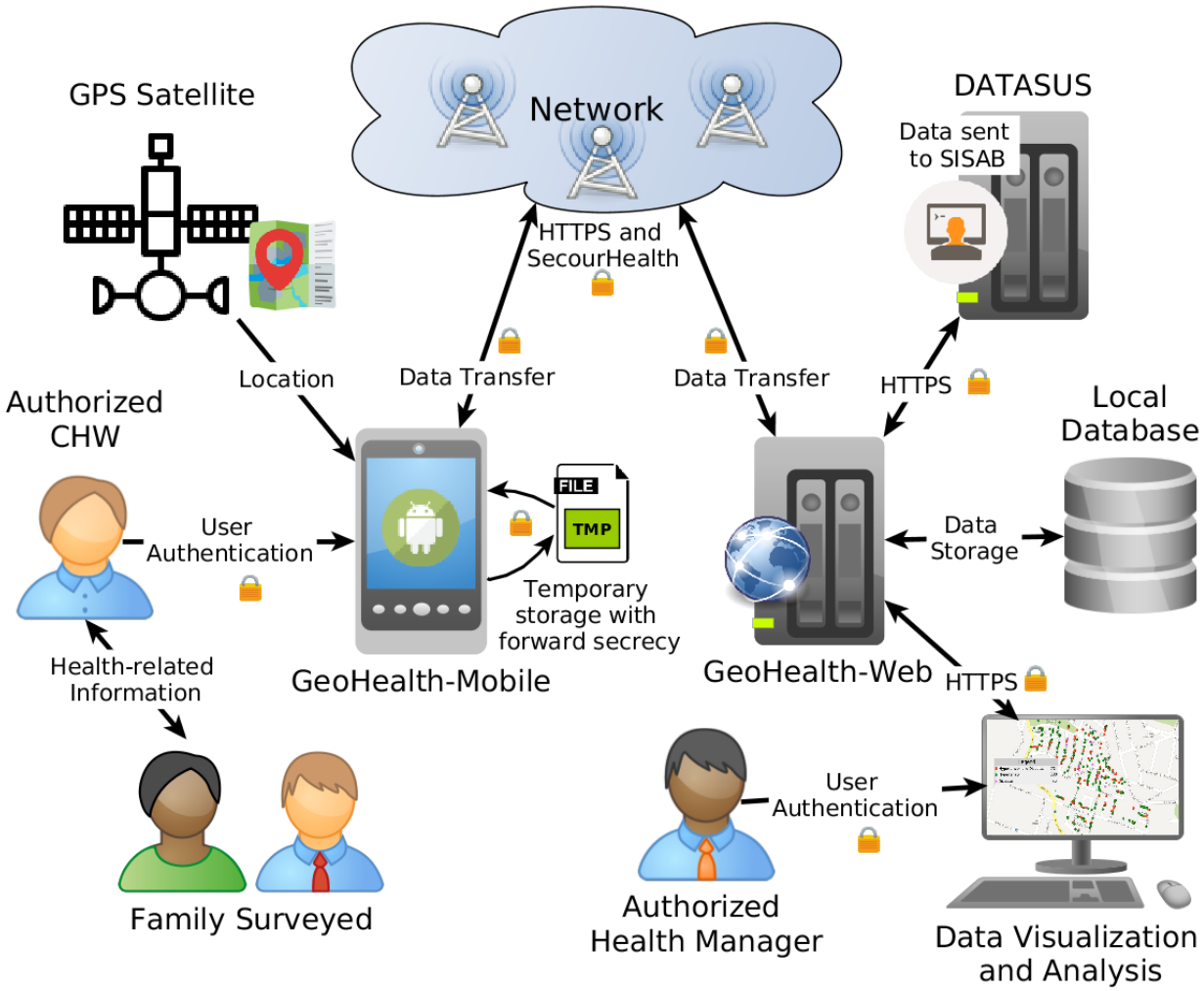
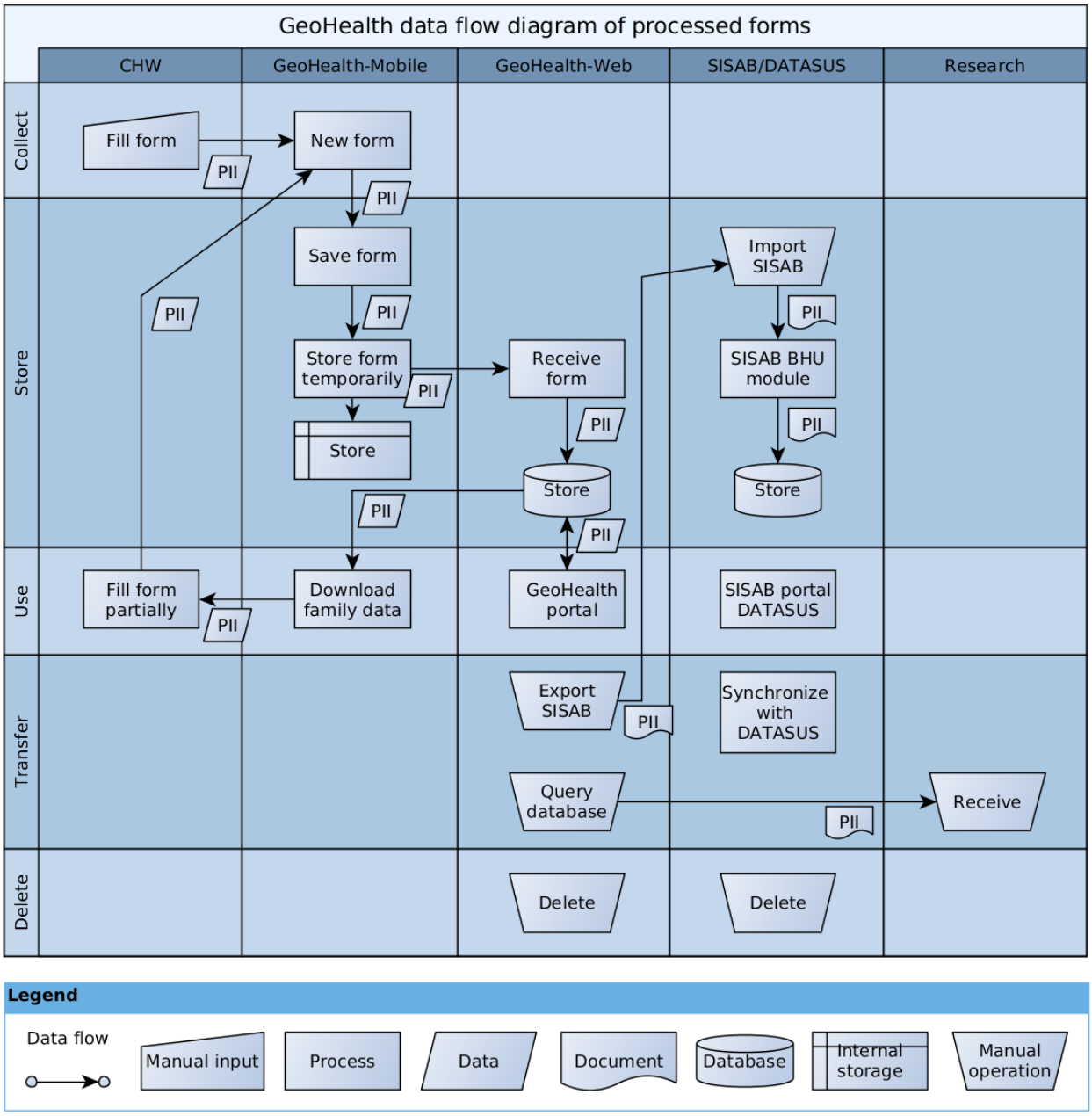


Figure 3. High-level data flow diagram of the GeoHealth environment. Acronyms: Personally Identifiable Information (PII); Basic Health Unit(BHU); Health Information System for Primary Care (SISAB); Department of Informatics of the Unified Health System (DATASUS).



Definition of Privacy Targets

After the system characterization, the next step is to determine the privacy principles that will be the basis of the design of our system. In the study by Oetzel and Spiekermann [17], the authors distinguish between *privacy principles* and *privacy targets*. Both terms were not explicitly defined, but privacy principles can be considered as a fundamental, primary, or general rule derived from the existing legal frameworks [12,42]. However, as explained by the study [17], these legal privacy principles must be translated into concrete, auditable, and functionally enforceable Privacy Targets and subsequent system functions. Furthermore, Privacy Targets should be formulated as action items, just like in widely accepted modeling techniques such as Unified Modeling Language and Architecture of Integrated Information Systems.

Textbox 1 presents a list of privacy principles and respective Privacy Targets derived from the European General Data Protection Regulation and originally conceived by Oetzel and Spiekermann [17,38]. Although this list was used as a baseline for this PIA, all Privacy Targets were reviewed in terms of applicability, meaning, and exhaustiveness in the context of GeoHealth. As a result of this revision, the principle *P5-Intervenability* was added and the targets that were previously listed under *P4 - Access Right of Data Subject* were moved to this new category (ie, P5.1, P5.2, and P5.3). Thus, now there is a clear distinction between data subject access (transparency) and intervenability. Furthermore, new Privacy Targets P4.2 and P5.4 were proposed and added to the list.

Textbox 1. List of Privacy Principles and Privacy Targets.

P1-Quality of data processing

- P1.1 - Ensuring processing in a lawful, fair, and transparent manner
- P1.2 - Ensuring processing only for legitimate purposes
- P1.3 - Providing purpose specification
- P1.4 - Ensuring limited processing for specified purpose
- P1.5 - Ensuring data avoidance
- P1.6 - Ensuring data minimization
- P1.7 - Ensuring data quality, accuracy, and integrity
- P1.8 - Ensuring limited storage

P2-Processing lawfulness (and informed consent)

- P2.1 - Ensuring legitimacy of personal data processing
- P2.2 - Ensuring legitimacy of sensitive personal data processing

P3-Information right of data subject (ex ante transparency)

- P3.1 - Providing adequate information in cases of direct collection of data from the data subject
- P3.2 - Providing adequate information where data has not been obtained directly from the data subject (eg, from third parties)

P4-Access right of data subject (ex post transparency)

- P4.1 - Facilitating the provision of information about processed data and purpose
- P4.2 - Facilitating the provision of an (electronic) copy of data

P5-Intervenability

- P5.1 - Facilitating the rectification, erasure, or blocking of data
- P5.2 - Facilitating the portability of data
- P5.3 - Facilitating the notification to third parties about rectification, erasure, and blocking of data
- P5.4 - Providing the ability to withdraw consent

P6-Data subject's right to object

- P6.1 - Facilitating the objection to the processing of personal data
- P6.2 - Facilitating the objection to direct marketing activities
- P6.3 - Facilitating the objection to disclosure of data to third parties
- P6.4 - Facilitating the objection to decisions that are solely based on automated processing of data
- P6.5 - Facilitating the data subject's right to dispute the correctness of machine conclusions

P7-Security of processing

- P7.1 - Ensuring the confidentiality, integrity, and availability of personal data storage, processing, and transmission
- P7.2 - Ensuring the detection of personal data breaches and their communication to data subjects

P8-Accountability

- P8.1 - Ensuring the accountability of personal data storage, processing, and transmission

Evaluation of the Degree of Protection Demand for Each Privacy Target

Each of the listed Privacy Targets was put in context and further evaluated. In this step of the PIA, Privacy Targets were ranked and priorities for the GeoHealth's privacy architecture were identified. To determine the right level of protection that each Privacy Target demands, a potential damage scenario had to be considered, that is, using the *"feared events"* technique by asking, *"What would happen if...?"* Every Privacy Target was challenged by its potential damage in case of noncompliance. Furthermore, the damage had to be considered from 2 perspectives: the system operator (eg, loss of reputation and

financial penalties) and its customer (eg, social embarrassment, financial losses, and jeopardize personal freedom).

A qualitative approach is used because privacy breaches are often "softer" or intangible (eg, hurt feelings, discredit, blackmail, and even death) rather than something with a specific monetary value (eg, a computer system or asset). Being qualitative is a major difference of the PIA methodology when compared with more quantitative asset-driven evaluations for security assessments. That is, assets such as data, software, and hardware are easier to quantify, such as loss and cost, whereas reputation, embarrassment, and harm to people's rights and freedoms are not. This part of the PIA process is detailed in Multimedia Appendix 2.

Identification of Threats for Each Privacy Target

For each Privacy Target, the threats that could impede us from achieving each target are systematically identified. A threat is essentially a noncompliance with the relevant privacy laws and standards that emerge from multiple sources, such as the lack of training and privacy awareness, inappropriate use, privacy-preserving technologies, or absence of privacy management and governance practices [17].

The identification of privacy threats for GeoHealth was presented as part of our previous work [38]. Further details can be also found in Multimedia Appendix 3. In summary, this threat analysis was built upon existing threats analyses for mHealth in general [6] or specifically for MDCSs [7,9], as well as privacy threats (for RFID) found in the study by Oetzel et al [18]. Thus, this threat analysis is not only based on the assessment of privacy experts but also on existing scientific literature, from which threats were reviewed and compiled.

As a result, 22 groups of threats and a total of 97 subthreats are identified. Threats can range greatly, jeopardizing principles such as data quality, processing legitimacy, informed consent, right to information, right to access, right to object, data security, and accountability. The threats were also classified as "likely" (n=86) or "unlikely" (n=11) to happen, enabling us to assertively assign controls.

Identification and Recommendation of Controls to Protect Against Threats

As a point of departure, a list of possible controls presented in a study by Oetzel et al [30] is used, combined with the security controls proposed in previous studies [7-9,43]. The final list is composed by 41 recommended controls (Table 1, further details in Multimedia Appendix 4) to cope with the identified privacy threats. According to the methodology, each control has up to 3 levels of rigor: (1) satisfactory, (2) strong, and (3) very strong. During the process of assigning controls for each threat, a level of rigor is also chosen, defining how extensive the control should be, which is likely costlier and more difficult. The level of rigor should match the previously defined level of protection demand determined in the section "Evaluation of Degree of Protection Demand for each Privacy Target." However, for the GeoHealth case study, all the threats are linked to at least one or more Privacy Targets with a "high" level of protection demand. Therefore, all controls in the consolidate list only need to be described for a "very strong" level of rigor (see Multimedia Appendix 4). Table 2 shows the association of controls to the identified threats.

Table 1. Consolidated list of controls. The detailed description of all controls can be found in Multimedia Appendix 4.

Control codes and short descriptions	Done?
C1.1 Service description	__[a]
C1.2 Information accessibility	—
C1.3 Language/semantics of information	—
C1.4 Information timeliness	—
C1.5 Privacy statement	—
C1.7 Purpose specification	—
C1.8 Ensuring limited data processing	—
C1.9 Ensuring purpose related processing	—
C1.10 Ensuring data minimization	Partly
C1.12 Ensuring personal data quality	Yes
C1.14 Ensuring data accuracy	Yes
C1.15 Enabling data deletion	—
C3.1 Obtaining data subjects' explicit consent	Partly
C4.1 Providing data processing information	Partly
C4.2 Providing information on third party information processing	—
C5.1 Informing data subjects about data processing	—
C5.3 Handling data subjects change requests	—
C5.4 Providing data export functionality	—
C5.5 Handling exemptions and derogations	—
C6.1 Notifying data subjects about sharing practices	—
C6.2 Handling objections (to automated decisions)	—
C7.1 Ensuring data subject authentication	—
C7.2 Ensuring staff authentication	Yes
C7.3 Ensuring device authentication	Partly
C7.4 Providing usable authentication	Partly
C7.5 Logging access to personal data	Yes
C7.6 Performing regular privacy audits	—
C7.7 Ensuring data anonymization	Partly
C7.8 Providing confidential communication	Yes
C7.9 Providing usable access control	—
C7.10 Ensuring secure storage	Yes
C7.11 Ensuring physical security of infrastructure	—
C7.12 Providing locked down devices	Yes
C7.13 Providing memory wipe	—
C7.14 Enabling offline authentication	Yes
C7.15 Network monitoring	—
C7.16 Preventing denial-of-service attacks	—
C7.17 Handling security incidents	—
C8.1 Demonstrate data privacy accountability	—
C8.2 Notification of authority	—
C8.3 Notification of data subjects	—

[a]The control was not implemented.

Table 2. Threat groups and associated controls. The detailed description of all subthreats can be found in Multimedia Appendix 3.

Threat Group	Description	Controls
T1.1-T1.5	Lack of transparency, missing or insufficient service information	C1.1, C1.2, C1.3, C1.4, and C6.2
T1.6-T1.10	Lack of transparency, missing or insufficient privacy statement	C1.5
T1.11-T1.18	Unspecified and unlimited purpose	C1.7, C1.8, C1.9, and C1.10
T1.19-T1.24	Collection and/or combination of data exceeding purpose	C1.8, C1.9, and C1.10
T1.25-T1.30	Missing quality assurance of data	C1.12, C1.14, and C7.1
T1.31-T1.34	Unlimited data storage	C1.15 and C1.10
T2.1-T2.8	Invalidation or nonexistence of consent	C3.1 and C5.5
T3.1-T3.5	No or insufficient information concerning collection of data from the data subject	C4.1, C4.2, and C5.1
T4.1-T4.4	Inability to provide individualized information about processed data and purpose	C5.1, C7.1, and C7.5
T5.1-T5.6	Inability to rectify, erase, or block individual data	C1.15, C5.3, C7.1, C7.5, and
T5.7	Inability to notify third parties about rectification, erasure and blocking of individual data	C5.3
T5.8-T5.10	Inability to support data portability for individual data	C5.4
T6.1	Inability to allow objection to the processing of personal data	C6.1 and C6.2
T6.2-T6.5	Inability to allow objection to the disclosure of data to third parties	C4.2, C6.1, and C6.2
T6.6	Inability to allow objection to being subject to decisions that are solely based on automated processing of data	C6.2
T7.1-T7.3	Identity threats, misuse and leakage of data subject identities [21]	C7.1, C7.5, C7.6, C7.7, and C7.8
T7.4-T7.11	Access threats, unauthorized access and modification of PHI[a] or PHR[b] [21]	C5.5, C7.2, C7.5, C7.6, C7.9, C7.10, and C7.11
T7.12-T7.19	Disclosure threats, unauthorised disclosure and data leaks of PII[c] and PHI [21]	C7.2, C7.3, C7.4, C7.5, C7.6, C7.8, C7.10, C7.12, and C7.13
T7.20-T7.21	Denial-of-service threats [22,24]	C7.3, C7.10, C7.14, C7.15, and C7.16
T7.22-T7.24	Inability to detect personal data breaches and communicate them to data subjects	C7.5, C7.6, C7.17, C8.2, and C8.3
T8.1-T8.2	Lack of accountability of personal data storage, processing, and transmission	C7.6, C8.1, and C8.4
T8.3-T8.6	Noncompliance with notification requirements	C8.2 and C8.4

[a]PHI: protected health information.

[b]PHR: personal health record.

[c]PII: personally identifiable information.

[c]Note that each group of threats has a number of more specific subthreats (eg, T1.1, T1.2, and T1.3). The technical or organizational controls (listed in Table 1) can then be associated to 1 or more subthreats.

Discussion

Principal Findings

In summary, GeoHealth's PIA is based on 8 Privacy Principles and 26 Privacy Targets derived from the EU GDPR. Associated to that, 22 threat groups with a total of 97 subthreats and 41 recommended controls are identified. Thus, offering a sound privacy analysis for a large-scale MDCS.

This research shows that the literature mostly focuses on the information security issues, solving only a fraction of the problem, that is, (P6) Security of Data. Currently, there is a lack of contributions on how to engineer privacy not only in MDCSs but also for the area of mHealth in general [5,19]. Our PIA helps to bridge this gap by exposing the problems and providing controls (see Multimedia Appendix 4). On the basis of this PIA, engineers have a clearer path toward solving the privacy issues and ideally being able to address them at the very early stages of the design process, when changes are often simpler and less costly.

In addition, the consolidated list of controls, in Table 1, also makes it clear that privacy cannot be dealt only with technical measures. In fact, most controls required a mixed approach of technical and organizational procedures that should be put in place to achieve privacy and data protection. One way of doing this is to integrate the organizational procedures related to privacy in an information security management system to facilitate for organizations and make the processes for both information security and privacy more efficient. This could be a task for further research.

Another important finding from the PIA is that some privacy issues are more challenging, requiring major changes on the existing MDCSs. However, it is not within the scope of a PIA to provide complete solutions to solve such challenges but rather to make them explicit. The main privacy challenges for MDCSs include the following: (1) individualized access to personal data to provide transparency and intervenability, (2) obtaining and handling explicit informed consent from data subjects and allowing consent withdrawal, (3) defining measures to object processing and allow data blocking or deletion, (4) employ security mechanisms, and (5) utilize appropriate anonymization techniques for data sharing. In the sections that follow, the discussion on each of these privacy challenges is expanded.

Transparency and Intervenability

Among the main findings, it is noticeable that existing MDCSs particularly fall short with respect to GDPR principles of *transparency and intervenability*, that is, (P1) Quality of Data Processing, (P4) Access Right of Data Subject, and (P5) Intervenability. In brief, MDCSs do not consider the data subjects' personalized access to their data in electronic form, and in fairness, they were designed to be accessed only by CHWs and medical staff. However, it is worth mentioning that to achieve GDPR compliance, nonelectronic access is sufficient. Nonetheless, as a matter of enhanced privacy by design (and not purely compliance), major redesign is required to add data subjects as system users and to support interaction with a personalized interface (eg, a privacy dashboard), somewhat similar to existing online medical records [44]. In this line, MDCSs would benefit from emerging Transparency-Enhancing Tools [45] that help to raise privacy awareness among data subjects by allowing them to know about the data that are collected and processed about them and the potential privacy risks (eg, discriminatory profiling, data breaches, and leaks). However, such changes greatly expand the system's attack surface (ie, a new category of users with access rights) and increase the costs of software development and underlying infrastructure. Therefore, the redesign of MDCSs requires further feasibility studies, especially for projects running in low- and middle-income countries.

Informed Consent

Explicit informed consent (ie, a signed written statement) [46] also has some particularities. Consent is a well-known requisite for providing medical treatment. In MDCSs, the consent is given for the processing of personal data. It refers to the data collection, processing, and access rights to the data and for the purpose stated, that is, it is about technologies and systems. Just as importantly, consent revocation needs to be as easily made as giving consent. As CHWs use smartphones for data collection, it is difficult for data subjects to withdraw their consent later, as they do not have direct computer access. Asking to revoke consent via telephone is not an easy solution either, as the data subjects must be properly identified first. There should also be routines for allowing to revoke the consent only for selected purposes (eg, a partial agreement, as there should be opt-in options for each purpose). Existing literature on MDCSs does not discuss opt-ins, but there are guidelines to help project managers [46].

On the other hand, consent is not the only lawful basis for personal data processing. Public health and social care can also rely on legitimate interests and the performance of a public task as justifications for the processing of personal data. However, some MDCSs can also be used for secondary purposes, which should be made optional to data subjects. For instance, linking the data subjects' personal data to other electronic health records or disclosing it for research and statistics outside the public health sphere. However, there is an immense power asymmetry between the public health system and the individuals. When the majority of the population relies uniquely on the public system, there is never really a free choice. That is, if data subjects are coerced or if there is a threat of disadvantage (eg, no health care) the consent can be rendered invalid.

Data Objection and Deletion

Features for *automated data deletion* are also missing in the existing MDCSs. That may be seen as a technicality that is just not explored in the MDCS literature, but it is associated with the well-known right to be forgotten and data minimization principle. For MDCSs, families may also change their address or move to other communities, which would require formal procedures for automated deletion, as well as *data portability* (ie, to send the family's data to another health unit). Data subjects may also require deletion or blocking of sensitive data that can impact their privacy. More importantly, medical conditions with strong genetic components can disclose information about the patient's relatives, that is, impacting other people's privacy. Individual privacy preferences pose challenges for executing data subject rights, as the data may refer to multiple data subjects, who all may have rights by different interest (eg, one may want the data to be deleted whereas the other would like data to be preserved). Routines are needed to handle such disputes and situations. In some cases, it may be possible to pseudonymize the identity of the person that wants his or her data to be deleted (eg, in case of infections), whereas in case of genetic relations, it may not currently be possible.

However, it is essential to know that medical information related to medical conditions and procedures cannot be deleted even if the data subject requests, that is, with respect to legal aspects of medical records alterations. Instead, because this is sensitive information, the protection mechanisms are even more important.

Security Mechanisms

Security frameworks specifically designed for MDCSs have already been proposed [7,8]. In brief, MDCSs need a Key Management Mechanism to provide Authentication and Key Exchange among parties (user's mobile and app server). Authentication protocols and key derivation schemes for MDCSs usually rely on symmetric cryptography, using password authentication. These protocols should also give support for online and offline user authentication so that users are not limited because of the lack of network connectivity or coverage. Other mechanisms should cope with the confidentiality of stored and in-transit data by means of encryption schemes for secure storage and transmission.

Anonymization

MDCSs also support the creation of rich repositories of health-related data needed for the planning, implementation, and evaluation of public health practice. These datasets are often used for secondary purposes by government agencies, researchers, and academics. In such cases, the data should be anonymized, that is, to protect privacy by making a number of data transformations so that individuals whom the data describe remain anonymous. The anonymization process can have variable degrees of robustness [47], depending on how likely is to (1) single out an individual in the dataset, (2) link records concerning the same individual, or (3) infer the value of 1 attribute on the basis of other values. In essence, all these circumstances should be avoided, resulting in an anonymized dataset. Anonymized data are not considered personal data; therefore, data privacy laws no longer apply. Although the literature on data anonymization is vast, fully anonymized datasets are difficult or even impossible to achieve. The Working Party 29 has already expressed an opinion on this matter [47].

Limitations

Although this PIA had been carefully designed and conducted, limitations of the research must be acknowledged. First, regarding methodological aspects, a parallel with other approaches for risk assessment can be drawn. That is, PIAs, as any risk assessment methodology, have inherent limitations [48]: (1) the estimation of risk is never complete in the mathematical sense, (2) a complete set of undesired events (threats) is never known, (3) no way is provided to deal with unknown vulnerabilities and attacks, and (4) continuous revision is always required. PIAs are not different. PIAs should be periodically reviewed, whenever assumptions change or when new threats are unveiled. Nonetheless, by performing a PIA and implementing controls, organizations demonstrate that they are tackling privacy and data protection issues due diligence.

Second, although the PIA RFID framework [17] offers a sound methodology, there are other PIA frameworks that are already published (eg, OAIC's PIA, British ICO's PIA Handbook, CNIL's PIA manual, and ISO/IEC 29134). Some approaches are more streamlined (eg, OAIC's PIA and British ICO's PIA Handbook) and consequently not so grounded on technical standards (eg, PIA RFID framework and ISO/IEC 29134). Moreover, as mentioned before, the chosen PIA framework also utilizes a qualitative approach for risk assessment, which differs from quantitative and asset-driven approaches that are more common for security risk analysis. A comparison study of PIA frameworks is outside the scope of this paper, but it may be beneficial to the community.

Third, a few remarks can be also made about the way in which the PIA was conducted. Ideally, the PIA should be carried out in consultation with all relevant stakeholders (eg, developers, health care workers, data subjects and/or representatives, and policy-makers). The PIA was conducted by the authors who come from multiple disciplines (information security, medical informatics, and law) and have first-hand experiences with MDCSs. Besides, input and feedback were provided by software engineers from 2 industry partners with experience in developing MDCS. In conducting this PIA, the authors adopted the role of the data subjects to articulate their perspectives and advocate for their privacy. Two of the authors are members of privacy interest organizations and/or former members of the advisory board of the Swedish Data Protection Commissioner. The authors are therefore used to taking the perspective of data subjects and are more experienced in analyzing privacy issues on behalf of the data subjects than most laypersons. Nonetheless, especially after the MDCS is rolled out, it is recommended to consult the families enrolled in the primary care programs directly and gather their perspectives and concerns regarding privacy on the basis of their personal experiences for conducting another iteration of the PIA.

Conclusions

CHWs are crucial in the Brazilian health care scenario, and empowering them with relevant tools can revolutionize the delivery of community-based primary care. MDCSs are proven effective tools to support the activities of CHWs in Brazil [3] and around the world [1]. However, solving privacy and data protection issues is imperative for the successful deployment of such systems. In fact, as advocated in previous studies [5,19], a careful look into privacy is still notably lacking in many mHealth projects and initiatives. This paper offers a full PIA for the GeoHealth MDCS aiming to unveil the privacy pitfalls that large-scale mHealth systems may have. Our results show that important privacy principles could be further enhanced, such as data minimization, obtaining consent, enabling data processing transparency, and intervenability. In fairness, existing research may not primarily account for privacy, as privacy-preserving features are considered as nonfunctional requirements or even because such considerations are beyond the scope of many papers. Nonetheless, systems that are already deployed, especially in health care, should be compliant with the principles of privacy by design.

Besides, as discussed, the literature on Privacy-Enhancing Technologies (PETs) already has a range of mechanisms for consent management, transparency, and intervenability. Therefore, the future work in MDCSs involves the evaluation of suitable PETs mainly accounting for the implementation of technical controls as well as to migrate organizational controls with information security management processes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Characterization of the System.

[PDF File (Adobe PDF File), 746KB - mhealth_v7i3e11642_app1.pdf]

Multimedia Appendix 2

Evaluation of degree of protection demand.

[PDF File (Adobe PDF File), 181KB - mhealth_v7i3e11642_app2.pdf]

Multimedia Appendix 3

Identification of privacy threats.

[PDF File (Adobe PDF File), 254KB - mhealth_v7i3e11642_app3.pdf]

Multimedia Appendix 4

Technical and non-technical controls.

[PDF File (Adobe PDF File), 94KB - mhealth_v7i3e11642_app4.pdf]

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Abbreviations

CHWs: Community Health Workers
CNIL: Commission nationale de l'informatique et des libertés
EU GDPR: European General Data Protection Regulation
FHS: Family Health Strategy
ICO: Information Commissioner’s Office
IEC: International Electrotechnical Commission
ISO: International Organization for Standardization
MDCS: Mobile Health Data Collection System
mHealth: mobile health
OAIC: Office of the Australian Information Commissioner
ODK: Open Data Kit
PETs: Privacy-Enhancing Technologies
PIA: Privacy Impact Assessment
RFID: Radio Frequency Identification
SISAB: Health Information System for Primary Care (Sistema de Informação em Saúde para a Atenção Básica)

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Original Paper

The Characteristics and Quality of Mobile Phone Apps Targeted at Men Who Have Sex With Men in China: A Window of Opportunity for Health Information Dissemination?

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Abstract

Background: A number of mobile phone apps has been developed specifically for men who have sex with men (MSM). We will call these mobile phone apps *MSM apps* for simplicity. At present, the characteristics and quality and purpose of these MSM apps are unclear.

Objective: The aim of this study was to objectively and comprehensively evaluate the characteristics and quality of the MSM apps to assess whether they disseminated health information among the MSM in China.

Methods: We searched 2 dominant mobile phone app stores (Apple Store and Android Market) to obtain MSM apps using the keywords *MSM*, *gay*, *lesbian*, *gay*, *bisexual*, and *transgender (LGBT)*, 男同，同志，男男性接触者，同性恋，基友, and 双性恋. Apps were excluded if they did not have a Chinese language interface or if their target population was not MSM. Basic information about the eligible apps for this study, such as app name, app store category, and date of last update was gathered from the specified app stores. The quality of apps was rated by 2 independent raters using Mobile App Rating Scale (MARS). The intraclass correlation coefficient (ICC) between raters was computed as a measure for interrater reliability of the MARS. All analyses were conducted using SPSS version 20.0 (SPSS Inc).

Results: A total of 575 apps were reviewed between September 15, 2018 and September 30, 2018, out of which, 532 apps were excluded. Finally, 43 apps were included. Of the 43 apps, 16 were from the Apple Store, 10 were from Android Market, and 17 were available in both app stores. In addition, 39 out of 43 apps were for social and sexual networking, whereas 10 contained sexual health information, for example, HIV/sexually transmitted diseases knowledge, HIV test, and condom use. The average rating was 4 stars. The number of downloads for 21 apps exceeded 10,000. A total of 31 apps had acceptable quality (as defined by a MARS score of >3), with functionality as the highest scoring domain, followed by information quality, esthetics, and engagement. Interrater reliability was excellent for the overall mean app quality scores (ICC=.946; 95% CI 0.904-0.970) and the subjective quality scores (ICC=.910; 95% CI 0.841-0.950).

Conclusions: By reviewing the available apps, we found that MSM apps are popular. The majority of MSM apps are for dating, whereas few of them contain HIV prevention and health information. The overall quality of the apps is acceptable. The utilization of mobile phone technologies is a promising way for delivering HIV prevention messages to MSM. We recommend that researchers and app developers should work together to disseminate health information for MSM via mobile technologies.

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KEYWORDS

mobile application; homosexuality, male; quality; character

Introduction

Background

In recent years, smartphone use has been growing rapidly worldwide. For example, in 2015, the global smartphone users were 1.91 billion, and the figure increased to 2.16 billion in 2016 [1]. In China, there were about 0.6 billion smartphone users in 2016, and the number is increasing year by year [2]. Mobile phone apps are computer programs designed to run on smartphones, tablet computers, and other mobile devices. The symbol *app* will be used to mean mobile phone app. Smartphone apps provide a new platform for information distribution and networking. Global mobile app downloads were 197 billion in 2017 versus 149 billion in 2016. By 2021, the total number of app downloads would jump to a stunning 352 billion [3].

In the vast app market, a number of smartphone apps have been developed specifically for men who have sex with men (MSM). These apps will be referred to as *MSM apps* for simplicity. MSM apps have a variety of purposes: social and sexual networking (gay apps) [4], life or entertainment, and research or health education. Traditionally, dating among MSM has been taking place in fixed physical locations such as parks and entertainment facilities (eg, gay-friendly bars or pubs, bathhouses, and saunas) [5,6]. Nonetheless, the gay app is quickly replacing traditional locations as the preferred site to find sexual partners. In 2014, gay apps (eg, Tinder and Grindr) had 90 million users per month worldwide [7]. In a study of 1342 Chinese MSM, 40.6% MSM had used at least one gay app [4]. In a sample of 369 MSM, 60% of MSM reported they used the gay app every day [8]. MSM app users are often young, single, and self-identified as gay [4]. For some MSM, smartphone apps like Grindr, Hornet, FindFred, Growlr, and Scruff have become a part of their daily life [9]. Many MSM used these channels for reasons other than sex seeking, including entertainment and socializing [10,11]. In China, a large proportion of MSM face severe stigma; therefore, they remain closeted. This new mode of communication is subtle and prudent, making it easy for MSM to avoid conflict with heterosexual hegemony in the traditional Chinese culture [12]. In addition, the virtual social platform made by MSM apps strengthens their self-identity and provides emotional support for homosexual identity [13].

MSM apps also provide a vital window of opportunity for health-related organizations to help MSM protect their health, given the rapid spread of HIV/sexually transmitted diseases (STDs) among MSM [14]. Some special apps have been developed by researchers to conduct behavioral intervention among the MSM [15,16]. For example, some MSM apps offer sexual health information, which lets MSM know where the nearest HIV testing center is, where they can obtain postexposure prophylaxis if they have been exposed to HIV, and other health promotion messages [9].

Objectives

There is a mass of MSM apps available in the Chinese market. However, the characteristics and quality of these apps are unclear. The aim of this study was to objectively and comprehensively evaluate the characteristics (including categories, audience, functional characteristics, contents, and popularity) and quality of MSM apps to assess whether these apps disseminate health information. Understanding this information could help guide the growing body of mobile phone–based health promotion efforts to guard the health of the users of MSM apps in China.

Methods

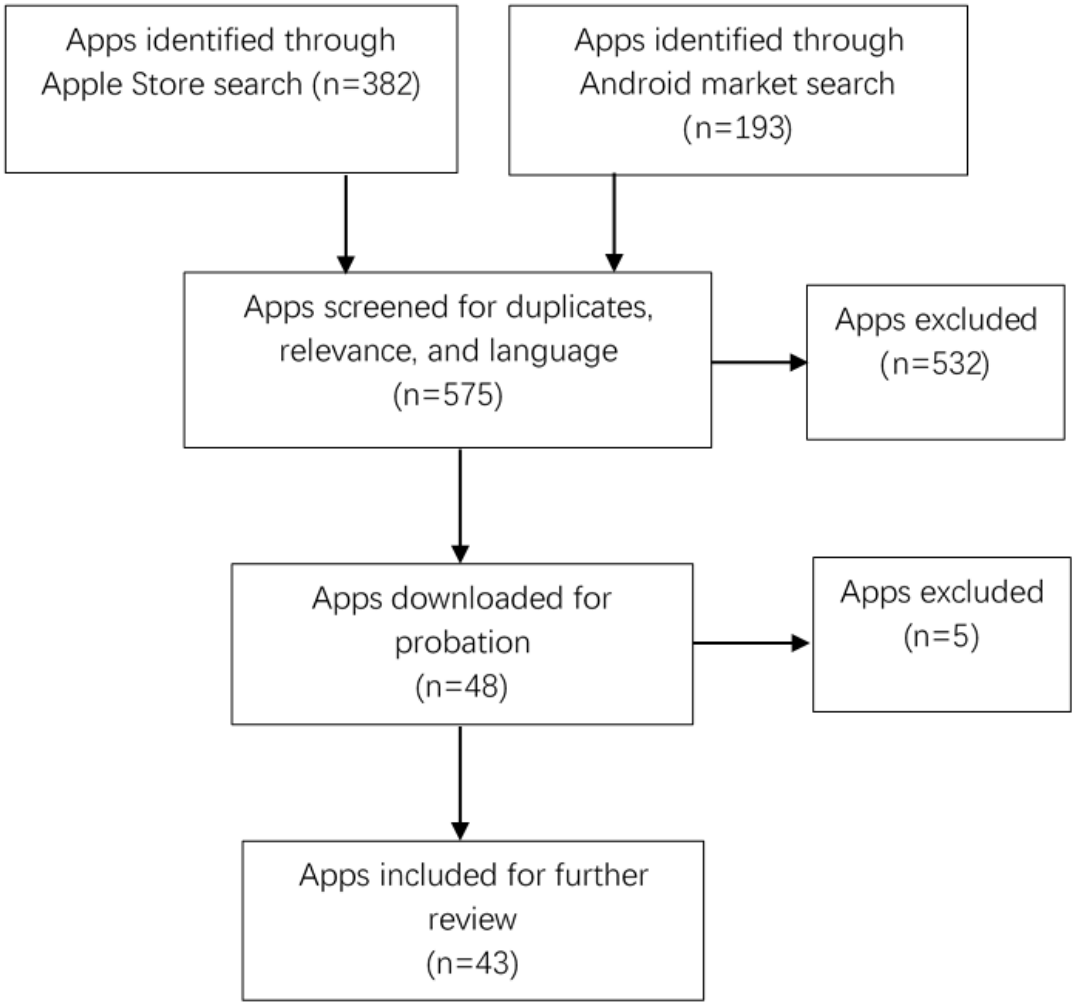
Search and Inclusion and Exclusion Criteria

Android operating systems (82.03%) and iOS (13.20%) are the 2 most dominant mobile phone operating systems, which together account for more than 95% of the Chinese mobile phone market [2]. Therefore, 1 iPhone (Apple Inc) and 1 Android phone (Xiaomi; MI Corporation, Beijing, China) were used to search apps from the Apple Store and Android Market, respectively. Search terms were either in English or in Chinese. English search terms were *MSM*, *gay*, *lesbian*, *gay*, *bisexual*, and *transgender (LGBT)*, whereas Chinese search terms were 男同，同志，男男性接触者，同性恋，基友, and 双性恋. Apps were excluded if they did not have a Chinese language interface or if their target population was not MSM.

Search Procedures

During the period between September 15, 2018 and September 30, 2018, the search in the Apple store and Android Market identified 382 and 193 apps, respectively (Figure 1). After reviewing the app titles and the app descriptions, 48 met the inclusion criteria. These 48 apps were then downloaded. However, 5 of them could not be opened or logged in. Therefore, they were excluded. Finally, 43 apps were reviewed. Some examples of MSM apps for iPhone and Android have been provided in Figures 2 and 3.

Figure 1. Search and screen flow for men who have sex with men apps.

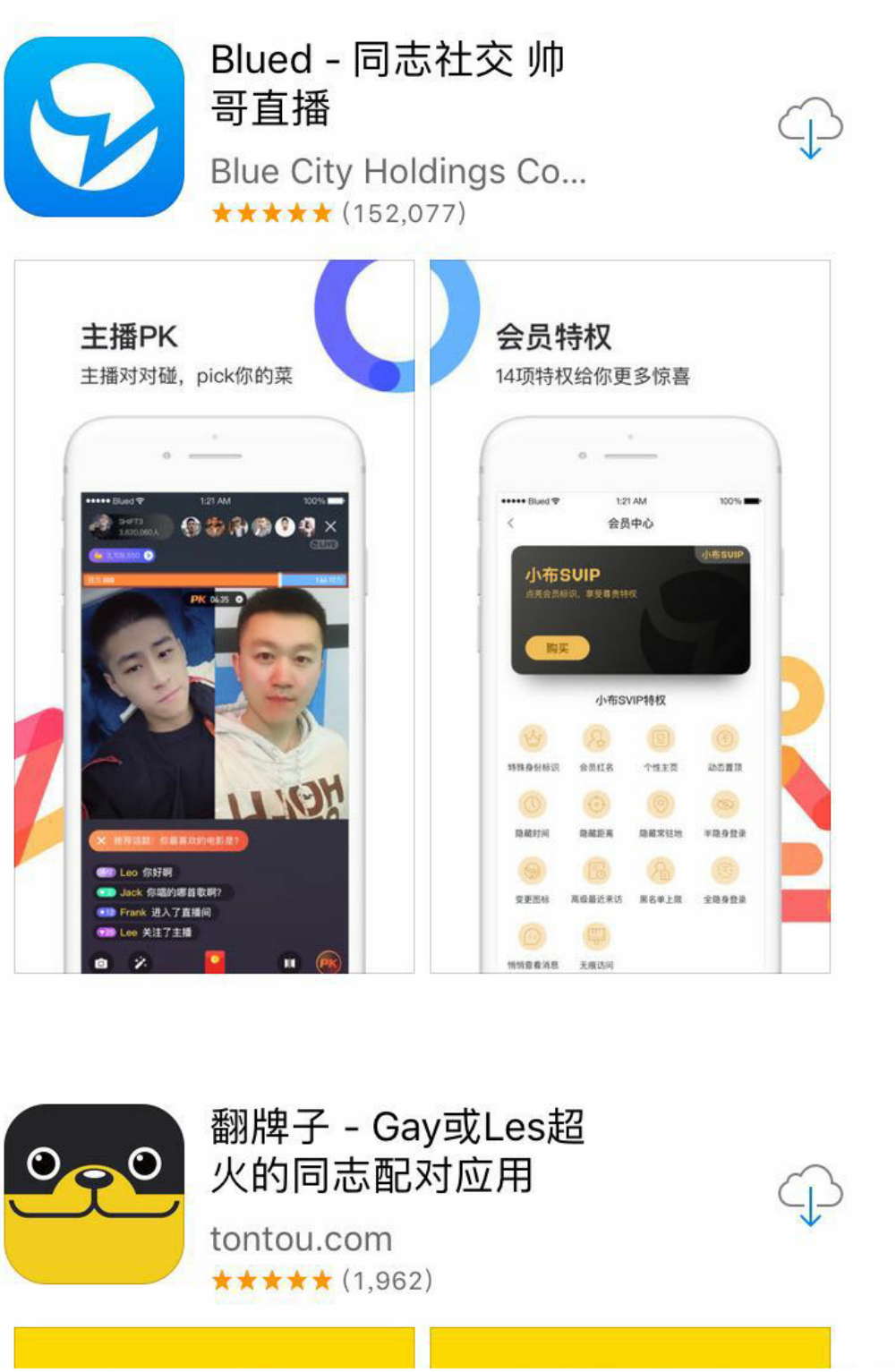


Review Process

The review process comprised 2 steps. First, basic information about the 43 eligible apps, such as app name, app store category, and date of last update was gathered from the 2 specified app stores. Apps were categorized into groups on the basis of their primary target groups. Popularity is a quantity related to the number of users who have installed and are currently using the software app [17]. There are many metrics indicating an app's popularity. This study chose the most commonly cited metrics: user rating and number of downloads [18]. These were extracted directly from the app stores if available. Second, all the 43 eligible apps were installed in a phone (Android or Apple). The Mobile App Rating Scale (MARS) was used to assess the apps' quality. There are 2 versions of MARS: 1 evaluates apps from the researchers' perceptive [19], whereas the other from the app users' perspective [20]. This study chose the MARS for researchers as it is suitable for checking whether there was health information contained in these apps that could compromise users' health and safety. Besides, the MARS for researchers provides a deeper evaluation of the quality of the health-related apps by testing them thoroughly for 10 min. This scale has been used in a similar app review, and it yielded good reliability and validity [21-23]. It includes objective quality and subjective quality. Objective quality has 4 domains including engagement, functionality, esthetics, and information. Each item in this 23-item scale is scored using a 5-point scale (1=Inadequate, 2=Poor, 3=Acceptable, 4=Good, and 5=Excellent). A cut-off of 3.0 has been previously identified as a minimum acceptable score [23].

Furthermore, 2 researchers independently assessed the 43 eligible apps using the MARS for researchers. Moreover, 1 of them was a research officer with a Research Master's degree in Psychology and 2 years of experience in mobile app development, and the other was a PhD candidate with a Master's degree in Nursing and over 6 years of experience in HIV-related research. These 2 researchers were first trained using Web-based video training resources to ensure that they correctly used the MARS scale. The 3 apps were used for the training and piloting purposes. All the 43 eligible apps were used for a minimum of 10 min when rating them. If there was any disagreement, a third reviewer would reassess it to achieve consensus, and interrater reliability was calculated.

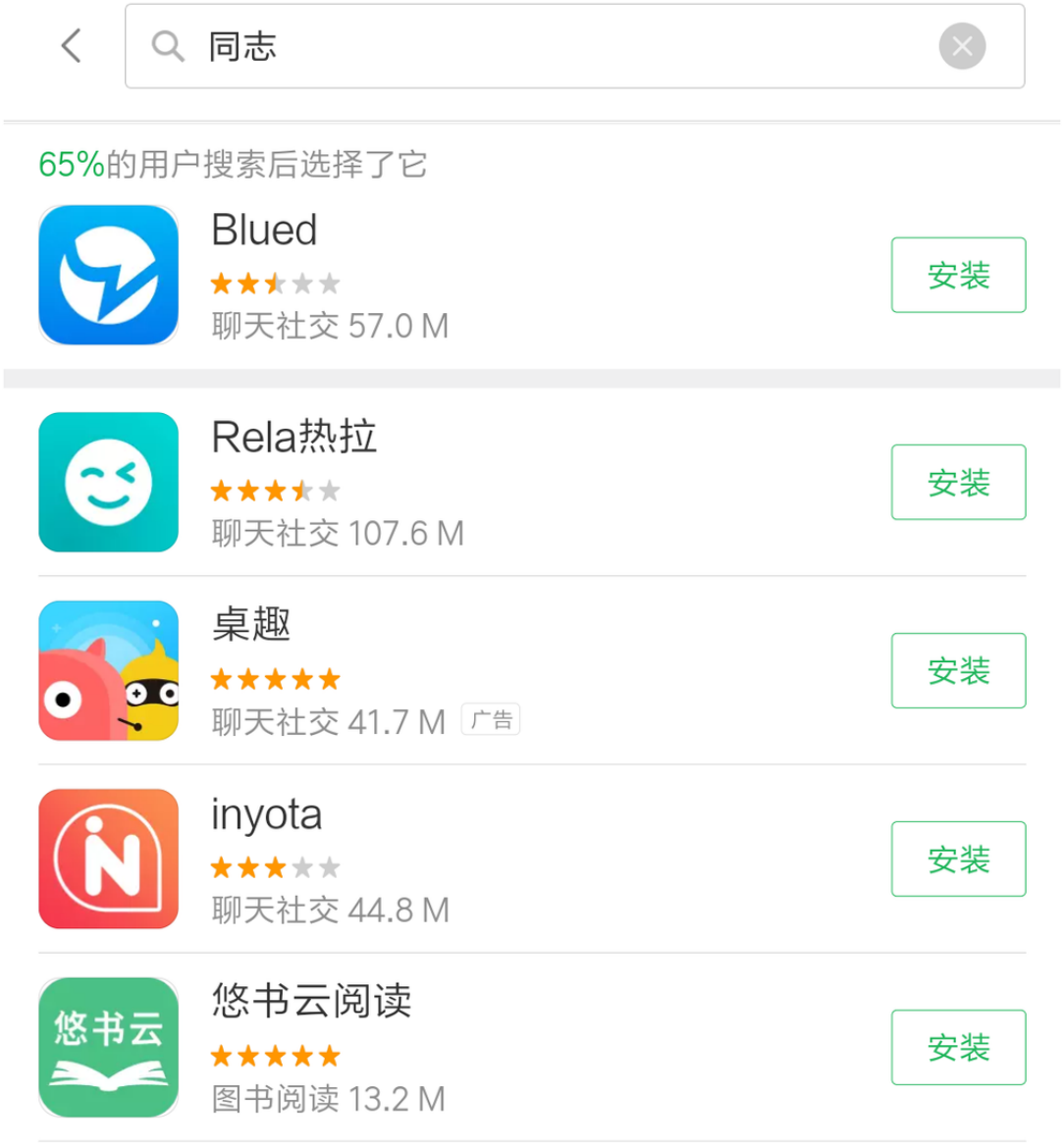
Figure 2. Some examples of MSM Apps for iPhone.



Statistical Analysis

All analyses were conducted using SPSS version 20.0 (SPSS Inc). Descriptive scores were calculated from the MARS scale. Intraclass correlation coefficient (ICC) among the raters was computed as a measure of interrater reliability for the MARS scale. A 2-way mixed, absolute agreement, average measures model was used to estimate the reliability of the average measures among the 2 raters.

Figure 3. Some examples of MSM Apps for Android.



Results

Overview

Among the 43 eligible apps, it was observed that 16 came from the Apple Store, 10 from the Android Market, and 17 from both the app stores. In addition, 3 apps needed to pay money for HIV test report verification when registering, whereas 40 apps were free to use. According to the 2 app stores, apps were categorized as social (n=29), life (n=5), entertainment (n=4), health and fitness (n=3), tool (n=1), and medical care (n=1). The primary target populations of the apps were gay (n=32), LGBT (n=5), gay or bisexual (n=3), gay or lesbian (n=2), and HIV-positive (n=1). Moreover, of the 43 eligible apps, 31 had been updated over the past year at the time of this study. In general, the apps were frequently downloaded, with 21 apps exceeding 10,000 downloads. Furthermore, 37 of the 43 eligible apps were rated by customers, yielding an average rating of 4 out of 5 stars. Moreover, 70% (26/37) were rated over 4 stars. Table 1 shows the details.

Characteristic of the Apps

Overall, 39 out of the 43 eligible apps were developed as social network tools for finding friends and sexual partners. Examples of these apps are Blued, Jack'd, Gaypark, and Grindr. These are particularly gay apps, which allow users to filter people they wish to see by age, height, weight, and location. In addition, they provide various services, such as Web-based talking, sharing personal training or experience, news delivery, and watching television shows. On the contrary, only 4 apps (A health, Healthscore, RrainbowLaw, and pop) did not have the function for seeking sexual partners. In particular, *A health* is an app that provides self-management information for HIV-positive people, and it can provide HIV counseling for MSM. In addition, *Healthscore* app was designed specifically for MSM to provide information about sexual health and drug use, HIV counseling, checking of HIV-test results, and behavior assessment. Besides, *RrainbowLaw* app was designed to offer legal knowledge for LGBT, whereas *pop* app was aimed at promoting sexual health by encouraging users to adhere to safe-sex practices. In total, 10 apps (Blued, Rainbow rabbit,

Healthscore, inyota, Blueboy, blueMr, homo, Bluefly, pop, and SMSM) contained sexual health information related to HIV/STDs, HIV testing, condom use, and links to Center for Disease Control and Prevention (CDC) or nongovernmental Organizations (NGOs). The name, target population, category, rating, update, and primary content areas of each eligible app are presented in Multimedia Appendix 1.

Table 1. Summary characteristics of men who have sex with men apps (N=43).

Characteristics of apps	Statistics, n (%)
Phone platform	
Apple Store	16 (37)
Android Market	10 (23)
Both	17 (40)
App store category	
Social	29 (68)
Life	5 (12)
Entertainment	4 (9)
Health and fitness	3 (7)
Medical care	1 (2)
Tool	1 (2)
Primary target population	
Gay	32 (74)
LGBT[a]	5 (12)
Gay or Bisexual	3 (7)
Gay or Lesbian	2 (5)
HIV-positive	1 (2)
Updated over the past year	
Yes	31 (72)
No	12 (28)
Number of app downloads[b]	
0-999	3 (11)
1000-9999	3 (11)
>10,000	21 (78)
User star rating	
N/A[c]	6 (14)
1-3.9	11 (26)
4-5	26 (60)

[a]LGBT: lesbian, gay, bisexual, and transgender.

[b]Information on number of app downloads is only available for apps in the Android Market (n=27).

[c]N/A: not applicable.

Table 2. Descriptive results of Mobile App Rating Scale scores (N=43).

Quality	Rater 1, mean (SD)	Rater 2, mean (SD)	ICC[a] (95% CI)
Engagement	3.21 (0.71)	3.17 (0.69)	.834 (0.715-0.906)
Functionality	3.78 (0.69)	3.64 (0.79)	.766 (0.609-0.865)
Esthetic	3.25 (0.95)	3.22 (0.96)	.841 (0.726-0.910)
Information	3.31 (0.66)	3.28 (0.77)	.792 (0.650-0.881)
App quality	3.41 (0.67)	3.23 (0.64)	.946 (0.904-0.970)
Subjective quality	2.95 (0.98)	2.98 (0.99)	.910 (0.841-0.950)

[a]ICC: Intraclass correlation coefficient.

Quality of the Apps

The quality of most apps (72%, 31/43) was identified as acceptable (MARS score>3). Functionality was the highest scoring domain, followed by information quality, esthetics, and engagement. In all, 3 apps (Blued, Gomeet, and Gtalk) achieved a score of 4.0 or more on both the overall quality and subjective scales, indicating high or excellent quality [23]. Interrater reliability was excellent for the overall mean app quality scores (ICC=.946, 95% CI 0.904-0.970) and the subjective quality scores (ICC=.910, 95% CI 0.841-0.950). Table 2 shows the details. Raw data of MARS scores are available in Multimedia Appendix 2.

Discussion

Principal Findings

This review assessed the characteristics and quality of 43 MSM apps in China, and it assessed whether these apps disseminated health information. With regard to the characteristics, a majority of the MSM apps (39/43) are used for social and sexual networking. The mobile app, Grindr, was released in 2009 and was the first to allow gay men to find potential sex partners nearby by using Global Positioning System (GPS) functions [24]. More apps have since been launched. Mobile phone apps have become the most common way for gay men to meet male sex partners. In this study, acceptability and popularity of MSM apps were roughly measured by users' ratings and number of downloads. Usually, apps that are downloaded far more frequently have high user rating. Thus, Blued, Aloha, and Gaypark were found to be downloaded more than 100,000 times from the Android Market, and their rating was over 4 stars. Although Jack'd is considered to be the world's fastest growing gay mobile app, the Chinese version of Jack'd was rated 2.5 stars by Chinese users even though it had a high number of downloads. The reasons why some international gay apps are rated poorly in China could be that they are translated versions of the international gay apps, and this might not fully cater to Chinese users' cultural characters; therefore, they may achieve lesser satisfaction among the MSM in China when compared with the MSM using original versions outside China. Nonetheless, measuring acceptability and popularity of apps using the number of downloads and users' ratings could lead to bias when the number of users is small. Therefore, it is important to highlight that there are many ways to measure and quantify the popularity using different metrics, namely chart rankings, user ratings and user reviews, downloads, the time spent by users on the mobile app, and the period between the installation of a mobile app and its removal from the user's phone [18]. The popularity information of mobile apps often varies frequently and has the instinct of sequence dependence [18]. It is not possible to analyze whether the app is really popular or not. Yet, user rating and number of downloads are useful to guide mobile app selection for users.

In general, the majority of the MSM apps (31/43) have acceptable quality in relation to the apps' characteristics, such as functionality, esthetics, usability, ability to engage users, and quality of information provided. Only 3 of 43 apps were identified as high quality. Features of high-quality apps include more engagement, multifunction, clear navigation, and layouts. As expected, high-quality apps had a higher average number of users and higher rating scores. As the main purpose of app developers is to make money, this suggests that developers have responded to users' preference for functionality and tried to attract and retain more users by exquisite design and function expansion [25,26]. In terms of MARS subscales, engagement scored the worst, especially the item about interactive function. Interactivity is defined within the parameters of user input, feedback, prompts, virtual rewards, Web-based-offline integration, and family involvement [27]. Well-designed apps allow the users to choose which app features they wish to use and select messages and notifications they wish to receive through the app. The interactive functions of reviewed apps in this study are available but limited. This leads to many of the functional features, like providing intervention and care services that cannot be covered in apps.

Apps offer convenience to both the users and the developers as they provide a flexible way to reach a large audience at an affordable cost [28]. Several studies have demonstrated that young adults consider sexual health promotion via apps acceptable [25,28]. Sun et al reported that approximately two-third of MSM were willing to receive sexual health–related information through apps, and 26% of them requested referrals for HIV and STD testing [29]. In this study, 10 apps contain information about HIV testing and sexual health promotion. There are 4 modes to display sexual health content: forum, blog posts, infection status in users' profiles, and links to sexual health information in the apps or linked websites. Each of these modes has its own limitations in reminding users of their sexual health. First, in-app blog posts or forum can be good places to display information regarding HIV/STDs if this information is

correct and updated frequently. Second, having HIV status on a profile can be a good way to assist users filter partners by HIV status. Apps (Bluefly, BlueMr, and Homo) require users to upload their HIV test reports when registering in these apps and pay some money (about 20 RMB) for verifying their reports. The advantage of integrating HIV testing report into apps is to promote HIV testing if MSM want to use these apps. MSM may feel safe to make friends through these apps. However, there are still some concerns. For example, potential stigma will be produced if MSM are HIV-positive, and information safety may be questioned by users. Third, some apps offer links to CDC or NGOs such that only the address and telephone number of these institutions can be found in the apps. Therefore, this might be less effective as users have to be actively looking for sexual health information, which is not provided on the contact information of these institutions in the apps.

Unfortunately, this study found that only 1 out of the 43 MSM apps had information about drug use despite the fact that drug use is common among MSM. Zhao et al found that 77.30% (1100/1424) of the MSM subjects reported ever using recreational drugs in their lifetime, and poppers are the most popularly used among MSM [30]. As popper users tend to have more sexual partners [31], gay apps could facilitate the organization of private sex parties involving recreational drug use [32]. The combined recreational drug use and gay apps may create a virtual risk environment for HIV transmission among MSM in China [30]. More work needs to be done to increase awareness of the risk of drug use via MSM apps.

Implication

MSM are disproportionately affected by HIV domestically and globally, and they are a key population for HIV infection and STDs prevention [33,34]. On the basis of existing evidence, the utilization of interactive Web-based and smartphone technologies to deliver sexual health information to MSM has shown promise. We suggest that public health researchers and app developers work together to promote sexual health through the existing popular MSM apps. For example, this can be realized by targeting and collaborating with some most frequently used MSM apps when advertising the benefits of prevention and intervention programs for MSM populations. Health information should be displayed in various ways to increase attraction, such as pop-up messages, blog post, webcast, forum, and links to sexual health information. In addition, it is possible for health providers to use GPS data from the apps and provide services according to users' physical locations, such as referral to HIV-testing centers. Exposing users to sexual health content when they are using these apps might be a good way to remind them of safe-sex practices. The impact of these messages on users' behavior and health outcomes needs to be explored in further studies. Nonetheless, it should be highlighted that certain subgroups of MSM in China still preferentially meet at these venues (eg, bathhouse, pub, or club). Venue-based interventions such as on-site provision of volunteer testing and counseling and HIV awareness and knowledge promotion should also be emphasized.

In China, there is a lack of standards for app auditing. The less rigorous audit system leads to uneven quality of app products. The policy makers should establish the platform for supervision and audit and improve the legal system to regulate smartphone apps. For instance, when developing new apps, the developers should integrate health information into apps, especially for HIV high-risk populations. Establishing relevant regulations could guard the sexual health of MSM app users.

Limitations

There are some limitations in this study. First, data collection only took place between September 15, 2018 and September 30, 2018. This means that the findings of this study could only provide a snapshot of the rapidly developing app market. MSM apps are changing rapidly; therefore, our search results might be different if repeated. Second, the quality of apps was assessed by MARS for researchers. The result might be different if assessed by the apps' users. Third, there are many Chinese words that can be translated into the term *gay* but not all of them were used in our search for the MSM apps. Therefore, the search terms used were not exhaustive. Finally, our search was limited to the Apple Store and the Android Market; therefore, our search neglected apps from other smartphone operating systems (eg, Microsoft, Symbian, and BlackBerry).

Conclusions

By reviewing the available apps, we found that MSM apps are popular. A majority of them are used for dating. Limited apps contain HIV prevention- and health-related information. The overall quality of the MSM apps is acceptable. MSM is a hidden population and a key population for HIV/STDs infection and prevention in China. Due to low rate of integration of sexual health information in gay apps, we suggest that public health researchers and app developers work together to promote sexual health through the existing popular MSM apps, which have the potential to increase HIV testing and linkages to appropriate care. The policy makers should establish the platform for supervision and audit to promote the health of the Chinese MSM app market.

Authors' Contributions

GY analyzed the data and drafted the paper as the first author. JL and DL contributed to data collection and analysis. SX and ACK contributed to language advisement.

Conflicts of Interest

None declared.

Multimedia Appendix 1

List of men who have sex with men apps.

[DOCX File, 23KB - mhealth_v7i3e12573_app1.docx]

Multimedia Appendix 2

Raw data of Mobile App Rating Scale.

[DOCX File, 23KB - mhealth_v7i3e12573_app2.docx]

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Abbreviations

CDC: Center for Disease Control and Prevention
GPS: Global Positioning System
ICC: intraclass correlation coefficient
LGBT: lesbian, gay, bisexual, and transgender
MARS: Mobile App Rating Scale
MSM: men who have sex with men
NGOs: nongovernmental organizations
STDs: sexually transmitted diseases

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Original Paper

Perspectives on Acceptance and Use of a Mobile Health Intervention for the Prevention of Atherosclerotic Cardiovascular Disease in Singapore: Mixed-Methods Study

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Abstract

Background: Cardiovascular disease, including atherosclerotic cardiovascular disease (ASCVD), is a growing public health threat globally and many individuals remain undiagnosed, untreated, and uncontrolled. Simultaneously, mobile health (mHealth) interventions using short messaging service (SMS) have gained popularity globally. There is an opportunity for innovative approaches such as mHealth to encourage and enable adherence to medications for ASCVD and its risk factors.

Objective: This study aimed to understand mobile technology acceptance, use, and facilitating conditions among the study population ahead of the design of an mHealth intervention.

Methods: Using data from a mixed-methods study conducted in Singapore, we conducted a cross-sectional survey with 100 participants and in-depth, semistructured interviews with 20 patients. All participants were over the age of 40 years with ASCVD or its risk factors. Interviews were conducted in English and Mandarin and if needed translated to English. Nvivo 11 (QSR International) was used for analyses.

Results: Participants reported their perspectives on technology use and preferences, including low or sporadic mobile phone use and usability concerns including small screen and text size, among others; the benefit of previous mHealth use in creating a favorable opinion of SMS for health information; trust in both the source of mHealth SMS, as well as in treatment; the formation of habits; and fear of sequelae or death for facilitating intention to use an mHealth intervention and adhere to medication. We also highlighted a case that underscored the importance of the period after diagnosis in habit forming as an opportunity for an mHealth intervention.

Conclusions: We explored both technology- and adherence-related factors that influence a patient's intention to use an mHealth intervention for adherence to ASCVD medication in Singapore. We highlighted the importance of identifying the right opportunity to engage with patients and promote an mHealth intervention for adherence, such as immediately following diagnosis when patients are establishing medication-taking habits.

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KEYWORDS

atherosclerosis; mHealth; eHealth; patient-centered care; patient acceptance of health care; medication adherence

Introduction

Background

Mobile health (mHealth) interventions using short messaging service (SMS) have gained popularity as the number of people using mobile technology increases globally [1]. Singapore has one of the highest mobile phone penetration and usage rates in the world, thus providing an interesting case study for such interventions [2]. SMS-based interventions have shown promise because of affordability and wide outreach and have been applied to many aspects of health including health promotion and to enable medication adherence [3-5]. Although mHealth has provided many opportunities to reach patients, especially vulnerable groups, it is important that contextually appropriate patient preferences, usability, and acceptance of technology are considered when undertaking these interventions.

Patient preferences and acceptance are of particular importance when considering mHealth interventions for chronic conditions such as cardiovascular disease (CVD). CVD, including atherosclerotic cardiovascular disease (ASCVD), is a growing public health threat globally, with mortality rates estimated to reach 23.3 million by 2030 [6]. Importantly, many individuals with risk factors for ASCVD remain undiagnosed, untreated, and uncontrolled [7,8]. This points to the need for greater attention to factors impacting adherence in these patients and innovative approaches, such as mHealth, to encourage and enable adherence to medications for ASCVD and its risk factors in this patient population.

A systematic review demonstrated evidence of the feasibility of mHealth for adherence to medications for CVD. All 10 completed trials included in the review showed improved medication adherence for patients with CVD; all studies also reported positive responses to mHealth use from patients, however, the authors highlighted the paucity of data on studies including user input on the design of the intervention [9]. Qualitative studies have also shown the potential of mHealth to provide education, optimize resources, and improve use of health care for CVD management [10]. Yet, there is a need for more contextual evidence on patient acceptance and use of mHealth interventions for adherence, specifically exploring the unique factors that influence the use and acceptance of mHealth adherence support for medications to treat chronic conditions. For example, elderly patients managing chronic conditions may face unique usability concerns including functional difficulties using the device, limitations in vision and hearing, as well as the need for appropriate message content [11]. To explore the needs of those with or at risk for ASCVD in Singapore, our study population comprised patients over the age of 40 years identified as having ASCVD, or risk factors for ASCVD including hypertension or hyperlipidemia.

This study is the development phase of a proposed mHealth intervention, the txt2heart trial, to support patient adherence to medications for ASCVD. The txt2heart trial is an international collaboration evaluating the efficacy and safety of SMS on clinical outcomes and adherence in different countries including Colombia, Ghana, India, and Singapore. This study sought to explore mobile technology acceptance, use, and facilitating conditions, as well as adherence factors, among the Singapore study population ahead of the design of the mHealth intervention.

The Study Setting: Singapore

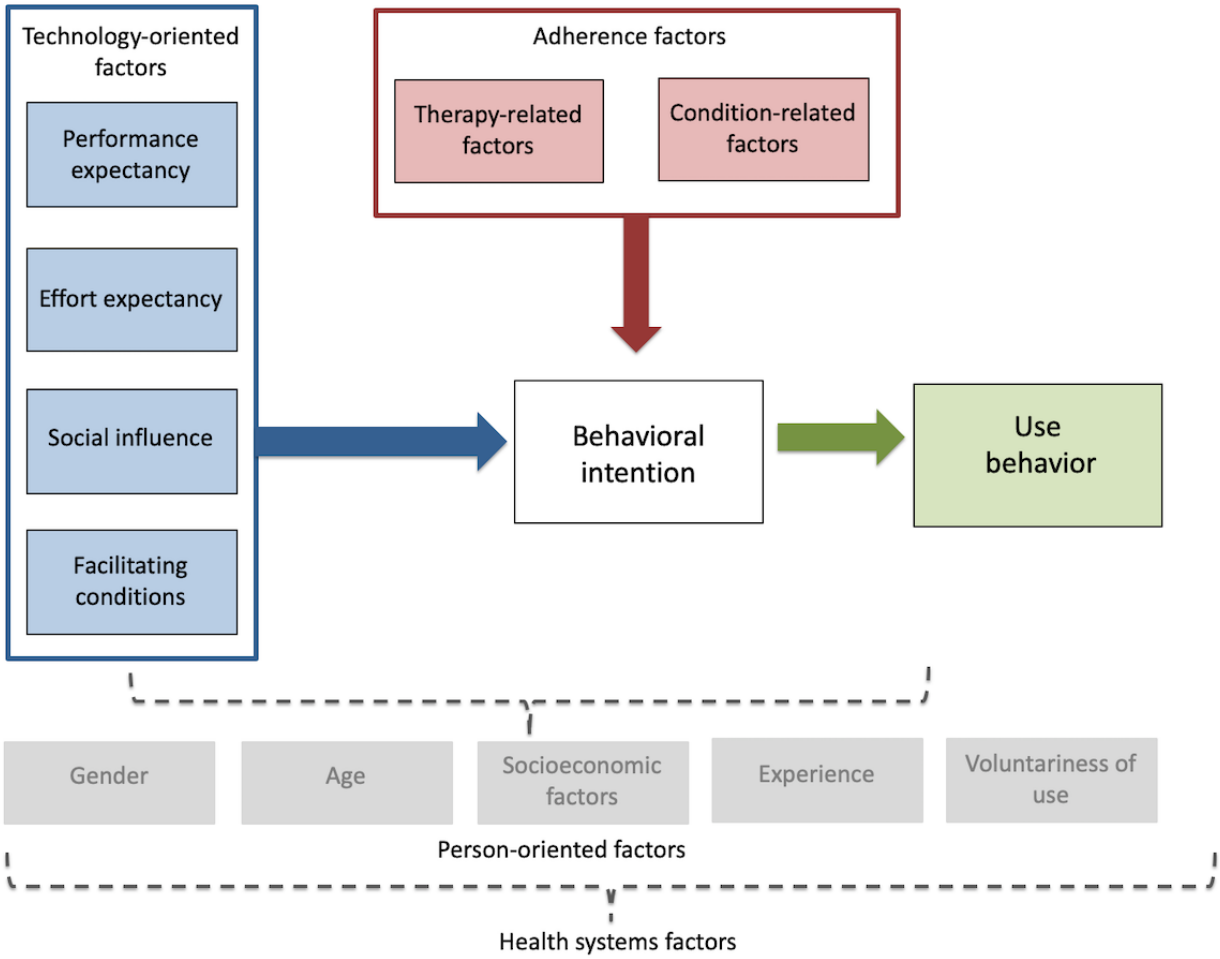
To better contextualize our findings, it is necessary to consider larger health system factors relevant to Singapore, primarily the ubiquity of affordable and accessible health care. Singaporeans have access to largely subsidized care offered in polyclinics (government subsidized general practice clinics), private general practitioners, and tertiary care facilities for primary care and chronic condition management. Furthermore, within the primary care setting, doctors regularly prescribe months' worth of medications, thus enabling ease of access to medications. The government also provides subsidies and various schemes for the management of chronic conditions; the majority of our participants reported availing these schemes to pay for their health care and most reported being able to afford and access their CVD medications.

Theoretical Framework

Using a deductive approach, we used the unified theory of acceptance and use of technology (UTAUT) model to analyze our qualitative findings. This was then complemented by emergent themes on medication adherence factors, which prompted us to apply the World Health Organization (WHO) adherence model to our data [12]. We then applied the modified and condensed UTAUT model to understand technology acceptance and use among participants with ASCVD and ASCVD risk factors (Figure 1). The UTAUT has been widely used to understand information technology (IT) adoption in general and has also been applied to health IT [13-17].

The UTAUT model employs 4 constructs through which to explore user factors; these being (1) performance expectancy, (2) effort expectancy, (3) social influence, and (4) facilitating conditions. Performance expectancy includes the perceived usefulness and personal outcome expectations associated with technology use. Effort expectancy is the perceived ease of use and complexity of the technology. Social influence includes subjective norms and technology use within a user's social milieu, whereas facilitating conditions include perceived behavioral control and wider contextual circumstances that support the use of technology. We have labeled these as technology-oriented factors as they explore the users' experience and preferences as oriented to their use and acceptance of technology.

Figure 1. Modified unified theory of acceptance and use of technology model for adherence factors adapted from Venkatesh (2003) and World Health Organization (2003).



Underpinning these constructs and impacting them in multiple complex ways are the influence of person-oriented factors including gender, age, socioeconomic factors, experience, and voluntariness of technology use. The confluence of these factors ultimately impacts one's behavioral intention and use behavior as well as the actual use of the mobile technology or intervention.

An important modification necessary to understand use and acceptance of an mHealth intervention for adherence is the adherence factor, which may contribute to the behavioral intention and use of the intervention [18]. For our purposes, we have adapted the WHO framework to focus on the condition-related and therapy-related factors impacting adherence. Condition-related factors are the illness-related demands faced by the patient, which ultimately impact a patient's risk perception, treatment beliefs, and the priority they place on adherence [18]. Therapy-related factors include side effects, treatment duration, treatment failures, and experience of side effects [18]. Although an intervention may meet the technology-oriented needs of a patient, the lived experience of their condition(s) and treatments could present barriers to their behavioral intention, both to adhere to treatment as well as to use an mHealth intervention to support treatment adherence.

In this study, we explore in detail the technology-oriented aspects of UTAUT as well as therapy- and condition-related adherence factors acting upon a patient's behavioral intention. Thus, we use the modified and condensed UTAUT model and key elements of the WHO framework as a way to better understand the factors impacting elderly Singaporeans' acceptance and use of mobile technology for an intervention to support adherence to ASCVD medication.

Methods

Sampling (Survey)

This cross-sectional component utilized data from a brief locally adapted survey created for this study, which sought to explore patient technology use. The survey used purposive sampling of an existing patient pool from the Singapore Population Health Study—Community Health Study to recruit those aged 40 years and above with established ASCVD or risk factors who fulfilled inclusion criteria (Textbox 1).

Textbox 1. Study inclusion and exclusion criteria.

Inclusion criteria:

- Patients with a history of ASCVD: coronary artery disease, ischemic stroke, peripheral artery disease, and atherosclerotic aortic disease; or
- At least one risk factor such as hypertension or hyperlipidemia in whom antiplatelet, antihypertensives, and/or statins are recommended.

Exclusion criteria:

- Participants unable to participate in a verbal interview;
- Participants who did not speak Mandarin, English, or Malay languages.

Both the survey and interview guide were developed as part of the larger txt2heart collaboration, which we then adapted to the Singapore context and covered topics including patients' sociodemographic characteristics, health care access, medication adherence, mobile phone technology usage (ownership, access, and utilization), and interest in mHealth (Multimedia Appendix 1).

Sampling (Qualitative)

The study took place in Singapore. We used purposive sampling from an existing patient list to recruit those aged 40 years and above with established ASCVD or risk factors for ASCVD (for complete inclusion and exclusion criteria, see Textbox 1).

Survey, Interviews, and Interview Guide

Trained research staff from the National University of Singapore (NUS) conducted the interviews or semistructured in-depth interviews in the participant's preferred language by staff fluent in that language. Interviewer training included description of research protocol, qualitative methods, and research ethics in practice.

Participants

The qualitative component involved semistructured in-depth interviews with 20 participants. Out of the 20 participants interviewed, 19 agreed to audio recording and 1 participant declined. For the latter, detailed field notes and an extensive memo were taken for inclusion in data analysis.

A total of 100 patients met the inclusion criteria for the quantitative survey and were recruited over the telephone. In total, 60 in-person and 40 telephone surveys were completed following informed consent from patients. A total of 100 surveys, inclusive of 1 incomplete survey on mobile phone technology usage section, assessed patients' sociodemographic characteristics, pattern of medication adherence, mobile phone technology usage (ownership, access, and utilization), and interest in mHealth.

Ethical Approval

Ethical approval for the study was obtained from the NUS Institutional Review Board. Informed consent for participation and recording was obtained before the interview started using a participant information sheet and consent form. Participants could refuse to answer any of the questions and/or discontinue their participation in the research at any time.

Statistical Analysis

Statistical analyses were performed using IBM SPSS version 24.0 (IBM Inc). Frequencies (n) and percentages (%) were used to summarize sociodemographic characteristics, clinical characteristics, patterns of mobile phone technology usage, and interest in mHealth.

Qualitative Analysis

A total of 2 research team members coded interviews using Nvivo 11 (QSR International) software applying interpretive and inductive approaches, thematic analysis, and techniques from the constant comparative method, where a line-by-line analysis of early interviews was used on subsequent interviews to test preliminary assumptions [19]. Interviews were recorded and transcribed in full. Reviewers agreed on identified codes and themes. To maintain confidentiality, all names reported were pseudonyms and identifying data were excluded.

Results

Participant Characteristics

The mean age of the 100 participants in the analysis sample was 65.3 (SD 9.6) years (Table 1). The largest proportion of participants, 55% (55/100), encompassed those aged greater than or equal to 65 years. The majority of patients (70/100, 70%) were male and 66% (66/100) were of Chinese ethnicity, with women and Malay, Indian, and other ethnicities representing a smaller proportion of the sample. Moreover, the majority of patients, 72% (72/100), reported having hyperlipidemia and 68% (68/100) reported having hypertension.

We conducted 20 in-depth interviews with participants who met the inclusion criteria. The detailed characteristics are presented in Table 2. Participants were largely of Chinese ethnicity (15/20, 75%) with fewer participants from Indian (4/100, 20%) and Malay (1/20, 5%) ethnic groups. Participants were mostly male (12/20, 60%) with 8 (8/20, 40%) female participants. The average age of participants was 72.5 years. The majority of participants (19/20, 95%) reported a hypertension diagnosis, followed by hyperlipidemia (16/20, 80%) and myocardial infarction/acute coronary syndrome (8/20, 40%) and stroke/transient ischemic attack (5/20, 25%).

Table 1. Quantitative participant characteristics table (n=100).

Sociodemographic characteristics	Total (n)
Ethnicity	
Chinese	66
Malay	19
Indian	14
Other	1
Gender	
Male	70
Female	30
Age (years)	
<65 years old	45
≥65 years old	55
Cardiovascular conditions	
Hyperlipidemia	72
Hypertension	68
Myocardial infarction or acute coronary syndrome	41
Stroke or transient ischemic attack	14

Table 2. Qualitative participant characteristics table (n=20).

Sociodemographic characteristics	Total (n)
Ethnicity	
Chinese	15
Indian	4
Malay	1
Gender	
Male	12
Female	8
Age (years)	
61-70	7
71-80	8
81-90	4
Missing	1
Cardiovascular conditions	
Hypertension	19
Hyperlipidemia	16
Myocardial infarction/acute coronary syndrome	8
Stroke/Transient ischemic attack	5

Quantitative Survey Results

A quantitative survey of 100 patients meeting the same criteria outlined above provided our study with descriptive data on our target population. Of the 99 participants who fully completed the survey, 90% (90/99) owned a mobile phone. Of those mobile phone owners, 77% (70/90) reported accessing their mobile phones in general at least once a day, and the same proportion of patients (70/90, 77%) reported using SMS at least once a day. In general, participants predominantly used their phones for phone calls (87/90, 97%), SMS (60/90, 65%), and other text messaging services such as Whatsapp (54/90, 61%; Figure 2).

Figure 2. Phone usage activities amongst mobile phone owners.

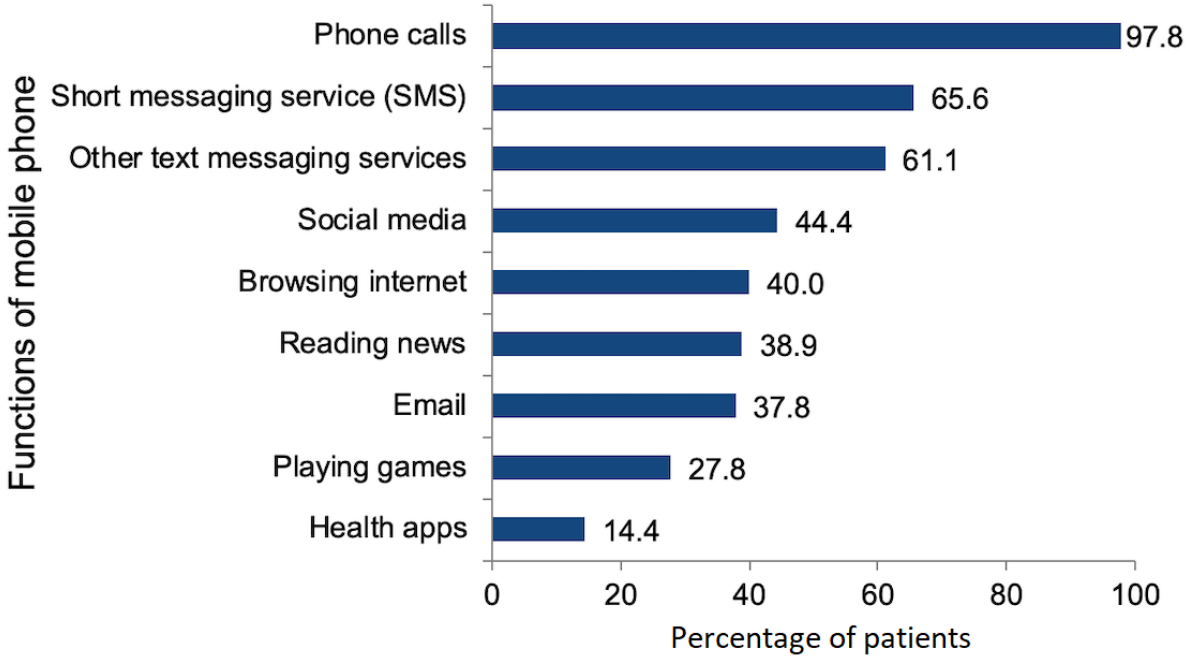
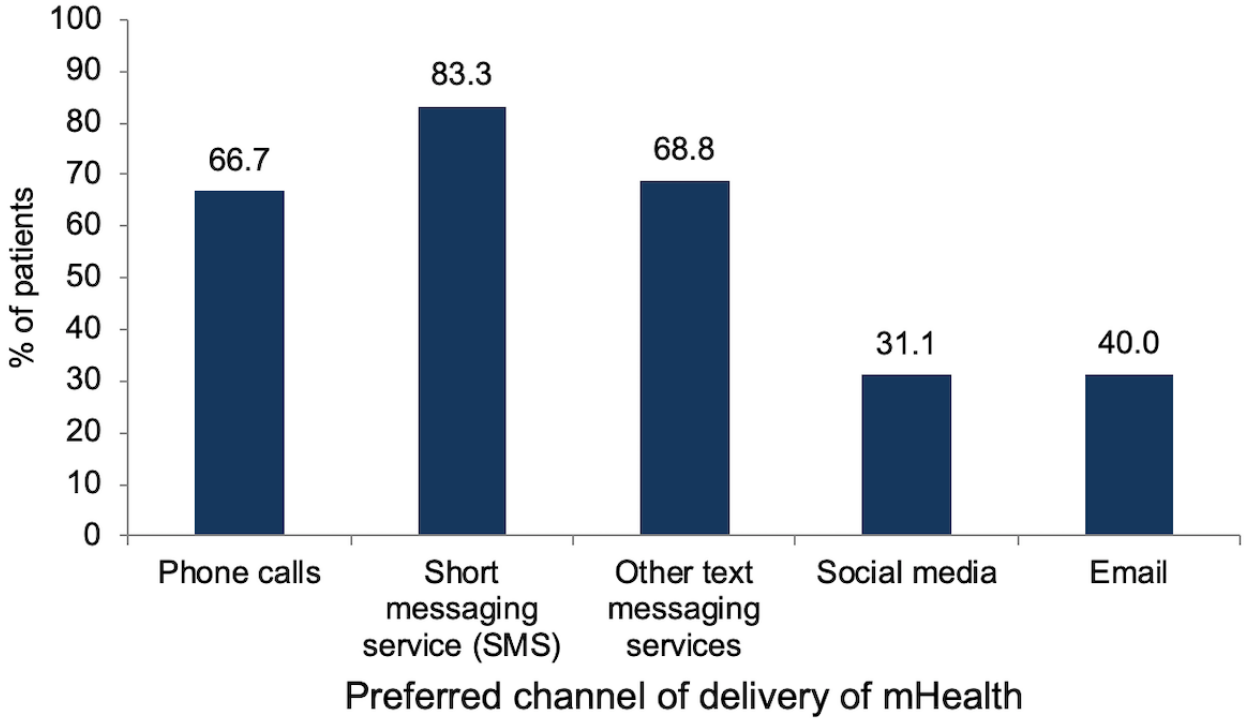


Figure 3. Preferred channel of delivery for mobile health intervention. mHealth: mobile health.



Of those who owned a mobile phone, 53.3% (48/90) indicated their interest in receiving medication information through their mobile phones.

Among those interested in mHealth services, SMS was the preferred mode of delivery of information on medication for 40 out of 48 participants (83%), followed by other text messaging services (33/48, 68%), phone calls (32/48, 66%), social media such as Facebook and email (15/48, 31%; Figure 3).

Qualitative Interview Findings

We reported our findings classified into themes based on our modified UTAUT model. In terms of technology-oriented factors, the first theme explored perceived usefulness of the mHealth intervention and personal outcome expectations. The second theme explored effort expectancy, including perceived ease of use, as well as other usability issues experienced by our elderly population. Next, we explored the social influences shaping technology use including the role of family and friends,

as well as the impact of social isolation. Then we looked at facilitating conditions for technology use including trust and previous mHealth use. We next explored adherence factors influencing behavioral intention, including therapy-related factors such as regime complexity, therapy duration, inconvenience, and adverse effects. Finally, we looked at condition-related factors including symptoms and effects of condition on the functional and mental state. See Multimedia Appendix 2 for key themes and examples of evidence.

Perceived Usefulness

Participants reported on their perception of the usefulness of having a reminder system to take their medications. Most participants reported that they saw no need for such a system, as they did not have difficulties remembering. As Yong Liat reported:

> *I can't forget. Every time I put it on top, and I write down there. So I know. People don't need to tell me. I know myself.* [IDI006_M_81-85_Chinese]

However, some participants did agree that hypothetically having reminders may be good for others who forget to take their medications. As Kim Huat explained:

> *They should see the message and it should help. After all the reminder for them to take the medication is actually beneficial for them, and they should heed the reminders.* [IDI009_M_71-75_Chinese]

Some participants also voiced that low phone usage may inhibit the usefulness of an SMS intervention. As Irene described:

> *I don't look at my phone...when the phone beeps with an SMS I'll think of checking it later, but I'll forget. Do you see how many unread and unanswered SMSes and WhatsApp message I have?* [IDI004_F_66-70_Chinese]

Personal Outcomes Expectations

The majority of participants explained that they personally felt an SMS intervention would not be useful or provide a useful outcome. This is partly because of some participants having low reliance on their phones, meaning the vehicle for delivery may not be aligned with the population's mobile uses. Furthermore, some participants expressed that the intervention does not address what they perceive to be the root causes of nonadherence, which they feel to be beyond the reach of mHealth. For example, an SMS intervention would not help those who intentionally do not take their medication. As Ah Siew explained:

> *If they want to take medication, they will. Some people they're not taking it on purpose. I don't take some of my medication too. We take only the important medicine and don't take those that we feel aren't important.* [IDI020_F_71-75_Chinese]

Another participant highlighted that regardless of the proposed intervention, a key factor in adherence is patient agency and responsibility in placing importance on their health. Yan Ting explained:

> *I think whatever method you want to use, it's nothing compare to convincing that patient that it is in their own interest and it is important for them to take the medicine regularly according to the schedule... I think if they are serious looking after themselves, it becomes a habit already.* [IDI018_M_76-80_Chinese]

However, some participants reported on factors that may be modifiable by an mHealth intervention. Irene summed up her perspective of the main factors for nonadherence, forgetfulness, dependency on others, and being busy:

> Interviewer: *How do you think we can use mobile phones to remind people to take their medication?*
>
> Participant: *When people forget to take their medications it's the following three reasons. First, they're forgetful, like me. I tell myself it's time to take my medication and walk to the kitchen. When I'm in the kitchen, I can't remember why I came into the kitchen. Second, they're dependent. They wait for people to tell them. Third, they are too busy. Just these three types of people.* [IDI004_F_66-70_Chinese]

Effort Expectancy

As mHealth interventions predicate on patients being able to interact with SMS, it is important to understand their perceptions of basic mobile technologies as well as their perceptions on their ability to learn how to use such technologies.

Perceived Ease of Use

Some participants described difficulty using a mobile phone, thus preventing them from being interested in an mHealth intervention. However, others were keen to keep up with technology and expressed initiative and interest in learning about their phones. Safiah explained how she previously did not know how to use some features of her phone, but now is able to:

> *Previously I SMS right-- previously aunty don't know how to SMS...So now everything I know. You live in the world of today...Every now and then, you must go out and learn everything. What the youngsters can do, the old also can do.* [IDI012_F_71-75_Malay]

Among those who are comfortable using technology, a few reported that SMS is a good and convenient way to convey health information:

> *It's also good via SMS or WhatsApp since it's more convenient and the information is in the phone. Sometimes we might not have time to answer a call.* [IDI009_M_76-80_Chinese]

Usability Issues

Many participants, however, reported on functional issues preventing them from comfortably using a mobile phone including small screens or font sizes that are barriers to reading SMS messages. As Cheng Han explained:

> *Our eyesight is also failing. Sometimes we see an"8" as an "S."It also makes it difficult to read our SMS. Our senses all deteriorate after 70 years old.* [IDI014_M_71-75_Chinese]

Another usability concern raised by many participants was that of the language of intervention. Most participants agreed the SMS reminders should be sent in local languages. As Kim Huat reported:

> *It would help if it's in Chinese, Malay, Tamil. Those of us who are older don't understand English, and thus the content in the SMS.* [IDI009_M_76-80_Chinese]

While Sow Tin explained that some older people had lower literacy and thus require simplified SMS content:

> *Firstly, I didn't really go to school. So I can only read really simple English and Chinese. I can speak better, but not write...I will just reply "Ok." If I don't know how to text back my response, I will send them a voice message. It's easier like that.* [IDI004_F_66-10_Chinese]

Social Influence

Another important component of technology uptake and use is that of social influence. Those with stronger social networks who use and look favorably on technology may use technology to connect and stay in touch, and these networks may in turn enable them to adopt technology.

Family and Friends' Technology Use

Some participants reported that the lack of a social support system is a reason for not being interested in using a mobile phone, and others reported using the phone less as their friends had passed away. As Wen Cheng explained:

> *I don't have many friends. I don't need to talk a lot now, or I just use the home telephone.* [IDI001_M_71-75_Chinese]

Among those who had stronger social supports, many described that their friends were an important factor in their ability to learn and keep up with technology. Others described how technology had enabled them to keep in touch with friends from abroad and that these groups were helpful to them, thus giving them a favorable impression of mobile technology. One participant described how technology and social support played a role in adherence. As Kavita reported:

> *She (friend) every time calls me, you know, because she know I forget."Hey, take medicine already?"She don't know which medicine I take but she give me a reminder.* [IDI013_F_61-65_Indian]

Facilitating Conditions

Our participants highlighted the importance of previous exposure to mHealth services and trust as facilitators to mHealth use.

Previous Mobile Health Use

A majority of participants reported positive experiences with previous mHealth apps, namely SMS appointment reminders. Participants felt these were useful and helped them to remember their appointments. Kim Huat explained:

> *They will send SMS to me, and they also give me a paper with the appointment date. They usually remind me via SMS a week before my appointment...It's a good reminder so that you don't forget.* [IDI009_M_76-80_Chinese]

One participant, Kamal, highlighted that patients may not be an appropriate audience to target the SMS reminders to and it would be more useful to engage primary caregivers in mHealth interventions:

> *Tell the person looking after the patient to remind them to take their medication...The person cannot remember...so if you tell the children or (caregiver) they will make sure they take the medication, as if the orders come from the doctor the caregiver will scared and make sure they take.* [IDI010_M_71-75_Indian]

Trust

An important facilitating factor reported by patients was that of trust. Some patients explained that they do not trust all the information they reiceve on the Web or shared through Whatsapp groups. As Kim Huat said:

> *There are a lot of fake information there (on the phone), not all are true.* [IDI009_M_76-80_Chinese]

Thus, highlighting the need for an mHealth intervention to come from a trusted and known source.

Kim Huat went on to explain how the underlying trust in treatment is important in an mHealth intervention for adherence to medications:

> Interviewer: *Who do you think this service will help?*
>
> Participant: *Those that believes that their medication is effective. After all if you face any issues while taking the medication, the doctor and change it for you.* [IDI009_M_76-80_Chinese]

This highlighted the need to not only understand user preferences and behaviors, but also to take into consideration the various adherence factors, which influence patient decision making and ability to adhere to medications.

Adherence Factors

Adherence factors include therapy-related and condition-related factors. To design an appropriate mHealth intervention, it is important to understand how both the medication itself and the condition may limit or enable adherence to medication.

Therapy-Related Factors

Complexity of Medication Regime

Some patients reported adjusting their medication to cope with a complex regime and to facilitate their ability to adhere to their medications. As Sow Tin described:

> *The doctor did tell me to take the blue pills before food. I thought it was troublesome to split them, so I took all my pills before food. So I can remember whether I've taken my medication...The doctor did say I was cheating. But it's okay. It's more time efficient for me.* [IDI004_F_66-70_Chinese]

Nearly all patients described how using a pillbox and the ritual surrounding taking their medication had enabled them to form habits. Patients also reported that they did not feel the need to

have an mHealth intervention to remind them as their current habits and pillbox use enabled them to ensure they had taken medications and prevented them from taking a double dose.

Duration of Therapy

The majority of patients also reported how the long duration of therapy for chronic conditions facilitated their ability to adhere to their medications. Thus, they felt that an mHealth intervention would not be of use, as they had already established habits over the course of managing their chronic conditions. As Karen reported:

> *I just follow...because I have been using it for long, it's no problem to me...It's all very systematic. No problem.* [IDI003_F_NA_Chinese]

Inconvenience With Lifestyle

Although most patients reported that they largely adhered to their medications and had habits to support their medication taking, some patients reported how lifestyle factors disrupted their routines on occasion. Largely, patients reported how going out of the house or travelling was disruptive. As Ah Siew described:

> *But if I go out, I won't bring and eat it. It's very troublesome to take it when I'm on the bus or (train). I'll just miss taking it. For instance, I went to Ipoh Malaysia the other day, I brought my medicine but I didn't take it for two days, as it's too troublesome.* [IDI020_F_71-75_Chinese]

Adverse Effects

Some patients reported how adverse effects caused them to be nonadherent to their medications. One participant reported that while the doctor wanted to titrate the dose, he decided to stop entirely. As Yong Liat reported:

> *Just recently. Because I told the doctor, I feel giddy then doctor say maybe this one caused...he asked me to take half...so I stopped.* [IDI006_M_81-85_Chinese]

Condition-Related Factors

Patients reported few condition-related factors as impacting their ability to adhere to their medications for ASCVD and its risk factors. One patient reported being prescribed various doses of medication and not taking it unless his blood pressure was high. As Cheng Han described:

> *Yes. I may forget my blood pressure medications...For blood pressure, I usually don't take the medications unless my blood pressure is high.* [IDI014_M_71-75_Chinese]

A few participants also reported how taking medications impacted their mental state, as they felt fearful of sequelae or death. For some participants, this caused them to titrate or change medications. As Sow Tin described:

> *You see, this cholesterol medication was given to me in March, and I still have so much leftover. If I show the doctor, he/she is going to scold me. So I won't tell the doctor...My sister told me that if I take a lot of these cholesterol medication, it will affect my kidneys. So I've stopped taking that one and take this one instead. I'm not as afraid of kidney trouble with this one.* [IDI004_F_66-70_Chinese]

Whereas, others reported that fear of disability and death motivated them to continue their habits and be adherent to their medications. As Yu Yan explained:

> *I take them right after washing my face as I scared I forget...It's okay to die, it's not okay to be disabled. So I take my medications...Because I'm scared to die, it motivates me to eat my medication, without even any reminder.* [IDI008_F_71-75_Chinese]

The Learning Curve and Mobile Technology

One participant highlighted in detail the learning curve after diagnosis and commencement of treatment as a potential opportunity for mHealth interventions for adherence to medications (Textbox 2).

This case explored how the uncertainty of a new diagnosis and discharge from hospital care is an opportunity for mHealth to provide adherence support to patients where they have a high intention to uptake adherence behaviors. Patients who have managed their chronic conditions for years may not be as receptive as they have established habits; however, newly diagnosed patients or newly discharged patients may be primed to receive support in their care.

Textbox 2. Case study on the learning curve.

David, a 64-year-old male, had no history of heart disease before having a severe heart attack, which required the insertion of a left ventricular assist device. He was admitted to the intensive care unit for over a month before being discharged. While in hospital, David reported being on 14 different types of medication, which were reduced to 11 upon discharge after he reported adverse side effects. Presently, he is only on 2 medications. David explained the role of his care coordinators, who taught him about his medications before discharge. He also explained how they interceded on his behalf with the doctors to reduce the number of medications he was prescribed. Importantly, he described how they were available to call or SMS when he had questions. When asked about the use of an mHealth intervention to remind patients to take their medications, he explained: "It will be useful for patients who just came out of the ward. But not for long-term patients, because we know what to do." [IDI007_M_61-65_Indian]; David reported that in the days following discharge, the care coordinators would check in daily and ask on his adherence and other required activities (dressing changes, etc); and now they check in every 2 weeks, and he is able to reach out to them should he require their assistance.

Discussion

Principal Findings

This mixed-methods study explored mobile technology acceptance, use, and facilitating conditions, as well as adherence factors among older Singaporeans ahead of an mHealth intervention to promote adherence to ASCVD medications.

Participants reported variable acceptance of mobile technology. Some participants were tech savvy and used mobile technology regularly and broadly to connect with their social networks, whereas others reported decreasing social connectedness as a reason for not using mobile technology. Participants widely reported usability concerns including reading difficulty because of screen and font size and hearing difficulties limiting their awareness of notifications. This is in line with other research on mobile technology use for health interventions with older participants [20]. These technology-oriented factors have an impact on user's behavioral intention to use technology, as well as their intention or interest in using an mHealth intervention for adherence to medications. Indeed, among our study population, whose mean age was 72 years for the qualitative component, participants were largely disinterested in SMS reminders, often citing low mobile phone usage or usability concerns as a barrier to uptake.

Suboptimal adherence to medications for ASCVD and its risk factors is well documented [6,21-23]; however, most of our participants reported not needing reminders to take their medication as they have their own established habits and report themselves as being adherent. Yet, some participants reported self-titration and nonadherence when lifestyle factors interfered with their ability to have medications on hand. Thus, caution is warranted in these self-reports of adherence. These reports of adherence may impact patients' behavioral intention to use an mHealth intervention, as many participants reported no interest in an mHealth intervention for adherence to medication, as they did not see personal benefit to such a service.

Despite these concerns, some participants did report that SMS was a good avenue through which to receive health information. This is in line with findings from other studies across health research where it has been shown that despite perceived usability issues or dissatisfaction with available options, patients believe in the capacity of mHealth interventions to facilitate better health outcomes [24-27]. In our study, a contributor to a favorable opinion of the proposed intervention was previous mHealth use. Participants who received appointment reminders from health care providers were more open to the idea of health content delivered through SMS, although they were ambivalent on the utility of medication reminders.

Another factor facilitating a positive perception of mHealth was that of trust; both trust in the SMS sender, and trust in the treatment plan. Participants described caution in believing Web-based sources for health information, reported receiving spam SMS messages, and underscored the importance of wanting a trusted source for any mHealth SMS. Other studies have shown that trust is an integral part of intent-to-use technology and predicates on the belief that the other party will not exploit the vulnerability of the user [28,29]. Participants also linked the success of any mHealth intervention to whether patients trusted their medications. There is ample evidence on the role of trust, both in treatment and in provider, in medication adherence [30-32], and these facets of trust in treatment are important in establishing the behavioral intention to use an mHealth intervention for adherence to medication.

Although technology-oriented factors directly influence a patient's ability and motivation to use and follow an mHealth intervention, adherence factors also play a role in determining if a patient is able to translate the behavioral intention triggered by the SMS into a use behavior. The use of habits and reminders is well documented in facilitating adherence to medications [33-35]. Our study adds to this evidence showing that patients perceive they are able to cope with treatment complexity by establishing their own habits and rituals and that given the length of treatment required they become accustomed to taking their medications. Importantly, however, patients did report self-titration because of adverse effects, as well as lifestyle factors that disrupted their ability to adhere to medications. These are important factors that may not be modifiable by an mHealth intervention but warrant consideration.

The unique case of David highlights the importance of the learning curve wherein patients develop these habits and rituals for medication taking. After diagnosis, patients may require additional support and be open to receiving that support, as they begin to develop habits and adopt behaviors relating to medication taking and lifestyle adjustment. Although, as is the case with David, this support may taper off over time once adherence behaviors are established, or the perceived utility diminishes. It also presents the opportunity to reintroduce the intervention should new medications be introduced or the patient requests additional support. Although technology-oriented factors, adherence factors, and contextual factors may pose challenges to uptake of an mHealth intervention, this case highlights the importance of identifying opportunities where the barriers to mHealth uptake may be lower as patients are actively seeking support as they take ownership of their care.

Strength and Limitations

A strength of our study is the use of in-depth interviews for the exploration of patients' perspectives on both medication taking, as well as technology use and the opportunities and challenges for mHealth interventions. Furthermore, the inclusion of participants from multiple ethnic backgrounds and older participants adds to the diversity of experiences reported.

A limitation of this study is that it excluded individuals with disabilities, which prevented them from participating in verbal interviews. Also, our participants were all over 60 years of age, thus we are not capturing the perspectives of those middle-aged persons taking medications for ASCVD and its risk factors who may have differing adherence patterns or mobile technology use behaviors. The fact that Singapore has a high mobile phone penetration rate, a small geographical size, and is a 100% urbanized city-state may limit its generalizability to other countries with differences in such characteristics. Furthermore, contextually, health system factors in Singapore, including high accessibility and availability of care may account for some of

the patient accounts of not needing reminders, as they are able to easily access follow-up care. Our study also did not include caregivers, who may be a more appropriate end user for the intervention, particularly among those older persons who rely on caregivers for their medication taking. Furthermore, we relied on self-reported adherence measures, thus some participants may have reported higher adherence to medication. A final limitation is that of desirability bias, whereby participants may be reporting more favorably on their experiences.

Conclusions

Our study had identified several important technology-oriented and adherence-related factors from the patient perspective that warrant consideration in the design of an mHealth intervention to support adherence to medications for ASCVD and its risk factors in Singapore. We also highlighted the importance of finding the right opportunity to engage with patients and promote an mHealth intervention, such as immediately following diagnosis when patients are establishing medication-taking habits. As health care professionals increasingly leverage on innovative approaches such as mHealth to promote adherence to medications for chronic conditions, it will be important to better understand both the technology-related behaviors that impact a patient's intention and ability to use an mHealth intervention, as well as therapy- and condition-related factors that may enable or inhibit successful adoption of such an intervention.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary qualitative interview guide.

[PDF File (Adobe PDF File), 29KB - mhealth_v7i3e11108_app1.pdf]

Multimedia Appendix 2

Key themes and examples of evidence.

[PDF File (Adobe PDF File), 29KB - mhealth_v7i3e11108_app2.pdf]

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Abbreviations

ASCVD: atherosclerotic cardiovascular disease
CVD: cardiovascular disease
IT: information technology
mHealth: mobile health
NUS: National University of Singapore
SMS: short messaging service
UTAUT: unified theory of acceptance and use of technology
WHO: World Health Organization

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Original Paper

Effective Engagement of Adolescent Asthma Patients With Mobile Health–Supporting Medication Adherence

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Abstract

Background: Mobile health (mHealth) apps have the potential to support patients' medication use and are therefore increasingly used. Apps with broad functionality are suggested to be more effective; however, not much is known about the actual use of different functionalities and the effective engagement.

Objective: The aim of this study was to explore the use and the effective engagement of adolescents (aged 12 to 18 years) with the Adolescent Adherence Patient Tool (ADAPT).

Methods: The ADAPT intervention consisted of an app for patients, which was connected to a management system for their pharmacist. The aim of the ADAPT intervention was to improve medication adherence and, therefore, the app contained multiple functionalities: questionnaires to monitor symptoms and adherence, medication reminders, short movies, pharmacist chat, and peer chat. For this study, data of the ADAPT study and a cluster randomized controlled trial were used. Adolescents with asthma had 6 months' access to the ADAPT intervention, and all app usage was securely registered in a log file.

Results: In total, 86 adolescents (mean age 15.0, SD 2.0 years) used the ADAPT app 17 times (range 1-113) per person. Females used the app more often than males (P=.01) and for a longer period of time (P=.03). On average, 3 different functionalities were used, and 13% of the adolescents used all functionalities of the app. The questionnaires to monitor symptoms and adherence were used by most adolescents. The total app use did not affect adherence; however, activity in the pharmacist chat positively affected medication adherence (P=.03), in particular, if patients sent messages to their pharmacist (P=.01).

Conclusions: mHealth apps for adolescents with asthma should contain different functionalities to serve the diverging needs and preferences of individual patients. Suggested key functionalities to promote use and effectiveness in adolescents with asthma are questionnaires to monitor symptoms and a health care provider chat.

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KEYWORDS

adolescent; asthma; medication adherence; pharmacists; telemedicine

Introduction

Mobile health (mHealth) interventions have the potential to support patients with their medication use and are therefore increasingly used [1-4]. Patients highly appreciate those type of interventions, mainly because of the high usability, feasibility, and acceptability of mHealth [5]. However, the evidence for efficacy of mHealth for chronic patients is limited, except for

moderate quality evidence of improvement in asthma patients [3].

mHealth seems, in particular, promising for specific patient groups such as adolescents because almost all adolescents own a smartphone (95%); they widely use their phone for social networking, and they are generally poor adherents [6,7]. However, until now, not many mHealth interventions are developed for adolescents, although mHealth interventions for adolescents were rated as feasible and acceptable with modest evidence for their efficacy in improving adherence [8-10]. Therefore, we developed the Adolescent Adherence Patient Tool (ADAPT), an interactive mHealth intervention to improve medication adherence in adolescents with asthma. A patient-centered approach and a theoretical framework were used to develop this intervention [11]. As a result, the intervention consisted of a smartphone app for patients, which was connected to a desktop application for pharmacists, enabling communication between patients and health care providers.

Previous studies showed that multifaceted mHealth interventions are more effective in improving medication adherence than interventions targeting only 1 aspect of nonadherent behavior [4,12-14] because medication adherence is a complex behavior affected by many factors [15]. Accordingly, the ADAPT intervention contained multiple functionalities to support medication adherence: questionnaires to monitor symptoms and adherence, medication reminders, short movies, pharmacist chat, and peer chat [11]. We evaluated the ADAPT intervention in a cluster randomized controlled trial and adherence improved significantly in adolescents with asthma having poor adherence rates [16].

Besides the efficacy of mHealth, it is important to study the actual use of mHealth interventions. Currently, little is known about the actual use of mHealth apps by adolescents with asthma. Moreover, it is important to identify the association between the use of different mHealth functionalities and the effect on the intended outcome, also known as *effective engagement*. This will provide directions for other mHealth interventions aiming to improve adherence, as there is still limited evidence for the efficacy of mHealth [17,18]. Therefore, the aim of this study was to explore the use of the ADAPT app, a complex adherence mHealth intervention, by an adolescent with asthma and to study the effective engagement of patients with the ADAPT app.

Methods

Data Collection

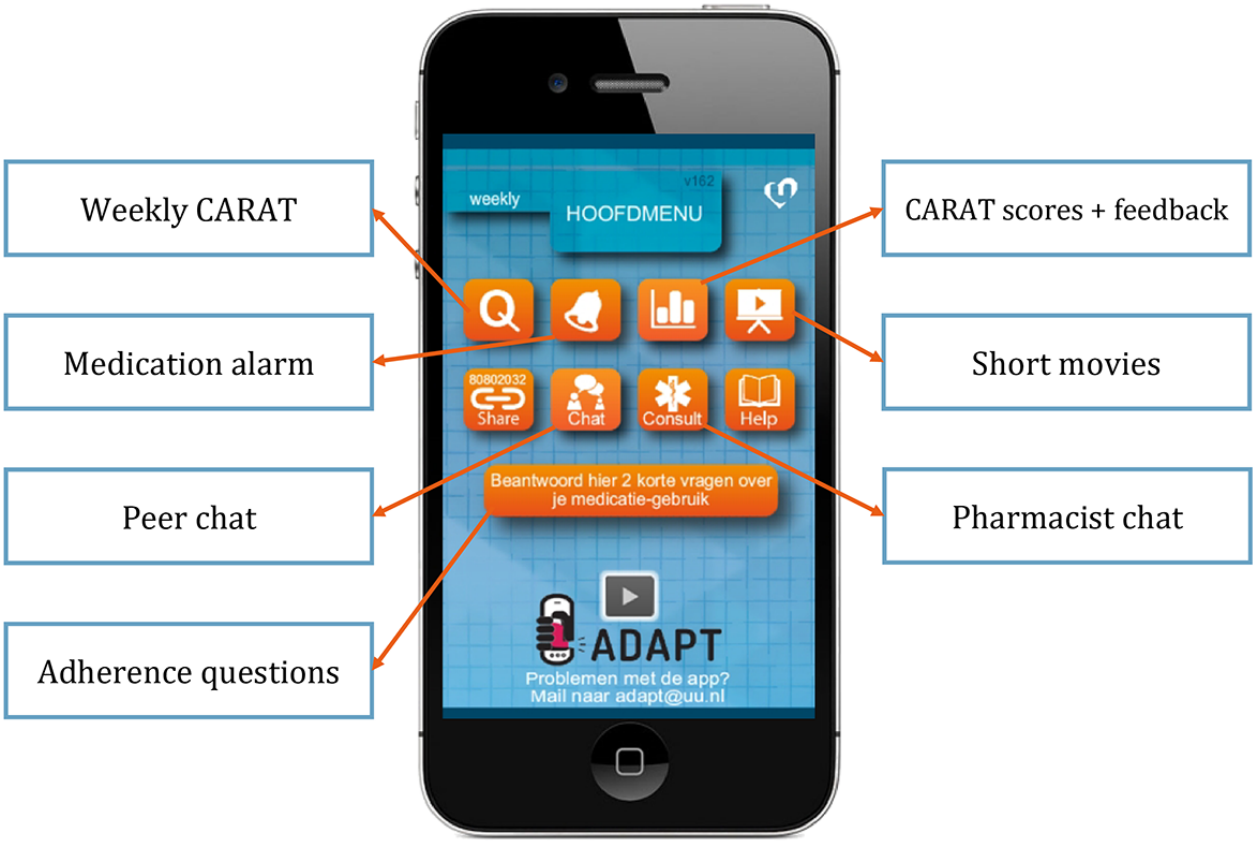
Data of the ADAPT study, a cluster randomized controlled trial, were used. The aim of the ADAPT study was to evaluate the effect of the ADAPT intervention on adherence, measured with the Medication Adherence Report Scale (MARS) [19]. The complete ADAPT study protocol and effectiveness of the mHealth intervention have been described elsewhere [11,16]. Briefly, adolescents with asthma (aged 12 to 18 years) who were in the possession of a smartphone were eligible for participation. In total, 638 patients were invited for the intervention group and 103 (16.1%) signed the informed consent. There was a 16% dropout rate (n=8 withdrew consent, n=7 did not download the app, and n=1 was lost to follow-up), resulting in 87 patients and 27 pharmacists, who had 6 months access to the ADAPT intervention. The control group consisted of 147 patients and 27 pharmacists (data not shown).

We asked patients in the intervention group (N=87) to use the app at least once a week; they received a weekly push notification. After 6 months upon completing the study, patients received a gift card (regardless of their app usage). All ADAPT app use was securely registered in a log file, that is, a document with an automatically produced and timestamped documentation of events.

Adolescent Adherence Patient Tool Intervention

The ADAPT app (Figure 1) was connected to a desktop application of the patient's own community pharmacist [11]. The different functionalities of the app are described below.

Figure 1. The Adolescent Adherence Patient Tool with the different functionalities. CARAT: Control of Allergic Rhinitis and Asthma Test.



Questionnaire to Monitor Symptoms

Patients received a weekly push notification (26 times in total) to complete the Control of Allergic Rhinitis and Asthma Test (CARAT) to monitor their symptoms [20]. This validated questionnaire consisted of 10 questions where a total score between 0 and 30 could be obtained (>24 indicated good disease control). The total score could be divided into 2 subscores: allergic rhinitis score (items 1 to 4, score>8 indicated good control) and asthma score (items 5 to 10, score ≥16 indicated good control). Patients had access to their obtained CARAT scores in the ADAPT app and received textual feedback about their results. The CARAT scores were also sent to the pharmacist's desktop application, and pharmacists received email notifications when patients had no disease control (CARAT score ≤24).

Medication Alarm

Patients could set a medication alarm to prevent forgetting. The alarm was adjustable to the patient's preferences, that is, patients could set the alarm once or twice a day at their preferred time. The alarm was not connected to their inhaler medication; thus, it did not register if medication was already taken. Unfortunately, use of the medication alarm was not registered in the log file, as the alarm settings were saved locally.

Short Movies

Almost every week a short movie about an asthma-related topic (eg, lifestyle, medication use, and friends) became visible in the app to educate and motivate the patient. Patients did not receive a push notification, although in the app a notification was visible when a new movie became available. In total, 21 movies became available during the 6-month study period. Pharmacists had access to the movie database and could send additional movies based on the patient's needs, for example, about inhaler techniques.

Peer Chat

The peer chat gave patients the opportunity to share experiences and discuss asthma-related topics with other participants. This was an age-specific functionality, as peers are important during adolescence [21]. Adolescents recommended this functionality during the developmental phase. The messages were divided over 6 topics: asthma, general, going out, pets, sports, and other. There was no moderator involved as we did not want to disrupt the interaction between adolescent peers.

Pharmacist Chat

The pharmacist chat facilitated direct contact between the adolescent and their pharmacist, which is important because adolescents are not often seen in the pharmacy [22]. Pharmacists voluntary signed up for the ADAPT study and were randomized to the intervention group. Pharmacists could contact their *own* patients via the intervention, as in the Netherlands every patient is registered at 1 pharmacy and mostly fill all their prescriptions there. Pharmacists received email notifications when patients sent a message. The aim of this functionality was to educate and motivate patients.

Adherence Questions

Once every 2 weeks (14 times in total), 2 questions concerning adherence appeared in the app. The questions were based on items of the MARS. The first question was related to unintentional nonadherence: *How often did you forget to take your medication in the previous week?* and the other was related to intentional nonadherence: *How often did you decided to miss out a dose in the previous week?* Patients could answer these questions using a 5-point Likert scale ranging from 1 (always) to 5 (never).

Data Analysis

Descriptive statistics of all variables were calculated. For skewed data, the median with interquartile range (IQR) is shown instead of the mean with standard deviation (SD). We divided the adolescents in 3 groups based on the frequency of the app usage during the 6-month study period: low (≤10), average (>10 and ≤25), and high (>25) frequent users. All log file data were converted to Excel and, thereafter, statistical analyses were performed using R (R Foundation for Statistical Computing, version 3.4.3) packages *nlme* and *lme4*. *P* values less than .05 were considered statistically significant.

Effective Engagement

We used (generalized) linear mixed-effects models to evaluate the effective engagement of adolescents and to compare groups. The 27 pharmacies of the ADAPT study (clusters) were used as random effects in the models.

Ethics and Confidentiality

The ADAPT study was approved by the Medical Review Ethics Committee of the University Medical Centre Utrecht (NL50997.041.14) and by the Institutional Review Board of Utrecht Pharmacy Practice network for Education and Research, Department of Pharmaceutical Sciences, Utrecht University [23]. All participants had to sign informed consent before the start of the study; for patients younger than 16 years, both parents also had to sign. The trial is registered in the Dutch Trial Register (NTR5061). All (personal) app data were encrypted using 128-bit Advanced Encryption Standard and were securely saved using Hypertext Transfer Protocol with a Secure Sockets Layer certificate (HTTPS).

Results

Descriptives

In total, 87 adolescents (mean age 15.0 SD 2.0 years; 55% females) downloaded the ADAPT app on their smartphone (Table 1), of which 86 adolescents used it 1975 times between October 2015 and April 2017. The median app use per person was 17 times (IQR 6-31; range 1-113) within a period of 5 months (IQR 3-6; range 0-8). Females used the app more often than males (median 20.5 vs 11; *P*=.01) and over a longer period (median 5 vs 6 months; *P*=.03).

The exact use per functionality is described in Table 1; the CARAT questionnaire, adherence questions, and short movies were used by most adolescents. There were differences in characteristics and functionalities used between the 3 user groups: low, average, and frequent users (Table 1). The low frequency app users had lower self-reported adherence rates compared with the average group (MARS 19.3 vs 21.4; *P*=.04), and the high frequency group contained more females compared with the low frequency group (73% (19/26) vs 44% (12/27); *P*=.04). Almost all low frequent users (93%; 25/27) completed the CARAT questionnaire, and more than half (56%; 15/27) completed the adherence questions at least once. No one sent a message in the peer chat. The majority of high frequent users sent a message to their pharmacist (81%; 21/26) and watched a movie (77%; 20/26), which differed significantly from the other groups (Table 1).

Adolescents used, on average, 3 different functionalities of the app (IQR 3-4; range 1-5). An overview of the combinations of different functionalities used is presented in Figure 2, showing a wide variety in app functionality use. All 5 functionalities were used by 13% (11/87) of the adolescents. Examples of the total app usage per person are shown in Multimedia Appendix 1.

Questionnaire to Monitor Symptoms

The CARAT questionnaire is the most frequently used functionality of the app; in total, 1047 questionnaires were completed by 85 (98%) adolescents (Multimedia Appendix 2). Adolescents received 26 weekly reminders during the study period (6 months) to complete the CARAT; however, they individually completed the CARAT on average 10 times (IQR 4-17). There was a lot of variation between patients; range 1-84.

Adherence Questions

The majority of adolescents (83%; 72/87) completed the adherence questions at least once, with a total of 221 completed questionnaires. The median of completed adherence questions per person was 2 (IQR 1-4; range 1-11), whereas the adherence questions appeared 14 times during the study period.

Short Movies

Half of the adolescents (51%; 44/87) watched at least one movie. More females (n=29) than males (n=15) watched movies (*P*=.04). In total, 21 short movies appeared in the app; however, on average, 4 different movies were watched per person (IQR 2-6; range 1-20), and each movie was seen once (IQR 1-1; range 1-4). The movies that appeared first in the app were seen most. In addition, 1 pharmacist sent an additional movie with inhaler instructions to support a patient; this movie was seen twice.

Table 1. Descriptives of the adolescent app users and the differences between the frequency groups.

Variable name	Total (N=87)	Low[a] (n=27)	Average[a] (n=34)	High[a] (n=26)	*P* value[b]		
					Low versus average	Low versus high	High versus Average
Female, n (%)	48 (55)	12 (44)	17 (50)	19 (73)	.59	.04	.08
Age (years), mean (SD)	15.0 (2.0)	15.4 (2.0)	15 (2.0)	14.6 (2.1)	.50	.16	.40
Adherence (MARS[c]), mean (SD)	20.4 (3.9)	19.3 (3.9)	21.4 (3.5)	20.3 (4.2)	.04	.30	.35
Asthma control (CARAT[d]), mean (SD)	19.3 (5.3)	18.7 (6.0)	19.6 (5.4)	19.5 (4.6)	.52	.72	.80
Allergic rhinitis	7.3 (3.2)	7.0 (3.5)	7.6 (3.1)	7.0 (3.2)	.48	.98	.47
Asthma	12.1 (3.2)	11.7 (3.6)	12.1 (3.1)	12.4 (2.8)	.68	.47	.72
Duration app use (months), mean (SD)	4.2 (2.1)	3.0 (2.4)	4.7 (1.6)	6.1 (1.3)	<.001	<.001	.008
Frequency app use[e], mean (SD)	22.5 (22.0)	4.3 (2.6)	17.1 (4.6)	48.6 (22.9)	<.001	<.001	<.001
CARAT, n (%)	85 (98)	25 (93)	34 (100)	26 (100)	—[f]	—	—
Adherence, n (%)	72 (83)	15 (56)	31 (91)	26 (100)	.003	—	—
Short movies, n (%)	44 (51)	7 (26)	17 (50)	20 (77)	.06	<.001	.04
Pharmacist chat, n (%)	38 (44)	2 (7)	15 (44)	21 (81)	.006	<.001	.009
Peer chat, n (%)	18 (21)	0 (0)	7 (3)	11 (42)	—	—	.04

[a]Frequency of app use: low=used the app ≤10 times; average=used the app >10 and ≤25 times; high=used the app >25 times.

[b]*P* values derived of (generalized) linear mixed-effects models.

[c]MARS: Medication Adherence Report Scale.

[d]CARAT: Control of Allergic Rhinitis and Asthma Test.

[e]Used at least once.

[f]Not applicable.

Figure 2. Overview of the combinations of functionalities used by 86 adolescents. Adh: adherence questions; CARAT: Control of Allergic Rhinitis and Asthma Test; peer: peer chat; pharm: pharmacist chat.

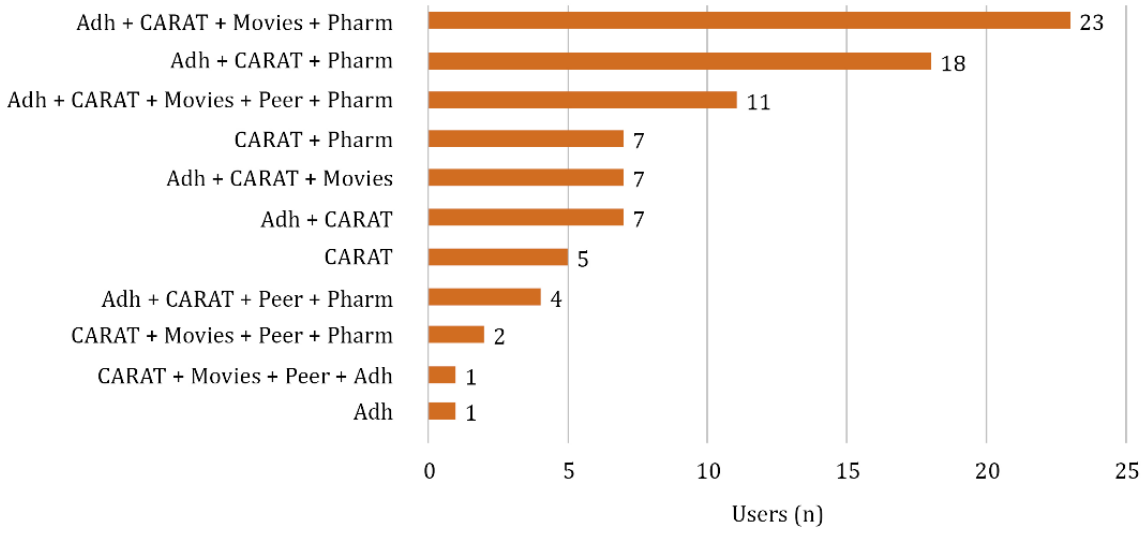


Table 2. Descriptives of pharmacists using the pharmacist chat.

Pharmacists who started the chat (n=53)	n (%)	No response, n (%)
Question about the CARAT[a] score	24 (45)	13 (25)
Welcome message	16 (30)	10 (19)
Welcome message and question	7 (13)	2 (4)
Comment on the CARAT score	4 (8)	1 (2)
Question	2 (4)	1 (2)

[a]CARAT: Control of Allergic Rhinitis and Asthma Test.

Table 3. Descriptives of patients using the pharmacist chat.

Patients who started the chat (n=12)	n (%)	No response, n (%)
Question about medication	5 (42)	3 (25)
Question about the app, asthma, or general	4 (33)	0
General comment	2 (17)	1 (8)
Medication comment	1 (8)	0

Pharmacist Chat

In total, 65 of the 87 adolescents (75%) sent or received 3 chat messages within the pharmacist chat (IQR 1-7; range 1-37), with a total of 347 messages. In most cases (82%; 53/65), the pharmacist started the chat; however, half of those pharmacists (51%; 27/53) did not receive a chat message back (Table 2). In general, the majority of pharmacists (82%; 22/27) sent messages with a median of 2 messages per adolescent (IQR 1-5; range 1-20).

Of the 12 adolescents who started the conversation, one-third (n=4) did not receive a message back (Table 3; reasons unknown). In total, 38 adolescents (44%) sent on average 2 messages (IQR 1-5; range 1-17) to their pharmacist, and more females (n=28) than males (n=10) sent messages to their pharmacist (*P*=.004). In total, 34 conversations were held where both pharmacists and patients sent at least 1 message; examples are shown in Multimedia Appendix 3.

Peer Chat

The peer chat was used by 21% (18/87) of the adolescents; in total, they sent 150 chat messages. Per adolescent, 4.5 messages (IQR 3-11; range 2-29) were sent. Most messages were sent within the topics *sports* (67 messages by 8 adolescents), *other* (34 messages about age, school, and residence by 6 adolescents), and *general* (24 messages about participating in the study and the app by 8 adolescents). The 18 adolescents participated on average in 2 topics (IQR 1-2; range 1-5). Examples of peer chat messages are shown in Multimedia Appendix 3.

Effective Engagement

The total app use was not associated with a difference in self-reported adherence (*P*=.12). Use of the CARAT questionnaire (*P*=.26), adherence questions (*P*=.65), short movies (*P*=.80), or peer chat (*P*=.21) also did not affect the adherence outcome. However, logged activity in pharmacist chat positively affected self-reported adherence (MARS score increased with 0.1 points per message; *P*=.03). Data showed that messages sent by pharmacists were not related to the outcome (*P*=.06), whereas activity of patients in the pharmacist chat did positively affect the outcome (*P*=.01), that is, if patients sent messages to their pharmacist, it positively affected adherence (MARS score increased with 0.3 points per chat message).

Discussion

Principal Findings

Adolescents have different preferences when using an mHealth app, as there was a wide variety in app usage per person. This supports the need for multifaceted mHealth interventions. The questionnaire to monitor symptoms was the frequently used functionality, for which they received weekly reminders. Females seemed to be more active in the ADAPT app; they used the app more often, for a longer duration, and more females sent messages to their pharmacists and watched movies. Total app use was not associated with the outcome; however, sending a chat message to the pharmacist positively affected medication adherence. On the basis of our results, we recommend a health care provider chat as a key functionality for mHealth interventions to improve adherence in adolescents with asthma.

The ADAPT intervention contained a unique combination of functionalities to improve adherence and targeted a specific patient population: adolescents with asthma. We showed that the adolescents who used the app for 10 to 25 times (average users) had the highest adherence score at the start (MARS 21.4). One would expect the highest adherence score among the low frequent users because if patients are highly adherent, they do not need the intervention, or that among the high frequent users, as they are also likely to be highly adherent to the intervention use. However, we did not find this, although there was no difference between adherence rates among average and high users; thus, higher adherence rates might be related to more frequent app use, that is, more adherent to the intervention.

The most used functionality was the questionnaire to monitor symptoms (Table 1), which was also shown in a study with adult asthma patients [24]. The symptom questionnaire provides patients (and their health care providers) insights into their disease symptoms over time, which should support self-management [25,26]. Surprisingly, we did not find an effect of the questionnaire use on adherence. Patients received a weekly push notification to complete the questionnaire, which might explain why this functionality was the most used functionality. However, the adherence questionnaire was the second most used functionality (Table 1), for which patients did not receive a push notification. The reason why most patients completed the questionnaires is unknown, among others, curiosity might play a role. On the basis of all these questionnaire data (adherence and symptom control), health care providers could deliver personalized care to support patients, which is suggested to be more effective than usual care [27-30]. Therefore, we recommend questionnaires as a useful functionality for mHealth aimed at adolescents.

The peer chat was an age-specific functionality based on the preferences of adolescents [11,31] because peers are important for them [32]. Previous studies showed positive effects of peer-led interventions for asthma patients in improving attitudes and quality of life [33,34], and online peer support groups increased self-confidence [35]. In our study, no effects of the peer chat were found on adherence. Only 21% of the adolescents (18/87) used the peer chat, suggesting that it was not appropriate for everyone. However, the adolescents who used it sent quite a lot of messages (8 per person). Therefore, more research is needed toward a peer chat functionality in a larger population, as more interaction is expected when more patients participate, which in turn might support the use of the peer chat.

The pharmacist chat is a new communication method for both patients and pharmacists. It provided pharmacists with a tool to personally reach patients, which is in particular relevant for adolescent patients, as their adherence is low and they are not often seen in the pharmacy [22]. This electronic consult might overcome patient's barriers to approach a health care provider. However, this study showed that not all adolescents and pharmacists were comfortable with using this new tool because only 44% of the adolescents (38/87) and 82% of the pharmacists (22/27) used the ADAPT pharmacist chat. Moreover, 4 adolescents (with different pharmacists) did not receive an answer to their question or comment (Table 3). For further implementation of mHealth, it is important that patients always receive an answer, otherwise it will hinder further implementation [36]. Health care providers should therefore be stimulated and motivated to actively engage in mHealth, and we suggest a back-up plan, for example, automatically sending personalized short message service text messages for patients who did not receive an answer within 24 hours or an urgent email notification for pharmacists.

For further implementation of mHealth in clinical practice, it is important to study the cost-effectiveness of the ADAPT intervention. Most mHealth interventions are cost-effective [37]; however, the active involvement of health care providers, in our case pharmacists, might negatively affect the cost-effectiveness. Thus, comprehensive economic evaluations are needed [38] to study the cost-effectiveness of the ADAPT intervention and to identify the optimal involvement of pharmacists (from an economical perspective).

Limitations

We used log data to analyze the ADAPT app usage, which is a reliable method; however, there are some limitations. Data used in this study are derived from a cluster randomized controlled trial; thus, there might be a response bias, that is, the participants were probably more motivated to use the intervention than the general population. However, use of the intervention still varied per person, suggesting that mHealth use depends on patients' needs and preferences. Another limitation is that patients received a weekly reminder to complete the CARAT questionnaire, which might be a reason why the CARAT is mostly used. Moreover, many researchers are using electronic monitors to measure adherence of youth with asthma; thus, further research should focus on effective engagement using electronic adherence measurements instead of self-reports. In addition, we studied the physical engagement of adolescents with the app (number of times used), although there is also psychological engagement with the intervention [17,39], which we did not measure. The psychological engagement might also explain why patients use certain functionalities. Moreover, the generalizability of our results is limited because our findings are based on a study among adolescents with asthma in the Netherlands. Therefore, more research is needed to confirm our findings in other countries and populations. However, these results suggest that the possibility to chat with a health care provider is an important functionality for mHealth interventions aiming to increase adherence.

Conclusions

This study showed that a complex mHealth intervention to support adherence is used differently by adolescents with asthma. The questionnaires to monitor asthma symptoms and adherence were used by most adolescents, which provided valuable data for health care providers and patients. Moreover, the use of the pharmacist chat positively affected adherence. These findings suggest that mHealth apps should contain different functionalities to serve the diverging needs and preferences of individual patients. A questionnaire to monitor symptoms and adherence and a chat with the health care provider are recommended key functionalities for mHealth apps for adolescents with asthma.

Acknowledgments

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Conflicts of Interest

PSVDW is a partner of Umenz Benelux BV, the company that developed the ADAPT app.

Multimedia Appendix 1

Examples of mobile health (mHealth) app use by adolescents with asthma during the 6-month study period, divided in low (1a), average (1b), and high frequent (1c) users. 1a. Low frequent users who used the intervention 4 (left) and 5 times (middle and right). 1b. Average frequent users who used the intervention 17 (left), 18 (middle), and 22 times (right). 1c. High frequent users who used the intervention 40 (left), 43 (middle), and 50 times (right). Horizontal lines: Red: Control of Allergic Rhinitis and Asthma Test (CARAT) score, dotted line represents the threshold (>24); Blue: adherence questions; Light blue: forgot to take, Dark blue: decided not to take (5=never, 1=always). Vertical lines: Green: pharmacist chat; Dark green: message sent by pharmacist; Light green: message sent by patient; Pink: watched a movie; Black: dotted line indicates the baseline and end of follow-up date of the study; Grey: dotted line indicates the push notification update of the mHealth app.

[PNG File, 250KB - mhealth_v7i3e12411_app1.png]

Multimedia Appendix 2

Overview of the 1047 Control of Allergic Rhinitis and Asthma Test (CARAT) scores of 85 adolescents; on average 12.3 scores per person. Blue: Total CARAT score, dotted line represents the threshold (>24); Green: Asthma subscore, dotted line represents the threshold (≥16); Red: Allergic rhinitis subscore, dotted line represents the threshold (>8).

[PNG File, 113KB - mhealth_v7i3e12411_app2.png]

Multimedia Appendix 3

Examples of chat messages sent in the Adolescent Adherence Patient Tool.

[DOCX File, 13KB - mhealth_v7i3e12411_app3.docx]

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Abbreviations

ADAPT: Adolescent Adherence Patient Tool
CARAT: Control of Allergic Rhinitis and Asthma Test
IQR: interquartile range
MARS: Medication Adherence Report Scale
mHealth: mobile health
SD: standard deviation

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Original Paper

Associations of Health App Use and Perceived Effectiveness in People With Cardiovascular Diseases and Diabetes: Population-Based Survey

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Abstract

Background: Mobile health apps can help to change health-related behaviors and manage chronic conditions in patients with cardiovascular diseases (CVDs) and diabetes mellitus, but a certain level of health literacy and electronic health (eHealth) literacy may be needed.

Objective: The aim of this study was to identify factors associated with mobile health app use in individuals with CVD or diabetes and detect relations with the perceived effectiveness of health apps among app users.

Methods: The study used population-based Web-based survey (N=1500) among Germans, aged 35 years and older, with CVD, diabetes, or both. A total of 3 subgroups were examined: (1) Individuals with CVD (n=1325), (2) Individuals with diabetes (n=681), and (3) Individuals with CVD and diabetes (n=524). Sociodemographics, health behaviors, CVD, diabetes, health and eHealth literacy, characteristics of health app use, and characteristics of apps themselves were assessed by questionnaires. Linear and logistic regression models were applied.

Results: Overall, patterns of factors associated with health app use were comparable in individuals with CVD or diabetes or both. Across subgroups, about every fourth patient reported using apps for health-related purposes, with physical activity and weight loss being the most prominent target behaviors. Health app users were younger, more likely to be female (except in those with CVD and diabetes combined), better educated, and reported more physical activity. App users had higher eHealth literacy than nonusers. Those users who perceived the app to have a greater effectiveness on their health behaviors tended to be more health and eHealth literate and rated the app to use more behavior change techniques (BCTs).

Conclusions: There are health- and literacy-related disparities in the access to health app use among patients with CVD, diabetes, or both, which are relevant to specific health care professionals such as endocrinologists, dieticians, cardiologists, or general practitioners. Apps containing more BCTs had a higher perceived effect on people's health, and app developers should take the complexity of needs into account. Furthermore, eHealth literacy appears to be a requirement to use health apps successfully, which should be considered in health education strategies to improve health in patients with CVD and diabetes.

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KEYWORDS

mHealth; eHealth; smartphone; telemedicine; health literacy; chronic disease; comorbidity; multimorbidity

Introduction

Cardiovascular Diseases and Diabetes

Cardiovascular conditions such as myocardial infarction, stroke, or coronary artery diseases are the main causes of death worldwide [1], and diabetes mellitus is a major risk factor for cardiovascular diseases (CVDs) [2,3]. In a large cohort study from the United Kingdom, for instance, about 18 percent of those with diabetes showed incident CVD over the 5.5 years of observation [4]. However, diabetes itself is a serious disease with substantial health consequences besides cardiovascular events, including end-stage renal diseases, loss of vision, or limb amputations [5]. Over the past decades, the prevalence of diabetes has dramatically increased worldwide, which has been labeled as a diabetes pandemic [6,7]. CVD and diabetes have been considered as concordant chronic comorbidities [8], as they have many risk factors in common, including overweight, smoking, hypertension, and physical inactivity [5,9]. Thus, CVD and diabetes frequently coexist as comorbidities within the same people [10]. Understanding medical management and self-care of (1) CVD, (2) diabetes alone, and (3) CVD and diabetes in combination may improve clinical outcomes and quality of life in people diagnosed with these conditions [8].

CVD and diabetes share common risk factors, most of which can be ameliorated via health behavioral changes [11-14]. Health behavior change is crucial to prevent and treat these chronic conditions [15-17]. As people diagnosed with CVD or diabetes commonly require continuous lifelong treatment, supporting individuals to implement behavior change recommendations is critical to improve the disease management. Mobile health apps are a promising tool to modify behavioral risk factors and support disease management [18-22].

Mobile Health Apps

Mobile health apps have changed most areas of daily living, including health and diseases management [19]. People now have the opportunity to access information, communicate with others at anyplace and anytime, track relevant behaviors and outcomes over time and location, and receive additional health behavior change input. Evidence from the general population suggests that people with chronic conditions, including CVD and diabetes, more frequently use mobile health apps compared with healthy individuals [23]. However, large proportions of individuals with chronic diseases do not engage in mobile health app use and potentially miss out on the benefits that novel health technologies have to offer [22,24-27]. The barriers to engaging in health apps require further attention, particularly in individuals with existing chronic conditions such as CVD and diabetes.

Evidence from systematic reviews of randomized controlled trials shows positive effects of mobile health apps for diabetes to support improvements in hemoglobin A_{1c} (HbA_{1c}) and glycemic control [28-31]. Mobile health apps for CVD, which focus on the modification of cardiovascular risk factors or medication adherence, have the potential to enhance people's health [32,33]. Although there are studies for those suffering from CVD or diabetes, studies that look into app use of patients with CVD and diabetes combined are needed.

Despite the potential for benefit of mobile apps, disparities in the access and variability in the effectiveness exist. For example, population-based surveys reported that people with low education are less likely [23,27,34] and those who are diagnosed with multiple chronic conditions are more likely to use health apps [23]. Moreover, more frequent engagement with apps has been found to be associated with better perceived effects [35,36]. In addition to app users' cognitive, health, and engagement factors, characteristics of the apps can influence their effectiveness. Ernsting et al (2017), Webb et al (2010), and Morrissey et al (2016) found that health apps applying specific behavior change techniques (BCTs) such as planning or monitoring were more effective in health promotion [23,37,38].

Health Literacy and Electronic Health Literacy

Health literacy is one of the key features for successful disease management [39-41]. It is a requirement to access and understand health information and make decisions concerning health care [42]. As mobile technologies have emerged, the concept of electronic health (eHealth) literacy was introduced, which is the ability to use information technology for health [43]. Emerging evidence suggests that general population samples and primary care patients with higher health literacy and eHealth literacy are more likely to use mobile health apps and perceive these to be more effective [23,25,27,43-45]. However, the specific relation of health literacy and eHealth literacy with app use among those with CVD, diabetes, or both has not yet been examined.

Aims of the Study

Although sociodemographic factors and health literacy and eHealth literacy related with the utilization of health apps among the general population are known, these associations among specific epidemiologically and clinically relevant subgroups, that is, those with CVD, diabetes, and both combined need investigation. There are no studies investigating these subgroups within 1 study.

Thus, the aims of the study were to investigate health literacy and eHealth literacy of app users beyond sociodemographic factors in clinically relevant subgroups and explore the association of these characteristics with the perceived effectiveness of mobile health apps on a participant's health. More specifically, we aimed for the following:

1. To estimate the utilization of health apps in a population-based sample among specific clinically relevant subgroups, that is, CVD, diabetes, and both combined.
2. To investigate which factors (ie, age, gender, education, health behaviors, disease burden, health literacy, eHealth literacy, and wearable use) are associated with health app use—separately for CVD, diabetes, and both combined.
3. To investigate which factors (ie, age, gender, education, health behaviors, disease burden, health literacy, eHealth literacy, and wearable use) are associated with the perceived effectiveness of health apps—separately for CVD, diabetes, and both combined.

Methods

Sample and Procedure

This study is a secondary analysis of the data of the Pfizer Monitor "App Utilization." Data were collected in January and February 2018. A population-based sample of 1500 individuals from Germany participated in this Web-based survey. An external and independent polling institute conducted the study (ie, "Gesellschaft für Innovative Marktforschung," corporation for innovative market research). An invitation to the Web-based questionnaire was sent via email to participants of former surveys.

Participants had to meet the following inclusion criteria: (1) aged ≥35 years and (2) diagnosed with at least 1 of the following diseases, self-reported hypertension, diabetes, stroke, myocardial infarction, and coronary artery disease. Ownership of a mobile device, for example, a smartphone, was not an inclusion criterion.

Participants took an average of 20 min to finish the survey. This study was conducted in compliance with the Declaration of Helsinki; Web-based informed consent was obtained from all participants [46]. An internal ethical and risk assessment was carried out by Pfizer, which approved the Web-based study. For analyses, from the total sample, we selected 3 subgroups: (1) those that reported having CVD (n=1325), (2) those that reported having diabetes (n=681), and (3) those who reported having both CVD and diabetes (n=524; Figure 1).

Measures

Sociodemographics

Sex, age, education (International Standard Classification of Education) [47], occupation, income, and migration background were assessed by standard survey items. Posttax household income by month was categorized as follows: low <€2100, moderate €2100 to €3600, and high >€3600 (1 Euro=US $1.16, August 27, 2018).

Cardiovascular Conditions and Diabetes

Cardiovascular conditions and diabetes were assessed by asking participants, "Have you been diagnosed with one or more of the following conditions: (1) CVD, (2) heart failure, (3) coronary artery disease, (4) peripheral artery occlusion disease, (5) myocardial infarction, (6) stroke, (7) hypertension, and (8) atherosclerosis." Participants were classified as having a CVD if they reported having at least 1 of the conditions. Participants were classified as having diabetes if they reported to have been diagnosed with diabetes. Participants were classified as having diabetes and CVD comorbid if they reported to have diabetes and at least 1 of the other cardiovascular conditions.

Participants were also asked to rate the stress caused by each condition on a scale from 1 (no stress at all) to 5 (very high level of stress). Thus, stress caused by diabetes was assessed with a single item, whereas the overall stress caused only by CVDs was estimated by calculating the mean across the specific present cardiovascular conditions. Assessing the overall stress induced by diabetes and CVDs, the mean stress level across diabetes and all present cardiovascular conditions was calculated.

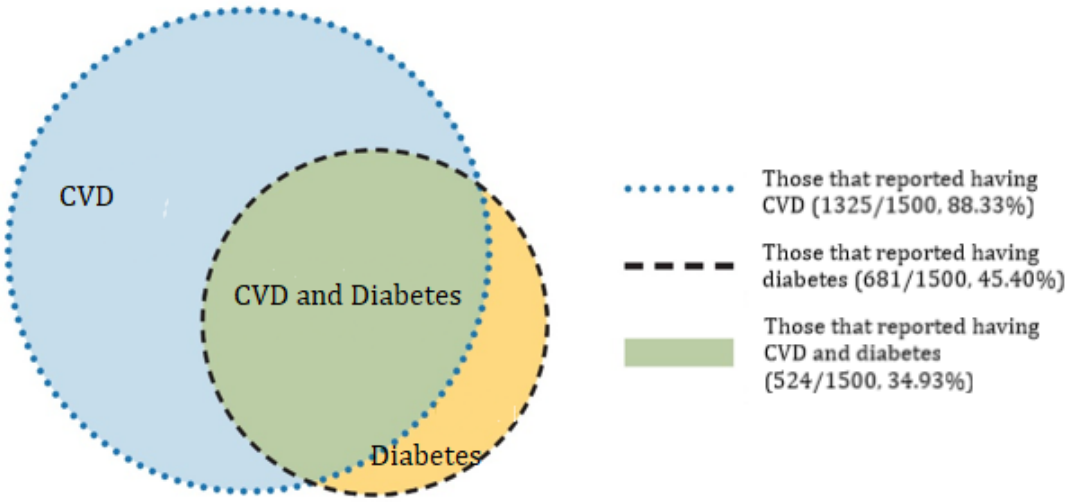
Health Behaviors

Health behaviors were assessed by providing a list of common health-related behaviors (ie, smoking, physical activity, and balanced diet). For smoking, participants were asked, "Do you smoke on a daily basis?" To assess physical activity, participants were asked, "Are you regularly physically active (following World Health Organization, WHO recommendation, ie, 30 min of moderate activity at least 5 times per week or 30 min of intensive activity at least 3 times per week [48])?" Consumption of a balanced diet was measured by asking participants, "Do you follow a balanced diet, that is, eat fruits and vegetables with every meal and including many wholegrain products?"

Perceived Health Literacy and Electronic Health Literacy

Health literacy was assessed by the 6-item short-form of the European Health Literacy Survey Questionnaire instrument with a Cronbach alpha of .81 in this study [49]. An example item was the following: "On a scale from very easy to very difficult, how easy would you say it is to find information on treatments of illnesses that concern you?" Answers had a 4-point response format on a Likert scale. eHealth literacy was assessed using the eHealth literacy scale "eHEALS" comprising 10 items [43]. Cronbach alpha was .92 in this study. Example items were as follows: "How useful do you feel the internet is in helping you in making decisions about your health?" and "I know how to use the internet to answer my questions about health." Answers had a 5-point response format on a Likert scale.

Figure 1. Sample composition and subsamples. CVD: cardiovascular disease.



App Use

App use was measured by asking participants, "Have you ever downloaded a health app for a smartphone or tablet?" Participants could choose one of the following answers: (1) "Yes, I have and I have used apps recently," (2) "Yes, I have and I used to use them frequently but not anymore," (3) "Yes, I have but I don't use them or just very seldom," and (4) "No, I have never downloaded a health app." Participants giving answer (1) or (2) were classified as app users, whereas those giving answer (3) or (4) were classified as nonusers. To assess behaviors targeted by the apps, participants were asked which behavior their most frequently used app targeted.

BCTs of the health apps were chosen in accordance to a taxonomy by Abraham and Michie [50]. In the questionnaire, we provided a list of BCTs, including, for example, *providing information*, *prompting self-monitoring of behavior*, and *prompting specific goal setting.*

To assess the perceived effectiveness of the most frequently used app on participants' health behavior, the "perceived impact" subscale of the user version of the Mobile Application Rating Scale Questionnaire [51] was used. The perceived effectiveness had a Cronbach alpha of .87 in this survey and a possible scale score ranging from 1 to 5. This scale comprises 66 items, for example, "Intention to change—The app has increased my intentions/motivation to address this health behavior" and "Help seeking—This app would encourage me to seek further help to address the health behavior (if I needed it)."

To access frequency of the use of the most frequently used app, patients were asked, "How often do you use this health app?" Possible answers were "less than once a month," "several times a month," "several times a week," "daily," and "several times a day."

To access duration of the use of the most frequently used app, patients were asked, "When did you start using this health app?" Possible answers were "less than one month ago," "less than six months ago," "less than a year ago," and "more than a year ago."

The use of wearables was assessed by asking participants, "Which of the following devices do you use?" One of the possible answers was: "A wearable/tracking watch".

Statistical Analyses

We analyzed the total sample (N=1500) as well as disease-specific subgroups, that is, (1) individuals reporting having at least CVD (N=1325), (2) at least diabetes (N=681), and (3) both CVD and diabetes combined (N=524; Figure 1). Descriptive sample characteristics were provided both for the total sample and the sample of app users except for the app-related variables, which were provided only for app users. Binary logistic regressions were conducted, and 3 parallel models with app use as outcome were calculated: individuals with CVD (model 1), individuals with diabetes (model 2), and individuals with CVD and diabetes (model 3). Covariates were age, gender, health behaviors (ie, smoking, physical activity, and balanced diet), educational level, health literacy, and eHealth literacy. Further covariates were the presence of diabetes and stress by CVD in model 1, the presence of CVD and stress by diabetes in model 2, as well as stress by both disease groups in model 3.

Finally, we applied linear regression analyses to estimate associations with the perceived effectiveness of mobile health apps in the total sample of app users (n=402). The following covariates were used in the model: age, gender, health behaviors, health literacy, eHealth literacy, stress caused by all present diseases including CVD and diabetes, the presence of diabetes, the presence of CVD, the presence of both CVD and diabetes comorbid, frequency and duration of app use, and the number of BCTs.

Results

Characterization of the Sample

A total of 1500 individuals completed this population-based Web-based survey (see Table 1). The mean age was 55.10 (SD 8.25) years and 56.53% (848/1500) were women. In terms of education, 70.60% (1059/1500) had a vocational qualification, 24.60% (369/1500) had a university degree, and 4.80% (72/1500) had basic qualification or none. Most participants were working full-time (622/1500, 41.67%) and had a medium household income (591/1500, 39.40%). A minority of 7.53% (113/1500) had a migration background.

Although we only included participants in the study with CVD and diabetes, the most commonly reported chronic conditions among the participants were hypertension (1224/1500, 81.60%) and diabetes (681/1500, 45.40%). Participants rated the overall stress caused by their chronic conditions, that is, CVD and diabetes, 2.64 out of 5 (SD 0.91). Concerning health behaviors, half of the sample reported to be engaged in regular physical activity (751/1500, 50.07%). Furthermore, most participants reported consuming a balanced diet (1074/1500, 71.60%), whereas every third individual was a smoker (553/1500, 36.87%). The mean health literacy was 2.76 out of 5 (SD 0.49), and the mean eHealth literacy was 3.68 out of 5 (SD 0.73).

In total, 87.27% (1309/1500) of the participants owned a smartphone, out of which, 29.49% (386/1309) used health apps. Overall, 26.80% (402/1500) of the participants were classified as health app users (Table 2). Among participants with CVD, 25.41% (339/1334) were mobile health app users, with 29.2% (199/681) of diabetic participants and 27.6% (146/529) of CVD and diabetic participants reporting app use. The most common behaviors that used apps targeted were physical activity (289/402, 71.9%), weight loss (150/402, 37.3%), and nutrition (146/402, 36.3%). The following BCTs were most frequently included within apps: Prompting self-monitoring of behavior (236/402, 58.7%), prompting specific goal setting (224/402, 55.7%), and providing feedback on performance (199/402, 49.5%). Less than 10% of the participants rated that the apps did not contain any BCT (34/402, 8.5%). A quarter of participants used their apps once a day (104/402, 25.9%) and 20.4% (82/402) reported app use several times a day (82/402, 20.4%). The duration of app use was more than a year for 38.1% (n=153/402) of participants, whereas 10.7% (43/402) started less than a month ago. App users rated the perceived effectiveness of the apps on their health 3.79 out of 5 (SD 0.73).

Table 1. Sample characteristics by subgroups (N=1500).

Item	Total sample (n=1500)	Participants diagnosed with CVD[a] (n=1334)	Participants diagnosed with diabetes (n=681)	Participants diagnosed with CVD and diabetes (n=529)	App users of the total sample (n=402)
Gender (men), n (%)	848 (56.53)	568 (42.58)	277 (40.7	200 (37.8)	251 (62.4)
Age (years), mean (SD)	55.10 (8.25)	55.47 (8.00)	54.91 (8.67)	55.68 (8.25)	51.61 (9.52)
Educational level (International Standard Classification of Education), n (%)					
No or basic qualification	72 (4.80)	60 (4.50)	36 (5.3)	26 (4.9)	4 (1.0)
Vocational qualification	1059 (70.60)	945 (70.84)	481 (70.6)	376 (71.1)	261 (64.9)
University degree	369 (24.60)	329 (24.66)	164 (24.1)	127 (24.0)	137 (34.1)
Occupational status, n (%)					
Working full-time	622 (41.67)	537 (40.25)	273 (40.1)	198 (37.4)	242 (60.0)
Working part-time	220 (14.67)	196 (14.69)	84 (12.3)	61 (11.5)	46 (11.4)
Not working	100 (6.67)	89 (6.67)	45 (6.6)	36 (6.8)	12 (3.0)
Retired	440 (29.33)	402 (30.13)	226 (33.2)	189 (35.7)	77 (19.2)
In school	6 (0.40)	6 (.45)	5 (0.7)	5 (1.0)	4 (1.0)
Other	112 (7.47)	104 (7.80)	48 (7.1)	40 (7.6)	21 (5.2)
Monthly posttax household income[b] , n (%)					
Low	513 (34.20)	453 (33.96)	248 (36.4)	196 (37.1)	94 (23.4)
Medium	591(39.40)	528 (39.58)	266 (39.1)	206 (38.9)	173 (43.0)
High	277 (18.47)	250 (18.74)	75 (11.0)	93 (17.6)	115 (28.6)
No answer	119 (7.93)	103 (7.72)	49 (7.2)	34 (6.4)	20 (5.0)
Migration background, n (%)	113 (7.53)	92 (6.90)	60 (8.8)	43 (8.1)	53 (13.2)
Chronic conditions, n (%)					
Heart failure	236 (15.73)	236 (17.69)	97 (14.2)	97 (18.3)	71 (17.7)
Coronary artery disease	259 (17.27)	259 (19.42)	95 (15.0)	95 (18.0)	79 (19.7)
Peripheral artery occlusion disease	678 (45.20)	146 (10.94)	95 (14.0)	74 (14.0)	40 (10.0)
Myocardial infarction	146 (9.73)	156 (11.69)	52 (7.6)	52 (9.8)	49 (12.2)
Stroke	156 (10.40)	141 (10.57)	40 (5.9)	40 (7.6)	33 (8.2)
Hypertension	1224 (81.60)	1224 (91.75)	487 (71.5)	487 (92.1)	306 (76.1)
Atherosclerosis	243 (16.20	243 (18.22)	97 (14.2)	97 (18.3)	64 (15.9)
Stress by CVD+diabetes, mean (SD)	2.64 (0.91)	2.63 (0.91)	2.68 (0.88)	2.69 (0.87)	2.84 (0.73)
Stress by CVD, mean (SD)	2.58 (0.94)	2.58 (0.94)	2.55 (0.95)	2.55 (0.95)	2.76 (0.91)
Stress by diabetes, mean (SD)	2.78 (1.02)	2.81 (1.04)	2.78 (1.02)	2.81 (1.04)	3.10 (0.97)
Health behaviors, n (%)					
Smoking	553 (36.87)	490 (36.73)	256 (37.6)	196 (37.1)	142 (35.3)
Physical activity	751 (50.07)	661 (49.55)	326 (47.9)	244 (46.1)	271 (67.4)
Balanced diet	1074 (71.60)	947 (70.99)	516 (75.8)	395 (74.7)	310 (77.1)
Health literacy, mean (SD)	2.76 (0.49)	2.75 (0.49)	2.77 (0.48)	2.74 (0.48)	2.88 (0.51)
Electronic health literacy, mean (SD)	3.68 (0.73)	3.68 (0.72)	3.65 (0.76)	3.64 (0.48)	4.01 (0.59)
App use, n (%)	402 (26.80)	339 (25.41)	199 (29.2)	146 (27.6)	402 (100)

[a]CVD: cardiovascular disease.

[b]Posttax household income: Low <€2100, moderate €2100-€3600, high >€3600 (1 Euro=US $1.2; May 30, 2018).

Table 2. Characteristics of health apps and health app use.

Item	Statistics
App use, n (%)	402 (100)
Perceived effectiveness, mean (SD)	3.79 (0.73)
Frequency of app use, n (%)	
<once a month	22 (5.5)
Several times a month	79 (19.7)
Several times a week	115 (28.6)
Once a day	104 (25.9)
Several times a day	82 (20.4)
Duration of app use, n (%)	
<1 month	43 (10.7)
<6 months	116 (28.9)
<1 year	90 (22.4)
>1 year	153 (38.1)
Behaviors targeted by the apps, n (%)	
Physical activity	289 (71.9)
Nutrition	146 (36.3)
Weight loss	150 (37.3)
Measuring, for example, blood pressure, blood sugar, and step counter	184 (45.8)
Sleep control	123 (30.6)
See patient's chart or labs	21 (5.2)
Relaxation	30 (7.5)
Records on disease	61 (15.2)
Stop health detrimental behavior	16 (4.0)
Contact doctor	23 (5.7)
Medication adherence	34 (8.5)
Health information	28 (7.0)
Other	10 (2.5)
Behavior change techniques, n (%)	
Providing information	101 (25.1)
Prompting self-monitoring of behavior	236 (58.7)
Prompting barrier identification	33 (8.2)
Prompting specific goal setting	224 (55.7)
Providing instruction	108 (26.9)
Providing feedback on performance	199 (49.5)
Providing instruction	58 (14.4)
Providing opportunities for social comparison	54 (13.4)
Planning social support	32 (8.0)
Relapse prevention	23 (5.7)
Training Emotional control	37 (9.2)
No BCT	34 (8.5)
Wearables used routinely	97 (24.1)

Table 3. Multivariate associations with app use.

Covariate	App use in CVD[a,b] (N=1325)		App use in diabetes[c] (N=681)		App use in CVD and diabetes combined[d] (N=524)	
	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Intercept	0.02[e]	<.001	0.01[e]	<.001	0.02[e]	.004
Age	0.93 (0.91-0.95)	<.001	0.94 (0.92-0.97)	<.001	0.93 (0.91-0.96)	<.001
Gender (men vs women)	0.68 (0.50-0.94)	.02	0.64 (0.42-0.98)	.04	0.70 (0.42-1.17)	.17
Health behaviors						
Smoking	0.84 (0.61-1.16)	.30	0.99 (0.66-1.49)	.95	0.89 (0.55-1.44)	.64
Physical activity	1.78 (1.30-2.43)	<.001	2.12 (1.40-3.20)	<.001	2.16 (1.34-3.47)	.002
Balanced diet	1.18 (0.83-1.69)	.35	1.31 (0.79-2.18)	.30	1.54 (0.85-2.80)	.16
Education						
No or basic qualification	Ref[f]	Ref	Ref	Ref	Ref	Ref
Vocational qualification	6.00 (1.71-31.03)	.005	2.90 (0.91-9.22)	.07	2.62 (0.65-10.48)	.18
University degree	8.38 (2.34-30.07)	.001	3.53 (1.06-11.75)	.04	3.59 (0.84-15.24)	.08
Health literacy	1.10 (0.79-1.53)	.58	1.22 (0.79-1.89)	.37	1.47 (0.88-2.46)	.14
Electronic health literacy	2.52 (1.94-3.28)	<.001	2.36 (1.69-3.29)	<.001	2.23 (1.50-3.31)	<.001
CVD	—[g]	—	0.88 (0.54-1.42)	.59	—	—
Diabetes	1.52 (1.12-2.06)	.008	—	—	—	—
Stress by CVD+diabetes	—	—	—	—	1.55 (1.17-2.04)	.002
Stress by CVD	1.29 (1.09-1.51)	<.001	—	—	—	—
Stress by diabetes	—	—	1.51 (1.23-1.85)	<.001	—	—
Wearable use	21.44 (11.60-39.63)	<.001	12.64 (5.48-29.12)	<.001	16.88 (5.92-48.14)	<.001

[a]CVD: cardiovascular disease.

[b]In this model, Nagelkerke R^2=.391.

[c]In this model, Nagelkerke R^2=.380.

[d]In this model, Nagelkerke R^2=.395.

[e]Missing data: CI.

[f]Ref: reference category set to 1.

[g]Not integrated in this model.

What Factors Are Associated With App Use?

Table 3 displays multivariate associations of app use for all 3 cohorts.

Participants Diagnosed With Cardiovascular Disease

Results from a binary logistic regression revealed that among people classified as having CVD (N=1325), app users were significantly younger (odds ratio, OR 0.93; *P*<.001) than nonusers (see Table 3). Furthermore, women used apps more frequently than men (OR 0.68, *P*=.02). App users more often report to meet the WHO norms for physical activity (OR 1.78, *P*<.001), and they reported a higher level of education than nonusers—ie, people with vocational qualification (OR 6.00, *P*=.005) and university degree (OR 8.38, *P*=.001) were more engaged in app use than participants with no or basic qualification. In addition, compared with nonusers, app users had higher eHealth literacy (OR 2.52, *P*<.001). Participants with diabetes as comorbidity were more likely to use health apps than those without having diabetes, (OR 1.52, *P*=.008). Furthermore, app users reported being more affected by their cardiovascular condition (OR 1.29, *P*<.001) than those who were not using apps. Finally, app use was strongly associated with the ownership of wearables (OR 21.44, *P*<.001). There was no association of app use with smoking, balanced diet, and health literacy.

Participants Diagnosed With Diabetes

Among participants classified as having diabetes (N=681), health app users were younger (OR 0.94, *P*<.001), more likely to be female (OR 0.64, *P*=.04), reported a higher level of education as people with university degree, and more engaged in app use than those participants with basic qualifications or none (OR 3.53, *P*=.04). Moreover, health app users were more likely to be physically active (OR 2.12, *P*<.001) than nonusers, had higher levels of eHealth literacy (OR 2.36, *P*<.001), and reported being more affected by diabetes (OR 1.51, *P*<.001). Finally, app users were more likely to own wearables than nonusers (OR 12.64, *P*<.001). There was no association of app

use with smoking, balanced diet, health literacy, and the presence of CVD.

Participants Diagnosed With Cardiovascular Disease and Diabetes

App users classified as having diabetes and CVD (N=524) were younger (OR 0.93, *P*<.001) and more likely to be physically active (OR 2.16, *P*=.002) than nonusers. Furthermore, app users had a higher level of eHealth literacy (OR 2.23, *P*<.001), were more affected by their diseases (OR 1.55, *P*=.002), and were more likely to use wearables (OR 16.88, *P*<.001). There was no association of app use with gender, smoking, balanced diet, education, and health literacy.

What Factors Are Associated With the Perceived Effectiveness of an App?

Among all app users, those who were younger (B 1.47, *P*=.006) were more likely to report that their apps had a positive effect on the targeted health behavior (see Table 4). Furthermore, participants with higher health literacy (B .24, *P*<.001) and eHealth literacy (B .47, *P*<.001), as well as those who were more affected by their present diseases (B .08, *P*=.04) perceived their app as more effective on their health behavior. Finally, those apps that were reported to contain more BCTs (B .05, *P*=.002) had a greater perceived effect on users' health behaviors. There was no association of the perceived effectiveness of an app with gender, health behaviors, education, CVD and diabetes, frequency and duration of health app use, and the use of wearables.

Table 4. Multivariate associations with the perceived effectiveness of the apps in all app users (N=402).

Item	Perceived effectiveness on health behavior[a]		
	B[b]	95% CI	*P* value
Intercept	1.45	0.51-2.39	.003
Age	−.01	−0.02 to 0.00	.007
Gender (men vs women)	−.05	−0.18 to 0.08	.46
Health behaviors			
Smoking	.07	−0.06 to 0.20	.30
Physical activity	.10	−0.04 to 0.24	.16
Balanced diet	.12	−0.03 to 0.28	.11
Education			
No or basic qualification	Ref[c]	—[d]	—
Vocational qualification	−.36	−0.97 to 0.25	.25
University degree	−.48	−1.09 to 0.14	.13
Health literacy	.24	0.11-0.38	<.001
Electronic health literacy	.47	0.35-0.59	<.001
Conditions			
Diabetes	Ref	—	—
CVD[e]	−.10	−0.29 to 0.09	.29
Comorbid CVD and diabetes	−.02	−0.16 to 0.12	.76
Stress by CVD+diabetes	.08	0.00-0.15	.04
Frequency of app use	.05	−0.01 to 0.10	.11
Duration of app use	.02	−0.04 to 0.08	.52
Number of behavior change techniques	.06	0.02-0.09	.002
Wearable use	−.05	−0.20 to 0.10	.49

[a]In this model, R^2=.345.

[b]Unstandardized coefficient B.

[c]Ref: reference category.

[d]Not applicable.

[e]CVD: cardiovascular disease.

Discussion

Principal Findings

This study aimed to investigate associations of health literacy, eHealth literacy, and sociodemographic factors with health app use in 3 distinct samples of patients: those with CVD, those with diabetes, and those with CVD and diabetes combined. Furthermore, we aimed to detect relationships between these factors and the perceived effectiveness in patients who used health apps. Across subsamples, we found that every fourth participant reported using apps for health-related purposes. In general, the association patterns were largely comparable across groups with CVD, diabetes, or both conditions. Across conditions, health app users were younger, more likely to be female (apart from those with comorbid CVD and diabetes), better educated, and tended to be physically active. App users had higher eHealth literacy and tended to be more affected by their condition than nonusers. Health literacy was not significantly associated with app use in all 3 condition subgroups. Mobile app users reporting a higher effectiveness of apps on their health behavior tended to be younger, more health literate, and more eHealth literate. Furthermore, they were perceived a stronger burden by their diseases. Apps that were reported as including more BCTs had a higher perceived effectiveness. Finally, the use of wearables was strongly related with health app use; however, wearables were not associated with the perceived effectiveness of health apps.

Strengths and Limitations

This survey was one of the first nationwide surveys in Germany focusing on mobile health app use. As only people with CVD or diabetes were included in the survey, we were able to examine different subgroups, including those with CVD and diabetes, which represent relevant chronic conditions in terms of prevalence, patient burden, and health care costs. We made use of validated scales such as for health literacy, eHealth literacy, and the perceived effectiveness of the apps. A limitation includes the use of perceived effectiveness rather than measures of behavioral or health outcomes in this study. Nonetheless, as CVD and diabetes are chronic conditions, which have to be treated over decades, it is very important to foster a patient's (1) awareness, (2) knowledge, (3) attitudes, (4) intention to change, (5) help seeking, and (6) behavior change. These facets are ingredients of the perceived effectiveness score used in the survey. Furthermore, perceived effectiveness has been shown to be a relevant predictor of app use and purchasing decision and outcome satisfaction [52,53]. In addition, perceived effectiveness has been shown to be related with health behavior and adherence [54]. Another limitation is related with the self-report measure of BCTs. Self-report of BCTs used by the health apps might not be a reliable measure as it might be difficult for the participants to identify specific BCTs. However, participants had the opportunity to look into their devices while filling out our questionnaires to gain more accurate reports. Moreover, BCTs that have been used frequently may be recalled more reliably than BCTs that were not used frequently. The parsimonious BCT assessment is another advantage, although future studies should validate users' self-reports with external BCT ratings. A further limitation was that the cross-sectional design and causation cannot be inferred. Thus, the novel associations found in this study need to be replicated in longitudinal and experimental studies. Finally, we used a brief self-report measure for health behaviors. Although this parsimonious measure is suitable for large-scale surveys, its overreporting of physical activity and underreporting of diet is common, and our findings need to be treated as a first approximation. The sample seems to be more physically active and eats healthier than the average population, although our sample is a clinical one that is likely to be different from the general population; therefore, it cannot be compared with the general population. Nonetheless, it is likely that health behaviors were overreported to a degree in this study.

Health App Use

The extent of health app use found in this study is comparable with those in the literature among general population samples [23,55]. Furthermore, we found age-related disparities in the use of health apps, which has been shown by previous research in the general population [23,25,27]. In our survey, higher eHealth literacy was associated with higher app use, whereas health literacy was not associated with app use. Previous surveys that did not differentiate between health literacy and eHealth literacy have shown a correlation between higher health literacy and app use [23,25,27]. In their survey, Cho et al examined the role of eHealth literacy on app use in a sample of 765 participants in South Korea [44]. In contrast to their previous expectations, they found that eHealth literacy did not have a direct effect on app use, but the association was mediated by health app use efficacy. In our survey, health app use efficacy was not measured; therefore, it might be possible that we missed out this mediating effect. Future studies should consider health app use efficacy as a relevant factor.

We found that women are more likely to use health apps compared with men. A possible explanation could be that women might care more about a healthy lifestyle [56,57]. Some studies showed that women were more often health app users [58], whereas others showed no sex difference [23,27]. Interestingly, sex was not associated with health app use in participants who reported having diabetes and CVD combined. It can be hypothesized that men diagnosed with multiple conditions care more about a healthy lifestyle than those with single conditions. This could balance the lead of women's awareness. More research is needed to understand this finding. Another difference in the analyses of the subgroups was that app users in the CVD subgroup tended to have diabetes as comorbidity, whereas diabetic app users did not tend to have CVD as comorbidity. A possible explanation is that the presence of diabetes is driving the intention to use health apps rather than the presence of CVDs, which tend to be less homogeneous in the symptoms and tend to be often asymptomatic, for example, in the case of hypertension [8].

For CVD patients, strategies such as raising awareness of asymptomatic phases of their disease are needed. Although we did not aim to compare the subgroups directly, overall, there were no considerable differences among the subgroups with CVD, diabetes, and CVD and diabetes combined. However, as Figure 1 displays, these 3 subgroups largely overlap and thus

cannot be considered as independent groups. A direct comparison among these overlapping groups is not possible. Nonetheless, providing separate estimates for these may guide practitioners and policy makers who are particularly interested in 1 of these subgroups. Furthermore, in terms of comorbidity and multimorbidity, our findings show that regardless of the specific condition, health apps may target shared risk factors such as physical inactivity, nutrition, and weight control, which may be beneficial for all 3 subgroups. Those with both CVD and diabetes may especially benefit, as a reduction of risk factors may result in relief of symptoms of both conditions. Finally, eHealth literacy was superior to health literacy in relation with app use across subgroups, which should be considered in interventions. Thus, interventions are needed that are specific to digital literacy and may be independent from general health literacy.

Perceived Effectiveness of Health Apps

Younger participants rated their apps to be more effective, in line with previous literature [34,44]. A possible explanation could be a burden of applicability and implementation among older people. Other associations of perceived effectiveness found in this study were health literacy and eHealth literacy, with better health literacy and eHealth literacy being associated with higher perceived effectiveness. People need high competences to adopt health apps effectively. As the importance of health apps is growing, it is necessary to improve people's health literacy competences. Another option to increase the effectiveness could be to improve the usability of health apps so that even people with limited health literacy might take advantage of health apps. We did not find that frequent health app use was associated with perceived effectiveness contrary to a recent systematic review that suggested that higher use of health apps was associated with an increase in actual health behavior [59]. It might be possible that people use apps for different reasons than improvement of health behaviors, for example, to connect with friends or for fun and enjoyment [60]. The association between app use and perceived effectiveness should be further examined in future research. Concerning properties of the apps themselves, we found that the more BCTs people perceived to be present, the superior was their effect on people's health. In general, the utilization of BCTs in interventions is a relevant factor for successful behavior change [50]. The integration of BCTs in interventions leads to better outcome in health apps as well [38,61]. For example, the most powerful BCT found in a systematic review was "stress management" or "general communication skills training" [37]. For health apps, planning and monitoring have been found to be BCTs that are related with higher extent of physical activity [23].

Implications for Further Research, Policy, and Practice

According to the WHO, 121 countries have already developed a national eHealth strategy [62]. Governments should consider that many people still have to face barriers in the use of mobile health apps [63]. Age- and literacy-related disparities should be taken into account. In our research, we found that health literacy and eHealth literacy are linked to superior effects of the apps. This might implicate that it is necessary to increase people's literacy competences. A possibility could be to integrate health literacy interventions within the apps to foster people's ability to adequately use apps. Moreover, we found eHealth literacy to be superiorly associated with app use compared with perceived health literacy, which has implications for practitioners and policy makers who aim to improve app use of the diabetes and CVD patient group. Following this new finding, specific interventions should directly target eHealth literacy beyond more general components of health literacy. Moreover, eHealth literacy should be established as an indicator of app use competencies in future app studies as well as in health monitoring of the population.

The current trends in mobile phone use indicate that older people are increasingly engaged in the use of mobile technologies [64]. It can be assumed that in the future, more people will use health apps as the youth grow older. This underlines the potential of mobile health in the future [65]. New ways of supporting health topics will become more relevant in the future. However, contemporary app developers should keep older people as a target group with special needs in their mind. For example, the design of health apps should be adapted, for example, by applying larger letters and few stimuli. General practitioners should learn more about the possibilities of health apps. Information about health apps could be integrated in doctors' further training. After such a training, a general practitioner might be more likely to recommend a health app. Furthermore, people with low health literacy should not be forgotten to reduce the "digital gap" between user and nonuser [66]. Low health literacy and eHealth literacy are linked to fewer rates of health app use and lower perceived efficacy of the apps. Better health education should be part of the educational system. Furthermore, about a quarter of those who use health apps also used wearables in this study. However, we did not find an improved perceived effectiveness among those using health apps and wearables combined. Future studies should elaborate on how wearables can contribute to better health monitoring and the possible barriers that may have led to the result in this study. For upcoming research, we recommend objective measures of effectiveness such as a reduced HbA_{1c} values in patients with diabetes and fewer cardiac event in patients with CVD rather than perceived effectiveness. In line of the present findings as well as the scientific evidence, it is indispensable to incorporate BCTs in health apps that have shown to be effective. This ensures efficiency and efficacy.

Our results have further implications for clinical practice. If a doctor wants his chronically ill patients to use health apps, he should have 2 things in his mind. First, not every patient is able to handle apps. Doctors have to select patients according to their literacy skills. Furthermore, doctors may recommend diabetes apps to diabetics, which are more likely to be used. For CVD patients, doctors need other strategies. For example, doctors should raise the awareness of patients especially during the asymptomatic phases of their illness to prevent long-term complications. Second, not every app is suitable to provide appropriate disease management. Especially, patients with CVD and comorbid diabetes are at high risk of developing complications. In this highly vulnerable subgroup, eHealth literacy seems to be a relevant factor of health app use, which

is a new finding from this study. However, we observed comparable patterns of app use and perceived effectiveness in those patients diagnosed with CVD, diabetes, and both conditions combined. Thus, clinical recommendations for app use may depend on comparable factors across these specific subgroups of patients. Although patient groups were largely overlapping, medical specialists such as endocrinologists, cardiologists, and general practitioners may be interested in our reporting of the specific patient group of interest. The quality of the apps and the use of theory-based interventions should be ensured [66]. More effective health apps are needed. Governmental recommendations or suggestions from independent institutions that are based on scientific evidence could give the clinical practitioners some orientation.

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Conflicts of Interest

None declared.

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Abbreviations

BCT: behavior change technique
CVD: cardiovascular disease
eHealth: electronic health
HbA_{1c}: hemoglobin A_{1c}
OR: odds ratio
WHO: World Health Organization

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Original Paper

Development and Implementation of a Person-Centered, Technology-Enhanced Care Model For Managing Chronic Conditions: Cohort Study

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Abstract

Background: Caring for individuals with chronic conditions is labor intensive, requiring ongoing appointments, treatments, and support. The growing number of individuals with chronic conditions makes this support model unsustainably burdensome on health care systems globally. Mobile health technologies are increasingly being used throughout health care to facilitate communication, track disease, and provide educational support to patients. Such technologies show promise, yet they are not being used to their full extent within US health care systems.

Objective: The purpose of this study was to examine the use of staff and costs of a remote monitoring care model in persons with and without a chronic condition.

Methods: At Dartmouth-Hitchcock Health, 2894 employees volunteered to monitor their health, transmit data for analysis, and communicate digitally with a care team. Volunteers received Bluetooth-connected consumer-grade devices that were paired to a mobile phone app that facilitated digital communication with nursing and health behavior change staff. Health data were collected and automatically analyzed, and behavioral support communications were generated based on those analyses. Care support staff were automatically alerted according to purpose-developed algorithms. In a subgroup of participants and matched controls, we used difference-in-difference techniques to examine changes in per capita expenditures.

Results: Participants averaged 41 years of age; 72.70% (2104/2894) were female and 12.99% (376/2894) had at least one chronic condition. On average each month, participants submitted 23 vital sign measurements, engaged in 1.96 conversations, and received 0.25 automated messages. Persons with chronic conditions accounted for 39.74% (8587/21,607) of all staff conversations, with higher per capita conversation rates for all shifts compared to those without chronic conditions (P<.001). Additionally, persons with chronic conditions engaged nursing staff more than those without chronic conditions (1.40 and 0.19 per capita conversations, respectively, P<.001). When compared to the same period in the prior year, per capita health care expenditures for persons with chronic conditions dropped by 15% (P=.06) more than did those for matched controls.

Conclusions: The technology-based chronic condition management care model was frequently used and demonstrated potential for cost savings among participants with chronic conditions. While further studies are necessary, this model appears to be a promising solution to efficiently provide patients with personalized care, when and where they need it.

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KEYWORDS

mHealth; mobile health; telemedicine; digital biomarker; person-centered care; chronic condition; chronic disease

Introduction

US health care costs continue to rise, driven in large part by the increasing prevalence of chronic conditions and longevity of those afflicted with them [1]. A chronic condition can be broadly defined as a reduction in health that is not transmittable and generally progresses slowly, lasting for an extended period of time [2,3]. Due to these factors, managing chronic conditions is a large burden [4]. With health care spending approaching 20% of gross domestic product and 20% to 40% of health care resources considered wasteful [5-7], reducing the cost of managing chronic conditions is paramount. Some overuse of health care services is attributable to fee-for-service payment systems that require face-to-face encounters for reimbursement [8,9]. While alternative payment models have been designed to mitigate waste [10] by engaging health care providers and their patients in self-care disease management [10], those models still tend to rely on face-to-face visits and irregular and infrequent measurement to manage chronic conditions.

Among those with chronic conditions, reliance on face-to-face visits may delay interventions to mitigate health deterioration until symptoms are acute, accelerating demand for expensive health care services such as hospitalizations, emergency room visits, and unplanned readmissions [11]. This is particularly true for persons with behavioral health issues, where early interventions can reduce the need for acute care [12]. Seemingly, redesign of chronic care management to engage patients in self-care, monitoring for early signs of deteriorating health, intervening early, and avoiding unnecessary care would create value by improving health outcomes and reducing care costs.

Because behavioral and social factors are implicated in over half of premature deaths [13-15], addressing these factors is critical to improving care value. Behavioral change interventions can successfully address those factors [16]; however, because behavioral change is difficult to induce and maintain [12,17], ongoing respectful patient engagement is essential [18]. Technologically enabled real-time information exchange resulting in just-in-time interventions can increase patient feelings of autonomy [19,20], build competence in self-management of chronic diseases [20], and help patients manage their chronic diseases [19,21]. Technology-based solutions like mobile health (mHealth, or health care that uses mobile phones and other mobile devices) have been shown to impact health-related behaviors [22].

Current technology allows for both active and passive collection of digital biomarkers, their subsequent aggregation and analysis, and immediate feedback of information [20,23-25]. With decreasing costs of devices and cloud computing [26], increasing mobile phone penetration [27], and advancements in deep learning, mHealth apps are increasingly being used [28]. While some of these apps have the potential to relieve the need for face-to-face encounters, they tend to focus on a specific disease (or body organ), typically do not interact with patient health care teams, and do not always enhance patient understanding of their health situation. A single app that is integrated with the patient medical record and supported by backend analytics could reduce the burden of interacting with technology while aggregating holistic in vivo data into actionable information for the patient, care team, and health system.

Implementation of mHealth interventions has been studied in a variety of settings and across many disease states [29]. Most studies have examined the disease-specific impact that mHealth apps (developed by academic groups and not designed for widespread use by consumers) have over a short time period within small sample populations [29,30]. To date, mHealth interventions have neither been integrated within a health system nor have allowed for comparison of users with chronic disease states with healthy patients [30]. Further, studies have not examined how support staff are used—a critical aspect of mHealth implementation as payers and care delivery system leaders need to consider workforce impact before they fund such efforts [30]. To address these gaps in the literature, we conducted a retrospective, observational secondary data analysis of an mHealth app and remote care system designed for broad consumer use, determined how and when staff were used to support the system, and calculated the cost impact of the app on individuals with and without chronic conditions.

In the spring 2016, Dartmouth-Hitchcock Health (DHH), an integrated health care system headquartered in Lebanon, New Hampshire, developed a technology- and sensor-based management and health care model called ImagineCare. The model was piloted with volunteer employees who were enrolled in its self-insurance product. Through secondary data analysis we describe the real-world implementation of an mHealth system and sought to determine ImagineCare's use by—and health care spending impact on—two groups within DHH's employee population: persons with and without chronic conditions.

This research had two main objectives: to describe the implementation of an mHealth system designed to help monitor and improve the health of an employed population and to examine differences in health services use and costs when comparing those with and without chronic medical conditions.

Methods

Developing and Implementing a Technology-Enhanced Care Program

A multidisciplinary team including nurses, physicians, designers, information technology (IT) developers, hospitality specialists, and researchers developed a new care model following an established methodology of disruptive innovation [31]. Over 3 years, the team explored aspects of managing chronic conditions: current care delivery models from the patient and provider perspective, evidence-based guidelines, and behavioral change methods. Devices and software were assessed and selected based on ease of use, technical integration possibilities, cost effectiveness, and clinical relevance.

The final ImagineCare delivery model was based on remote monitoring, digital communication, cloud-based analytics, and personal behavioral change support. The model consisted of (1) a 24/7 care support center with staff trained in behavioral change, (2) a clinical workflow application, (3) a mobile app with companion Bluetooth-enabled devices for the participants, and (4) a cloud-based data processing solution (Figure 1).

The care support center consisted of a clinical care team available 24/7 to the participant through text- or voice-based communication. The team was staffed by licensed nurses and health navigators (nonmedical staff trained in customer service and basic health services). Both groups were specifically trained in behavioral change and remote support of patients; they were also coached to provide high-quality customer service designed to keep participants engaged with their health and well-being. Behavioral change training was based on the transtheoretical model of behavioral change, focusing on preparing patients for action and supporting them through plan development and follow-up communication. The staff responded to incoming calls and messages from participants and to alerts that were triggered by collected data. Health navigators passed conversations on to nursing staff based on triage guidelines, clinical judgment, or at the participant's request. Navigators reached out to participants when cloud-based algorithms identified declining engagement, out-of-normal range monitored vital signs, or negatively trending vital signs.

The iOS-developed app had 3 core functional areas: health data, personal profile, and secure messaging. Health data were collected through sensors, by manual entry, and by participant response to questions. The personal profile section provided valuable context to clinicians by documenting health goals, personal preferences, and social data. The secure messaging function allowed participants to connect to the care team when it suited them best.

To complement personal messages sent by the clinical care team, the system automatically communicated clinical information and suggestions, nudges, and support throughout the app. All system-generated messages used variations on language and collated participant-specific information to make the communication feel personalized. Colors and language were deliberately chosen to support positive behavior change and enjoyment and reduce stress and anxiety. The app itself had either password or biometric security, depending on participant preference.

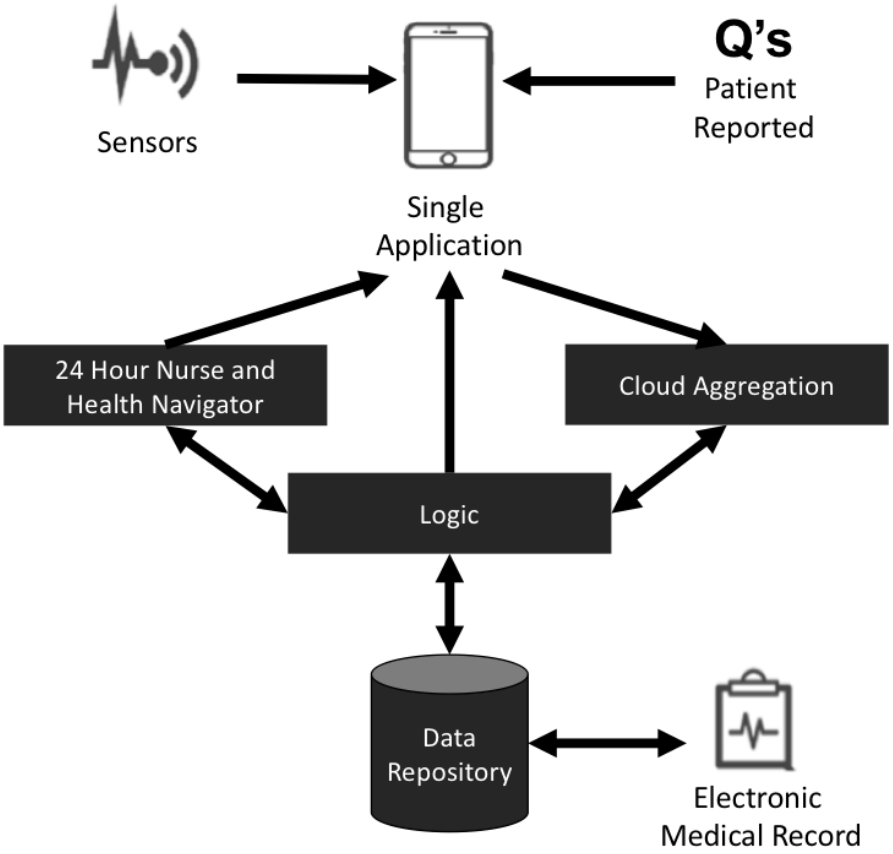
The system collected data through passive or active encounters with participants, stored data in a cloud-based database, and automatically analyzed them according to medical condition–specific care pathway algorithms. Condition-specific care pathways had been developed through adaptation of systematic reviews of clinical evidence to the patient population via team clinician consensus and by tailoring pathways to enhance self-care opportunities. Safety was held paramount, as no logic made a diagnosis and all decision points were examined by a nurse or health navigator for a final intervention recommendation. All cloud processes and information were stored on Health Insurance Portability and Accountability Act–compliant data services. All algorithms were tested by the developers to ensure patient safety. The app and databases were subject to rounds of vulnerability testing by a third party, ensuring that personal participant information was secure.

Device connectivity, app functionality, and message communication were tested over a 2-month period by 50 healthy individuals. Each device was tested for its ability to connect to the app, collect data, engage algorithms, and respond to both the app and the clinical care team. The testing confirmed that the patient and clinician experiences were good, data collection and algorithm execution were accurate, and no patient safety issues arose.

Voluntary enrollment in ImagineCare began in March 2016, and ImagineCare was launched in May 2016. Volunteers were solicited through emails directed at employees who were insured by DHH's self-insurance product; 2894 volunteers enrolled, which entailed creating a secure personal account verifying basic information, downloading the mobile app, receiving Bluetooth-enabled sensory devices by mail, and connecting those devices to the mobile app.

The devices that were sent were dependent on the participants' needed support. For those without a chronic condition, a fitness tracker smartwatch was sent to support general healthy living and wellness, which included collecting data and providing feedback on sleep, physical activity, and mental health. In addition to this support, those with chronic conditions received care and collected data specific to their conditions; for example, blood pressure was measured for those with hypertension, weight was measured for those with congestive heart failure, and blood glucose was measured for those with diabetes.

Figure 1. Architecture of ImagineCare care model.



Use of the ImagineCare System

To analyze the use of the app for chronic disease management, we classified volunteers into 2 mutually exclusive groups: persons with and persons without chronic conditions. Persons with chronic conditions were defined by documentation of *International Classification of Diseases, Ninth Revision*, codes indicating diabetes, hypertension, congestive heart failure, and/or chronic obstructive pulmonary disease in the prior year. Persons without these codes were defined as without chronic condition. In this pilot project, other chronic conditions were not included, as they were not specifically actionable within the initial implementation of the mHealth system. After comparing demographics for these 2 groups of participants (including a US Census Bureau estimate of the mean family income of each volunteer's zip code of residence), we evaluated how they used the ImagineCare system in 3 ways. First, we examined their enrollment, over time, and the number of days it took each participant to complete enrollment. Second, we examined how often participants uploaded vital sign data (data collected from any of the peripheral devices that were connected to the app). Third, we evaluated the frequency and timing of conversations that members of each group had with the system. A conversation was defined as a conglomeration of texts and/or phone calls having to do with a particular event; the date and time of the conversation was that of the first interaction regarding the event, whether it was precipitated by participant, staff, or system logic. The purpose of the conversation was recorded by the ImagineCare nurse or health navigator who communicated with the participant at the time of completion of the communication.

Impact on Care Costs

Finally, for a subset of 1235 volunteers who had been employees for the prior year and remained in the program throughout the entire pilot period, we assessed total allowed health care charges that the participant incurred, partitioned into 3 types of care: hospital, emergency room (ER), and outpatient care (including medications). To make this comparison robust, we used age, sex, hierarchical condition category (HCC) score [32], and chronic condition status to match volunteers to nonparticipating employee controls, using a 3:5 ratio. We conducted a difference-in-difference analysis that compared the intervention period to baseline charges incurred during the same 9-month period in the prior year for participants and controls, for both with and without chronic condition groups.

We used R version 3.4.1 (R Foundation for Statistical Computing) to conduct all analyses. We used Student *t* tests to compare continuous variables and the chi-square test to compare categorical variables; all significance tests used 2-tailed alpha=.05. As charge data were highly skewed and kurtotic, we log-transformed them to conduct statistical analyses; although for ease of interpretation, we also report nontransformed results. This secondary data analysis was approved by Dartmouth College's Committee for the Protection of Human Subjects (CPHS #30385).

Results

Use of the ImagineCare System

Of the 2894 participants in the pilot project, 2518 were considered without chronic condition and 376 were considered to have a chronic condition; participants without a chronic condition were younger and more likely to be female than persons with chronic conditions (Table 1). The 2 cohorts took a similar amount of time to enroll in the program after having been emailed an invitation to do so and had similar estimated annual incomes.

Cumulative enrollment of participants with and without a chronic condition was similar over time (Figure 2). Enrollment was fastest between March and May and slowed somewhat between May and September, when it essentially stopped. The proportion of participants who submitted at least 1 vital sign each month consistently fell for both persons with and without a chronic condition during the pilot, dropping to less than 10% (220/2518, 8.73%) of persons without a chronic condition by the end of the pilot period; persons with chronic conditions remained somewhat more engaged with the system throughout the pilot period, although that engagement waned (Figure 3A). The per capita number of vital signs submitted by engaged patients remained stable for the cohort without a chronic condition but increased somewhat among persons with chronic conditions between May and October before stabilizing (Figure 3B). Although they comprised only 12.99% (376/2894) of the population, persons with chronic conditions contributed 28.34% (62,011/218,794) of all submitted vital signs.

Table 1. Characteristics of participants with and without a chronic condition in the ImagineCare pilot.

Characteristics	Chronic condition (n=376)	Without chronic condition (n=2518)	*P* value
Age in years, mean (SD)	52.0 (11.7)	39.3 (12.2)	<.001
Sex, n (%)			<.001
Female	215 (57.2)	1889 (75.0)	N/A[a]
Male	235 (47.2)	625 (24.8)	N/A
Other/unknown	6 (1.6)	4 (0.2)	N/A
Days to complete enrollment, mean (SD)	12.0 (33.3)	10.4 (23.6)	.24
Estimated zip code level income ($), mean (SD)	67,500 (21,400)	66,200 (19,700)	.25

[a]N/A: not applicable.

Figure 2. Cumulative enrollment in the pilot program for without chronic condition (dotted line) and chronic condition participants (solid line), March 2016 to January 2017.

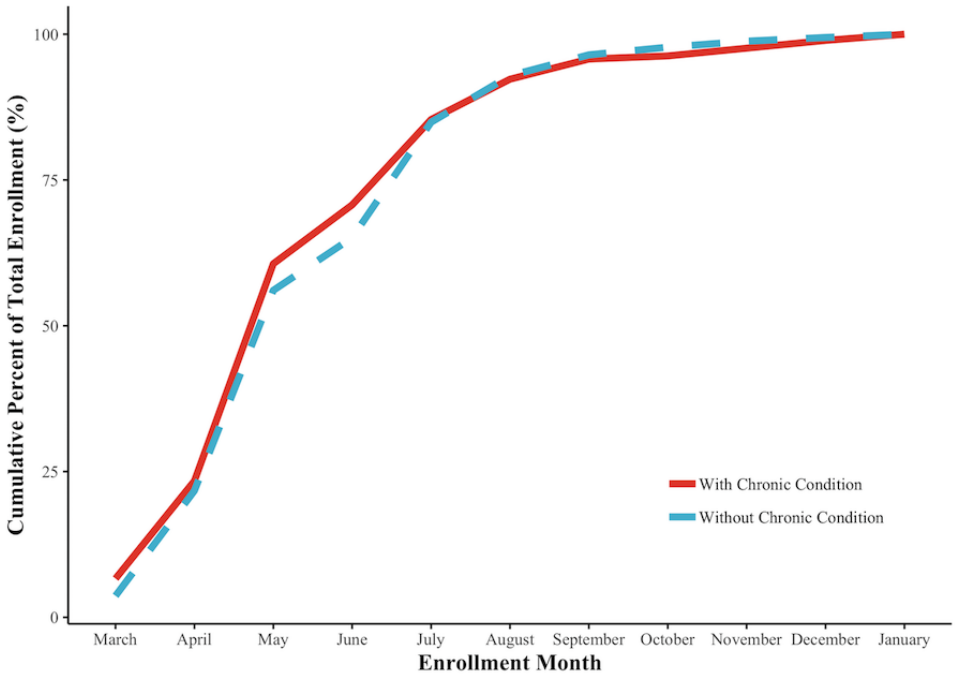


Figure 3. Submissions by without chronic condition (dotted lines) and chronic condition (solid lines) cohorts for each month of the pilot. A) Percentage of enrollees submitting at least 1 vital sign. B) Average number of vital signs submitted (for individuals who submitted at least 1 vital sign that month).

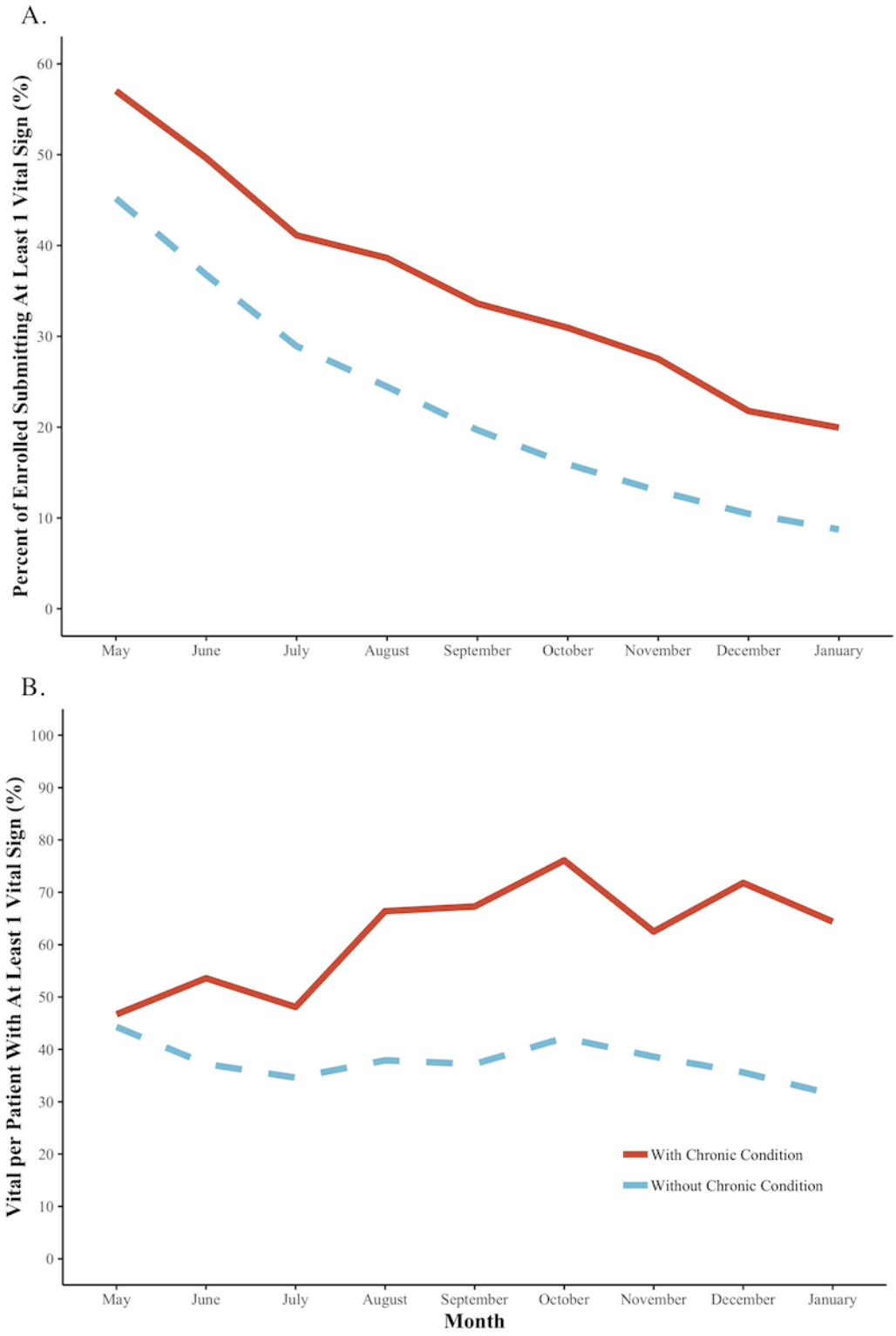


Table 2. Number of total conversations and conversations per patient between staff and participants with and without chronic conditions by shift, purpose, and staff role.

Characteristics	Conversations between staff and participants				*P* value
	Chronic condition		Without chronic condition		
	Total, n	Per capita	Total, n	Per capita	
Overall	8587	1.14	13,020	0.32	
Shift					
16:00-24:00	4229	1.73	6001	0.48	<.001
08:00-16:00	2993	1.16	5159	0.34	<.001
00:00-08:00	1365	0.53	1860	0.15	<.001
Purpose					
Administrative	3469	6.97	9701	3.85	<.001
Clinical alert	3198	6.42	263	0.1	<.001
Health coaching	362	0.73	299	0.12	.012
Lack of engagement	341	0.68	1190	0.47	.003
Technical question	938	1.88	1263	0.50	.002
Other/undetermined	279	0.56	304	0.12	.004
Team member type					
Health navigator	4968	22.36	11,492	0.78	<.001
Nurse	3619	15.35	1528	0.19	<.001

Persons with chronic conditions also accounted for 39.74% (8587/21,607) of all staff conversations, with higher per capita conversation rates for all shifts (*P*<.001 for all, Table 2). For both with and without chronic condition cohorts, participants engaged in conversations significantly more frequently in later hours, toward the 16:00-24:00 shift (Table 2). Administrative conversations accounted for 74.51% (9701/13,020) of conversations between persons without chronic conditions and with staff; administrative conversations and clinical alerts each accounted for 40.40% (3469/8587) of conversations that persons with chronic conditions had with staff. Conversations were most common with health navigators (16,460/21,607, 76.18%); however, persons with chronic conditions were much more commonly referred to nursing staff (3619/8587, 42.15% vs 1528/13,020, 11.74% for without chronic condition participants, *P*<.001). A total of 70.31% (3619/5147) of all nursing staff conversations were with the chronic condition group as compared to 29.69% (1528/5147) of health navigator staff conversations.

Patterns of communication across time of day and day of week differed somewhat when comparing with and without chronic condition cohorts. Both groups had their highest concentration of conversations after noon, regardless of day (Figure 4); however, when compared to the without chronic condition group, persons with chronic conditions had relatively more conversations in the late night, and Mondays appeared to be the day on which participants without a chronic condition most frequently communicated with the system. Relatively high concentrations of communications with nurses were more sporadic than those with health navigators throughout the week; however, as the week progressed, health navigators and nurses had similar concentrations of conversations (Figure 5).

There were no reports of adverse health events. System bugs were limited to incorrect responses to question scores, which were investigated and fixed.

Impact on Care Costs

Our subanalysis that used matched controls to conduct a difference-in-difference analysis of the cost-impact of the new care model found that the variables used for matching were similar for participants and controls for with and without chronic condition cohorts with the exception of prior period ER charges, which were higher for participants without a chronic condition than for matched controls (*P*=.01; Table 3). Our difference-in-difference analysis found that program participation was associated with trends toward lowered ER charges for the without a chronic condition cohort (29% reduction, *P*=.08) and lowered outpatient (20% reduction, *P*=.052) and total charges (16% reduction, *P*=.06) for the cohort with chronic conditions (Table 4).

Figure 4. Time of communications by day, hour, and cohort for March 2016 to January 2017. Each week is separated by hours scored by percentile of conversations for that hour. The percentile of conversations (0 corresponding with 0 conversations for that hour) for persons with chronic conditions (With CC) and without chronic conditions (Without CC) are plotted for each hour in each day. The largest concentration of conversations for participants without chronic condition was on Mondays between 14:00-15:00, while it was on Sundays between 15:00-16:00 for persons with chronic conditions.

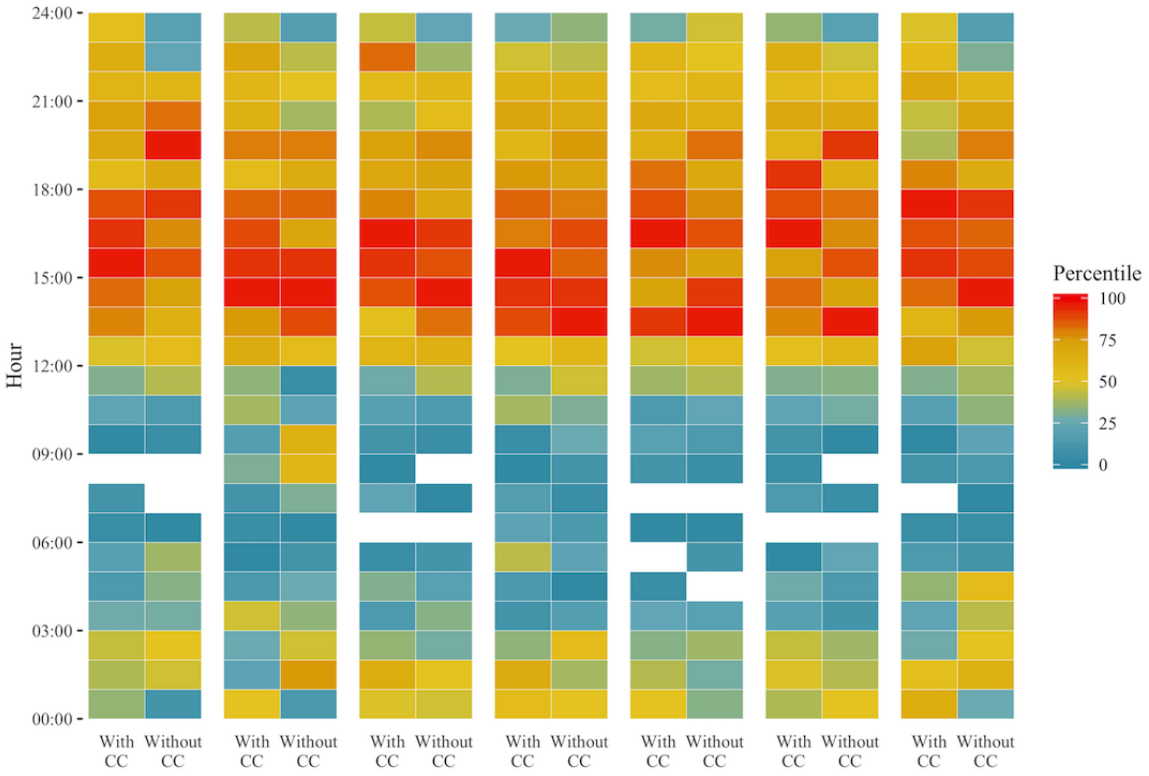


Figure 5. Time of communications by day, shift, and staff role for March 2016 to January 2017. Each week is separated by hours scored by percentile of conversations for that hour. The percentile of conversations (0 corresponding with 0 conversations for that hour) for health navigators and nurses are plotted for each hour in each day. The largest concentration of conversations with health navigators was Mondays between 14:00-15:00; with nurses, it was Sundays between 15:00-16:00.

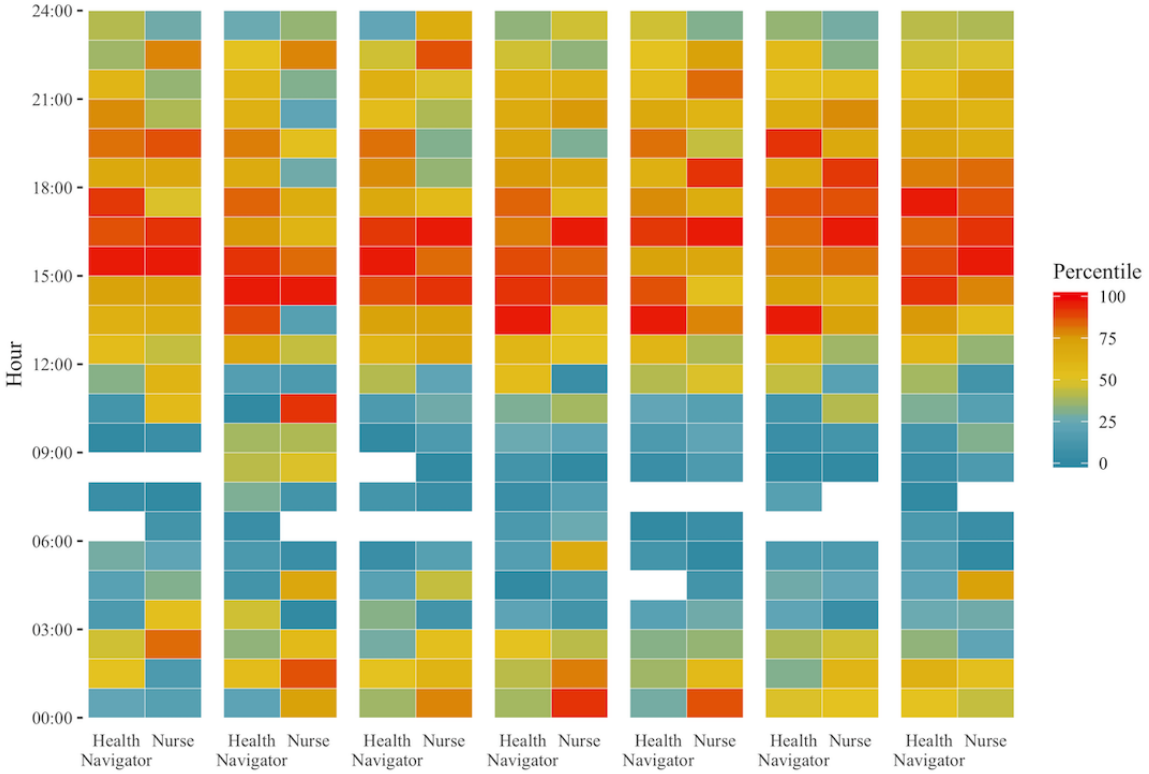


Table 3. Comparison of the characteristics and pre- and postintervention charges for program participants and matched controls in the with and without chronic condition cohorts (actual mean values are provided, but *P* values for charge data are based on results using log-transformed data).

Characteristics	Chronic condition			Without chronic condition		
	Program participants (n=193)	Matched controls (n=343)	*P* value	Program participants (n=1042)	Matched controls (n=1730)	*P* value
Age in years, mean	51.1	51.9	.37	39.7	40.3	.17
Male, n (%)	70 (36.3)	125 (36.4)	.97	274 (26.3)	446 (25.8)	.77
HCC[a] score	4.13	4.6	.16	1.77	1.69	.30
Prior period, mean						
Acute care charges ($)	1545	1674	.74	274	771	.45
ER care charges ($)	296	356	.17	191	156	.01
Outpatient charges ($)	8456	7533	.07	3970	4773	.82
Total charges ($)	10,297	9563	.09	4435	5700	.74
Intervention period, mean						
Acute care charges ($)	1305	1178	.73	317	548	.89
ER care charges ($)	252	479	.06	192	213	.89
Outpatient charges ($)	8402	9159	.59	5201	5192	.70
Total charges ($)	9959	10,816	.53	5710	5953	.65

[a]HCC: hierarchical condition category.

Table 4. Results of the difference-in-difference charge analysis for with and without chronic condition cohorts showing only the difference-in-difference statistic. The regression included the following variables: age, sex, HCC score, time, case, and time*case (which represents the difference-in-difference statistic after adjusting for the other variables). Where *P*<.10 for the natural log of the charge categories, 95% confidence intervals (CIs), and the *P* value and coefficient (β) for non–log-transformed charges are provided; if *P*≥.10, cells are left blank. Neither the with nor the without chronic condition cohort had difference-in-difference statistics that were *P*<.10 for acute care.

Type of charge	Chronic condition				Without chronic condition			
	β LN[a] charge	95% CI	*P* value	β[b] charge $	β LN charge	95% CI	*P* value	β charge $
Acute care	—	—	—	—	—	—	—	—
ER[c] care	—	—	—	—	–0.2	–0.422 to 0.022	0.08	–56
Outpatient	–0.43	–0.868 to 0.004	0.05	–1679	—	—	—	—
Total	–0.44	–0.884 to 0.009	0.06	–1590	—	—	—	—

[a]LN: natural log.

[b]Coefficient for non–log-transformed charges.

[c]ER: emergency room.

Discussion

Principal Findings

Within its self-insured employee population, DHH designed, piloted, implemented, and studied a remote monitoring system designed to improve patient self-management of their health status, particularly for persons with chronic conditions. We found that persons with or without chronic conditions signed up for the volunteer program similarly; however, those with chronic conditions were older and more likely to be male. Persons with chronic conditions used ImagineCare differently than did participants without a chronic condition: although both groups used the system less as time progressed, persons with chronic conditions appeared to be actively engaged with the system for a longer time period. Engagement fell considerably in both groups over the pilot period at similar rates. Interestingly, even at the beginning of the pilot, only about half of the participants in either cohort were actively engaged with the system. Finally, among persons with chronic conditions, our difference-in-difference analysis uncovered a substantial potential for reductions in care costs when compared to matched controls, while the participants without chronic conditions did not demonstrate such large charge reductions.

Our results suggest that effort needs to be expended to engage patients in the use of mHealth apps. While the engagement we experienced was higher than that found in a Federally Qualified Health Plan [33], several approaches might improve system engagement going forward. First, evaluation of participant eHealth literacy—the ability of patients to communicate through written text, a working knowledge of computers or mobile

phones, and a basic understanding of their health and treatment [34,35]—might have helped to target participants who lacked such understanding or demonstrate to them that use of the system might have been beneficial [36]. While the observed higher engagement might have resulted from the testing process and user-centered design, the engagement might have been improved by ensuring that there was a good fit between the app, end users, recruitment approach, and treatment process [33]. Nonetheless, the relatively low engagement suggests that more should be done to encourage customers of such systems to use technology to monitor and manage their health.

Our results suggest that care models like ImagineCare can be integrated into traditional health care delivery systems but that a focus on enrolling patients with chronic conditions would be wisest: they are more likely to remain engaged and have the greatest potential to generate cost savings. While the pilot effort was successful, there were substantial technical challenges in managing and coordinating data input from a multiplicity of systems, which, as others have noted, highlights the lack of standards for technology interoperability in implementing mHealth programs [37]. Not only were data collection and storage difficult because of the need to integrate firmware, schema, and data types, ongoing data analytics overwhelmed the initial computational power provided to run the system. Much of the system's success relied on difficult integration of devices that traditionally run on third-party applications; this creates an opportunity for device manufacturers to produce devices with open software development kits. Should health care organizations want to develop similar care models, they should use existing technologies and leverage existing capacity for large data management and analysis.

Appropriate technical and clinical staffing levels are also necessary to effectively and efficiently run such systems; staffing levels must be adapted to meet the needs of particular patient populations by shift, day, and time since enrollment. Given the high variability in the type and time of communications, the timing of communications during a week, and the decline in communications over time, flexible scheduling based on system engagement may be most efficient [33,38,39]. Our results indicate that systems managing a higher proportion of persons with chronic conditions might require more nursing staff, particularly in later shifts and later in the week.

The use of remotely collected data that monitors health and behavior is an emerging area of research [40]. Such data could be considered digital biomarkers [41]—objective information that can be used to predict changes in health status. It is difficult, costly, and time consuming to collect, process, and analyze nondigital predictors [42,43], and the use of digital biomarkers offers a more efficient method of identifying such markers as the use of devices continuously collecting data increases. One critical requirement in the development of digital biomarkers is connecting these novel measurements to health outcomes [41]. In the context of accelerating US health care spending [44] and private endeavors to address spending growth [45], care models that can use digital biomarkers might have market advantages.

The potential cost savings due to a remote monitoring care system could be highly dependent on the payment model of the implementing health system. Fee-for-service models may have the least to gain as the goal of remote monitoring care is to reduce the use of standard face-to-face services through prevention and point of need interventions. Payment models such as accountable care organizations, value-based models, or those that use bundled payment structures might have much greater savings.

Limitations

Our analysis has several limitations. First, ours was an open study and our cost comparison used retrospectively matched controls. To better evaluate the impact of such systems on the health of the population and care costs, future studies should prospectively identify control groups and concurrently collect data from them. Second, our definition of having a chronic condition was limited. We believe that this potential bias was minimal as HCC scores between the cohorts were meaningfully different, and we observed differences in use. If such a threat to internal validity were large, observed differences would be biased to the null. Third, more in-depth analyses of how patients used the system would be valuable. For instance, analysis of time spent interacting with the system, responses to system-generated automated messages, eHealth literacy, and measures of patient engagement would be valuable. Fourth, we did not evaluate the impact of the system on clinicians within the health care delivery system; analysis of their ability to integrate data obtained from such programs into their clinical decision-making processes and patient encounters would be valuable. Additionally, we only examine the use of the monitoring model and not the health status of participants measured by it. Fifth, we examined an employed population; while some of them had a chronic condition, they remained employed throughout the study. Findings may not generalize to patients with chronic conditions that preclude their ongoing employment. Finally, we analyzed the implementation of a single monitoring model in a single organization for a relatively brief time period; longer studies including nonemployed patients is needed to gather more knowledge about the use of remote monitoring systems in health care.

Conclusions

Our results suggest that persons with and without chronic conditions used a remote monitoring care model differently and that their needs for support within such systems differed. This new care delivery model showed promising results, but the long-term success will depend on sustainably engaging patients to participate in the system, developing triage structures that meet patient and health system needs, and appropriately staffing the system so patients get the care that they want and need, nothing more and nothing less.

Acknowledgments

We would like to acknowledge the work of all the individuals that contributed to the conception, development, and implementation of ImagineCare, and recognize Ethan M Berke, MD, MPH; Robert A Greene, MD, MHCDS; Nathan Larson; Ramesh M Yapalparvi, PhD; and Kevin F Spratt, PhD.

Conflicts of Interest

JNW and CLP helped develop and implement the ImagineCare health care management product evaluated herein at Dartmouth-Hitchcock. ON is a minority owner and employee of Lifecarex Sweden, the distributor of the ImagineCare product; JNW serves on its board and has stock options. JNW and WBW are currently employed by Microsoft. CLP is funded through the Burroughs Wellcome Fund for Big Data In The Life Sciences at Dartmouth.

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Abbreviations

DHH: Dartmouth-Hitchcock Health
ER: emergency room
HCC: hierarchical condition category
IT: information technology
mHealth: mobile health

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Original Paper

Accuracy of Consumer Wearable Heart Rate Measurement During an Ecologically Valid 24-Hour Period: Intraindividual Validation Study

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Abstract

Background: Wrist-worn smart watches and fitness monitors (ie, wearables) have become widely adopted by consumers and are gaining increased attention from researchers for their potential contribution to naturalistic digital measurement of health in a scalable, mobile, and unobtrusive way. Various studies have examined the accuracy of these devices in controlled laboratory settings (eg, treadmill and stationary bike); however, no studies have investigated the heart rate accuracy of wearables during a continuous and ecologically valid 24-hour period of actual consumer device use conditions.

Objective: The aim of this study was to determine the heart rate accuracy of 2 popular wearable devices, the Apple Watch 3 and Fitbit Charge 2, as compared with the gold standard reference method, an ambulatory electrocardiogram (ECG), during consumer device use conditions in an individual. Data were collected across 5 daily conditions, including sitting, walking, running, activities of daily living (ADL; eg, chores, brushing teeth), and sleeping.

Methods: One participant, (first author; 29-year-old Caucasian male) completed a 24-hour ecologically valid protocol by wearing 2 popular wrist wearable devices (Apple Watch 3 and Fitbit Charge 2). In addition, an ambulatory ECG (Vrije Universiteit Ambulatory Monitoring System) was used as the gold standard reference method, which resulted in the collection of 102,740 individual heartbeats. A single-subject design was used to keep all variables constant except for wearable devices while providing a rapid response design to provide initial assessment of wearable accuracy for allowing the research cycle to keep pace with technological advancements. Accuracy of these devices compared with the gold standard ECG was assessed using mean error, mean absolute error, and mean absolute percent error. These data were supplemented with Bland-Altman analyses and concordance class correlation to assess agreement between devices.

Results: The Apple Watch 3 and Fitbit Charge 2 were generally highly accurate across the 24-hour condition. Specifically, the Apple Watch 3 had a mean difference of −1.80 beats per minute (bpm), a mean absolute error percent of 5.86%, and a mean agreement of 95% when compared with the ECG across 24 hours. The Fitbit Charge 2 had a mean difference of −3.47 bpm, a mean absolute error of 5.96%, and a mean agreement of 91% when compared with the ECG across 24 hours. These findings varied by condition.

Conclusions: The Apple Watch 3 and the Fitbit Charge 2 provided acceptable heart rate accuracy (<±10%) across the 24 hour and during each activity, except for the Apple Watch 3 during the daily activities condition. Overall, these findings provide preliminary support that these devices appear to be useful for implementing ambulatory measurement of cardiac activity in research studies, especially those where the specific advantages of these methods (eg, scalability, low participant burden) are particularly suited to the population or research question.

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KEYWORDS

electrocardiography; Apple Watch 3; digital health; Fitbit Charge 2; heart rate; mobile health; passive sensing; photoplethysmography; wearables

Introduction

Background

Wrist-worn smartwatches and fitness monitors or wearables have been widely adopted by consumers and are currently gaining increased attention by researchers for their potential contribution to digital measurement of health, especially in *big data* studies as these devices are scalable, unobtrusive, and potentially provide greater ecological validity (ie, the degree to which a research design matches naturalistic environments to generalize results to real-life settings), as compared with laboratory studies. These devices contain a multitude of sensors, often including an optical sensor that uses photoplethysmography (PPG) that allows these devices to collect pulse rate or volumetric changes in blood profusion that act as a surrogate for heart rate (HR). Although often used interchangeably, it is important to note that pulse rate and HR are 2 different physiological signals [1], with pulse rate representing the rate of change in blood pressure because of the ventricular ejection of blood, whereas HR represents the rate of heart contraction as indexed by heart electrical impulses. As such, the goal of wearable HR accuracy validation studies is to assess that device measurements, such as those between wearables and a reference method (ie, electrocardiogram; ECG), are not outside of clinically important limits of agreement (LoA), so that devices can supplement, replace, or even be used interchangeably [2].

Recently, there have been a variety of studies that have examined the accuracy of wearable PPG sensors as compared with ECG [3-9], polar chest straps [10,11], or pulse oximeters [12] across various controlled laboratory conditions, including sitting, treadmill protocols for walking and running, cycling, weight training, and sleeping. The current gold standard reference method for assessing HR is the ECG, which highlights the limitations of many studies that have utilized chest straps [10,11] or pulse oximeters [12], which themselves contain a degree of error when compared with ECG. Therefore, many studies are comparing wearable HR accuracy with suboptimal comparison methods, which likely undermine findings. Below, we primarily reviewed the existing wearable HR literature that has used an ECG as the comparison method.

Previous research comparing wearables with the gold standard ECG, which uses electrodes to measure cardiac muscular contractions from electrical activity of the heart, has shown that that wearables underestimate absolute HR as compared with reference methods [3-4,6,8-11,13]. Prior research has also shown that the Apple Watch has greater accuracy than Fitbit devices [7-9]. Specifically, prior research has found that the Apple Watch has lower overall error [3,7,10], lowest mean difference [8], and higher agreement with ECG than Fitbit devices [3,9], but that wearables' accuracy depends on activity [5]. Research has shown that at rest, wearables can perform similarly to an ECG but not with moderate exercise [14]. There has been a substantial amount of research that has shown that wearable devices are more accurate during rest and low intensity exercise as compared with exercises at higher intensity [3,5,9,15-17], which may be because of the position of the device during rest [18] and less movement of the wearable device around the wrist at rest, although this is not found in all studies [7,10-11,19]. Specifically, 1 study found that there was not a significant difference in HR accuracy across baseline or vigorous activity [10], whereas a second study found that HR accuracy was highest during running—a very intense activity [19], and a third found that walking, running, and cycling were more accurate for some devices than sitting [7]. Therefore, it is possible that activity intensity may be less important to device accuracy than the degree of erratic wrist movements performed during physical activity, which tend to co-occur with more vigorous physical activity.

Four Challenges Limiting Progress for Wearable Heart Rate Accuracy

Currently, prior research has greatly improved our understanding of wearable HR accuracy, but there remain 4 challenges that limit progress in this area. First, as mentioned above, many studies lack an appropriate comparison method by opting to utilize chest straps [10,11] or pulse oximeters [12], rather than an ECG, which themselves contain a degree of error when compared with ECG. Therefore, many studies are comparing wearable HR accuracy with suboptimal comparison methods, which likely undermine findings. Second, wearable manufacturers use proprietary algorithms to translate PPG signals to HR measurements. These algorithms are likely altered with firmware updates, yet most studies fail to report firmware information. This may lead to poor reproducibility as 2 studies investigating the same device with different firmware versions might actually come to different conclusions even if all other variables are held constant. Third, almost all prior studies have utilized laboratory paradigms, rather than naturalistic settings. Recent research has called for the test of devices in the *setting appropriate for intended use* [20]. Although controlled laboratory settings are important for maintaining experimental control, this design involves a trade-off that often creates an artificial environment during which individual behaviors may deviate from that in naturalistic settings of lived daily experience. For example, laboratory settings tend to test specific movements within predetermined time frames, whereas consumers use wearables in naturalistic settings that often involve more variable and sporadic movements, which may not be accurately captured during laboratory paradigms. As such, the accuracy of wearables in controlled settings may deviate from accuracy during the daily living conditions of consumers. The 2 studies that were identified to have been conducted in more naturalistic settings have either occurred within a medical setting [6], which inherently does not capture the vast majority of consumer device use conditions, or only collected a maximum of 6 hours of free-living nonsleep conditions without the use of a gold standard ECG as a reference method [21]. Finally, the

speed of wearable technological advancements often outpaces the typical research cycle [22], making it very difficult for studies to validate each new iteration of wearables. This calls for novel rapid response designs to quickly assess initial wearable HR accuracy in order for the research cycle to keep pace with technological advancements.

This study addresses each of the current limitations in wearable studies as it (1) uses a gold standard comparison method for movement within daily life—ambulatory ECG, (2) reports firmware versions, (3) increases the ecological validity of wearable HR accuracy by taking place during actual consumer device use conditions across a 24-hours period, and (4) takes place within an individual, rather than a traditional group of research participants, which creates an agile and novel rapid response design to quickly assess initial wearable HR accuracy in order for the research cycle to keep pace with technological advancements. This design also controls most between-subject variability and potential confound variables, allowing wearable devices to be the only study variable that varies; thus, providing a powerful (albeit potentially less generalizable) test of device accuracy.

Study

This study was preregistered (hypotheses and methods) with open code and data on Open Science Framework (OSF) [23]. The objective of this study was to determine the HR accuracy of 2 of the most popular wearables, the Apple Watch 3 and Fitbit Charge 2, as compared with the gold standard method for continuous recording in real-world settings—an ambulatory ECG. As mentioned above, a single-subject design was used for this initial study on the ecological validity of wearables to provide a proof-of-concept research design that will allow research cycles to keep pace with the technological advancements of wearables, while also eliminating between-subject variability. Although a single-subject design is a limitation, a recent study has highlighted the possibility that group-level findings do not apply to the individual [24] and that N of 1 trials are a promising approach to empirical decision making [25]. Furthermore, single-subject designs are being increasingly used [26-28], even in leading journals [29-31]. One strength of this design is that all potential confound variables can be held constant, except for the wearable devices; thus, providing a powerful test of accuracy of the devices *per se*.

This study hypothesized that (1) the Apple Watch 3 would be more accurate at measuring HR than the Fitbit Charge 2 when compared with an ambulatory ECG across all conditions, (2) both wearables would underestimate HR across all conditions, and (3) device measurement of HR would become increasingly inaccurate as activity intensity increased.

Methods

Recruitment

We investigated the accuracy of wearable HR from 2 popular devices in a single healthy human (first author) who completed a 24-hour protocol. The participant (29-years-old Caucasian male; body mass index=21.1; Fitzpatrick skin tone measure=2; right wrist (cm)=7.0; left wrist (cm)=6.5; right hand dominant) conceptualized and initiated this study, with the purpose of having the data published. Therefore, approval from the University of Oregon ethics committee was unnecessary and not obtained. The first author gave consent for collecting and using the data for study purposes.

Study Protocol

Participant's psychophysiology recordings began at 18:28 on day 1 and briefly stopped at 17:10 on day 2 before the run condition. Recording resumed at 17:37 for the run condition and stopped at 18:50 on day 2. Age, gender, height, and weight were used to set up both wearable devices.

Conditions

A total of 5 daily conditions were recorded throughout the 24-hour study using a digital notebook (Google Sheets) to record activity times, resulting in 84 start and stop marker times. These included sitting, which included any seated activity; walking; running (this occurred on a treadmill to allow for a stable ambulatory ECG signal); activities of daily living (ADL), which included activities such as cleaning, brushing teeth, and cooking; and sleeping. Although prior research has excluded HR data during activity transitions, these were not excluded in this study to preserve ecological validity of device usage in real-world conditions. Therefore, although transition periods generally yield higher device error, we wanted to capture this variability as part of device accuracy in this study.

Gold Standard Reference Method

ECG data were acquired using a standard 3-lead ambulatory ECG (Vrije Universiteit Ambulatory Monitoring System) [32,33]. ECG sampling frequencies were 1000 Hz, and HR was exported in 1-min epochs, from 00 seconds to 59 seconds.

Wearable Devices

Apple Watch 3

The Apple Watch Series 3 (2017 version, Apple Inc, California, USA, v. 4.2.3) 42 mm was worn on the right wrist. According to Apple, the Apple Watch 3 samples HR approximately every 10 min or continuously during workouts using PPG with either a green light emitting diode or infrared light and photodiode sensors. In other words, during this study, the Apple Watch 3 collected HR data as would occur in real-world conditions, continuously for walking and running and approximately every 10 min during all other activities. The Apple Watch 3 was synced with the Apple Health app on the iPhone and then exported in XML format for analysis. The Apple Health Analysis GitHub repository [34] was used to convert the XML file to a data frame in R Studio to access per min data for analysis. When more than 1 heart rate measurement was collected each min during continuous HR recording for walking and running activities, the average of these measurements was used in line with prior wearable research [7].

Fitbit Charge 2

The Fitbit Charge 2 (2017 version, Fitbit Inc, California, USA, v. 22.55.2) was worn on the left wrist. According to Fitbit, the PurePulse PPG technology utilizes green LED light to continuously index HR. The Fitbit GitHub repository [35] was

used to interact with the Fitbit app programming interface to access per minute data for analysis.

Error

To assess error, we used mean error (ME), mean absolute error (MAE), and mean absolute percent error (MAPE). In line with prior wearable research [3,11,23,36,37] as well as recommendations from the Association for the Advancement of Medical Instrumentation, the Consumer Technology Association [38] and the American National Standards Institute [39], we defined an acceptable error rate for a physical monitoring device to be ±10%, as this is considered an accurate threshold for medical ECG monitors. We recognize that this is more lenient than some prior health sciences research on wearable HR accuracy [7] and pedometer step counting accuracy [40,41] that have defined an acceptable error rate to be ±5%. In line with recent recommendations [37,38], we used MAPE to determine acceptable error rate. Outliers were not removed as this would interfere with determining device accuracy during consumer use conditions.

Statistical Analysis

All analyses were performed in R (version 3.4.3) using R Studio (version 1.1.383). Scripts can be found on GitHub [34,35] and OSF [23]. Data can be found on OSF. Analyses were performed using the beats per minute (bpm) separately for each wearable device as compared with the gold standard ECG data for HR calculated as bpm.

Mean Error

The ME was calculated as the difference between the device measurement and the gold standard measurement.

Mean Absolute Error

The MAE was calculated as the average absolute distance between the device measurement and the gold standard measurement.

Mean Absolute Percent Error

The MAPE relative to the ECG was calculated for each wearable device by averaging the individual absolute percent errors.

Bland-Altman Analysis

Bland-Altman analysis and 95% LoA were calculated using the blandr [42] and BlandAltmanLeh R packages [43]. This is the recommended method to determine agreement between medical instruments [2,44], rather than other methods of agreement, because it is unlikely that devices will have an exact agreement, and therefore, the importance lies in how close pairs of observations are, as small differences between devices are unlikely to impact patient decisions [45].

Concordance Class Correlation

Finally, although not one of the analyses that was preregistered, we also ran concordance class correlation (CCC) analyses between the ECG and each wearable device separately across all conditions using the DescTools R Package [46] to assist in Bland-Altman plot interpretation. In line with prior wearable research [8], the strength of agreement was interpreted based on the following, weak (CCC<.5), moderate (CCC=.5-.7), and strong (CCC>.7).

Results

Descriptives

The ECG collected 1424 HR observations, the Apple Watch 3 collected 394 HR observations (only collects measurements every 10 min, except during walking and running), and the Fitbit Charge 2 collected 1425 observations, resulting in a total of 3243 HR observations across devices (see Figure 1). See Table 1 for number of observations and HR descriptive statistics for each condition. See Figure 2 for descriptives of HR trajectories across the 24 hours with activity type (note that the bottom figure has less resolution as the Apple Watch 3 collected HR every 10 min, except for walking and running conditions).

Figure 1. Rainbow plot of heart rate observations for electrocardiogram (ECG), Fitbit Charge 2, and Apple Watch 3. bpm: beats per minute.

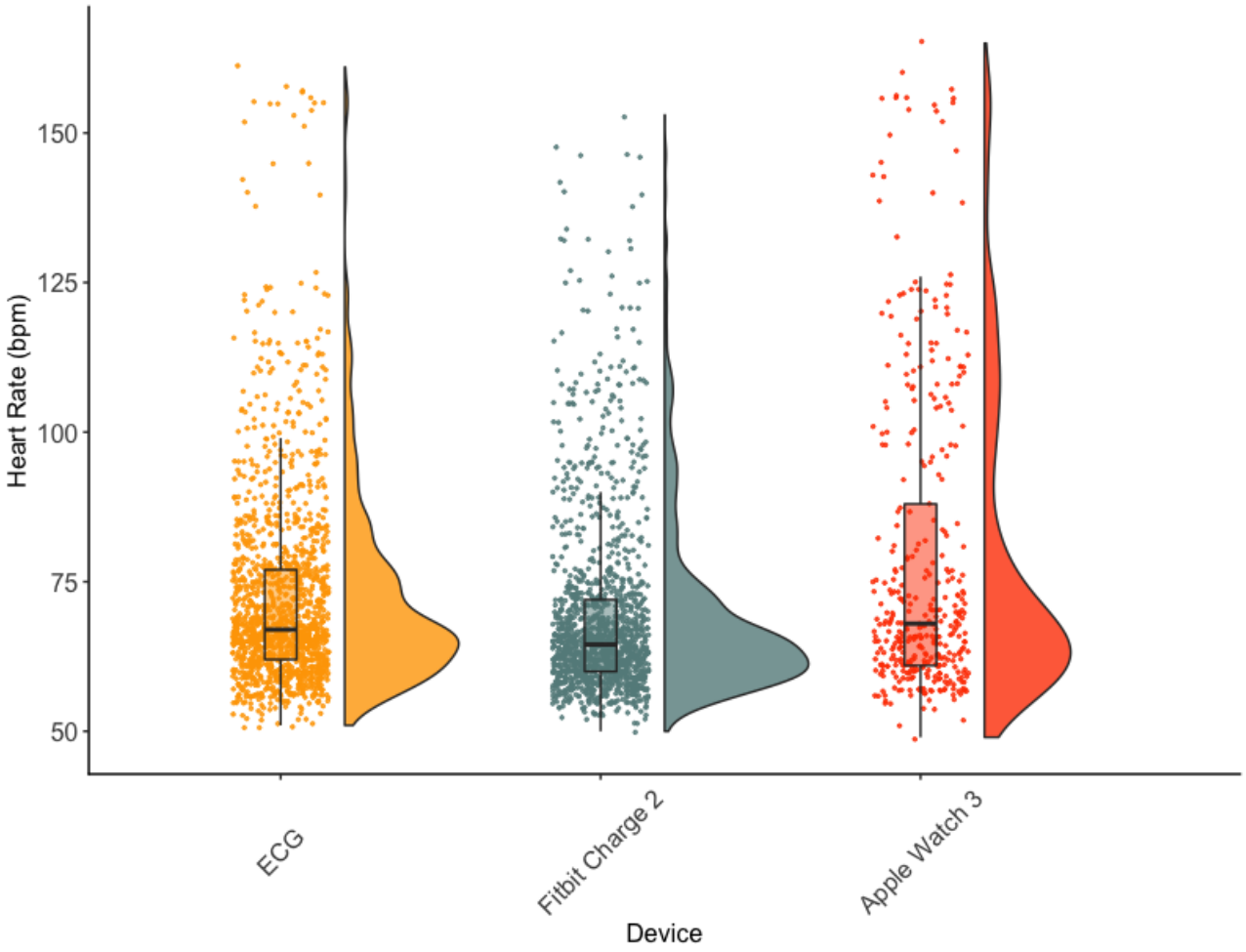
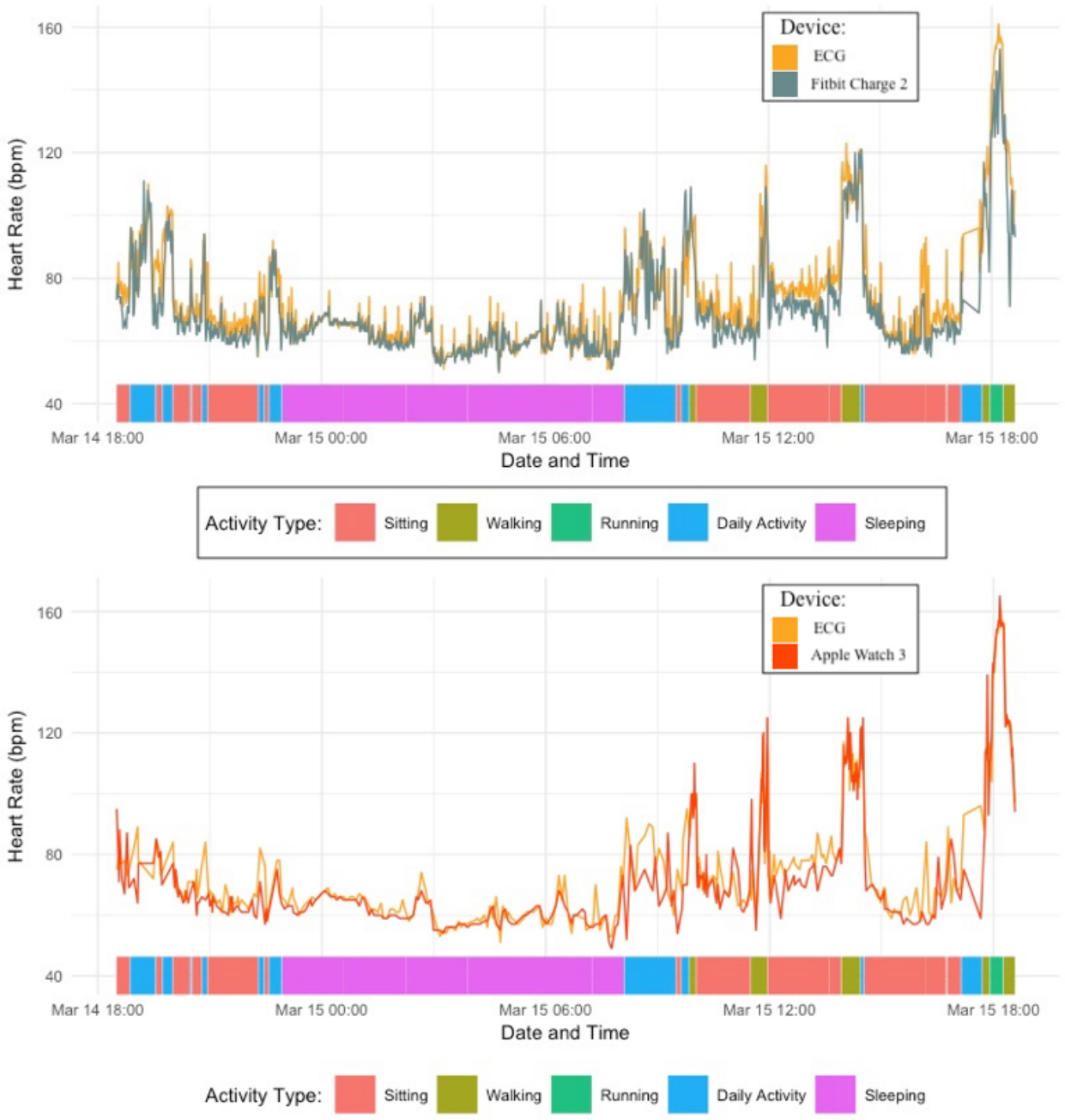


Table 1. Heart rate descriptive statistics by condition.

Activity and device	Observations, n	Heart rate, mean (SD)	Heart rate range
24 hours			
ECG[a]	1424	72.65 (16.92)	51-161
Apple Watch 3	394	78.78 (25.74)	49-165
Fitbit Charge 2	1446	69.10 (15.10)	50-153
Sitting			
ECG	535	70.41 (7.24)	55-97
Apple Watch 3	144	67.91 (7.69)	54-98
Fitbit Charge 2	535	65.72 (5.51)	55-91
Walking			
ECG	100	102.32 (16.87)	61-127
Apple Watch 3	79	106.06 (15.03)	55-139
Fitbit Charge 2	100	95.47 (17.88)	54-132
Running			
ECG	22	147.82 (13.13)	104-161
Apple Watch 3	22	149.59 (10.24)	120-165
Fitbit Charge 2	22	133.09 (12.72)	95-153
Activities of daily living			
ECG	216	84.16 (11.28)	58-115
Apple Watch 3	34	74.94 (14.53)	52-125
Fitbit Charge 2	214	80.38 (13.08)	56-121
Sleeping			
ECG	551	61.93 (4.94)	51-78
Apple Watch 3	110	60.60 (4.06)	49-73
Fitbit Charge 2	551	60.82 (4.40)	50-74

[a]ECG: electrocardiogram.

Figure 2. Fitbit Charge 2 (top) and Apple Watch 3 (bottom) compared to the electrocardiogram (ECG) across 24-hours. bpm: beats per minute.



Percent Error

Overall, across the 24-hour recording, the Apple Watch 3 had a MAPE of 5.86%, whereas the Fitbit Charge 2 had MAPE of 5.96%. During sitting conditions, the Apple Watch 3 had a MAPE of 7.21%, whereas the Fitbit Charge 2 had a MAPE of 6.93%. During walking conditions, the Apple Watch 3 had a MAPE of 4.64%, whereas the Fitbit Charge 2 had a MAPE of 9.21%. During the running condition, the Apple Watch 3 had a MAPE of 3.01%, whereas the Fitbit Charge 2 had a MAPE of 9.88%. During ADL, the Apple Watch 3 had a MAPE of 13.70%, whereas the Fitbit Charge 2 had a MAPE of 8.29%. Finally,, during the sleep condition, the Apple Watch 3 had a MAPE of 3.12%, whereas the Fitbit Charge 2 had a MAPE of 3.36% (see Table 2 for percent error statistics and Figure 3 for MAPE by device across activities).

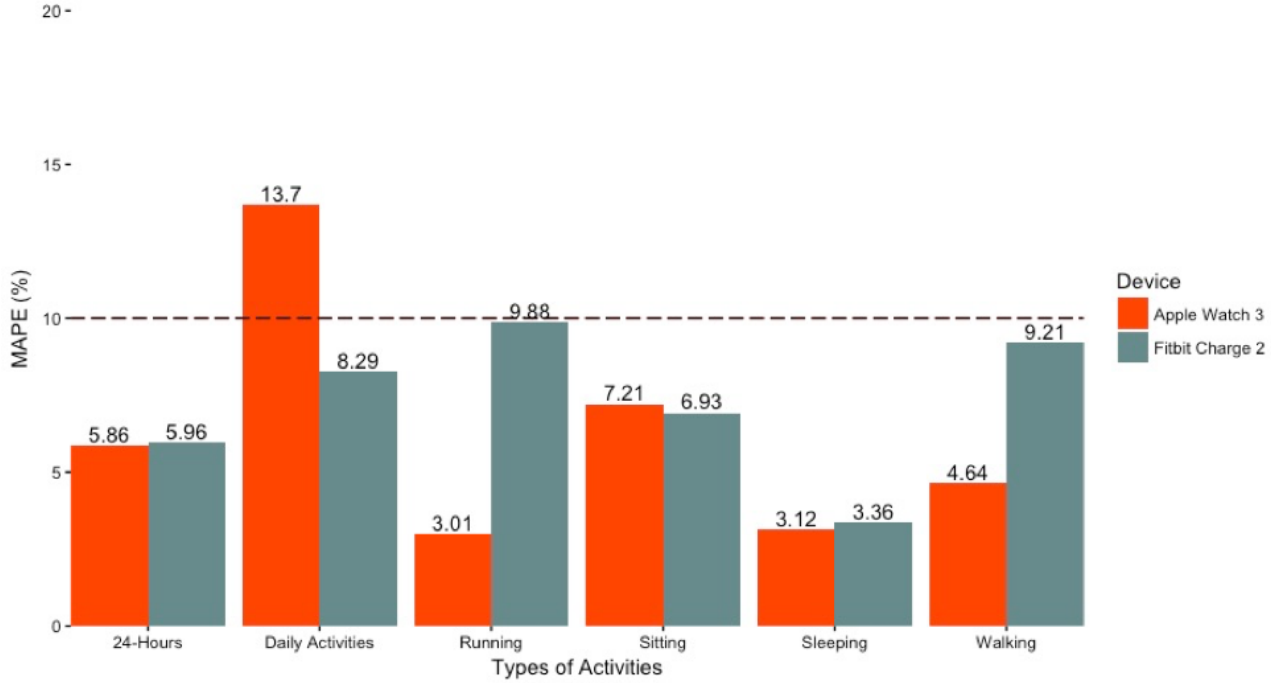
Table 2. Device error statistics and Bland-Altman analyses.

Activity and device	Device error			Bland-Altman analysis	
	Mean absolute error	Mean absolute percent error[a] (%)	Mean error (SD)	Lower LoA[b]	Upper LoA
24 hours					
Apple Watch 3	4.72	5.86	−1.80 (7.40)	−16.31	12.71
Fitbit Charge 2	4.71	5.96	−3.47 (6.17)	−15.55	8.62
Sitting					
Apple Watch 3	5.24	7.21	−2.47 (7.39)	−16.94	12.01
Fitbit Charge 2	5.93	6.93	−4.69 (4.90)	−14.29	4.91
Walking					
Apple Watch 3	4.77	4.64	0.11 (7.29)	−14.18	14.41
Fitbit Charge 2	9.55	9.21	−6.85 (11.05)	−28.51	14.81
Running					
Apple Watch 3	4.05	3.01	1.77 (5.90)	−9.78	13.33
Fitbit Charge 2	14.73	9.88	−14.73 (7.67)	−29.77	0.31
Activities of daily living					
Apple Watch 3	11.74	13.70	−8.50 (12.90)	−33.78	16.78
Fitbit Charge 2	7.05	8.29	−3.73 (8.24)	−19.88	12.41
Sleeping					
Apple Watch 3	1.96	3.12	−0.95 (2.78)	−6.39	4.50
Fitbit Charge 2	2.15	3.36	−1.11 (3.20)	−7.28	5.17

[a]Validity was established as devices having a MAPE value <10%.

[a]LoA: limits of agreement.

Figure 3. Mean absolute percent error (MAPE) by device across types of activities. Note: Horizontal line represents threshold for validity.



Bland-Altman Analysis and 95 Percent Limits of Agreement

Overall, across the 24-hour recording (see Figure 4), the Apple Watch 3 had an ME of −1.80 bpm (lower LoA-upper LoA: −16.31 to 12.71 bpm) and an MAE of 4.72, whereas the Fitbit Charge 2 had an ME of −3.47 bpm (lower LoA-upper LoA: −15.54 to 8.62 bpm) and an MAE of 4.71. Visual inspection of the Bland-Altman plots revealed a tendency for the Apple Watch 3 to both over- and underestimate HR values when observations were between 70 bpm to120 bpm, whereas the Fitbit Charge 2 had a tendency to underestimate HR values, particularly once HR values exceeded approximately 80 bpm (see Table 3 for Bland-Altman statistics).

During sitting conditions, the Apple Watch 3 had an ME of −2.47 bpm (lower LoA-upper LoA: −16.94 to 12.01 bpm) and an MAE of 5.24, whereas the Fitbit Charge 2 had an ME of −4.69 bpm (lower LoA-upper LoA; −14.29 to 4.91 bpm) and an MAE of 5.93. During walking conditions, the Apple Watch 3 had an ME of 0.11 bpm (lower LoA-upper LoA: −14.18 to 14.41 bpm) and an MAE of 4.77, whereas the Fitbit Charge 2 had an ME of −6.85 bpm (lower LoA-upper LoA: −28.51 to 14.81 bpm) and an MAE of 9.55. During the running condition, the Apple Watch 3 had an ME of 1.77 bpm (lower LoA-upper LoA: 9.78 to 13.33 bpm) and an MAE of 4.05, whereas the Fitbit Charge 2 had an ME of −14.73 bpm (lower LoA-upper LoA: −29.77 to 0.31 bpm) and an MAE of 14.73. During ADL, the Apple Watch 3 had an ME of −8.50 bpm (lower LoA-upper LoA: −33.78 to 16.78 bpm) and an MAE of 11.74, whereas the Fitbit Charge 2 had an ME of −3.73 bpm (lower LoA-upper LoA: −19.88 to 12.41 bpm) and an MAE of 7.05. Finally, during the sleep condition, the Apple Watch 3 had an ME of −0.95 bpm (lower LoA-upper LoA: −6.39 to 4.50 bpm) and an MAE of 1.96, whereas the Fitbit Charge 2 had an ME of −1.11 bpm (lower LoA-upper LoA: −7.28 to 5.17 bpm) and an MAE of 2.15 (see Table 3 for device error and Bland-Altman statistics and Figures 5-9 for Bland-Altman plots by activity type).

Figure 4. Bland-Altman plot and density plots across 24-hours of the Apple Watch 3 (left) with 394 heart rate observations and Fitbit Charge 2 (right) with 1425 heart rate observations.

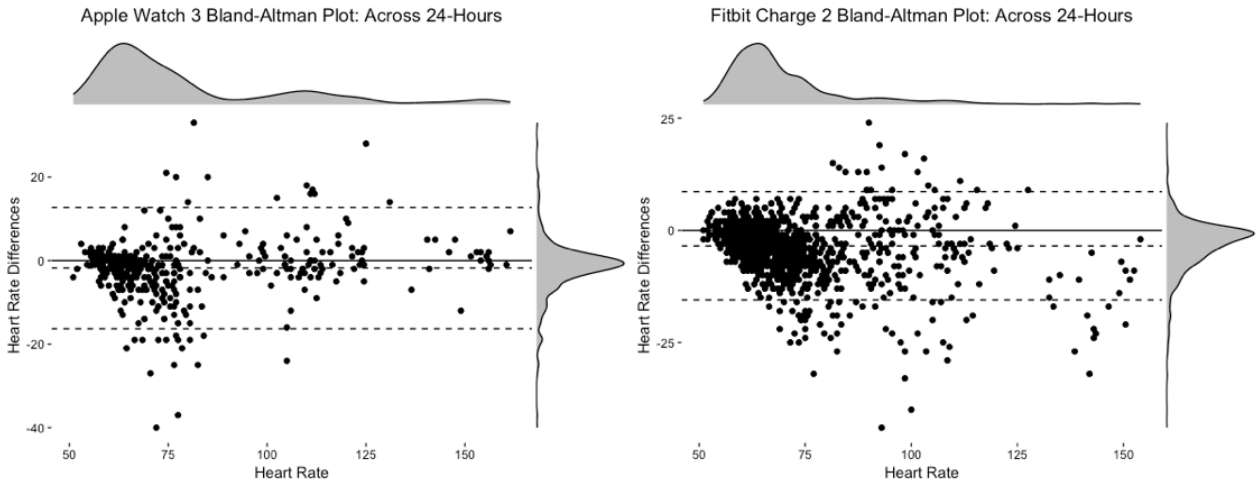


Table 3. Device error statistics and Bland-Altman analyses.

Activity and device	Device error		Bland-Altman analysis	
	Mean absolute error	Mean error (SD)	Lower LoA[a]	Upper LoA
24 hours				
Apple Watch 3	4.72	−1.80 (7.40)	−16.31	12.71
Fitbit Charge 2	4.71	−3.47 (6.17)	−15.55	8.62
Sitting				
Apple Watch 3	5.24	−2.47 (7.39)	−16.94	12.01
Fitbit Charge 2	5.93	−4.69 (4.90)	−14.29	4.91
Walking				
Apple Watch 3	4.77	0.11 (7.29)	−14.18	14.41
Fitbit Charge 2	9.55	−6.85 (11.05)	−28.51	14.81
Running				
Apple Watch 3	4.05	1.77 (5.90)	−9.78	13.33
Fitbit Charge 2	14.73	−14.73 (7.67)	−29.77	0.31
Activities of daily living				
Apple Watch 3	11.74	−8.50 (12.90)	−33.78	16.78
Fitbit Charge 2	7.05	−3.73 (8.24)	−19.88	12.41
Sleeping				
Apple Watch 3	1.96	−0.95 (2.78)	−6.39	4.50
Fitbit Charge 2	2.15	−1.11 (3.20)	−7.28	5.17

[a]LoA: limit of agreement.

Figure 5. Bland-Altman plots by daily activity. Left: Apple Watch 3 during sitting; right: Fitbit Charge 2 during sitting.

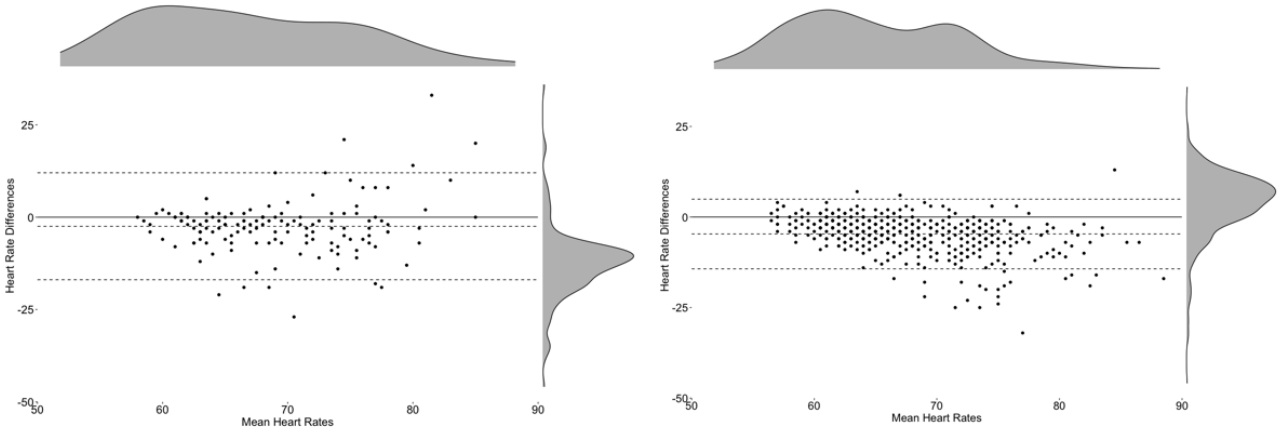


Figure 6. Bland-Altman plots by daily activity. Left: Apple Watch 3 during walking; right: Fitbit Charge 2 during walking.

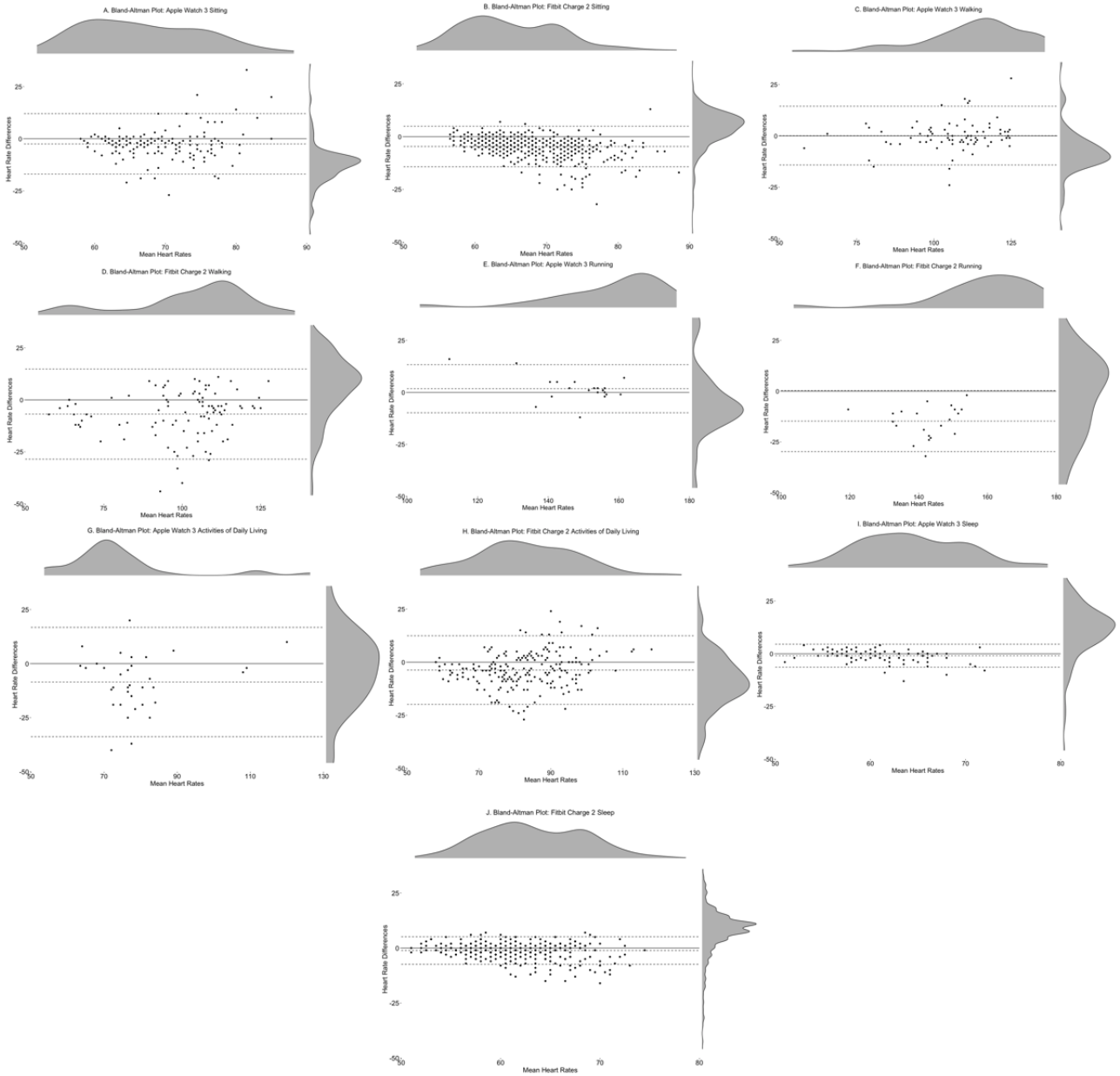


Figure 7. Bland-Altman plots by daily activity. Left: Apple Watch 3 during running; right: Fitbit Charge 2 during running.

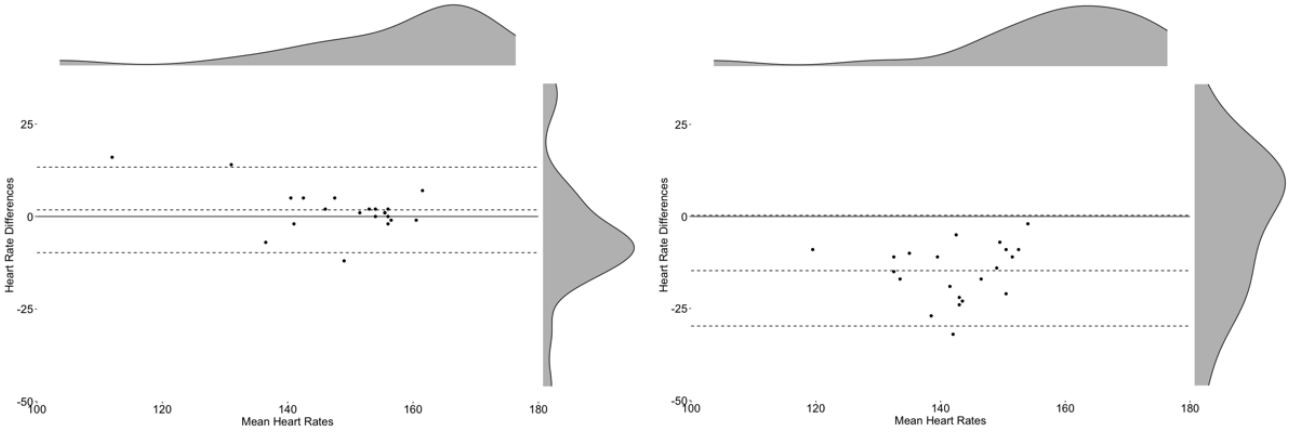


Figure 8. Bland-Altman plots by daily activity. Left: Apple Watch 3 during activities of daily living; right: Fitbit Charge 2 during activities of daily living.

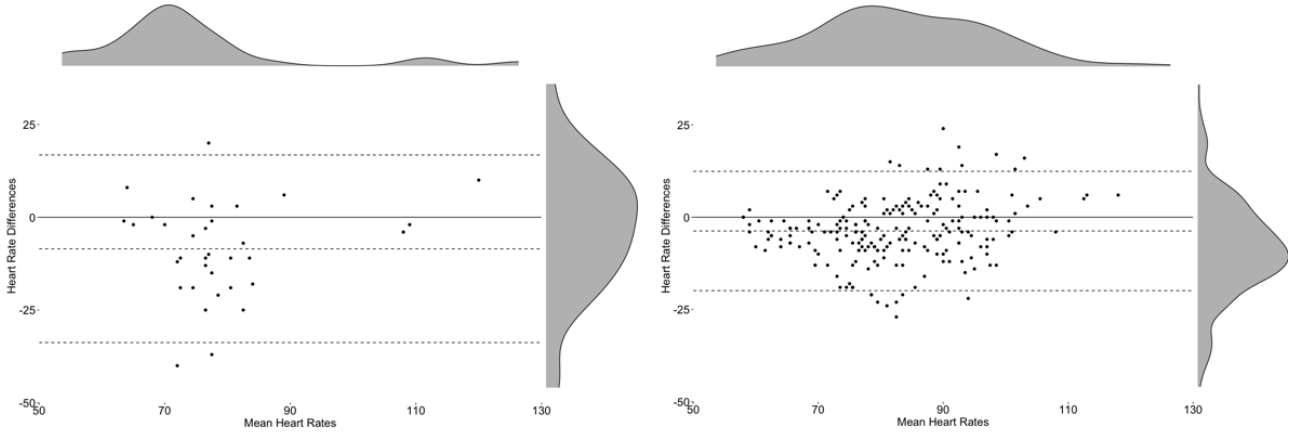
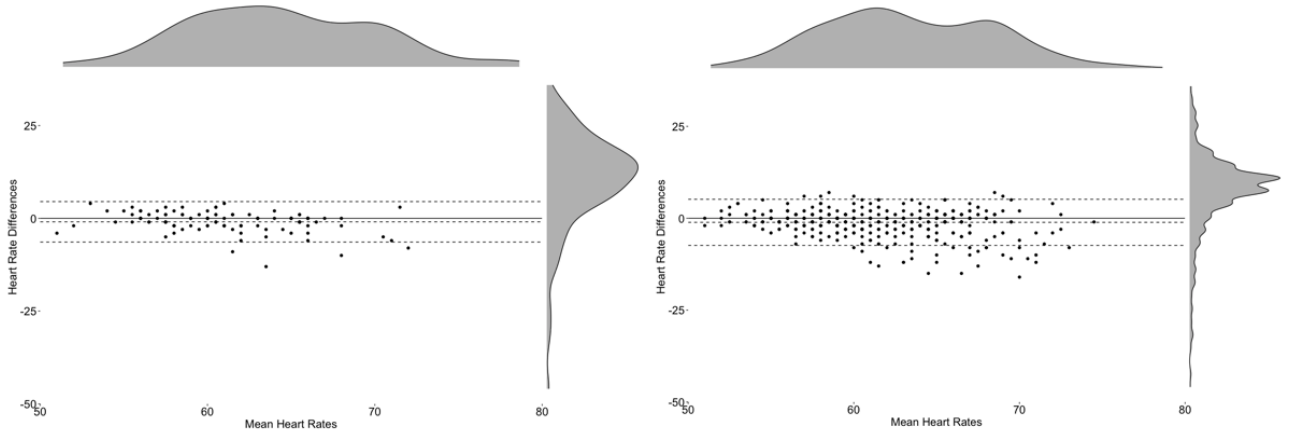


Figure 9. Bland-Altman plots by daily activity. Left: Apple Watch 3 during sleep; right: Fitbit Charge 2 during sleep.



Concordance Class Correlation

Overall, across the 24-hour recording, the Apple Watch 3 (CCC=.955, 95% CI 0.945-0.963) and the Fitbit Charge 2 (CCC=.906, 95% CI 0.896-0.914) had strong agreement with the reference method. During sitting conditions, the Apple Watch 3 (CCC=.453, 95% CI 0.321-0.567) had weak agreement and the Fitbit Charge 2 (CCC=.561, 95% CI 0.515-0.603) had moderate agreement with the reference method. During all walking activities, the Apple Watch 3 (CCC=.871, 95% CI 0.807-0.915) and the Fitbit Charge 2 (CCC=.740, 95% CI 0.645-0.812) had strong agreement with the reference method. During the running condition, the Apple Watch 3 (CCC=.864, 95% CI 0.731-0.934) had strong agreement with the reference method, whereas the Fitbit Charge 2 (CCC=.490, 95% CI 0.268-0.663) had weak agreement with the reference method. During the ADL condition, the Apple Watch 3 (CCC=.460, 95% CI 0.204-0.656) had weak agreement with the reference method, whereas the Fitbit Charge 2 (CCC=.739, 95% CI 0.676-0.791) had strong agreement with the reference method. Finally, during the sleep condition, the Apple Watch 3 (CCC=.791, 95% CI 0.715-0.849) and the Fitbit Charge 2 (CCC=.745, 95% CI 0.707-0.779) had strong agreement with the reference method.

Discussion

Principal Findings

This study provided the first continuous and ecologically valid assessment of the accuracy of the Apple Watch 3 and the Fitbit Charge 2 as they were devised to be used by consumers (ie, during ecologically valid daily activities) during a 24-hour paradigm of consumer device use conditions.

In line with previous controlled laboratory research [4,5,7-9,11,12], our findings indicated that both wearable devices provided acceptable overall aggregated accuracy (<10% MAPE) across the 24-hour recording period as well as during each type of activity, except for the Apple Watch 3 during ADL. In addition, in line with previous research, both the Apple Watch 3 and the Fitbit Charge 2 slightly underestimated HR across the 24-hour study as compared with ECG and other reference methods [3,4,6,8-11], although this underreporting of absolute HR is unlikely to be problematic in most contexts as this was less than 5 bpm. Although these wearables slightly underestimated HR when values were aggregated by activity, there were a number of individual observations that were inaccurate by significantly large margins, which would be problematic in some contexts (eg, medical settings). This has potential implications for liability of device usage in medical settings [47], indicating that although overall summary statistics

may be very accurate for research purposes, any single observation in real time may have a large degree of error, which could be significant for moment-to-moment observations in medical settings. In addition, we found it surprising that the Apple Watch 3 had such a high MAPE (13.70%) during ADL as compared with the Fitbit Charge 2 MAPE (8.29%). This difference was likely because of the fact that the Apple Watch 3 was worn on the dominant hand, which may have made more erratic movements than the Fitbit Charge 2 on the nondominant hand during ADL. In other words, this may have potentially moved the position of the wearable more frequently on the dominant hand, making it more difficult for the PPG sensor to assess and accurately measure HR, as has been found in prior studies [18].

Overall, the Apple Watch 3 had acceptable error across the entire 24-hour period as well as all activities except when the error rate rose above the ±10% threshold for the Apple Watch 3 during ADL (13.70%), while the Fitbit Charge 2 had acceptable error across the entire 24-hour period as well as all activities, although its error got close to the ±10% threshold during walking (9.21%) and running (9.88%). In addition, both devices slightly underestimated heart rate. Finally, as movement became more erratic during certain conditions and as HR increased, the devices became less accurate.

Strengths and Limitations

This study had a number of strengths that addressed 4 current limitations in wearable studies: this study (1) used a gold standard comparison method for movement within daily life—ambulatory ECG, (2) reported firmware numbers, (3) increased the ecological validity of wearable HR accuracy by taking place during actual consumer device use conditions across a 24-hour period, and (4) took place within an individual, rather than a traditional group of research participants, which creates a novel rapid response design to quickly assess initial wearable HR accuracy in order for the research cycle to keep pace with technological advancements while also controlling for between-subject variability and most potential confounding variables, which allowed for the wearable devices to be the only study variable that varied, thus, providing a powerful test of device accuracy. Furthermore, prior research has shown that there is a 24-hour circadian rhythm to HR [48] and that this can be particularly important as adverse cardiovascular events such as heart attacks, stroke, and cardiac deaths tend to occur in the late mornings [49]. The approach of this study also captured the 24-hour circadian rhythm HR from 3 different devices during real-life conditions, which indicates that these devices can detect changes in HR across the day.

In addition to these strengths, there were also a number of limitations. First, the single-subject design limited various participant demographic factors, such as body mass index, skin tone, and wrist circumference, which have been shown to correlate with HR error rate [7,16]. Future studies should attempt to replicate these results across multiple individuals with diverse body mass index, wrist circumference, skin tone, fitness level, and stress level. Another limitation in this study was that the Fitbit Charge 2 and Apple Watch 3 collected HR measurements at different frequencies. Specifically, the Fitbit Charge 2 recorded an HR measurement each minute, whereas the Apple Watch 3 collected continuous HR measurements during walking and running tasks (the average of these measurements was used for each minute in line with prior research [7]) and every 10 min for all other activities. This discrepancy in device sampling rates combined with proprietary underlying algorithms for the way per minute HR is calculated for each wearable device might help account for the lower reported accuracy of the Apple Watch 3 during the ADL condition. In addition, the single-subject design combined with the Apple Watch 3 sampling rate of approximately every 10 min led to a small number of observations for some conditions. Although continuous recording was not activated on the Apple Watch 3 to approximate real-world usage conditions, future studies should aim to collect larger numbers of subjects to increase the observations for each condition and potentially activate continuous recording on this device. Similarly, although this study had the strength of providing the first 24-hour continuous and ecologically valid assessment of wearable accuracy in real-world conditions, this was also a limitation as this design inherently could not take place within more controlled laboratory settings that used a stationary ECG, rather than an ambulatory ECG that may introduce some additional error. In fact, the running condition had to take place on a treadmill to keep the ECG device stable enough to prevent excessive artifacts. Another limitation of this study is that although that overall error rates of both devices were low, there were some individual observations that were inaccurate by significantly large margins. This indicates that although overall summary statistics for conditions may be very accurate, any single observation in real time may have a large degree of error. Researchers should keep this in mind when using wearable devices in research settings, and this finding emphasizes the importance of data cleaning. Implementing these devices in research settings would likely benefit from automated outlier detection and deletion techniques as would the underlying scoring algorithms. Finally, this study did not counterbalance wrist placement of the wearables to rule out potential influences of wrist circumference, musculature, or movement on the accuracy of HR readings. The subject was right-handed, and therefore, the lower accuracy of the Apple Watch 3 as compared with the Fitbit Charge 2 during the ADL condition may have been because of more erratic wrist motions that accompany many activities in this condition as prior research has indicated that the lack of smooth wrist movements introduces larger HR measurement error [10]. Future studies should provide both between-subjects analyses and within-subjects analyses with devices on both wrists to assess the accuracy of wearables, as hand dominance may influence accuracy.

Conclusions

This study provided the first continuous and ecologically valid assessment of the accuracy of the Apple Watch 3 and the Fitbit Charge 2 HR measurements as they were devised to be used by consumers out in the real world during a 24-hour paradigm of actual consumer device use conditions. Overall, both the Apple Watch 3 and Fitbit Charge 2 had acceptable HR accuracy when aggregated overall across the 24-hour period and during each condition, except for the Apple Watch 3 during the ADL

condition. In addition, both the Apple Watch 3 and Fitbit Charge 2 slightly underestimated HR. Furthermore, both erratic wrist movements and higher HR were associated with lower device accuracy. It is important to note that although overall HR accuracy statistics for most conditions were acceptable, there were a number of individual observations that varied widely from the gold standard ECG, which indicates that any single measurement viewed in real time cannot be interpreted as an accurate measurement that has implications for medical liability of device usage [47]. Overall, wearable devices likely will not be replacing the gold standard ECG in a medical setting anytime soon, but both the Apple Watch 3 and the Fitbit Charge 2 can be used to supplement these gold standard methods in research and clinical applications. They may be particularly useful in big data studies as these devices had acceptable error rate in almost all activities while being relatively cheap, mobile, unobtrusive, and scalable as compared with gold standard medical equipment.

Conflicts of Interest

None declared.

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Abbreviations

ADL: activities of daily living
bpm: beats per minute
CCC: concordance class correlation
ECG: electrocardiogram
HR: heart rate
LoA: limit of agreement
MAE: mean absolute error
MAPE: mean absolute percent error
ME: mean error
OSF: Open Science Framework
PPG: photoplethysmography

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Original Paper

Physical Activity Trend eXtraction: A Framework for Extracting Moderate-Vigorous Physical Activity Trends From Wearable Fitness Tracker Data

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Abstract

Background: Moderate-vigorous physical activity (MVPA) offers extensive health benefits but is neglected by many. As a result, a wide body of research investigating physical activity behavior change has been conducted. As many of these studies transition from paper-based methods of MVPA data collection to fitness trackers, a series of challenges arise in extracting insights from these new data.

Objective: The objective of this research was to develop a framework for preprocessing and extracting MVPA trends from wearable fitness tracker data to support MVPA behavior change studies.

Methods: Using heart rate data collected from fitness trackers, we propose Physical Activity Trend eXtraction (PATX), a framework that imputes missing data, recalculates personalized target heart zones, and extracts MVPA trends. We tested our framework on a dataset of 123 college study participants observed across 2 academic years (18 months) using Fitbit Charge HRs. To demonstrate the value of our frameworks' output in supporting MVPA behavior change studies, we applied it to 2 case studies.

Results: Among the 123 participants analyzed, PATX labeled 41 participants as experiencing a significant increase in MVPA and 44 participants who experienced a significant decrease in MVPA, with significance defined as $P<.05$. Our first case study was consistent with previous works investigating the associations between MVPA and mental health. Whereas the second, exploring how individuals perceive their own levels of MVPA relative to their friends, led to a novel observation that individuals were less likely to notice changes in their own MVPA when close ties in their social network mimicked their changes.

Conclusions: By providing meaningful and flexible outputs, PATX alleviates data concerns common with fitness trackers to support MVPA behavior change studies as they shift to more objective assessments of MVPA.

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KEYWORDS

mHealth; fitness trackers; activity trackers; exercise; health behavior; physical activity; health; mental health; perception; social network

Introduction

Motivation

Recently labeled as 1 of 5 low-risk healthy lifestyle factors associated with reducing all-cause mortality and extending life expectancy, moderate-vigorous physical activity (MVPA) is fundamental to maintaining proper health [1]. MVPA, such as brisk walking, running, or aerobic exercise, boosts the immune system, lowers stress levels, and has been linked to the prevention of many chronic diseases including cardiovascular disease, diabetes, cancer, hypertension, obesity, depression, and anxiety [2-6]. Although a critical component of health, many individuals still lead predominantly sedentary lifestyles, increasing their risk of developing health complications [7,8].

In response, a wealth of research investigating MVPA behavior change has been conducted across all ages, ranging from longitudinal and exploratory studies to targeted interventions [9-11]. However, many of these studies have relied on subjective and intermittent measures of MVPA with surveys acting as the primary method of data collection, often administered only twice: at baseline and follow-up assessments. To leverage more objective measures of MVPA, many recent study designs have begun to incorporate wearable fitness trackers [12].

Although the mobility and minimally invasive nature of these wearable devices posit them as ideal tools for objective MVPA assessments, data generated from these devices cannot be as readily analyzed in comparison to survey data [13]. Preprocessing steps must be taken to address biases in device measurement and the highly granular nature of time series data [14].

To leverage the strengths of fitness tracker data for MVPA behavior change studies, a framework is necessary to alleviate data concerns and extract meaningful trends, which better conform to more traditional statistical analyses.

Background

To ensure more objective measurements of MVPA, recent behavior change studies have begun to adopt wearable fitness trackers. Despite the long-term capabilities of these devices, many study designs track participants for only a limited time (typically 1 week) during assessment periods [15-20]. Through this design, the amount of MVPA performed in each assessment window can be summed and treated as any other repeated measures variable, more akin to survey responses.

Investigations into gathering new insights from these intermittent measurements have also been conducted. Sprint et al proposed a framework for automatically detecting behavior changes given 2 windows or samples of fitness tracker data [21]. The work expanded upon activity change detection to determine whether the change was significant, providing visualizations and summary data to better understand what type of change had occurred.

Many novel approaches exist for detecting behavior change; however, their focus is often outside of MVPA, such as investigating smart home sensors for eldercare monitoring and security threats [22,23]. Although other works focus on general change-point detection in time series, they lack the insights necessary for understanding physical activity (PA) data [24]. As such, limited work exists that focuses specifically on using highly-granular long-term data to monitor MVPA behaviors.

Objectives

The objective of this research was to develop a framework for assessing MVPA behavior changes using continuous and objective data provided by fitness trackers. To do so, we propose Physical Activity Trend eXtraction (PATX): a framework for preprocessing and extracting MVPA trends from heart rate (HR) data. To demonstrate how these extracted trends can support MVPA behavior change research, we provide 2 case studies, drawing comparisons to previous research and demonstrating novel behavior change analysis.

Methods

NetHealth Study

Study Design and Data

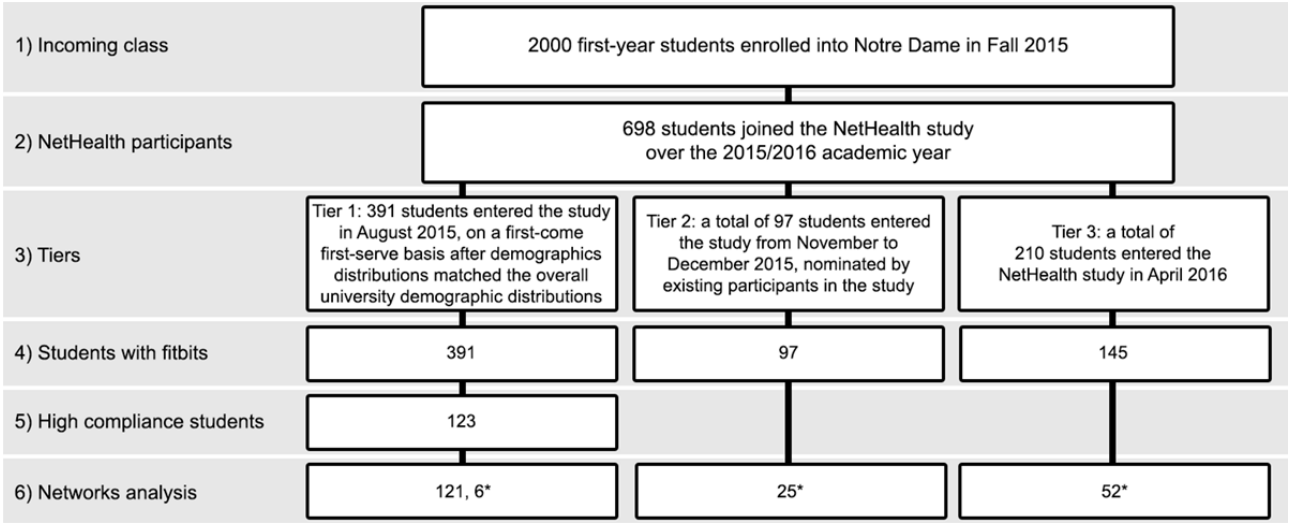
The data used in this paper come from the NetHealth study conducted at the University of Notre Dame. All procedures were fully approved by the institutional review board before distribution.

Participants were recruited across 3 tiers based on when they entered the study, the process and sample numbers are outlined in Figure 1. A total of 391 Tier-1 participants were recruited via an interest survey in June 2015 and solicitations made through email and a Facebook page. Recruitment was on a first-come, first-serve basis after matching the overall demographic distributions of the university. A total of 97 Tier-2 participants were then recruited in November and December 2015, nominated by existing participants in the study. Finally, 210 Tier-3 participants entered the study in April 2016. Participants received a Fitbit Charge HR either before arriving on campus, after arrival, or in the Spring 2016 semester, depending on when they entered the study.

The NetHealth study features a collection of demographic, psychometric, social network, and health behavior data. Demographic and psychometric data were collected through surveys administered to participants once a semester. Health behaviors, PA, and sleep were captured through Fitbit Charge HRs. Participants were asked to wear their devices as much as possible and sync them every 4 to 7 days. Participants' social networks were mapped through phone calls and short message service (SMS) text messages recorded via a smartphone app.

Fitbit data spanned 2 academic years: 2015 to 2016 and 2016 to 2017. Seasonal breaks were removed from consideration as compliance issues were most severe during these times and days were not representative of a participant's time on campus [25]. This left a time span of 18 months with 9 months per academic year equating to roughly 4 and 1/2 months per semester.

Figure 1. Consort diagram of NetHealth recruitment and participants selected for this analysis in this paper. Asterisks indicate participants added as additional alters for the ego-network analysis in case study 2.



Cohort Selection

Among the 698 NetHealth participants, 65 were removed from consideration as they were not issued Fitbits, with reasons ranging from participants declining them to dropping the study before the device could be issued (Figure 1, level 4). Furthermore, we chose to investigate only Tier-1 participants as Tiers 2 and 3 did not enter the study until late Fall 2015 and Spring 2016. Including sufficient data from Fall 2015 was critical to our analysis as the initial weeks in this semester served as our best proxy to understanding participants' MVPA behaviors before entering college and fully adjusting to a different environment and forming new social networks.

Participants with extended periods of missing data were excluded to avoid biases from noncompliance. This was measured by the number of compliant days in each participant's *least compliant* semester. A day was considered *compliant* if the participants wore their Fitbit for a minimum of 80% (19 hours). This threshold was determined by computing the total number of daily records that would be eligible for analysis at each minimum daily wear time. Sweeping from 100% to 0% with a step size of 10, we found 80% acted as an inflection point for minimum daily wear time, making 77% of all daily records eligible, after which any gain in the cumulative number of records rapidly diminished. Furthermore, this allowed for consistency with other NetHealth studies including subjects with at least 80% of compliance, as this threshold was noted as appropriate for accurate estimation of PA and sleep [25].

A distribution of the number of compliant days in each participants' least compliant semester is shown in Figure 2. A total of 182 participants had a semester of 0 compliant days, which can be attributed to participants dropping the study. Ignoring these participants, the median number of compliant days in a participant's least compliant semester was 49, approximately *half* of the total days in a semester. A total of 123 participants were above this median of 49 compliant days per semester and were selected as the cohort for analysis in this paper (Figure 1, level 5). A demographic overview of these participants is provided in Table 1. Comparisons were made between the 123 participants included in the study and the 510 excluded, which we address in our *Limitations* section.

Figure 2. Distribution of participants' number of compliant days in their least compliant semester across the 4 semesters measured.

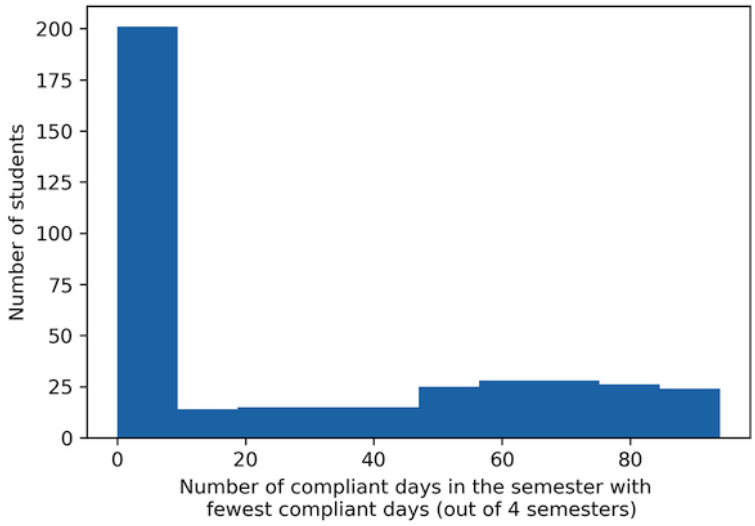


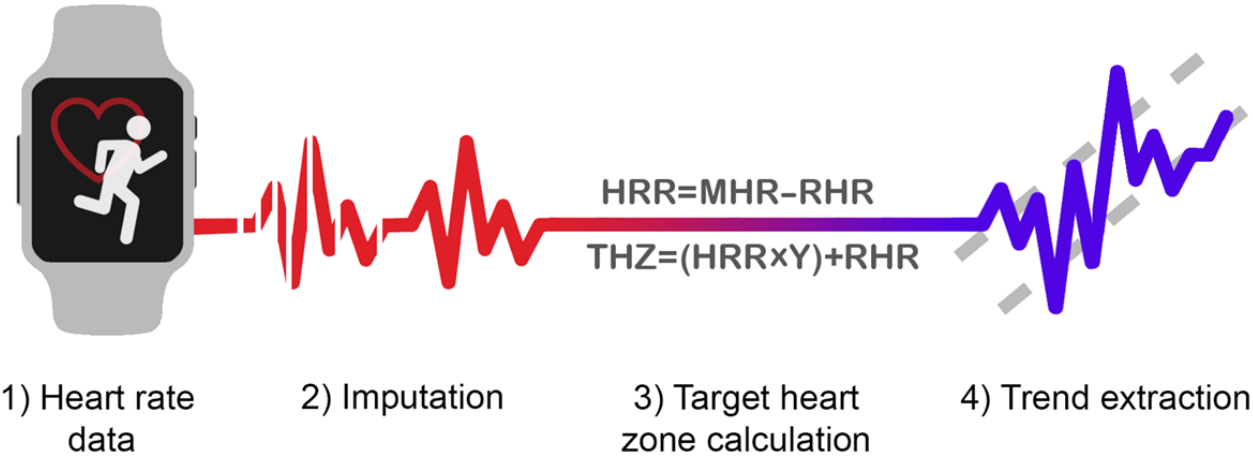
Table 1. Comparison of baseline characteristics between Fitbit participants included in this analysis and participants excluded based on compliance.

Variable	Included (n=123)	Excluded (n=510)
Age (years), mean (SD)	17.8 (0.4)	17.7 (0.5)
Gender, n (%)[a]		
Male	65 (52.8)	265 (51.9)
Female	58 (47.1)	245 (48.0)
Race, n (%)[b]		
White	81 (65.8)	335 (65.6)
Latino	21 (17.0)	57 (11.1)
Asian	12 (9.7)	46 (9.0)
Black	4 (3.2)	34 (6.6)
Foreign	4 (3.2)	38 (7.4)
Unknown	1 (0.8)	0 (0.0)
High school, n (%)[a]		
Public school	64 (52.0)	253 (49.6)
Private school	59 (47.9)	245 (48.0)
Home school	0 (0.0)	2 (0.3)
Other	0 (0.0)	10 (1.9)
Parents' income, n (%)[a]		
Less than $25,000	3 (2.4)	27 (5.2)
US $25,000-$49,999	10 (8.1)	29 (5.6)
US $50,000-$74, 999	14 (11.3)	38 (7.4)
US $75,000-$99,999	10 (8.1)	47 (9.2)
US $100,000-$149,999	25 (20.3)	97 (19.0)
US $150,000-$199,999	12 (9.7)	55 (10.7)
US $200,000-$249,999	10 (8.1)	50 (9.8)
US $250,000 or more	34 (27.6)	143 (28.0)
Unknown	5 (4.0)	24 (4.7)

[a]N=633, 100%

[b]N=632, 99.8%

Figure 3. Overview of Physical Activity Trend eXtraction (PATX): a framework for moderate-vigorous physical activity trend extraction from raw heart rate data.



Physical Activity Trend eXtraction

To accurately capture trends in participants' MVPA, we propose PATX, a framework for preprocessing HR data to extract meaningful trends in behavior. First, we justify using HR as our input for this framework and then walk through each component of PATX: imputation, target heart zone calculation, and trend extraction (Figure 3).

Inputs

Minute-by-minute HR data were used for determining MVPA. HR data were favored over steps as steps are a widely involuntary measure of one's PA. Many factors may influence steps over time, especially dynamic environments such as a college campus where destinations within daily routines are subject to change with each semester. Furthermore, steps alone cannot guarantee meeting the intensity or bout length guidelines necessary to confer health benefits, as such, benchmarks including the 10,000 steps per day goal have fallen under scrutiny [26].

Through HR data, PATX captures when individuals enter their target heart zone: a personalized HR range entered when an individual is performing MVPA [27]. To demonstrate the disparity between *minutes spent in the target heart zone* and *steps*, we conducted 2 correlation tests between these measures. The first test considered only days when users logged *steps*, and the second considered only days when users *entered their target heart zone*. For the *steps* only test, the Spearman correlation was minimal (r_s=.1) but was far stronger in the *target heart zone* only test (r_s=.85). These comparisons suggest that more time spent performing MVPA (being in the target heart zone), on average, results in more steps; however, more steps do not always result in more MVPA.

Despite favor over steps, HR is not a perfect measure of MVPA. Earlier studies have shown many wearable trackers, such as Fitbit Charge HRs, are affected by systematic errors and overestimation of certain HR zones [28,29]. To account for these errors, PATX includes 2 preprocessing steps: imputation and heart zone calculation.

Imputation

Apart from missing data because of noncompliance, we found a user's HR was not always recorded during bouts of MVPA. These gaps could be attributed to moisture interfering with the readings or the band sliding outside optimal wrist placement. Such artifacts are illustrated in Figure 4: HR begins to increase, at which point data are received only intermittently, and as HR decreases, the recordings become steady, suggesting the bout of activity has ended. As Fitbit's *cardio* and *peak* minutes do not account for these missing data, the first step in PATX was to impute such data, forming complete bouts of MVPA.

To determine the best imputation method, several algorithms were tested on complete 24-hour HR records with blocks of time set to *missing* to evaluate the accuracy of each algorithm. Incomplete 24-hour HR records were then analyzed to determine the most frequent time spans of missing data. Moreover, 1 record of daily data was pulled from each NetHealth participant at random, which had 20% of its data missing. This threshold was used as no records involved in this analysis had more than 20% of data missing as per our compliance threshold. Each record was then parsed to determine the average length of consecutive minutes that were missing. The most common missing data lengths ranged from 2 to 25 min; however, lengths as high as 150 min were also present. Given these variations, time spans of 25, 50, and 150 min were selected.

Figure 4. Minute-by-minute Fitbit recordings during a bout of elevated heart rate.

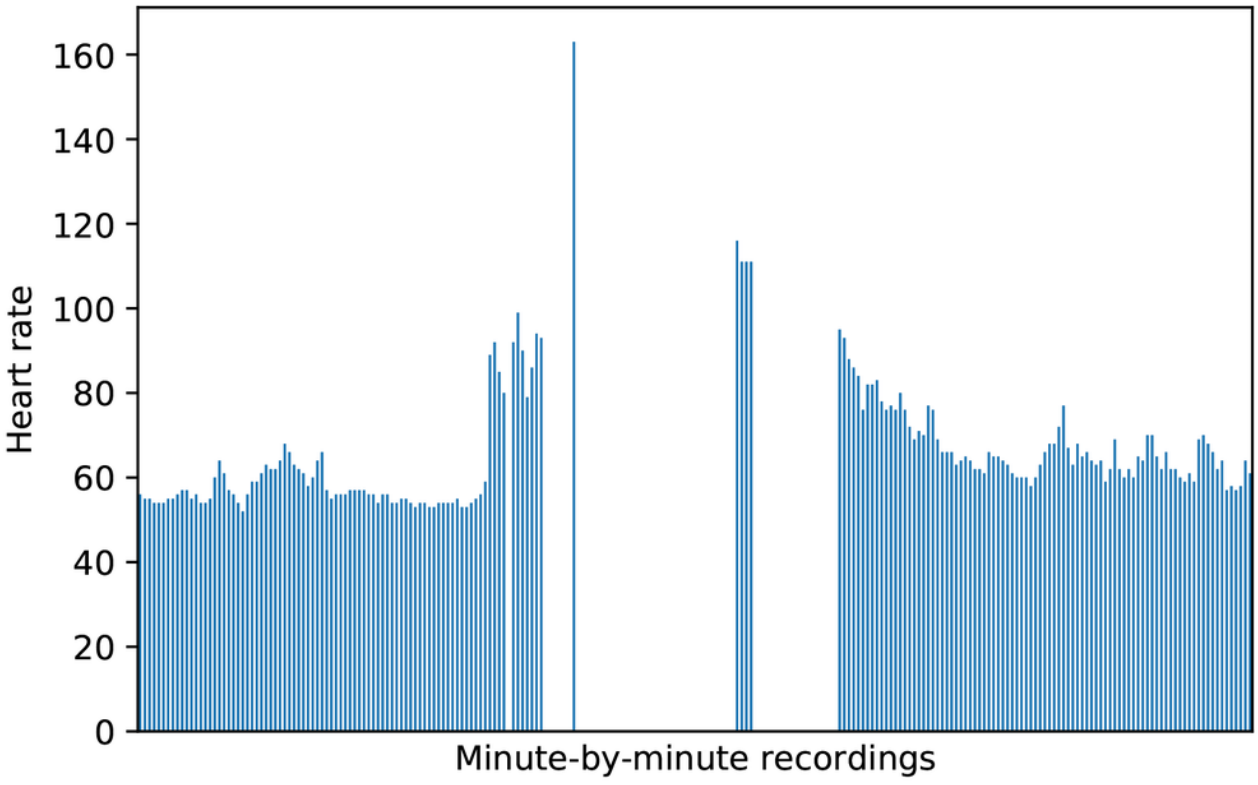


Table 2. Root-mean-square-error of best performing imputation method across various lengths of missing data.

Missing data length and method	RMSE[a]
25 min	
Kalman ARIMA[b]	10.5
Linear interpolation	10.9
Kalman structural time series	10.9
50 min	
Kalman ARIMA	13.2
Linear interpolation	12.3
Kalman structural time series	12.3
150 min	
Kalman ARIMA	14.2
Linear interpolation	13.7
Kalman structural time series	13.8

[a]RMSE: root-mean-square error.

[b]ARIMA: autoregressive integrated moving average.

Complete 24-hour HR records were then divided into blocks of 25 min, blocks were deleted at random until roughly 20% of the record was missing. Several imputation algorithms were then executed, including linear interpolation, an autoregressive integrated moving average model with a Kalman smoother, and a structural time series model with a Kalman smoother [30]. All imputation methods were evaluated using root-mean-square error (RMSE). Tests were then repeated using block sizes of 50 and 150 min, respectively. Linear interpolation produced the smallest RMSE (Table 2) for blocks of 50 and 150 min. Given the negligible difference among the algorithms for blocks of 25 min, linear interpolation was chosen for imputing the HR data.

Target Heart Zone Calculation

Following imputation, target heart zones were computed for each NetHealth participant using the Karvonen formula to determine when bouts of MVPA occurred [31]. Although this formula is, at best, a proxy for determining target heart zones, we found it to be the most appropriate method given our sample's truncated age range and limited resources for more robust measurement [32]. The formula is outlined for convenience below. Although the constant *Y* can be modified, 0.5 is typically recommended by the American Heart Association [33]:

1. Y=0.5
2. Heart rate reserve (*HRR*)=max heart rate−resting heart rate (*RHR*)
3. Target heart zone minimum=(*HRR*×*Y*)+*RHR*

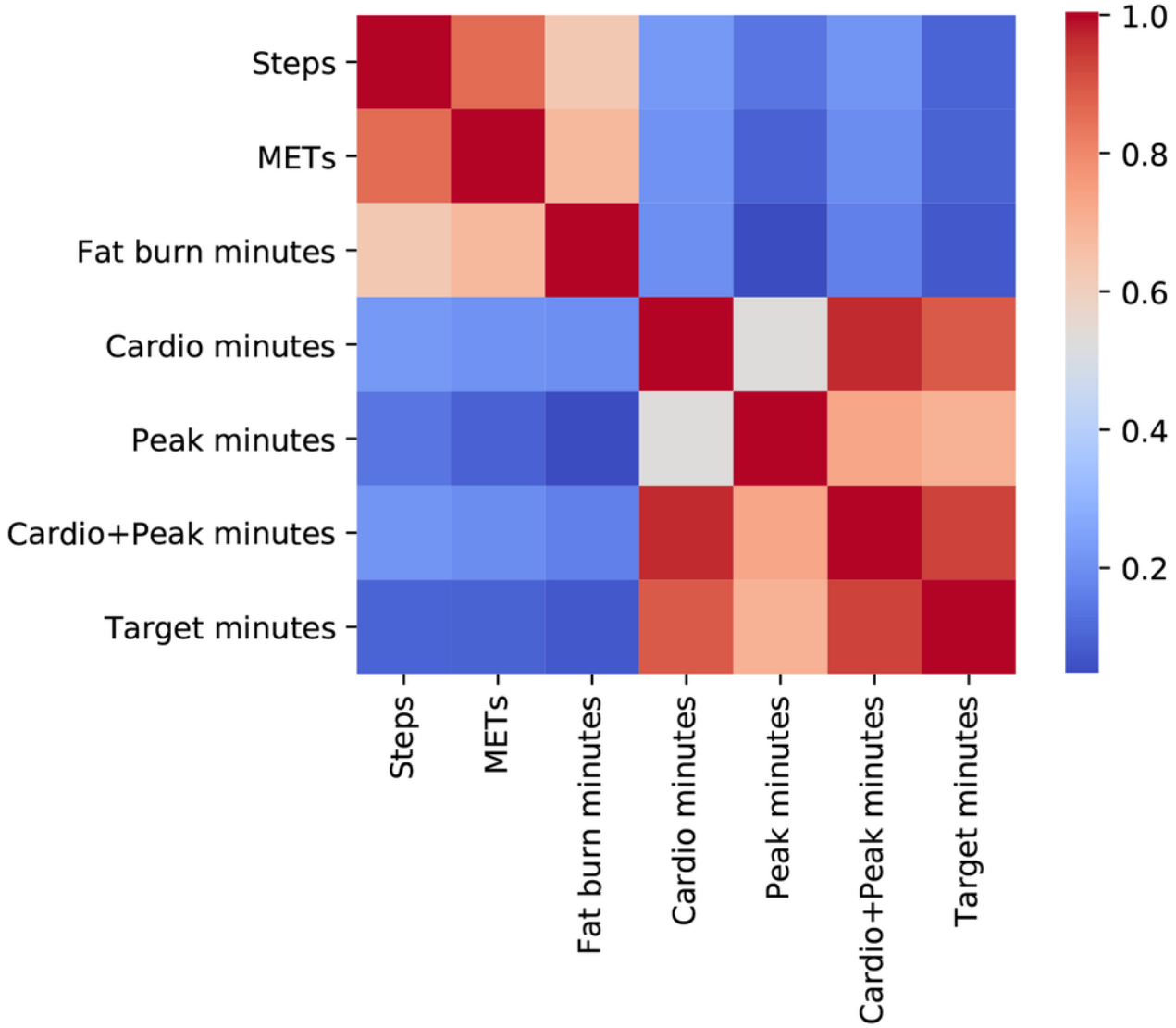
Target heart zones were calculated for each user by each day to account for potential changes in resting HR over the 2 academic years.

Bouts of MVPA required participants to stay within their target heart zone for at least 10 consecutive minutes, a threshold in line with the US Department of Health and Human Services PA guidelines [34]. Although recent work shows bouts of any duration may still result in mortality benefits, at the time, there is stronger support for bouts of at least 10 min [35]. To further account for any errors in device recording or HR falling temporarily outside the target heart zone, consecutive bouts separated by 1 min outside the target heart zone were combined. Finally, bouts of MVPA were then aggregated into daily sums, which we further refer to as *target minutes*.

In comparison to daily aggregates of PA data collected by Fitbit (Figure 5), we find target minutes correlated positively with all Fitbit measures and strongly with Fitbit's *cardio* (r_s=.9) and *peak* (r_s=.7) heart zone measures, which also utilize the Karvonen formula [36].

Fitbit *cardio* and *peak* minutes were then aggregated and compared with target minutes. We observed a mean absolute error of 6.20, with a session of MVPA typically resulting in 6 more target minutes than the combined *cardio* and *peak* minutes.

Figure 5. Spearman correlation matrix comparing target minutes to other physical activity measures provided by Fitbit.



Trend Extraction

To adjust for the 18 months of data collection, participants' daily target minutes were downsampled to sums of target minutes per month. The time series of each NetHealth participant spanned from August 2015 to April 2017, with the summer months May, June, and July withheld. The sum of target minutes for each month was then divided by the participants' number of compliant days in that month. This was done to normalize months with breaks such as December and account for differences in participants' compliant days per month. Trends were then extracted from each time series using additive seasonal decomposition with a frequency of 9 to account for the repeated academic years [37]. For time series of varying lengths, this frequency can be modified accordingly, or the decomposition can be replaced with a Loess smoother if no seasonality is present. A Mann-Kendall test was then performed on each extracted trend to determine whether it constituted a significant monotonic upward or downward trend [38]. Statistically significant trends were determined using a *P* of .05.

Finally, considerations were made to ensure trends were truly reflective of changes in MVPA and not of systematic differences in *when* participants were more complaint. For example, participants with a negative trend (NT) may have contributed fewer compliant days overtime, potentially capturing less MVPA. Although such a bias should be corrected for when normalizing by how many days a participant was compliant each month, to ensure a bias did not exist, Kruskal-Wallis H-tests were performed, measuring the distribution of compliant days per month across the 3 trend types, using an alpha of .05 [39,40]. No statistically significant results were found, suggesting participants from each trend group contributed a similar number of compliant days to each month.

Case Studies

Although PATX was able to extract MVPA trends from HR data, we believe these trends alone are needless if they cannot provide meaningful insights. To evaluate this, we performed 2 case studies. The first examined the association between changes in MVPA and mental health, determining whether PATX would be consistent with earlier work. The second assessed self-perceptions of PA relative to a friend's activity to demonstrate how PATX could support novel behavior change studies.

Case Study 1: Associations Between Changes in Physical Activity and Mental Health

To observe associations between trends in MVPA and mental health, participants' depression—Center for Epidemiologic Studies Depression (CESD) Scale—and anxiety—Beck Anxiety Inventory (BAI) and State-Trait Anxiety Inventory (STAI)—screenings were evaluated along with self-reports of overall health, body-image, and self-esteem [41-43]. As a reminder, surveys containing these questions were administered once per semester.

As our focus was to assess how each participant's response changed overtime, within-group methods were used for analysis. This included nonparametric repeated measures analysis of variance (ANOVA; Friedman test) or the Wilcoxon signed-rank test, depending on how frequently each survey question was asked. Any missing survey values were imputed using forward fill to keep the participants' answers consistent across the missing responses.

Case Study 2: Assessing Self-Perceptions of Physical Activity Relative to Friend's Activity

Our second case study focused on an exploratory analysis of how participants in these MVPA trends perceived their own levels of PA relative to their friend's PA overtime. Survey data were again utilized with 2 questions asked: "During the current semester, how physically active would you say you are?" and "How physically active is your typical Notre Dame friend?" All comparisons were made using nonparametric repeated measures ANOVA (Friedman test).

To further explore participants' perceptions of their friend's PA, ego-network analyses were conducted where participants acted as the focal node (ego) of their network. The network was then populated with only that participant's immediate friends (alters), all of whom were connected to the participant. A total of 2 participants were omitted from this analysis as they had no SMS data.

Given that only Tier-1 study participants were selected for analysis, this reduced the chances of capturing their full ego networks. To compensate, we allowed previously excluded participants to be reconsidered but *only as alters*. Since survey assessments of self and friend's PA began in the Spring 2016 semester, we were only interested in whether the alters' MVPA changed from this semester onward; therefore, sufficient compliance was not necessary for Fall 2015.

Compliance restrictions followed the same threshold of *at least 49 compliant days per semester*. Recall that Tier-2 participants entered the study toward the end of the Fall 2015 semester and Tier-3 participants entered near the end of the Spring 2016 semester. Due to this, Fall 2015 was ignored for Tier 2 and the Fall 2015 and Spring 2016 semesters were ignored for Tier-3 participants. Lessening these compliance restrictions added 83 more eligible participants to be considered as alters, among whom 31 were from Tiers 1 and 2, and 52 were from Tier 3.

These participants' HR data were then processed through PATX. Tier-1 and Tier-2 participants had 13 months (Spring 2016-Spring 2017), whereas Tier-3 participants had 9 months (Fall 2016-Spring 2017). Among these participants, 9 were labeled with an NT and 2 with a positive trend (PT), these 11 participants were from Tiers 1 and 2. No Tier-3 participant was labeled with significant trends.

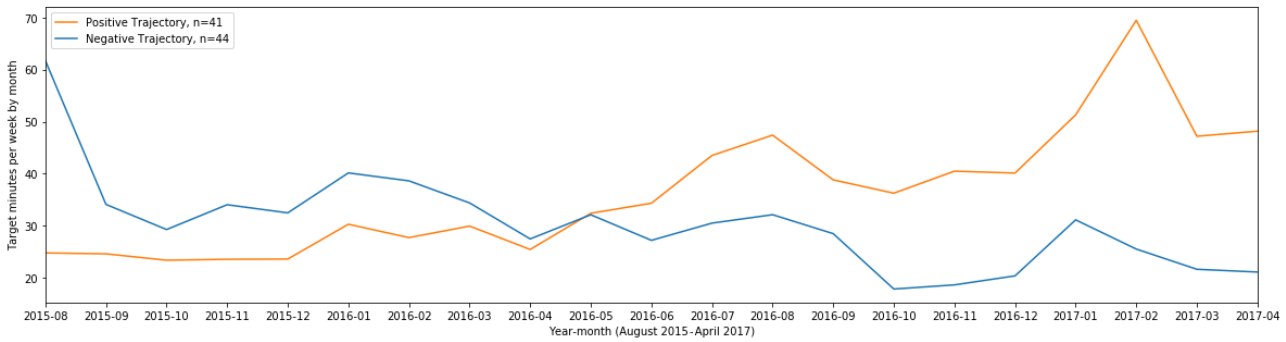
Finally, each ego network was limited to the top 5 strongest ties. This ensured all participants had comparably sized networks and prevented noise introduced from larger networks with weaker ties. Tie strength was measured using the total number of days 2 participants exchanged SMS text messages, with more days indicating stronger ties.

Results

Physical Activity Trend eXtraction

Among the 123 participants examined, 41 were labeled with a significant PT and 44 with a significant NT. An average time series for these trends is visualized in Figure 6. We observe that, on average, NT participants engaged in 30 min to 60 min of MVPA in a given week across their first academic year (August 2015 to April 2016) and 15 min to 30 min per week in their second academic year (August 2016 to April 2017). PT participants typically engaged in 20 min to 30 min of MVPA per week in their first academic year and 30 min to 70 min in their second.

Figure 6. Average trend for each group from August 2015 to April 2017, which includes May, June, and July of 2016.



Case Studies

Case Study 1: Associations Between Changes in Physical Activity and Mental Health

Table 3 presents the findings for changes in survey responses regarding mental health across the 2 academic years. We observe that for PT participants, self-reports of health, self-esteem, and body image increased (+7%, +4%, and +6%). However, no significant results were observed for changes in anxiety or depression screenings. For NT participants, we observed a decline in self-reported health (−3%) and no significant changes in self-esteem or body image. Regarding screenings, we observed an increase in the risk of anxiety and depression (BAI +5%, STAI +8%, and CESD +9%).

Case Study 2: Assessing Self-Perceptions of Physical Activity Relative to Friend's Activity

Table 4 presents the findings for changes in perception of self and friend's PA stratified by MVPA trend. For PT participants, no significant changes were observed for the perception of their own PA; however, PT participants perceived increases in their friend's level of PA (+4%). NT participants perceived a decrease in the level of their own and their friend's activity respectively (−8%, −7%). These changes in perception of friend's activity motivated our ego-network analysis.

For each ego network, we first examined the number of same-trend alters. Referring to Figure 7, we observed 15 PT participants with no PT alters among their top 5 strongest ties and 26 with at least one PT alter. For NT participants, we observed 17 with no NT alters and 25 with at least one NT alter. Table 5.

Partitioning each trend group into *presence of same-type alter* and *absence of same-type alter* in their ego network, we revisited the PA perception questions now stratified by these 2 conditions. Referring to Table 5, we observed that PT participants *with* PT alters did not perceive significant changes in their own or their friend's level of PA. However, PT participants *without* PT alters perceived a significant increase in the level of their own PA (+4%) and a decrease in the level of their friend's PA (−4%). Moving to NT participants, we observed that NT participants *with* NT alters perceived a significant decrease in their friend's level of activity (−8%), whereas NT participants *without* NT alters perceived no significant changes in their friend's activity. Finally, we observed evidence suggesting NT students with no NT alters perceived a decrease in their own activity (-10%) and no significant changes for NT students with NT alters.

Table 3. Summary of descriptive statistics for moderate-vigorous physical activity trajectories based on survey responses. *Change* refers to the percent difference between the average score for the first and last survey administered.

Category	Positive MVPA[a] Trend Change (*P* value)	Negative MVPA Trend Change (*P* value)
Self-image (higher score indicates a more positive perception)		
Health	+7% (.02)	−3% (<.001)
Self-esteem	+4% (.01)	<1% (.32)
Body image	+6% (.04)	−2% (.97)
Mental health, risk of...(higher score indicates a higher risk)		
Anxiety (BAI[b])	<1% (.60)	+5% (.01)
Anxiety (STAI[c])	+3.7% (.10)	+8% (<.001)
Depression (CESD[d])	+2.3% (.72)	+9% (<.001)

[a]MVPA: morderate-vigorous physical activity.

[b]BAI: Beck Anxiety Inventory.

[c]STAI: State-Trait Anxiety Inventory.

[d]CESD: Center for Epidemiologic Studies Depression.

Table 4. Summary of descriptive statistics related to perceptions of participants' own activity and their friend's activity based on survey responses. *Change* refers to the percent difference between the average score for the first and last survey administered.

Category	Positive MVPA[a] Trend Change (*P* value)	Negative MVPA Trend Change (*P* value)
Perception (higher score indicates a higher level of physical activity)		
Level of own activity	+2% (.17)	−8% (.01)
Level of friend's activity	+4% (.01)	−7% (.03)

[a]MVPA: moderate-vigorous physical activity.

Figure 7. Distribution of same-trend alters in positive trend and negative trend ego networks. NT: negative trend; PT: positive trend.

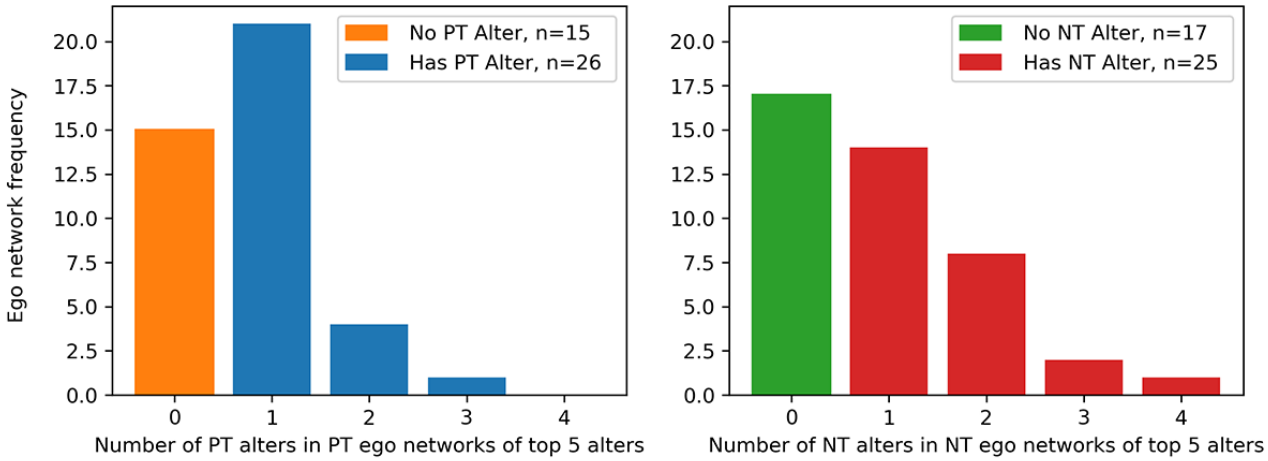


Table 5. Summary of descriptive statistics related to perceptions of participants' own physical activity and their friend's physical activity based on survey responses stratified by presence of same-type alters in individuals' ego networks. *Change* refers to the percent difference between the average score for the first and last survey.

Category	Positive MVPA[a] trend		Negative MVPA trend	
	No PT[b] alter (n=15), change (*P* value)	Has PT alter (n=26), change (*P* value)	No NT[c] alter (n=17), change (*P* value)	Has NT alter (n=25), change (*P* value)
Perception (higher score indicates a higher level of activity)				
Level of own activity	+4% (.03)	−1% (.98)	−10% (.05)	−2% (.31)
Level of friend's activity	−4% (.004)	+6.5% (.21)	−3% (.22)	−8% (.02)

[a]MVPA: moderate-vigorous physical activity.

[b]PT: positive trend.

[c]NT: negative trend.

Discussion

Principal Findings

In this paper, we presented PATX, a framework for capturing trends in MVPA habits using HR data from wearable fitness trackers. With a dataset featuring HR data across 2 academic years from a cohort of college students, PATX labeled 41 students as significantly increasing their MVPA overtime and 44 significantly decreasing their MVPA overtime. To demonstrate the value of these trends, 2 case studies were performed: the first, showing these trends could be used to support a body of previous work investigating the association between MVPA and mental health, and the second, establishing PATX's value in supporting novel MVPA behavior change analyses such as the association among perceptions of individuals' PA relative to their social networks.

In constructing our framework, we aimed to alleviate data quality issues related to fitness trackers including missing data and biases in measurement. By extracting trends in MVPA from the processed data, PATX offers a way to label individuals with increasing or decreasing trends. These trends provide a flexible manner to further examine changes in behavior, allowing for traditional statistical analyses to be performed on exposure variables among participants or groups.

Our first case study demonstrating this flexibility sought to support earlier work investigating the relationship between MVPA and mental health. Earlier work suggests engaging in MVPA may improve mental health, whereas abstaining may lead to complications [44-46]. Our observations conformed with these previous suggestions as participants with positive MVPA trends reported improved self-image, self-esteem and health, whereas participants with NTs increased in risk of anxiety and depression.

The second case study sought to examine how individuals perceive their own MVPA relative to their friends' MVPA. For both MVPA trends, we observed that participants were *less* likely to report changes in their own MVPA when their close friends exhibited similar changes in MVPA. However, participants without friends exhibiting similar changes were *more* likely to report changes in their own MVPA. Although previous work investigating perceptions has shown individuals accurately perceiving their level of fitness, our findings suggest noticing changes in fitness may be more difficult when such changes are mirrored by close ties in one's social network [47]. Therefore, to improve the efficacy of MVPA behavior change interventions, designs may need to be extended to incorporate one's social circle.

By applying PATX to each of these case studies, we were able to utilize the objective and continuous measures of MVPA provided by fitness trackers across the entire period participants

were under observation, providing a stronger representation of participants' MVPA habits compared with measuring only intermittent weeks.

Comparison With Previous Work

Although previous works have investigated long-term changes in MVPA, many have only measured their participants intermittently, typically administering fitness trackers to participants for 1 week at each assessment [15-20]. Although a more feasible method of data collection, such designs are prone to several biases.

First, intermittent weeklong measurements across multiple years depend heavily on which weeks are measured as seasonality must be accounted for with winter months likely to yield less MVPA than summer [48]. Studies with shorter intervals among assessments are also prone to this bias as follow-ups at the third, sixth, and ninth months will capture variations between these seasons. To account for this, when appropriate, we utilize seasonal trend decomposition using Loess to account for any seasonality [37].

Furthermore, weeks *when* activity data are collected are subject to social desirability bias as participants may exhibit short-term changes in behavior when they are aware their behaviors are being monitored [49]. The novelty of simply having these devices for a week may also bias behaviors as fitness trackers themselves have been shown to spur short-term activity changes [50]. Although longer-term continuous tracking studies may be subject to the same bias, research is still inconclusive as to whether these devices promote long-term PA changes [51].

Even though other methods have been proposed to gather insights from PA data, many extend behavior change to a broader scope [21]. Although this is important for investigating how PA changed, it answers a different question than that addressed in this paper. Our method is more focused in that we specifically aim to examine whether a significant increase or decrease in an individual's MVPA took place over an extended period.

Limitations

We note our sample size as a limiting factor of this study and address the potential selection bias introduced regarding participants included in this analysis as opposed to the excluded participants (Table 1). We compared the 123 participants included in the study and the 508 who were withheld to ensure our demographics were still reflective of the overall university demographic distributions. We found no significant differences in demographic distributions among age, gender, or race between our sample and the participants excluded.

Not all questions asked of participants were present in each survey, some questions were only asked in certain waves to prevent the surveys from extending beyond a reasonable duration for completion, which otherwise may cause participants to provide less accurate answers. Furthermore, although many within-study ties exist among participants in the NetHealth study, we were unable to capture any MVPA changes among an ego's ties to participants outside the study, prohibiting a complete representation of MVPA changes throughout an ego network. As such, future studies may benefit from asking participants about those in their social network who cannot be directly observed to gather a more complete representation.

Finally, we note that given the nature of the NetHealth study, our sample has minor variation in age, truncated variation in socioeconomic background, and the fact that all participants were observed in the same environment. As a result, additional studies are necessary across different age groups and backgrounds to validate these findings.

Conclusions

The transition from surveys to fitness trackers for measuring MVPA in behavior change studies delivers more objective assessments but introduces a new set of challenges. Data preprocessing steps and alternative means of analysis must be considered when using these devices. In this paper, we present a framework for navigating these data issues and extracting meaningful trends in MVPA from fitness trackers. With 2 case studies, we demonstrated the efficacy and flexibility of the outputs provided by our framework and how they can be used to support future MVPA behavior change studies.

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Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
BAI: Beck Anxiety Inventory
CESD: Center for Epidemiologic Studies Depression
HR: heart rate
HRR: heart rate reserve
MVPA: moderate-vigorous physical activity
NT: negative trend
PA: physical activity
PATX: Physical Activity Trend eXtraction
PT: positive trend
RHR: resting heart rate
RMSE: root-mean-square error
SMS: short message service
STAI: State-Trait Anxiety Inventory

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Original Paper

Efficacy of a Mobile Social Networking Intervention in Promoting Physical Activity: Quasi-Experimental Study

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Abstract

Background: Technological interventions such as mobile apps, Web-based social networks, and wearable trackers have the potential to influence physical activity; yet, only a few studies have examined the efficacy of an intervention bundle combining these different technologies.

Objective: This study aimed to pilot test an intervention composed of a social networking mobile app, connected with a wearable tracker, and investigate its efficacy in improving physical activity, as well as explore participant engagement and the usability of the app.

Methods: This was a pre-post quasi-experimental study with 1 arm, where participants were subjected to the intervention for a 6-month period. The primary outcome measure was the difference in daily step count between baseline and 6 months. Secondary outcome measures included engagement with the intervention and system usability. Descriptive and inferential statistical tests were conducted; posthoc subgroup analyses were carried out for participants with different levels of steps at baseline, app usage, and social features usage.

Results: A total of 55 participants were enrolled in the study; the mean age was 23.6 years and 28 (51%) were female. There was a nonstatistically significant increase in the average daily step count between baseline and 6 months (mean change=14.5 steps/day, *P*=.98, 95% CI –1136.5 to 1107.5). Subgroup analysis comparing the higher and lower physical activity groups at baseline showed that the latter had a statistically significantly higher increase in their daily step count (group difference in mean change from baseline to 6 months=3025 steps per day, *P*=.008, 95% CI 837.9-5211.8). At 6 months, the retention rate was 82% (45/55); app usage decreased over time. The mean system usability score was 60.1 (SD 19.2).

Conclusions: This study showed the preliminary efficacy of a mobile social networking intervention, integrated with a wearable tracker to promote physical activity, particularly for less physically active subgroups of the population. Future research should explore how to address challenges faced by physically inactive people to provide tailored advices. In addition, users' perspectives should be explored to shed light on factors that might influence their engagement with the intervention.

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KEYWORDS

mobile apps; fitness trackers; exercise; social networking

Introduction

Background

There is strong evidence of the effectiveness of regular physical activity in the prevention of several chronic diseases and associated premature death [1,2]. Furthermore, there appears to be a dose-response relationship between physical activity and health status [3,4]. Yet, despite the importance of physical activity, 27.5% of adults worldwide are insufficiently active [5], highlighting the need for interventions to promote physical activity.

Behavioral informatics interventions (ie, using health information technology to facilitate behavior change) have become increasingly popular in recent years [6]. A key element to behavior change success is the use of behavior change theories, models and techniques to better understand the causal mechanisms and influencing factors of the behavior, and the context of the intervention [6]. In addition, in recent years, researchers have encouraged intervention developers to describe their interventions in terms of the specific behavior change techniques [7]. A behavior change technique is an *observable, replicable, and irreducible component* of an intervention, intended to alter causal processes that regulate behavior [7]. Behavior change techniques can be linked to existing theories and models, and they provide a more transparent, replicable approach to the design and evaluation of behavior change interventions [7,8].

To date, several behavior change theories and models have indicated the importance of the link between social factors and health-related behaviors [9-11]. In particular, researchers have demonstrated that existing networks of friends and family exert great influence on individual health behavior [12,13], suggesting the potential of leveraging social networks to deliver physical activity interventions [14]. Social networks refer to the webs of an individual's relationships, which give rise to various functions such as social influence, social companionship, social support, and social comparison [15]. To date, several studies have found strong evidence that behavior change techniques such as social support and social comparison increase physical activity levels [16-18]. Though these interventions seem promising, their potential can be missed when they are not easily disseminated or accessible to a large audience [19]. A potentially useful way to disseminate social network interventions for physical activity is through the use of Web-based social networks. Web-based social networks, which are now ubiquitous in our lives, allow users to create a personal profile and connect with other users [20]. Several meta-analyses have found that online social networks can have positive, significant effects on behavior change [21,22].

In addition to social aspects, many studies have also highlighted the importance of other behavior change techniques, such as self-monitoring or goal setting, in physical activity [23,24]. Mobile health (mHealth) technologies such as mobile apps and wearable trackers offer new opportunities to deliver these behavior change techniques. In particular, recent mHealth technologies can reach individuals continuously, allowing users to self-monitor their physical activity [25] and providing real-time feedback [26]. mHealth interventions have increasingly been used in physical activity interventions, reporting significant, moderate improvements in step counts [27-29]. Given their potential, interventions combining mHealth technologies and online social networks might be particularly effective in promoting physical activity.

To date, researchers have largely examined the effects of mHealth and Web-based social networks on physical activity in isolation [30-37]. There are a few studies that evaluated the feasibility and effectiveness of interventions with both mHealth and Web-based social network components, showing user acceptability and moderate increases in physical activity levels [38-42]. However, these studies often examine online social networks as an additional feature (eg, a Facebook group), not integrated within a mobile app. In addition, it is also essential to examine usage metrics and usability determinants of mHealth interventions, as these factors reflect true user engagement and can largely influence the effects of the intervention [43].

Objectives

The aim of this study was to pilot test a social networking mobile app, connected with a wearable tracker to promote physical activity. In particular, we investigated (1) the intervention efficacy on physical activity and (2) participant engagement and usability of the intervention. The secondary aims were to explore the effects of social features on physical activity levels and the association between engagement with the mobile app and physical activity levels.

Methods

Study Design

This study is part of a larger mixed-methods feasibility study on the use of a social networking mobile app to promote physical activity and weight management [19]. In particular, this paper reports on the quantitative results related to the physical activity outcomes of a pre-post, 1-arm quasi-experiment where participants were subjected to the intervention for a 6-month period. Results related to weight outcomes of the study will be reported in a forthcoming publication. The design and conduct adhered to the Consolidated Standards of Reporting Trials 2010 statement—extension to randomized pilot and feasibility trials, where applicable [44].

Ethics

Ethics approval was granted by Macquarie University's Human Research Ethics Committee for Medical Sciences (ethics reference number 5201600716).

Study Settings and Participants

A total of 55 participants (mean age 23.6 years, 51% [28/55] female), mostly Macquarie University students and staff (Sydney, Australia), were recruited using purposive sampling techniques. Given the nature of this study, the sample size was pragmatically chosen to enable a comprehensive assessment of the feasibility of the intervention before conducting a randomized controlled trial (RCT) [44]. Recruitment channels included posters around university campus, website information, and Facebook. Eligible participants were healthy adults with

sufficient knowledge of English to understand and participate in the study, they had planned to be living in Sydney for the duration of the study and owned a mobile phone (iOS or Android) with internet access. Exclusion criteria were pregnancy, body mass index (BMI) below 17, earlier history of eating disorders, or having diabetes or other comorbid conditions that could impact study participation (eg, severe mental illness, end-stage disease). Participants were screened for eligibility via an online questionnaire.

Eligible participants were invited to attend the initial study session at the research center, where they received information about the purpose of the study and signed the consent form. Subsequently, participants filled in a questionnaire about their demographic characteristics and smartphone usage (eg, type of smartphone used, hours per day using the smartphone), and their baseline measurements (ie, weight, height) were assessed. At the end of the study, participants were invited to attend a postintervention session in which they completed the System Usability Scale (SUS) survey [45], and their weight was measured again.

Intervention Description

The intervention bundle involved 3 components, including a mobile app (named fit.healthy.me), a wearable tracker, and short message service (SMS) text messages and emails. In particular, the fit.healthy.me app was developed on the basis of several behavior change techniques, such as self-monitoring of physical activity, social support, and social comparison. In the app, the social features were composed of *My team*, *Social forum*, and *Private messages*. *My team* allowed participants to visualize and compare their step counts with others and *follow* other people, whereas *Social forum* and *Private messages* allowed participants to interact and provide social support to each other.

To enable the automation of self-monitoring, the fit.healthy.me app was integrated with the Fitbit Flex 2 wearable tracker [19]. In particular, the Fitbit Flex 2 was wirelessly synced with fit.healthy.me (via the Fitbit app programming interface). Fitbit Flex 2 uses accelerometer technology to measure acceleration signals, which are then converted to step count—a common indicator of physical activity. Research has demonstrated good reliability and validity in using Fitbit Flex 2 for measuring step count in free-living conditions [46,47].

In addition, prompts and cues (ie, SMS text messages and emails) were sent every 2 weeks to remind users to wear the fitness tracker during waking hours and check fit.healthy.me at least once every day. A detailed description of the modes of delivery and features of the intervention is presented in Table 1. Screenshots of the mobile app are provided in Multimedia Appendix 1.

Before the study commencement, the fit.healthy.me app underwent development testing [48] within the research center. Participants were provided access to the intervention by downloading the app from the Apple app Store or Google Play. During the study, participants could email or call the study team if they required any technical assistance. A research team member with clinical expertise also regularly monitored the study and responded to any concerns raised by participants. As an incentive for participation in the study, individuals were offered to keep the tracker at the end of the 6-month period.

Measures

This paper specifically reports on 3 aspects of the study results: (1) the efficacy of the intervention on physical activity measures, (2) participant engagement with the intervention, and (3) the usability of the fit.healthy.me app.

Efficacy in Promoting Physical Activity

The primary outcome measure for this study was the difference in the daily step count between baseline and 6 months, which was measured using the Fitbit Flex 2 and retrieved via the Fitbit app programming interface. To enable the collection of baseline daily step count, participants underwent a 7-day period after the initial study session where they were not able to log in to fit.healthy.me but were asked to use the Fitbit Flex 2 every day; the baseline measure was obtained by averaging the number of steps per day the first 7 days. The final step count was determined by computing the average number of steps per day on the last week where participants had at least four valid days [49]. A valid day of step count was defined as at least 10 hours of wear time during that day (Table 2) [47]. The wear time was calculated by subtracting nonwear time from 24 hours; nonwear time was defined if no step counts were detected over a period of at least 60 continuous min, allowing for 2 min of counts between 0 and 100 [49,50].

Posthoc subgroup analysis was carried out for participants with different physical activity levels at baseline (≥10,000 steps per day vs <10,000 steps per day). A total of 10,000 steps per day were used as a threshold, as this goal is acknowledged as a reasonable target for healthy adults [51-53].

Participant Engagement

Participant engagement with the intervention was assessed using multiple measures (Table 2). In particular, retention was defined as attendance at the 6-month final session. Participants who came to the final sessions were considered *completers* and participants who did not come were considered to have dropped out of the study. For the Fitbit Flex 2, engagement was measured by the mean number of days a valid step count was logged (participants were considered to have a valid step count if they wore the Fitbit for at least ten hours on any given day). For the fit.healthy.me app, engagement was measured by both the length of usage (ie, the mean number of days of usage) and frequency of usage (ie, the number of times participants used the app and each feature). A participant was considered to have used the app in a day if he or she used any features of the app at any time of that day. Similarly, a participant was considered to have used a social feature if he or she clicked on any of *My team*, *Social forum*, and *Private messages* features at any time. Every time a participant used an app feature, the timestamp and the name of that feature were automatically saved into our local database. These data were summarized to show participant engagement with the fit.healthy.me app at the end of the study.

Table 1. Intervention features and behavior change techniques.

Modes of delivery	Features	Behavior change techniques[a]
fit.healthy.me app	My measures	Self-monitoring of behavior (ie, number of steps per day)
	My team	Social comparison
	Social forum	Social support (emotional); Social comparison
	Private messages	Social support (emotional); Social comparison
	My journey	Instruction on how to perform the behavior
Fitbit Flex 2	Fitness wearable tracker	Self-monitoring of behavior (ie, physical activity)
SMS[b] text messages and emails	Reminders	Prompts/cues

[a]Classified according to the behavior change techniques taxonomy developed by Michie et al [7].

[b]SMS: short message service.

Table 2. Definition and calculation of engagement measures.

Engagement measures	Definition
Retention[a]	
Completers	Participants who came to the final sessions
Noncompleters	Participants who did not come to the final sessions (dropout attrition)
Retention rate	Percentage of completers out of all 55 participants
Fit.healthy.me app usage	
Length of usage	The mean number of days of usage
Frequency of usage	The mean number of times participants used the app and each feature
Nonusage attrition	Participants who did not use the app at all in the last month of the study
Fitbit Flex 2 tracker usage	
Length of usage	The mean number of days a valid step count was logged
A valid day of step count	Having at least ten hours of wear time
Wear time	Calculated by subtracting nonwear time from 24 hours
Nonwear time	Defined if no step counts were detected over a period of at least sixty continuous minutes, allowing for 2 min of counts between 0 and 100 [49,50]

[a]Adapted from Eysenbach (2005) [43].

Usability

Participants completed the SUS [45] to assess the usability of the fit.healthy.me app. The SUS is a validated questionnaire comprising a standard set of 10 statements that seek users' opinions on the usability of a system [45]. SUS has been widely used to evaluate usability within commercial and research studies (including mobile apps) for over 30 years [54-56]. Participants were asked to rank the statements on a 5-point Likert scale from strongly disagree (scored as 1) to strongly agree (scored as 5). Final scores of the SUS can range from 0 to 100, with higher scores indicating better usability [57]. A study collecting 10-years' worth of SUS data from over 200 studies found that the average score is around 70, suggesting that a SUS score of 70 might be considered acceptable [57]. A list of the statements and explanation for calculation of the SUS scores is provided in Multimedia Appendix 2.

Statistical Analysis

Participants' demographic characteristics, intervention usage data, and engagement metrics were analyzed descriptively using means, SD, and frequency counts. Wilcoxon signed-rank test was used to determine whether the number of days participants used the fit.healthy.me app differed between the first and last (sixth) month of the study. SUS score was calculated to determine the usability of the fit.healthy.me app [45].

To investigate the efficacy of the intervention, the difference between average step count at baseline and final weeks was assessed using a paired, 2-tailed *t* test. A total of 3 participants did not have valid data for at least four days at the end of the study, and thus they were excluded from the analysis. Kendall tau-b test was used to measure the correlation between total engagement with the fit.healthy.me app and changes in daily step count.

Posthoc subgroup analyses were carried out for participants with different levels of steps at baseline, app usage, and social

features usage. As mentioned above, in terms of physical activity, 10,000 steps per day were used as a cut-off point to define high- versus low-level physical activity [51-53]. In terms of app usage and social features usage, the median was used as a cut-off point to determine frequent versus nonfrequent usage. Independent 2-sample *t* tests were used for normally distributed numerical data; for nonnormal data, the Wilcoxon rank-sum test was used. Chi-square tests were used for categorical data. For statistically significant results, effect sizes (ie, Cohen *d*) were calculated [58].

Data were analyzed using R version 3.5.0 (R Foundation for Statistical Computing) [59-63]. The significance level for all statistical tests was set at $P<.05$, 2-tailed, and 95% CIs were calculated where applicable.

Results

Participant Flow and Recruitment

Recruitment occurred from April to May 2017. A total of 423 people completed an online questionnaire to assess their eligibility; 55 of them met the eligibility criteria, consented to participate, and attended the preintervention session. The most common reasons for ineligibility were pregnancy and chronic diseases. After each participant completed the 6-month period, they were sent an automatic email, inviting them back for the final sessions. Out of 55 initial participants, 45 participants returned for the final session (ie, completers). Step data were collected for all 55 participants during the 6-month intervention period. Given our definition of valid days and the condition that at least four valid days were needed to compute the weekly average, not all participants had the final step count in week 26 (median final week number: 21; interquartile range: 10-25).

Sample Characteristics

A summary of the differences in baseline characteristics between enrolled participants and completers is presented in Table 3. At baseline, participants had a mean age of 23.6 years (SD 4.6). Furthermore, 28 (51%) were female, and 42 (76%) were university students. The average BMI was 26.5 kg/m^2 (SD 6.8), with nearly half of the participants (24/55, 44%) in the normal weight range. Participants reported using a smartphone for 5.6 hours (SD 3.4) per day, on average; most users (36/55, 66%) had an iPhone. The majority of participants (49/55, 89%) said that the most used apps in their phones were social media apps, whereas 10% (6/55) said fitness apps. There were no statistically significant differences between enrolled participants and completers.

Physical Activity Measures

On average, daily step count did not change between baseline and 6 months (mean difference=14.5, $P=.98$, 95% CI –1136.5 to 1107.5). A subgroup analysis comparing the higher physical activity group with the lower physical activity group (at baseline) showed that the lower physical activity group experienced a statistically significant increase of 3025 steps in daily step count between baseline and post intervention ($P=.008$, 95% CI 837.9-5211.8], Cohen $d=0.80$; Table 4 and Figure 1). Multimedia Appendix 3 shows box plots for participants' daily step count at each week of the study. There were no statistically significant changes in average daily step count between different levels of app usage ($P=.42$; Multimedia Appendix 4) or different levels of social feature usage ($P=.25$; Multimedia Appendix 5). Total engagement with the fit.healthy.me was not directly associated with change in daily step counts (Kendall tau-b=–0.11, $P=.25$).

Table 3. Differences in baseline characteristics between enrolled participants and completers.

Measures	Enrolled participants (n=55)	Study completers (n=45)	*P* value
Age, mean (SD)	23.6 (4.6)	24.2 (4.7)	.51[a]
Female, n (%)	28 (51)	22 (50)	.52[b]
Weight (kg), mean (SD)	78.1 (22.3)	77.8 (21.2)	.99[a]
Body mass index (kg/m^2), mean (SD)	26.6 (6.8)	26.7 (6.5)	.94[a]
Body mass index categories[c], n (%)			
18-18.49	3 (6)	1 (2)	.14[b]
18.5-24.99	24 (44)	22 (49)	.19[b]
25-29.99	15 (27)	10 (22)	.16[b]
≥30	13 (24)	12 (27)	.48[b]
Steps/day, mean (SD)	10,967.2 (3907.4)	10,896.3 (4206.2)	.93[a]

[a]Assessed using 2-sample *t* tests.

[b]Assessed using chi-square tests.

[c]According to the World Health Organization, a body mass index of less than 18.5 is classified as underweight, 18.5-24.9 is normal, 25-29.9 is preobese, and ≥30 is obese [64].

Table 4. Differences in characteristics between lower and higher physical activity subgroups at baseline.

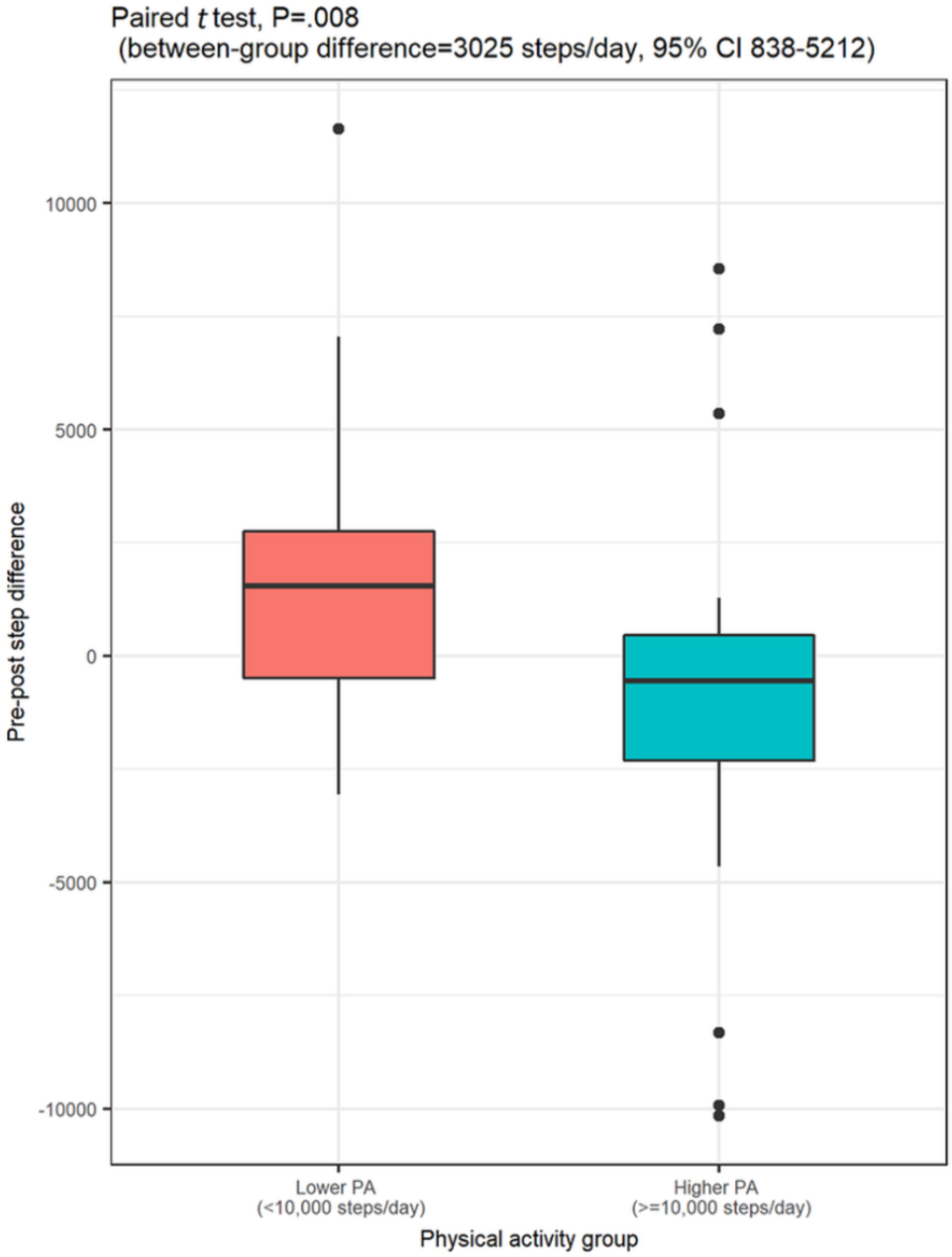
Measures	<10,000 steps/day (n>=20), mean (SD)	≥10,000 steps/day (n=35), mean (SD)	*P* value (95% CI)
Baseline weight (kg)	77.0 (26.3)	78.6 (20.1)	.80[a] (–14.3 to 11.0)
Baseline body mass index (kg/m^2)	26.4 (7.8)	26.6 (6.2)	.91[a] (–4.1 to 3.6)
Duration of app usage (days)	16.1 (15.3)	15.4 (17.0)	.51[b] (–4.0 to 7.0)
Intensity of app usage (times)	1487.0 (1244.7)	1719.1 (1561.6)	.79[b] (–559 to 860)
Pre-post intervention step difference	1992.3 (3598.3)	–1032.6 (3894.7)	.008[c] (837.9-5211.8)

[a]Assessed using 2-sample *t* test.

[b]Assessed using Wilcoxon rank-sum test.

[c]denotes statistical significance.

Figure 1. Boxplots of the differences in pre-post daily step count between the lower and higher physical activity groups. PA: physical activity.



Participant Retention and Engagement

The retention rate was 82%. Overall, the length of usage of the Fitbit Flex 2 tracker was higher than app and social features. *My Team* and *My Measures* had a higher level of engagement compared with *Social Forum* and *Private Messages* (Table 5). In general, app usage decreased over time (Figure 2). In particular, the number of days participants used the app in the last month of the study significantly decreased from the first month of the study (P<.001, 95% CI –5.5 to –4). In total, 4 participants did not use the app at all throughout the study. Subgroup analyses showed that there were no statistically significant differences in any characteristics between frequent and nonfrequent app users (Multimedia Appendix 4).

System Usability Scale

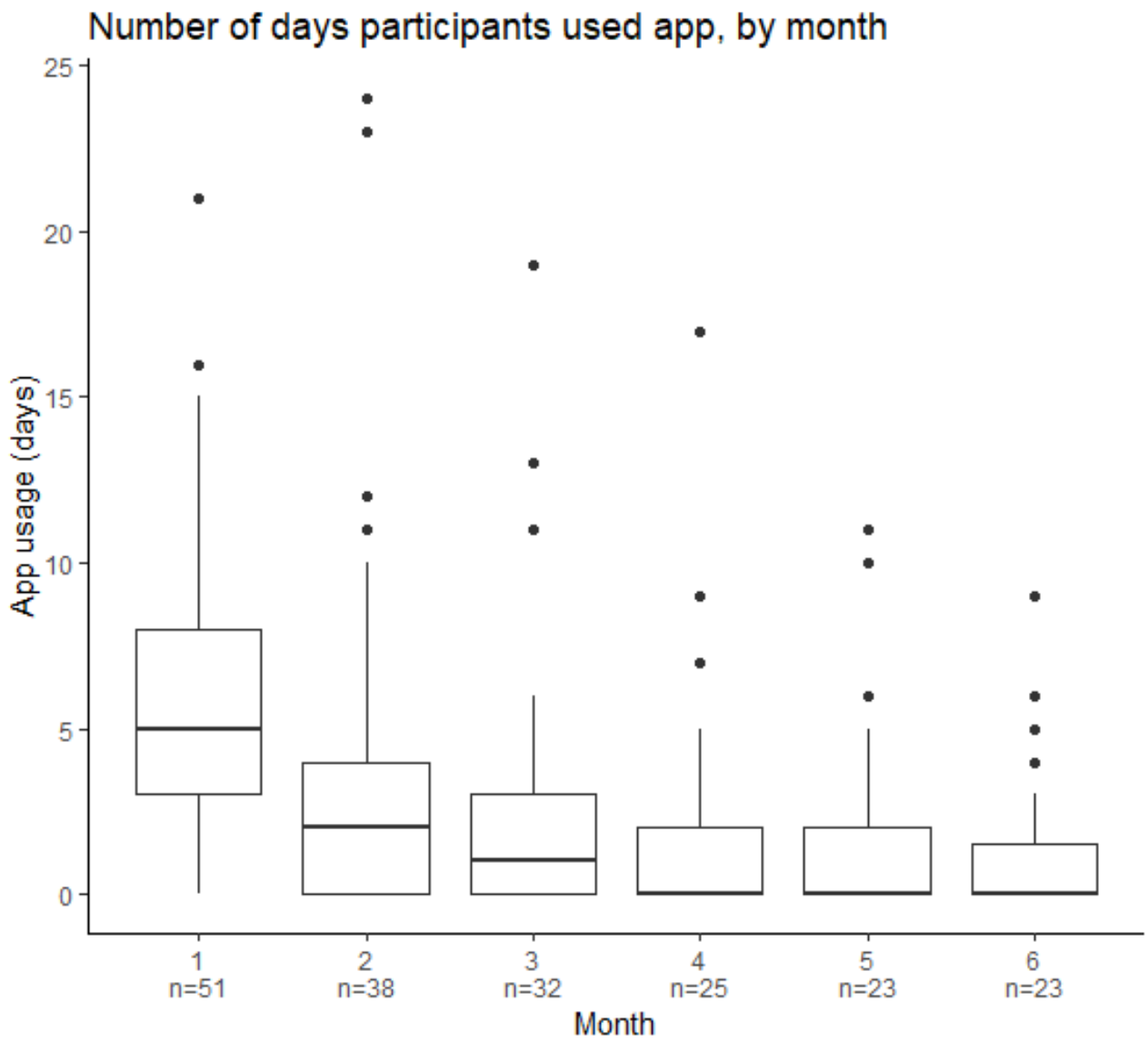
Out of 55 participants, only 45 returned to the postintervention sessions and completed the SUS. The mean SUS score was 60.1 (SD 19.2). Two-third of the participants (N=30) gave a SUS score lower than 70, indicating low usability [57]. Furthermore, 7 participants rated the app's usability as moderate and 8 participants rated it as having high usability. Multimedia Appendix 2 presents responses to individual SUS statements. Posthoc subgroup analysis indicated that frequent app users gave a higher SUS score than nonfrequent users (P=.04, 95% CI 0.6-25.3; Multimedia Appendix 4).

Table 5. Length and frequency of usage of the Fitbit Flex 2, fit.healthy.me app, and social features. Study duration was 183 days.

Engagement measures and usage data	Mean (SD)	Range
Fitbit Flex 2 usage		
Days valid step count were logged via Fitbit (days)	66 (48.7)	5-183
App usage		
Length (days)	15.7 (16.2)	0-63
Frequency (times)	1634.7 (1446.8)	0-6317
App features usage		
Frequency (times)		
My measures	44.2 (47.8)	0-228
My team[a]	59.0 (51.6)	0-203
Social forum[a]	21.8 (37.5)	0-213
Private messages[a]	9.2 (20.8)	0-88
My journey	17.0 (13.0)	0-63

[a]Social features included *My team*, *Social forum*, and *Private messages*.

Figure 2. Boxplots of the number of days participants used the fit.healthy.me app, by month.



Discussion

Principal Findings

There was a nonstatistically significant increase in the average daily step count between baseline and 6 months. Subgroup analysis comparing the higher and lower physical activity groups at baseline showed that the latter experienced a statistically significant increase in average daily step count between baseline and postintervention, suggesting the app might be more beneficial for specific subgroups of the population (eg, less physically inactive individuals). At 6 months, the retention rate was 82%; 42% participants used the fit.healthy.me app at least once during the last month of the study.

To the best of our knowledge, our study is the first to evaluate a mobile social networking intervention integrated with a wearable tracker. Other studies have examined interventions composed of either mobile technologies [30-33] or online social networks [34-37] in isolation, and thus evidence on the efficacy and feasibility of an intervention combining both was limited until now. Even though several studies have incorporated social features in mHealth interventions, these features were often included as an additional component (eg, Facebook group) rather than being fully integrated with the mobile app [38,39,41,42,65,66].

Efficacy in Promoting Physical Activity

Our study found that compared with the higher physical activity group, the lower physical activity group at baseline experienced a significant increase of 3025 steps in daily step count, suggesting that specific populations (eg, less physically active people) might benefit more from the use of a mobile social networking app. Earlier research has outlined the importance of considering particular challenges and barriers that inactive people might face when designing fitness technology. For example, several studies have suggested that although self-regulation techniques (ie, goal setting, self-monitoring, and feedback on behavior) and social support are often present in fitness technology, other behavior change techniques such as action planning or environment restructuring are present less often and might be particularly useful for inactive people [67,68]. It is worth noting that even increases of 2000 steps per

day are associated with reduced risk of cardiovascular disease, given the dose-response relationship between physical activity levels and health benefits [69]. Altogether, the use of behavioral informatics such as ours seem promising, and it should be confirmed by fully powered RCTs.

User Retention, Engagement, and Usability

The retention rate of our study was 82%, which is consistent with the reported retention rates of around 70% to 90% in other mHealth and online social networks interventions [21,38,39,70-72]. Our study also revealed that app usage declined over time—a phenomenon frequently observed in other apps for physical activity [29,73,74]. It is known that initially, users tend to be attracted to new technologies; over time, disengagement can be triggered by either internal factors such as lack of time, or it can be triggered by external factors such as usability issues and technological problems [75]. A possible explanation for the decline in usage of our app could be usability issues. In fact, two-third of our users gave a SUS score of lower than 70 to the fit.healthy.me app, indicating low usability [57]; nonfrequent users were more likely to give a lower SUS score. Indeed, when a user experiences a usability flaw, the negative experience might outweigh other positive features of the technology (a phenomenon known as *negativity bias*) [76], and it can subsequently lead to lower engagement. The link between usability and engagement has been frequently demonstrated in previous research [75]. Of note, the technology acceptance model highlights the importance of perceived usefulness and perceived ease of use (concepts overlapping with many aspects of usability) [45,77-79] in users' acceptance and adoption of technology [80,81]. Hence, it is important to address usability to maximize user engagement.

We also found that usage levels varied among different features. In particular, *My team* attracted a significantly higher level of engagement compared with *Social forum* and *Private messages*. This difference could possibly be because of the format and content presented in each feature: *My team* supports social comparison via displaying summary statistics and graphs, whereas the *Social forum* and *Private messages* features support discussion among users. It can be hypothesized that users found more utility in the numerical and graphical social comparison aspects of *My team* to the discussion-based nature of other social features, suggesting the need to explore how to effectively deliver social behavior change techniques to maximize engagement.

Strengths and Limitations

This study has several strengths. First, we assessed a range of features supporting different behavior change techniques to examine the individual aspects of this multicomponent intervention. Second, we reported different measures of engagement, including retention rate, nonusage attrition, and engagement metrics with different intervention components to shed light on the attrition problems in behavioral informatics interventions [43,82]. Finally, the intervention was fully integrated with wireless tracking devices, and thus the wireless tracking devices eliminated the reliance on self-reported data.

The findings of this study must be interpreted in light of some limitations. Given that this was a quasi-experimental study with a single-arm pre-post design, we cannot infer causation from our results. Possible confounders might have been at play, and thus the results should be interpreted with caution. Moreover, we had a purposely small and homogenous sample, which affects generalizability of the study. Another limitation is related to the handling of missing data in daily step count. Due to our definition of valid days of step count and the condition that participants needed to have at least four valid days of daily step count within a week to compute the weekly average, not all participants had the final step count in the last month of the study; therefore, we calculated the final step count on the basis of the last week where participants had at least four valid days. Although this method allowed us to include more participants in the analysis (and thus avoid selection bias resulting from excluding participants from the analysis), it can potentially bias the results in other ways (eg, overestimation of the final step count in case the daily step count decreases over the study duration). In addition, as the fit.healthy.me app was developed for research purposes, it lacked the advanced features and design aspects that would be available in commercially available fitness apps. Usability testing was assessed using the SUS and not done extensively. All posthoc subgroup analyses were exploratory and might be subject to type I error. In particular, in our analysis comparing different physical activity subgroups, our focus was on the difference between baseline and final weeks, and the analysis did not take into account all 26 weeks (Multimedia Appendix 3). Future work exploring the time series nature of physical activity data and analyzing and modeling weekly trends might reveal more in-depth information about users' behavioral patterns and provide more robust results. Finally, in this study, we only used step count as a measure of physical activity. Future research might consider other measures, such as intensity of physical activity (light, moderate, and vigorous) or sedentary time [83,84].

Implications

This study highlights several important implications regarding the design and implementation of behavioral informatics interventions for physical activity. First, our findings suggest that wearable devices and mobile social networking apps can work in synergy to facilitate behavior change, particularly in physically inactive groups. In particular, wearable trackers can automate self-monitoring—an important task in behavior change [23,85], whereas mobile apps can provide a platform to support other relevant behavior change techniques, such as providing feedback on behavior, goal setting, or social comparison [86]. Several studies have also suggested that social interaction can enhance engagement [28,87], highlighting the potential of integrating social features in technological interventions.

Furthermore, it is important to note that physically inactive groups might face additional challenges, and thus future research should also consider the potential of other behavior change techniques in these interventions. Perhaps fitness technology could prompt individuals to identify the particular barriers they face regarding physical activity [67], and it could facilitate the tailoring of specific recommendations accordingly. Tailored advices can be more helpful and relevant to users [88,89],

potentially leading to more effective interventions in this subgroup of the population. In addition, future research should also explore users' preferences and perspectives on factors that might influence their engagement, to maximize the effectiveness of mHealth interventions in promoting physical activity.

Conclusions

Our study showed preliminary evidence that mobile social networking interventions, integrated with wearable trackers, can help to promote physical activity. Future research needs to explore how to best support barriers faced by physically inactive people and accordingly provide tailored recommendations to maximize intervention effectiveness.

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Authors' Contributions

Study conceptualization: HLT, EC, LL. Data collection: HLT, PM. Data analysis: HLT, EC, WT, YW, JCQ, LL. First draft: HLT, LL. All authors critically revised the manuscript and approved the final version.
Data availability statement: Summary data supporting the findings are available within the paper and its supplementary information files. The raw datasets are not publicly available because of ethical restrictions.

Conflicts of Interest

EC could benefit from the commercialization of fit.healthy.me.

Multimedia Appendix 1

Screenshots of fit.healthy.me app.

[PDF File (Adobe PDF File), 241KB - mhealth_v7i3e12181_app1.pdf]

Multimedia Appendix 2

Responses to individual System Usability Scale statements.

[PDF File (Adobe PDF File), 113KB - mhealth_v7i3e12181_app2.pdf]

Multimedia Appendix 3

Boxplots of the 55 participants' daily step count over 26 study weeks.

[PDF File (Adobe PDF File), 88KB - mhealth_v7i3e12181_app3.pdf]

Multimedia Appendix 4

Differences in characteristics between frequent app users and nonfrequent app users.

[DOCX File, 15KB - mhealth_v7i3e12181_app4.docx]

Multimedia Appendix 5

Differences in characteristics between frequent users and nonfrequent users of the social features in the fit.healthy.me app.

[DOCX File, 14KB - mhealth_v7i3e12181_app5.docx]

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Abbreviations

BMI: body mass index
mHealth: mobile health
RCT: randomized controlled trial
SUS: System Usability Scale

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Original Paper

See-Through Type 3D Head-Mounted Display–Based Surgical Microscope System for Microsurgery: A Feasibility Study

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Abstract

Background: The surgical microscope is used primarily for microsurgeries, which are more complicated than other surgical procedures and require delicate tasks for a long time. Therefore, during these surgical procedures, surgeons experience back and neck pain. To solve this problem, new technology, such as wearable displays, is required to help surgeons maintain comfortable postures and enjoy advanced functionality during microsurgery.

Objective: The objective of this study was to develop a surgical microscope system that would work with wearable devices. It would include a head-mounted display (HMD) that can offer 3D surgical images and allow a flexible and comfortable posture instead of fixed eyepieces of surgical microscope and can also provide peripheral visual field with its optical see-through function.

Methods: We designed and fabricated a surgical microscope system that incorporates a see-through type 3D HMD, and we developed an image processing software to provide better image quality. The usability of the proposed system was confirmed with preclinical examination. Seven ENT (ear, nose, and throat) surgical specialists and 8 residents performed a mock surgery—axillary lymph node dissection on a rat. They alternated between looking through the eyepieces of the surgical microscope and viewing a 3D HMD screen connected to the surgical microscope. We examined the success of the surgery and asked the specialists and residents to grade eye fatigue on a scale of 0 (none) to 6 (severe) and posture discomfort on a scale of 1 (none) to 5 (severe). Furthermore, a statistical comparison was performed using 2-tailed paired t test, and P=.00083 was considered significant.

Results: Although 3D HMD case showed a slightly better result regarding visual discomfort (P=.097), the average eye fatigue was not significantly different between eyepiece and 3D HMD cases (P=.79). However, the average posture discomfort, especially in neck and shoulder, was lower with 3D HMD display use than with eyepiece use (P=.00083).

Conclusions: We developed a see-through type 3D HMD–based surgical microscope system and showed through preclinical testing that the system could help reduce posture discomfort. The proposed system, with its advanced functions, could be a promising new technique for microsurgery.

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KEYWORDS

3D imaging; head-mounted display; microsurgery; surgical microscope

Introduction

The surgical microscope is mainly used for microsurgeries, such as in neurosurgical application, ENT (ear, nose, and throat) surgeries, ophthalmic surgeries, plastic and reconstructive surgeries, and dental treatments. Microsurgery requires accurate and stable task performance with small and delicate instruments, and surgeons spend long sessions with their eyes on the eyepieces of the microscope. Therefore, due to their awkward static postures during operations, surgeons experience back and neck pain, musculoskeletal fatigue, and injuries [1-4]. In a national cross-sectional survey of 325 ENT consultants by Babar-Craig et al [2], 72% reported having experienced either back or neck pain or both, with most reports coming from otologists, relating their symptoms to lengthy microscopic work and prolonged sitting. Overall, 53% of respondents attributed their symptoms directly to previously performed ENT surgeries. Other predisposing factors include static postures and bending during endoscopic procedures, similar to their general surgical colleagues [2]. A survey of 5 different specialists in the United Kingdom—general surgery, otorhinolaryngology, plastic surgery, orthopedics, and trauma surgery and neurosurgery—indicated that the back and neck were the most common areas of pain. Posture was the most common cause of pain (46%), followed by the use of microscopes or surgical instruments (21% each) and surgical loupes or head-mounted lights (11%) [3]. However, many surgeons pay little attention to their health, and their work-related illness has been reported to be above average compared with that of professionals from other industries [1]. Therefore, new technologies should be adopted in the workplace to reduce posture-related discomfort, provide better visualization during surgical procedures, and help with pain management.

Heads-up microscopy using a high-definition (HD) 3D monitor has been proposed as an ergonomic alternative. This system transmits the surgical microscopic images to a 3D monitor for the surgeon and assistants to view in more comfortable positions. In addition, it allows the surgeon to recognize the surgical environment easily [5]. However, in heads-up microscopy, a surgeon's head and eyes are directed toward a monitor, which causes an eye-hand coordination mismatch and requires an uncomfortable posture for surgeons. Head-mounted displays (HMDs) have been adopted to solve the abovementioned drawbacks in the case of endoscopy and laparoscopy, which use the same kinds of 3D monitors [6-13]. The use of HMD helps eliminate these problems by delivering optical information directly to the surgeon's eyes, independent of the head and body position and the position of the sources of images. Therefore, HMDs can relieve back and neck strain and improve technical proficiency. In addition, 3D functions of the HMD-based laparoscopic system and endoscopic surgery system provide benefits such as improved operation times, minimized complications, shortened learning curves, and greater surgeon comfort [14,15].

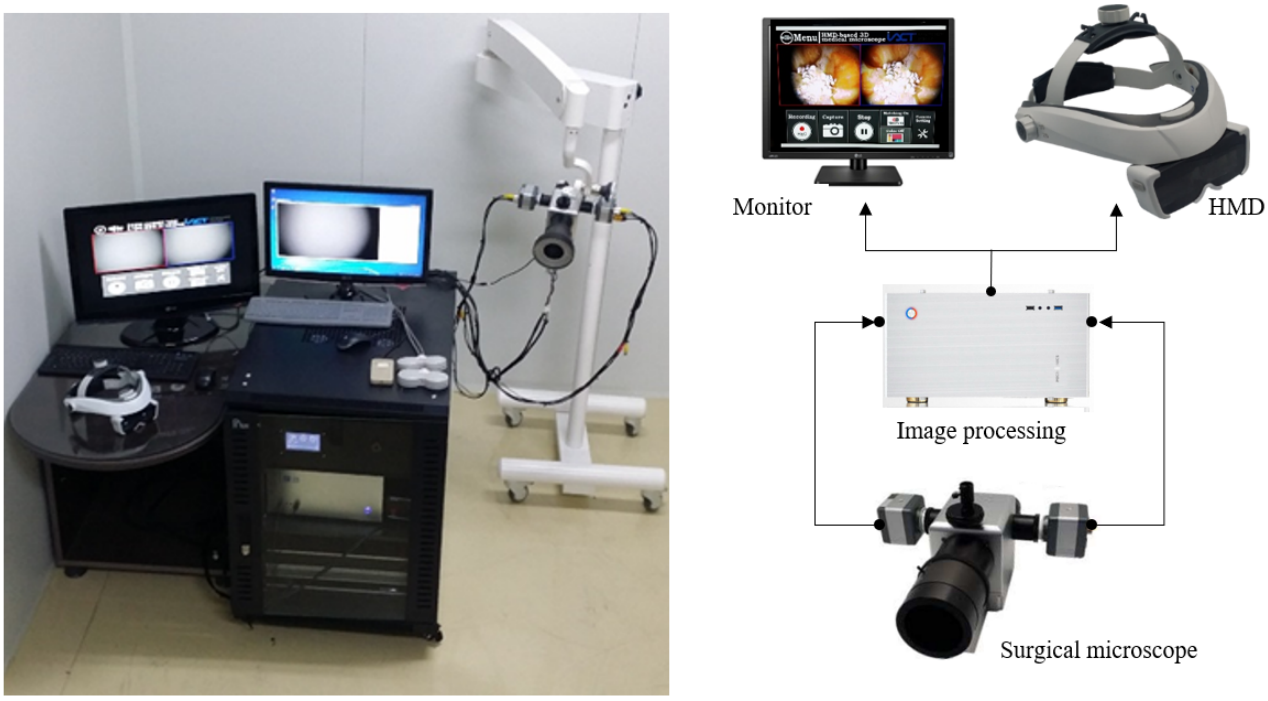
Despite the several advantages of the HMD, the associated disadvantages still limit its use in surgery. Many of the proposed HMDs have inadequate resolution, and they are bulky, cave-like, and heavy [6-10]. Although a higher-resolution HMD has recently been proposed for endoscopy, it has a fully opaque and closed, nonsee-through configuration [11-13]. Because this type of HMD can only deliver virtual information to the eye, it is difficult to obtain a direct physical view and to observe the surgical environment in the operating room. Therefore, in this study, we propose a surgical microscope system based on a high-resolution 3D HMD with a see-through configuration that enables optical superposition of digital information onto the physical view. Using the proposed system, 3D surgical images can be observed with more comfortable postures, and a peripheral view of the surgical field can also be easily accessed during microsurgery via the see-through configuration. We designed and fabricated a stereoscopic surgical microscope and see-through 3D HMD and developed image processing software. The feasibility of the proposed HMD-based surgical microscope system was evaluated with preclinical examination, and the results were compared with the results obtained with the conventional eyepieces of the system.

Methods

Surgical Microscope System Using Head-Mounted Display

We implemented a surgical microscope system incorporating a see-through type 3D HMD and image processing computer, as shown in Figure 1 (image on the left). A surgical microscope was developed that comprises a binocular headpiece with adjustable eyepieces and 2 charge-coupled device (CCD) cameras, optical see-through type 3D HMD mounted on a headband, and image processing software. The measured surgical images are directly observed through eyepieces, and the measured surgical images from the 2 CCD cameras on the surgical microscope are sent to an image processing computer for better image quality and for 3D image reconstruction in real time, as described in Figure 1 (image on the right). The processed images are displayed on a monitor and the proposed 3D HMD. Furthermore, two-dimensional (2D) side-by-side images are displayed on the monitor, and 3D surgical images are displayed by the HMD.

Figure 1. Left: surgical microscope system based on see-through type 3D head-mounted display (HMD); right: surgical images measured using 2 charge-coupled device cameras are displayed on a monitor in two dimensions and displayed on HMD in 3D after the image processing procedure.



Stereoscopic Microscope

We designed and fabricated a stereoscopic microscope with 2 CCD cameras for use as a surgical microscope. The device used a binocular design with a single common main objective, as described in Figure 2. The microscope comprised a light source, 2 CCD cameras, and optical components: one common main objective, a pair of turrets, a prism, an eyepiece, and a closed-circuit television (CCTV) lens. A white light emitting diode light source (NET-260SL, Mega Medical Co Ltd) was attached to the illumination port of the microscope. The continuous zooming turret, having a focusing component, a zooming component, and a compensating component was adopted, and it was connected to a DC motor and foot switch. A varifocal lens with a motor drive was used for autofocusing. The step control was 0.18 degrees, and the autofocusing precision was 1.2 μm. The magnification ratio was 1× to 4×, and the object distance was 200-400 mm. The CCTV lens was connected to the turret lens, and it delivered images to the CCD cameras. HD CCD cameras (HDC-SD041BS, WatchCam Co Ltd) were attached next to the CCTV lenses. The camera had a 1/3-inch complementary metal-oxide-semiconductor sensor, and the total pixels were 2010 (H)×1108 (V). The video output was set to 1280×720, which was the same as the pixel size of the microdisplay for the HMD. The measured resolution of the microscope was 79 line pairs (lp) at 200-mm distance and 105 lp at 400-mm distance. The microscope was implemented with water resistance of IPX4. The specifications of the optical system of the proposed stereoscopic microscope are listed in Table 1.

Figure 2. Left: optical design of the stereoscopic microscope; right: picture of the fabricated stereoscopic microscope. CCTV: closed-circuit television; CCD: charge-coupled device; CMO: common main objective.

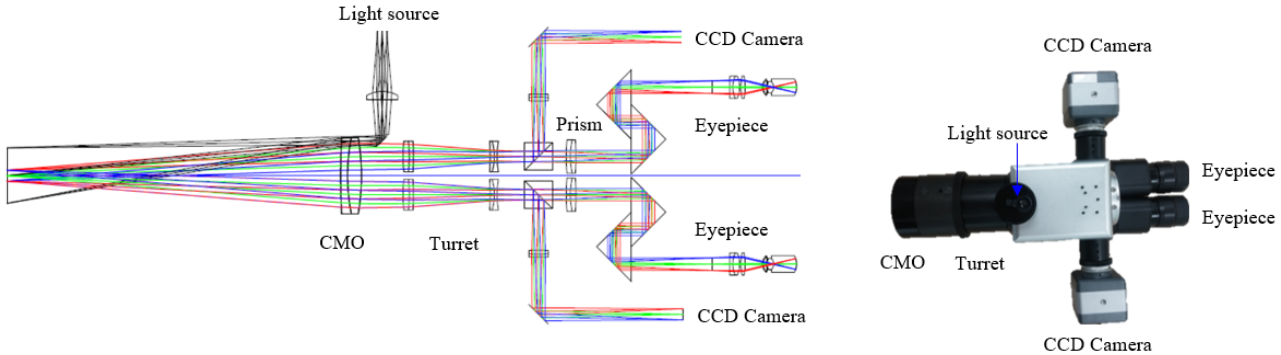


Table 1. Specification of the optical system of the proposed stereoscopic microscope.

Feature	Specification
Resolution	79 line pairs at 200 mm
Charge-coupled device resolution	1280×720
Magnification	Continuous zoom (1:4)
Object distance	200-400 mm
Autofocusing resolution	1.2 μm
Waterproof	IPX4
Display	Eyepieces, monitor, head-mounted display

See-Through Type 3D Head-Mounted Display

A see-through type 3D HMD was designed and fabricated for obtaining not only the 3D surgical image but also a direct physical sight. The binocular design has 2 separate displays with 2 input channels, 1 for each eye, which makes it possible to observe stereoscopic images. Optics designing software (ZEMAX LLC, Optic Studio) was used to create an optical design using 2 prisms and a curved mirror. As shown in Figure 3 (top left image), the image from the microdisplay was enlarged and reflected by the curved mirror and then transferred to the eye after being reflected on the surface of the prism. Using a compensation prism, the sight from outside can also be seen at eye position without distortion. A polarizing film was attached on the prism surface, and a 1/4 λ wave plate was placed between the prism and the curved mirror to minimize optical power loss. The polarizing film can only transmit p-waves and reflect s-waves, and the efficiencies of both are over 80%. Therefore, although the nonpolarized input beam is reduced to half of its original amount by the polarizing film, 40% of p-waves are transmitted. The transmitted p-waves are rotated to s-waves by passing through the 1/4 wave plate twice. Finally, over 34% of the input beam is delivered to the eye. The curved mirrors are fabricated of a glass material (N-BK7). To reduce the weight of optical module, polymethyl methacrylate was used in the fabrication of the optical prisms that are most bulky part in the optical module, and the outside of the effective optical path in optical prisms were cut, as shown in Figure 3 (top right image). Optical components were attached using optical adhesive, and 2 optical modules were placed at the designed positions in relation to the microdisplay.

A 0.61-inch organic light emitting diode display (MDP02BCWF, MICROOLED) with pixel sizes of 1280×1024 was used as a high-resolution microdisplay. The output pixels were set to 1280×720 pixels. The microdisplay driving board with a high-definition multimedia interface (HDMI) and USB power port was custom fabricated. The electric control board was assembled with the optical module, as shown in Figure 3 (top right). The integrated HMD module was mounted on a headband, and the HDMI cable and USB power cable were housed at the rear of the headband for comfortable weight balance. Figure 3 (bottom images) shows the design of the HMD and the fabricated item itself. The headband is designed to adjust in size to fit any user's head. The height and angle of the HMD module were made to be adjustable to match a user's eye. The performance of HMD was measured using a home-constructed measurement system and approved target. The measured field of view was 41 degrees in the diagonal direction, and the distortion was 2.4%. The eye relief was 15 mm, and the horizontal and vertical dimensions of the eye box were 10 mm and 4 mm, respectively. The measured weight of the HMD, without the headband, was about 92 g. To deliver the surgical image dominantly, a polarization window with <10% transparency was applied in front of the HMD. Therefore, we can observe the 3D surgical image as the primary image in the field of view and can also acquire a peripheral view outside the effective area. The specifications of the HMD are listed in Table 2.

Figure 3. Top left: optical design of see-through type 3D head-mounted display (HMD); top right: integration of the control board and the optical module; bottom left: headband design; bottom right: fabricated see-through type 3D HMD.

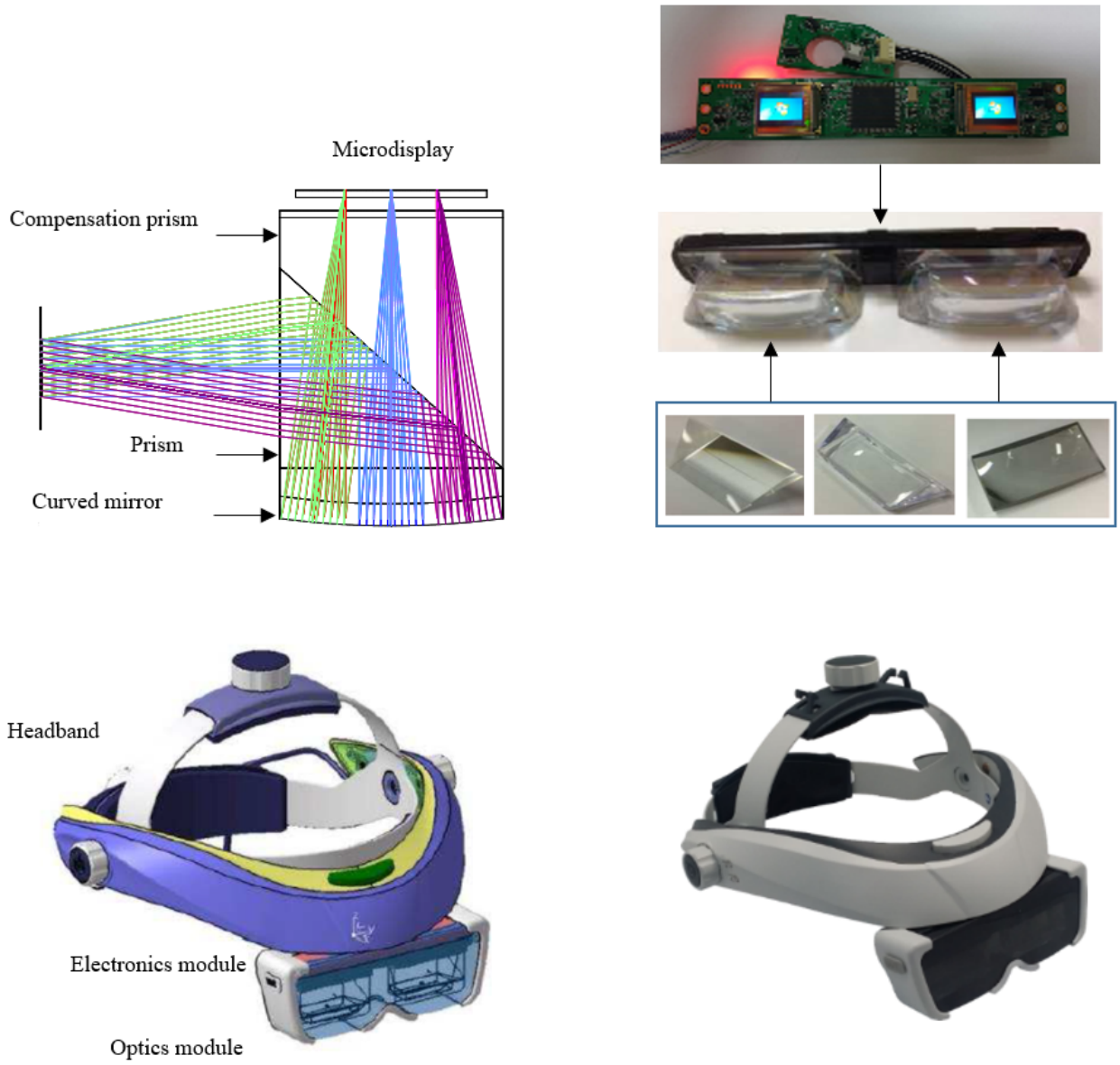
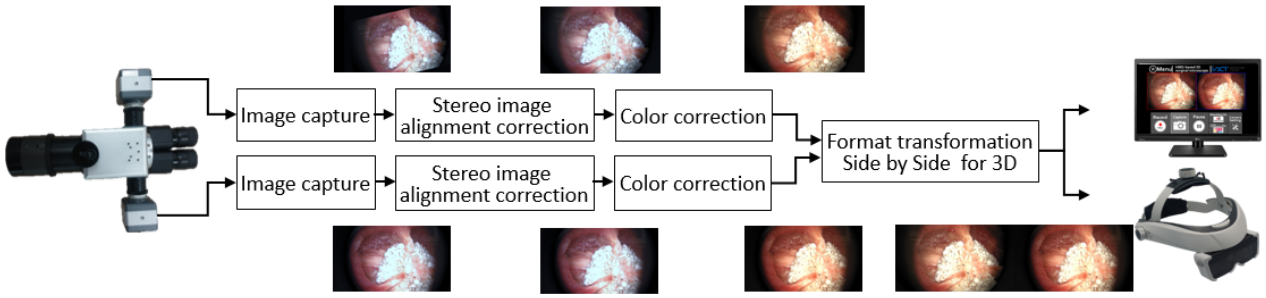


Table 2. Specification of the head-mounted display.

Feature	Specification
Resolution	High definition (1280×720)
Display	Organic light emitting diode
Type	See-through (2D or 3D)
Field of view	41 degrees (diagonal)
Eye Relief	15 mm
Eye box	10 mm×4 mm (H×V)
Distortion	2.4%
Interface	High-definition multimedia interface
Weight	92 g (without headband)

Figure 4. Top: image processing flow; bottom: system control and image processing software.



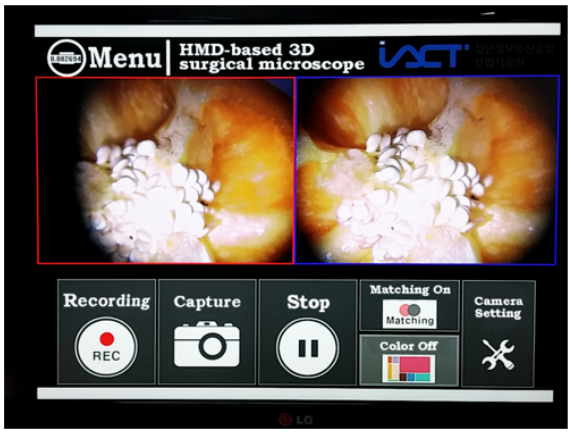


Image Processing Software

The key roles of the image processing software are to improve the image quality and transform the format for 3D HMD. In general, the side-by-side 3D image is made from half-size left and right images reduced in the horizontal dimension, but we used full-size left and right images to achieve a better image quality for medical applications. As shown in Figure 4 (top image), the captured 1280×720 left and right microscope images are transformed into a 2560×720 side-by-side image for HMD through two main image processing procedures: stereo image alignment correction and color correction. The stereo image alignment correction function is intended to restore left and right image alignment error caused by optical misalignment of the microscope. In the stereo image alignment correction process, the left and right images are converted by homography matrix. The matched feature point pairs extracted using by Speeded-Up Robust Features algorithm in the left and right images are used to calculate the homography matrix [16,17]. After correcting the stereo image alignment, the vertical error of the matched feature points was 0%, the rotational error was 1.1°, and the zoom size error was 2%. The color correction function is intended to repair the color distortion caused by the characteristics of the camera image sensor and, therefore, to make the color of the image equal to the color of the real object. We used the colorimetric matching method to correct color distortion [18,19]. In this method, the characteristics of the camera sensor are modeled from the XYZ values of the original object measured using the color meter device and the RGB (red, green, and blue) values of the camera image. After finding the matrix of the camera model, the invert matrix of the camera matrix is used to convert the camera image to its original color. We used the 140-color ColorChecker to find the matrix of the camera model; after correcting the color, the average CIELAB color difference between the measured color and corrected color for the 140 patches was 4.35.

In addition, we developed the graphical user interface for user convenience functions, such as still shot, recording, play, and pause, as shown in Figure 4 (bottom image). Furthermore, camera settings such as brightness, contrast, and sharpness can be directly controlled, which reduces software load for image processing.

Results

Head-Mounted Display–Based Surgical Microscope System Performance

The performance of the proposed system was evaluated by measuring test samples of *Capsicum annuum*. Figure 5 represents left and right images directly captured at the eyepieces (top left) and HMD (bottom left) at eye position. By those slightly different angled images, we can observe 3D images through the eyepieces and the HMD. Different brightness and fields of view were observed because of the different optics between the eyepieces and the CCD camera. Brighter images were observed through the eyepieces and better fields of view were observed via the HMD, as shown in Figure 5 (top and bottom left images, respectively). The camera setting and image processing procedure were optimized to acquire microscope-like 3D reconstruction images from the HMD that were more comfortable to eyes. Through the HMD, we can mainly observe

the measured object and can also recognize environmental situation from peripheral view due to its optical see-through design, as shown in Figure 5 (top and bottom right images).

Preclinical Study

We tested the feasibility of the see-through type 3D HMD–based surgical microscope system through preclinical trial surgery. The preclinical experiment was conducted according to the protocol of the Korea University Medical Center. Male mice aged 8 weeks were used. Experimental methods involving animals were approved by the Institutional Animal Care and Use Committee of Korea University. Mice were anesthetized with 2.5% isoflurane. The surgical sites were aseptically prepared and draped to provide a sterile field. The axillary lymph nodes were exposed after dissection of the skin and fascia (Figure 6, top image); 3 lymph nodes were collected from each site. The collected lymph nodes were checked and confirmed by another surgeon. A nonabsorbable suture was used for skin closure. Suture removal was performed 7 days later under isoflurane anesthesia as necessary. Mice were checked-up once a day until suture removal, then once every week for 1 month.

We used the proposed surgical microscope with and without the see-through type 3D HMD for comparison, as shown in Figure 6 (bottom images). The experiment was a preclinical test of axillary lymph node dissection in white mice. Seven ENT surgical specialists and 8 residents participated in the test, all of whom were experts in microscopic procedures. The evaluation items were the success of the operation, the eye fatigue test, and the postural discomfort test.

First, the success of the operation was evaluated with regard to 4 different categories, as shown in Table 3. The failure criteria for the preclinical trial surgery were as follows: (1) if the operation time exceeds 1 hour; (2) if the tester cannot collect >6 lymph nodes; and (3) if white mice have been bleeding or are unable to survive.

As shown in Table 3, the experimental results demonstrated that 6 trials of surgeries using the proposed 3D HMD–based surgical microscope were successfully performed without bleeding in mice. The average operation time was similar with eyepieces and with the 3D HMD.

Figure 5. Top left: measured left and right images using eyepieces; bottom left: measured left and right images using head-mounted display (HMD); top and bottom right: a demonstration of the see-through type 3D HMD.

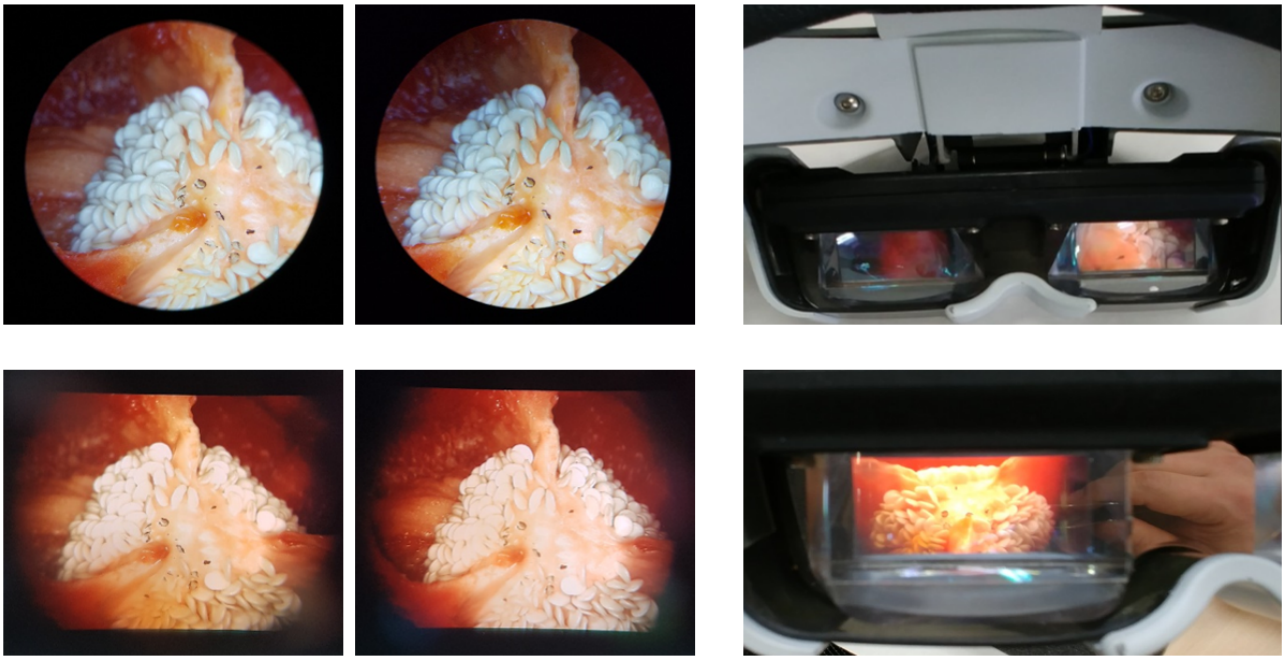


Figure 6. Top: preclinical test of axillary lymph node dissection in white mice; bottom left: preclinical test using eyepieces; bottom right: preclinical test using see-through type 3D head-mounted display.

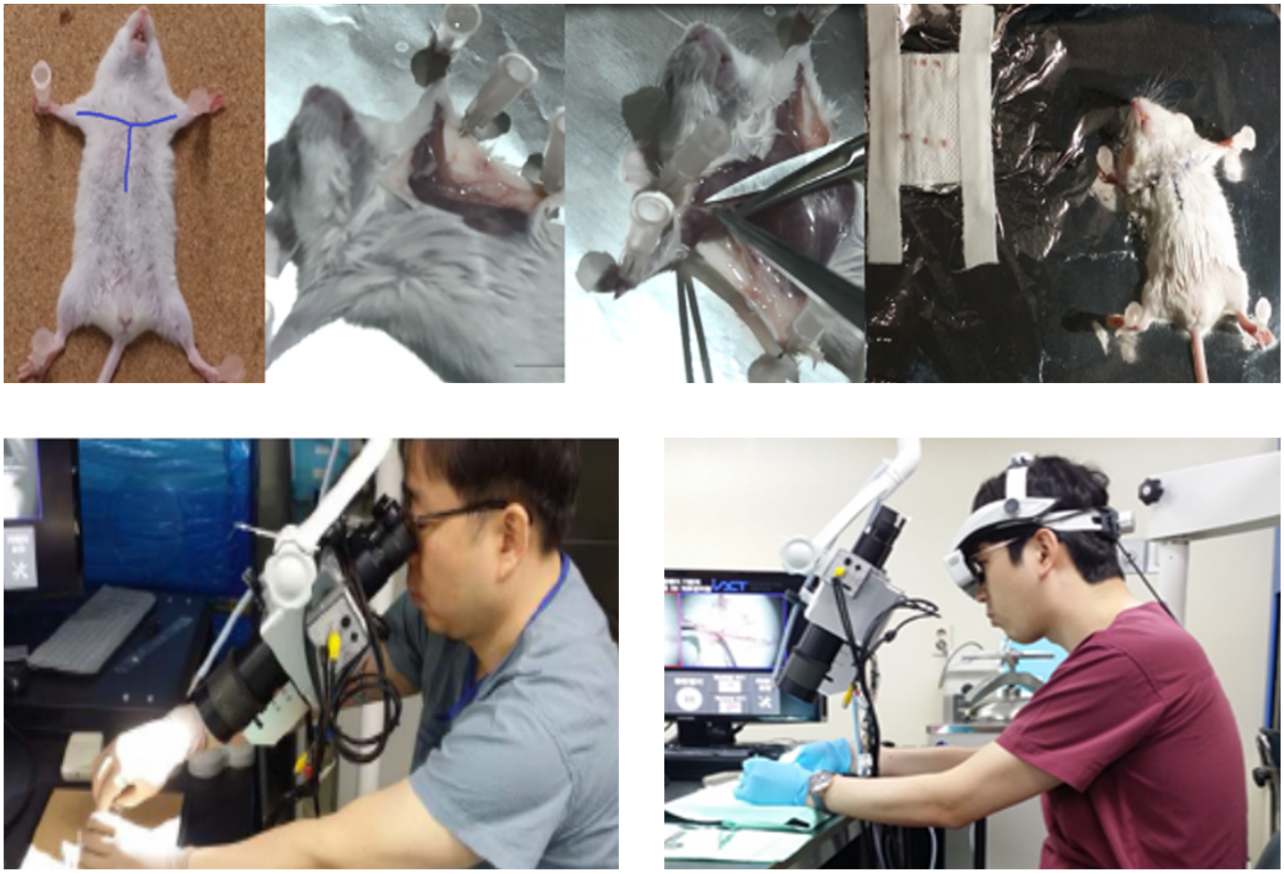


Table 3. Comparison of preclinical experiment results obtained using head-mounted display (HMD) and eyepieces.

Category and device	Result	Success or Failure	Experiment success criteria
Average operation time			
HMD	21 minutes 41 seconds	Success	1 hour
Eyepieces	22 minutes 42 seconds	Success	
Number of lymph nodes sampled			
HMD	6	Success	6
Eyepieces	6	Success	
Bleeding			
HMD	No	Success	No
Eyepieces	No	Success	
Survival			
HMD	Survival	Success	Survival
Eyepieces	Survival	Success	

The eye fatigue test measured subjective fatigue from 0 to 7 points for tired eyes, sore or aching eyes, irritated eyes, dry eyes, eyestrain, hot or burning eyes, blurred vision, difficulty focusing, and visual discomfort. In addition, headache, dizziness, nausea, and decreased concentration were evaluated. The eye fatigue test was evaluated before and after the preclinical trial surgery tests.

In the preclinical test using the eyepieces of the surgical microscope, the eye fatigue scores were in the order of tired eyes (2.3), difficulty focusing (1.9), and vision discomfort (1.9). Using the proposed 3D HMD technology, the results were in the order of tired eyes (1.9), difficulty focusing (1.7), and eyestrain (1.2). The 2-tailed paired *t* test of tired eyes showed no significant difference between the use of eyepieces and the use of HMD (P=.79). However, in the case of visual discomfort,

the *P* value was .097 (Figure 7), which means that the HMD has the potential to help reduce visual discomfort.

The posture discomfort test measured discomfort with a rating of 1 to 5 points for discomfort associated with the lower back, upper back, hand or wrist, elbow, arm, neck or shoulder, eye, and head after the preclinical test. After the preclinical test using the eyepieces of the surgical microscope, the posture discomfort scores were in the order of neck or shoulder (2.9), eyes (2.7), and upper back (2.5). Using the HMD-based surgical microscope, the scores were in the order of eyes (2.2), head (1.9), and neck or shoulder (1.8). The mean of the posture discomfort score with and without using the HMD was 12.5 and 18.5, respectively. The results of the paired *t* test of posture discomfort scores showed a significant difference between the use of the eyepieces and the use of the HMD (*P*=.00083; Figure 8); these results confirmed that the proposed see-through type 3D HMD can reduce posture discomfort, especially regarding neck and shoulder pain, during surgical procedures.

We analyzed the total scores for eye fatigue and posture discomfort. Using the eyepieces, the eye fatigue and posture discomfort scores were distributed from 3 to 51 points (average 15.1) and 12 to 27 points (average 18.5), respectively. Using the 3D HMD, the eye fatigue and posture discomfort scores were distributed from 4 to 33 points (average 14.5) and 10 to 17 points (average 12.8), respectively. Paired *t* test results showed no significant difference between the 2 technologies regarding the total eye fatigue scores, but there was a significant difference regarding the total posture discomfort scores (Figure 9). In conclusion, posture discomfort can be reduced using the proposed see-through type 3D HMD instead of the traditional eyepieces of the surgical microscope.

Figure 7. Results of eye fatigue test. HMD: head-mounted display.

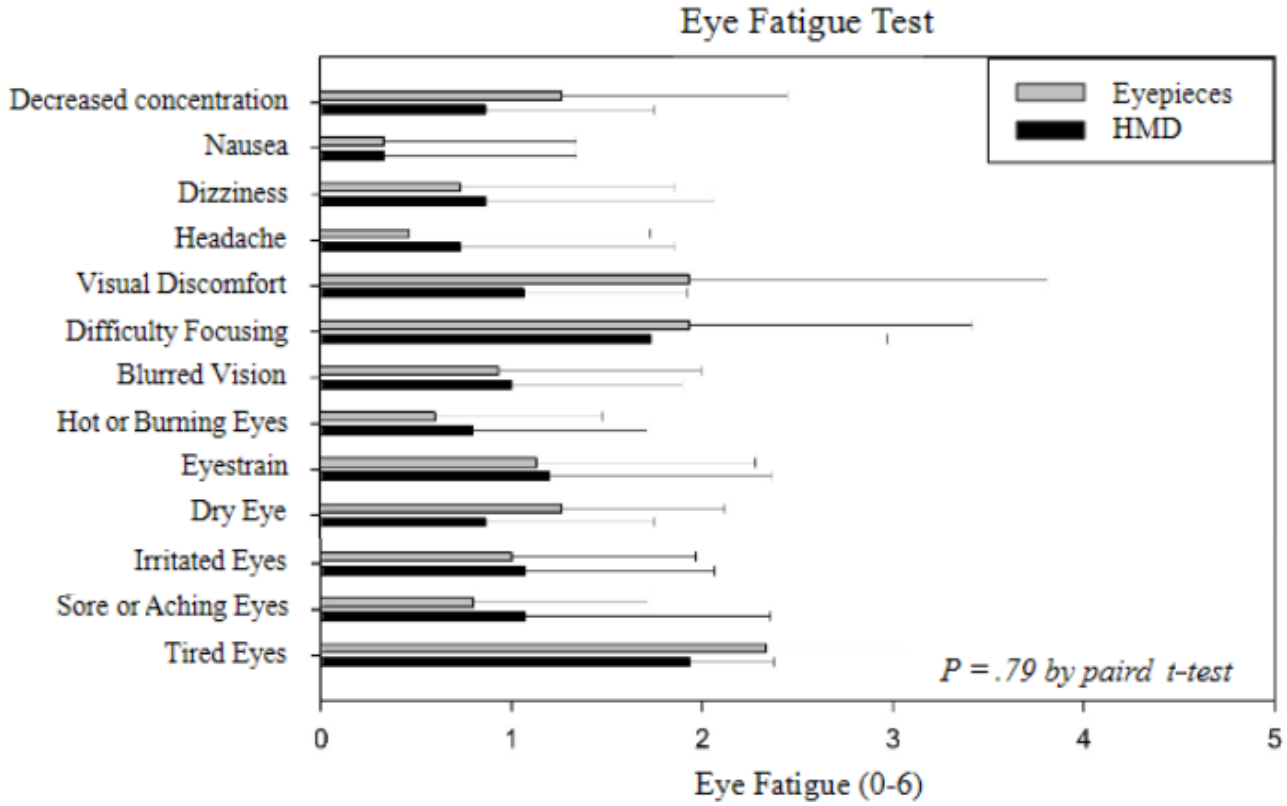


Figure 8. Results of posture discomfort test. HMD: head-mounted display.

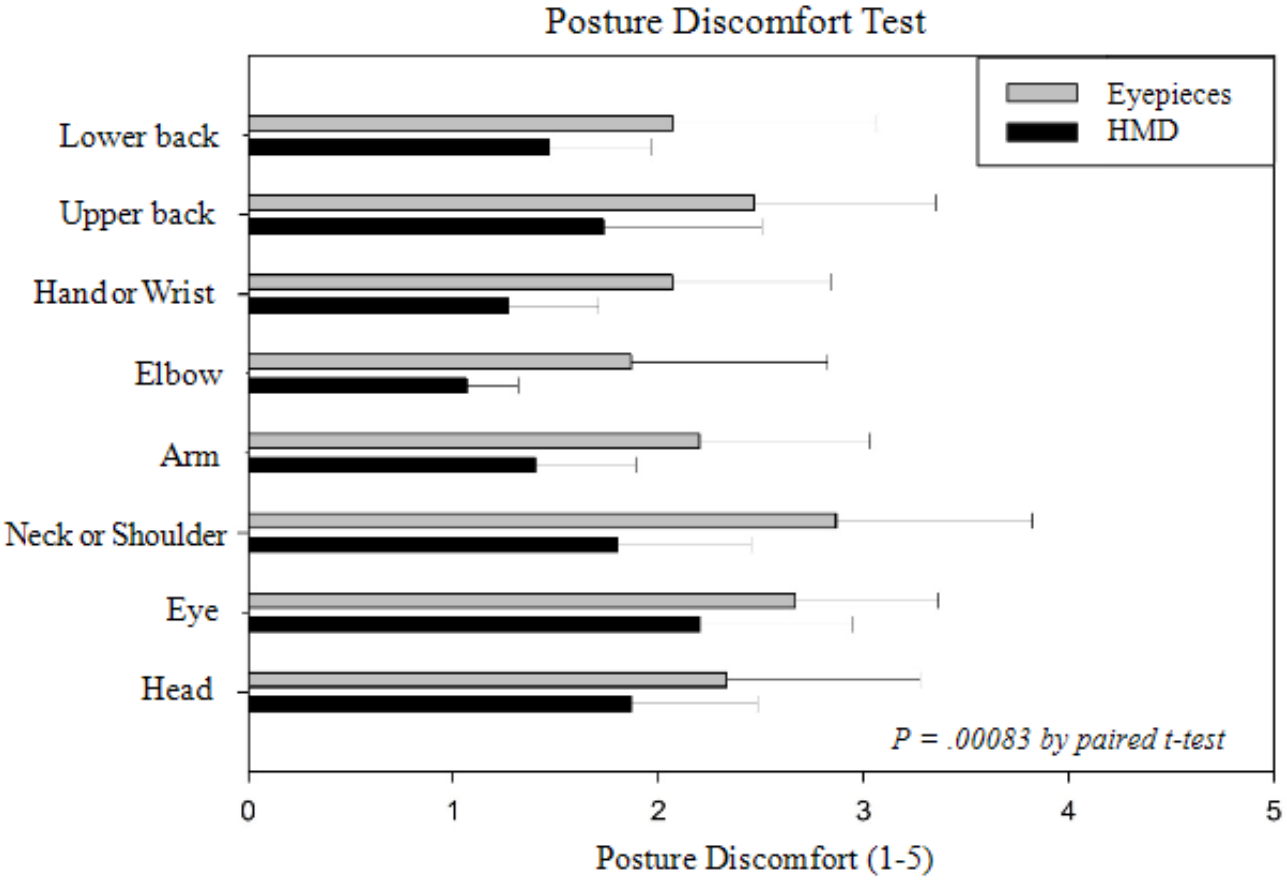
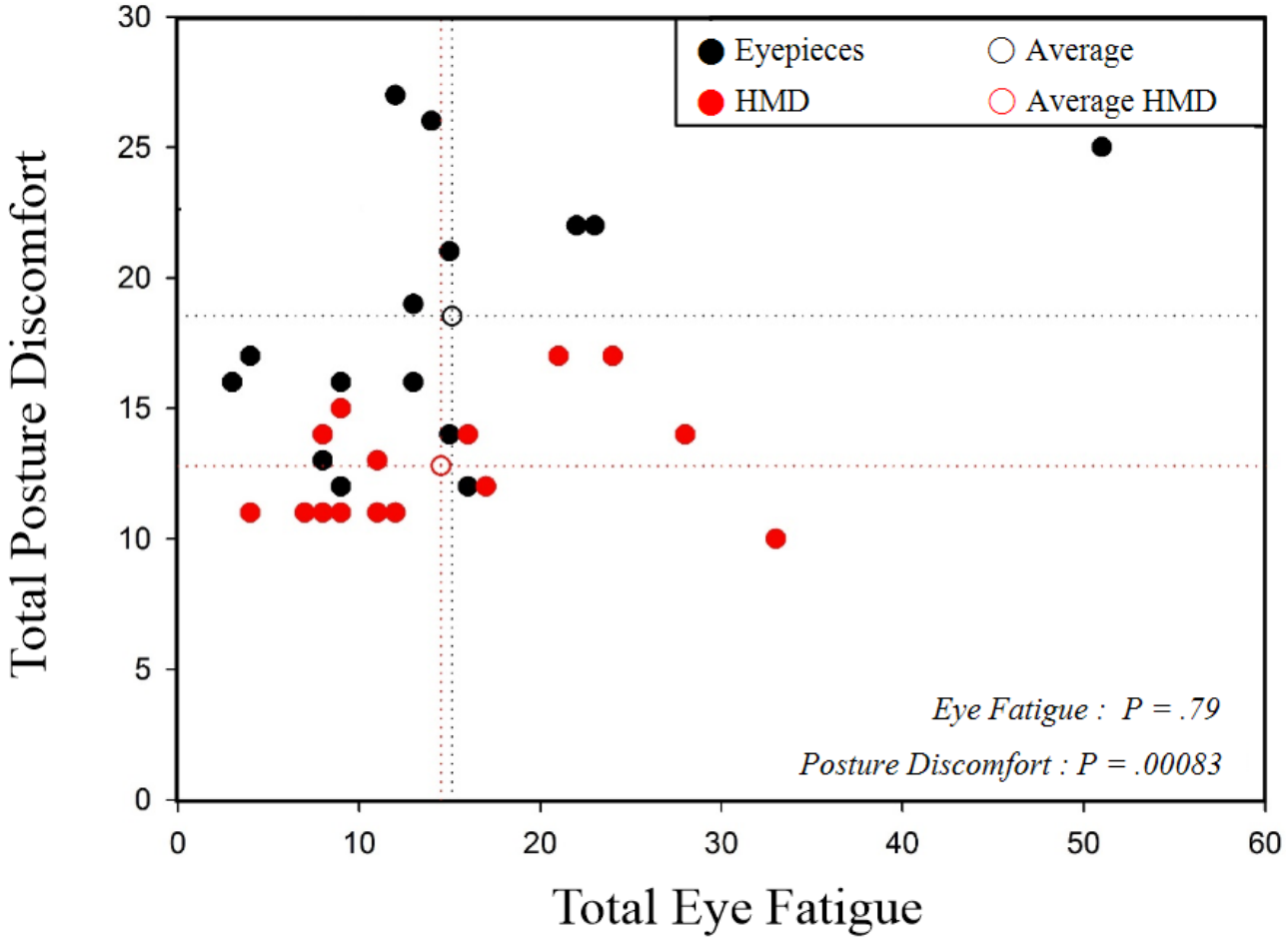


Figure 9. Comparison of eye fatigue and posture discomfort scores for head-mounted display (HMD) and eyepieces.



Discussion

Principal Findings

Surgical microscopy is an indispensable system for microsurgery. Although with currently available systems, surgeons can match their eye-hand coordination during surgical procedures, their eyes must be kept on the fixed eyepieces of the microscope for long periods, which requires them to maintain uncomfortable postures that can cause a musculoskeletal disorder. To provide surgeons with the freedom to change their viewing positions, we proposed a high-resolution, see-through type 3D HMD–based surgical microscope system. With this system, surgeons can obtain high-definition 3D surgical images with more comfortable and flexible postures by acquiring the images from a 3D HMD mounted on a headband, instead of keeping their eyes on fixed eyepieces. Furthermore, surgeons can observe a broader surgical environment in addition to the local surgical field using the optical see-through type configuration in the HMD design. Although we used an optical window to block the intensity of the physical view over 90% to provide a brighter surgical image, the see-through type configuration helps in obtaining the peripheral view more easily than a nonsee-through type configuration.

In this proposed system, we used a headband design to remove the weight from the user's nose. In addition, we used light-weight material for the optical module, and the nonessential area was cut away to minimize the weight of the HMD. However, additional efforts are required to reduce the weight while maintaining a large field of view. Using a thin and light-weight optical module, such as a waveguide or light guide, an HMD with more compact glasses can be achieved [20]. With recent technologies, additional functions of the HMD are easily accessible, such as voice control and a display of additional medical information. Using several HMDs, assistants or students can see the same surgical images as surgeons, which will be helpful in making surgeries and medical education more effective. We are planning to improve the proposed system in our future work.

The results of the feasibility study conducted by preclinical trial surgery showed that the see-through type 3D HMD could provide surgical images with performance similar to that of conventional eyepieces in terms of eye fatigue. In this test, the eye fatigue scores of a few items, including dizziness, were shown to be slightly higher when the HMD was used. One of the main reasons for these increased scores was interpupillary distance (IPD) mismatch. Correspondence between the observer's IPD and the distance between the optical centers of the binocular HMD is critical for visual comfort. In this work, we set a fixed IPD of 65 mm, a value within the IPD range (50-74 mm) of most adult females and males. Thus, some people who have a short or long IPD can feel dizzy or feel soreness in eyes. Such fatigue can be reduced by adopting adjustable frames of both optical modules for IPD adjustment. We plan to apply

an IPD controllable frame in the next version of the HMD. In addition, horizontal, vertical, or rotational deviations of the input images to the eye can bring about eye fatigue or dizziness. Therefore, the alignment of the 2 cameras of the microscope and the 2 microdisplays is also important for reducing eye fatigue. In this work, alignment correction is included in the image processing software for the 2 camera alignments. In addition, fine alignment of the 2 microdisplays has been performed during the packaging process of the optical module.

Conclusions

In this study, we have introduced a high-resolution, see-through type 3D HMD–based surgical microscope system that is suitable for stable and comfortable microsurgery with advanced functions, such as flexibility of viewing posture and a broad surgical view. The results of the preclinical examination showed that the proposed system has sufficient performance to relieve posture discomfort. The proposed system would be advantageous in overall ENT surgery. To be specific, the main application fields are mastoidectomy and tympanoplasty because they both require long surgical times.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CCD: charge-coupled device
ENT: ear, nose, and throat
HDMI: high-definition multimedia interface
HMD: head-mounted display
IPD: interpupillary distance

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Original Paper

An Argument Against Cross-Platform Development: Lessons From an Augmented Reality App Prototype for Rural Emergency Responders

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Abstract

Background: Mobile augmented reality (MAR) apps offer potential support for emergency responders in rural areas.

Objective: In this report, we described lessons learned from the development process of augmented reality (AR) Farm Mapping to Assist, Protect and Prepare Emergency Responders (MAPPER), a MAR app that provides emergency responders onsite information about the agricultural operation they enter.

Methods: Cross-platform frameworks were used to create AR MAPPER to accommodate budget constraints and overcome issues with markerless MAR technologies. Although the single codebase and Web technologies streamlined development, cross-device hardware limitations impacted location accuracy, lengthened the development cycle, and required regular updates to third-party libraries.

Results: A hybrid development approach of using Web-based technologies with native tie-ins for specialized components and enhanced performance cut time and costs. This also led to consistency across multiple platforms and ensured that there is only a single set of source files to modify for Android and iPhone operating systems. Meanwhile, active development was delayed by some major hurdles. Apple and Google both released new versions of their operating systems, and the Wikitude framework issued four major updates, each of which brought with it some important enhancements and also led to some new issues.

Conclusions: Developers should consider single platform native development to benefit from platform-specific MAR implementations and to avoid development, testing, and maintenance costs associated with cross-platform implementation. Emergency response organizations may be more likely to utilize a single platform across the devices used by their command staff. This also reduces the benefits of cross-platform development. Furthermore, providing map-based, non-AR cross-platform apps for landowners, farmers, and ranchers would help improve and maintain data quality, which is crucial for the utility and user experience of MAR apps.

(JMIR Mhealth Uhealth 2019;7(3):e12207) doi:10.2196/12207

KEYWORDS

rural health; mhealth; telemedicine; emergency medical services

Introduction

Augmented reality (AR) [1] combines a view of the real world with digitally overlaid content. Recently, mobile augmented reality (MAR) apps have become increasingly popular, where virtual objects are combined with objects in the real environment in real time and aligned based on the user's point of view through their mobile device display [2]. MAR games and improving support from mobile platform providers have made MAR accessible to end users and developers. However, users have several expectations toward MAR apps and that the underlying technology will influence the user experience (UX). MAR interfaces are expected to be able to provide valid, up-to-date, and relevant content to the user [3]. This may be particularly true in the context of apps created for medical education, health care service delivery, and other industries where unreliable and irrelevant content could have material and safety implications. Given these requirements, decisions made early in development have a significant effect on whether MAR apps provide reliable and relevant content. Developing a modern and cross-platform MAR app can easily accumulate significant expenses because of the sheer magnitude of resources required [4]. In practical terms, a key decision is whether to develop native apps for 1 or multiple mobile platforms or to use a cross-platform approach whereby hybrid app development frameworks are utilized to deliver the app to multiple platforms.

Farm Mapping to Assist, Protect and Prepare Emergency Responders (MAPPER) provides emergency responders onsite information about the agricultural operation they are entering [5]. This case report describes development lessons learned in creating the AR Farm MAPPER, specifically addressing cross-platform development. The MAR prototype of Farm MAPPER improves on the earlier, static overhead version by incorporating a real-time depiction of icons, such as hazards, resources, and points of entry. This offers the possibility for on-scene commanders to have a heads-up display. This report, which builds upon a previously published manuscript [6], may be of more interest to researchers and practitioners working with MAR in the medical informatics field and, particularly, when considering issues related to the choice of approach—cross-platform development versus targeting single platforms. The specifics of the original Farm MAPPER app and its applicability to agricultural injury prevention interventions are the topic of another paper [6].

Methods

The project was led by a research team, which was administratively housed within a private rural health care system in the Upper Midwest. The skill set needed to develop and test MAR technology can be difficult to find. No internal resources were available. Thus, the lead developer (third author) recruited for this project was self-employed and subcontracted, although residing in the same community as the research team. The lead developer had significant experience in Web and mobile app development, with some familiarity with AR. The developer's portfolio included first place awards for back-to-back public app development competitions run by Intel, the only developer to have done so. Few stakeholders were involved in this prototype's development, which did not include formal usability testing.

The benefit of a Web-based approach is the ability to leverage any of the thousands of freely available libraries and extensions, many of which are licensed under MIT, Apache, or GNU, which makes them fully available for distribution in any type of app, free or commercial. This can save tens of thousands of work hours to reinvent many already existing components. Moreover, the complexity of managing multiple software development kits with their differing application programming interfaces (APIs), build systems, and tools can be avoided [7]. This approach, as opposed to developing fully native apps for each platform, represents a more efficient way to deploy a product that will work on most modern mobile platforms. This can be particularly useful if the app is expected to be used by multiple organizations, some of which may have already committed to a specific platform.

Although the window of time between our first written proposal and the final completion and delivery of the product extended more than a year, the fixed development budget only accommodated approximately 292 hours of actual labor (roughly equivalent to 7 full-time work weeks by a single person). Although remaining conscientious of the available budget and the relatively uncharted nature of markerless AR, we had to make some development decisions early on to effectively accommodate the various requirements. This led to the use of a third-party framework to simplify the AR mathematics and presentation as well as the use of Web-based technologies to retain a single universal codebase.

Results

What Went Right

It appears that taking a hybrid app approach toward development by using Web-based technologies (with native tie-ins for specialized components and enhanced performance) was a decision that had some benefits. This strategy helped ensure consistency across multiple platforms and ensured that there is only a single set of source files to modify for Android and iPhone operating system (iOS, Apple Inc) combined. We were able to also borrow from various user interface (UI) libraries, notably OnsenUI [8] and the Wikitude [9] frameworks, to expedite the implementation of key features while ensuring a consistent UX across both Android and iOS devices. The key benefits of Wikitude are the ability to program AR content using basic Web technologies and easy porting of apps between platforms [10].

Traditional development would have required use of native UI elements for all facets of the app; any changes made on one platform would then have to be manually worked into the source of the other platform. Requiring constant synchronization of 2 native apps would have effectively reduced the available work time by half. Conversely, the use of an existing and long-standing AR framework that supported hybrid apps within a universal API represented a substantial savings of time. Despite only an evaluation copy of the Wikitude framework

being used throughout development and the considerable work that was still required to satisfactorily integrate it into the overall app, it offered a positive demonstration of the current capabilities and technical limitations of developing location-based AR.

What Went Wrong

Physical Hardware Limitations

Going into this project, we knew that one of the largest setbacks we would encounter related to the technical limitations of modern-day hardware, particularly geolocation and global positioning system (GPS) accuracy. During testing across various devices, it was not uncommon for the variance in GPS accuracy to range anywhere from 30+ feet all the way up to 1400+ feet. This poses a problem when the objective of the app is to allow emergency responders the ability to quickly locate points of interest on a property. The nature of GPS also tends to require a delay between the initial GPS probe and an accurate fix. Although most modern cellular phones can typically lock onto GPS quite rapidly using assisted GPS technology, some devices we tested, including the LG G2, could take up to 10 min. Certain modern Android devices also lacked gyroscope functionality, which caused the AR framework to fail even though it was meant to be a universal solution. This then required additional correspondence with the framework developers who had to try and implement a workaround specifically for the affected devices.

Lapse in Timeline of Development

Despite a relatively short active development time (comparable with 1-2 months of dedicated work), the prolonged overall timeline of this project adversely impacted numerous aspects of it. There were multiple extended gaps between development from January to September, due in part to external occurrences, contractual matters, and other commitments. Although the generous timespan seemed appealing to better accommodate availability, it also led to struggles in having to make continual updates to the various frameworks and then retest all aspects to ensure no newfound issues emerged when subsequent operating system (OS) versions and libraries were released.

Within the project's timeframe, Apple and Google both released sweeping new versions of their OS (iOS 11.0 and Android 8.0, respectively). Meanwhile, the Wikitude framework issued 4 major updates (from 6.0.1 to 7.1), each of which brought with it some important enhancements and also led to some new issues.

Given the basic prototype goals of this project, it would have been reasonable to develop and deploy the baseline product within a couple of months of dedicated work compared with stretching it over the course of a year and having to regularly update and recheck major components as the technologies evolved. A more focused, short-term deadline could have alleviated some of these obstacles.

Discussion

Arguments Against Cross-Platform Development

Cross-platform development is a popular buzzword. In many instances, it is indeed beneficial to accommodate all major platforms—currently Android and iOS. However, that is not always the case, and in retrospect, we would propose that this prototype could have benefited more directly if it had been built only for a single target platform. Organizations that provide work-appointed devices almost always adhere to a single platform strategy, such as a health clinic's laptop distribution. This way, they only need to be concerned that the apps being used function as intended on the single platform and OS that they support.

The intent of this MAR project was to create a conceptual example of what emergency responders could use to locate areas of interest on a rural or agricultural property through visual cues such as hovering AR icons representing hazards, resources, and items of interest. Rather than relying on the emergency staff's own personal phones for such activities, it is more probable that the facilities would supply identical, company-owned units to all personnel or at least individual shift leaders. In this respect, focusing on a single platform with a limited set of technology-related variables could help provide a more consistent UX.

In related research, a survey of the Google Play Store revealed that hybrid development is more popular as an approach to creating data-intensive apps and correspondingly less popular in apps that require closer interaction with the underlying OS [11]. App reviews show that native apps are generally perceived as more performant and less buggy (ibid.), and hybrid apps on iOS and Android were more prone to complaints in user reviews [12]. Mobile app developers may also favor native development, particularly when better UX and access to device-specific features were needed [13]. Several case studies have shown that although a reasonable UX can be achieved by using a cross-platform framework, there are still limitations with performance, UX, and usability [14-16].

Benefits of Developing for iPhone Operating System Only

With the consideration to develop natively for a single platform, iOS would be an ideal choice if it is to be used as an internal company app. Although Android is equally capable and more versatile in many ways, from a development and industrial perspective, Android also has a vastly more diverse blend of devices, OS versions, and varying limitations that can impede development time and testing.

iOS also has a more streamlined adoption rate in which new OS versions are generally installed soon after being released (more than 95% of all iOS users are within 1 version of the latest OS) [17]. In comparison, Android users often must stick to older versions because of their carrier and device restrictions; so the adoption rate to newer versions is quite low (less than 40% of all Android users are within 1 version of the latest OS) [18].

Table 1. Potential app features.

Feature	Brief description
Caching and prefetching of map data	Currently, the top-down map imagery first begins downloading when the map view is brought into focus and is based on the user's current location. For situations in which network data connectivity may be sparse, caching of data would prove valuable so that the location imagery and marker data can be fetched while somewhere with a strong connection instead of after arriving onto the site. With such functionality, the map could immediately download the image data of all quadrants surrounding the loaded markers for future access.
Sorting of markers by distance	The option to sort all markers by distance to user would allow the user to quickly review the closest resources when viewing the marker list view.
Enhanced GPS[a] simulation	The current version includes rudimentary support for manually entering a static GPS location to simulate that vantage point. In a more robust integration, the simulated coordinates could be obtained automatically from the loaded location and allow the user to physically move within the simulated coordinates for remote practice and exploration.
Distance from one marker to another	It could prove beneficial to be able to quickly approximate the distance from one placed marker to another while reviewing the loaded data. For instance, to see how far a water source is to a barn.
Speech recognition and audio navigation	In cases where directly viewing and holding the phone may not be accommodating, being able to use speech (eg, "Find Water Source") and have the app return audio cues on which direction to travel to find it could be helpful.

[a]GPS: Global Positioning System.

Finally, although Android OS spans thousands of different devices with a highly varying list of specs, iOS devices all use the same underlying architecture and are very limited in variety. An app developed for a modern version of iOS is almost certain to function identically on all the latest iPhones, with minimal design or developmental changes required to compensate for device-specific issues.

Perhaps most importantly, developing on only a single platform would allow the use of each platform's respective AR framework. Apple shipped ARKit [19] alongside iOS 11 for the latest generation of iPhones, whereas Google debuted its competing system dubbed ARCore [20]. Neither of these frameworks are cross-platform, and they were not publicly available for much of this app's lifecycle, but if developing a native AR app in the future, they should be highly considered. We anticipate that open-source libraries for hybrid apps will be developed to transparently support both AR toolsets depending on the platform, which will rival many features currently found in Wikitude.

The Alternative iPhone Operating System–Only Approach—Heightened Focus on Functionality

Developing a custom AR component may have been more achievable had the focus been devoted entirely to a single platform. If so, this could have alleviated the need to depend on a costly and proprietary third-party commercial framework, which itself includes many excess features not needed or used by AR MAPPER.

During this project, a sizeable amount of time was spent troubleshooting and resolving device-specific issues while testing on Android. Even when using the popular hybrid approach, some native components still caused issues depending on the device. When Wikitude 7.0 was released, for example, it inadvertently broke the app on a couple of Android devices we used for testing that did not have certain sensors. This led to more time spent troubleshooting and ultimately having to point out the issues to the framework developers, who addressed the issue, but not formally for another 3 months.

Other Potential Features for This Type of App

The time and budget for this project elapsed before several considered features could be properly assessed or integrated. A summary of such imagined features is described in Table 1.

Evaluating Mobile Augmented Reality Apps

Although the proposed MAR app was not formally tested, several options exist to assess the success of mobile apps. Usability heuristics have been adapted to the design and evaluation of AR apps [21,22], but they are of somewhat limited utility when performance in the field is of interest. Success of AR app concepts can also be evaluated via surveys before design and development [23] or based on user reports on the use of an AR app [24]; however, these methods also suffer from lack of direct access to the real-world context of use. Although appropriate methods for field testing mobile apps are well understood [25], field evaluation of MAR has generally received less attention [26]. In situ, MAR evaluations have included various combinations of task-based assessment, observation, and subjective feedback collection through questionnaires and interviews [27-30]. Although such short-term, task-based evaluation can provide a baseline assessment of the immediate success of the MAR app, longitudinal studies would be more appropriate for uncovering issues that users would face in their day-to-day interactions.

This brief report is a snapshot in time in the development of a better, more useful farm mapping tool for emergency responders. As a part of a Centers for Disease Control and Prevention–funded research project, the original Farm MAPPER has been integrated as a tool for high-quality emergency planning for rural firefighters and the agricultural operations in their coverage areas. During trainings, these emergency responders are given a preview of the MAPPER AR and have been highly receptive. Of the 50 or so trainees, nearly all have

voiced support for the heads-up style display that MAR technology allows. In future development, it is anticipated that valuable usability feedback will be easily attained, yielding meaningful and actionable results. Despite the limitations of the development caused by accommodating multiple platforms, the purpose of the new technology appears to be valued enough by the end users to allow for additional studies and builds.

Despite the rapid advancement and adoption of MAR, little is known about the effectiveness of these technologies in real-world rural emergency response [6]. Researchers in related disciplines, such as medical education, have also struggled to evaluate the technology's place and effectiveness [31-36]. Next steps and future research must address the effectiveness and feasibility of this technology in the agricultural or occupational and patient care environments.

Conclusions

From the early design and mockup phases to the final steps of development and testing, this project presented challenges. Many different frameworks and design methodologies were considered to satisfy the original scope and requirements while remaining within the budget. The result is a cross-platform, multi-view prototype app with aerial and AR components.

Undeniably, the biggest hurdle continues to be present-day hardware limitations, which cannot always guarantee a reliable connection to satellites or cellular towers required to parse data and track very granular and specific points of interest. This approach is not suitable for indoor navigation or other areas with heavy ground obstructions or tree foliage. An even greater concern exists in that many rural locations still do not have adequate cellphone reception. Although GPS signal is generally obtainable in these areas, the app still depends on network connectivity to download satellite imagery and initialize the various components correctly. Thankfully, the spread and improvement of carrier coverage and adoption of mobile devices continue to penetrate rural areas.

Developers should consider single platform native development to benefit from platform-specific MAR implementations and to avoid development and testing costs associated with cross-platform implementation. Emergency response organizations may be more likely to utilize a single platform across their devices, reducing the benefit of cross-platform development. Furthermore, providing map-based, non-AR cross-platform apps for landowners, farmers, and ranchers would help improve and maintain the data quality of AR content.

With the recently-launched Apple ARKit and Google's ARCore framework and more broad concepts such as its Visual Positioning Service for indoor GPS tracking, we can assume that MAR will play increased roles in emergency response, health care delivery, and everyday life in the years to come. Enhancing everyday reality with accurate, meaningful, and visualized data can transform the training and execution of any number of skills, including emergency medical services and bedside health care. MAR technology can increase the amount of contextual data in emergency responses, thereby improving the decision-making capabilities of the users. In turn, this can expedite response times and protect responders. Combined, these elements may improve patient outcomes and increase other successes further downstream in health care delivery.

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Authors' Contributions

All authors participated in the conception or design of the work; the acquisition, analysis, or interpretation of data for the work. BW acquired funding, drafted the proposal and early drafts of the manuscript with input from all authors. MP led the development of the MAR app. BW, TH, and MP drafted and revised the manuscript. All authors reviewed and revised it critically for important intellectual content. All authors provided final approval of the version to be submitted or published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface
AR: augmented reality
GPS: Global Positioning System
iOS: iPhone operating system
MAPPER: Mapping to Assist, Protect and Prepare Emergency Responders
MAR: mobile augmented reality
OS: operating system
UI: user interface
UX: user experience

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Original Paper

Temporal Stability of Smartphone Use Data: Determining Fundamental Time Unit and Independent Cycle

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Abstract

Background: Assessing human behaviors via smartphone for monitoring the pattern of daily behaviors has become a crucial issue in this century. Thus, a more accurate and structured methodology is needed for smartphone use research.

Objective: The study aimed to investigate the duration of data collection needed to establish a reliable pattern of use, how long a smartphone use cycle could perpetuate by assessing maximum time intervals between 2 smartphone periods, and to validate smartphone use and use/nonuse reciprocity parameters.

Methods: Using the Know Addiction database, we selected 33 participants and passively recorded their smartphone usage patterns for at least 8 weeks. We generated 4 parameters on the basis of smartphone use episodes, including total use frequency, total use duration, proactive use frequency, and proactive use duration. A total of 3 additional parameters (root mean square of successive differences, Control Index, and Similarity Index) were calculated to reflect impaired control and compulsive use.

Results: Our findings included (1) proactive use duration correlated with subjective smartphone addiction scores, (2) a 2-week period of data collection is required to infer a 2-month period of smartphone use, and (3) smartphone use cycles with a time gap of 4 weeks between them are highly likely independent cycles.

Conclusions: This study validated temporal stability for smartphone use patterns recorded by a mobile app. The results may provide researchers an opportunity to investigate human behaviors with more structured methods.

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KEYWORDS

temporal stability; smartphone use; smartphone addiction; smartphone; mobile phone

Introduction

Background

The excessive use of smartphones has become a substantial worldwide social issue because of increasing smartphone penetration. Recording human behaviors (eg, smartphone use, exercise, and sleep time) via a smartphone is a feasible and popular method in modern society. A previous study has found that smartphone use patterns can reflect social economic status in Rwanda [1]. Given the convenience of smartphones, health-related mobile apps might serve as a "digital lifeline," particularly in rural and low-income regions, helping mental health care professionals with medical intervention and behavioral modification [2]. Using smartphone use data to assess human behaviors and to assist monitoring pattern of behaviors has become a crucial issue in this century.

For the assessment of smartphone use patterns, we introduced several app-generated parameters to delineate smartphone usage. There are 2 fundamental app-generated parameters about smartphone use, namely use frequency and use duration. To assess core elements about Web-based behaviors, we also developed 2 parameters—root mean square of successive differences (RMSSD) and Similarity Index (SI)—to assess the reciprocity between use and nonuse patterns. We calculated the RMSSD and SI within a day and applied the average daily RMSSD and SI to indicate impaired control and compulsive behaviors for smartphone use [3]. Furthermore, previous studies claimed that self-reported problematic smartphone use did not correlate with actual use recorded by an app [4,5]. It implies that problematic smartphone use pattern may not be captured through self-reported scales. However, we have found that proactive use may be more representative to addictive behavior than total use. To investigate the relationship between smartphone use behaviors and self-reported problematic smartphone use, this study also conducted an exploratory analysis of associations between app-generated parameters and smartphone addiction symptoms.

However, frequent short-period smartphone use is difficult to measure with either self-reporting or the reporting of others. Thus, an app that automatically detects smartphone use is likely a more reliable assessment tool with ecological validity as it can record smartphone use behaviors in a naturalistic setting. Few studies have used mobile apps to measure smartphone use behaviors directly [4,6,7]. The total duration of data collection varies in different studies, ranging from 1 to 6 weeks [4,7,8]. A previous study demonstrated that a relatively short duration of behavioral data is required to qualify a 2-week use period [5]. However, even a 1-month record might not be enough to allow detection for patterns of smartphone use [3]. For an app-generated parameter, it may need a detection time period of longer than 1 month. Our previous study also found that smartphone use behaviors demonstrate a weekly cycle [7]. In addition, previous studies did not discriminate active smartphone use (ie, proactive use) from smartphone use triggered by a notification (ie, reactive use) [4,5]. It may be crucial to separate proactive smartphone use from total smartphone use to make a more reliable inference for actual use in natural setting. To determine the shortest duration of smartphone use, data are required to reliably infer a pattern of smartphone use, validating long-term temporal stability for daily smartphone usage, and examining more app-generated parameters except frequency and duration are urgently needed.

Objective

The specific aims of this study were to (1) illustrate the time periods or span of weeks required to reliably infer patterns of long-term smartphone use, (2) investigate how long could a smartphone use cycle perpetuate by assessing maximum time intervals (TIs, ie, weeks) between 2 smartphone use periods, and (3) validate smartphone use and use/nonuse reciprocity parameters.

Methods

Participants and Procedure

The "Know Addiction" database collected smartphone use data from March 2017 to March 2018. We selected 33 healthy adult participants (28 men, mean age 29.48, SD 10.44 years, range: 18-62) who had smartphone use data for at least 8 weeks. Data collected on the first day and the last day were excluded because of the incomplete nature. We used a 5-item questionnaire to assess smartphone addiction. This study was approved by the institutional review board of National Health Research Institutes, who waived the need for written informed consent as the data were analyzed anonymously.

Measures

The App-Generated Parameters

We defined an episode of smartphone use as a time period from screen-on to the successive screen-off. Know Addiction calculated daily episode count as total use frequency (F). Similarly, the total daily episode lengths were calculated as total use duration (D). Next, we distinguished "proactive use" from "reactive use." A proactive use was defined as 1 use episode without any notification within 1 min before the screen-on. It is conceivable that proactive use may be more representative of addictive behavior and total use [3]. We calculated daily episode counts and total length of proactive use as the proactive use frequency (PF) and the proactive use duration (PD), respectively.

We developed 3 parameters to delineate the reciprocity between the use and nonuse patterns in our previous study, namely RMSSD, SI [3], and an updated version of SI, Control Index (CI). Figure 1 shows the algorithm of the RMSSD. First, we calculated the difference between the adjacent duration of use (A_i) and nonuse episodes (A_{i+1}). Sleeping time was excluded from the nonuse episode. Next, each use/nonuse difference was passed through a sum of the squares and divided by (n-1) number of episodes. Finally, the RMSSD was calculated to be the square root of the mean square [3].

Figure 1. Use/nonuse reciprocity parameters. (a) A schematic and the equation used to calculate the root mean square of the successive differences (RMSSD). Ai is the duration of a use or nonuse epoch. There are (n-1) successive differences of use/nonuse episodes. The RMSSD was calculated to be the square root of the mean square. (b) A schematic and the equation used to calculate the Similarity Index (SI), Xi refers to the duration of a nonuse (gray) episode, Yi refers to the duration of a use (black) episode. Each nonuse episode (Xi) corresponds to 3 successive use epochs (Yi, Yi+1, and Yi+2). k is the number of nonuse episodes in a day. Thus, the SI is the average absolute difference between the nonuse and use episodes. (c) A schematic and the equation used to calculate the Control Index (CI), Xi refers to the duration of a nonuse (gray) episode and Yi refers to the duration of a use (black) episode. Each nonuse episode (Xi) corresponds to 3 successive use epochs (Yi, Yi+1, and Yi+2). k is the number of nonuse episodes in a day. Thus, the CI is the average of the absolute differences between 1 nonuse episode and the total of the following 3 use episodes. RMSSD: root mean square of the successive differences.

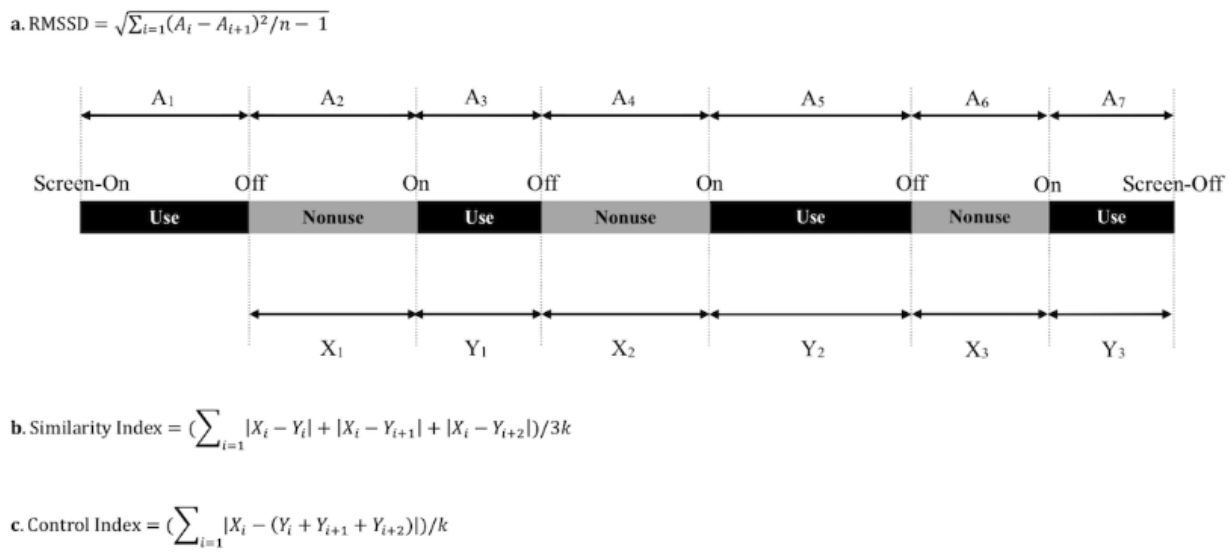


Figure 1 also shows the algorithm of the SI and CI. We calculated the absolute differences between 1 nonuse episode (X_i) and its corresponding 3 successive use episodes (Y_i, Y_{i+1}, and Y_{i+2}). The SI was calculated to be the average of the absolute differences between 1 nonuse episode and the nonuse and use episodes within a day. The CI was calculated to be the average of the absolute differences between 1 nonuse episode and the total of the following 3 use episodes.

In our previous study, we delineated the compulsive smartphone use parameters by 1 nonuse episode corresponded to 3 successive use episodes. This is because the use/nonuse parameter (ie, SI) was the most consistent parameter with psychiatrists' clinical diagnosis [9]. The CI is an updated version of the SI, which may be a more representative index for the control ability of smartphone use.

A lower RMSSD indicates a lower variability and a higher similarity. However, RMSSD delineates only the reciprocity of the adjacent use and nonuse episodes. To demonstrate a more generalized form of use/nonuse reciprocity, we proposed the SI and the CI to investigate the craving to use the smartphone by assessing the reciprocity of 1 nonuse episode with its upcoming 3-use episodes. In this study, the temporal stability of smartphone use parameters (ie, F, D, PF, and PD) and use/nonuse parameters (ie, RMSSD, SI, and CI) was both examined.

The 5-Item Smartphone Addiction Inventory

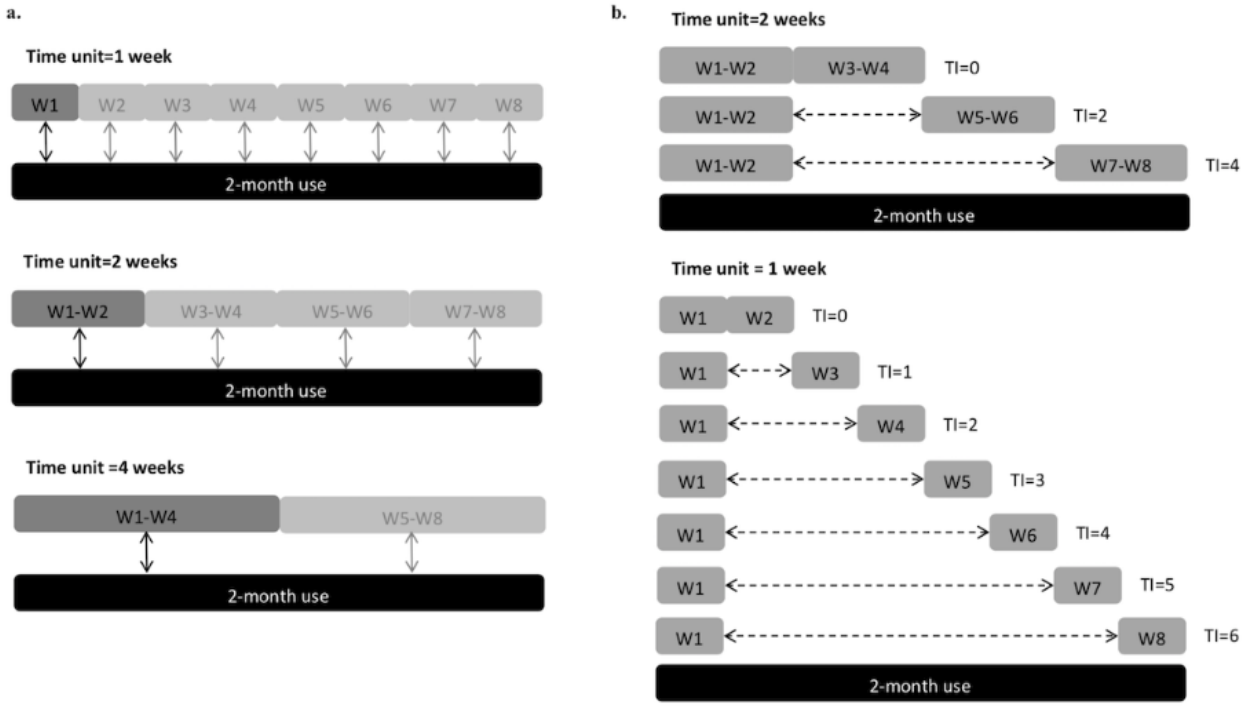
The 5-item Smartphone Addiction Inventory (SPAI-5) is a 5-item version of the SPAI. The original SPAI is a 26-item self-reported inventory [10]. Participants were asked to rate items on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). The SPAI demonstrated very good internal consistency (Cronbach alpha=.94).

Statistical Analysis

Pearson correlation coefficient was used to demonstrate the relationships between app-generated parameters and the total score of SPAI-5. To illustrate the minimum number of weeks required to reliably infer patterns of smartphone use for a 2-month period, we chose 1 week, 2 weeks, and 4 weeks as the fundamental time units. The average daily app-generated parameters within the 2-month period were used. The correlations among different time units and the 2-month use were analyzed to provide an indication of how well a time unit is representative of a typical 2-month's use (Figure 2). We adopted .75 as a criterion of "high correlation" for evaluating the efficiency of these time units.

Therefore, we investigated how long a smartphone use cycle could perpetuate by assessing maximum TIs between 2 smartphone periods for determining an independent cycle of smartphone use (Figure 2). For example, when the time unit used is 1 week, we first calculate the Pearson correlation coefficients between adjacent weeks (eg, week 1 vs week 2). A total of 7 correlation coefficients were calculated and then averaged to form a general index of temporal reliability for TI equal to 0. Next, the index for TI equals 1 (eg, week 1 vs week 3) was also calculated. Finally, the index for TI range 6 (ie, week 1 vs week 8) was calculated.

Figure 2. Illustration of validating the temporal stability of app-generated parameters. (a) Fundamental time unit. We chose 1 week, 2 weeks, and 4 weeks as the fundamental time units. The correlations among different time units and the 2-month use were analyzed. (b) Independent cycle. We determined independent cycle of smartphone use by calculating the correlations of 2 independent use periods with different time intervals. W1, W2,...W8: Week 1, Week 2,...Week 8; TI: Time interval (week).



Results

The Correlations Between App-Generated Parameters and Smartphone Addiction

Table 1 shows the descriptive statistics and correlation coefficients between app-generated parameters and the total scores of SPAI-5 within 2 months. The proactive use frequency (mean 22.97, SD 14.11) accounts for 40% of the total use frequency (mean 57.29, SD 22.96). The proactive use duration (mean 4806.66, SD 10279.38) accounts for 23% of the total use duration (mean 20666.96, SD 12702.38). There was a significant correlation between proactive use duration and smartphone addiction (r=.40, P=.02).

The Temporal Stability of App-Generated Parameters

To determine the shortest duration of smartphone use data required to reliably infer a pattern of long-term smartphone use, we calculated correlations for app-generated parameters between 3 time units (ie, 1 week, 2 weeks, and 4 weeks) and a 2-month period. Figure 3 shows the correlation coefficients between 1-week use and 2-month use for app-generated parameters. For 7 parameters, all correlations are statistically significant and above .75 from week 1 to week 6. There is a decrease for correlations of RMSSD after week 6 (week 7: r=.64, P<.001; week 8: r=.39, P=.03). The correlations of use frequency, proactive use frequency, and SI also show a decreased trend at week 8.

The correlation coefficients between 2-week use and 2-month use for app-generated parameters are shown in Figure 3. All correlations are statistically significant and above .75 between week 1 to 2 and week 7 to 8. The correlation coefficients between 4-week use and 2-month use for app-generated parameters are also shown in Figure 3. The correlations are statistically significant and above .90 between week 1 to 4 and week 5 to 8. The averages of correlations for app-generated parameters between 3 time units and 2-month use are summarized in Table 2.

Table 1. Means, SDs, and correlations of app-generated parameters, and the total score of the 5-item Smartphone Addiction Inventory.

Number	Parameters	Mean (SD)	1	2	3	4	5	6	7
1	F[a]	57.29 (22.96)	—[b]	—	—	—	—	—	—
2	D[c] (second)	20666.96 (12702.38)	−.078	—	—	—	—	—	—
3	PF[d]	22.97 (14.11)	.688[e]	−.103	—	—	—	—	—
4	PD[f] (second)	4806.66 (10279.38)	−.218	.551[e]	.180	—	—	—	—
5	RMSSD[g]	3070.41 (1421.50)	−.724[e]	.140	−.428[h]	.356[h]	—	—	—
6	SI[i]	1417.35 (853.55)	−.803[e]	.164	−.466[e]	.368[h]	.934[e]	—	—
7	CI[j]	1949.38 (1492.87)	−.666[e]	.608[e]	−.347[h]	.727[e]	.777[e]	.838[e]	—
8	SPAI-5[k]	12.55 (2.41)	−.089	.297	−.136	.403[h]	.139	.099	.314

[a]F: total use frequency.

[b]—:not applicable.

[c]D: total use duration.

[d]PF: proactive use frequency.

[e]*P*<.01.

[f]PD: proactive use duration.

[g]RMSSD: root mean square of the successive differences (between the adjacent duration of use and nonuse episodes).

[h]*P*<.05.

[i]SI: Similarity Index.

[j]CI: Control Index.

[k]SPAI-5: 5-item Smartphone Addiction Inventory.

Figure 3. The temporal stability of app-generated parameters: Fundamental time unit. (a) The correlation coefficients between 1-week use and 2-month use for app-generated parameters. (b) The correlation coefficients between 2-week use and 2-month use for app-generated parameters. (c) The correlation coefficients between 4-week use and 2-month use for app-generated parameters. CI: Control Index; F: Total use frequency; D: Total use duration; PD: Proactive use duration; PF: Proactive use frequency; RMSSD: root mean square of the successive differences (between the adjacent duration of use and nonuse episodes); SI: Similarity Index.

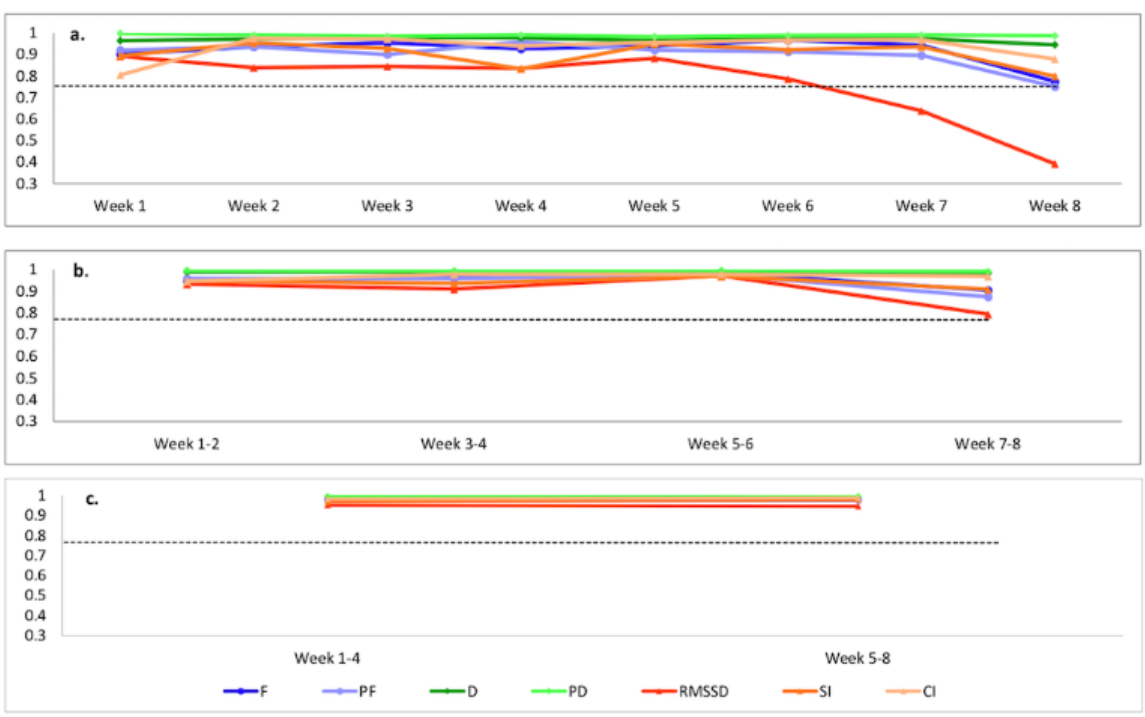


Table 2. The averages of correlations for app-generated parameters between 3 time intervals and 2-month use.

Number	Parameters	1 week	2 weeks	4 weeks
1	F[a]	.918	.952	.979
2	D[b]	.969	.988	.993
3	PF[c]	.900	.943	.975
4	PD[d]	.990	.996	.998
5	RMSSD[e]	.764	.903	.950
6	SI[f]	.902	.942	.975
7	CI[g]	.933	.969	.986

[a]F: total use frequency.

[b]D: total use duration.

[c]PF: proactive use frequency.

[d]PD: proactive use duration.

[e]RMSSD: Root mean square of successive differences (between the adjacent duration of use and nonuse episodes).

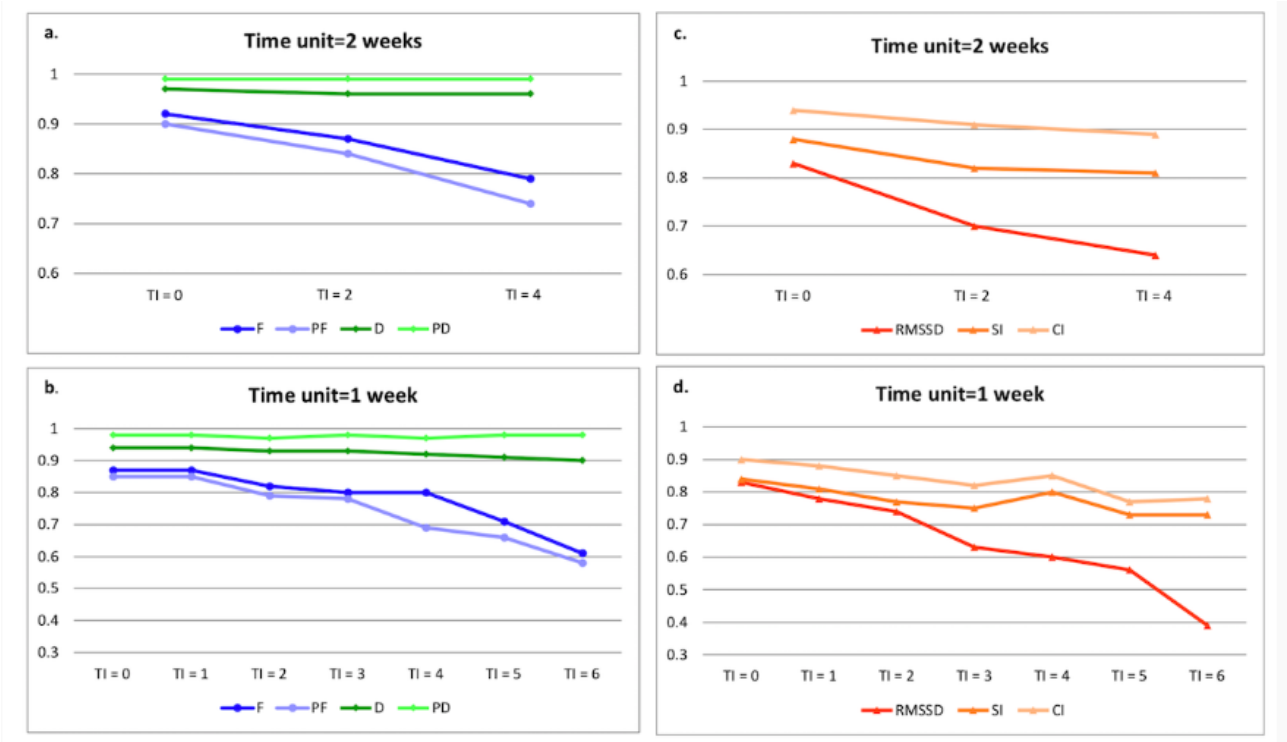
[f]SI: Similarity Index.

[g]CI: Control Index.

Figure 4 shows the correlations of 2 independent 2-week uses with different TIs for daily use frequency and duration parameters. All correlations between 2 adjacent 2-week use periods (TI=0) for frequency and duration parameters are above .90. For 2 2-week use periods with a 2-week interval (TI=2), the correlations are all above .75. However, with regard to 2 2-week periods with 4-week intervals (TI=4), the correlation of proactive use frequency drops below .75. Figure 4 shows the correlations of 2 independent 1-week use periods with different TIs for daily use frequency and duration. All correlations between 2 1-week use periods with a TI less than 3 weeks (TI=0, 1, 2, and 3) are above .75. For 2 1-week use periods with a TI more than 4 weeks (TI=4, 5, and 6), the correlation of proactive use frequency drops below .75. The correlation of use frequency also drops below .75 when TI is more than 5 weeks (TI=5 and 6). It is worth noting that, for use duration parameters, all correlations between 2 2-week use periods and 1-week use periods are all above .90, regardless how many TI s exist.

Figure 4 shows the correlations of 2 independent 2-week use periods with different TIs for RMSSD, the SI, and the CI. All correlations between 2 adjacent 2-week use periods (TI=0) are above .80. For 2 2-week-use periods with a 2-week interval (TI=2), the correlations of the SI and the CI are above .75 but not RMSSD. For 2 2-week use periods with a 4-week interval (TI=4), the correlation of RMSSD drops below .65. Figure 4 shows the correlations of 2 independent 1-week periods with different TIs for RMSSD, the SI, and the CI. For RMSSD, the correlations between 2 1-week-use periods with a TI more than 2 weeks (TI=2, 3, 4, 5, and 6) drop below .75 (r=.39, for TI=6). For the SI, the correlations between 2 1-week use periods drop below .75 when with a TI more than 4 weeks (TI=5 and 6). For the CI, all correlations between 2 1-week use periods are above .75, regardless of how many TIs exist.

Figure 4. The temporal stability of app-generated parameters: Independent cycle. (a) The correlations of 2 independent 2-week uses with different time intervals for daily use frequency and duration parameters. (b) The correlations of 2 independent 1-week uses with different time intervals for daily use frequency and duration parameters. (c) The correlations of 2 independent 2-week-use periods with different time intervals for RMSSD, the SI, and the CI. (d) The correlations of 2 independent 1-week-use periods with different time intervals for RMSSD, the SI, and the CI. CI: Control Index; D: Total use duration; F: Total use frequency; PD: Proactive use duration; PF: Proactive use frequency; RMSSD: root mean square of the successive differences (between the adjacent duration of use and nonuse episodes); SI: Similarity Index; TI: Time interval (week).



Discussion

Principal Findings

This study adopted a 2-month period data to validate temporal stability of smartphone use. This study will enable researchers to construct a more structured methodology when collecting longitudinal behavioral data via the app. Most self-report scales assessing problematic mobile use also request the responders to report their smartphone usage within 3 months [10-12]. However, “digital phenotype” is a new concept referring to data generated passively from day-to-day interaction with a smartphone, it can provide real-time data on an individual’s environment and possibly the individual’s mental state [13]. Our findings highlight a crucial methodological issue on delineation of human behaviors by smartphone. If researchers want to investigate a 2-month period of smartphone use, a 2-week period of use data should be collected for consistency. In addition, when the TI between 2 smartphone use periods is more than 4 weeks, we should consider that these 2 periods belong to different use cycles, regardless of whether the use periods are for 1 week or 2 weeks.

Strengths and Limitations

Our findings extend the previous work on tracking smartphone use pattern in several ways. First, a previous study had demonstrated that a relatively short duration of behavioral data (ie, 5 days) is required to qualify as a 2-week use period [5]. We assessed smartphone use for a longer time framework. Our previous studies have also found that smartphone use and nonuse patterns are reciprocal and have a cycle repeated weekly [7]. Therefore, a complete record comprising weekdays and weekends may be crucial to reflect typical smartphone usage. Even a 1-month record might not be enough to allow detection for patterns of smartphone use. In this study, we extended the app-recorded time frame to 2 months, which included at least 8 weekly cycles of smartphone use data. Our finding suggested that a 2-week smartphone use duration is an adequate fundamental time unit to infer a 2-month period of use, namely a record which accounts for 25% of the total use period may be sufficient. Investigating reliability such as temporal stability of measurements (ie, app-recorded parameters) is the very first step for collecting longitudinal data. Future studies examining smartphone use behaviors, self-reported variable relevant to smartphone use, and their interactions over time are urgently needed. Second, self-reported problematic smartphone use did not correlate with actual use recorded by an app in previous studies [4,5]. They concluded this may be because of the automatic nature of compulsive use and therefore cannot be captured through self-reported scales. However, we found a significant correlation between proactive use duration in 2 months and smartphone addiction. Self-reported smartphone addiction may correlate with long-term rather than short-term smartphone use. It may also imply that only proactive use duration correlates with self-reported smartphone addiction. Finally, we adopted more app-generated parameters than previous studies and evaluated their efficacy. The current findings support our previous study, which showed that not only use frequency and duration but also use/nonuse reciprocity is important when delineating smartphone use behaviors.

There are several implications of our findings related to the 3 series of app-generated parameters. Total use frequency and use duration are parameters that should be studied most often. Previous literature also demonstrated that self-reported total use duration is a risk factor of problematic smartphone use [14,15]. The parameters regarding total use may reflect a general pattern of human-device interaction. In this study, any smartphone use episode was recorded as screen-on to screen-off. It provides an opportunity to distinguish between proactive and reactive use. Our previous studies have found that proactive use is more relevant to the addictive behavior, whereas reactive use should be treated more like "signal noise" with regard to its passive nature [3]. In this study, only proactive use duration significantly correlated with self-reported smartphone addiction. Proactive use may be more important than checking behaviors following notifications as it reveals more information about intention, such as compulsive checking for messages or craving for a specific app. Furthermore, averaged daily RMSSD and SI have been applied to indicate impaired control for smartphone use in our previous study [3]. The use/nonuse parameters (ie, RMSSD, SI, and CI) give us a chance to assess the reciprocal patterns of smartphone use and may represent control ability of individuals. In this study, CI demonstrated better temporal stability than SI and RMSSD. The CI may be a more representative parameter to reflect smartphone users' control ability.

There are several methodological limitations that should be noted. First, smartphone uses were defined by screen-on and screen-off. This definition cannot completely represent the status of smartphone use. Second, the study utilized a selected sample with excessive smartphone use (average daily smartphone use duration: 5.74 hours/day), which limits the ability to generalize these findings. Third, our sample size is small and from a convenience sample (85% of the sample is male). A larger sample size and nongender-biased sample are also needed for future study evaluating the efficacy of app-generated parameters in smartphone use. More transnational and cross-culture research is needed to validate the temporal stability of app-generated parameters in other countries. Fourth, we reported utility and temporal stability of use/nonuse parameters in this study as our previous works showed that these parameters were highly consistent with psychiatrists' clinical diagnosis. A higher value of use/nonuse parameters represented lower use/nonuse similarity, and it was also associated with higher flexibility of smartphone use. However, different smartphone use patterns may still generate identical value on these parameters. For example, frequent, long use periods spread out in very even short intervals may generate similar CI with sparse use period with sporadic checking. It is still noteworthy that all the app-generated parameters that we introduced were only objective measurements used to delineate smartphone use patterns, and future studies are needed to elaborate their definition and utility.

Conclusions

In conclusion, this study validated temporal stability for smartphone use patterns recorded by an app. Our findings suggest it is necessary to collect biweekly use data for evaluating smartphone use behaviors. In addition, the long-term smartphone use duration recorded objectively in a naturalistic setting is relevant to subjectively reported symptoms of smartphone addiction. The results may provide researchers an opportunity to investigate human behaviors longitudinally, using more structured methods via smartphone.

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Conflicts of Interest

None declared.

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Abbreviations

CI: Control Index
RMSSD: root mean square of the successive differences
SI: Similarity Index
SPAI-5: 5-item Smartphone Addiction Inventory
TI: time interval

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Original Paper

Perception of Older Adults Toward Smartwatch Technology for Assessing Pain and Related Patient-Reported Outcomes: Pilot Study

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Abstract

Background: Chronic pain, including arthritis, affects about 100 million adults in the United States. Complexity and diversity of the pain experience across time and people and its fluctuations across and within days show the need for valid pain reports that do not rely on patient's long-term recall capability. Smartwatches can be used as digital ecological momentary assessment (EMA) tools for real-time collection of pain scores. Smartwatches are generally less expensive than smartphones, are highly portable, and have a simpler user interface, providing an excellent medium for continuous data collection and enabling a higher compliance rate.

Objective: The aim of this study was to explore the attitudes and perceptions of older adults towards design and technological aspects of a smartwatch framework for measuring patient report outcomes (PRO) as an EMA tool.

Methods: A focus group session was conducted to explore the perception of participants towards smartwatch technology and its utility for PRO assessment. Participants included older adults (age 65+), with unilateral or bilateral symptomatic knee osteoarthritis. A preliminary user interface with server communication capability was developed and deployed on 10 Samsung Gear S3 smartwatches and provided to the users during the focus group. Pain was designated as the main PRO, while fatigue, mood, and sleep quality were included as auxiliary PROs. Pre-planned topics included participants' attitude towards the smartwatch technology, usability of the custom-designed app interface, and suitability of the smartwatch technology for PRO assessment. Discussions were transcribed, and content analysis with theme characterization was performed to identify and code the major themes.

Results: We recruited 19 participants (age 65+) who consented to take part in the focus group study. The overall attitude of the participants toward the smartwatch technology was positive. They showed interest in the direct phone-call capability, availability of extra apps such as the weather apps and sensors for tracking health and wellness such as accelerometer and heart rate sensor. Nearly three-quarters of participants showed willingness to participate in a one-year study to wear the watch daily. Concerns were raised regarding usability, including accessibility (larger icons), notification customization, and intuitive interface design (unambiguous icons and assessment scales). Participants expressed interest in using smartwatch technology for PRO assessment and the availability of methods for sharing data with health care providers.

Conclusions: All participants had overall positive views of the smartwatch technology for measuring PROs to facilitate patient-provider communications and to provide more targeted treatments and interventions in the future. Usability concerns were the major issues that will require special consideration in future smartwatch PRO user interface designs, especially accessibility issues, notification design, and use of intuitive assessment scales.

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KEYWORDS

smartwatch; focus group; ecological momentary assessment (EMA); patient-reported outcomes (PRO)

Introduction

About 100 million adults in the United States are affected by chronic pain, including pain caused by arthritis, costing US $560-$635 billion annually [1]. Pain is a complex experience [2] that varies across time and people [3,4]. Recent research on pain in arthritis patients has shown that pain fluctuates significantly both across and within days [3]. Traditionally, researchers and practitioners have relied on patients' recall to assess pain, as well as to track and evaluate pain management routines [5]. While still a convenient method, many recent studies point to memory errors and distortions that influence pain recall [6-9]. For example, the "peak-end effect" causes the more recent experiences to have an especially strong influence on recall [10], and the "duration neglect" results in a tendency to ignore periods without pain [11]. To provide valid patient-reported outcomes (PROs) on pain that do not rely on patients' long-term recall capability, researchers have used various ecological momentary assessment (EMA) approaches such as paper-and-pencil and electronic diaries [6,12], Twitter feeds [13], and smartphone apps [14,15]. EMA methods ask individuals to provide systematic daily diaries of their experiences at random occasions. These approaches can provide finer resolution and possibly more valid assessments, while also providing the ability to examine the fluctuations and variation of pain over time. The use of digital EMA tools can be especially important for enhancing the accuracy of assessments in older adults, who are more likely than younger adults to experience memory lapses [16].

Smartphones have increased in popularity as convenient digital EMA tools for real-time assessments [14,15]. This trend even expands in older adults, with 70% of the population currently owning a smartphone. While this is encouraging for the feasibility of using smartphone research–related apps [17], it has not carried forward into smartwatches [18]. Older adults may lack the requisite knowledge and skills for effectively using a smartwatch for EMA and for monitoring other health-related characteristics. In this study, we examined the perception and attitude of older adults towards smartwatch technology for capturing pain PROs. We specifically used the Samsung Gear S3 smartwatch. It is less expensive than a smartphone, highly portable, and discrete due to its sleek design resembling a regular watch. These factors promote higher compliance. A smartwatch also has a much simpler user interface than a smartphone, and due to its enhanced portability, a smartwatch provides an excellent medium for continuous data collection.

We hypothesized that since a smartwatch can be worn all day, this will potentially result in a higher compliance rate compared to a smartphone. A smartwatch, coupled with the embedded sensors including accelerometer, global positioning system (GPS), ultraviolet (UV), and heart rate sensor can provide additional information such as physical activity intensity and duration, location, UV exposure, and heart rate. Previous EMA interventions based on basic watch-type EMA tools for assessing fatigue have been reported to be successful at characterizing the temporal changes of fatigue [19], demonstrating the potential for momentary assessments. We assessed the attitudes of older adults towards smartwatch technology for capturing pain PRO measures in a focus group to guide hardware and software development and our long-term studies. A preliminary version of the PROMPT (Patient Reported Outcome of Mood, Pain, and faTigue) app was developed, along with the server infrastructure, which were provided to the participants during a demo session. The focus group discussions and suggestions were summarized and analyzed to assess the potential of smartwatch technology for PRO assessment and to guide future developments for use in older adults.

Methods

Study Population

We recruited 20 older adults aged 65-89 years, and 19 of them participated in the focus group. The inclusion criteria included age ≥65 years and diagnosis of unilateral or bilateral symptomatic knee osteoarthritis. Some of the exclusion criteria included failure or inability to provide informed consent; significant cognitive impairment, defined as a known diagnosis of dementia; and being unable to communicate because of severe hearing loss or speech disorder (see Multimedia Appendix 1 for eligibility criteria). A convenient sample of older adults was identified through posting flyers at University of Florida's Institute on Aging research and patient clinics and direct mailings to age-eligible participants from approved registries. Each participant received compensation of a US $50 gift card. The focus group protocol was approved by the University of Florida Institutional Review Board.

Smartwatch App and Server Framework

The PROMPT framework is made up of two components: (1) the server software and (2) the smartwatch app. This integrated framework is designed and developed to perform several tasks including remote data collection, storage, retrieval, and analysis. Figure 1 depicts the main component of the system. The PROMPT framework was developed at the University of Florida to enable real-time capturing of patient-generated information, including wearable sensor data, along with self-report PRO assessments as described previously [20].

The PROMPT app was developed to show assessment notification every 4 hours by asking users to enter their current pain, fatigue, and mood assessments. No messages were shown during the nighttime to avoid any sleep disruptions. Messages were provided only from 8 a.m.-8 p.m. Sleep quality was programmed to be assessed every morning with a message randomly displayed between 8 a.m.-12 p.m. Using the PROMPT interface, the assessment ratings could be easily entered by rotating a bezel and could be saved by pressing a button located on top of the bezel (Figure 2). While we have presented only the pain assessment screen (Figure 2), similar screens have been developed for assessing fatigue, mood, and sleep quality. We used the Numerical Pain Rating Scale (NRS) [21] for pain assessment by showing pain intensity on a scale of 0-10. Other auxiliary PROs including mood, fatigue, and sleep were shown similarly using a numerical scale of 0-10 [22,23]. All these scales except for the sleep quality designated 10 as the worst possible outcome (ie, highest pain level, highest fatigue level, or the most negative mood).

The same bezel rotation and saving mechanism was also used to capture current user activities (Figure 3). Our current list of activities included lying down, standing, walking, sitting, and "other activities" representing other possible activities such as gardening and exercise.

Figure 1. The PROMPT (Patient Reported Outcome of Mood, Pain, and faTigue) framework: the smartwatch app and the server application.

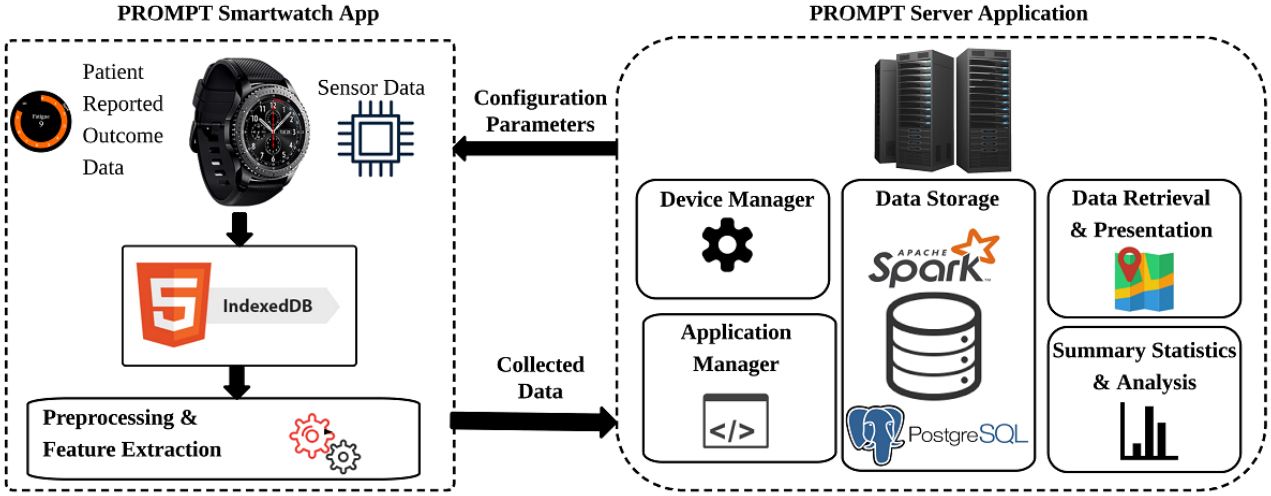


Figure 2. The Samsung Gear S smartwatch used in the PROMPT (Patient Reported Outcome of Mood, Pain, and faTigue) study. Ratings are entered by rotating the bezel to select pain ratings. The color schema also changes as the ratings are increased or decreased. Ratings are saved by pressing the top button (physical button), located on top of the bezel.

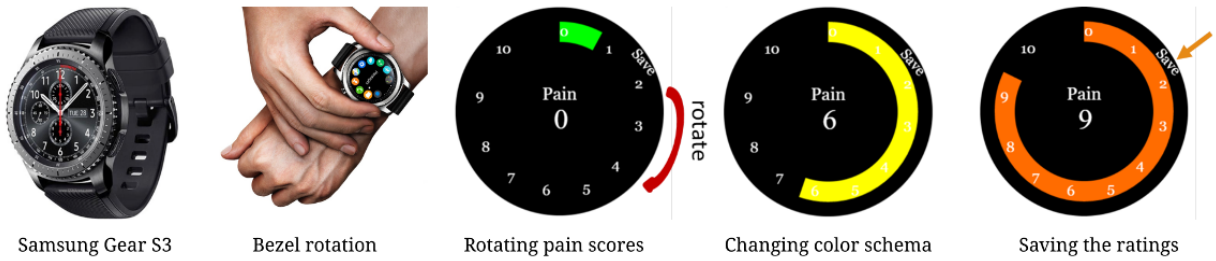


Figure 3. Users can choose activities by rotating the bezel.

Focus Group Set-Up

The focus group was conducted by a team consisting of a moderator and 2 assistant moderators. The focus group formation and content analysis were guided by memo writing, qualitative sampling, and metacoding [24-26]. The moderator used a semistructured interview to present information with a goal of promoting uninhibited dialogue and nonjudgmental feedback. Research assistants took notes of verbatim quotes. The assistant moderators also observed and documented participants' expressions and reactions. No audio recording was performed for privacy reasons and to provide a more inviting discussion atmosphere. Both assistant moderators helped facilitate the discussions. One of the assistants took notes on a large easel pad, clearly visible to all participants, while also posting participants' notes on the easel using Post-it notes provided to the participants at the beginning of the session. The other assistant moderator took notes on a laptop computer and tallied the number of participants discussing each topic.

The first 30 minutes of the focus group was dedicated to introducing the smartwatch technology, explaining the rationale of the study, and showing screenshots of the interface. Then the participants were provided with 10 Gear S3 smartwatches preloaded with the PROMPT app. They were assisted in using the PROMPT app, as necessary. The watch configuration was changed to show notifications every 5 minutes to better allow for exploration of the app in a timely manner. Last, to better capture design preferences, the participants were asked to sketch their own smartwatch face design.

Focus Group Orientation and Questions

The focus group was designed to be an open-ended forum, starting with several directed questions. We asked 12 questions that related to the impression of the smartwatch technology and mimicked questions that are traditionally used to evaluate computer app and mobile app interfaces, including the System Usability Scale [27] and Mobile App Rating Scale [28]. These questions were designed to provide feedback on the PROMPT user interface, using a smartwatch for PRO assessment, long-term study logistics, and potential future improvements. While the questions had direct responses, all question included time and discussion for open-ended feedback (Table 1). Most of the questions related to the user interface were based on current PROMPT interface implementation to identify necessary improvements. Alternative scenarios, such as using emoticons on the assessment screens using the Wong-Baker FACES Pain Rating Scale [29], were shown during the presentation (Figure 4).

The rationale for including questions a.1 (watch size) and a.2 (first impression) was to identify the general acceptability of a smartwatch in daily settings, or in a one-year study (questions d.1 and d.2). The rationale for including questions b.1-6 was to assess the existing user interface and identify possible issues and to outline smartwatch interface guidelines for older adults' population. Finally, questions c.1 and c.2 were included to specifically solicit information on assessing PROs through a smartwatch interface.

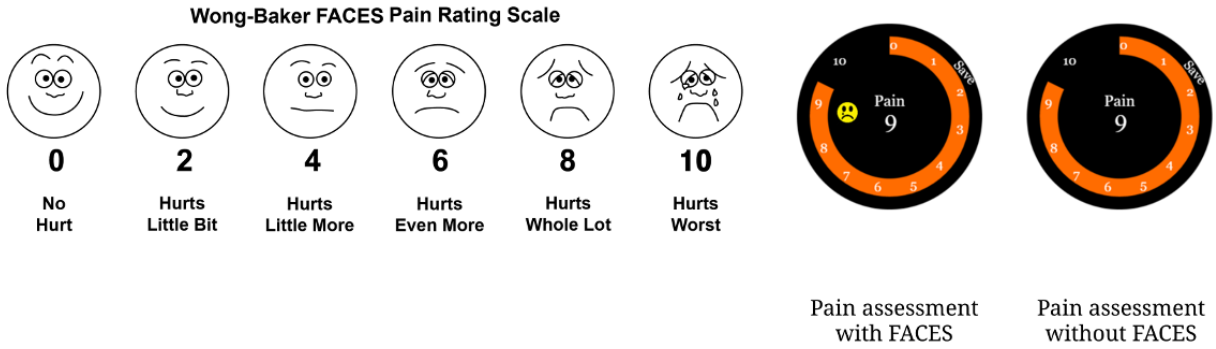
Analysis

Following the focus group, the notes were compiled and summarized by the assistant moderators. Major topics were identified across the discussions by the assistant moderators and were grouped based on the underlying themes. The theme codes were developed based on note data to categorize data into overarching interpretive themes. The codes were then refined to fit data through an iterative summative process [30]. This process continued until themes and properties were easily distinguishable and succinct [30]. Chi-square tests were used to test for differences in proportions in dichotomous variables.

Table 1. Focus group questions summarized according to their topic.

Topic	Questions
a. Smartwatch impression	a.1 What is your opinion about watch size and its accessory bands?
	a.2 What is your first impression of the watch itself?
b. PROMPT interface	b.1 Do you like the PROMPT color schema for PRO assessment?
	b.2 Do you like the app flow? Any need for a back button?
	b.3 Would you like to add emoticons to the assessment screen?
	b.4 Do you like the activity icons? Would you prefer icons or text?
	b.5 What type of notification do you prefer to receive, and why?
	b.6 Is the text large enough to read?
c. PRO assessment	c.1 How many times per day would be too burdensome to ask you?
	c.2 Other issues you would like the researchers and doctors to know?
d. Study logistics	d.1 How likely are you to participate in a one-year research study asking you to wear the smartwatch daily for up to a year?
	d.2 What other options would help you to participate?

Figure 4. Wong-Baker FACES Pain Rating Scale (left). PRO assessment with and without emoticons. Source: Wong-Baker FACES Foundation.



Results

User Statistics

Of the 20 participants who consented to the study, 19 participated in the focus group study. The session lasted about 90 minutes. Table 2 depicts the demographics information of participants. Test of proportion was performed on characteristics among male and female participants for applicable responses.

Content Analysis

The content analysis revealed several major subtopics and themes under each major topic (Table 1), as shown in Tables 3 and 4. A total of 109 verbatim quotes from participants were coded, and nine of the quotes were considered to be irrelevant. The themes emerged under the four groups of questions (ie, smartwatch impression, PROMPT user interface, PRO assessment, and study logistics). We identified 13 major themes and 48 detailed subthemes.

Theme percentages do not include the tally questions. Some discussion items were included under multiple themes. The discussion on user interface options was the most comprehensive (just over half of all the topics discussed), spanning issues from accessibility for visually impaired users to specific details of design. The participants expressed a desire for customization, for example, to choose how to be notified when it is time to enter the PRO assessments (eg, sound, vibration, and music) or to customize the list of activities or medications. Initially, most participants showed interest in using emoticons like the Wong-Baker FACES Pain Rating Scale [29] to guide them during assessment, but after working with the app on the watch, they felt there was no need for emoticons, given the color change during rating. Participants were also asked about issues and possible improvements in the PRO assessment process. Answers included the ability to provide more detailed information, such as indicating fluctuations, activity dependent measures, pain location, and the ability to provide medication usage. Besides existing PROs, participants showed interest in tracking joint stiffness and sleep.

The participants were asked about several issues regarding the PROMPT app user interface, including the need for emoticons on PRO scales, the use of back button, font size, and displaying additional information such as heart rate or step count (Figure 5). The participants were asked to indicate their response by raising their hand for an affirmative response. The assistant moderators documented the counts.

The participants were asked about their notification method of choice (Figure 6) and whether they would prefer sound, vibration, flashing light, or a combination of all. The participants were also asked about preferred number of notifications per day (Figure 7). The PRO assessment discussions led to the comment that EMA might not be able to capture the maximum pain experience during the day, if sampled at certain times. It was suggested that instead of displaying messages for PRO assessments four times a day, it might be better to display the messages three times, while asking for a summary assessment at the end of the day to better capture daily fluctuations. Additionally, 74% (14/19) of the participants mentioned that they would be willing to participate in a one-year study in which they would wear the watch every day. This increased to 89% (17/19) when we clarified that the watch can be worn during domestic and international travel.

Table 2. Characteristics of the focus group participants (N=19).

Characteristics	Total	Female	Male	*P* value
Participants, n (%)	19	14 (74)	5 (26)	.01
Age (years), mean (SD)	72.7 (6.1)	72.0 (6.7)	75.5 (5.8)	.22
Access to Wi-Fi, n (%)	17 (89)	—[a]	—	—
Own a smartphone, n (%)	14 (74)	—	—	—
Own a smartwatch, n (%)	1 (5)	1 (7)	0 (0)	1
Active in water, n (%)	4 (21)	—	—	—

[a]Data were not collected per female/male, only collectively.

Table 3. Themes and subthemes reported by the focus group participants (percentages are the percent reported with respect to all the other themes).

Topic, themes, and subthemes	n (%)
Smartwatch impression (25%)	
Desired functions (32%)	
Time display[a]	1 (5)
Apps[a]	3 (16)
Water resistance[a]	1 (5)
Backlight[a]	1 (5)
Security[d]	1 (5)
Desired apps (27%)	
Weather[a]	3 (16)
Email[a]	1 (5)
Phone[a]	2 (11)
Appearance concerns (32%)	
Heavy body[b]	2 (11)
Accessory bands[a]	4 (21)
Band durability[c]	1 (5)
Desired sensors (9%)	
Step count[a], heart rate[a], GPS[a]	2 (11)
PROMPT user interface (54%)	
Color schema (12.5%)	
Accessibility for color-blind individuals[c]	2 (11)
Customized color schema[c]	3 (16)
Mapping colors to mental states[c]	3 (16)
Icons (18.7%)	
Icon ambiguity[b]	2 (11)
Expanded list of activities[c]	1 (5)
Customized list of activities[c]	1 (5)
Activity intensity[c]	1 (5)
Emoticons[c]	4 (21)
Notifications (33.3%)	
Notification preferences[c]	3 (16)
Disruptive notifications[d]	2 (11)
Notification type customization[c]	1 (5)
Context-dependent notifications[c]	1 (5)
Silent mode[a]	1 (5)
Number of notifications[d]	7 (37)
Start time customization[c]	1 (5)
Usability and accessibility (27.0%)	

Topic, themes, and subthemes	n (%)
Easy setup[a]	4 (21)
Automatic messages[a]	1 (5)
Speech input[c]	1 (5)
Larger font size[c]	3 (16)
Large icons[c]	3 (16)
Notification customization for visually or hearing impaired[c]	1 (5)
Assessment scales (6.25%)	
Scale visual aid[c]	2 (11)
Neutral value visual aid[c]	1 (5)
Flow (2.0%)	
Back navigation button[c]	1 (5)
PRO assessment (18%)	
Capturing pain (50%)	
Ability to indicate fluctuation and intermittent pain[c]	2 (11)
Ability to indicate activity dependent measures[c]	1 (5)
Ability to indicate pain location[c]	1 (5)
Weekly or daily summary[c]	1 (5)
Ability to indicate medication use[c]	3 (16)
Other PROs (50%)	
Ability to indicate stiffness[c]	1 (5)
Receiving more positive feedback instead of negative[c]	4 (21)
Ability to track sleep[c]	3 (16)
Study logistics (2%)	
Study participation (100%)	
Use during travel[c]	1 (5)
Frequent clinic visit, Impact on personal data plan[d]	1 (5)

[a]Positive existing feature (I liked it).

[b]Undesirable existing feature (I did not like it).

[c]Desired future feature (I would like to see that).

[d]Undesirable/concerning future feature (I would be concerned about that).

Table 4. Selected participants' quotes on discussed themes grouped according to topic.

Topic and subtopic	Example quotes
Smartwatch impression	
Function	"Can you download its apps like on a smartphone?"
Apps	"I would wear it as it is; it is excellent, but the more apps, the better."
Appearance	"I like the extra band, lighter."
Sensors	"Can its GPS be used to track if I am at the gym?"
PROMPT user interface	
Color schema	"When it shows my good mood as green, I don't like it, not my mental model of happiness."
Icons	"Standing can represent both washing dishes or cooking."
Notifications	"My hearing is bad, and I might be active and might not see it."
Usability & accessibility	"Voice-activated recording might be helpful to record details of activities."
Assessment scales	"For feeling down, is the scale going up or down?"
Flow	"I would like an erase or back button when I make a mistake."
PRO assessment	
Capturing pain	"I have intermittent pain walking for five minutes, then no pain, coming and going."
Other patient-reported outcomes	"It is important to emphasize when you are feeling good, feeling up. To emphasize fatigue, it is negative, and it is going to be measured in a negative way."
Study logistics	
Study participation	"How would the watch affect my data plan usage?"

Figure 5. Participant preferences on various user interface issues related to PROMPT (Patient Reported Outcome of Mood, Pain, and faTigue). Bars indicate the percentage of users who responded "Yes".

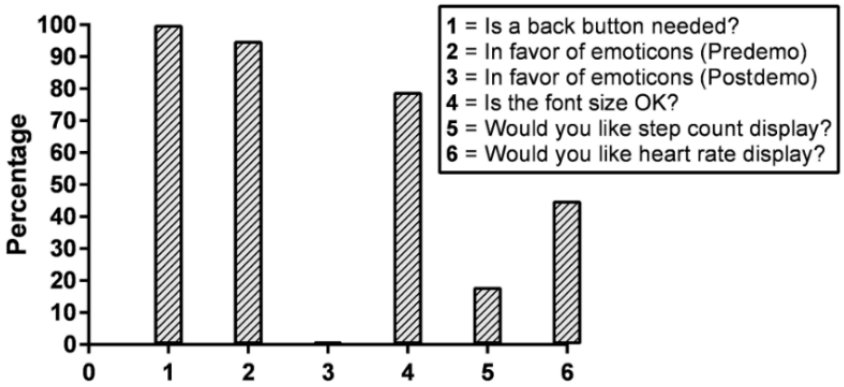


Figure 6. Participant preferences on notifications type.

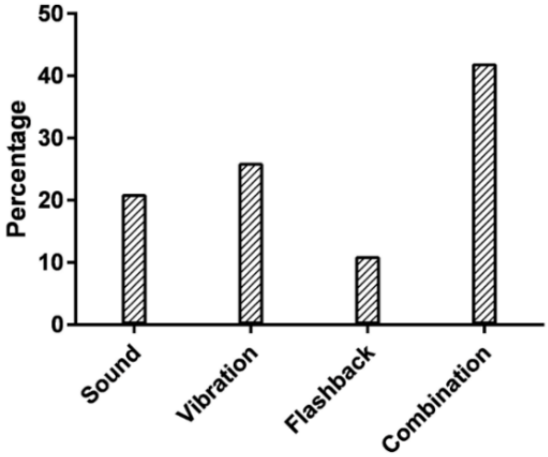
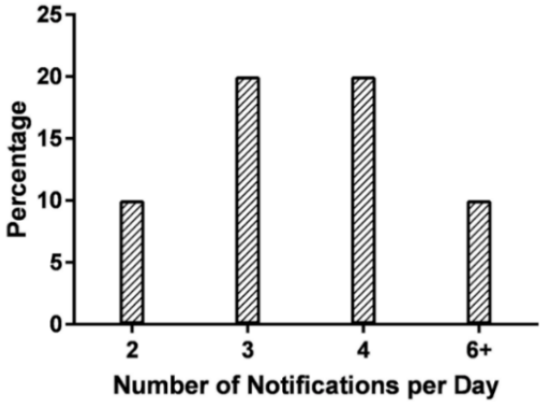


Figure 7. Participant preferences on notifications frequency.



Discussion

Principal Findings

A review of the literature shows the lack of systematic evaluation of smartwatch technology among older adults. While several recent studies have developed smartwatch apps for fall detection [31], mood assessment [32], or gait estimation [33], there has been limited research [32] on using smartwatch technology for PRO assessment in the general population and more specifically among older adults.

This study allowed us to explore the attitudes and perceptions of older adults towards smartwatch technology, specifically for PRO assessment. Most participants in our study expressed enthusiasm for wearing the smartwatch, despite its weight and lack of several desired features, which points to the potential feasibility of using such a device in long-term studies or daily settings. In general, while it has been shown that older adults are less likely to use new technology compared with younger adults [34], there is ample evidence that they also desire interaction with new technologies to remain active and engaged with society [35]. In a recent framework, Lee and Coughlin identified 10 factors that affect how technology is adopted by older adults, including perceived value, usability, affordability, accessibility, technical support, social support, emotion, independence, experience, and confidence [36]. Our results are consistent with these factors and with previous studies on the use of technology among older adults [37-39], indicating an interest in adopting new technology given perceived usefulness and potential benefits.

Several previous studies also have found that anxiety is positively correlated with age while self-efficacy is negatively correlated, resulting in lower self-confidence and higher anxiety in older adults when facing new technology [34,40]. As Lee and Coughlin point out [41], it is important to build an intuitive design to enhance self-confidence among older adults. Our focus group results demonstrate that a smartwatch provides a significant degree of familiarity by resembling a regular watch, thus facilitating knowledge transfer and overcoming the learning barriers, possibly building confidence in older adults' ability to use this new technology [41].

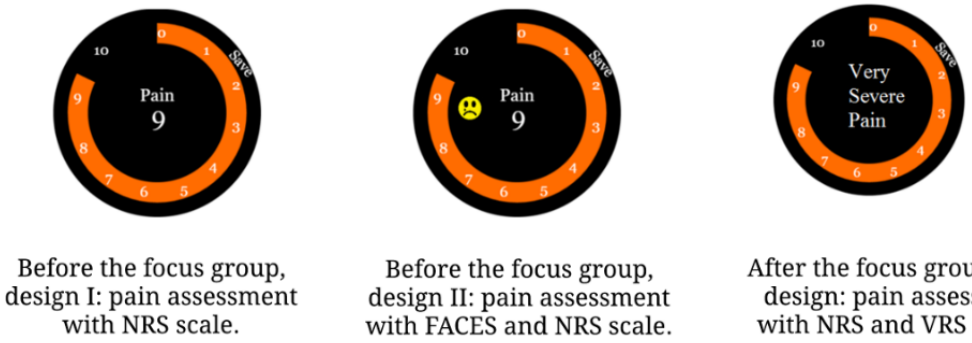
In general, the participants perceived the smartwatch technology and its use for PRO assessment as an empowering tool as it allows them to provide real-world symptomology to caregivers. This is particularly true for chronic pain, which is often highly variable [42]. They also indicated that a simple interface, technical support, and clear instructions are needed to tackle the technological barriers, which is consistent with other studies [36,43]. App interface customization also was a recurring theme throughout the focus group discussions, pointing to the need to tailor the app to users' individual needs and preferences and to accommodate hearing and visual impairment, further underlining the need for usability and accessibility.

We found that participants' mental models of assessment scales can greatly impact how they assess their outcomes ("For feeling down, is the scale going up or down?"). For example, initially we used NRS [44] for pain assessment by representing pain intensity on a scale 0-10 (Figure 8). Based on our focus group discussion, we changed our design to reflect a combination of NRS and the Verbal Pain Rating Scale [45] (Figure 8) to avoid confusion and to better allow the participants to map the smartwatch scale to their mental scale. As discussed before, interestingly, the participants did not think it was necessary to use the Wong-Baker FACES Pain Rating Scale [29] to guide them during rating (Figure 8). Similar verbal scales are used in our refined design for mood, fatigue, and sleep assessment. We adopted existing verbal scales such as a modified version of the Visual Analogue Mood Scale [46] for mood assessment. We also changed some of the wording such as "feeling down" to "mood" to reflect a more neutral sentiment and to avoid negative thought reinforcement.

We also found that, in general, the touchscreen interface on the smartwatch was difficult to operate by some older adults due to the small size of icons, as well as their decreased motor resolution and coordination, as observed in previous studies on older adults with smartphones [47]. Most participants preferred using the bezel rotation and the physical button pressing. Based on this feedback, our redesigned app uses only these mechanisms for interacting with the app.

The participants also expressed interest in several future features, most notably the capability to keep their health care provider in the loop through a health care provider portal or through Electronic Health Records integration. They also showed interest in a patient Web portal for viewing their collected data in more detail on a larger screen device. Connectivity to other smart devices such as smart scales was also discussed by participants.

Figure 8. Different pain assessment scales used before and after the focus group. NRS: Numerical Pain Rating Scale; VRS: Verbal Pain Rating Scale.



Before the focus group, design I: pain assessment with NRS scale.

Before the focus group, design II: pain assessment with FACES and NRS scale.

After the focus group, final design: pain assessment with NRS and VRS scales.

Finally, an emergency option, the ability to call 911 or relatives in case of emergency, was on top of their future desired features.

Limitations

Though our results point to interesting insights, our study had several limitations. Our focus group participants were recruited locally and might not represent the broader population of older adults. This is reflected in a higher rate of smartphone ownership among our participants compared to the national smartphone ownership in the older adult population. The results also are based on a single focus group session following limited interaction with the technology, and different results could emerge if feedback was obtained after wearing and using the device for an extended period. Finally, we studied the smartwatch technology primarily in the context of pain assessment and participants reporting knee pain. These results might differ if the focus group was conducted on the use of smartwatch for different applications or when targeting populations with different medical histories. Nonetheless, our results point to the feasibility of using smartwatches for PRO assessment in older adults, and they offer invaluable insights for improving the current interface and technology.

Future Research

Future studies are needed to explore the perceptions of older adults toward such PRO assessment interfaces and how their perceptions change after wearing the smartwatch for a given period. We plan to use our PRO assessment app for quantifying and comparing PROs such as pain among different populations of older adults in real-life settings. Future work will also compare the use of PRO assessment tools on different devices, including smartphones, tablets, and smartwatches, to better identify the differences among such mediums. Finally, there is a need to integrate patient-generated information with routine care data in a format that is useful to care providers.

Conclusions

Our study examined the acceptability for using smartwatch technology as a PRO assessment in older adults in a focus group setting. Our questions on participants' willingness to take part in a one-year study, as well as questions on the appeal of smartwatch size and interface design, reflect the potential feasibility of using a smartwatch in long-term studies or daily settings. Usability and intuitive design, personalization, and accessibility were found to be important for adopting and using PROMPT smartwatch technology. The choice of different PRO assessment methods (eg, visual vs verbal scales) was also found to impact how older adults use smartwatch technology for reporting their pain, mood, fatigue, and sleep quality. Finally, the participants expressed interest in the ability to observe these assessments in more detail on a Web portal and to be able to share them with their health care providers. These findings can be used to guide the future smartwatch software design, as well as to guide developing new EMA methods for PRO assessment.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Inclusion and exclusion criteria.

[PDF File (Adobe PDF File), 68KB - mhealth_v7i3e10044_app1.pdf]

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Abbreviations

EMA: ecological momentary assessment
GPS: global positioning system
NRS: Numerical Pain Rating Scale
PRO: patient-reported outcomes
PROMPT: Patient Reported Outcome of Mood, Pain, and faTigue
UV: ultraviolet

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