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Review

Bridging the Human Resource Gap in Primary Health Care Delivery Systems of Developing Countries With mHealth: Narrative Literature Review

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Abstract

Background: Mobile health (mHealth) has the potential to solve human resource issues in the health care sector. mHealth is of particular interest in developing countries, where widespread mobile networks and access to devices are connecting people like never before.

Objective: The aim of this paper was to review published and unpublished literature, field projects, and pilot studies on mHealth usage in overcoming shortage of human health resources in developing countries.

Methods: A narrative literature review was undertaken using an iterative approach in extracting literature focused on mHealth and human health resources of low-income countries, especially India. The present review has undertaken comprehensive coverage of the work on related field projects that have been either published, accepted for publication, or pilot tested.

Results: This review presented the use of mHealth across various dimensions of primary health care, including data collection, disease surveillance, health education, supervision, monitoring, and feedback. Field studies of fast, error-free data collection and transmission using mHealth were also documented. New apps for supervision, monitoring, and utilization of innovative health education tools were documented in the current review. Practical limitations of mHealth and challenges set forth in developing countries included issues of data security, cost constraints, health provider privacy, and technical barriers.

Conclusions: In the present review, we have documented a few mHealth projects that contribute to the proficient use of human resources. These projects pave the path for the efficient utilization of mHealth, offering solutions to emerging human resource challenges and simultaneously revamping the health care delivery in resource-limited settings.

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KEYWORDS

mHealth; human resource; health; developing countries; projects

Introduction

The world today is experiencing an extraordinary progress in the field of interpersonal communication. Several developing countries such as India have witnessed an explosive annual growth rate of nearly 39% in wireless subscriber base during the year 2010-2011 [1]. Mobile technologies have already changed and will continue to make an impact on the lives of millions. Mobile phones, because of their high penetration levels, hold tremendous potential and provide opportunities never imagined before in the areas of communication, entertainment, education, employment, and health. However, the health sector has been slower in adopting mobile

technologies into routine operations, and its adoption would benefit patients and providers alike.

The health sector faces several challenges, and many of these problems could be circumvented by the intelligent use of mobile phone technology. Inadequacy of human resources in the health sector is an identified bottleneck in achieving universal access to quality health care [2,3]. Health workforce is defined as "all people engaged in actions with primary intent to enhance health" [4]. According to the World Health Report 2006, a shortfall of health workforce has been documented in 57 countries. The scenario is worse in Southeast Asian regions, which accommodate 25% of the world's population and take 30% of the global disease burden, as these have only 10% of the global health workforce [5]. In India, 20 health workers and 1 doctor for every 10,000 people translates to a shortage of nearly 2.6 million health workers [6]. The health workforce inequity exists between genders, regions, and categories of health workers [7]. At present, mobile phones with their reach, connectivity, and features of smartphone have the capability to provide potential solutions to many of these challenges.

Mobile health (mHealth) is a relatively recent term for medical and public health practices supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. The term "mHealth" was coined by Professor Robert Istepanian as the use of "emerging mobile communications and network technologies for healthcare" [8]. It is a simple, low-cost, and immensely user-friendly service capable of enhancing the speed and accuracy of health care delivery. mHealth applications include the use of mobile devices for collecting community and clinical health data; delivery of health care information to practitioners, researchers, and patients; real-time monitoring of patients' vital signs; and direct provision of care (via mobile telemedicine) [9].

Interest in the application of mobile phone technology has been growing in developing countries, where widespread mobile networks and access to devices are connecting people like never before. The present paper attempts to present a literature review on the utilization of mHealth services for bridging human resource gap in the health care sector. It is expected that the summary of the extent of utilization of this technology in current field situations presented in this review will guide any future work in this domain.

Methods

The present paper presents a narrative literature review using an iterative approach in extracting relevant literature from developing nations on the utilization of mobile technology for bridging human resource gap in health care sector. A comprehensive coverage of work on many papers and field projects that had either been published, unpublished, or are being pilot tested has been ensured. The search was restricted to literature sources in English; however, no time restriction was imposed. Search engines such as PubMed, IndMed, Directory of Open Access Journals, and Google Scholar were used to identify published and unpublished/in-progress studies, references, and citations of articles of interest. Search terms that were used in the process were "mHealth," "projects," "health manpower," "human resource," "rural," "underserved area," and "India." These terms were searched individually and in conjunction with professional classifications such as health workers, nurses, doctors, and midlevel workers. All studies, project reports, and policy statements that dealt with the use of mobile phones for epidemiological purposes in health, for example, data collection, supervision and feedback, health promotion, and workload reduction, were included in the study. In addition, manual search of literature was also performed in the institute library to collect relevant information. A systematic search of pertinent journals, such as *Journal of Medical Internet Research* and *Indian Journal of Medical Informatics*, was also undertaken. Unpublished literature (using authors' knowledge of the field) was included in the review along with inputs from experts using the snowballing technique to identify additional studies. The websites with mHealth project databases, for example, Royal Tropical Institute mHealth project database for low-resource settings, were searched for key projects on mHealth. Reports of using audiovisual aids, computers, and e-devices in hospitals and health care sector were excluded from the review. mHealth projects that appeared to have no influence on the work burden or bridging manpower gap were also excluded from the study. Finally, a total of 28 relevant projects on mHealth were included in the review.

Results

Primary Results

mHealth projects have been initiated on various dimensions of health care, for example, data collection, surveillance, training, health education, awareness, supervision, and monitoring. A large-scale implementation of such projects could become the forerunner of health care reforms in the future. mHealth applications and tools can significantly contribute to reducing the workload and improving the performance of health care workers. In addition, skill mix of health care workers is ensured as they perform multiple tasks through smartphone aids. Thus, this results in the twin benefits of reducing human resources needed for various tasks and greatly improving service quality.

Data Collection and Disease Surveillance

Paper-based field data collection and transmission has remained a cost-intensive and time-consuming activity until now. But using mobile applications helps in transmission of real-time data, quick calculations, easy transfers, and distant supervision. Mobile applications help in lowering cost, saving time, and improving data accuracy by reducing the possibility for human error and avoiding duplication of reports. Health surveys, in context of mHealth, are defined as the use of mobile devices for health-related data collection and reporting.

The pilot project led by International Centre for Diarrheal Disease Research and National Institute of Preventive and Social Medicine was conducted in Bangladesh using PDAs to collect data [10]. PDAs were also successfully deployed to collect data for Global Adult Tobacco Survey in India [11].

Smartphones enable health care workers to download several health-related applications. EpiSurveyor, a mobile data

collection tool, offers data collection forms for medical projects. In 2008, Kenyan health workers were successful in preventing a potential polio epidemic using online software to track emergency vaccination campaign against poliomyelitis. In 2010, the same mobile phone application was field tested in Malawi for feasibility and scalability in a pilot project to monitor availability of malaria medicines. The project helped provide quality services and reduce the workload of health workers [12]. Curioso et al, in their study in Peru, observed that self-designed Cell-PREVEN system had proven effective in real-time reporting of adverse events from health workers, or from a doctor reporting outbreak of a disease [13]. Similarly, Media Lab Asia, in collaboration with All India Institute of Medical Sciences, New Delhi, India, helped in creating accessible and sustainable health system to the community in which an open source software application was used to collect medical and demographic data. In this effort, a high adoption of the technology was observed and also a significant reduction in total time needed for data entry was noted [14].

A door-to-door cancer campaign was conducted in the state of Punjab, India, in 2012 covering 2.3 million people. Health workers used simple mobile phones for data transfer, and negligible errors were reported in the process. This process helped in completing the survey in a record time of 20 days, as use of mobile phones significantly reduced transport time and separate time required for data entry and transfer [15].

Mobile phones can be appropriately utilized as a cost-effective tool for real-time disease surveillance. Quick dissemination of health information can enable health administrators with limited field staff and supervisors to take timely action. mHealth helps in real-time monitoring of diseases and public health problems, thereby reducing the workload on health workers.

Muthiah et al investigated the effectiveness and efficiency arising out of the application of mobile phone technology for early detection of disease outbreaks on a real-time basis from July 2008 to July 2010. The data were collected from outpatient health units of primary health centers and subcenters using mobile applications. Adverse events were rapidly disseminated via text messaging (short message service, SMS), email, and through Internet using Web-based software. The entire process of data collection and reporting was highly efficient [16].

The Community Health Information Tracking System (CHITS) in Philippines empowered local communities with information and enabled a 2-way data flow using mobile technology. CHITS trained local health workers on how to use the information system, enabling them to take action and empower others [17]. A pilot project Real-Time Biosurveillance Program was implemented by Sarvodaya and LIRNEasia to investigate the conditions for effective deployment of wireless technologies in disease surveillance. This project proved effective in the early detection of clusters of population affected by chicken pox, acute diarrheal disease, respiratory tract infection, dengue, and viral fever in Kurunegala district, Tamil Nadu, India [18].

Mobile phones have been pilot tested extensively in the communicable disease surveillance programs of various developing nations: for example, malaria in Uganda and Botswana, dengue in Mexico, tuberculosis (TB) in Pakistan, infectious disease surveillance after earthquake in China, and setting up an electronic disease surveillance and response system in Tanzania [19].

Mobile phones were found acceptable and feasible in the collection of maternal and child health data from women living with human immunodeficiency virus (HIV) in South Africa [20].

To summarize, mHealth technology has proven effective in increasing the efficiency of data collection and disease surveillance with reduced human resource requirements.

Health Education and Training Tool

Health information and messages can be disseminated on a large scale to public using mobile phones. Commercial films and videos delivered on the mobile phones can help in improving the efficiency of health education sessions in outreach sessions where elaborate audiovisual aids cannot be arranged.

AIDS was a taboo in Georgia but the adoption of mobile phones was high. Mobile phones were effectively used for disseminating knowledge about HIV/AIDS through video films featuring popular actors. This fast transfer of knowledge on HIV through video was the first kind of use of mHealth for education and awareness in Georgia. This paved way for other successful programs utilizing mHealth in the country [21].

Mobile phone games have also been used in the fight against the spread of HIV/AIDS. The project, Freedom HIV/AIDS in Africa, was the first-ever initiative to focus on HIV/AIDS awareness using mobile phone games. By Play-and-Learn method, these games make learning exciting and help in the enhancement and retention of knowledge among children [22].

Project Masiluleke in South Africa focused on raising HIV awareness. It encouraged people to get tested for HIV/AIDS and to undergo treatment by ensuring that those who tested positive adhered to individualized treatment regimens. In the first phase of project (2009), text messages were sent to encourage utilization of testing and treatment services for HIV/AIDS. This significantly increased call volume to National AIDS Helpline with a large number of people reaching out to health workers for information [23].

African Medical and Research Foundation, an international African organization, initiated a pilot project through which community members in 4 districts received TB-related quiz questions and awareness messages in local dialect as well as in English through mobile phones. Participants who successfully completed quiz questions were rewarded with prizes (eg, free airtime, mobile phones, and T-shirts). This contributed to significant increase in the number of TB patients taking medication [24].

A nongovernment organization in Uganda, Text to Change, created awareness about HIV/AIDS by providing an SMS-based quiz to a large number of mobile phone subscribers. It focused on improving health education through text messaging, using anonymity and capability of mobile having a greater reach among population. This program aimed to encourage citizens to seek voluntary testing and counseling for HIV/AIDS. Free airtime was offered to users to encourage their participation in

the program. The quiz was interactive and focused on general knowledge about HIV transmission and the benefits of voluntary testing and counseling [25]. Similarly, AIDS hotline and free AIDS text messages in Ethiopia, HIV Confidant project in South Africa, and Jalaaka Project in India facilitated education and spreading awareness about HIV among the community and high-risk groups [19].

mHealth has also been used for educating community in projects focused on family planning, adolescent health, and antenatal care. CycleTel, a mobile-based application launched in India, helps the user implement family planning using Standard Days Method. It calculates fertile period for women and advocates sex avoidance during that period [26]. Community health workers in Bihar, India, used mobile phone application CommCare to disseminate information on common adolescent health issues such as menstrual hygiene, sexually transmitted diseases, and family planning methods among adolescent girls and women. The outcome of the project was encouraging in that it had a wider outreach among adolescents, even as health workforce was scarce [27].

Projects that used mobile phones to access the community to provide them information and education, as well as for communication, were developed by several nonprofit organizations. Project mDHIL Health Information on mobiles in India, Project Zumbido for HIV/AIDS in Mexico, and Sex-Ed-Thru Text in Indonesia are some examples of such projects [28].

Thus, behavior change communication through mobile phone eliminates the need for a larger health workforce, as it has the capability to reach a large section of the population automatically and creates considerable impact.

Supervision and Monitoring

Supervision in health care system is suffering due to lack of role clarity, time, and cost constraints, in addition to poor access to peripheral health centers. Supervisors, at all levels, are overburdened with their primary responsibilities. Therefore, a supervisor's workload is reduced through a mobile application, using which long-distance supervision can be performed and feedback delivered through mobile apps. It reduces the frequent need for on-site supervision without compromising work quality.

Tracking of health workers using global positioning system (GPS) technology or viewing location of employees on Google Maps installed on their mobile phones has proven very effective in streamlining management oversight and improving worker attendance. Econz Timecard GPS is one such mobile time card application enabling supervision through mobile technology [29].

A project on malaria monitoring, diagnosing, and treatment was launched in Botswana in 2012 with the assistance of local mobile network providers. Local health workers were trained to diagnose malaria by conducting rapid diagnostic tests. The results were reported via mobile phones, offering real-time access to malaria data, trends, and locations. The information collected proved useful for decision makers in planning vital elements of malaria control program, for example, supply of adequate malaria medicines, bed nets, and sprays [30].

Alam et al (2010), in their study on assessing the scope of mobile-based solutions to improve maternal and child health in Bangladesh, showed that by installing a smart algorithm in mobile phones of health workers, delivery of efficient health services to pregnant mothers and neonates was possible with reduced human resources [31].

Mother and Child Tracking System under National Rural Health Mission in India was introduced to ensure delivery of comprehensive maternal and child health services through the use of mobile phones. Work plans and reminders for antenatal and postnatal checkups were sent via mobile phones to respective health workers. This eliminated the need for paper work to draft the work plan and manual delivery. Repeated reminders through phone calls and SMS ensured better and timely health care delivery to the beneficiaries [32].

Similarly, female health workers in Pakistan were provided with mobile phones to remain in touch with the officials and provide efficient service delivery to the community [33]. Rapid SMS project in Rwanda in Africa enabled community health workers to track pregnant women, monitor antenatal care, identify and refer women at risk, and improve communication with health facilities during emergencies [34].

A Web-based application, Colecta-PALM delivered on PDAs, was used for sending messages about behavior based on risk-assessment responses to people living with HIV and AIDS in Peru [35]. Similarly, SMS printers linked to HIV testing centers were successfully pilot tested in Mozambique. The test results, stored in the health centers, were immediately available through a single command from the HIV center [36].

Project Mobile-DOTS for tuberculosis patients in Kenya (2008) had been successful in drug delivery to TB patients. Treatment supporters were asked to capture videos of patients as they took medications daily and view motivational and educational text and video health messages. This was submitted for review by health professionals. It was observed that most patients preferred MDOT to clinic DOT (patient visiting health center for TB drug administration) or DOT delivered by visiting community health workers [37].

Although not rigorously tested, regular monthly review of remote health facility functions can be performed effectively via mHealth applications. This eliminates the need for physical presence of health workers for the monthly meeting and frees their time to focus on their activities for implementing national health programs.

A vast majority of people in rural areas make decisions on where to seek treatment primarily based on the consultations they make with the field worker. Instead, health workers can deliver information to these people about the available health facilities through text messages. A similar SMS-based network was established in Cambodia to gather data on adverse events following immunization and guide patients for immediate referral as soon as a danger sign was noticed. Mobile phones can thereby help in setting up referral mechanisms and maintaining smooth patient flow in the process [38].

A pilot project was undertaken by the School of Public Health, Postgraduate Institute of Medical Education and Research,

Chandigarh, in the area of rural field practice in 2006 with the objective of enhancing the outreach of health care services. A senior resident (public health specialist) gave his mobile phone number stamped on outpatient department slips to patients, municipal committee members, anganwadi workers, sarpanches, and mahila mandals for a period of 3 months. The phone calls that the senior attendant received were answered, a record of which was duly maintained in the personal pocket diary of the senior resident. Callers sought information on availability of doctor, health problems, and immunization services. The study concluded that public at large is favorable to the idea of mobile phone usage for medical consultation [39].

Feedback Mechanism

mHealth can be utilized in feedback assessment of health services. An interactive voice response system allows the user to provide feedback on health care service delivery. Supervisors can send messages to people asking for feedback and for tracking service delivery in their area of work using mHealth. Business organizations and mobile operators have mHealth systems in place already. Data generated through the feedback process can be used to rank health care facilities, thereby contributing to improving the health care system and performance of people. In many countries, helpline phone numbers exist for patients to call for medical consultations and help. In India, health helpline (phone number 104) is provided by Health Management and Research Institute in collaboration with state governments (Maharashtra, Rajasthan, Assam, and Andhra Pradesh). At a very minimal cost, any citizen can have medical consultation or lodge a service complaint against any public health facility.

Discussion

Challenges in mHealth

Most of the mHealth projects are funded by external donors and are not self-sustaining, thereby affecting long-term sustainability of such initiatives. Few shortcomings such as loss of privacy, cost issues for sustainability, nonavailability of responsive technology support, and lack of training support were noticed in using mHealth for data collection and reporting. Attitudinal barriers of health care providers toward mHealth must be addressed effectively. Some issues with regard to technical feasibility in the form of doubts about the quality of data entry and analysis also arise. Data security is another important issue in using mHealth applications. Using mHealth technologies causes various legitimate concerns about the security of citizen information collected for various programs. In particular, security lapse in message transmission and data storage can lead to compromising the collected data if the necessary precautions are not taken. Health hazards of radiation emitted from mobile phones is another concern drawing attention. Moreover, initiating mHealth project is a cost-intensive activity. A prerequisite to provide mobile phones to the workers or reimburse their phone bills should be inbuilt into the program. Otherwise, it adds to the financial burden on the worker, leading to sustenance issues. Privacy concerns of health workers in mHealth must be clearly addressed as it has been observed that many irrelevant calls are made at odd hours.

Conclusions

To conclude, mHealth care can bring about a *revolution* in health care in India and other developing nations. Vast reach and penetration of this technology can be effectively harnessed for health care delivery where access is the key barrier. Investment in mHealth reduces spending on stationery, travel, and time, and thus meets the challenge of shortage in human resources (both quantity and quality). Moreover, adoption of mHealth by workers in their day-to-day work helps them improve their productivity and efficiency, which is translated into enhancing quality and job satisfaction. Continuing health education of workers through mobile phones helps them remain motivated and up-to-date with the latest guidelines and developments.

mHealth is a new development in health care, the potential of which remains underutilized. A need to go beyond the pilot testing of projects and scale it to the national level is required [40]. Well-designed research studies are needed to explore existing challenges in mHealth and experiment with newer applications. Issues such as large capital cost, data security, disturbed privacy, and sustainability of several projects require great attention. The present review provides an overview of some key mHealth projects and studies undertaken in developing countries. Considering human resources crunch and issue of poor accessibility in rural and underserved areas of India, mHealth is the only existing viable solution.

Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

CHITS: Community Health Information Tracking System
GPS: global positioning system
HIV: human immunodeficiency virus
mHealth: mobile health
PDA: personal digital assistant
SMS: short message service
TB: tuberculosis

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Original Paper

Position and Orientation Tracking in a Ubiquitous Monitoring System for Parkinson Disease Patients With Freezing of Gait Symptom

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Abstract

Background: Freezing of gait (FoG) is one of the most disturbing and least understood symptoms in Parkinson disease (PD). Although the majority of existing assistive systems assume accurate detections of FoG episodes, the detection itself is still an open problem. The specificity of FoG is its dependency on the context of a patient, such as the current location or activity. Knowing the patient's context might improve FoG detection. One of the main technical challenges that needs to be solved in order to start using contextual information for FoG detection is accurate estimation of the patient's position and orientation toward key elements of his or her indoor environment.

Objective: The objectives of this paper are to (1) present the concept of the monitoring system, based on wearable and ambient sensors, which is designed to detect FoG using the spatial context of the user, (2) establish a set of requirements for the application of position and orientation tracking in FoG detection, (3) evaluate the accuracy of the position estimation for the tracking system, and (4) evaluate two different methods for human orientation estimation.

Methods: We developed a prototype system to localize humans and track their orientation, as an important prerequisite for a context-based FoG monitoring system. To setup the system for experiments with real PD patients, the accuracy of the position and orientation tracking was assessed under laboratory conditions in 12 participants. To collect the data, the participants were asked to wear a smartphone, with and without known orientation around the waist, while walking over a predefined path in the marked area captured by two Kinect cameras with non-overlapping fields of view.

Results: We used the root mean square error (RMSE) as the main performance measure. The vision based position tracking algorithm achieved RMSE = 0.16 m in position estimation for upright standing people. The experimental results for the proposed human orientation estimation methods demonstrated the adaptivity and robustness to changes in the smartphone attachment position, when the fusion of both vision and inertial information was used.

Conclusions: The system achieves satisfactory accuracy on indoor position tracking for the use in the FoG detection application with spatial context. The combination of inertial and vision information has the potential for correct patient heading estimation even when the inertial wearable sensor device is put into an a priori unknown position.

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KEYWORDS

Parkinson disease; Freezing of Gait; context-aware system; indoor localization; person orientation

Introduction

Background

Freezing of Gait (FoG) is a temporary, involuntary inability to initiate or continue movement lasting just a few seconds, or on some occasions, several minutes [1]. FoG is experienced by approximately 50% of patients with advanced Parkinson disease (PD) [2]. It is described by the patients as a feeling of having the feet glued to the ground and being temporarily unable to start walking again. FoG usually depends on the walking situation. It often occurs at turns, start of walking, upon reaching the destination, and in open spaces [3]. It can also occur when people approach narrow spaces, such as doors, and when people are in crowded places [4]. In a home environment, freezing episodes are usually reported by patients to occur at the same location every day.

In cognitive psychology, attention set-shifting is defined as the ability to move back and forth between tasks, operations, or mental sets in response to the changing internal goals or the changes in the environment perceived through senses. According to Naismith et al [5], the ability to keep different tasks, motor and cognitive, active at the same time is reduced in persons with FoG. The flexibility to shift from one response set to another is therefore impaired which may trigger episodes of FoG. Additionally, this behavior may be emphasized by other provoking features such as increased cognitive load, dual-tasking [6], stress, anxiety, and depression [7]. Irrespective of what causes it, FoG is mostly characterized by a decrease in stride length, an increase in stepping frequency preceding the episode, and the presence of a highly abnormal frequency of leg movements during the episodes [8].

The usual pharmacological way of treating FoG is the same as the general treatment of PD. Research has shown that dopamine treatment helps in reducing the number of occurrences of the symptom, but that it cannot eliminate the symptom completely [9]. Some of the patients developed different ways to deal with FoG on their own. These involved various techniques for solving start hesitation, such as lateral swaying, stepping over someone's foot, and stepping over lines on the floor. Observations of these techniques led to the development of a theory of sensory cueing as a feasible therapeutic option. Evidence was found that external sensor "cues" (visual, auditory, or haptic) may compensate for the defective internal "cueing system" for initiating and maintaining movement [10]. The research of cueing techniques led to the development of several commercial products intended to help FoG sufferers to improve their gait performance (eg, PDGlasses [11]). The disadvantage of existing commercial products is that they are not adaptable to the walking rhythm of each patient, so that the offered permanent stimulation is not optimally effective [12].

Wearable Systems and Gait Monitoring

Active monitoring technology has the potential to alleviate FoG through timely episode detection and sensory stimulation. Timely detection is based on online data acquisition of motor symptoms of PD. The usual approach is to use wearable inertial sensors in order to obtain kinematic parameters of the movements of body segments. As already mentioned, gait alterations like short shuffling steps and festinations are characteristic of FoG. Therefore, the analysis of gait parameters is a good indicator of the patient's state. The foundation of the work on adaptive systems for ambulatory monitoring of FoG was established with the offline detection algorithm based on frequency analysis of leg movements proposed by Moore et al [13]. The authors used accelerometer located at the ankle to take measurements, and associated a frequency band between 3 and 8 Hz with the leg movements when a patient suffered from FoG. Moore's algorithm for FoG was later successfully applied in an online wearable gait assistant for PD patients developed at ETH Zurich [14]. This system used a three-axial accelerometer fixed on the shank and one unique threshold for all patients. Sensor position on the thigh above the knee and at the hip was also tried.

So far, there has been no consensus on the best inertial sensor combination/position for the ambulatory analysis of human gait. The system for FoG detection and gait unfreezing presented by Jovanov et al [15] used an inertial platform consisting of a three-axial accelerometer and two-axial gyroscope placed on the knee. Zabaleta et al [16] performed a pilot study with two PD patients, using sensors to measure acceleration in three axes and angular velocity in two axes. In this study, sensors were used to monitor foot, shank, and thigh movements. The majority of existing systems demonstrate that the best results in FoG detection can be expected when using inertial sensors placed directly at the lower extremities. However, one big drawback of this approach is that strapping sensors on the legs is not optimal for use in daily life.

In the area of assistive technology, user acceptance of technological solutions is crucial. It has been proposed that using one light inertial measurement unit (IMU) fixed on the lateral side of the waist of the user is the most user-friendly position, which also gives satisfying results in gait analysis [17]. The proposal for the sensor placement on the hip can be further supported by the recent results presented by Mazilu et al [18]. Using one sensor fixed at the hip and training a machine learning algorithm specifically for a patient with that patient's data, they achieved excellent results for specificity and sensitivity (both above 98%). However, the presented approach is patient-specific and based on data from a controlled environment. At the moment, the best reported detection accuracy with the sensor placed on the waist and the algorithm targeted at the general PD population is still around 70% to 80% in terms of both specificity and sensitivity.

The amount of information that can be extracted from one sensor device is finite, and it is reasonable to expect that the overall detection accuracy of such a system cannot be higher than the accuracy of a system composed of multiple sensors. Furthermore, wearable inertial sensors currently used for gait

analysis are able to sense only physical context of the user, while it is known that the FoG episode onset can also be under direct influence of other types of context (situation, location, and/or cognitive load). It would be nice to keep the ease-of-use of the gait monitoring system composed of only one wearable sensor, and at the same time to enhance its reliability. One way to achieve this improvement is through the use of spatial context, which is the term used to describe a combination of the patient's location and his relation toward elements triggering FoG in his environment.

Spatial Context in Freezing of Gait

In their home environment, PD patients are likely to encounter narrow passages such as doorways or dynamically changing spaces created by the presence of other people and movable objects such as chairs. When PD patients perceive the space as too narrow for the dimensions of their body, adaptive postural changes during locomotion may be needed to achieve collision-free passage [19]. Experiments with PD patients show that there might be a direct correlation between the width of the narrow space and the tendency for a FoG episode [20]. It has been reported that freeze-like events were successfully provoked near a doorway and that their prevalence significantly increases with the narrowness of the doorway [21]. Furthermore, the measurements of gait based on objective criteria showed that a decreasing door width caused progression velocity to drop approximately 20% in the region preceding the doorway, or immediately after it.

When inferring spatial context in FoG, we are primarily interested in the locomotion behavior of the patients. Examples from literature show that a two-dimensional (2D) point representation on a floor map is sufficient for this kind of task [10]. Contextual triggers of FoG that can be identified from 2D motion in a robust and efficient way under realistic conditions are starting of walking, approaching the destination, approaching narrow spaces, and being near locations where FoG occurs every day. Additionally, many affected people are experiencing FoG during turns. Wider turns seem to be easier for them to perform than axial turns on the spot, and slow turns are easier to perform than rapid turns [22]. A rapid turn on the spot is hard to track using only a 2D point as the representation of the tracking target. The observation of *on-the-spot* turns can be achieved only by precisely estimating angular velocity of the person, which requires additional tracking of the heading angle. This is the reason why we propose the 2D pose, expressed by two floor position coordinates (x, y) and one heading angle (θ), as the minimal tracking representation to be used in the spatial context inference process for FoG detection.

Position and Orientation Tracking for Freezing of Gait Detection

One of the main objectives of our research is to discover if spatial context and the principle of direct geometric correlation can effectively be used to improve automatic detection of FoG in a home environment. This objective requires design and development of a technical system that is able to observe people and their environment, along with the ability to apply correct contextual rules using the observed data. The hypothesis of the direct correlation between geometry of the surrounding environment and FoG episodes has so far been tested only in controlled laboratory environments. There is a need for behavioral data of FoG patients from homes, because a clinical environment is not perceived by people in the same way as their natural environment. As a result, freezing episodes do not happen in the artificial setting in the same way that they would happen at home. The lack of domestic behavioral and environmental data of FoG patients is a significant obstacle that must be taken into account during the analysis of requirements for the design of a future context-aware system.

We divided the development process of the system into two principal stages. The goal of the first stage is to establish a people-tracking system for the collection of behavioral data in the homes of people with FoG. Collected data will be used to build the needed contextual model of FoG. In the second stage, the contextual inference part will be added to the existing tracking system with the goal of testing the finalized system through long term deployment. During the first stage, short term, one day long experimental sessions are expected in both clinical settings and home environments. Because of this, the position and orientation tracking system being developed needs to have the properties of a portable system, allowing for fast installation and setup. Besides reliability and accuracy in tracking people's position and orientation, the system also needs to be modular allowing for scalability in the coverage of an indoor space. Additional requirements for permanent deployment are the ability to identify the FoG patient among members of a household, usability on a daily basis, and ultimately, affordability.

Taking into account the above requirements, we have designed a solution for an improved, pervasive context-aware home-based system for PD patients based on distributed sensing. In the development process, we have come to the end of the first stage, where we have obtained a prototype of the indoor position and orientation tracking system. The prototype consists of a network of Microsoft Kinect [23] cameras and one smartphone worn by the patient, and it needs to be tested for accuracy before starting behavioral data collection in the home environment.

The main objective of this paper is to present a functional and architectural solution for the ubiquitous context aware system for FoG detection, with special attention given to the accuracy evaluation of the developed prototype system for indoor position and orientation tracking.

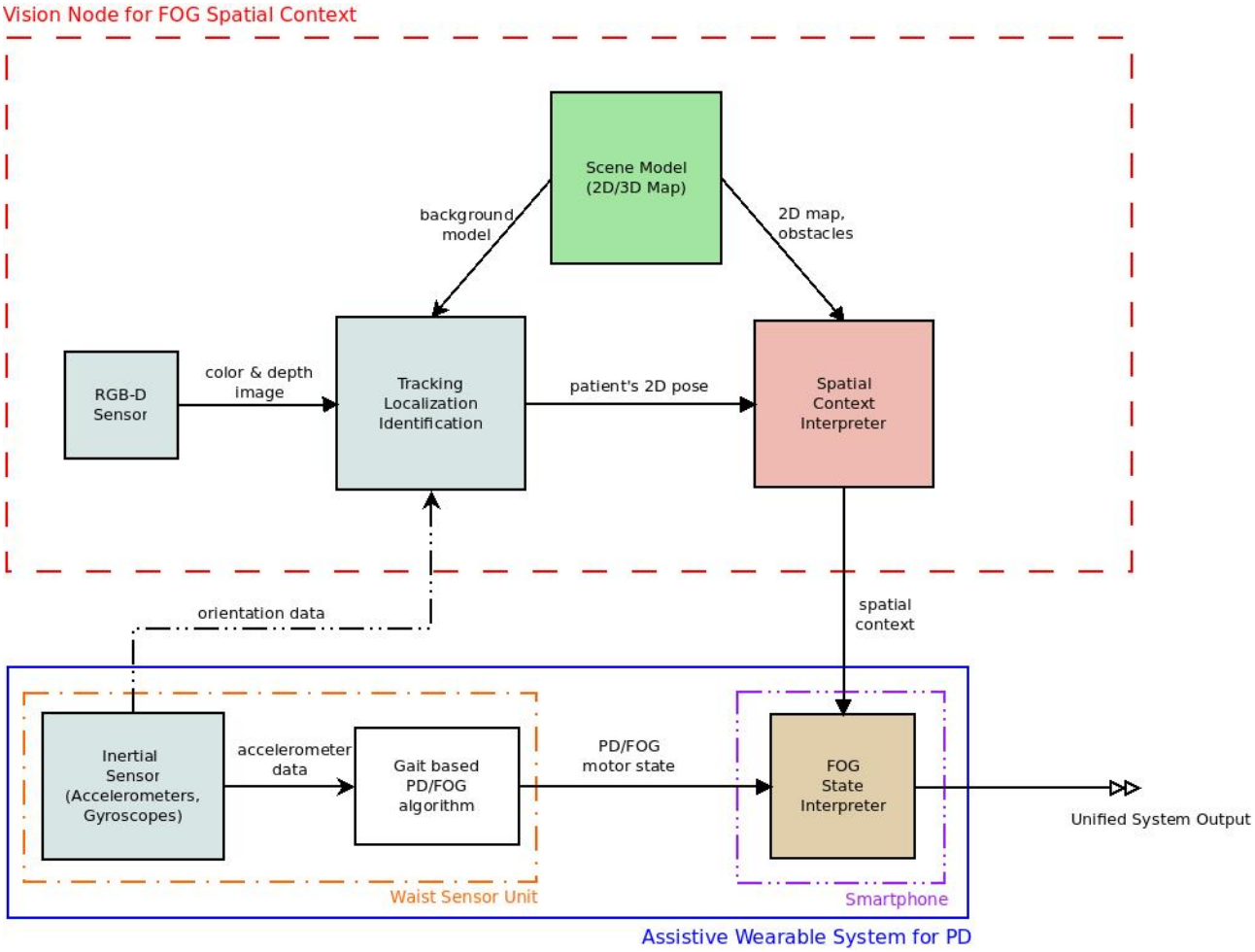
Methods

Ubiquitous Monitoring System for Freezing of Gait

In the concept of a ubiquitous FoG monitoring system [24,25], a wearable assistive system is used to monitor gait with inertial sensors and to treat the FoG patient via a cueing device at any time or place during the day. REMPARK (Personal Health Device for the Remote and Autonomous Management of Parkinson Disease) is an example of one such system [26]. The sensing capacity and detection capabilities of the wearable assistive system are expanded with a network of vision sensors installed in the patient’s home environment, placed in the least sensitive areas concerning privacy, such as the living room,

kitchen, and hall. The vision system runs image-based tracking, environment mapping, and context inference on a dedicated home gateway server. The concept and the components of the system are presented in the block diagram in Figure 1.

Figure 1. Block diagram for the concept of the ubiquitous monitoring system. The wearable system independently detects FoG based on inertial data (blue rectangle). Gait-based detection is complemented by the user's spatial context from the vision sensor system (red rectangle) in the areas of the home where such a system is present.



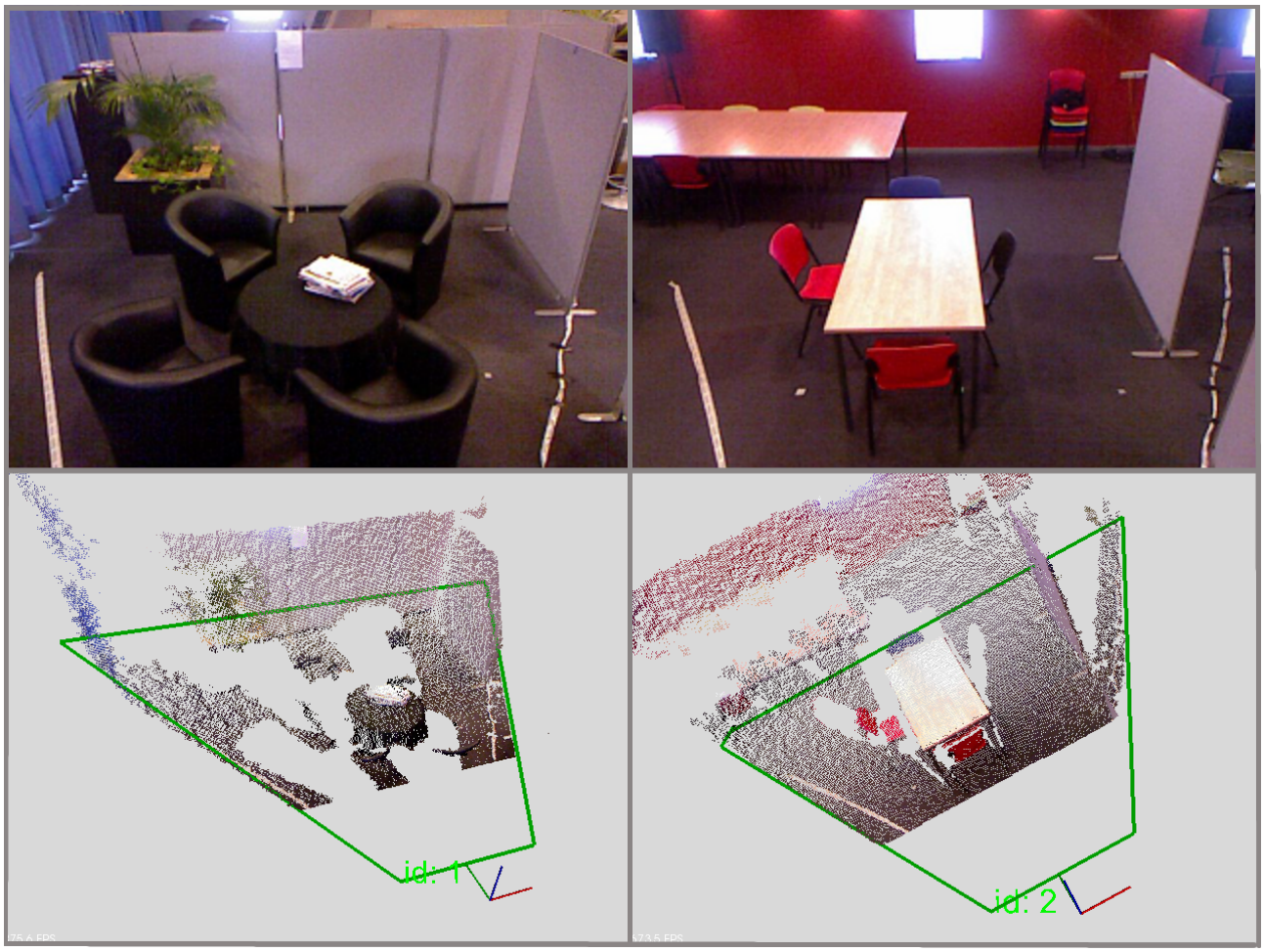
Distributed Home Vision System

Video cameras and video processing are often used in smart environments for event detection and context inference. Cameras enable the observation of changes in the environment, and at the same time, they are able to provide sub-meter accuracy of indoor localization. Limitations of the usual color (RGB) camera system are its sensitivity to changing lighting conditions, shadows, and occlusions. Active range cameras, such as the Kinect's depth sensor can be applied to overcome the drawbacks of color cameras. Furthermore, one depth sensor is enough to retrieve the three-dimensional (3D) information about the environment compared to a setup of multiple calibrated color cameras usually required for the same task.

To achieve the maximum spatial coverage for each Kinect sensor in an indoor environment with normal ceiling height, we decided to use these sensors in an over-head mounting position. Also, to achieve the most effective coverage inside a home with a minimum number of vision sensors, we decided to use non-overlapping scene coverage with only one or two Kinect sensors per room. An example of the intended spatial coverage is given in Figure 2.

Multiple person tracking and identification should be included in the system since the majority of PD patients live with at least one other person (see Multimedia Appendix 1). Each color and depth (RGB-D) camera in the system is intended to work as an independent vision node in terms of positional tracking. This means that each camera should have the map of the scene in front of it and that it should track people in the coordinates of its own frame. Context rules will be evaluated only for the camera that is tracking the patient. The intended application in unpredictable home environments brings a series of requirements. Besides support for multiple people tracking and patient identification, the vision system should have near real-time performance with at least 15 Hz frequency rate, robustness to dynamic backgrounds, and lighting changes and sub-meter position tracking accuracy.

Figure 2. Example of a test bed with two scenes being independently covered by Kinect sensors. Mock-up of a living room on the left and a dining room on the right. Images in the top row depict the point-of-view of the cameras when they are mounted in the overhead position. The bottom row displays colored point clouds of scenes that are obtained from depth sensing. Green trapezoid indicates the area in which it is possible to track people.



Context Inference Process and Freezing of Gait Detection

The workflow diagram of the system is given in Figure 3. The diagram shows how one RGB-D camera is paired with a wearable sensor in order to achieve improved FoG detection and cueing actuation. This process can be executed for each RGB-D camera.

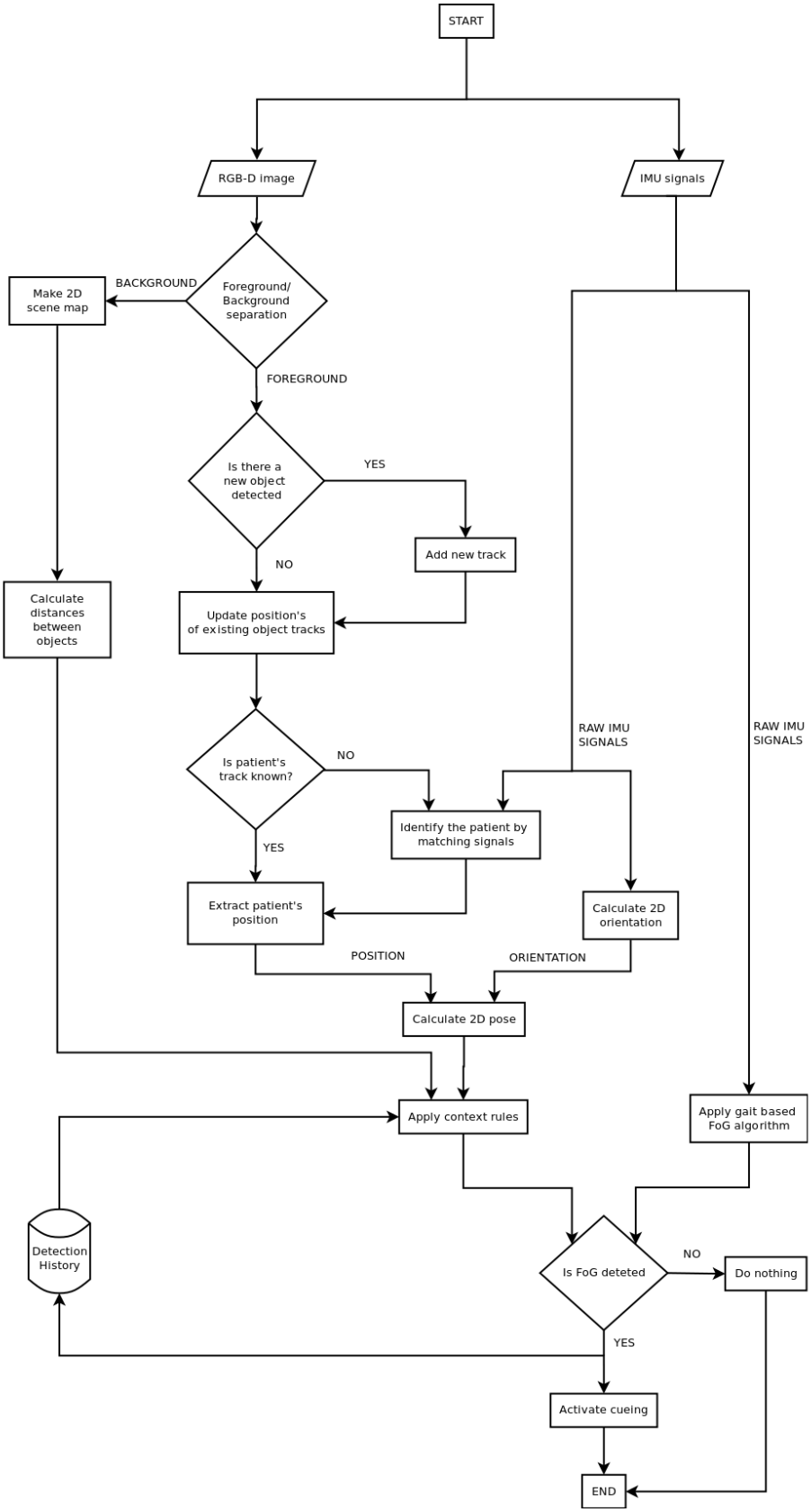
Independent elements of the process include 2D position tracking and 2D scene map calculation using RGB-D image, 3D orientation calculation using inertial data from the wearable sensor, and gait-based detection of FoG from inertial signals. These elements have to work independently, so that FoG detection can be achieved using the wearable sensor even when the patient is not in front of the camera.

The main prerequisite for position tracking is background subtraction in each frame. Background subtraction is based solely on the depth image. The background model for subtraction is set by periodic updates of the 3D point cloud of the whole observed scene. These periodic updates are done every few minutes on occasions when no tracked objects are present in the field of view. Furthermore, this background model is used to build the 2D map of the scene, which is used as one of the inputs for spatial context inference.

The foreground image obtained after background subtraction is used to build point clouds for updating the positions of the persons being tracked and to detect any new person in front of the camera. After the detection of new persons, positions of all tracked persons are updated. We are only interested in the position of the patient. If the track of the patient is not identified, the process of matching all known track histories against inertial sensor data is executed. If the match is successful and the patient's track is known, the position of the matched track is used in the calculation of the patient's pose. If none of the tracks in front of the camera are identified as the patient, the camera data is excluded from FoG detection.

Pose calculation involves a combination of the position obtained from the vision tracker and the 2D heading obtained from the wearable sensor. The estimated 2D pose is combined with the 2D map information and history of FoG detections to infer contextual probability of a FoG episode. This probability is published over a wireless network and read by the FoG State Interpreter (FSI) module running on a smartphone device. The FSI module conducts a high level probabilistic fusion of spatial context and gait detector outputs and produces the final system output which can be used to activate cueing.

Figure 3. Workflow diagram for FoG detection using the distributed sensor system.



System Prototype

The hardware prototype of our distributed sensing system consists of two static Kinect devices and one Samsung Galaxy Nexus smartphone, worn by the user. Each Kinect is connected to its own notebook computer, which acts as a processing unit for data acquisition and also runs one instance of the vision tracking algorithm. The notebooks are connected in a dedicated local area network (LAN) and they are synchronized with respect to time. Each Kinect acquires a depth and color image

of resolution 640×480 pixels at a frequency of 30 Hz. The smartphone has connectivity with the dedicated wired LAN over a software access point running on one of the notebook computers. The smartphone reads data from its internal inertial sensors, three-axial accelerometers, gyroscopes, and magnetometers with the frequency of 100 Hz.

After the investigation of available middleware systems for intelligent environments, we chose an open source, community-supported middleware from the robotics domain to develop our distributed sensor system. The Robot Operating System (ROS) [27] is a meta-operating system that runs on top of the real operating system (Linux Ubuntu). A great advantage of using ROS in our project is that ROS program packages provide automatic hardware support and integrated access to various open source processing libraries. The main libraries we use are the Open Source Computer Vision Library [28] and the Point Cloud Library [29]. The algorithms for the vision tracking system were developed in C/C++. The Galaxy Nexus smartphone with Android OS runs the ROS node application, which shares raw inertial data with other nodes in the ROS framework. Image compression and data recording tool packages provided by ROS enable the efficient and synchronized recording of the entire raw sensor data produced in the distributed system.

Position Estimation

Although the nominal operation range of the Kinect depth sensor is 0.8-3.5 m, our goal was to apply the sensor in the extended range up to 6 m, which more than doubles the area coverage. At the distances greater than 3 m, the quality of Kinect depth sensor data degrades due to noise and low resolution of measurements [30]. The requirement of having a uniform tracking method, which is equally applicable at all distances from the camera, motivated our use of a probabilistic approach to tracking.

Plan-view tracking is a computer vision approach that uses 3D data as input and combines geometric analysis, appearance models, and probabilistic methods to track people on the 2D floor plane [31]. The main prerequisite for successful implementation of any plan-view tracking algorithm is to define the 3D pose of the camera in relation to the floor plane. For our application, we developed a semi-automatic procedure to detect the floor plane with minimal input from the user during the setup of the system. After calculating the floor plane equation in the camera image frame, we define the coordinate frame for 2D position tracking which is set at the base of the camera, on the ground floor level. The known transformation between the camera image frame and its referent 2D tracking frame is used to project a colored point cloud of the foreground onto the floor plane. The projected points are used to calculate three plan-view feature maps (height, occupancy, and color), which are used as observations in the tracking algorithm. Our adaptation of the plan-view tracking algorithm for the Kinect sensor is based on the work of Muñoz-Salinas [32]. This tracking approach uses multiple particle filters, one for each person. A first order linear dynamic model with Gaussian noise is used in the filter's prediction step. The correction step uses a Gaussian mixture of the three feature maps as the observation support.

For FoG detection, it is sufficient to track people when they stand. This can be a mitigating circumstance under real world conditions. When detecting people who are standing, it is sufficient for the system to observe only the 3D environment above a certain height. Setting a height cut-off threshold at around 1.0 m solves two frequent problems in indoor tracking, which are static object occlusions by furniture like chairs and tables, and background updates. Using such a threshold implies that changes in the scene below the height of the threshold do not have any influence, which results in a more robust tracking algorithm.

Person Orientation Estimation

The combination of the accelerometer, gyroscope, and magnetometer signals from the smartphone allows the estimation of the absolute 3D orientation of the device toward the fixed global coordinate system defined by directions of gravity and magnetic North. The focus of our work in people orientation estimation is not on the development of new fusion algorithms for inertial devices, but it is on the development of methods for the use of existing inertial fusion orientation algorithms in the context of our distributed system.

There are two reasons why the measured orientation of the device cannot be used without adaptation in our tracking system. First, the estimation of the user's (patient's) orientation is needed in the distributed system only when the user is viewed by any of RGB-D cameras. Each camera in the system has its own coordinate system. Therefore, the orientation of the user at the given moment needs to be expressed as the angle in the coordinate system of the camera which performs the tracking, instead of global magnetic-North-referenced world frame. Second, we must strictly differentiate between the orientation of the inertial device and the orientation of the user, and emphasize that they cannot be considered equal. When the inertial device estimating orientation in reference to the global frame is fixed on the body of the user, its orientation in reference to the user's body must be exactly known in order to be able to correctly calculate the user's orientation toward the global frame of reference. In the real-world, every-day scenario, there are no means to exactly know the device orientation in reference to the user, even if the sensor is fixed in the correct position. When the smartphone is placed in a horizontal belt case by the user, there is an uncertainty because the device is not fixed directly on the user. The belt case could actually be positioned anywhere on the belt around the waist.

We have developed two methods for transforming the orientation of the inertial device into the 2D heading of the user, expressed in the referent camera coordinate system. In our methods, we use the very good and proven device orientation estimation algorithm introduced by Madgwick [33]. The algorithm uses numerical integration of the orientation data in the quaternion representation. There are two versions of the algorithm depending on the number and the type of sensors available in the inertial sensor system where it is applied. The basic version of the algorithm is suitable for IMU devices consisting only of gyroscopes and accelerometers, enabling the tracking of rotational and translational movement. This basic version of the algorithm uses gradient descent optimization,

which makes it possible to obtain the relative orientation of the device toward the gravity field based on accelerometer input. When referring to this version of the algorithm in the rest of the paper, we will use the name Gravity Relative Orientation Estimation (GROE) algorithm. This basic algorithm is not able to give absolute 3D orientation, since there is no absolute reference in the plane perpendicular to the gravity vector. To achieve complete measurement of 3D orientation in the gravity field, Earth's magnetic North reference system, it is necessary to have the ability to sense the Earth's magnetic field. A MARG (Magnetic, Angular rate, and Gravity) sensor is an extension of IMU, which also incorporates a tri-axis magnetometer. An extended version of the algorithm that can be applied on MARG sensory platform computes its result by numerically integrating changes of orientation measured by gyroscopes, and then correcting gyroscopic measurement errors using a compensation component obtained from the combination of accelerometer and magnetometer measurements. The gradient descent algorithm that uses the combination of accelerometer and magnetometer data takes care of achieving absolute 3D orientation in several iterations after the algorithm initialization. We will refer to this version of the algorithm as the Absolute Orientation Estimation (AOE) algorithm. Both versions of the algorithm are stable, computationally inexpensive, and effective at low sampling rates.

The first method we developed for person orientation estimation uses data only from wearable inertial sensor. The method employs *AOE* algorithm to obtain absolute 3D orientation of the device and relies on the following three assumptions: (1) the sensor device is worn in the predetermined orientation and at the predetermined position relative to the body of the user, (2) the heading is estimated only when the user is standing, and (3) the angle between the magnetic North frame and ground camera frame is known in advance.

We defined the user's orientation as a vector along his dorsoventral axis with the direction from the dorsal to the ventral side of the body. As the predetermined position for placing the smartphone, we chose the left hip. As the reference coordinate system orientation for the smartphone, we set the x-axis facing upward along the anteroposterior axis of the body, the y-axis parallel to dorsoventral axis, and the z-axis facing left from the body along the left-right axis. Expected smartphone positioning is depicted in Figure 4b.

When the smartphone is in the expected ideal position and orientation on the user's body, the vector of gravity will be along its negative x-axis, while y-axis and z-axis define the plane parallel with the floor (see Figure 4b). Thus, we can obtain the 2D heading of the device in the floor plane by measuring the angle between the y-axis of the smartphone and the axis of magnetic North (α) with *AOE* algorithm. Since there is no difference between the presumed direction of the y-axis of the smartphone and the user's heading vector ($\delta = 0$), angle α also gives the heading of the user in reference to the magnetic North, as shown in Figure 5. Our final goal is to obtain the heading of the user in the camera frame (θ). Two corrections with known static angle values are necessary. To get the user's heading θ, first the measurement of the smartphone (α) is corrected for angle (ψ) between the yc-axis of the camera coordinate system and the ym-axis of pointing to magnetic North. This gives angle ϕ, which defines the user's heading in reference to the yc-axis of the camera coordinate frame. Since user's heading θ is always expressed as the angle toward xc-axis, a final correction is executed by adding 90° to angle ϕ.

Our second person orientation estimation method uses wearable inertial sensor data in combination with the classification of the person's orientation conducted in the vision tracking system. The goal of the method is to eliminate the set of assumptions used in the first method, making it more robust and applicable for use in uncontrolled home environments. The method uses the previously-introduced *GROE* algorithm, which estimates the 3D orientation of the device relative only to gravity. As the algorithm can align just two of the inertial device's axes with the plane perpendicular to the gravity (presumed floor plane), this leaves the final angle of the device unknown. To calculate the device's heading in the floor plane, an external reference angle is needed. If, instead of the gravity-magnetic North, we use as the referent frame for the external reference angle the frame in which the camera is currently tracking the user's position, we can eliminate the need for finding the angle between the camera tracking frame and the gravity-magnetic North frame. Furthermore, the assumption of having the wearable sensor in the predetermined position can be eliminated if the external heading reference angle given to the inertial sensor contains information about the true heading of the user expressed in the common frame of reference. Providing the necessary external heading reference is therefore the task of the vision tracking system, because of its ability to observe the user directly in the camera reference system.

The implemented vision-based orientation classifier was inspired by the work of Harville [34], where the person's plan-view height templates are used to classify eight different headings in the range between 0° and 360° with a 45° resolution for humans standing upright (see Figure 6). Our neural network classification algorithm was trained with the features of 4 persons of different heights. To achieve uniformity of the visual orientation detection in the whole area covered by one camera, training data was collected from people standing at different distances and positions in relation to the camera. The positions for data collection were set using a grid of 0.5×0.5 m rectangles on the floor. People were asked to move horizontally, vertically, and diagonally on the grid, akin to pieces in chess, and to stop in the middle of each rectangle of the grid for one second. During post-processing, a total of 6022 height templates for 4 persons were extracted and labeled with their pertaining classes. The feature vector for classification consists of 443 attributes, the first 441 being normalized pixel values coming from the 21×21 pixel height image template, and the last two being height normalization constant and the number of non-zero elements in the template image. The neural network has an input layer with 443 neurons, a hidden layer with 25 neurons and an output layer with 8 neurons. Classic back-propagation training algorithm with symmetric sigmoid activation function was utilized.

The classification accuracy test on 100 height templates gave 92% correct classifications. During testing under real-world circumstances (ie, when movement paths and poses of people

were not in the strict consensus with the eight trained orientations), a significantly higher amount of incorrect classifications was observed. Errors were noticed in classification between opposite directions and also in classification of body poses that differ too much from upright standing. This is the source of the possible error in the heading reference.

When the classifier proposes the orientation reference for wearable system, its accuracy needs to be ensured. A high confidence level for the heading reference can be achieved with the use of two additional sources of information: the quality score of the classification result, and the position history of the person. The quality score of the classification result is calculated using values at output neurons. An eight class neural network has eight output neurons, and the rule is that the output class of the whole classifier is assigned to the neuron with the maximum probability. The output neuron with the maximum probability has a high value when the user's height template is similar to a training template. This probability number can be used as the quality indicator for classification. A high confidence level using the classification quality score is achieved through a temporal process, where the classifier output is tracked for consistency to be above a certain threshold during several consecutive frames. When this consistency holds, the orientation angle represented by the class can be taken as the person's heading proposition. We call this angle *static heading*. To further strengthen the heading proposition and minimize the probability of assigning the opposite direction, the kinematic properties of the person's track are used. Using position history, the velocity vector for the tracked 2D point is calculated. This vector in relation to xc-axis of the referent coordinate frame gives the angle called *dynamic heading*. Ultimately, when the angular difference between the static and dynamic heading is inside a specified error boundary (ie, +/- 15°) for 3 consecutive image frames, the *static heading* is confirmed to be the external heading reference for inertial system.

When the person is upright and wears the smartphone in the belt case, one of the axes of the device points approximately along the gravity vector, while the other two axes span the plane, which is almost parallel with the floor. This can be seen in Figure 4b, where the x-axis of the smartphone is pointing upward and axes y and z are forming the specified “almost parallel” plane. Since the *GROE* algorithm estimates the angle of orientation of the smartphone toward the gravity, it measures how much the plane formed by y and z axes is deviating from being fully parallel with the floor plane. This angle can be used to calculate the projection of y and z axes on the floor plane. Axes y' and z' shown in Figure 7a are the result of such projection.

The external heading reference angle θ*s* is not always available, but only when the vision tracker has a heading proposition of sufficient quality. When the external heading reference angle θ*s* is known, it is possible to calculate the value of the correction angle δ*c* between the external heading reference vector and the referent orientation axis of the inertial sensor system. In Figures 4b and 4c, the y-axis is set closer to the user's dorsoventral axis, so we choose its projection y' to be the referent orientation axis for the fusion. Figure 7a shows the relation between the x-y-z coordinate frame of the smartphone, the xc-yc-zc coordinate frame of the camera, and the linking zc-y'-z' frame used for the fusion at the moment in time when the static heading is known. Correction angle δ*c* is calculated as the difference between the angle θ*i* of y'-axis and the external heading reference angle θ*s*, which at that moment also represents the person's true orientation θ.

In the subsequent frames when no external heading reference is available and there is the dependency only on the inertial system orientation estimation, angle δ*c* is subtracted from the observed angle θ*i* to get the person's true heading θ. This is demonstrated in Figure 7b.

Figure 4. Frame definitions. a) Smartphone reference axes. b) Smartphone in the correct predetermined orientation at the expected position and orientation on the waist. c) Smartphone in the non-expected position and orientation on the waist. There is an angle of error in the transverse body plane between the device's real (green arrow) and expected (yellow arrow) orientation.

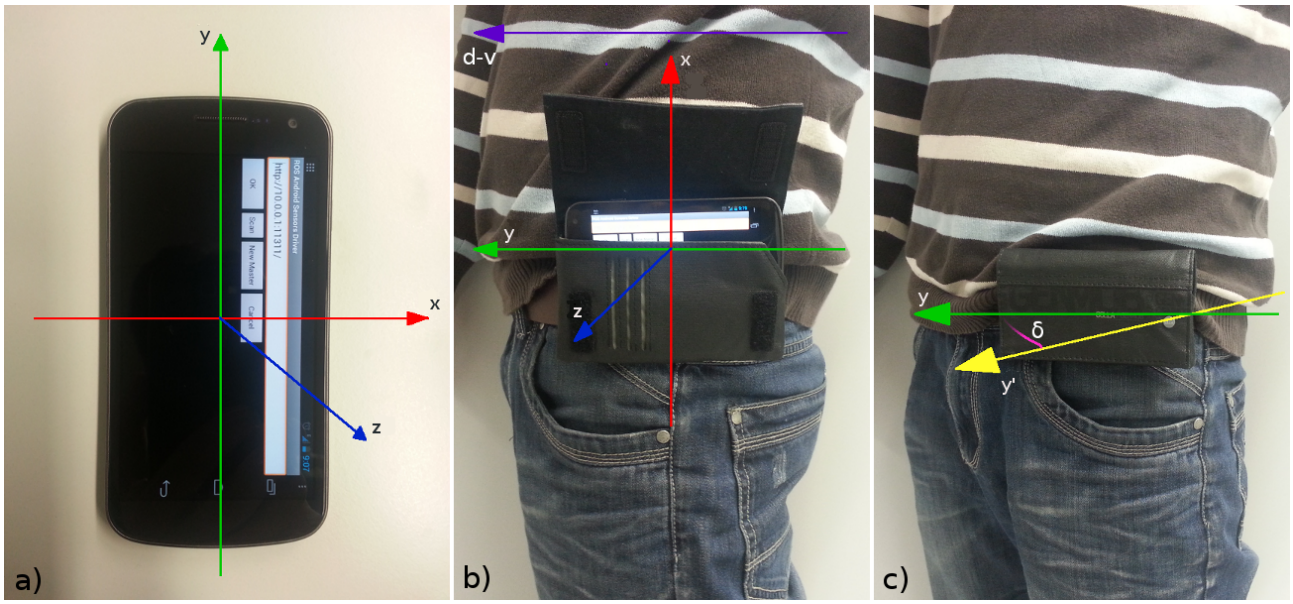


Figure 5. Overhead view of the relations between the different frames in the system.

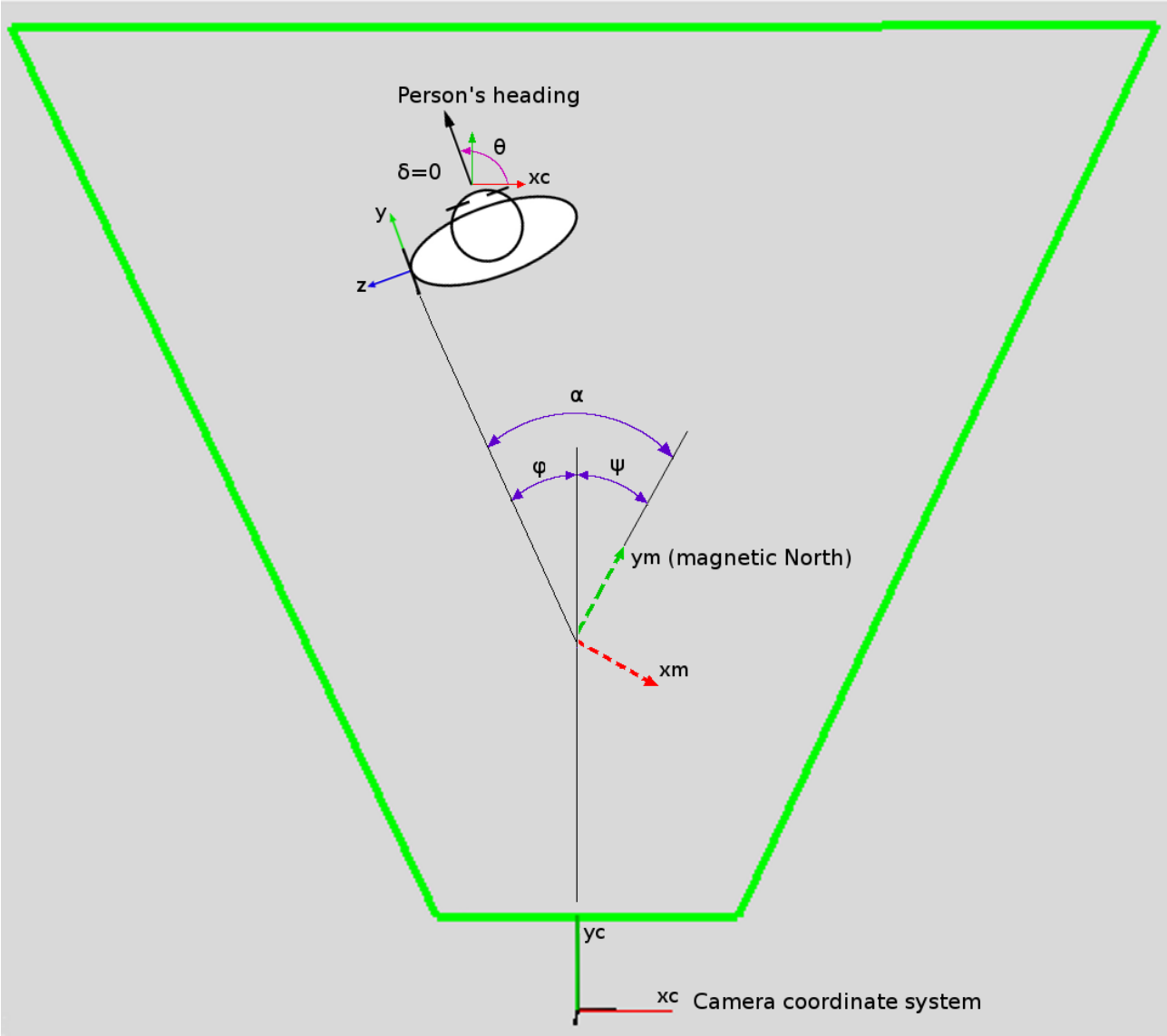


Figure 6. The top row shows eight headings for one person at the same position in reference to the camera. The bottom row contains examples of related height templates used in orientation classification with neural network.

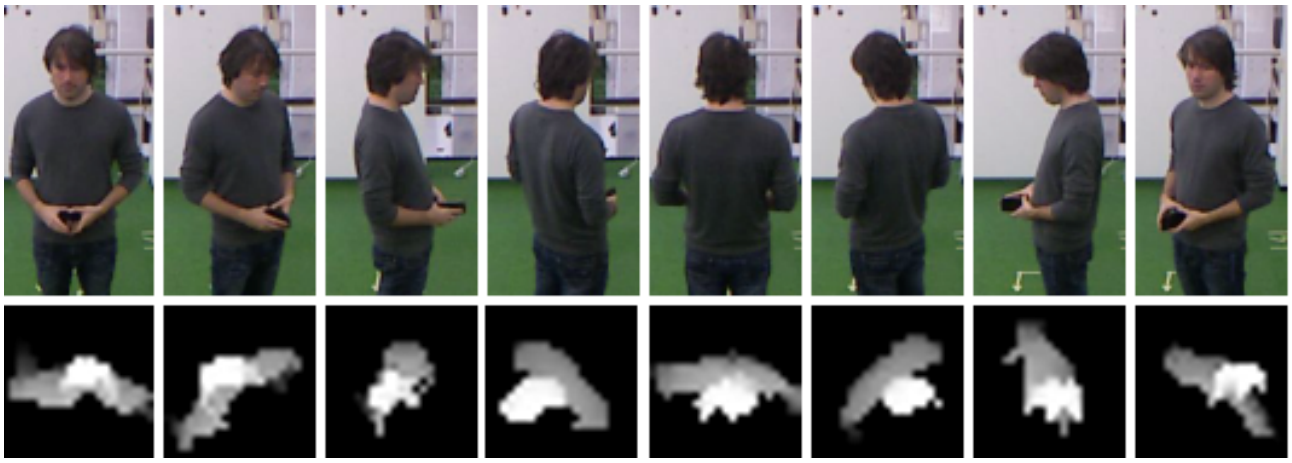
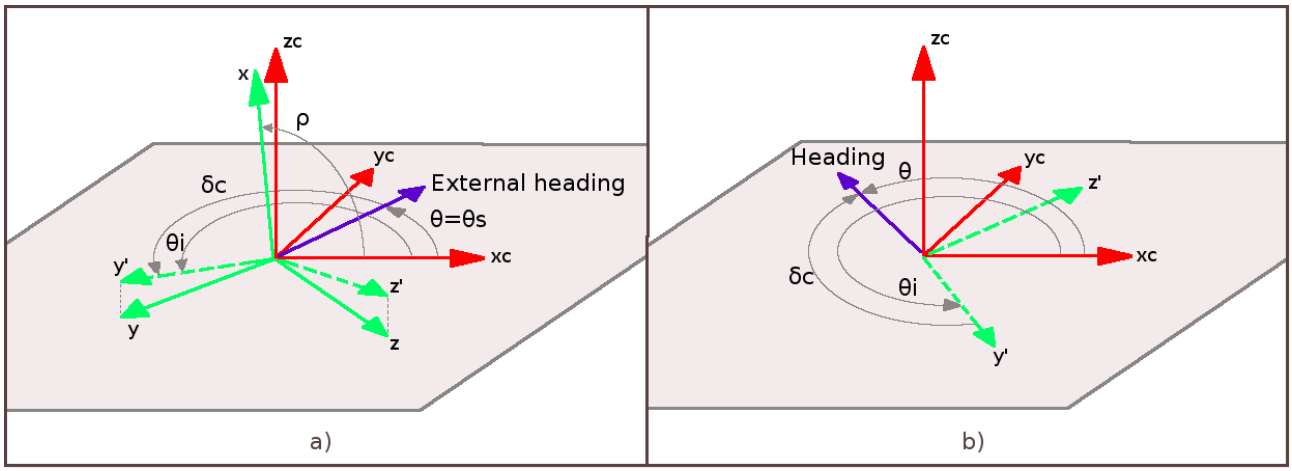


Figure 7. Coordinate frames in the process of fusion of vision and inertial information for orientation estimation. a) The moment in time when the external heading reference is available. b) Using the calculated correction angle to get person's heading at times when only the inertial orientation estimation is available.



Experiment

The purpose of the experiment was to confirm the functionality of the position and orientation tracking system for different users, and to collect sufficient data for the statistical analysis of the system accuracy. Additionally, we wanted to show that the user's position can constantly be estimated within certain statistical error limits irrespective of his distance from the camera and his orientation. We chose the approach with the known static ground truths for position and orientation to enable an evaluation based on comparing with known referent values. The smartphone position on the waist of the participant was taken as a parameter in this experiment with the objective of assessing how each of the two heading estimation methods adapts to a change in the sensor attachment position.

The experiment had 12 participants (9 male, 3 female), who were recruited from among the staff and graduate students of the Industrial Design Department of Eindhoven University of Technology. The average height of the participants was 174.2 +/- 8.8 cm. None of the participants had gait problems. The area used for walking had dimensions 8×5 m, and it was covered with a green carpet which had a visible grid of squares of size 0.5×0.5 m. Two Kinect devices were set at a height of 2.25 m facing downward with a pitch angle of approximately 25°. The devices were placed to cover the walking area in a non-overlapping manner. A unique world frame for the experiment was set at the corner of the walking area, with its orientation equal to the base frame orientation of Kinect 1. To confirm the uniformity of the magnetic field in the walking area, we executed control measurements of its quality at approximate waist height (1.0 m) before and after the experiment.

On the green carpet surface, markers were placed to indicate points on the floor, where the participants are supposed to stop in predefined orientations (see Figure 8). For each designated pose, two parallel lines of 0.5 m length were drawn on the floor at the mutual distance of 0.25 m. As the reference for measuring the marker position, the center point between two lines was taken.

The experimental condition was the sensor attachment position with two possibilities, *Position1* with the smartphone fixed at the iliac crest on the left hip (see Figure 4b) and *Position2* with the smartphone rotated between 50° and 60° around the waist and put on the frontal left side under the belly (see Figure 4c). *Position1* is the expected sensor position for the method using the *AOE* algorithm, while *Position2* is substantially deviating from the expected position for the same method. The second method using the *GROE* algorithm and video orientation classifier has no expected sensor position. The test for each sensor position was split into two walks, one walk with predominantly left turns (see Figure 9) and the other one with predominantly right turns (see Figure 10). Walks were designed with multiple consecutive turns in the same direction in order to induce possible orientation bias. Participants were instructed to walk to each marked position, where they were told to stand still for 3 seconds before continuing toward the next marked point (see Multimedia Appendix 2). The procedure was repeated for each subsequent point. Each test walk lasted around one minute. Each participant first did two walks for condition *Position1*, followed by two walks for condition *Position2*.

During the experiment, color images and depth data of each Kinect were recorded along with the data from the smartphone which encompassed raw accelerations, orientation, magnetometer measurements and calculated orientations for *GROE* and *AOE* algorithms. Estimation of the positions obtained from the video tracking algorithm along with the absolute heading estimation angle for the two orientation estimation methods were stored in a SQL database. Post-processing consisted of annotation of frames when participants were standing still on the marked floor positions and calculation of the average position coordinates and heading angles from sensor data. A video segment of around one second was extracted each time a participant stood still at a reference point.

The vision-based position tracking algorithm gives a new estimation of the position for each frame. With a 30 Hz frame rate, approximately 30 position estimations were available to calculate the average value of the *x* and *y* coordinates during a one second video. Average values with a sufficiently small standard deviation (<0.04) were taken as the measured position coordinates. In total, 288 pairs of position coordinates were obtained (12 participants × 12 reference points × 2 sensor

attachment positions). The average value of the heading angle was calculated using temporal alignment of inertial signals with video segments. For the first method using *AOE* approximately 80-100 orientation estimation values were extracted for each 1 second video segment to calculate average angle value. In total, 288 average angle values were calculated. For the second method using *GROE*, the combination of vision-based orientation classification information and smartphone inertial information was collected at the smallest common denominator update rate, which is the rate of the video tracking algorithm. Around 30 orientation estimates were produced each time a person stood on a reference point. The total of 288 average angle values was expected, but orientation was not registered due to an algorithm failure, in 11 out of 288 cases.

Figure 8. The experiment venue. Markers on the floor indicate the start and end points and numbered reference points for standing in a predefined orientation. Additional markers also show which part of the area is covered by which Kinect device.

Figure 9. Schematic of marker positions and numbering for walks starting from the left side.

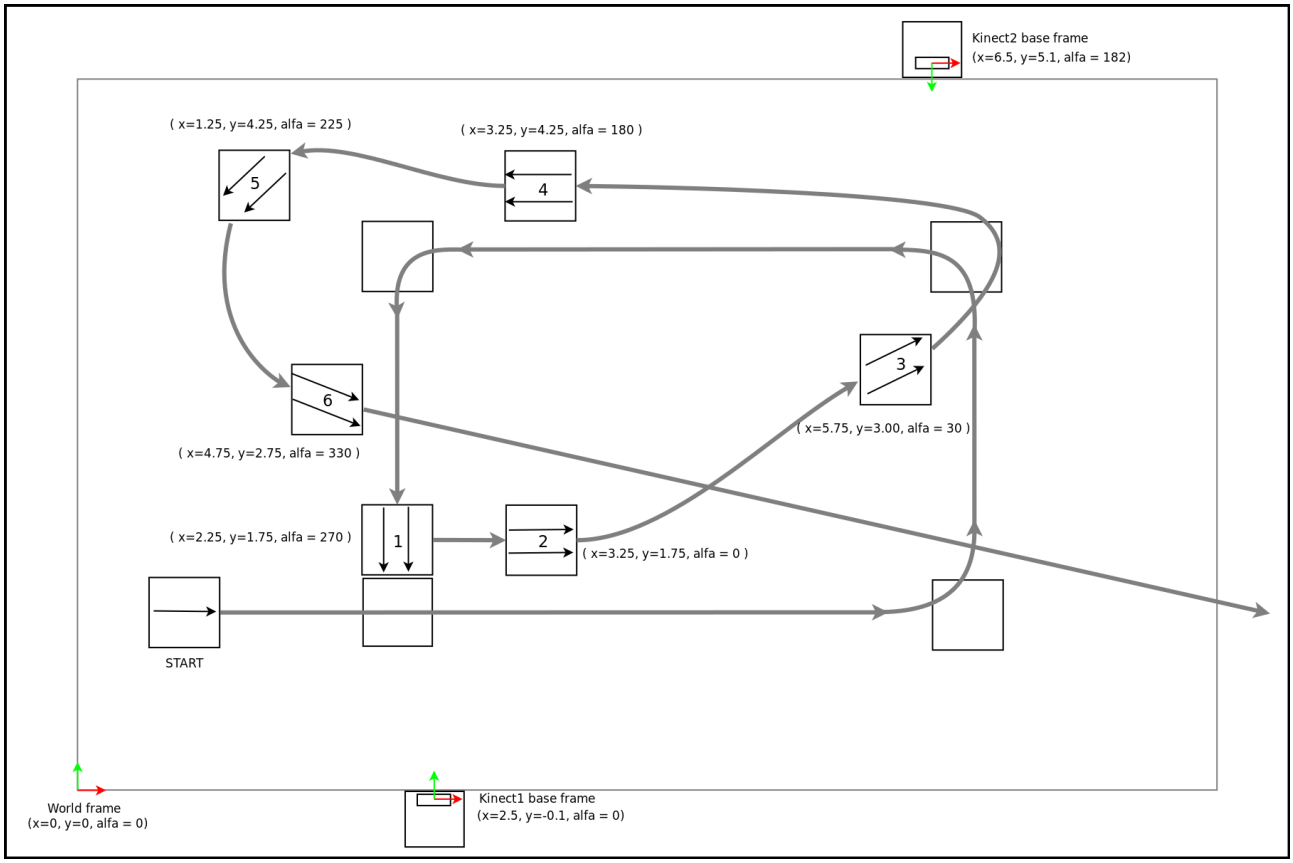
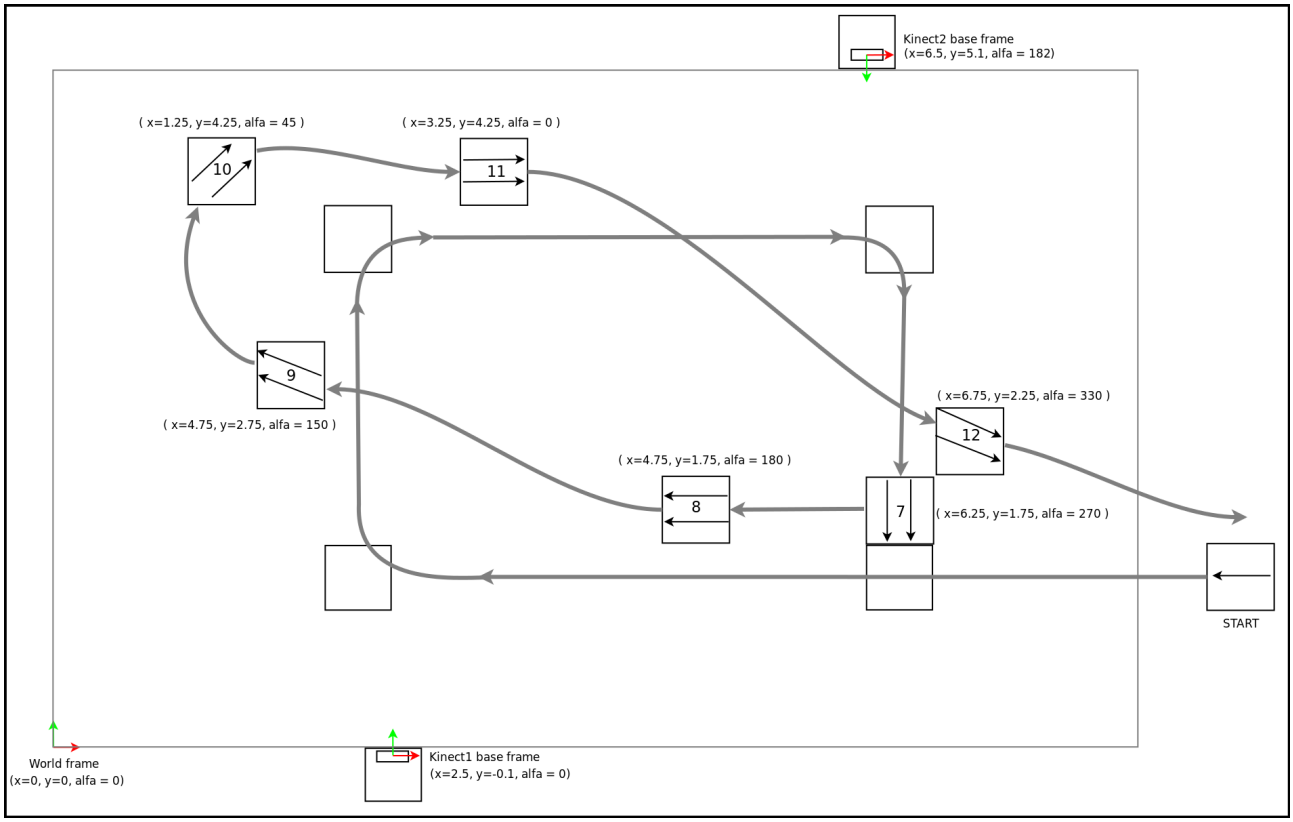


Figure 10. Schematic of marker positions and numbering for walks starting from the right side.



Results

Position Estimation

Calculated position values from all test walks were aggregated on a per point basis to enable comparison with reference values. Statistical results (see Table 1) include average value, average error, and root-mean-square error (RMSE) for each of the two position coordinates at each stopping point. Under the presumption of normal distribution, the average error value is an indicator of the presence of a bias in the measurement. In our experiments, the overall randomness of the error values does not point to any significant positive or negative bias, or bias in any of the coordinates. The RMSE, which is a good measure of accuracy, indicates that the estimated position was on average in the majority of points 0.16 m or less from the true position.

Person Orientation Estimation

The results of the estimation of person orientation closest to the ground truth were expected for tests with the sensor in Position1 when all assumptions needed to get the correct result were satisfied. The results for Method1 (*AOE* algorithm) with the smartphone in Position1 are reported in Table 2. The average angle value for a stopping point (each row in Table 2) was calculated from the set of direction angles estimated for each of the 12 participants. The average angle was compared with the point's reference angle value to give the average error and RMSE. We also added the observation of the maximal error, extracting a single case when the participant's orientation was furthest away from the ground truth.

The average error values do not point to the existence of any specific bias. We took the highest observed value of the RMSE as the reference for error. Statistically, an average error of 17° can be expected if the initially assumed conditions about smartphone placement and upright walking posture hold.

Table 3 provides the data for the comparison of the two different smartphone attachment positions when Method1 (*AOE* algorithm) was used. The data in the table was obtained by aggregating on a per participant basis. This means that to get the data of one row in the table statistics were based on a set of 12 different orientations calculated for the stops of one person. The most notable observation is the uniformly negative angle of the average orientation error obtained for Position2. This negative angle is anticipated considering the orientation change of the smartphone performed for the tests with Position2. The average error values in each row of Table 3 indicate how much the smartphone was rotated around the anteroposterior axis for each participant. Negative angle values of the average error for Position2 closely match values of the RMSE.

Evaluation results of the person orientation using Method2 (see Table 4) are similar to those achieved in Method1 (see Table 2), with the exception of bigger RMSE values maximum errors, which indicate worse behavior of Method2 at certain moments.

Our expectation is that Method2 is able to compensate for the unknown orientation change of the attachment point of the smartphone. The adaptive nature of the method is visible in Table 5 from the fact that there is no significant difference in the observed average errors and RMSE between the two attachment positions.

Table 1. Statistical results for position measurements of reference points.

Point ID	Coordinate	Ref. value [m]	Avg. value [m]	Mean error [m]	RMSE [m]
1	x	2.25	2.21	-0.04	0.07
	y	1.75	1.74	-0.01	0.06
2	x	3.25	3.14	-0.11	0.16
	y	1.75	1.66	-0.09	0.13
3	x	5.75	5.65	-0.10	0.15
	y	3.00	3.02	0.02	0.05
4	x	3.25	3.23	-0.02	0.09
	y	4.25	4.19	-0.06	0.10
5	x	1.25	1.22	-0.03	0.06
	y	4.25	4.31	0.06	0.10
6	x	1.75	1.64	-0.11	0.16
	y	2.75	2.77	0.02	0.06
7	x	6.25	6.20	-0.05	0.07
	y	1.75	1.89	0.14	0.20
8	x	4.75	4.79	0.04	0.08
	y	1.75	1.93	0.18	0.25
9	x	1.75	1.73	-0.02	0.07
	y	2.75	2.72	-0.03	0.06
10	x	1.25	1.14	-0.11	0.16
	y	4.25	4.21	-0.04	0.08
11	x	3.25	3.17	-0.08	0.13
	y	4.25	4.19	-0.06	0.10
12	x	6.75	6.71	-0.04	0.08
	y	2.25	2.27	0.02	0.06

Table 2. Statistical results aggregated per marker point for person orientation estimation method using *AOE* algorithm (Method1) with the smartphone on the hip (Position1).

Point ID	Ref. angle [°]	Avg. angle [°]	Avg. error [°]	RMES [°]	Max. error [°]
1	270	278	8	11	24
2	0	-2	-2	8	20
3	30	37	7	13	24
4	180	181	1	7	13
5	225	231	6	10	19
6	330	333	3	7	13
7	270	269	-1	10	26
8	180	181	1	9	16
9	150	150	0	9	17
10	45	41	-4	12	22
11	0	-8	-8	13	23
12	330	331	1	12	22

Table 3. Statistical results aggregated per participant for the orientation estimation method using *AOE* algorithm (Method1) with two sensor attachment positions.

	Position1		Position2	
Participant	Avg. error [°]	RMSE [°]	Avg. error [°]	RMSE [°]
1	-8	9	-66	66
2	-7	13	-41	42
3	3	8	-60	62
4	3	5	-60	60
5	3	5	-43	43
6	7	8	-55	55
7	-8	8	-62	63
8	-6	14	-57	57
9	8	8	-50	50
10	11	11	-47	47
11	13	15	-58	58
12	5	7	-39	40

Table 4. Statistical results aggregated per marker point for orientation estimation using vision based classification and the *GROE* algorithm (Method2) with the smartphone on the hip (Position1).

Point ID	Ref. angle [°]	Avg. angle [°]	Avg. error[°]	RMSE [°]	Max. error [°]
1	270	276	6	15	47
2	0	2	2	15	44
3	30	50	20	21	32
4	180	188	8	10	15
5	225	236	11	17	37
6	330	334	4	13	33
7	270	272	2	14	27
8	180	187	7	16	35
9	150	143	-7	24	32
10	45	40	-5	17	32
11	0	-6	-6	13	22
12	330	313	-17	18	28

Table 5. Statistical results aggregated per participant for the person orientation estimation method using vision based classification and *GROE* algorithm (Method2) with two sensor attachment positions.

	Position1		Position2	
Participant	Avg. error [°]	RMSE [°]	Avg. error [°]	RMSE [°]
1	11	28	5	13
2	-2	19	3	14
3	-4	20	4	21
4	10	14	13	22
5	-3	15	4	14
6	4	17	6	16
7	0	13	1	14
8	4	12	11	17
9	-3	12	0	13
10	0	13	-6	18
11	0	14	13	12
12	8	12	9	16

Discussion

Technical Properties

The final goal of the experimental measurements of the position orientation tracking subsystem is to properly model its output as a virtual sensor that senses 2D poses and has known characteristics in terms of accuracy and noise. This will enable the output of the patient localization subsystem to be combined with environment mapping data using probabilistic principles, similar to the ones already developed in robotics [35].

The position estimation errors in Table 1 have two principal sources. The first source is the tracking algorithm based on the noisy depth sensor data. The second source is the random nature in which participants arrived at marked points, since during the experiment they were allowed to stop anywhere along the 0.5 m marker line inside a target square. With the current experimental design, it is impossible to separate the contribution of each source to the obtained position errors, so we will impose a strict rule and assign the whole error to the tracking algorithm.

The RMSE is equal or less to 0.16 m for all the measurement points in Table 1, except for points 7 and 8. A greater error in these points can be explained by the combination of body position, camera placement, and depth sensor characteristics. When a person is sensed by a depth camera, depth measurements are taken only on the side of the body directly exposed to the camera. Close to the camera in the overhead position (points 1 and 2), a depth sensor will collect more 3D points from the head and upper shoulder, which are the parts closer to the vertical body center. At the middle distances (2-4 m) from the camera (points 7 and 8), the depth sensor will collect the majority of points from the exposed side of the body. In point 7 this part of the body is at the back, and in point 8 at the right side of the body. This anomaly happens only when people are exposed to the camera under orientation angles close to 0°, 90°, 180°, 270°, and 360°. When a person is oriented diagonally toward camera, more depth points are taken from the body center. At the bigger distances (after 4 m), depth sensor noise and smaller occupancy values influence the tracking algorithm to give more significance to height values, estimating a position more toward the true center of the person.

The comparison of the average orientation errors for the same points across Tables 2 and 4 implies that there was no significant magnetically-caused bias at any marker position. The accuracy comparison based on the maximum RMSE and maximum errors in the same tables reveals that the first method with *AOE* algorithm performed better when the sensor was in Position1. The RMSE values, and especially the maximum error values, presented in Table 4 indicate that Method2 in its current implementation under-performs in terms of accuracy. The cause for this is incorrect static orientation (45° left or right from true value) registered as the external heading reference at certain moments. This could be improved by decreasing the allowed angle error between static and dynamic headings. However, this decrease in error angle can prolong the time necessary to fulfill conditions for registering the external heading reference after entering the camera scene. With the current setup, the detection time for the external reference of a person's heading can sometimes be delayed for one second, depending on how close the trajectory of the movement is aligned with the eight principal orientations of the classifier. This delay is also the reason for the algorithm failure in 11 of the recorded cases. On the positive side, our adaptive vision-inertial sensor information fusion method performed as predicted in conditions of unknown sensor placement, evidently outperforming the non-adaptive method, as seen in the results for Position2 in Tables 3 and 5.

Implications for Freezing of Gait Monitoring in a Home Environment

For FoG detection based on location, it is of great importance to achieve sufficient accuracy when measuring the distance between the patient and an obstacle. For the case when the system needs to observe that the patient is passing through a door frame, necessary accuracy of location sensing is in the

range of several decimeters. The same is true for the case when the patient is standing next to an object, such as a chair. Proximity to an object in a congested space can easily be inferred when the person is standing at a very short distance (<0.4-0.5 m). To set the criteria for sufficient accuracy, we can use the literature about the minimal distance from objects that was observed for people during locomotion behavior. According to Weidmann [36], a person walking in a corridor keeps on average a minimal distance of 0.25 m to a wall made of concrete and 0.20 m to a wall made of metal. Obstacles in a general environment are avoided with a gap of at least 0.10 m. The achieved result of RMSE=0.16 m is acceptably close to the given minimal distance values.

The heading of the patient should be observed with the goal of inferring if he is facing any specific landmark on the map. When observing the patient's relation with the landmark, such as having the intention of going through a door or facing a kitchen sink, the heading error of 15-20 degrees left or right from the true angle is acceptable, because such an error cannot change the perception about the patient being generally directed toward the object. As the indicator of the orientation accuracy for each method we took the worst RMSE value in its related table (Table 2 for Method1; Table 4 for Method2). For Method1 we obtained RMSE=17°, which is satisfying in relation to the acceptable error of 15-20^{o}. Method2 gave RMSE=24°, which falls just outside of the desired error range. Results in Table 5 show similar RMSE for different attachment positions of the sensor (28° vs 22°) which proves that Method2 is able to adapt to an unknown sensor attachment situation.

In conclusion, for the orientation data collection from patients in controlled conditions, the recommendation is to use the smartphone and *AOE* algorithm, because it is the simplest solution with acceptable accuracy. For uncontrolled conditions, like a home environment, we propose to apply the method based on the fusion of vision and inertial sensor information. A successful real-world application of this method depends on the improvement of the algorithm to achieve faster detection of the person's true orientation after entering the camera scene.

Implications for Freezing of Gait Monitoring in a Clinical Environment

We had a chance to deploy the prototype of the tracking system in its current form in a clinical environment, where we observed a rehabilitation session of one 80-year-old PD patient with a 13-year history of PD and high affinity toward FoG. The purpose of the test was to confirm that the system can be used as a portable system and to find out its applicability and value for clinical rehabilitation. Two Kinects were set on special 2.5 m high tripods and put in the corners of two rooms (both size 4.5×4.5 m) in the rehabilitation facility. The time necessary to setup the system was around 15 minutes. The patient was wearing the smartphone at the hip position. First, the usual therapy protocol which included warm-up, Get-up and Go exercise and walking with the visual and audio cues inside one of the rooms was observed. Our first addition to this protocol was the exercise for the patient which included quarter turns on the marked position in front of the camera. The second addition to the protocol was the exercise in which the patient started by sitting on the chair in one room and then had to walk to the chair in the other room passing two doorways and a hallway in-between the rooms. Each Kinect covered a part of one room with a doorway and a chair.

The quarter turns exercise gave us the opportunity to observe the influence of the patient's stooped posture on positional tracking and visual orientation classification. We had been aware that the change of the posture might influence the final tracking output, although we are using a non-articulated tracking model. Initial qualitative results indicate that the stooped posture has minor influence on the positional tracking, while its influence on the orientation classification is higher than expected, which was manifested as an increase in the rate of incorrect classifications.

The exercise with sitting and walking between the rooms was a combination of Get-up and Go exercise, door passing, and on-the-spot-turning, and it was very demanding for the observed patient who experienced multiple FoG episodes. During the exercise the system was able to track the patient when he was standing, walking, and sitting. Taking this into account, we envisage the use of this tracking system in the clinical setting. We base the exploitation possibilities of the system on the idea of the quantitative assessment of the effectiveness of the therapeutic tests, in order to monitor the long-term advancement of the patient. Since the system uses 3D data, it can measure the height of the patient and give his temporal height profile. Height is useful during a sit-to-stand test to measure posture transition times. Furthermore, the system can collect positional and velocity data to compare walking with and without applied visual and audio cues, and to objectively measure the effect that cues have on the patient when walking straight. By tracking orientation, the same approach can also be applied to the evaluation of the patient's response to cueing during turns.

Limitations of the Study and Future Work

There were several limitations to the presented experimental study of the accuracy of this system. The main limitation is that the study was conducted in healthy people, who were able to maintain an upright posture. The usual posture of PD patients is a stooped posture, and the future system should accommodate for that. This is especially important for template based recognition of static orientation. The next iteration of the prototype will try to take this fact into account. The benefit of developing the new specialized classifier is that by being able to detect the stooped posture, the system will have additional information to infer the general PD state of the patient. Moreover, this information could be used to improve the identification of the patient during long-term system deployment. Additional data from real PD patients will be needed in order to perform quantitative, statistical evaluation of the posture change influence on the system accuracy.

Position accuracy was measured only for persons who were not occluded. Position measurement with multiple persons would offer better insight into position errors caused by partial occlusions. Furthermore, positions and orientations were only analyzed in static cases. Analysis of the dynamic properties would offer better insight into the characteristics of the system. For this kind of experiment, it would be necessary to have a

tracking system with higher accuracy and adequate spatial coverage. A comparison with the Vicon system [37] could be a possible solution.

In the presented orientation tracking methods, the assumption of upright posture needs to be upheld to obtain accurate results. The final orientation algorithm should be aware of the current posture of the person. This calls for the development of an even more contextually aware system.

Conclusions

In this work, we presented a solution that rethinks the problem of FoG detection and monitoring from the standpoint of technology that could be offered in the context-aware homes of the future. The most interesting novelty from the medical aspect is that we decided to form technical prerequisites for the collection of patient data about FoG which takes into account external contextual factors regarding the symptom and the relation of the patient to the environment.

We proposed using a combination of two technologies: 3D vision and wearable sensing with smartphones, which have developed a strong commercial presence in recent years. It is expected that this trend will continue in the future with wearable sensing offering smaller and more energy efficient devices, and 3D vision cameras offering better resolutions and smaller frame factors.

The study of the characteristics of the system prototype showed that at the current moment, we have a system that has sufficient position tracking accuracy for use in the intended FoG-monitoring application. The study of orientation algorithms gave us the necessary insight into the properties of smartphones for indoor orientation tracking in the context of FoG. The proposed method of data fusion for orientation tracking showed not only how it can improve usability, but also disclosed the factors that need to be improved. Future work goes in the direction of the improvement of the current system prototype toward home deployment and pilot experiments with PD patients. To enable the deployment of the system in real homes with multiple people, long-term identification based on inertial and vision sensor data matching needs to be implemented. In addition, to collect the data for contextual modeling, preparations are being made to undertake recordings of the daily activities of people with FoG in their homes using the current prototype of the system.

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Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

An example scenario for multiple people tracking and re-identification. One camera covers the living room space, while the other is installed in the dining room. The scenario depicts a caretaker and a patient at home with two visitors. The goal is to sustain identities for all the subjects in spite of short term occlusions, pose changes, and changes between cameras.

[AVI File, 7MB - mhealth_v1i2e14_app1.avi]

Multimedia Appendix 2

An example of pose tracking during one test walk. Orientation is estimated using the proposed camera and wearable data fusion algorithm. The red arrow shows the estimated orientation of the person. The purple arrow shows how the orientation would be without correction from the vision-based system.

[AVI File, 3MB - mhealth_v1i2e14_app2.avi]

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Abbreviations

2D: two-dimensional
3D: three-dimensional
AOE: Absolute Orientation Estimation
FoG: Freezing of Gait
FSI: FoG State Interpreter
GROE: Gravity Relative Orientation Estimation
IMU: Inertial Measurement Unit
LAN: local area network
MARG: Magnetic Angular Rate and Gravity
PD: Parkinson disease
RGB: red green blue
RGB-D: red green blue and depth
RMSE: root mean square error
ROS: Robot Operating System
SQL: Structured Query Language

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Original Paper

Trust Information-Based Privacy Architecture for Ubiquitous Health

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Abstract

Background: Ubiquitous health is defined as a dynamic network of interconnected systems that offers health services independent of time and location to a data subject (DS). The network takes place in open and unsecure information space. It is created and managed by the DS who sets rules that regulate the way personal health information is collected and used. Compared to health care, it is impossible in ubiquitous health to assume the existence of a priori trust between the DS and service providers and to produce privacy using static security services. In ubiquitous health features, business goals and regulations systems followed often remain unknown. Furthermore, health care-specific regulations do not rule the ways health data is processed and shared. To be successful, ubiquitous health requires novel privacy architecture.

Objective: The goal of this study was to develop a privacy management architecture that helps the DS to create and dynamically manage the network and to maintain information privacy. The architecture should enable the DS to dynamically define service and system-specific rules that regulate the way subject data is processed. The architecture should provide to the DS reliable trust information about systems and assist in the formulation of privacy policies. Furthermore, the architecture should give feedback upon how systems follow the policies of DS and offer protection against privacy and trust threats existing in ubiquitous environments.

Methods: A sequential method that combines methodologies used in system theory, systems engineering, requirement analysis, and system design was used in the study. In the first phase, principles, trust and privacy models, and viewpoints were selected. Thereafter, functional requirements and services were developed on the basis of a careful analysis of existing research published in journals and conference proceedings. Based on principles, models, and requirements, architectural components and their interconnections were developed using system analysis.

Results: The architecture mimics the way humans use trust information in decision making, and enables the DS to design system-specific privacy policies using computational trust information that is based on systems' measured features. The trust attributes that were developed describe the level systems for support awareness and transparency, and how they follow general and domain-specific regulations and laws. The monitoring component of the architecture offers dynamic feedback concerning how the system enforces the polices of DS.

Conclusions: The privacy management architecture developed in this study enables the DS to dynamically manage information privacy in ubiquitous health and to define individual policies for all systems considering their trust value and corresponding attributes. The DS can also set policies for secondary use and reuse of health information. The architecture offers protection against privacy threats existing in ubiquitous environments. Although the architecture is targeted to ubiquitous health, it can easily be modified to other ubiquitous applications.

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KEYWORDS

ubiquitous health; privacy; computational trust; policy; context-awareness

Introduction

Overview

Both ubiquitous health and pervasive health are terms that describe a new business model (these terms have been used in many papers synonymously). Similarly to health care, its goal is to make health services available to everyone, but many of its features separate it from health care [1]. According to Ruotsalainen et al, ubiquitous health is a metasystem that is a dynamic network of interconnected systems offering health services to a data subject (DS) in an unsecure information space [1]. Contrary to health care where the services are defined by health professionals, in ubiquitous health, the DS creates the network, selects the systems, and sets rules (policies) that regulate how and by whom the DS' health information is used and shared. In ubiquitous health, the existence of predefined trust between the DS and systems cannot be assumed, and systems' features, their business goals, and regulation systems followed are often unknown. Furthermore, health care-specific regulations do not rule the ways health data is processed and shared [1]. It is evident that ubiquitous health features generate privacy and trustworthiness challenges that should be solved to make it successful.

Privacy is a complex, personal, and situation-depending concept that can be interpreted in various ways [2]. Westin defined privacy as "the claim of an individual to determine what information about himself or herself should be known to others and what uses will be made of it by others" [3]. Privacy is also a human right that is protected by international directives and constitutions. Privacy protection approaches aim at hiding user's identity and/or some part of the personal identifiable information (PII), whereas privacy management offers transparency to the DS concerning the collection and processing of PII.

Trust can be understood as the subjectively perceived probability by a DS that a system will perform an action before the DS can monitor it [4]. It indicates uncertainty about the features of communication partners [5,6]. Trust is also context-dependent and the ways it is formulated vary, for example, it can be based on the recommendation received from others, it can be reputation-based, or it may be a subjective degree of belief of others [7,8].

Privacy and trust are interrelated concepts, that is, "data disclosure means loss of privacy, but an increased level of trustworthiness reduces the need for privacy" [1]. The DS interest is to get maximum benefit from services and at the same time to minimize the loss of privacy.

In health care, internationally accepted principles, good practice rules, and domain-specific legislation define patient's rights and service providers' responsibilities. Health care-specific legislation also states how patient's privacy must be protected [1]. Researchers have started to develop such kind of principles for ubiquitous health. Ruotsalainen et al have developed the THEWS (Trusted eHealth and eWelfare Space) principles for trustworthy ubiquitous health. The THEWS principles state that the DS possesses the right [1]: to verify the trustworthiness any system that collects or processes his or her personal health information (PHI). Principles state that DS should also have the right for controlling the processing of PHI, both inside the systems and between them. DS should define personal privacy policies, which regulate how his or her health data is collected, processed, disclosed, shared, stored, or destroyed. The principles also require the DS to be aware of all events, situations, and contexts where his or her health data is collected, processed, stored, and disclosed.

Furthermore, systems and stakeholders have the responsibility to publish information needed for trust verification and support openness and transparency of data processing.

Ubiquitous health features and its ubiquitous environment suggest that trustworthiness and privacy are real concerns [9,10]. In ubiquitous health, it is difficult to understand the processing of data inside the systems [11], as systems do not always perform in accordance with their policies, and the privacy preferences of DS might conflict with the business objectives of the system [12]. As a result, the DS cannot assume that the existing legal framework guarantees the processing of PHI lawfully and according to the rules proposed by him or her [13,14]. In addition, DS also cannot assume that systems have implemented security rules and functional privacy requirements derived from laws and standards [1,15]. A big challenge in ubiquitous health is that different stakeholders (eg, systems, customers, third parties, and regulators) can have their own privacy policies.

Here we hypothesize that in order to be successful, ubiquitous health requires trustworthiness and privacy management made by the DS. Without these two features, DS will not dare to use its services. Furthermore, the architecture supporting ubiquitous health should fulfill the THEWS principles presented above. As traditional security and trust mechanisms used in today's health care information systems may not provide adequate security and privacy in ubiquitous health [1,2,16], a novel architecture is required.

Prior Work

The development of ubiquitous systems and the growing use of ubiquitous computing have raised the following question: What kind of trust and privacy models, services, and architectures offers acceptable level of privacy and trustworthiness?

Trust Models

Trust models such as belief, organizational trust, dispositional trust, recommended trust, and direct trust have been proposed for pervasive systems [8,17,18]. Dispositional trust describes the general trusting attitude of the trustor [17]. Direct trust is derived from the outcomes of interactions with peers [19]. In recommended trust, an agent makes a recommendation based on the beliefs that other entity is trustworthy at certain degree. Organizational or institution-based trust is based on the

perceived properties of, or the reliance placed on, a system or institution [7]. Reputation is a recommended rating based on the opinions of others [8]. All of them are situational, that is, the amount of trust that a DS experiences depends dynamically on situation and service-specific trust features [20,21].

A trust is typically based on the trustor's characteristics such as ability, integrity, and benevolence and should not be a blind guess [5]. It is expressed either by value, rating, or ranking or as probability or belief [22]. Trust attributes such as integrity, motivation, competence, and predictability are proposed to measure the confidence level [23]. Attributes proposed by Hussin include trustee's identifier, certificate, ability, predictability, trustee's privacy policy, legal requirements, and system's properties such as transparency, authenticity, confidentiality, and nonrepudiation [24]. Researchers have developed mathematical methods such as Bayesian probability, Beta probability, maximum likelihood, game theory, weighted arithmetic means, and average of weighted recommendations to measure the degree of belief or recommended trust [25-27]. Trust degree can also be measured from interaction frequencies between trustor and trustee [28], or from context-dependent direct and indirect recommendations collected from selected users [19].

In contrast to belief and recommended trust, computational trust built on abstractions of human concept of trust has been proposed by researchers [25,29]. Within ubiquitous computing, computational trust means automation of decisions in the presence of unknown, uncontrollable, and possibly harmful agents [29]. Computational trust value has been calculated using trustor's experience, recommendations, interactions, knowledge, measurements, distance, and density of events [13,25,28,30,31]. Service level agreements, contractual agreements, reputation based on the brand's name, trust manifesto, trust negotiation, exchanging and evaluating credentials, and recommendations made by a trust authority (TA) are also widely used in commercial eServices [32,33].

The aforementioned trust models have noticeable weaknesses in ubiquitous environment. Recommendations are unreliable because they are based on unsecure opinions. It is difficult to force everyone to accept certificates or common TA, and many virtual organizations do not have connection to it. A common ontology that is required for successful negotiation and calculation of trust attributes seldom exists. Trust manifesto assumes that the DS blindly trusts that service providers will deliver their promises. Furthermore, the reliability of reputations is difficult to measure, and credentials are difficult to evaluate [25].

Privacy Models and Formula

Many privacy models developed by researchers are useful in ubiquitous environment. Lederer et al proposed a model of situational faces [34]. The model proposed by Hong et al uses control and feedback [10]. The model suggested by Friedwald et al included actors, environment, activity, information flow, control level, and enabling technology [35]. Adams and Sasse look at privacy as preferences and constraints, and use a computer-understandable language for expressing them [36]. Jiang and Landay used an information space model [37], and Kapadia et al applied virtual walls for privacy management [38]. Diaz et al proposed entropy as measure of privacy level [39].

Privacy management model proposed by Lederer et al combined Adams's perceptual model and Lessing's societal privacy models [40,41]. In the model by Lederer et al, a preferred privacy level depends on legislation, market features, norms, technology used, nature of personal information disclosed, contextual features, information sensitivity, characteristics of information user, and expected cost-benefit ratio. A limitation of this model is that its variables are qualitative and abstract.

Trust and Privacy Technologies and Solutions

Numerous trust and privacy technologies have been proposed for ubiquitous systems. In Gray's solution, the trust is based on the belief of a person that systems have implemented proper de-identification structures and safeguards. It also includes a compliance checker and a trust value calculator [42]. PoliCyMaker, KeyNote, Simple Public Key Infrastructure, and Pretty Good Privacy solutions use credentials [43]. The Trust-X approach by Bertino et al uses digital credentials, which are iteratively disclosed and verified [32]. Becerra et al proposed intelligent agents to evaluate which other agents can be trusted [23]. According to the Skopik's approach, rule-based trust interpretation takes into account the subjective nature of trust [44]. Joshi et al noted that it is possible to make security and privacy decisions based on trust attributes [45].

Computational trust is either based on direct measurements, observed (monitored) features, or past experiences [46]. In ubiquitous environment, successful monitoring requires common ontology and measurable indicators [22]. The trust manager architecture proposed by Salah et al collects trust aspects for calculator that computes a trust score. The architecture also includes recommendation manager, monitor services, context provider, log service, and policy manager [47]. In the EnCoRe architecture, the TA keeps track of promises, manages decryption keys, discloses them, and verifies systems properties [48]. Thereby, the customer should trust on the system's released willingness to fulfill the personal policies of DS.

Privacy is often protected by using privacy enhancement solutions such as data filtering and minimization, anonymization, and adding noise to disclosed information (eg, data hashing, cloaking, blurring, and identity hiding) [41,49]. In metadata approaches, privacy policies can be injected to application, tagged to the metadata, or added to the database or an active agent [50]. Berghe and Schunter's "privacy injector" adds privacy rules to existing applications [11]. The EnCoRe architecture uses the sticky policy paradigm where the DS can stick machine-readable rules to the data before it is disclosed [48]. Metadata can include embedded (active) code that enables self-destruction (apoptosis) in the case the environment is not trusted [51]. Apoptosis can also be context- or situation-aware (ie, programmed death) [52]. As per Pallapa et al, active privacy metadata dynamically controls the transparency of data in a context [53].

Other solutions also exist for privacy protection. Kapadia et al created a virtual personal space (a room) to control information

flow through its "walls" [38]. In the PICOS platform from Kahl et al, a privacy advisor helps the DS to create own policies [54]. In the United States, a flexible approach that uses privacy and security labels is under development. In this standardized solution, PHI is segmented and security and privacy labels are bound to those segments [55].

In pervasive systems, privacy requirements are typically expressed as policies that are context-dependent. Policies define what is permitted or prohibited, and which are permitted actions [45]. From the DS viewpoint, policy can be understood as a statement (rules) about how a certain system should behave [56]. Policies are typically published in the form of credentials or metadata, and rules are expressed using policy language [33]. The successful use of policies requires policy matching, mismatch notification, policy lifecycle management, risk analysis, regulatory compliance checking, and possibility to model privacy regulations [48,57]. It is also necessary that the DS can enforce personal polices [58]. Policies should also be checked for ontological compatibility [59].

The increasing use of the Internet, peer-to-peer systems, multi-agent systems, and social networks has been main drivers for discussed privacy and trust models and solutions. Unfortunately, most of them are focused on one feature (eg, encryption or context). Ubiquitous health requires much wider approach. Like Bryce et al, we also state that pervasive systems require an architecture that combines dynamic privacy policies, a priori trust validation, privacy management, and a posteriori measurement (ie, feedback) what systems are doing [2]. Regulatory compliance is also needed.

In this paper, we propose a novel privacy management architecture for ubiquitous health. As ubiquitous health is a new concept without widely accepted principles and privacy and trust models, it is necessary to select on which principles and models the architecture is based. THEWS principles, as previously presented, have been selected by the authors on the basis of the architecture, that is, the architecture should be compliant with them. The solution should take into account features of ubiquitous health and enable the DS to dynamically manage the privacy by defining system-specific privacy policies. The architecture should mimic the way humans use trust information in creation of personal policies. The architecture should also offer protection against many known privacy threats existing in ubiquitous environment.

Methods

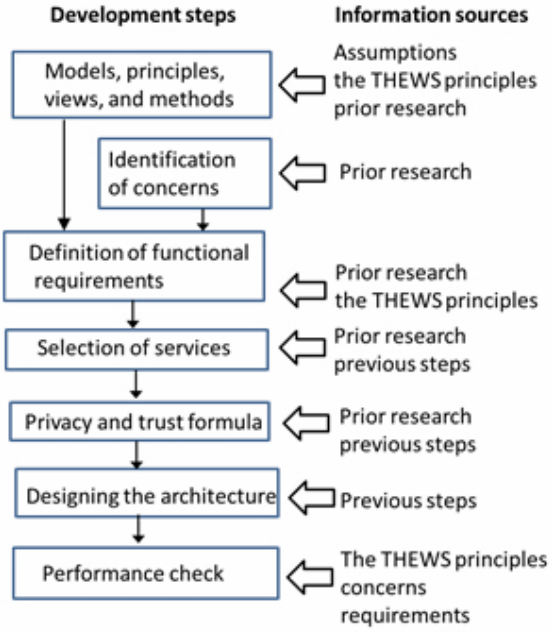
From system theory and systems engineering perspectives, ubiquitous health is a metasystem that is characterized by its structure, its function/behavior, and how its interrelated components are composed in an ordered way. Instead of creating artificial scenarios or making quantitative privacy risk/threat analysis, a more system-oriented sequential method that combines methodologies used in systems engineering, requirement analysis, and system design is used (Figure 1).

The method used in this study includes the following steps: definition of basic requirements; selection of values, privacy and trust models, and views; identification of concerns; definition of functional requirements; selection of services; developing privacy and trust formula; and designing the architecture. Finally, it is checked how the architecture meets purposes and requirements for which it has been intended.

On the background of processing of health information stay ethical values and codes, principles, and common rules. Selection of these features has also strong impact on the architecture and its services. For some environments (eg, health care), widely accepted codes and rules already exist; however, this is not the case in ubiquitous health. Therefore, the first step is to select privacy and trust models and approaches that are in line with principles and without noticeable weaknesses. This is achieved by carefully analyzing existing research published in journals, conference proceedings, and standards documents. Similarly, identification of concerns and definition of functional requirements are also done. Finally, the architecture combines selected services in such a way that principles and requirements are fulfilled.

In this paper, privacy and trust needs are examined from the DS's viewpoint. Other views are not discussed. To reduce the complexity, only components that are relevant for the privacy management needs of the DS are included in the architecture.

Figure 1. Method for the development of the THEWS architecture.



Results

General Overview

Ruotsalainen et al have noted that privacy rules in ubiquitous health are based on trust [1]. Therefore, privacy and trust models selected should take into consideration features of ubiquitous health, trust and privacy aspects of systems offering health services, regulatory requirements, and the DS's privacy needs. The asymmetric relationship between systems providing health services and the DS should also be considered (ie, the DS seldom has the power to force a system to put personal rules into effect). Furthermore, in practice, the DS has no tools to make personal observations of systems' internal security and privacy features and policies [51,60].

Principles, Models, and Views

In spite that privacy is widely accepted as human right (value), different privacy models do exist in real life. Regulatory and self-regulatory models are widely used [15]. Privacy can also be considered as personal property [20]. Regulatory model is insufficient in ubiquitous environments [13], and self-regulation made by business community gives systems as stronger partner much freedom to set rules [15]. Because in ubiquitous health the DS has the right to set personal rules to regulate and control his or her health information, self-regulation model that uses privacy as the DS's personal property has been selected for the architecture.

Suitability of widely used privacy protection and management approaches in the context of ubiquitous health is shown in Table 1. Based on Table 1 and the fact that pervasive systems require dynamic and context-aware privacy management [46], the foremost privacy approach for ubiquitous health is privacy management that uses context- and content-aware policies and supports transparency and regulatory compliance.

Trustworthy ubiquitous health requires that used trust model enables the DS to work out the level of trustworthiness of systems. Characteristics and weaknesses of widely used trust models in regard to features of ubiquitous health are shown in Table 2. As a result, trust in ubiquitous health cannot be based on the belief or reputation, and the DS usually does not have a right to verify recommended trust. Credentials typically assume that Hobson choice and privacy labels have inappropriate granularity. Although some researchers assume that the protection power of laws is sufficient and certification offers acceptable level of trust [12], the regulations and certificates are found to be insufficient in ubiquitous health.

Computational trust that is based on systems' measurable or observed properties can offer reasonable information to the DS in designing personal privacy policies [25]. The limitation that the information content of a single trust value is too low for policy formulation [61] can be overcome by using additional system-specific attributes. Therefore, computational organizational trust with attributes is selected as the trust model for ubiquitous health.

From the DS viewpoint, the architecture should mimic humans' ways to design policies, support more rational choices than intuition, and give feedback to the DS. Louviere's stated customer choice method fulfills these requirements by including awareness, learning, evaluation and comparison, preference formulation, and choice and post-choice [62]; hence, it is selected for the method that the DS uses in the formulation of privacy policies.

Table 1. Suitability of common privacy protection and management approaches for ubiquitous health.

Approach	Suitability
Privacy protection using security services (eg, authentication, authorization, and access control)	Security cannot offer reasonable level of privacy in ubiquitous health. Access control alone is insufficient. The DS is not familiar and cannot control authorization rules used inside a system
Privacy control by hiding the DS's identity	Health care and health services require the knowledge of the DS's identity
Delegation approach	Delegation requires knowledge to whom the DS delegates access rights. Systems specifically do not publish this kind of information to the DS
Privacy labels	Rules deployed in a label might be inadequate and in conflict with the DS policy that may or could not be specified in labels
Privacy management using context- and content-aware policies	Supports dynamic policies, but requires computer-understandable policy language. Common ontology, ontology harmonization (matching, mapping, etc.), or reasoning is needed
Metadata approach	All systems do not accept injected or active code
Data filtering and adding noise to data	Health services require large amount of PHI for correct and effective services, as incomplete PHI can lead to wrong decisions or prevent the use of services

Table 2. Characteristics and weaknesses of common trust models.

Model	Characteristics and weaknesses in ubiquitous health
Dispositional trust and recommended trust	Characteristics: Based on belief, attitude, or others' opinions (recommendations)
	Weakness: Recommendations are unreliable and based on unsecure opinions. It is difficult or even impossible to check the reliability of others' recommendations
Blind trust	Characteristics: Based on belief or attitude that organization has implemented sufficient safeguards
	Weakness: Does not guarantee trustworthiness
Predefined trust	Characteristics: Based on assumption that an organization has implemented required regulatory services
	Weakness: Static model. Unsuitable for dynamic environments.
Trust label	Characteristics: Based on organizational or personal labels
	Weakness: Inappropriate granularity and insufficient consideration of dynamic contextual conditions
Trust manifesto	Characteristics: Based on assurance of service provider
	Weakness: Based on belief or attitude. The DS should blindly trust
Reputation	Characteristics: Based on subjective opinions of others
	Weakness: The reliability of reputations is difficult to measure
Computational trust	Characteristics: Based on system's measured or observed features
	Weakness: A simple trust value or rank might offer insufficient information for the DS in designing personal policies
Risk- and threat-based models	Characteristics: Based on risk or threat assessment
	Weakness: Difficult or even impossible to measure personal privacy risks
Trust management using credentials	Characteristics: Based on credentials issued by authorities. It is targeted to create trust between organizations
	Weakness: Credentials are static. Difficult to evaluate and require a network of trusted authorities. It is difficult to force everyone and virtual systems to accept credentials or a TA

Identification of Concerns

Typical stakeholders in ubiquitous health are the DS, health service providers, other organizations, and secondary users. Different stakeholders have different concerns [1]. This paper is focused to the DS concerns. The main concerns of the DS are as follows: (1) how trustworthy the system is, (2) why is lack of awareness and transparency in data collection and processing, (3) who is using the data inside a system, (4) how to guarantee that data is processed lawfully, and (5) according to the DS's policies, how to prevent post-release of data and control unnecessary secondary use.

Functional Requirements

Derived from previously mentioned assumptions and selections and the proposals made by other researchers, the architecture should identify the following functional requirements. The architecture should offer tools for the DS to define purposes of

data collection, express computer-understandable rules regarding the sensitivity of data elements, design protection needed, rule how long data is stored, and which data is disclosed and for what purposes [14,48].

The architecture should support dynamic content-, context-, and purpose-aware privacy management. It should also offer to the DS system-specific computational trust information with attributes that describe systems' features, infrastructures, policies, and relations in advance. Humans' way to design policies, to support more rational choices than intuition, and to give feedback should need to be mimicked. The architecture must be compliance with Louviere's stated customer choice method. It should support situations where the DS discloses PHI and where data collection or disclosure is made autonomously by a system. The architecture also enables the DS to be aware of data-processing events, and to set policies regulate the secondary use and reuse of PHI.

Trust and Privacy Services

Services of the architecture should fulfill above-mentioned requirements, and take into account expected concerns. Trust and privacy services selected for the THEWS architecture are shown in Table 3.

Table 3. Trusts and privacy services for the THEWS architecture.

Concern/Function	Service
System's trustworthiness	Trust calculation service
	Context service
	Identification service
	Trust interpreter service
The DS's information autonomy	Decision support service
	Policy-binding service
Awareness and transparency	Monitoring, trust calculation, and notification services
The use of PHI inside the system	Monitoring and notification services
Does the system use PHI according to the DS's policies	Monitoring and notification services
Choice and secondary use and post-release of PHI	Policy-binding service
	Metadata (eg, sticky policy or active code for apoptosis)
Designing privacy policies and comparison and preference formulation	Decision support service
Policy formulation and post-choice and new policy creation	Policy management service
	Policy assistant service
	Ontology service
System's features and relations	Trust calculation service
Feedback and alarm or conflict notice	Monitoring service
Learning	Trust interpreter and policy assistance services

Privacy and Trust Formula

The THEWS principles and functional requirements determine that the DS can use trust information in the formulation of privacy policies [1]. The following formula has been developed to illustrate how trust information, privacy variables, and privacy policy are related:

Privacy_policy=f(TI, IS, SE, PU)

In this formula, TI refers to *trust_information* offered by the architecture to the DS. IS, SE, and PU are privacy variables proposed by Lederer [40]. IS refers to the sensitivity of the data, SE describes the situation where information is used, and PU defines the purpose of data collection or use.

To avoid the drawback of a single calculated trust value and to enable attribute-based creation of personal policies [61], the following trust information formula was developed:

Trust_information=Trust_value+Trust_feature_vector

Trust_feature_vector gives the system- and environment-specific information to the DS about systems' regulatory compliance and their willingness to follow the DS's policies and support openness. Slightly modified trust attributes originally proposed by Hussin et al have been selected for trust value calculation [24]:

Trust_value=(E, T, P, PO, Pre, Tran, Ab)

where E represents domain specific environmental factors such as legal requirements and system's contextual features. T represents the type of service provider's organization (eg, public health care provider, private health service provider, Internet service provider). P (properties) consists of systems architectural and technological aspects and PO is system's privacy policy. Predictability (Pre), transparency (Tran), and ability (Ab) are different parameters that can be calculated from the system's past history or by direct measurements. For *Trust_feature_vector*, the following formula was developed:

Trust_feature_vector=(DGD, DRB, SPO, DSP, ASP, CD, ATV, AUT, RP, PBL, DSA)

where DGD and DRB describe the level of system's regulatory compliance. The DGD is the degree of data processing made by the system in compliance with international privacy protection directives. The DRB is the degree of data processing performed by the system compliant with health care-specific laws and rules. SPO and RP are parameters that are related to openness. SPO informs if the system has made its privacy policies openly available, and RP tells the status if the system has published its relationships. DSP, ASP, ATV, and AUT are willingness parameters. DSP describes the degree by which the system follows its own privacy policies. ASP informs that the system either enables or rejects the DS to inject personal policies to PHI collected or processed by the system. The ATV expresses whether the system accepts external monitoring of events related to the processing of PHI, and AUT tells whether the system enables external access to its audit trails. The PBL and CD are trustworthiness parameters. CD informs whether the system has been certified, and PBL informs about the position of the system on the blacklist. The DSA is an optional attribute that can be defined by the DS. For DGD and DRB, a linear scale (0...1) is used, whereas all others attributes have only binary values. In case of no or insufficient data, the attribute value is zero.

Using proposed *Trust_information*, the DS can predict system's willingness or ability to process PHI legally and follow rules set by the DS. The *Trust_information* informs the DS about how much it can trust on a system, how system's policy and technical architecture look like, and to what extent system's policy is compliant with domain-specific regulations and laws. If needed, the DS can use attributes to mark a system untrusted (eg, in the case it will not publish its policies nor would accept monitoring). Most attributes can be calculated from information the system has, or should have, published; however, some attributes might require direct observations. Attributes such as DSP can be calculated from the system's past history.

The THEWS Architecture

A layered framework model that describes trust and privacy services of the THEWS architecture is shown in Figure 2. The top layer of the model consists of common services that are offered to all stakeholders. The middle layer includes privacy and trust services needed. Ubiquitous health, stakeholders, other users, and PHI are located in the lowest layer (ie, network layer).

As it is difficult or even impossible for the DS to evaluate the trustworthiness of systems, an independent agent, the trust calculator (TC), is used for this task. The role of TC is not to make trust decisions. Similar to HL7 Privacy, Access and Security Services architecture, the TC should be understood as an information point that sends trust information to the DS [55].

The TC calculates *Trust_information* (ie, *Trust_value* and related *Trust_feature_vector*) by using the information that system has published, and available contextual data, system's measured or monitored features, and system's past history. It also detects malicious or fake systems by using information obtained from context and monitoring services. Two assistance services are offered to the DS: (1) trust interpreter and (2) policy assistance service. The DS can use the trust interpretation to understand the meaning of received *Trust_information*.

The context service collects systems' contextual data, interprets it, and makes it available to TC and DS, using ontologies. The DS deploys policy management, policy-binding, policy assistance, and decision support services in policy formulation.

The monitoring service offers feedback, reduces risk, and recognizes policy conflicts. It records and assesses how a system in real life processes PHI. It recognizes policy conflicts and alarms the TC and the DS of possible malicious or illegal use of PHI. The notification service works as communication and transparency tool between the DS, systems and services. Using this service, the DS expresses personal policies to systems that in turn publish their policies and relations.

An architectural model describing the interconnection of the THEWS services is shown in Figure 3. In the architecture, the policy formulation is a decision-making process, where the DS chooses privacy rules, privacy management services, and the amount of PHI he or she wants to trade in according to expected service benefits. The selected rules and services depend on privacy needs, *Trust_information*, and the purpose of data request. Typical privacy management services that can be activated before data disclosure are encryption, anonymization, and data filtering. The DS may also inject policies and/or active code to the metadata.

The THEWS architecture not only fulfils the THEWS requirements but also offers protection against many of the known privacy threats existing in pervasive systems as shown in Table 4.

Figure 2. The framework model for the THEWS architecture.

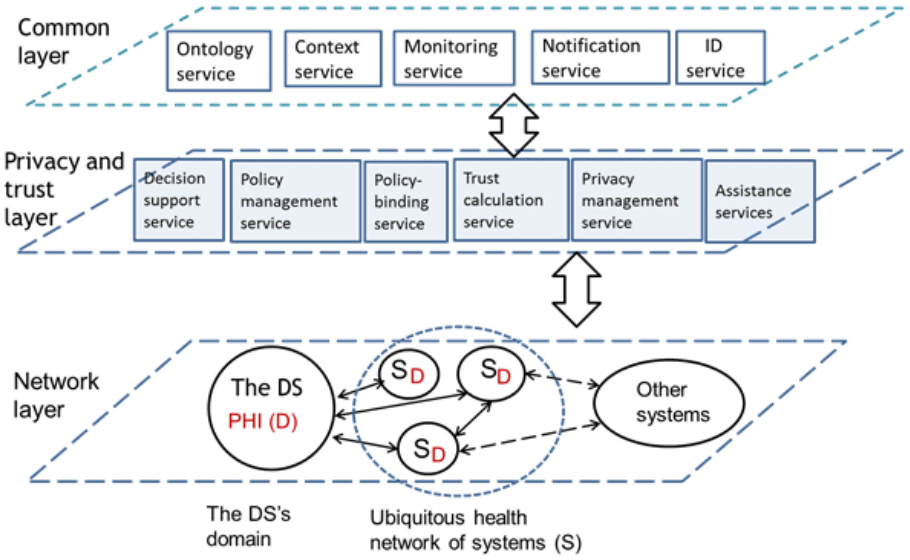


Figure 3. The interconnection of privacy and trust services in the THEWS architecture.

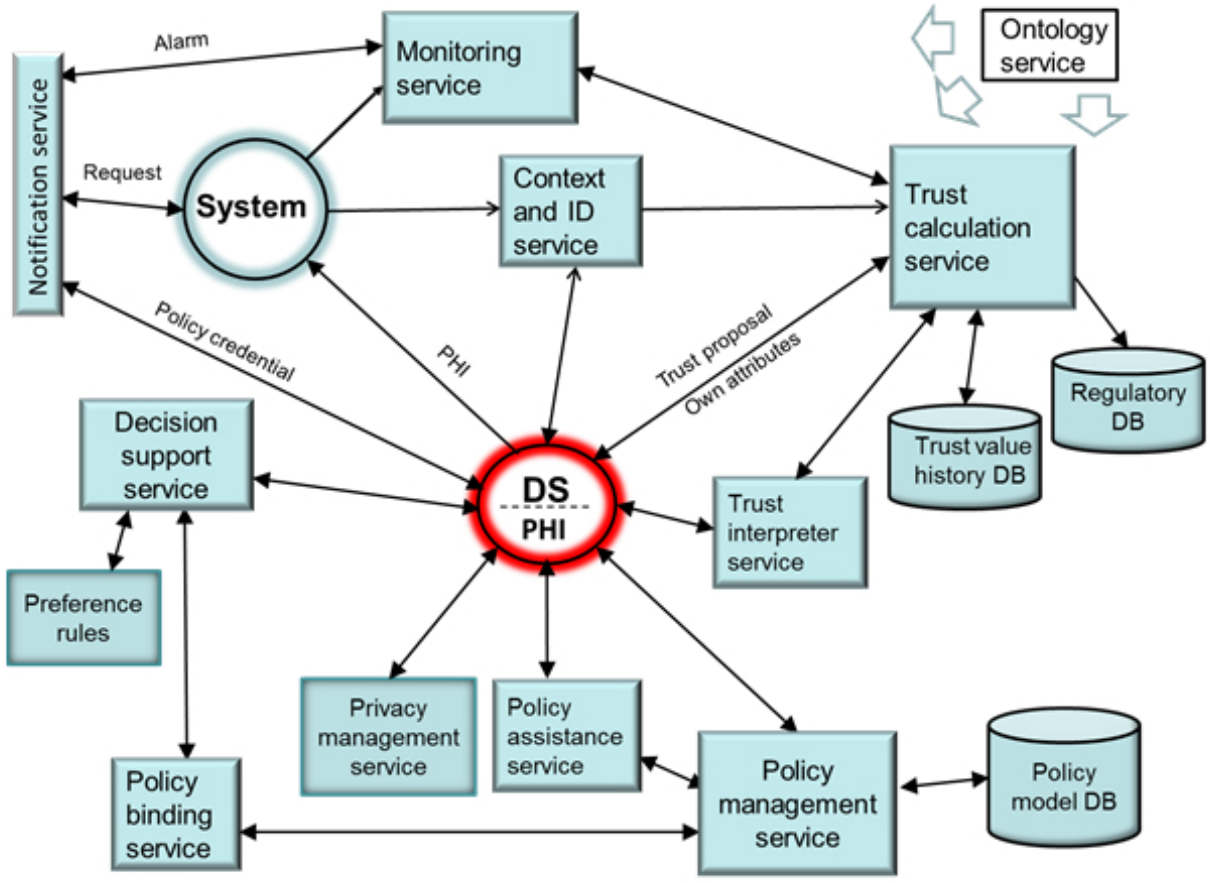


Table 4. The THEWS architecture approach for the challenges existing in pervasive systems.

Challenges and threats	THEWS approach
Pervasive systems are dynamic in nature (eg, ad hoc networks) where static rules and privacy services will not work	Dynamic rules and services are used
	Dynamic creation and management of the DS's privacy service portfolio
No predefined trust	Dynamic trust calculation based on systems' measured properties
The need of PII is dynamic and purposes are unpredictable	Dynamic context-aware polices support ad hoc purposes
Organizations do not always follow their own policies, and laws will be ineffective without sufficient control and penalties	The way systems process PHI is dynamically monitored, and the regulatory compliance is checked
Users want to control how systems use PII	The DS define system-specific policies that rule the use, storing, and sharing of PHI
It is difficult to know what is the actual privacy status of an enterprise (ie, what data and under what policy)	Status and policies are inspected and informed dynamically to the DS
It is difficult to know how data has been used inside the enterprise	The monitoring service can check internal use
Relationships between systems can be unknown	Systems must publish their relations
All service providers do not use certificates	Trustworthiness is not based on certificates
Selection of service provider needs trust and/or reputation	The TC offers calculated trust value and trust attributes to the DS
	Reputation is not used
Determining of systems' trustworthiness is challenging	The TC calculates trust using direct measurements
	The monitoring service gives feedback to the TC
Which action the DS must take in the case of privacy breach?	The TC and/or monitoring service inform the DS of privacy breaches
	The DS can change policy dynamically
How to guarantee that data is processed lawfully and according to the DS's policies	Trust attributes offer required information
	The monitoring service notifies misuse
Lack of awareness	Systems must publish their rules and relationships
	Awareness by monitoring service
How to know what actions are permitted or forbidden in a context and what actions must be performed?	The DS defines personal context-aware rules
How we can trust on systems privacy notices (or privacy manifesto)?	Privacy notice/manifesto is not used
Threats caused by surveillance, identity theft, or malicious attacks	Communication platform and systems must implement reasonable safeguards
Code of conduct, legal framework, and accreditation of centers will not guarantee trustworthiness	Those models are not used
Consent does not guarantee adequate protection	Consent is only one possible item in the policy
Anonymization such as "we know" will not guarantee adequate protection	Anonymization is only a value-added service
Secondary use of PII must be monitored	Monitoring service
Citizens need audit information	The monitoring service assesses the audit log and informs findings to the DS
	The TC can maintain a list of untrusted or malicious systems
Data requestors can have subjective views of trust	The TC defines the used trust ontology
How can we manage trust for systems with incomplete credentials?	Credentials are not used

Discussion

In this study, novel privacy architecture is developed for ubiquitous health. It enables the DS to ensure and manage information privacy by choosing personal context-aware privacy policies for each system with the help of computational trust information that includes a trust value and system-specific trust attributes. The architecture combines many trust and privacy services proposed by researchers for pervasive systems such as trust calculation and interpretation, policy management, policy assistance, policy binding and design, and context services and monitoring. The architecture goes far beyond the security

services with traditional access control used in health care, and it also illustrates how the THEWS principles can be realized. Furthermore, the architecture offers protections against many privacy threats caused by ubiquitous computing and unsecure environment. Instead of continuous validation of systems' trustworthiness, the architecture monitors functioning of the systems, detects and informs the DS of policy conflicts and data misuse, and thereby enables the DS to dynamically change policies.

Contrary to a widely used trust manifesto that is based on incomplete, insufficient, or inconclusive information [33] or a single trust value that offers only Hobson's choice to the DS, the architecture gives information to the DS that indicates the level of transparency and openness of a system, how system follows health-specific privacy rules and regulations, and how mature the system is to accept the DS's policies. Using this information and policy assistance, decision support, and policy-binding services of the architecture, the DS can construct context- and content-dependent policy profiles and assign them to systems. The architecture is user-friendly, and there is no need to interactively calculate the trust value against the DS's dynamic privacy needs.

For all pervasive systems, some of the unsolved privacy challenges are as follows: (1) How to prevent data from being collected and used in a way that DS cannot recognize? (2) How to prevent systems for breaching their promises? and (3) How to prevent the misuse of PHI after it has been released for secondary use?

Regulation and monitoring can give partial solution to first two challenges. Policy agents, self-destroying files, programmed death (apoptosis), destruction of cryptographic keys, and mutation engines have been proposed by researchers to give protection in the case of post-release [52,63]. The flexibility of developed architecture enables the DS to deploy any of these engines to control the secondary use of PHI.

In addition, there remain some more important challenges. The TC should understand both international and national regulations, and rules used by systems. Translation of narrative rules into machine-readable policies is an ongoing challenge [14]. The use of computer-understandable and context-aware polices requires either that all stakeholders accept a common policy language (such as Ponder, KAoS, Security Assertion Markup Language, eXtensible Access Control Markup Language, Rei, XPath-Based Preference Language, P3P, and APPEL) or that they use a method that enables semantically correct transformation between languages, based on ontologies [43,64,65]. Meta-policies such as P3P and Rei are candidates for the latter case [64,66,67]. In ubiquitous health, the use of a single policy language and a common ontology might be impossible. A possible solution is that the TC and the DS simply inform to systems about the ontology and policy language they use. If this is not possible, a service that maintains interoperability between policy languages and offers ontology reasoning should be developed [68]. In addition to policy, context and trust ontologies and other ontologies such as information and communication technology ontologies that describe systems' architectural and organizational aspects and mechanisms are needed. Considering the future work, the authors will evaluate the architecture, and validate its feasibility and functionality in pilot setting. As a minimum, the proof of concept will be done. The authors will also demonstrate that the proposed solution is technically valid, safe to use, and efficient.

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

DS: data subject
PHI: personal health information
PII: personal identifiable information
TA: trust authority
TC: trust calculator
THEWS: Trusted eHealth and eWelfare Space

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Original Paper

Differences in Trunk Accelerometry Between Frail and Nonfrail Elderly Persons in Sit-to-Stand and Stand-to-Sit Transitions Based on a Mobile Inertial Sensor

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Abstract

Background: Clinical frailty syndrome is a common geriatric syndrome, which is characterized by physiological reserve decreases and increased vulnerability. The changes associated to ageing and frailties are associated to changes in gait characteristics and the basic functional capacities. Traditional clinical evaluation of Sit-to-Stand (Si-St) and Stand-to-Sit (St-Si) transition is based on visual observation of joint angle motion to describe alterations in coordination and movement pattern. The latest generation smartphones often include inertial sensors with subunits such as accelerometers and gyroscopes, which can detect acceleration.

Objective: Firstly, to describe the variability of the accelerations, angular velocity, and displacement of the trunk during the Sit-to-Stand and Stand-to-Sit transitions in two groups of frail and physically active elderly persons, through instrumentation with the iPhone 4 smartphone. Secondly, we want to analyze the differences between the two study groups.

Methods: A cross-sectional study that involved 30 subjects over 65 years, 14 frail and 16 fit subjects. The participants were classified with frail syndrome by the Fried criteria. Linear acceleration was measured along three orthogonal axes using the iPhone 4 accelerometer. Each subject performed up to three successive Si-St and St-Si postural transitions using a standard chair with armrest.

Results: Significant differences were found between the two groups of frail and fit elderly persons in the accelerometry and angular displacement variables obtained in the kinematic readings of the trunk during both transitions.

Conclusions: The inertial sensor fitted in the iPhone 4 is able to study and analyze the kinematics of the Si-St and St-Si transitions in frail and physically active elderly persons. The accelerometry values for the frail elderly are lower than for the physically active elderly, while variability in the readings for the frail elderly is also lower than for the control group.

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KEYWORDS

frail syndrome; sit-to-stand; stand-to-sit; mobile phone; inertial sensor

Introduction

Clinical frailty syndrome is a common geriatric syndrome which is characterized by physiological reserve decreases and increased vulnerability and which may, in the event of unexpected intercurrent processes, result in falls, hospitalization, institutionalization, or even death [1]. Detection and diagnosis of frailty depend on the following domains. *Medical:* Presence of chronic diseases, gait disturbance, sensory deficit, recurrent

falls and hospitalization, and polypharmacy. *Functional:* Dependence in basic activities of daily living and instrumental activities of daily living. *Socioeconomic:* Living alone, recent widowhood aged over 80 years, and low income. *Cognitive and affective criteria:* Depression and cognitive impairment. *Need for institutionalization:* Live in retirement homes and nursing homes [2].

A previous study in the frailty detection [2] concludes that it is necessary to make a multimodal correct assessment of the whole clinical record. In this sense, this study established a set of clinical parameters from the laboratory report belonging to the patient record. Different groups of clinical factors had been identified: nutritional assessment, cognitive assessment, etc. The present study is focused only in the physical function. It however seems particularly worthwhile to measure mobility and balance (physical function) as a means of knowing whether acutely ill older people who are frail are recovering from their illness or becoming more ill [3-6].

The changes associated to ageing and frailties are associated to changes in gait characteristics and the basic functional capacities of the individual [7]. This variability in different movement patterns has been interpreted as a more conservative gait pattern in order to increase gait stability and reduce the risk of falls [8]. The new, more conservative gait pattern has greater cognitive involvement and produces a result focused entirely on movement, while the perception of unexpected trigger factors may be overlooked [9]. Dual tasks have been shown to affect normal gait development even in healthy persons [10].

As people get older, the ability to rise from a chair, usually labeled as the sit-to-stand (Si-St) and stand-to-sit (St-Si) postural transition, becomes a more demanding functional daily task [11,12]. Traditional clinical evaluation of Si-St and St-Si transition is based on visual observation of joint angle motion to describe alterations in coordination and movement pattern [11,12]. However, the validity of such assessment essentially depends on clinicians' experience and training. Results might not have the precision needed to objectively assess the effect of rehabilitative intervention or the decline over time in frail elderly persons [11-13]. Kinematics of the trunk appears essential to maintain balance during Si-St transition [11,12,14]. The dynamic body movements using body-worn inertial sensors have been investigated [11,12,15-19].

A previous study concludes that inertial sensors can offer an accurate and reliable method to study human motion [20]. Algorithms for characterizing the gait of pedestrian using accelerometer and gyroscope signals recorded in a handheld device have been developed and presented in previous studies. This study concluded that the pattern recognition open new research options toward free-inertial tracking of pedestrian using handheld inertial sensors, which are already widely embedded in smartphones nowadays [21]. The latest generation smartphones often include inertial sensors with subunits such as accelerometers and gyroscopes that can detect acceleration and inclination [22]. The numerous applications developed for these smartphones mean the data from the accelerometer and the gyroscope can be read, stored, transferred, and displayed [23,24]. These applications evaluate and assess kinematic variables related to gait [25], measuring Cobb angles in x-rays, or as an objective method to classify levels of physical activity, and an indicator of the degree of functional capacity and quality of life [22,26].

There are two goals in the present study. First to describe the variability of the accelerations, angular velocity, and displacement of the trunk during the Si-St and St-Si transitions in two groups of frail and physically active elderly persons, through instrumentation with the iPhone 4 smartphone; and second, to analyze the differences and performance of the variance between the study groups (frail and healthy).

Methods

Design and Participants

A cross-sectional study that involved 30 subjects over 65 years, 14 frail and 16 fit subjects. The participants were classified with frail syndrome by the Fried criteria (unintentional weight loss, self-reported exhaustion, weakness, slow walking speed, and low physical activity) [1]. Exclusion criteria were no history of pain in the last twelve months, previous surgery, presence of a tumor, and musculoskeletal disorders in the upper or lower extremity. Patients with impaired cognition, musculoskeletal back comorbidities, and problems associated with exercise intolerance were also excluded. A physiotherapist clinically examined all participants, and none of them have the exclusion criteria. Table 1 shows the characteristics of the sample.

Fit participants were recruited through advertisements in the Sport and Health Center in Torremolinos, Spain. Frail participants were recruited through advertisements in the Geriatrics Centers in Torremolinos and Benalmadena, Spain. Written informed consent was obtained from each individual. The ethics committee of the Faculty of Medicine at the University of Malaga, Spain approved the study.

Data Collection and Procedures

Analysis was performed with SPSS version 15 for Windows while the data collection phase used inferential analysis between variables by type and normal. The nonparametric test Mann-Whitney [27] was used as determined by the variables normality of distribution. The statistical significance level was set at $P<.05$.

Table 1. Characteristics of sample (N=30).

	Mean		Standard deviation	
	Frail (n=14)	Fit (n=16)	Frail (n=14)	Fit (n=16)
Age (years)	83.71	70.25	6.37	3.32
Weight (kg)[a]	56.21	71.03	9.64	13.11
Height (cm)[b]	155.79	159.44	7.81	10.61
Body mass index (kg/m^2)[c]	23.36	27.87	3.48	3.79

[a]kg=kilograms
[b]cm=centimeters
[c]m=meters

Results

Table 2 summarizes the acceleration-based measures of the Si-St and St-Si transitions in the two groups.

Table 3 summarizes the gyroscope-based measures of the Si-St and St-Si transitions in the two groups.

Table 2. Acceleration-based values from the Si-St and St-Si transitions (N=30).

	Mean		Standard deviation			
	Frail (n=14)	Fit (n=16)	Frail (n=14)	Fit (n=16)	U[a]	*P* value
Si-St (m/s^2)[b,c]						
x[d].acc[e].max[f]	2.004	3.353	0.761	1.475	49.50	.009
x.acc.min[g]	-1.443	-3.136	1.211	1.198	30.50	<.001
y[h].acc.max	3.069	6.248	1.240	1.913	15.00	<.001
y.acc.min	-1.471	-6.182	0.788	2.415	0.000	<.001
y.acc.mean	0.668	0.018	0.513	0.690	45.00	.005
RV[i].acc.max	7.065	8.972	2.233	2.506	58.00	.025
RV.acc.mean	2.975	4.215	1.063	0.964	44.00	.005
St-Si (m/s^2).						
y.acc.max	3.567	6.200	2.028	1.752	26.50	<.001
y.acc.min	-2.950	-9.003	2.441	4.334	14.00	<.001
z[j].acc.max	5.830	3.834	2.170	2.682	62.00	.038
z.acc.min	-3.770	-6.645	1.928	2.374	35.00	<.001
z.acc.mean	0.874	-1.611	1.672	1.701	36.00	.002
RV.acc.max	7.213	10.652	2.566	3.501	41.00	.003
RV.acc.min	0.364	0.808	0.255	0.479	38.00	.002
RV.acc.mean	3.188	4.263	0.708	1.048	45.00	.005

[a]U=U-Mann-Whitney
[b]m=meters
[c]s=second
[d]*x*=*x*-axis
[e]acc=acceleration
[f]max=maximum
[g]min=minimum
[h]*y*=*y*-axis
[i]RV=resultant vector
[j]z=z-axis

Table 3. Gyroscope-based values from the Si-St and St-Si transitions (N=30).

	Mean		Standard deviation			
	Frail (n=14)	Fit (n=16)	Frail (n=14)	Fit (n=16)	U[a]	*P* value
Si-St						
roll.rotation.max[b](deg)[c]	102.920	196.544	98.755	109.519	35.00	.001
roll.rotation.mean (deg)	-24.754	83.837	58.165	150.560	61.00	.034
rate[d].yaw.min[e](deg/s)[f]	-47.813	-26.131	17.501	25.998	42.00	.004
rate.pitch.max (deg/s)	27.414	123.404	15.552	141.318	28.00	<.001
rate.roll.max (deg/s)	18.924	165.437	8.843	120.989	0.000	<.001
rate.roll.min (deg/s)	-19.796	-62.597	10.956	39.321	56.00	.020
rate.roll.mean (deg/s)	0.459	49.993	1.289	82.129	59,00	.028
St-Si						
roll.rotation.min (deg)	-163.264	-61.157	38.955	108.358	60.00	.031
roll.rotation.mean (deg)	-15.487	83.102	40.876	142.182	62.00	.038
rate.yaw.max (deg/s)	41.309	130.470	11.316	138.379	57.00	.022
rate.yaw.min (deg/s)	-67.449	-37.077	21.053	30.776	49.00	.009
rate.roll.max (deg/s)	38.146	145.150	18.918	129.161	13.00	<.001
rate.roll.min (deg/s)	-25.596	-70.275	16.433	50.714	58.00	.025

[a]U=U-Mann-Whitney

[b]max=maximum

[c]deg=degrees

[d]rate=angular velocity

[e]min=minimum

[f]s=second

Discussion

Principal Results

The present study has described and examined the identification, analysis, and differentiation in the performance of kinematic variables using the inertial sensor fitted in the iPhone 4 during Si-St and St-Si transitions in healthy and frail elderly people. Significant differences were found between the groups of elderly people in the accelerometry and angular displacement variables obtained in the kinematic readings of the trunk during the both transitions.

The results obtained in this study show a series of weakness in the frail elderly population group. The most significant deficits found in the Si-St and St-Si transitions corresponded to accelerometry (see Table 2), with the frail elderly persons obtaining lower maximum and minimum accelerations than the physically active elderly persons in the y-axis during these transitions.

Comparison With Prior Work

As far as we are aware, this is the first study that has used iPhone 4 technology to analyze and study the kinematics of healthy and frail persons aged over 65 years during the Si-St and St-Si transitions. Moreover, it is the first study that has shown the possibility of differentiating kinematic patterns in both transitions. The instrumented kinematic analysis of the Si-St and St-Si transitions was analyzed previously [11,15-19]. Moreover, in these studies no data were provided regarding magnitudes of acceleration and angular velocity obtained with a smartphone. By way of example, the results of the present study obtained in Table 2 show kinematic data that inform us that in the Si-St transition the linear acceleration of the trunk on the y-axis showed significant differences between healthy and frail elderly persons, while linear acceleration in the z-axis did not show any statistically significant differences.

It should be noted that frailty is defined as a clinical syndrome in which three or more of the following criteria should be present: unintentional weight loss, self-referred exhaustion, muscular weakness, low walking speed, and low physical activity levels [1]. Generically, the gyroscope and accelerometry data obtained for the Si-St and St-Si transitions were similar to other studies with other types of study groups or other types of functional tasks. In the present study, the frail elderly showed low magnitudes in the kinematic values with low variability (very small standard deviations) compared to the controls, the same as the subjects affected by Parkinson's disease [28-30], the elderly with a high risk of falls [7] and the frail elderly in a previous study [11,12,31].

There are two recent studies [11,12] that have instrumented the Si-St and St-Si transitions, differentiating and analyzing the

kinematic data in each of the transitions between two groups of elderly persons. However, unlike the present study, they did not use iPhone 4 technology to collect kinematic variables.

Another recent study which has worked on the instrumentalization of the Timed Get Up and Go [7] test systematically evaluated the accelerometry values in elderly persons with a high risk of falls during the traditional three meter test, focusing solely on transitions in Si-St and St-Si. Like the present study, this study found numerous variables deriving from acceleration that showed differences between groups. However, the variables in this study were different, as was the methodology, and other things. Moreover, the measurement units were not coincident, and this study was based on the acceleration increase amplitude and the acceleration slope.

From a clinical perspective, the present study demonstrates that these new accelerometry parameters play an important role in differentiating between subjects with different functional states. These results provide new knowledge, extending existing knowledge on the isolated study of Si-St and St-Si transitions in frail and physically active elderly persons [11,12,31].

With regards to analysis of the data obtained in the present study, the differences between the frail and the physically active elderly show a series of deficits in the group of frail persons in both transitions. It is notable that the most significant deficit for the frail elderly in the Si-St and St-Si corresponded to accelerometry, with the frail elderly obtaining much lower minimum and maximum accelerations than the physically active elderly in the y-axis (see Table 2). In kinematic terms, this axis corresponds to accelerations in the VT-axis, leading us to believe that the frail elderly have less strength to carry out the impulse in concentric contraction of the quadriceps femoris muscle and the decrease in eccentric contraction of the same muscle on the VT-axis, as required for the transition from sitting to standing and vice versa. A study of the factors which influence this transition in 669 institutionalized elderly people showed that quadricep strength is the most important determinant factor for this transition, although there are other factors such as proprioception, movement execution speed, and psychological aspects which also influence ability to successfully carry out this functional test. Other factors, which may influence this transition, are foot position, anthropometry of the individual, or the height of the chair [16].

Limitations and Future Work

The present findings motivate future investigations along these lines, but this study presents some limitations. First, men and women have different characteristics and it would be very interesting to provide the differences between them after the St-Si/Si-St exercise. A new study is needed to compare between genders. Moreover, prospective studies are needed to determine if acceleration-derived measures, perhaps in combination with other metrics and previously described measures of fall risk, can predict. Additional work is also needed to explore other properties of accelerometer-derived measures of the Si-St/St-Si. Note that here we specifically focused on timing of transition and a subset of the properties of the signal; further analysis of the complete waveform and other time points may provide additional utility. Indeed, it appears that the proposed approach not only may offer a more refined scale for assessing older adults, but it may also help to pinpoint specific problems that give rise to an abnormal performance of functional tasks (eg, Si-St/St-Si transitions). In the meantime, the present results demonstrate the potential of using an accelerometer to measure Si-St/St-Si performance, while maintaining simplicity and requiring no additional time to acquire the data.

Conclusions

The inertial sensor fitted in the iPhone 4 is able to study and analyze the kinematics of the Si-St and St-Si transitions in frail and physically active elderly persons. The accelerometry values for the frail elderly are lower than for the physically active elderly, while variability in the readings for the frail elderly is also lower than for the control group. This suggests that the frail elderly carry out the test in a more careful, restricted way during the functional tasks, which make up the transitions, possibly showing their reduced ability to regulate movement when performing these tasks and transitions. The compensation mechanisms also play an important role. These results indicate that the additional, relevant information for future discriminant analysis comes mainly from the acceleration signal during the Si-St and St-Si transitions.

Authors' Contributions

Authors' Contributions: ACV conceived of the study, participated in its design and coordination, and drafted the manuscript. ACV also had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Both authors performed the statistical analysis and provided critical content revision of the manuscript. Both authors read and approved the final manuscript.

Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

RPY: roll, pitch, and yaw
RV: resultant vector
SDs: standard deviations
SI-ST: sit-to-stand
ST-SI: stand-to-sit
VT: vertical axis

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Original Paper

The Development of a Mobile Monitoring and Feedback Tool to Stimulate Physical Activity of People With a Chronic Disease in Primary Care: A User-Centered Design

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Abstract

Background: Physical activity is an important aspect in the treatment of patients with chronic obstructive pulmonary disease or type-2 diabetes. A monitoring and feedback tool combined with guidance by a primary care provider might be a successful method to enhance the level of physical activity in these patients. As a prerequisite for useful technology, it is important to involve the end-users in the design process from an early stage.

Objective: The aim of this study was to investigate the user requirements for a tool to stimulate physical activity, embedded in primary care practice. The leading principle of this tool is to change behavior by self-monitoring, goal-setting, and feedback.

Methods: The research team collected qualitative data among 15 patients, 16 care professionals, and several experts. A prototype was developed in three stages. In stage 1, the literature was searched to identify end-users and context. In stage 2, the literature, experts and patient representatives were consulted to set up a use case with the general idea of the innovation. In stage 3, individual interviews and focus groups were held to identify the end-user requirements. Based on these requirements a prototype was built by the engineering team.

Results: The development process has led to a tool that generally meets the requirements of the end-users. A tri-axial activity sensor, worn on the hip, is connected by Bluetooth to a smartphone. In an app, quantitative feedback is given about the amount of activity and goals reached by means of graphical visualization, and an image shows a sun when the goal is reached. Overviews about activity per half an hour, per day, week, and month are provided. In the menu of the app and on a secured website, patients can enter information in individual sessions or read feedback messages generated by the system. The practice nurse can see the results of all patients on a secure webpage and can then discuss the results and set personalized goals in consultation with the patient.

Conclusions: This study demonstrates that a user-centered approach brings in valuable details (such as the requirements for feedback in activity minutes per day) to improve the fit between the user, technology, and the organization of care, which is important for the usability and acceptability of the tool. The tool embedded in primary care will be evaluated in a randomized controlled trial.

(JMIR Mhealth Uhealth 2013;1(2):e8) doi:10.2196/mhealth.2526

KEYWORDS

user-centered design; self-management; physical activity; accelerometry; remote sensing technology; primary health care

Introduction

Lack of physical activity is an important risk factor for cardiovascular disease, hypertension, diabetes mellitus, obesity, stroke, some cancers, and osteoporosis. It is recommended that the general population is physically active at a moderate to vigorous intensity for at least 150 minutes per week [1]. Unfortunately, physical inactivity remains highly prevalent [2,3]. It is particularly important for people with a chronic disease to be physically active. It has not only been proven that an active lifestyle prevents diseases but also an active lifestyle improves the health-related quality of life and psychological status for people with a chronic disease [4,5]. An active lifestyle reduces dyspnea in chronic obstructive pulmonary disease (COPD) patients [6] and complications in patients with diabetes [7]. Due to the health benefits and the need for support by most COPD and type-2 diabetes (DM2) to increase their physical activity, stimulating physical activity is regarded as one of the main treatment goals in primary care [8,9]. This should be accomplished with support for self-management. Self-management implies that people are in charge of their own lives with their disease and its treatment, enabling motivation to change. Supporting self-management requires a different role of health care professionals and patients, for which new skills and tools are needed [10].

Professionals can be more successful at improving an active lifestyle by increasing patients' awareness through self-monitoring, goal setting, and discussing self-efficacy [11,12]. The provision of tailored feedback on physical activity has been proven to be effective in several interventions [13-15]. Persuasive technology can help professionals in accomplishing their coaching role. A "simple" pedometer gives feedback about the frequency of steps or distance walked in a day and it seems to be a useful tool that incorporates elements for self-monitoring, goal-setting, and feedback. Self-reporting studies revealed that the use of pedometers is an effective approach to increase physical activity [16-18]. It is, however, still unknown to what extent the observed changes are sustainable or whether it is possible to continue to accumulate benefits as a result of long-term adherence [16,18]. Due to new technological developments, such as pedometers being improved to (tri-axial) accelerometers and mobile phones being transformed into mini-computers, new possibilities for activity monitoring have become available. Numerous activity monitors are commercially available [19]. For example, the Fitbit provides feedback on steps, distance, and calories [20]. The activity monitor, PAM, engages the participant by giving points for the activities in a "PAM-score" and detailing a historical overview on a personal website [21].

Furthermore, systems are developed in which pedometers/accelerometers are connected wirelessly to a mobile phone [22-24]. This connectedness with mobility makes it possible to give more detailed readily available feedback on a larger screen. Linking self-monitoring technologies with a coach or embedding such technologies in the care process could further enhance effectiveness of behavior change strategies [25-27]. especially when technology and care are carefully developed and aligned with each other.

In the project "It's LiFe!", an innovative monitoring and feedback tool was developed which is embedded in primary care practice. The tool aims to support the self-management of people with COPD or type-2 diabetes to obtain an active lifestyle by measuring their activity behavior, giving automatically generated tailored feedback to the patient and to the care professional. The care intervention in which the tool will be embedded is named the Self-management Support Program (SSP). The program consists of a limited number of behavior change consultations with a health care professional.

As a prerequisite for useful technology and a successful intervention that meets the requirements and preferences of end-users, it is important to involve the end-users in the design process at an early stage [28]. In the project "It's LiFe!", this inclusiveness of end-users was ensured by a user-centered design process in which people with COPD or type-2 diabetes and their health care professionals were involved in the development of the technology and the SSP.

The aim of this paper is to report on the user-centered design process in which the user requirements for a monitoring and feedback tool were investigated. In particular, users were involved to reveal:

1. Which feedback patients and professionals need to optimally support self-management of physical activity?
2. How this feedback can best be presented?
3. How the tool can be made attractive, persuasive, easy to use and suitable to wear on a daily basis?

Methods

User-Centered Design Process

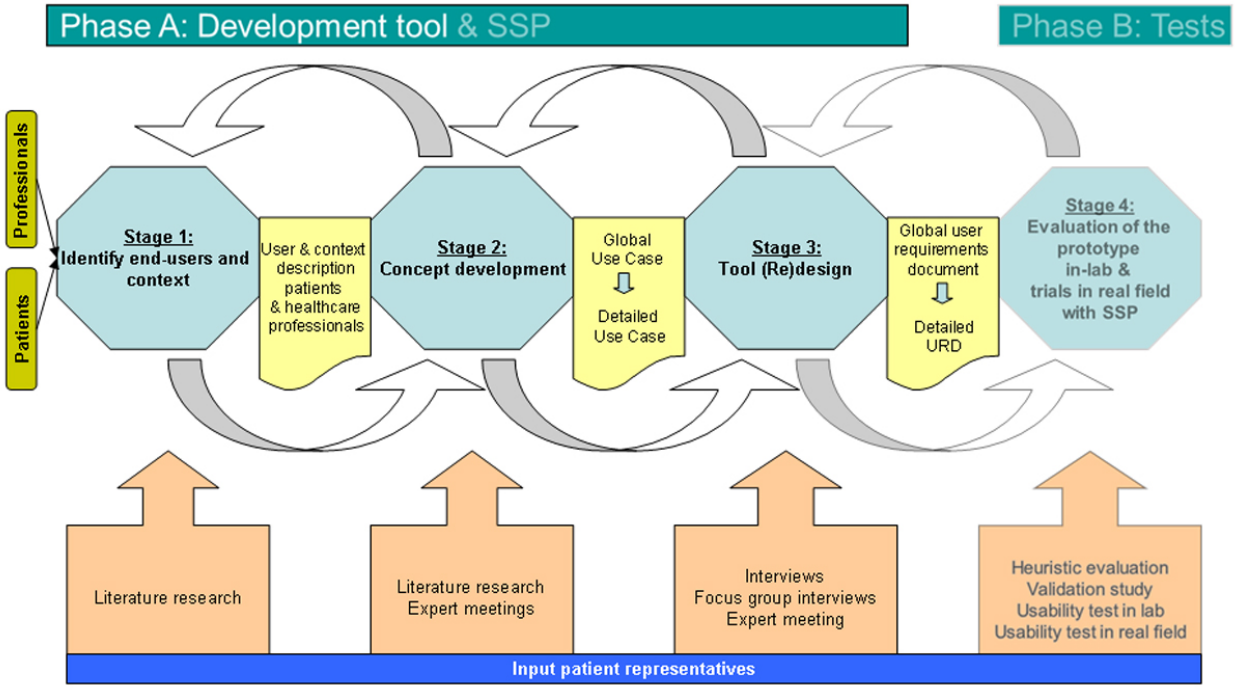
A user-centered design (UCD) process was followed. User-centered design is a broad term that describes design processes in which end-users influence how a design takes shape. To increase the success rate of the usability in computerized systems [29], it is of importance to understand the context of use and the user requirements [30,31].

To ensure UCD from the outset, two patient representatives were recruited from the national patient associations for COPD and diabetes, participated in the research team. These representatives reflected on the needs, demands, and restrictions of the patients. Furthermore, the representatives provided feedback on the comprehensibility of interview questions, the use cases, and other documents which were intended for patient participants in the study. The research team gathered the user requirements and an engineering team translated these into technical solutions. During the development process for the monitoring and feedback tool, there was a continuous interaction between the research team and the engineering team. This

interaction facilitated the match between the user requirements and the technical solutions.

The design process of the monitoring and feedback tool was based on a combination of existing methodologies, but mainly on Shah's methodological framework for medical device development [28,32-34]. The tool was developed in three iterative stages, depicted as phase A in Figure 1. The end-users, people with COPD or type-2 diabetes and their primary care professionals, were extensively involved. In the fourth stage (phase B), the tool will be tested in laboratory situations and real-life settings. The three development stages are described below.

Figure 1. The It's LiFe! user-centered design process. First the end-users and context were defined based on the literature. Second the conceptual idea of the tool was described in a use case, based on input from literature, an experts meeting and patient representatives. In stage 3 the use case was discussed with patients and health care professionals to elicit the user requirements for the tool. During the whole process the research team deliberated with the engineering team, to find out what was technically possible. After a detailed user requirements document was composed the engineering team translated the user requirements in technical solutions.



Stage 1: Identify End-Users and Context

To outline the context in which the monitoring and feedback tool should be used, end-users' and environmental characteristics were identified by analyzing the literature and clinical practice guidelines [8,9]. This resulted in a narrative description of users and context.

Stage 2: Concept Development

Literature was studied about behavior change strategies and technologies to stimulate physical activity that would match with users and context. The user and context description and the literature findings were discussed with experts (physicians, human-movement scientists, technicians, and implementation experts). The results of stage 2 were specified in a global use case; describing the interaction between a user and the system to be developed in a step-by-step manner [35]. The use case was designed to demonstrate the conceptual idea of the tool to end-users, without giving too much direction to their thoughts.

Stage 3: Tool (Re) Design

In order to elicit user requirements for the tool, the use case was the object of discussion with patients in 15 semi-structured interviews (in 2 rounds), and 2 focus group discussions were held (1 for COPD and 1 for diabetes. In the focus groups (FG), the patients discussed and complemented the interview results. After another 16 interviews with health care professionals, all of the results were discussed with the same experts from stage 2 plus an independent eHealth researcher and an opinion leader from a general practice. For the interview topics see Table 1. After the interviews and focus group discussions, a first draft of the user requirements document was established. The requirements document was deliberated upon with all of the project members, particularly with the engineering team, to confirm the technical possibilities and to ensure that no important issues were neglected.

Table 1. Interview topics regarding the tool for patients and professionals.

Main topics	Subtopics
Tool architecture	
	Place activity sensor
	Requirements activity sensor
Goal setting	
	What kind of goal
	Who should set the goal
	On what condition should the goal be adaptable
Feedback	
1. Amount of activity	In what unit should it be presented
	Where should it be visible
	In what format should it be visible
2. Amount of activity compared to goal	In what unit should it be presented
	Where should it be visible
	In what format should it be visible
3. Response of a health professional based on the activity results	Which health care professional should be involved
	How should the health care professional react on the results
	How do patients feel about the possibility for a health care professional to look at their activity results
Data sharing (only discussed with patients)	
	Share activity results with peers
	Share activity results with relatives

Recruitment and Data Sampling

Patients and health care professionals were recruited by snowball sampling, by using contacts from the national patient associations and the researchers' networks. Interviews lasted approximately 90 minutes and were held in the respondents' natural environment (at home) or at Maastricht University. Interviewees were asked to read the use case and give their opinion about the conceptual idea of the technology, integration into primary care and their specific requirements for such a tool. During the interviews, the questions and the use case were continuously specified.

Data Analysis

All of the interviews and focus group discussions were audio-taped with the consent of the respondents. The first 8 interviews with patients and all interviews with health care professionals were transcribed verbatim. Transcripts were generated, read, and open-coded using the NVivo 2.0 software package. Two researchers independently open-coded 4 interviews (2 from patients and 2 from health care professionals) and reached a consensus about final coding with themes and subthemes. Next, all of the transcripts were (re-)coded using the themes and subthemes as an analytical coding scheme that further evolved during the analysis. After analysis of interviews for round 1 (IR1), questions for each end-user group were rephrased from open to closed questions. For example, in the first interview round the patients were asked, "where do you want to wear the activity sensor", whereas in the interviews for round 2 (IR2) all of the previously mentioned answers which were technically possible were given for the patient to choose from. However, other additional options were also welcomed. The audio recordings of the second round of patient interviews and the focus groups were transcribed per code and analyzed by two researchers independently. By means of member check, the results of the focus group discussions were verified by a focus group participant and an observer who was present at both of the focus group discussions.

Ethical Approval

This study was approved by the medical ethical committee of azM/UM.

Results

Stage 1: User and Context Description

Concerning the users and context, it was considered that the resulting intervention (tool + SSP) would be focused on anybody who will benefit from support during physical activity. However, for the scope of the research project, people with COPD or type-2 diabetes, aged less than 70 and over 40, treated in a primary care setting were chosen. These two patient groups were chosen since they represent a large part of the chronically ill people in primary care and can both benefit from lifestyle changes. More importantly, these two groups have diverse physiological and psychological states and therefore different

support needs [36]. Involving this heterogeneous group in the development should lead to a tool that is applicable for a wide audience. However, this implies that the tool should have customizable components to meet the specific needs of different target groups. It was also decided to develop an intervention for people in the contemplation (thinking about change) and preparation (making small changes in behavior but not enough) phase of the Trans-theoretical Model of Behavior Change [37,38]. We believe that people in these stages benefit most from support in self-management. People in the precontemplation phase need to be convinced of the importance of an active lifestyle first. Based on the clinical practice guidelines [8,9], the practice nurse was the logical health care professional to be involved.

Stage 2: Concept Development

Literature Findings

In order to develop an effective intervention, it must be clear which determinants are relevant for the target behavior and which of them can be influenced. For the initiation and maintenance of physical activity, the relevant and changeable personal determinants are: awareness, knowledge, attitude, self-efficacy, intention and intrinsic motivation [39,40]. Strategies to influence these determinants include: self-monitoring, providing tailored feedback, providing information, action planning, working with role models, and proposing activities that are feasible for the patient [40]. It is important to note that intention to change is not sufficient; intentions account for only 20-30% of the variance in behavior [41]. In order to narrow the gap between intentions and actual behavior, it is important to set realistic goals and to identify potential barriers. The Goal-Setting Theory states that a goal should be specific, challenging but realistic, set by the patient himself (or in collaboration with the health care professional), and easily monitored [42].

Physical activity can be measured with questionnaires, energy expenditure measurements and activity monitors. For daily use, activity monitors are most suitable [43]. There are three classes of activity monitors; pedometers, accelerometers and integrated multisensory systems. Pedometers estimate the number of steps taken but are limited to measurement of the vertical plane. Accelerometers detect acceleration in one, two or three directions and can determine the amount, intensity and duration of movements. Integrated multisensory systems try to optimize physical activity assessment using the combination of accelerometry and other sensors that measure physiological responses to exercise, such as skin temperature or heart rate. However, there is little evidence that adding another physiological measure significantly improves the assessment of energy expenditure [44]. Numerous accelerometers are developed with different wearing positions, such as the hip, waist, ankle, upper leg, and wrist. An accelerometer is most accurate in assessing daily life physical activity if worn on the lower back or hip [44]. However at this position, cycling is not captured very well. A promising development is monitors that integrate Global Positioning Systems [43] which could make it possible to measure cycling. Unfortunately at the moment, this is too energy consuming for daily use.

From other monitoring and feedback tools it was learnt that feedback and incentives should be provided whenever progress is made and not only when the goal is achieved [18]. From the development and evaluation of two mobile systems, Houston [23] and Ubifit [24], it can be seen that mobile interventions can be a powerful way of promoting health behavior changes. This is achieved by supporting the persistent activation of health goals, focusing on patterns of activity, and facilitating optional social support [45].

Global Use Case

The literature findings and meetings with experts led to the following concept of the tool. This concept of the tool was elaborated in the global use case, which was presented as a narrative scenario, and was the input for stage 3. Basically, the tool, consisting of a sensor and a feedback system, will focus on the stimulation of daily activity and not on sports. The sensor is placed somewhere on the body and measures physical activity. The patient sets a personal activity goal together with the health care professional, and receives feedback about the current activity level related to the pre-set activity goal. The health care professional and a relative also receive a periodic summary of the activities. When the patient is performing well, the patient receives compliments from the tool, the health care professional, and their relative.

Stage 3: Tool (Re-)Design

The purpose of this stage was to further specify the conceptual idea to the user requirements and preferences of the patients and health care professionals. The characteristics of patients and professionals who participated in the interviews and focus groups are described in Tables 2-4. Four main topics relevant for the tool were identified from the interviews: (1) Tool architecture; (2) Goal setting; (3) Feedback; and (4) Data sharing. For each topic, user requirements and preferences were elicited. For the resulting design of the tool and a visualization of the feedback loops (described under “feedback consequences”) see Figure 2.

Table 2. Characteristics of respondents with COPD from the interviews and focus groups.

	Interview round 1 (n=4)	Interview round 2 (n=3)	Focus group (n=6)
Age mean (SD)	64 (7.2)	61.5 (5.3)	61.8 (5.7)
GOLD	2-4	3-4	2-4

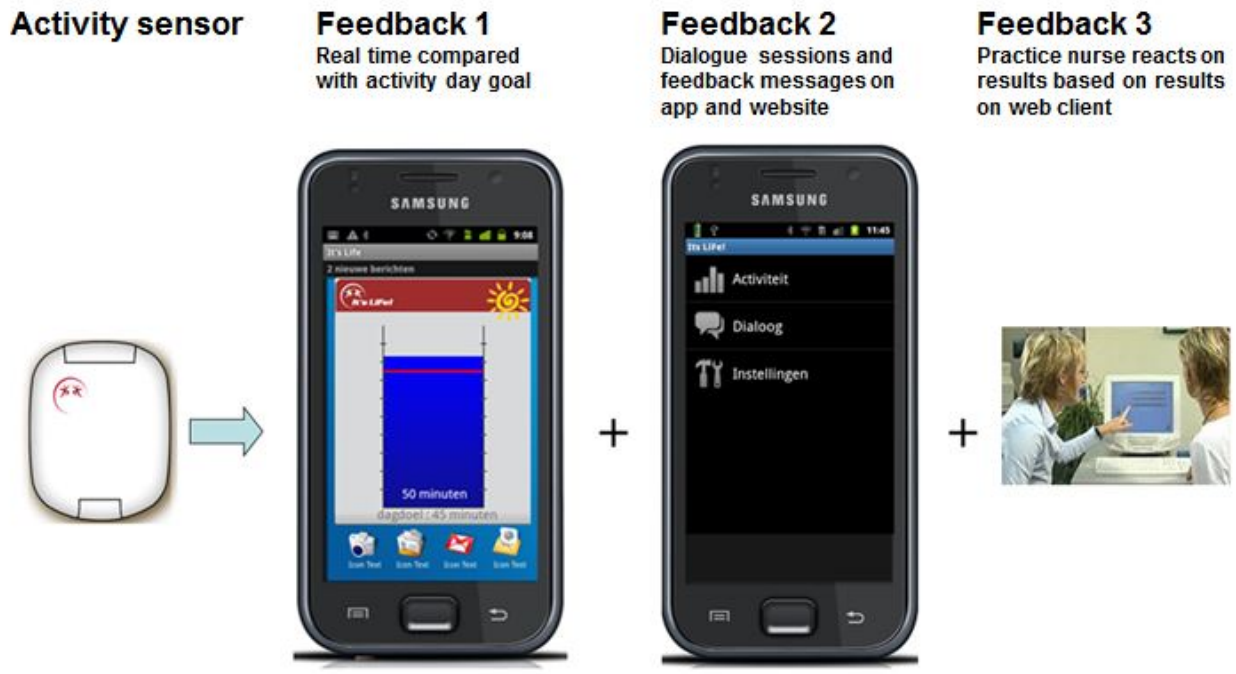
Table 3. Characteristics of respondents with DM2 from the interviews and focus groups.

	Interview round 1 (n=4)	Interview round 2 (n=4)	Focus group (n=5)
Age mean (SD)	61.5 (5.3)	62.8 (12.8)	56.8 (8.2)

Table 4. Characteristics of health professional respondents from the interviews and focus groups.

	Interview round 1 (n=11)	Interview round 2 (n=5)
Practice nurse	2	5
Diabetes nurse	2	0
Pulmonary nurse	2	0
General practitioner	3	0
Physiotherapist	2	0
Age mean (SD)	42 (11.5)	42 (11.8)

Figure 2. The monitoring and feedback tool that was developed, based on the requirements of the end-users. The tri-axial activity sensor is connected via Bluetooth to the smartphone. The smartphone gives directly visible feedback about the amount of activity in a bar chart, which dynamically fills up. When the goal (indicated by the red line) has been reached, a sun rises. In the app and on a secure webpage, people can see their activity history and answer dialogue sessions and read feedback messages generated by the system. The practice nurse can monitor the results of all patients on the secure web page to discuss during patient visits.



Tool Architecture

During the interviews, several requirements relevant for the activity sensor arose. The most important requirements were that it should measure all activities. The specific design was not important as long as it did not hinder movements or was obtrusive. For the location of the sensor, the hip and wrist were the most popular.

> *A place where it is not visible and does not hinder you. If you wear a wristwatch for example, people may ask you what it is. That is nice for the first few times, but after 13 times it is not. So something like a watch, but then for around your ankle. Or something around the belt that is always hidden.* [IR2, DM2, man, 60 years]

Only two respondents did not prefer a sensor on the hip, with the argument that it may be problematic for women wearing a dress and people doing many arm activities.

> *I think this is a man's idea, since a woman cannot wear this sensor when they wear a dress. And people with COPD GOLD 1 or 2 do not feel sick yet, so they will not wear an inelegant device.* [FG, COPD, female, 57 years]

Immediate feedback should be visible at a glance. Respondents preferred to receive feedback on a mobile phone, since it has a larger screen than an activity sensor and is more readily

accessible than a computer. For more comprehensive use, however, such as manual data entry and consulting activity histories, a computer was considered more feasible.

Consequences for Tool Architecture

Based on the results above, it was decided that the "It's LiFe!" tool would consist of three elements (presented in Figure 2):

1. An activity sensor with Bluetooth connectivity worn on the hip and clipped on the belt.
2. A smartphone with an app for mobile feedback.
3. A Web client for comprehensive feedback and data entry for patient and practice nurse.

The "It's LiFe!" activity sensor is a 3D accelerometer with a sample frequency of 25 Hz. This newly developed activity sensor (4.0 x 4.5 centimetre) is based on the Ciro Activity Monitor (CAM) also manufactured by Maastricht Instruments [46]. The validity of the sensor will be tested in a subsequent study on a treadmill and in free-living conditions. The smartphone and web client would be connected to a web server with facilities for data storage and feedback generation. Nearly all of the user requirements were met. For budget reasons, however, the activity sensor could not be made suitable for cycling and swimming. It was decided that the amount of swimming and cycling activities should be entered by the users manually. The final architecture of the activity sensor was chosen from two prototypes by the patient representatives.

Goal Setting

Patient respondents preferred to set their goals together with the practice nurse. This would prevent the under- or overestimation of their abilities. In general, daily goals were preferred since weekly goals lead to postponing activities. Some respondents with COPD, however, indicated that they feel different every day, so they did not like the idea of a static goal per day. Patients indicated that they preferred to be able to change the goal themselves because they do not see the health care professional often enough. However, changing goals should only be possible after a permissive message from the tool, to prevent downwards adjustments too easily.

Consequences for Goal Setting

Based on the results above, it was decided to set goals in a three-step process.

1. *Calibration*. During a two-week pre-measurement, the activity pattern of the users will be assessed, in order to set a realistic goal that is based on an objective measurement. In addition, the patient will receive questions (dialogue sessions) on the smartphone and website to identify which kind of activities the patient prefers and which barriers have to be overcome.
2. *Goal setting*. After the initial two weeks, the results of the pre-measurement will be evaluated by the practice nurse and discussed with the patient. Together, they will set an appropriate goal in minutes of moderate to vigorous physical activity per day. Appropriate means challenging, but within realistic margins, and personalized. Patients can adapt their goal themselves after a permissive message based on their activity results or by contacting the practice nurse.
3. *Activity planning*. Once at home, the patient will be invited by the tool to plan concrete daily activities to reach their goal. This will be facilitated by a dialogue session on the smartphone or on the website (at choice). This trigger to plan activities in detail (such as when, with whom and where you will be active) will narrow the gap between intention and behavior and make it more likely that the patient will reach the goal [47].

Feedback

There was consensus among respondents about how daily physical activity should be visualized on the smartphone. Activity performance should be set out against daily goals at any time. Performance data should be formatted as minutes of activity per day, rather than in calories (too complicated) or points (too abstract). Performance should be denoted in percentages of their goal, visualized in images, and color, but not using a childish animation. People did not state a preference to hear a sound when they reach their goal because it could interrupt them, could be noticed by others, and may become irritating. To monitor progress or decline, a historic overview of activity results over the last few months was deemed important. Some respondents indicated that they wanted to distinguish intensity rather than the type of activity (ie, sitting, biking, or swimming). Some respondents wanted to see a difference between moderately-intense and high-intensity activities, because this would stimulate them to do more high-intensity activities and they also wanted to receive more credits for those activities. Other respondents argued that they will feel the intensity themselves and that they will be happy to meet their goal anyway. This led to a lot of discussion during the focus groups and in the technical and research meetings. Another point of discussion was the choice between an absolute or relative threshold between the levels of intensity. Advocates of a relative threshold stated that everybody would experience high-intensity activities differently; for some chronically ill patients, a walking pace of 3 km per hour is exhausting, for others 5 km per hour is more appropriate. A relative threshold could be set per individual, based on a two week pre-measurement period. However, respondents with COPD also indicated that the difficulty of being active may differ from day to day.

> *Even for me, as an individual person, it is very hard to set a threshold. One day I am very fit, I exercise and nothing is wrong, the next day the ambulance is needed!* [FG, COPD, male, 65 years]

Everybody agreed that details about intensity need to be visible at a glance. Feedback messages from the server must be short, subtle, and positive in nature; without being paternalistic. Most respondents liked the idea that a health care professional could monitor their activity performance, because this would be an additional motivational factor. However, people thought they should also be able to make annotations to the activity data, in order to explain lower performance if one was sick (dyspnea), the weather was bad, etc.

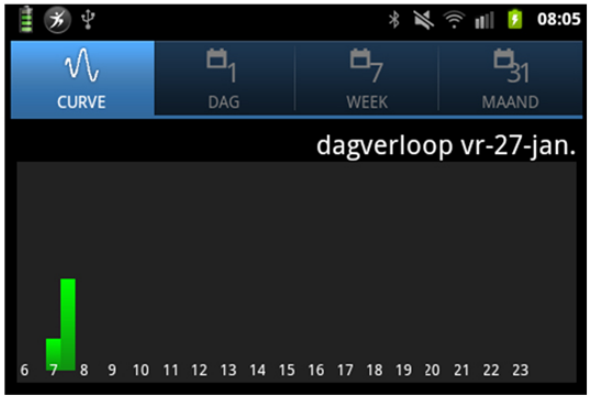
Yeah, I think if a health care professional can watch your results that it has a psychological effect. You don't want to disappoint the people who pay attention to you. [IR 1, DM2, female, 62 years]

Consequences for Feedback

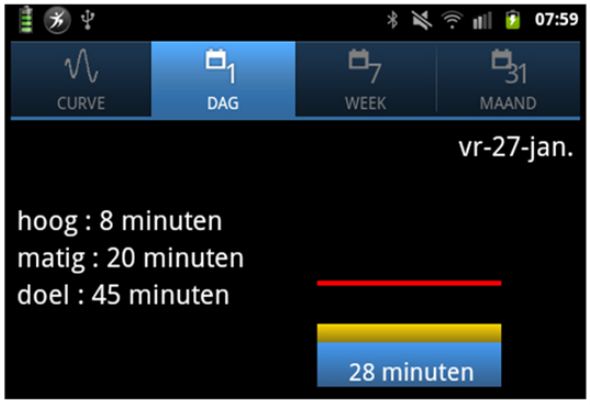
Based on the results above, it was decided that feedback will be given in 3 loops as already shown in Figure 2.

1. In the first loop, data is directly visible on a widget on the smartphone. In a bar diagram, realized activity in minutes (≥3 Mets) is compared with the daily goal (see Figure 2). When the daily goal has been reached, a sun becomes visible as a subtle reward (see Figure 2). In addition, when opening the app, historic activity data can be viewed; in minutes per day, aggregated in days, weeks or months, as well as distinguishing between moderate (3-5.9 Mets) and intense (≥ 6 Mets) activities (see Figure 3).
2. In the second loop, periodic feedback messages will be sent after 3, 5, or 14 days. Various messages will be used, depending on the progress of performance, such as encouragement, positive trends, rewards, and suggestions to overcome barriers or to adjust personal goals.
3. In the third loop, users will receive feedback from the practice nurse. This will happen after 2 to 3 months and after 6 months, when the patient visits the practice nurse to evaluate the results and discuss barriers and facilitators. In between consultations, the practice nurse can monitor the activity results and is free to choose whether to react to this or not.

Figure 3. Activity menu on the smartphone app. The blue part of the bars indicates the moderately intense activity in minutes; the yellow part denotes the high-intensity activities. The red line indicates the daily goal.

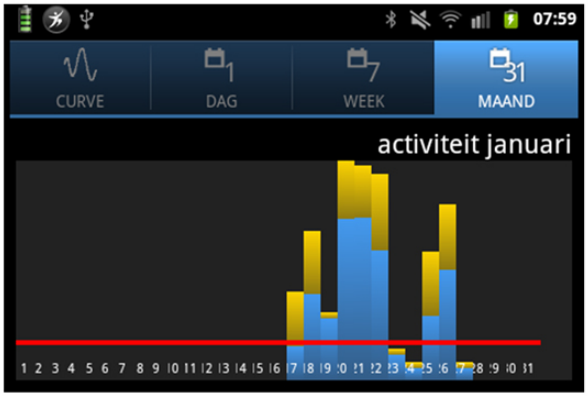


A. Day view per hour from 6am to 11pm



B. Day view. 'Hoog' is 'high'. 'matig' is 'moderate', 'doel' is 'goal', 'minuten' is 'minutes'.

C. Week view.



D. Month view.

Data Sharing

Although most respondents perceived peer support as being important, only a few respondents were willing to share their activity results with relatives or peers. (eg, on a forum or social network, such as Facebook or Twitter.)

Sharing results on the internet is not motivating because the data and people are anonymous. Mutual support in real life is. And then you can decide to go hiking together. [IR2, male, DM2, 60 years]

Consequences of Data Sharing

Activity data will only be shared with the practice nurse and not with peers. Sharing data through social media is not a priority. However, the involvement of relatives in the process of becoming more active will be encouraged in other ways.

Requirements of Health Care Professionals

Health care professionals admitted that they usually pay too little attention (approximately 10% of the consultation-time) to physical activity and that they welcome technological support to improve this. Most professionals viewed the tool as a mainly diagnostic instrument, since patients generally overestimate their level of physical activity. The activity pattern should be presented to them in time, intensity, steps, METS or calories, with aggregated information about the patients' adherence and goal attainment. For their own convenience, they preferred to consult activity data within their own patient information system.

Regarding goal setting, professionals agreed on setting a goal together with the patient. Goals should be flexible, personal, and comorbidities should be taken into account. There was little to no enthusiasm, however, about the idea of giving feedback to the patients themselves in between consultations. An alternative idea of automated feedback messages was more appreciated. Professionals agreed with the patients that feedback messages should be positive (with a smiley face or flower), short and clear, but not pedantic. Performance should be visualized in numbers and graphs, including visible trends.

Design Principles Concerning the Requirements of Health Care Professionals

Based on the information above, it was decided that practice nurses will have their own web client (The "It's LiFe!" Monitor) with two levels of information:

1. An overview window with aggregated information about the status of their patients' goals.
2. A detail window presenting activity minutes per day and results from dialogue sessions.

With this information, the practice nurse can better prepare the patient consultation and can estimate appropriate patients' goals more readily. The total physical activity counseling protocol will be published elsewhere. The integration with different patient information systems will not be realized during the "It's Life!" project.

Discussion

Principal Results

In this study, the UCD process of a monitoring and feedback tool to enhance the self-management of physical activity for patients with COPD or type-2 diabetes is described. The research team gathered the user requirements and an engineering team translated these into technical solutions, to avoid data gathering with presuppositions. This tool is designed to be combined with a self-management support program for embedding in primary care. It provides a combination of behavior change techniques to increase knowledge, awareness (by self-monitoring) and self-efficacy. Personal goals are set and personalized feedback is provided based on the degree of goal attainment. The user-centered development process gave insight into the wishes and needs of the end-users, which will increase the likelihood of success. The main requirements for the tool derived from this process were:

- An activity sensor placed on the hip that measures activity accurately.
- Goals set in collaboration with the practice nurse after a pre-measurement period, in minutes activity per day. Personalized goals tailor the tool to individual needs.
- Feedback provided at different levels: immediate feedback, visible on the smartphone as a percentage of their daily activity goal, or presented as an image and in color; periodic feedback messages, always given with positive verbal; and aggregated feedback to the nurse practitioner, which should be used during the patient consultations.
- Activity data sharing with a care professional, not with peers on a forum or social media.
- An opportunity, for the patient to make annotations to their activity pattern.

Both end-user groups did not agree on all requirements. Patients want support from the practice nurse in between consultations, while care providers indicated that this is unmanageable due to time constraints. Therefore, automated feedback was incorporated to fulfill the need of patients of extra support. This makes it more suitable for daily practice in primary care. Most respondents were not open for sharing activity data on social media this may be influenced by the age of this group. The monitoring and feedback tool should be prepared for changes in this attitude.

Limitations

A convenient sample of people with COPD or type-2 diabetes and health care professionals was used. Those who were interested in issues related to physical activity and/or technology may have been more likely to participate compared with others. Consequently, the study may have a self-selection bias. On the other hand, credibility [48] was increased by involving patient representatives in the research team in all decisions, and by the use of multiple data collection methods. Reliability was ensured by investigator triangulation, since the interviews were held by two different researchers and multiple researchers were involved in the analysis and the interpretation of data.

Other limitations included contextual restraints, such as budget, time, and the capabilities of technology in general and the engineering team. This led to some concessions, such as an activity sensor which is not waterproof, which mean there could be no registration of activity during swimming. Furthermore an activity sensor worn on the hip, is not able to register cycling. This may cause frustration among users that spend considerable time on these activities. It may also discourage users from developing these activities. The possibility to make annotations should compensate for this limitation.

Comparison With Prior Work

Prior work has documented the effectiveness of pedometers to increase physical activity [16-18]. However, these were all short-term studies. It is unknown to what extent these changes are sustainable, since pedometers are still not routinely used in health care. An exceptional feature of our tool is the automated connection to the primary care professional via a secure website. Furthermore, the tool is embedded in a support program which is carefully aligned and simultaneously developed with the tool.

Patients in this study indicated that the combination with coaching from the health care professional is a benefit, since health care professionals can serve as an extra motivator.

In this study, we developed a monitoring and feedback system in an iterative process inclusive of patients and health care professionals, to enhance the likelihood of success. While this study was conducted, a framework was published to improve the uptake and impact of eHealth technologies [49]. This framework, which is based on an extensive review, confirms the importance of end-users' participation and an iterative development process. Furthermore, this framework emphasizes the importance of taking the conditions for implementation into account during the development process. In this study, this was achieved by involving health care professionals in the project and also by developing a self-management support program for the tool, which describes how the health care professional can support the patient.

The final design of the monitoring and feedback tool is in agreement with the proposed design strategies from Consolvo for technologies that support behavior change [50]. These strategies are based on the experiences from three persuasive technology interventions: Breakaway [51], Fish 'n' Steps [52] and Houston [23]. Consolvo's 8 proposed strategies are: (1) Abstract & Reflective, (2) Unobtrusive, (3) Public, (4) Aesthetic, (5) Positive, (6) Controllable, (7) Trending/Historical, and (8) Comprehensive**.**

In addition, the developed tool, together with the self-management support program, is in line with Fogg's theory of persuasive technology. According to Fogg, an intervention to change people's behavior should focus on ability and motivation and provide a trigger to change [53]. Our intervention targets people who have the motivation to change their behavior but have not previously managed to do so. The self-monitoring tool makes people aware of their inactivity, which can lead to further motivation. The patient's abilities are taken into account in the dialogue sessions, personal goals, and support from the practice nurse. In addition, our intervention provides a trigger to act by delivering feedback on physical activity on a timely basis and in an actionable format, namely related to tangible personal goals.

Conclusions

In this paper, the development process of a monitoring and feedback tool is described as the preparation of an intervention to support the self-management of physical activity. It illustrates how a user-centered approach allows the consideration of valuable details to make the fit between the user, technology, and organization of care, which is important for the usability and acceptability of the tool. The leading principle of this intervention is to change behavior by self-monitoring, goal-setting, and feedback. The tool connects three technologies: an accelerometer, a smartphone app, and an Internet application. Feedback is given in three loops: direct feedback on daily activity compared with personal targets, periodic feedback on historical performance, and personal feedback by the practice nurse during consultations.

Having followed a user-centered design, we expect that the usability and acceptability of the tool has increased. This will be tested in a usability study in a lab environment and a pilot study in two general practices. The effect of the final tool embedded in primary care will be evaluated in a cluster randomized controlled trial.

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Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

Results of three rounds of information gathering revealed from people with COPD or type 2 diabetes in stage 3, illustrating the dynamic specification process of requirements.

[PDF File (Adobe PDF File), 9KB - mhealth_v1i1e8_app1.pdf]

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Abbreviations

azM/Um: Univeristy Hospital Maastricht/Maastricht University
CAM: Ciro Activity Monitor
COPD: chronic obstructive pulmonary disease
DM2: type-2 diabetes
FG: focus group
IR1: interview round 1
IR2: interview round 2
NWO: The Netherlands Organization for Scientific Research
UCD: user-centered design
SSP: Self-management Support Program
ZonMw: The Netherlands Organization for Health Research and Development

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Original Paper

The Architecture of an Automatic eHealth Platform With Mobile Client for Cerebrovascular Disease Detection

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Abstract

Background: In recent years, cerebrovascular disease has been the leading cause of death and adult disability in the world. This study describes an efficient approach to detect cerebrovascular disease.

Objective: In order to improve cerebrovascular treatment, prevention, and care, an automatic cerebrovascular disease detection eHealth platform is designed and studied.

Methods: We designed an automatic eHealth platform for cerebrovascular disease detection with a four-level architecture: object control layer, data transmission layer, service supporting layer, and application service layer. The platform has eight main functions: cerebrovascular database management, preprocessing of cerebral image data, image viewing and adjustment model, image cropping compression and measurement, cerebrovascular segmentation, 3-dimensional cerebrovascular reconstruction, cerebrovascular rendering, cerebrovascular virtual endoscope, and automatic detection. Several key technologies were employed for the implementation of the platform. The anisotropic diffusion model was used to reduce the noise. Statistics segmentation with Gaussian-Markov random field model (G-MRF) and Stochastic Estimation Maximization (SEM) parameter estimation method were used to realize the cerebrovascular segmentation. Ball B-Spline curve was proposed to model the cerebral blood vessels. Compute unified device architecture (CUDA) based on ray-casting volume rendering presented by curvature enhancement and boundary enhancement were used to realize the volume rendering model. We implemented the platform with a network client and mobile phone client to fit different users.

Results: The implemented platform is running on a common personal computer. Experiments on 32 patients' brain computed tomography data or brain magnetic resonance imaging data stored in the system verified the feasibility and validity of each model we proposed. The platform is partly used in the cranial nerve surgery of the First Hospital Affiliated to the General Hospital of People's Liberation Army and radiology of Beijing Navy General Hospital. At the same time it also gets some applications in medical imaging specialty teaching of Tianjin Medical University. The application results have also been validated by our neurosurgeon and radiologist.

Conclusions: The platform appears beneficial in diagnosis of the cerebrovascular disease. The long-term benefits and additional applications of this technology warrant further study. The research built a diagnosis and treatment platform of the human tissue with complex geometry and topology such as brain vessel based on the Internet of things.

(JMIR Mhealth Uhealth 2013;1(2):e20) doi:10.2196/mhealth.2550

KEYWORDS

cerebrovascular; eHealth platform; Ball B-Spline; statistical segmentation; volume rendering

Introduction

Background

Cerebrovascular disease is the number one threat to people's health, especially for people over the age of 50. Statistics indicate that as many as 15 million people die from cerebrovascular disease every year worldwide [1]. Cerebrovascular disease is characterized with long latency, quick onset, intense demand of timely rescue, and long follow-up treatment time. China is a big county with a large population and vast geographical areas. If the government depends solely on the traditional center hospital mode to diagnose and prevent the cerebrovascular diseases, it would result in heavy burdens on hospitals and increase difficulty on patients to see doctors. Development of medical imaging technologies, ultrasound, computed tomography angiography (CTA), magnetic resonance angiography (MRA), and 3-dimensional (3D) rotational angiography (3DRA) have achieved higher precision and lower cost on cerebrovascular disease imaging. By using the general medical image, we can extract the cerebrovascular area. This technology is easily accepted by people because it is non-invasive, efficient, and has no side effects. Brain scans have become part of the routine physical examination for employees in China every year. As a result, every worker has accumulated a lot of image data from computed tomography (CT) or magnetic resonance imaging (MRI) scans. Our platform is constructed with efficient use of these data, which can achieve cerebrovascular automatic query, segmentation, reconstruction, testing, and evaluation. The platform can combine information technology and cerebral medical technology to promote the development of eHealth technology and create the new situation of the brain medical care in China.

The Internet of Things and Platform Design

Professor Kevin Ashton proposed the concept of the Internet of things (IOT) first. The basic idea of this concept is the pervasive presence around us of a variety of things or objects, such as radio frequency identification devices (RFID), tags, sensors, actuators, mobile phones, etc. Through unique addressing schemes, they are able to interact with each other and cooperate with their neighbors to reach common goals [2]. RFID technology and sensor technology are applied to everyday objects to form "the Internet of things". Facing the problem of cerebrovascular disease, the application of the Internet of things in the medical field can realize the monitoring of severe patients, daily health care of ordinary users, detailed analysis of the popularity of cerebrovascular disease, and in depth teaching about cerebrovascular disease in the medical school. Traditional cerebrovascular detection and analysis of brain tissue image sequences rely on the CT or MRI machine. Doctors observe the instrument screen image or film by eye to determine cerebral vascular disease with high subjectivity and poor spatiality. In addition, cerebral blood vessels make up a low proportion (<5%) of the brain tissue. Using the manual method to extract the region of interest has some unexpected results, such as incomplete area, unreachable viewpoint, fatty tissue scattered points affecting the observations and so on. At the same time, the observers must rely on graphics workstations connected with the CT or MRI.

In 2005, the conference of Asia Pacific Electronic Health held in China launched domestic research in applications of the Internet of things in medicine. In 2006, the national 863 special project carried out telecommunication network, television network and computer network (3NET) fusion of electronic health information systems research. In 2009, the research group conducted a preliminary trial in ChangNing, Shanghai for the electronic case and health care combining with the phone, television, and Internet [3]. Now, the eHealth platform of IOT is mainly used in health care (eg, alcohol dependence [4] and personal health record [5]), disease recovery (eg, cardiac rehabilitation [6,7]), and social public domain (eg, impact disease detection [8], psychological health intervention [9], cancer detection [10], and the vicious epidemic monitoring [11]). Before the research on the Internet of things was applied in the medical field, some electronic application platforms of vascular diseases had existed, but most of them were facing virtual operation and virtual endoscope with a single computer, which worked mainly for the services of the central hospital. Correlation studies on vascular virtual operations such as the CathSimsystem [12], CathI heart operation system [13], and the NeuroCathsy system Singapore [14] mainly focused on model construction and force feedback calculation in virtual operation. Since then, other important works have been done linking vascular diseases with IOT, such as monitoring the heart disease [15] and the retinal vessel detection [16]. These platforms currently do not completely use all the available data. The development history of domestic cerebrovascular health platform of cerebral vessels indicate that platforms are mostly used in the primary application areas of electronic health for the processing and remote transmission of electronic case, doctors' offsite health information, and the popularization of health knowledge, but it is less used in the human abnormal detection and the development of chronic disease. The current domestic cerebrovascular health platform is limited to use by technically trained staff in the hospital. Our platform is designed such that anyone can use it. Our platform combined computer technology with the medical imaging technology to detect and analyze cerebral vessels. It can extend the virtual display and medical assistance advisory services to the model analysis and quantitative calculation, achieving wider application through the Internet media.

This paper is organized as follows. In the Methods section, we illustrate the level architecture of the platform in our work and describe the 8 main functions of the platform in detail. The client part of the platform will also be illustrated in this section. We then present our results on clinical datasets and give the analyses.

Methods

System Platform Design

The architecture of what has been accepted as the Internet of things still follows the traditional network architecture. It is divided into three levels [17]: (1) generalization perception network, (2) communication infrastructure of integration network, and (3) the supporting system of pervasive application service. These are usually simply referred to as the perception layer, network layer, and application layer. The eHealth platform in this paper adopts the 4 layer-platform architecture proposed by Professor Ma Huadong [18](Figure 1): (1) object control layer, (2) data transmission layer, (3) service supporting layer, and (4) application service layer.

Based on this framework, we realized the extended application facing the cerebral vascular medicine. The object control layer achieves the physical object perception and data acquisition, including various tests identified by the RFID, sensor nodes of widespread deployment, the wireless sensor network, a remote digital imaging and communications in medicine (DICOM) data transmission, and a variety of test data provided by the natural human and examination center. Data transmission layer provides the transparent information transmission through various cable networks and wireless networks. Service supporting layer mainly provides the intelligent processing of the data acquisition from the network and service-applying platform, including intelligent server management and cloud computing platform. Application service layer provides service by transmitting the information to the content. The server based on the cloud platform is the core part of the system, which completes the basic functions of the system. The client offers the doctor user interface and the common user interface. Brain image data of the common user obtained from center hospital and medical center is transmitted to medical server platform through the network. The server finishes the data storage and reconstruction of cerebral vascular. It can also make the reconstruction results and automatic detection results feedback to the common user through the network. The doctor browses the patient information through the login interface, which can also provide diagnostic information and fuse the system diagnosis result to send back to the common user. The user can use the mobile phone to query brain image data to finish the automatic detection of cerebral vascular health, and receive the diagnosis and treatment recommendations given by the doctor to realize remote independent medical service. Unlike the traditional remote diagnosis system, the main evaluation means and diagnosis method of this system are relying on the system itself instead of the direct judgment of the doctor. The whole platform is an automatic system. The brain vessel can be segmented, reconstructed by the platform automatically, and the suspicious region of cerebrovascular disease can also automatically be detected by the system. Because the doctor only needs to provide the corresponding aid support, this greatly reduces the workload of doctors and develops the application degree of the system.

It can be found that the main work associated with cerebrovascular disease is realized at the application service layer. The system function structure is shown in Figure 2. The overall frame can be summarized as 4 layers and 6 databases. The implementation scheme includes 5 steps. The 4 layers are the data support layer, the basic technology layer, the service technology layer, and the application system layer. The six databases are the original image database, the normalized volume database, the vascular lesions model database, the center line of blood vessels model database, the brain vessel model database, and the physiological anatomy knowledge database.

The main flow of the 5 steps is as follows:

1. Construction of image database. CT or MRI cerebral images containing basic information of the patient are obtained from the hospital and medical center. After denoising and normalization, the raw data can be used to construct the normalized body database to facilitate subsequent processing.
2. Brain vascular segmentation model. The segmentation of the point cloud model, the geometric model of brain vessel data, and segment brain vessel tissue are realized through the statistical method.
3. Construction of cerebrovascular model. The cerebrovascular skeleton is extracted based on the cerebrovascular point cloud data, and calculate radius of cerebral vessel. The Ball B-spline is used to reconstruct the brain vessel. At last, the brain vessel model and reconstruction model are imported into the database to provide the prior knowledge for the segmentation.
4. Rendering of cerebrovascular model. Graphics processing unit (GPU) compute unified device architecture (CUDA) allows for real-time and accelerated rendering, while fuse surface rendering and volume rendering finishes the mixed rendering of hierarchical model.
5. Cerebrovascular virtual wandering and lesions automatic detection. The model database and prior knowledge database are combined to realize the automatic tagging of organs. The suspicious lesions can be confirmed as below based on the physical parameters of organs according to the organization intensity, shape information, and prior knowledge to carry out the electronic biopsy. Auxiliary detection and analysis of lesions is designed with volume of interest (VOI) enhance analysis, realize focal and quantitative analysis through a variety of means. The rapid positioning and the navigation of target area can be determined by the prior knowledge automatically, and the corresponding path is established to facilitate intra operative real-time navigation. The comparison between the preoperative and postoperative is evaluation of the focal change before and after surgery through the registration between the prior model and the segmentation or reconstruction results.

This system adopts the Client/Server (C/S) structure based on ASP.NET platform, which uses the AJAX technology, SQL Server 2008 database management system, and ADO.NET database access technology. The front-end JS framework and corresponding components adopt Ext and the server is coded using Visual Studio 2005.

Figure 1. The hierarchy of the Internet of things eHealth platform about cerebrovascular treatment.

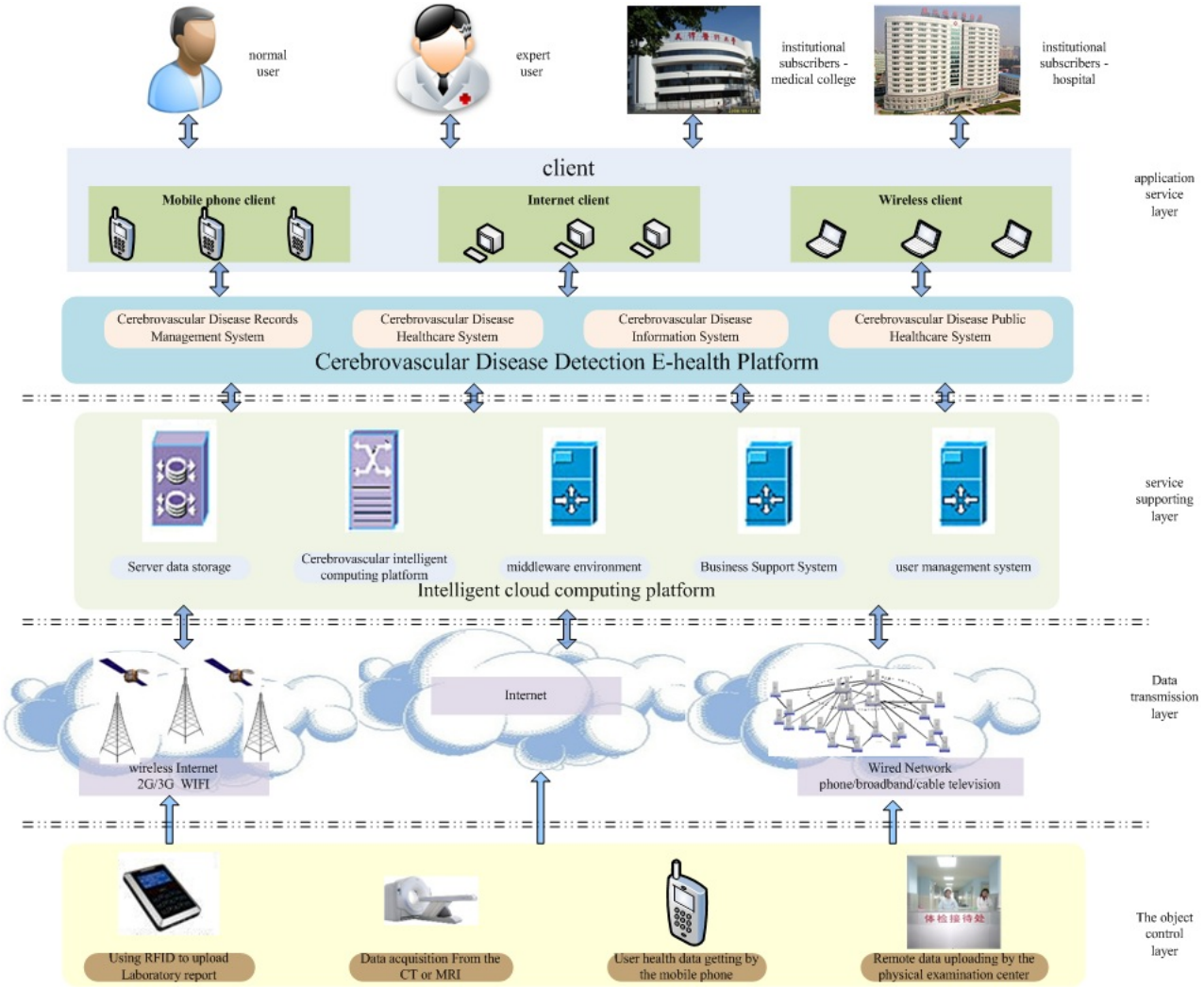
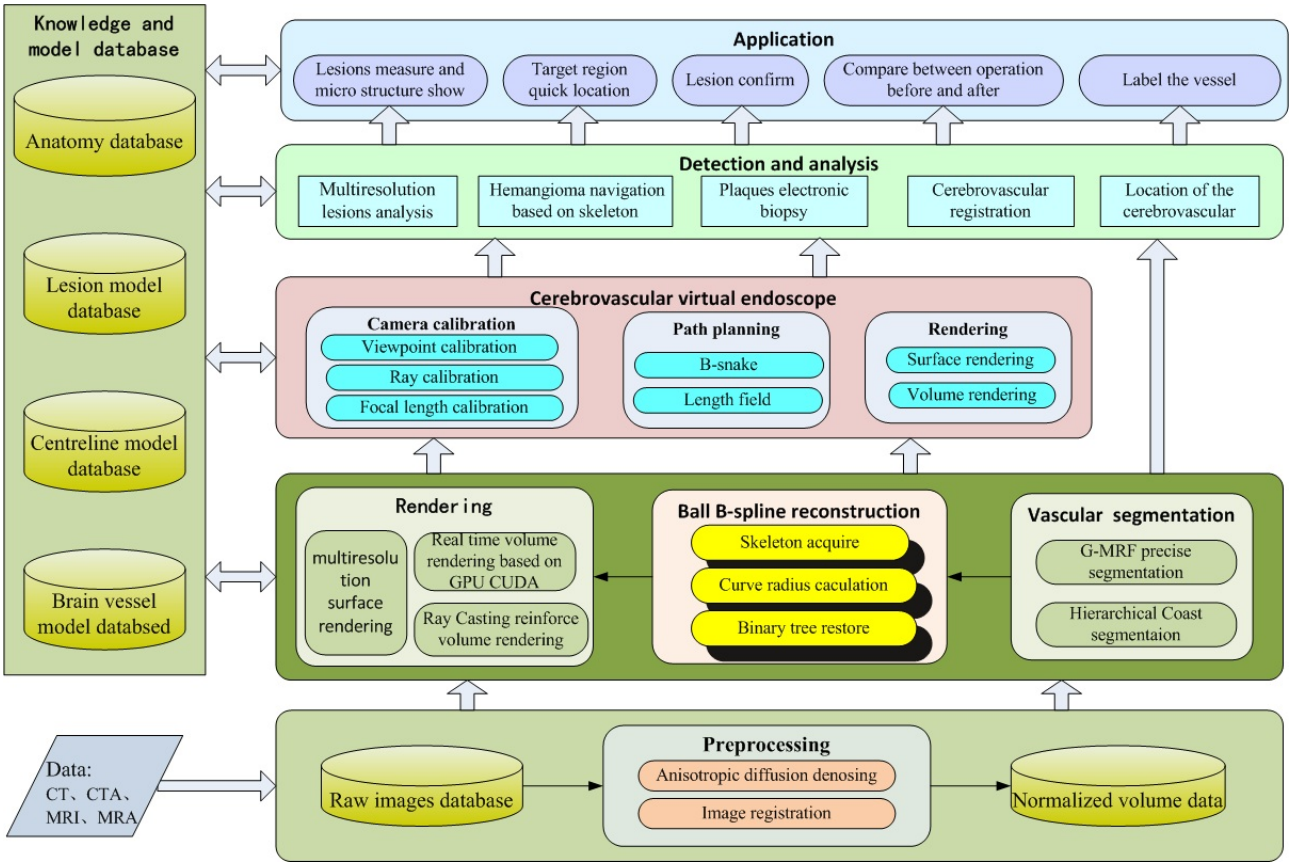


Figure 2. The function structure of medical service platform about cerebrovascular disease.



The Main Functions of Cerebrovascular Disease Detection eHealth Platform

The server adopts ASP.NET to provide WEB services through building the .NET platform and uses ADO.NET to realize the persistence of access layer. It can obtain more precise OOP features to use the .NET platform, such as inheritance, encapsulation, and reflection. At the same time, .NET provides many powerful functions components, improves the speed of development and enhances the stability and correctness of the system. In addition, the .NET platform can improve the manageability, availability, safety, and other aspects of the overall system. In addition, the powerful visual studio is used to develop the system in order to obtain a more efficient development process.

Whole Introduction of Server System Functions

The system at the server is used for the segmentation and reconstruction of cerebral CT and MRI image, which mainly adopts the statistical algorithm to finish cerebral vascular segmentation and the method of B-spline surface for the reconstruction of vessels. Methods of volume rendering and surface rendering are used to display the results after segmentation and reconstruction, and the virtual endoscope is used to achieve automatic detection of cerebral vascular diseases. In addition, the platform can realize the transformation between DICOM, raw, and BMP data. The overall characteristics of the system are: (1) processing many kinds of common data structure (raw, DICOM, BMP etc), (2) using a variety of segmentation methods to make the segmentation results accurate and effective, (3) powerful ability of user interaction, (4) friendly interface, convenient operation, (5) choosing a variety of display strategies and comparing the visual effects, (6) strong practicability and the results of every step can be viewed in real-time.

Cerebrovascular Database Management

MRI and CT imaging equipments are used to realize the data acquisition and the data of this part is mainly obtained from picture archiving and communication system(PACS) and examination center of hospital. In Figure 3, the visual database management module is divided into two subsystems, the data management and database security management. Combined with a relational database management system, all kinds of data involved in the study are organized and managed. This module contains three major functions: function of database link, function of data management, and function of database security management. The data involved in this project mainly includes: the 2-dimensional (2D) original medical image data, the 2D medical image data after preprocessing, data of cerebral vascular segmentation model, data of cerebral vascular skeleton, data of cerebral vascular remodeling model (Ball B-spline data) as well as basic attribute information data of the basic personal. Database link function mainly completes the link and disconnection operation of front interface and the backstage database. The login password management is involved in implementation. The function of database security management includes: add, delete, and modify the role; user information and user permissions; modification of personal information; information view of all users; and journal management. At the same time, cerebral vessel data management system based on relational database and the generalized system of safety

certification are established. Data flow chart of data management system is shown in Figure 4.

Preprocessing of Brain Image Data

Since brain images are affected by acquisition equipment, acquisition environment, sports of acquisition object, and the transmission process, a lot of noise will be produced, which directly affects the image quality and is extremely easy to cause the error analysis and error segmentation results of blood vessels. Therefore, the denoising, enhancement, and standardization of the cerebral image are the foundation for further analysis and processing. There is a lot of Gauss noise and random noise in cerebral images, so filtering image to reduce the interference of noise is a very common strategy, which is mainly divided into spatial filtering and frequency domain filtering. A hierarchical noise reduction processing method is used to achieve progressive process of 3D image sequences. In the processing of low order noise reduction, the template method is mainly used, where the directional weighted median (DWM) filter to remove the random impulse noise, and the Gauss template to remove other noise. In the processing of higher order noise reduction, the multi-scale method and the anisotropic diffusion method [19] is used, which can better maintain the vessel edge while removing noise. At the same time, Laplace sharpening is used in the images to highlight the edge of brain image. Robert operator is used to extract the edge of the scalp in the brain image, because the brain skeleton is fixed and the epidermis only has slight deformation, which can be regarded as rigid body. The method based on the edge feature can realize the brain image registration and interpolation normalization. The accuracy of subsequent processing would be improved. Figure 5 is the result after second order noise reduction on the 110th picture of example data. After first order Gaussian filter and DWM filter and second order anisotropic diffusion filter, the difference between two images is not obvious. The red lines are the 248th line of 110th image of example data. Figure 6 is the comparison chart of pixel intensity distribution in the same line position (red) between the original image and the corresponding picture after anisotropic diffusion filter. The intensity distribution of original image is shown with blue curve, and the intensity distribution after the anisotropic diffusion is shown with red curve, where x-axis represents the distance between the current pixel and left starting point on red line, y-axis represents the intensity value after intensity value of current pixel mapped (divided by 928) to [0,1] according to the intensity maximum. It can be seen in large gradient area of blue curve (the upper and lower steep slope section of curve, namely the picture boundary location), red curve appropriately retained the big wave crest and big wave trough of the blue curve. In the area shown by the blue curve where the intensity is flat, red curve showed obvious smooth processing. This shows that the hierarchical noise reduction processing method remove the noise and at the same time keeps the detailed information of edge.

Figure 3. Platform of database management.

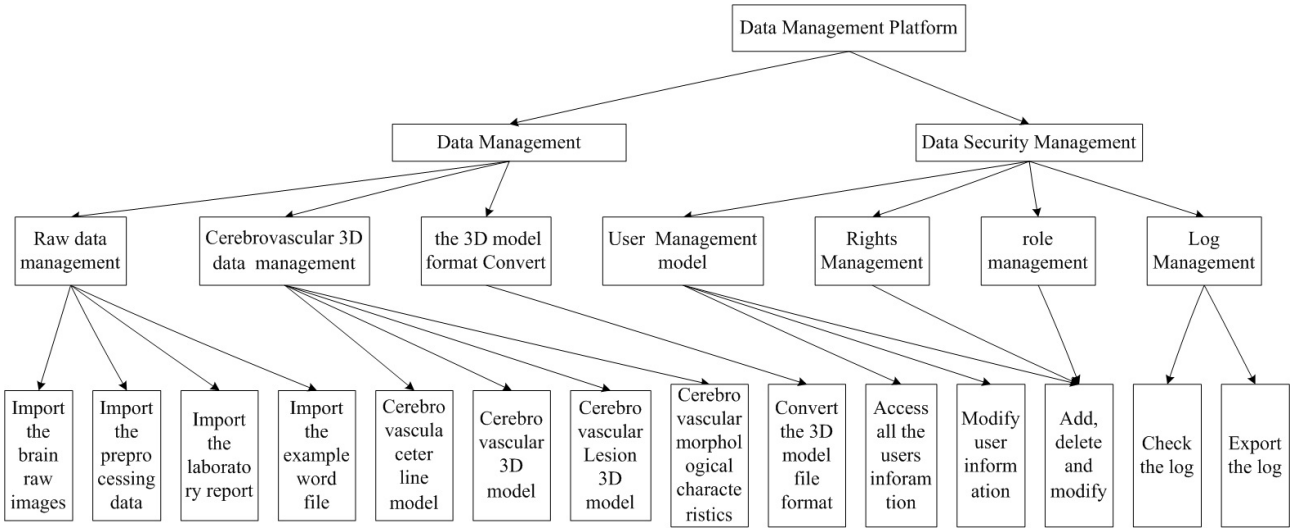


Figure 4. Data flow diagram of database management.

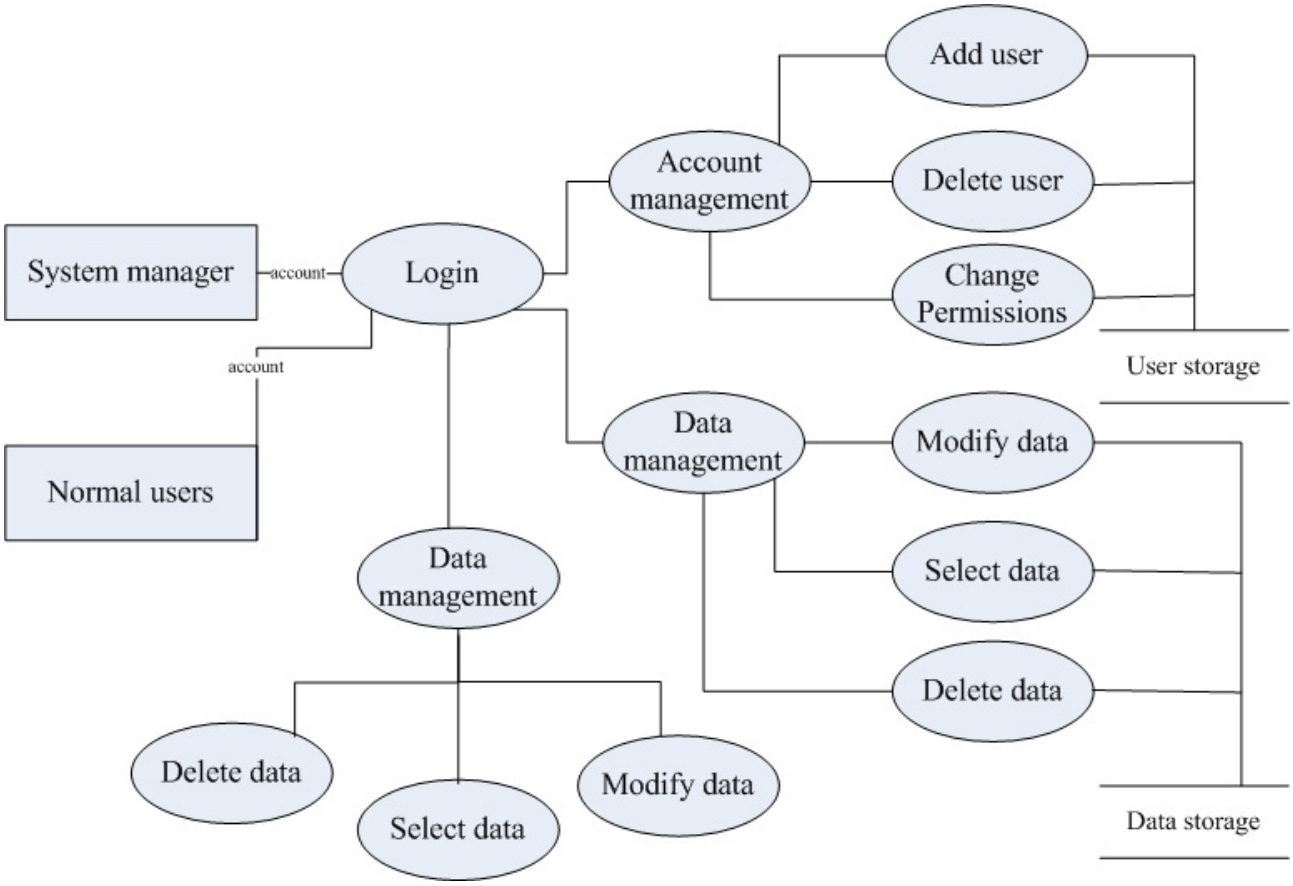


Figure 5. Level noise reduction. Left: Original image; right: Anisotropic diffusion result.

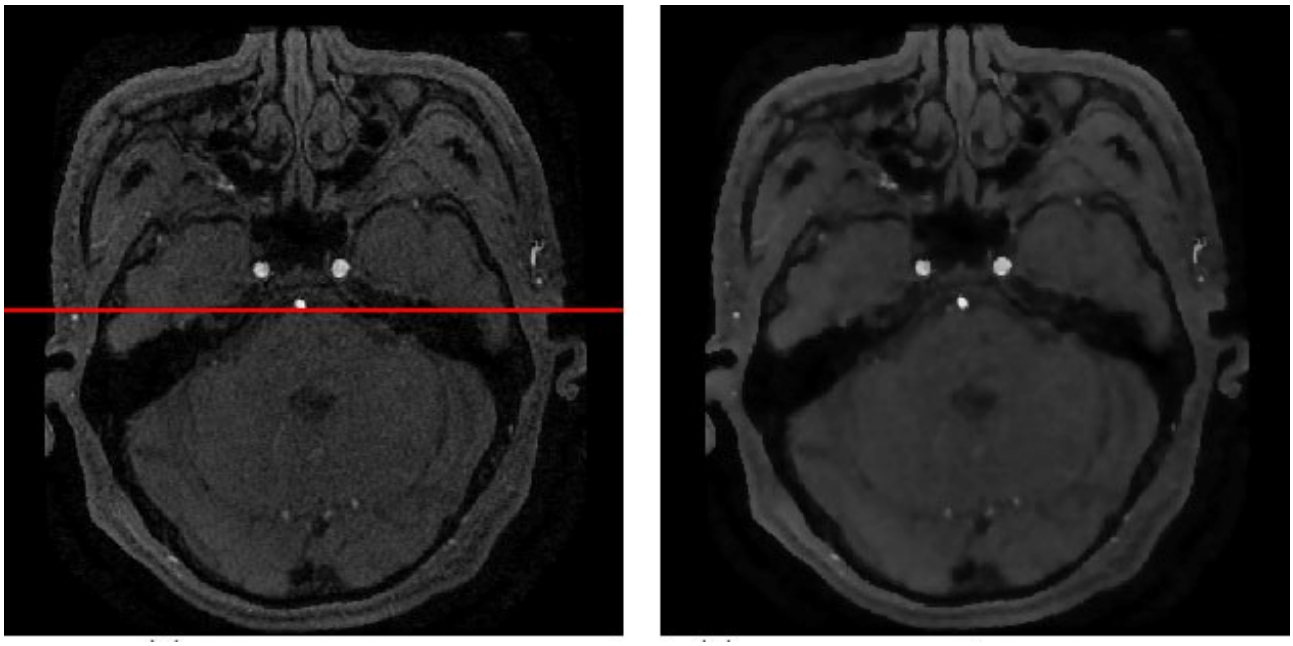


Figure 6. Intensity contrast of images before and after anisotropic diffusion.

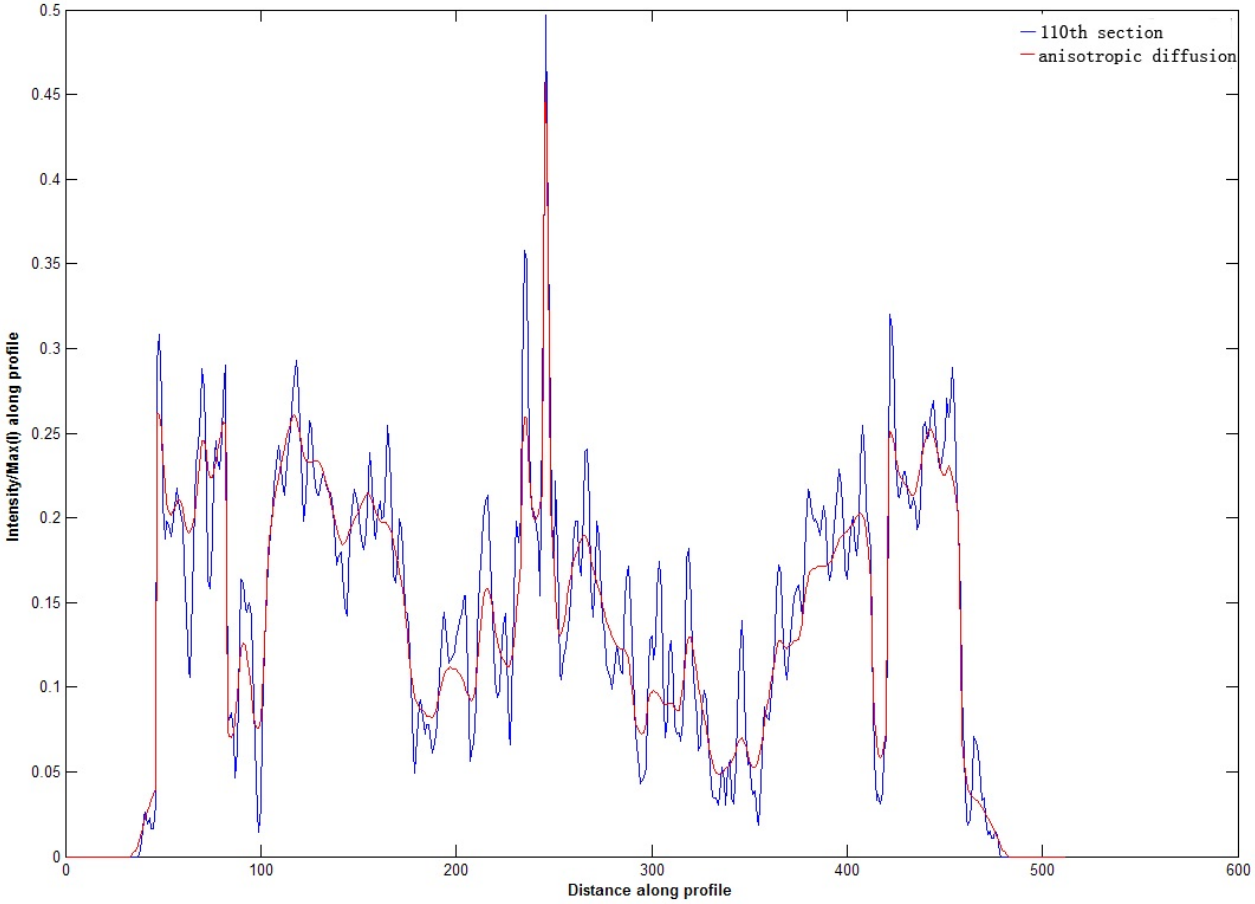


Image Viewing and Adjustment of Window Width and Window Level

CT and MRI image can display the distribution of some physical quantity in space. CT shows the distribution of intensity information, while MRI obtains the electromagnetic signal from human body. The human tissue CT values range from −1000 to +1000, which is a total of 2000 degrees, but the resolution of the MRI is lower than CT. The human eye can only distinguish 16 intensity levels, so if all the degrees are shown, only a small part can be recognized by human eye, which will lose a lot of details. In order to improve the details of the organizational structure displayed and distinguish two tissues whose difference is small, we need to adjust the contrast and the display range of the image. Therefore, cerebral vessels will be better displayed through the adjustment of window width and window level. The window width is the display range of the CT or MRI image. The organizational structure in this range is divided into 16 degrees (intensity) from white to black according to the values of physical quantity acquired. Window level refers to the average value of window width in the CT or MRI image. Because CT (MRI) values of different tissues are different, the best choice to observe the fine structure of the CT or MRI image is to choose the CT (MRI) value of the organization as the center to scan, and this center is set to the window level. So the contrast is strong and resolution intensity is close to the organization or structure. When we see the image through the default window width and window level, the image often looks fuzzy, but we can see the cerebral vessels clearer by adjusting the window width and window level.

Image Cropping, Compression, and Measurement

Either CT data or MRI data of cerebral image is usually large images. A lot of useless data of cerebral image occupy more memory of the system, which is time consuming. In order to get better region of interest (ROI) presentation, we can appropriately crop and compress images to improve the processing speed while ensuring the effect. At the same time, we need to measure the image in order to obtain some parameters of the image. Image processing functions of visualization toolkit (VTK) are used to achieve image cropping, compression, and measuring. Display of 3D data requires the establishment of space coordinate system. When data are cut, since the target result is still a cube, we choose the two peaks of body diagonal, which can be easily used to calculate other peaks of the cube. The image cropping is completed by excluding the points out of the cube. Image compression first requires that the 3D compression ratio be set artificially and to filter the points according to the proportion, such as setting the ratio 4 at the axial direction, and then at this direction we can choose one in each 4 points (up, down, left, and right). Image measurement obtains the coordinates, length, angle, and other basic information by using the measurement tools provided by VTK. The appropriate data cutting and compression can enhance the image and speed up the image processing.

Brain Vascular Segmentation

The cerebral vascular image acquired is often about the whole brain, but only the vessel part should be used to realize the feature extraction and target recognition. Thus, the segmentation of cerebral vessel is the basis for the further work. The system platform needs network transmission to guarantee the amount of calculation and . The existing cerebrovascular automatic detection eHealth platform was designed mainly for the patients, and the interaction of setting the right initial seed points and defining contour model and the curve evolution equation requires more medical knowledge, so it obviously does not suit the requirements. Instead, the statistical model method without manually inputting the parameters and the initial position is suitable for our platform [20,21].

An automatic statistical approach based on the Gaussian-Markov Random Field Model (G-MRF) is employed. The voxels are classified as either blood vessels or background noise by a finite mixture of two Gaussian distributions. 3D MRF is employed to improve precision and those parameters are estimated by the Stochastic Estimation Maximization (SEM) algorithm, which converges to the true likelihood under a large lattice. The MRF field embeds the spatial neighborhood information to the parameters statistical model and increases regional morphology information in the gray statistic information. With this method, more three-level brain vessels can be achieved. The cerebral vascular segmentation algorithm based on SEM hybrid model solves the traditional slow convergence and local minimum problem of expectation maximum (EM) algorithm. From Figures 7 and 8, compared with double Gauss model [22], our algorithm can effectively segment the main branch and the surrounding smaller branches of brain vessel, and its convergence speed improves greatly than the traditional EM algorithm.

3D Cerebrovascular Model Based on Ball B-Spline Curve

Ball B-Spline Curves (BBSC) [23] are skeletons based on the parametric solid model, which are particularly suitable for representation of tubular shapes. They can be viewed as the extensions of B-Spline Curves from which many properties are inherited [24].

A ball is defined in equation (1) in Figure 9. Here c is the center of the ball and r is the radius. $N_{i,p}(t)$ is the i-th B-Spline basis of degree p with knot vector equation (2) in Figure 9. The ball B-Spline Curve is defined in equation (3), Figure 9, where P_i is called control point, r_i is called control radius. The number of control points, the dimensionality of the knot vector and the degree p are not independent, they satisfy equation (4) (Figure 9), so a Ball B-Spline Curve can be viewed as two parts, the center curve (or skeleton; equation (5), Figure 9), a 3D B-Spline curve, and the radius function equation (6) in Figure 9, a B-Spline scalar function. Owing to the perfect symmetry property of balls, the curve $C(t)$ constructed from the centers of balls is exactly the skeleton of the 3D region represented by the BBSC.

Ball B-Spline modeling methods are very similar to those of B-Spline. Interpolation, approximation, and deformation, which are typical modeling methods in B-Spline, can be easily extended to BBSC by applying algorithms of B-Spline curve and function to the center curve and the radius function of BBSC respectively. When a series of points $\{Q_i\}$, i=0,…,m on the central curve and their corresponding radius $\{R_i\}$ are given, a BBSC whose center curve passes these data points $\{Q_i\}$ and whose maximum radius is $\{R_i\}$ can be obtained by interpolation. In order to obtain BBSC interpolation, we used the B-Spline interpolation method to interpolate the center curve, as well as B-Spline scalar function method to interpolate the radius respectively. Other methods can be implemented similarly. For more properties and algorithms about BBSC, please refer to [23,24]. The dataset size of cerebrovascular model based on Ball B-Spline Curve is far smaller than triangle mesh, point cloud, and other representations when representing a 3D tubular object. Typically, the size of medical image data of one patient is tens or hundreds of megabytes. The BBSC model, which only costs several kilobytes space for a patient's data, is an excellent way to store and transmit data in telemedicine, and suitable for our eHealth platform. The reconstruction results are shown in Figure 10.

Figure 7. Comparison of G - MRF and double Gaussian model segmentation result. Left: G - MRF segmentation result; right: double Gaussian model segmentation result.

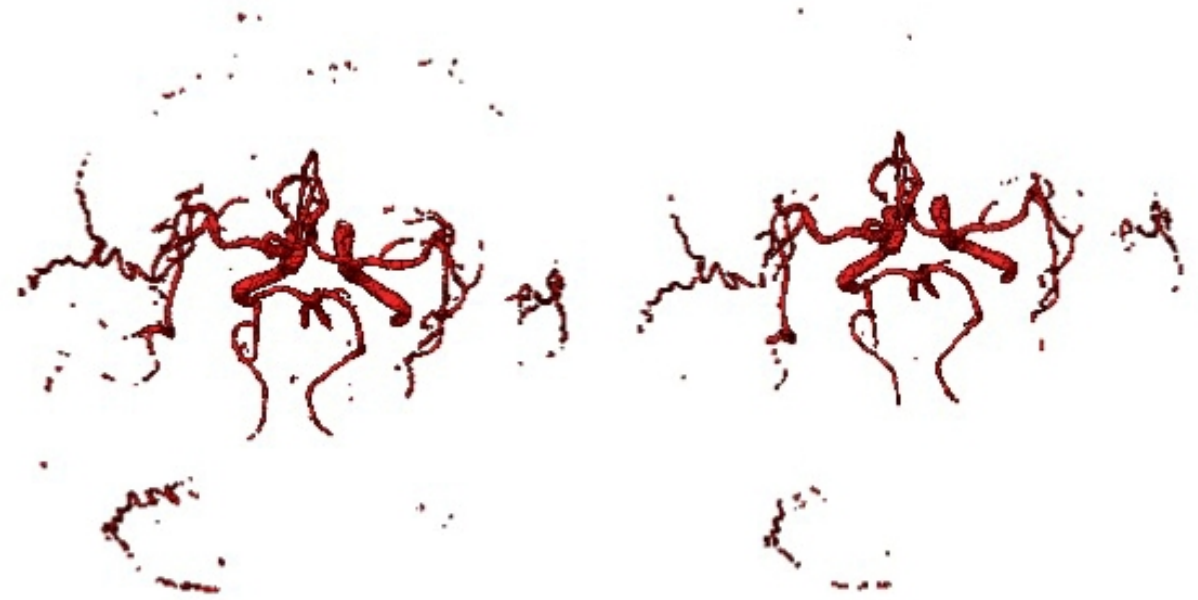


Figure 8. Comparison of segmentation details between G-MRF model and double Gaussian model of example data. From left to right: Detail 1 of G-MRF segmentation; detail 1 of Double Gauss segmentation; Detail 2 of Double Gauss segmentation; Detail 2 of G-MRF segmentation.

Figure 9. The equations of the paper.

$$< c; r >= \left\{ x \in R^3 \mid |x - c| \le r, c \in R^3, r \in R^+ \right\} \quad (1)$$

$$[u_0, \ldots u_m] = \{\underbrace{a, \ldots, a}_{p+1}, \quad u_{p+1}, \ldots, u_{m-p-1}, \quad \underbrace{b, \ldots, \quad b}_{p+1}\} \quad (2)$$

$$< B > (t) = \sum_{i=0}^{n} N_{i,p}(t) < P_i; r_i > \quad (3)$$

$$< B > (t) = \sum_{i=0}^{n} N_{i,p}(t) < P_i; r_i > = \sum_{i=0}^{n} < N_{i,p}(t) P_i; N_{i,p}(t) r_i > = < \sum_{i=0}^{n} N_{i,p}(t) P_i; \sum_{i=0}^{n} N_{i,p}(t) r_i > \quad (4)$$

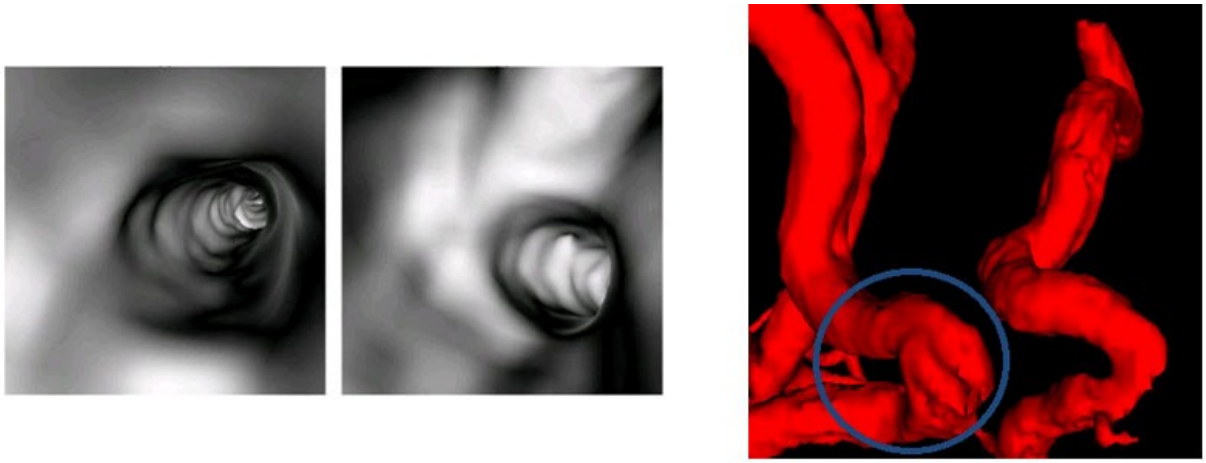
$$C(t) = \sum_{i=0}^{n} N_{i,p}(t) P_i \quad (5)$$

$$r(t) = \sum_{i=0}^{n} N_{i,p}(t) r_i \quad (6)$$

Figure 10. Reconstruction of segmentation result. From left to right: Model of Cerebrovascular segmentation; The corresponding radius of cerebral vessels; The cerebral vessels model represented by ball B-spline.

Figure 11. Volume rendering results of cerebral vessels. From left to right: The contour enhancement based on gradient; The contour enhancement based on curvature; The boundary enhancement based on depth.

Figure 12. The virtual endoscope and automatic detection result. From left to right: Cerebrovascular virtual endoscopic results of the lumen;Cerebrovascular virtual endoscopic results of vessel cross region; Automatic detection results of cerebral vessels.



Cerebrovascular Rendering Technology

The cerebral vascular image data is based on the 3D scalar field, the visualization method can be divided into surface rendering and volume rendering algorithms. Marching cube algorithm is a typical surface rendering algorithm, which uses the patch rules to approximate surface and extracts the surface information from the object of interest. Compared with the surface rendering algorithm, the volume rendering algorithm will regard all the information of 3D data field as input, which can vividly display the internal structure of rendering objects and have obvious advantages in data mining of intrinsic hidden information. The expression of such small cerebral vessels of complex structure is more effective than the surface rendering. But cerebral vascular structure can be restored with great detail using this technology, which can show its spatial adjacency details and have important clinical value in the diagnosis of cerebrovascular diseases. In the process of volume rendering, some ideographic means of the feature enhancement are proposed to characterize the complex spatial structure and continuous topological relationship of the brain vessel. Based on the high quality ray casting volume rendering with CUDA, we propose the silhouette enhancement based on the curvature to perform the silhouette width information, the boundary enhancement based on the depth to make the near boundary clearer than the distant boundary. The technology of depth cue based on stereoscopic is displayed by using the gradually changed color and stereoscopic display, which provides intuitive understanding for the observers and provides support for research and analysis of disease [25]. The characteristics of ray casting algorithm is beneficial to preserve detail and render a high quality image. It is especially suitable for the 3D imaging of the rendering region with fuzzy characteristics and voxel features of high correlation, which meets the need of presentation of cerebral vessels. The curvature can reflect the degree of local concave and convex surfaces of the objects, which represents the structure information. In order to enrich the contour information, we bring in the width factor based on the idea of the contour enhancement of curvature. So we can effectively increase the opacity of contour area to highlight contour and increase the interactivity and flexibility of contour enhancement through the adjustment of the opacity of vascular data. The junction of different substances will be highlighted in the volume rendering of cerebral vessels, which makes the physical distribution clearer in the result image. In order to make the rendering result containing depth information, a higher edge enhancement can be implemented in the part of smaller depth, while a lower edge enhancement can be implemented in the part of larger depth, which makes the near boundary clearer than the distant boundary.

Cerebrovascular Virtual Endoscope and Automatic Detection

In the key technology of virtual endoscope navigation, path planning is the base of virtual endoscope mirror to realize navigation. Because manual navigation is very difficult, time-consuming, and easy to get lost, the path needs to be carefully planned and the viewpoint must match the planned path. This project studied the interactive central path planning algorithm based on B-Snake model, and the algorithm does not require prior segmentation of the organs to directly extract the center path of tubular organ in the original image. The algorithm makes full use of the advantages of the active contour model and B-spline function and omits the internal energy of the traditional Snake model in the B-Snake model, which reduces the parameters of the model and is easy to control. The mobile polyhedron center method is used in the algorithm. The mobile polyhedron is defined in the chamber of the vessel, and the external force of the B-snake is defined as the force stretching the polyhedron centroid to move towards the center of the vessel chamber, which is robust to the noise of image. The curve extracted by this model is smooth and continuous, which meets the requirements of virtual endoscope navigation. At the same time, local support and continuity of the B-spline curve are used to obtain the smooth central path with less time. The vascular diameter information can be obtained after the vessel reconstruction using the Ball B-spline. The vessel radius is measured according to different sequence at the same vessel. If the difference between vessel radius and the adjacent node radius exceeds the threshold, it is thought area of lesion and needs to be marked. Based on the identification, it can help doctors and patients to judge.

Introduction of the Client

The system adopts C/S model to achieve the overall function. In order to ensure information security and reduce the amount of communication, the fat server/thin client model is used. The main functions of the system are concentrated in the server, and the client provides remote uploading and browsing of data, disease detection, and other functions.

Introduction of the Mobile Client Realization

Mobile cerebral vascular eHealth client mainly provides remote uploading of data, data browsing, segmentation, reconstruction, and automatic detection functions. The mobile client on android platform is realized by the JS and can be secondly developed based on remote desktop protocol (RDP). Because the preview and operate of the graphic and image are necessary in our system, the RDP and virtual network computing (VNC) protocols are more suitable for these requirements. Comparing these two types of protocols, we can see that RDP has the advantages of less transmission flow than VNC, fast response, low operation delay, and is more applicable to the Windows system. Our system uses the basic RDP protocol and implements a second phase of development and optimization to better adapt to the mobile client. In the mobile client, the display and manipulate of the cerebral vascular system is necessary, so the RDP can be cut and optimized for this use. The transmission rate of mobile client can be chosen from 8, 16, 32 bit color. The sound support, printer support, communication port support, and clipboard support are removed to improve transmission rate. The file system is transformed to support the definition, which is convenient for the directional transmission of vascular images. At the same time, the cerebral vascular image on the client is chosen to transmit to the specified directory of the server, and the task is divided to build different folders to store files. The vascular initial data is analyzed by the operating procedures. The mobile client displays the result in 3D, and allows users to interact with the client and set the parameters to upload them to the server through the mobile phone client.

Introduction of the Network Client

Network client provides the functions of uploading, data browsing, cutting, segmentation, reconstruction, and automatic detection of remote brain image slice data. Network client is mainly applied in the implementation of HTML and XML, because the transmission and display of 3D model is implemented at the client through the Virtools software. The server uses the Visual Studio, the client uses VC to create Windows Sockets support and increases CRequest Socket to realize the communication between client and server. The message response function OnReceive is added in the CRequest Socket class for receiving the data sent by the server. Network client implements the client-side application based on the browser and allows the entire system only deploy and update in the center of the WEB server, which eliminates the necessity that any part of the application is explicitly deployed to the client computer. At the same time, this model enables users to efficiently and conveniently make the application public to a large scale of various external audiences, which realizes the online inquiries, large-scale information publication and service sharing function.

Results

So far, our system has stored the brain CT data or brain MRI data of 32 patients, and the relevant system has been preliminarily tested and applied in cranial nerve surgery of First Hospital Affiliated to the General Hospital of People's Liberation Army and radiology of Beijing Navy General Hospital. Our system also has some applications in medical imaging specialty teaching of Tianjin Medical University. We use SQL Server 2008 to construct cerebrovascular database and the submission system of remote data management at the server. The application software platform at the server background is Microsoft ASP.NET, Visual Studio 2005, and VTK 5. The system is in the process of testing. The hardware system is Inter (R) Xeon (R) E5410 2.33GHz, graphics card is NVIDIA GeForce GTX 570, the GPU architecture is CUDA 3.2. A group of DICOM medical data is used to demonstrate the clinical effect of the system, including 136 time of flight (TOF) MRI image, which we call example data. The maximum interval is 2.1mm and the minimum is 0.7mm between images. The diameter of reconstruction is 200mm. Other data related to privacy of patients are not provided here.

The function screenshots of each part of the system are as follows: Web-based remote submission system interface is shown in Figure 13 left. The vascular function figure of Ball B-spline reconstruction display of the client is shown in Figure 13 right. Mobile customer interface is shown in Figure 14. Figure 14 left is the maximum intensity projection (MIP) of remote observation of slice data structure at mobile phone client, which simulates the vascular DSA angiography image. Figure 14 right is the display of reconstruction detection results of cerebral blood vessels on the mobile phone.

The medical services platform of cerebrovascular diseases at the server side is used for vessel segmentation and reconstruction of the CT and MRI brain images, which mainly uses segmentation algorithm based on statistical methods to finish segmentation and uses Ball B-spline surfaces on vascular reconstruction. At last, the volume rendering and surface rendering are used to display the vessels after segmentation and reconstruction or the vessels enhanced after adding the capillary vessels. In addition, our platform can also achieve the transformation, processing, and organizational measurement of the DICOM, Raw, and BMP sequence cerebrovascular data. The system can handle many common data structure, and has powerful user interaction and friendly interface which is easy to operate. Figure 15 row 1 left is an imported image of brain data. Figure 15 row 1 right is the cropping result of the brain image data. Figure 15 row 2 left is the window and width adjustment of the data with clear view effect. And Figure 15 row 2 right is a 2D measurement of the brain image. Figure 15 row 3 left is the statistical segmentation result of the cerebral vessels. Figure 15 row 3 right is the reconstruction result of Balls B-spline method. Figure 15 row 4 left is the volume rendering result and Figure 15 row 4 right is the cerebrovascular virtual endoscopic result.

Figure 13. The interface of the network client .Left: Landing interface at remote Client; right: The Ball B-spline structure at remote client.

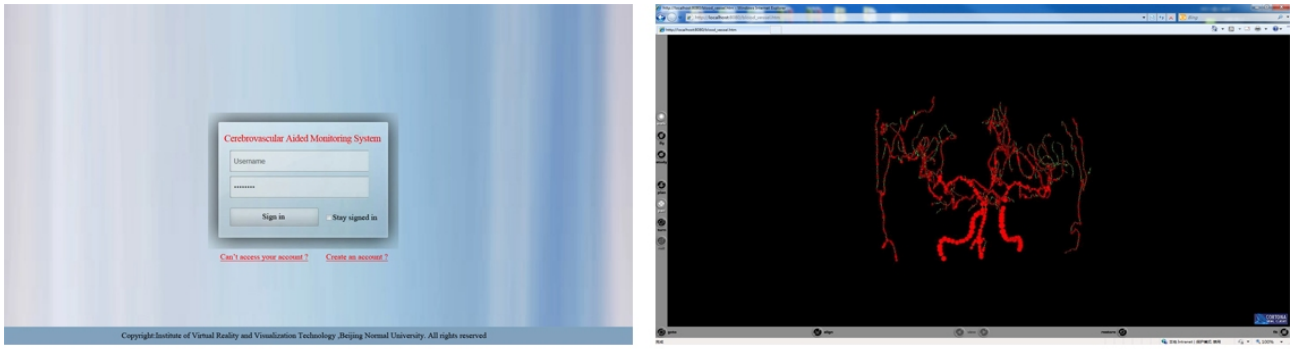


Figure 14. The interface of the mobile phone client. Left: MIP projection data displayed at mobile phone Client; right: Segmentation results at mobile phone Client.

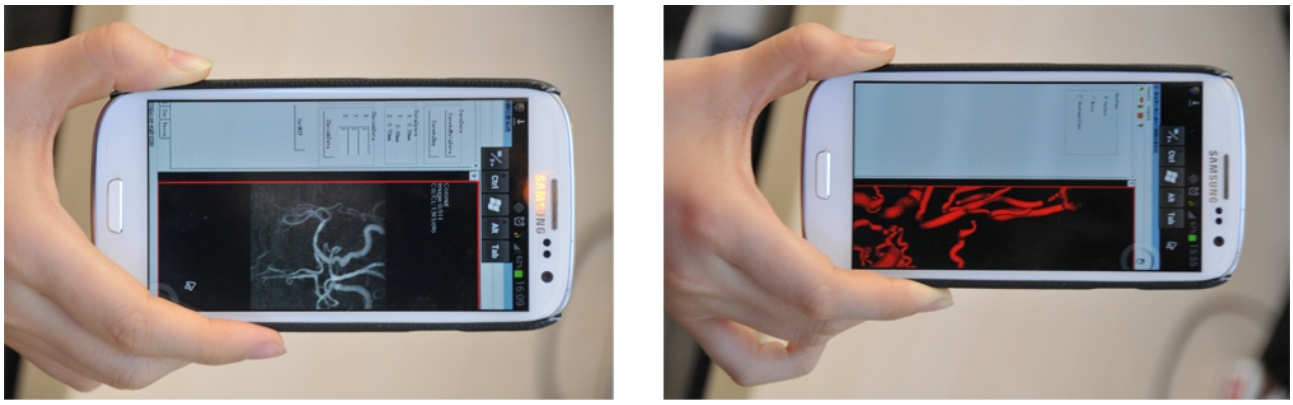
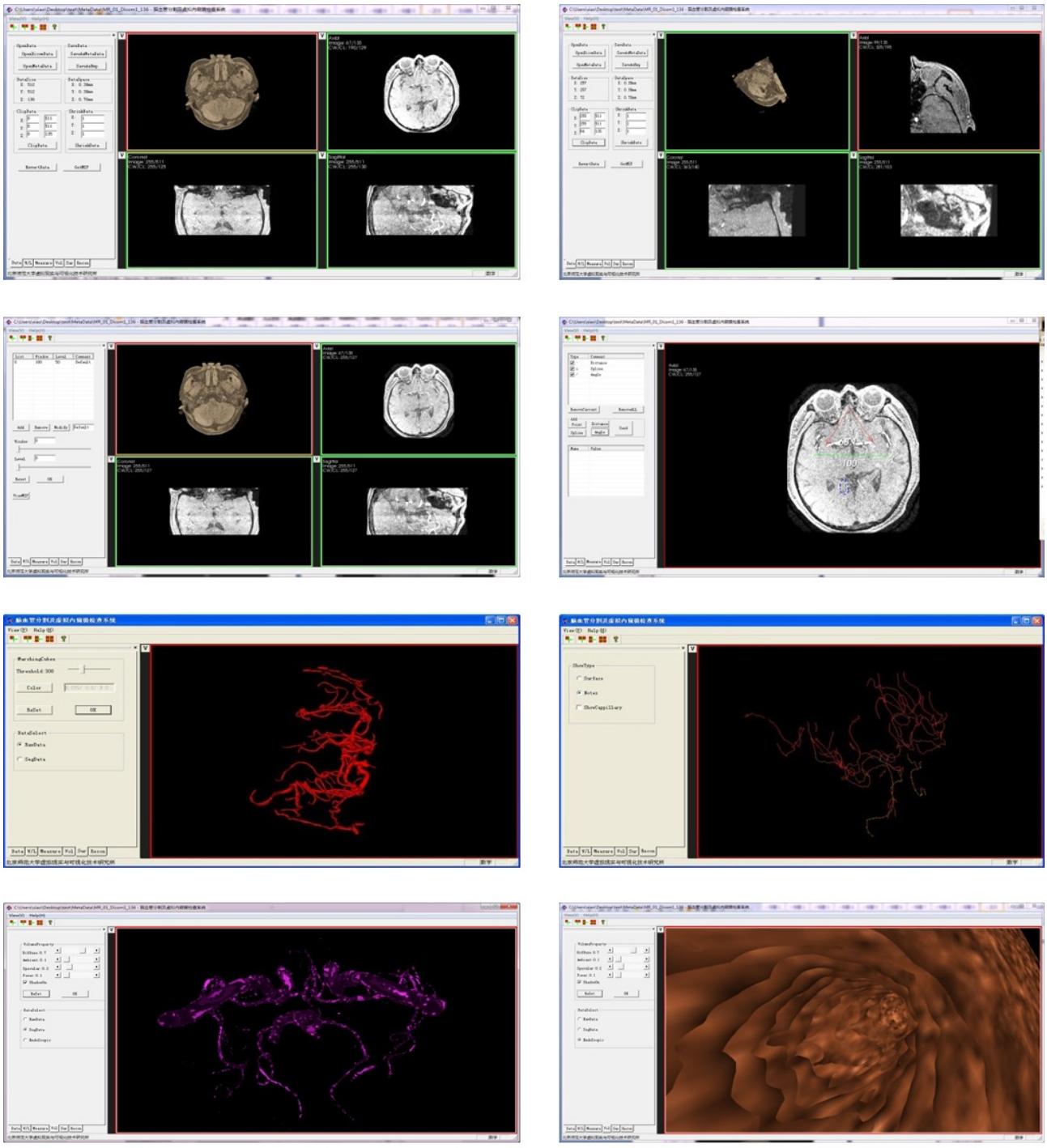


Figure 15. The function introduction of the platform. Descriptions for each row are from left to right. Row 1: an imported image of brain data; the cropping result of the brain image data. Row 2: window and width adjustment of the data with clear view effect; 2D measurement of the brain image. Row 3: statistical segmentation result of the cerebral vessels; reconstruction result of Balls B-spline method. Row 4: volume rendering result; cerebrovascular virtual endoscopic result.



Discussion

This paper introduces the basic framework and functions of cerebrovascular eHealth electronic medical platform. The platform can carry out the remote diagnosis and test other organs with complex geometric structure, and provide application examples for remote eHealth detection. Users can realize the automatic acquisition, management, detection, and diagnosis of remote information to realize medical information at home, thus it reduces the health care costs and improves the health care at the level of encephalopathy. Our system provides the basic medical image processing functions for browsing, window and width adjustment, cropping, and maximum projection map. Here, we have also proposed some innovative technology in automatic segmentation of cerebral vessels, Ball B-spline reconstruction, and ideographic enhanced volume rendering. Manual and automated search of brain lesions are also achieved through the virtual endoscopic and automatic detection. The

system provides network client and mobile client platforms, which can realize any health function at any time. However, we only constructed a basic framework and achieved the basic functions, so we hope to further construct the registration algorithms and realize the automatic monitoring of encephalopathy to develop the function of our platform. The platform is still at the online testing phase with a small sample population, it needs to increase data management and parallel computing ability at the testing stage with a larger population sample. We need to strengthen the application of our system in hospitals and medical schools to improve the stability of the platform in the experiments with a large population.

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

2D: 2-dimensional
3D: 3-dimensional
3DRA: 3-dimensional rotational angiography
3NET: telecommunication network, television network and computer network
AJAX: Asynchronous JavaScript and XML
BBSC: Ball B-Spline Curve
C/S: Client/Server
CT: computed tomography
CTA: computed tomography angiography
CUDA: compute unified device architecture
DICOM: digital imaging and communications in medicine
DWM: directional weighted median
EM: Estimation Maximization
G-MRF: Gaussian-Markov random field model
GPU: graphics processing unit
IOT: Internet of things
JS: JavaScript
MIP: maximum intensity projection
MRA: magnetic resonance angiography
MRF: Markov random field
MRI: magnetic resonance imaging
OOP: object oriented programming
PACS: picture archiving and communication system
RDP: remote desktop protocol
RFID: radio frequency identification devices
ROI: region of interest
SEM: Stochastic Estimation Maximization
SQL: structured query language

TOF: time of flight
VNC: virtual network computing
VOI: volume of interest
VTK: visualization toolkit

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Original Paper

Ideas and Enhancements Related to Mobile Applications to Support Type 1 Diabetes

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Abstract

Background: Mobile devices have become increasingly important to young people who now use them to access a wide variety of health-related information. Research and policy related to the integration of health information and support with this technology do not effectively consider the viewpoint of a younger patient. Views of young people with type 1 diabetes are vital in developing quality services and improving their own health-related quality of life (HRQOL), yet research on their lifestyle and use of Web and mobile technology to support their condition and in non–health-related areas is sparse.

Objective: To develop insight into young people with type 1 diabetes and their current use of Web and mobile technology and its potential impact on HRQOL. This can be achieved by constructing an in-depth picture of their day-to-day experiences from qualitative interviewing and exploring how they make use of technology in their lives and in relation to their condition and treatment. The goal was then to build something to help them, using the researcher's technical expertise and seeking users' opinions during the design and build, utilizing sociotechnical design principles.

Methods: Data were collected by semistructured, in-depth qualitative interviews (N=9) of young people with type 1 diabetes aged 18-21. Interviews were transcribed and loaded onto NVivo for theme identification. Data analysis was undertaken during initial interviews (n=4) to locate potential ideas and enhancements for technical development. Latter interviews (n=5) assisted in the iterative sociotechnical design process of the development and provided additional developmental ideas.

Results: Six themes were identified providing an understanding of how participants lived with and experienced their condition and how they used technology. Four technological suggestions for improvement were taken forward for prototyping. One prototype was developed as a clinically approved app. A number of ideas for new mobile apps and enhancements to currently existing apps that did not satisfactorily cater to this age group's requirements for use in terms of design and functionality were suggested by interviewees but were not prototyped.

Conclusions: This paper outlines the nonprototyped suggestions from interviewees and argues that young people with type 1 diabetes have a key role to play in the design and implementation of new technology to support them and improve HRQOL. It is vital to include and reflect on their suggestions as they have a radically different view of technology than either their parents or practitioners. We need to consider the relationship to technology that young people with type 1 diabetes have, and then reflect on how this might make a difference to them and when it might not be a suitable mechanism to use.

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KEYWORDS

patient education; type 1 diabetes; mobile; apps; sociotechnical design; lifeworld; humanising healthcare; patient voice; empathy; ideas; enhancements

Introduction

The World Health Organization has identified the treatment and care of diabetes as a major challenge for health care systems worldwide [1]. In the United Kingdom, the National Health Service (NHS) spends at least £3.9 billion a year on diabetes services, with around 80% spent on treating avoidable complications [2].

Type 1 diabetes occurs when the body produces no insulin because of autoimmune destruction of the pancreatic cells that normally produce it [3]. It can occur at any age but usually develops before the age of 40, often during teenage years. Patients with type 1 diabetes need to take insulin injections for life and, in order to reduce their risk of developing complications, must ensure their blood glucose levels are sufficient to balance their insulin doses, diet, and activity. They must also carry out regular blood testing. The primary diabetes outcome is glycemic control, as measured by a blood test (glycosylated hemoglobin or HbA1c) that indicates average plasma glucose for the previous 2-3 months [4]. Poor glycemic control has been related to short-term consequences such as hypoglycemia and diabetic ketoacidosis, as well as serious health consequences later in life [4]. Completion of recommended self-care tasks is considered critical to glycemic control, with the primary tasks that help maintain control—such as monitoring blood glucose levels, injecting insulin, and dosing insulin according to meter results or other factors—needing to be carried out several times per day, often around mealtimes in different contexts and locations [4]. Type 1 diabetes is the most common form of diabetes in most parts of the world, although wide variations exist between the incidence rates of different populations [5]. In the United Kingdom, it accounts for 10% of all people with diabetes and 90% of young people with diabetes [6].

In November 2012, a UK Public Accounts Committee (PAC) published its report on the management of adult diabetes services in the NHS, stating that the standard of care for diabetes in England was “depressingly poor”, causing unnecessary deaths and disabilities. This report followed critical studies on diabetes care from both the National Audit Office [7] and Diabetes UK [8]. The PAC Chair stated [2] that although the Department of Health had set out clear minimum standards for diabetes care—including nine basic checks for the early signs of avoidable complications—fewer than half of people with diabetes were receiving all nine tests. Variations in the level of progress across the NHS also meant that there was an unacceptable “postcode lottery” of care, whereby quality of care varied dramatically around the country. In November 2012, members of the House of Lords debated the management of diabetes services in the NHS following the PAC report. Lord Harrison, who had lived with type 1 diabetes for 43 years, stated his biggest concern was that the onus of care and of making important decisions was becoming the sole burden of the individual with the condition [9].

Education about long-term complications via access to information could help patients with diabetes empower themselves to manage their condition more effectively, thereby reducing complications. It has been acknowledged [10] that better information on the ways in which social support operated was vital for enhancing diabetes patient self-care, insuring adherence to advice, encouraging lifestyle changes, helping to improve outcomes of care, and increasing personal freedom.

Lamb’s article on integrating technology into adolescent type 1 diabetes care highlighted how metabolic control varied with age [11]. Results from this study showed a progressive rise in HbA1c values throughout adolescence, peaking through the ages of 18 and 22, before falling again in early adulthood. Lamb considered a number of factors to be at work that could affect an inability to control HbA1c during late adolescence, and for these reasons, suggested that it was not surprising that metabolic control deteriorated while the incidence of acute complications such as diabetic ketoacidosis increased during adolescence [11]. Walker [12] defined health-related quality of life (HRQOL) as the level of well-being and satisfaction associated with an individual’s life and how this was affected by disease, accidents, and treatment.

To date, there exists little data analyzing how young people with type 1 diabetes make use of Web and mobile technology and its impact on their HRQOL. Franklin’s [13] study was the first randomized control trial (RCT) that explored the impact of SMS text messaging (short message service)-enabled behavioral support, with intensive therapy in a young age group. However, the study made no mention of engaging with the target audience to discuss what they would like to use, in order to influence the hypothesis of the study. Similarly, Pena’s [14] cross-sectional Web-based survey of parents with children who had diabetes focused on adults, again lacking a focus on the concerns of the young people, which were neither addressed nor included. Reporting on an Internet-based self-management intervention, the authors [15] stated that their research was the first trial of an Internet program to improve problem solving in adolescents with type 1 diabetes. However, the study again made no reference to having asked young people their opinions during the design of the intervention. In 2012, an article [4] highlighted how little was currently known about how young people used mobile phones for diabetes and as yet only a small proportion of apps available had been the subject of any research [16]. This view was most recently reaffirmed [17] in research that noted a lack of literature available on strategies to promote greater engagement of youth in behavioral interventions for type 1 diabetes, with even less information on the use of the Internet and mobile technologies for minority and low-income youth.

This poses the question as to why more health professionals, researchers, and technologists have not approached this age group for their opinions and suggestions. Why have these views seemingly been ignored? Is it a trust issue or perhaps professionals consider themselves more knowledgeable about the condition and its effects than the actual people with the long-term condition? There is a real need to explore how young people with type 1 diabetes relate to their condition; how they use and interact with technology and the Internet in health and non–health-related situations; and what they think would be useful in new health-based technological innovations. This could be achieved by talking to them and asking them for their opinions and suggestions. The research question was: *How do young people with type 1 diabetes interact with technology in their lives and in relation to their condition and how can their views and experiences inform the development of a patient-centric mobile health app?*

In recent years, qualitative research methodology has become more recognized and valued in diabetes behavioral research [18] because it helps answer questions that quantative research might not, by exploring patient motivations, perceptions, and expectations. Lifeworld studies concerning diabetes [19-21] have also started to appear more often in research literature. The study aimed to gain a deep understanding of the perspective of young people with type 1 diabetes and connect with their views by building a picture of their everyday experiences with the condition and how they used technology both socially and for health, as influenced by approaches from qualitative research in health care such as the lifeworld. Then, aiming to integrate this perspective within the creation of a mobile or Web tool influenced by these opinions, which would help to improve an aspect of HRQOL by using humanizing sociotechnical principles [22] during the design and build.

Methods

A generic qualitative approach was adopted that would allow for the development of a breadth (allowing participants "maximum freedom in expressing the range, scope, and boundaries of the complex experience" [23]) and depth (further exploration of specific events and experiences in the participants' lives [24]) of understanding regarding the nature of the studied experience. Recruitment was conducted at a district hospital located in south west England (SWDC) and a local university, with data collected by qualitative interviews with young people with type 1 diabetes aged 18-21. Although the clinic had children under 18 attending, the focus was on older members as this alleviated the need for parental consent. The upper limit was set at 21 years as this was the age participants no longer attended the Young Person's Clinic on a regular basis. The sampling strategy utilized a nonrandom convenience sample, as selection was from participants who had type 1 diabetes within the population definition. The sampling strategy was purposive (nonrandomized). Participants were considered eligible if they had type 1 diabetes, were 6 months post diagnosis, were within age range at time of recruitment, and were fluent in English.

The design used in-depth, 1-hour, semistructured interviews. Semistructured interviews are used when the researcher knows what questions they want to ask but does not know what answers to expect [25]. Question stems are usually asked in the same order during each interview and responses to open-ended questions can then be probed, so that the interviewee has the freedom to respond as they wish [25]. In-depth interviews are typically used when seeking information on individual, personal experiences from people about a specific issue, to capture their own voices and stories [26]. It was decided to progress with individual interviews rather than use focus groups, as SWDC staff indicated that a young age group with a mix of male and females would not produce good quality results. It was also noted that this age group had a preference for talking individually and that some interviewees might find talking about particular aspects of their condition and lifestyle embarrassing or stressful within a group setting. Finally, as Morse [25] noted, focus group opinions are offered publically, so they might not always reflect the interviewee's actual response.

A semistructured interview guide [27] was developed. Some broad questions and areas of interest were prepared beforehand, but it was recognized there was also a need for improvisation during each interview, based on anticipated and unanticipated responses. The general purpose of each interview was to discuss, in detail, specific topics related to the interviewee's knowledge and its relevance to the research question and objectives [28], which were to explore young people with type 1 diabetes perspectives of their day-to-day lives and how they made use of Web and mobile technology and to identify from these views and experiences, how they used technology (if at all) in relation to their condition and treatment. The core focus of each interview moved from the interviewee's first mobile phone and the historical timeline of different phones they had owned, to questions about the history of other mobile and computer technology they used. This usually led to a discussion about their usage of different Internet software and social media tools. This was then followed at an appropriate point by a question about their diagnosis date, which might then lead to talking about their diagnosis and how they had used technology (if at all) since then. This could then lead into a discussion of different aspects of their day-to-day life with diabetes; their experiences of the clinic, GP surgeries, and other health services they encountered; experiences socially, at school, at home, and at work; how they coped with and used technology related to diabetes; and, if they had used any health-related apps. When discussing any problems they had experienced, we would then explore what ideas or enhancements they might have for something that could improve that aspect of their lifestyle or others, and whether a technical solution might be of any help.

In total, (N=9) interviews were conducted (m=2 and *f*=7), transcribed, and loaded onto the qualitative data analysis tool, NVivo. The interviews were then analyzed to gain a deeper understanding of the perspective of the young person with type 1 diabetes and to construct a picture of their everyday experiences. Credibility refers to the accuracy of information obtained during a study and is maintained via triangulation of data sources, methods, and investigators. One way that credibility was achieved was by prolonged exposure to the

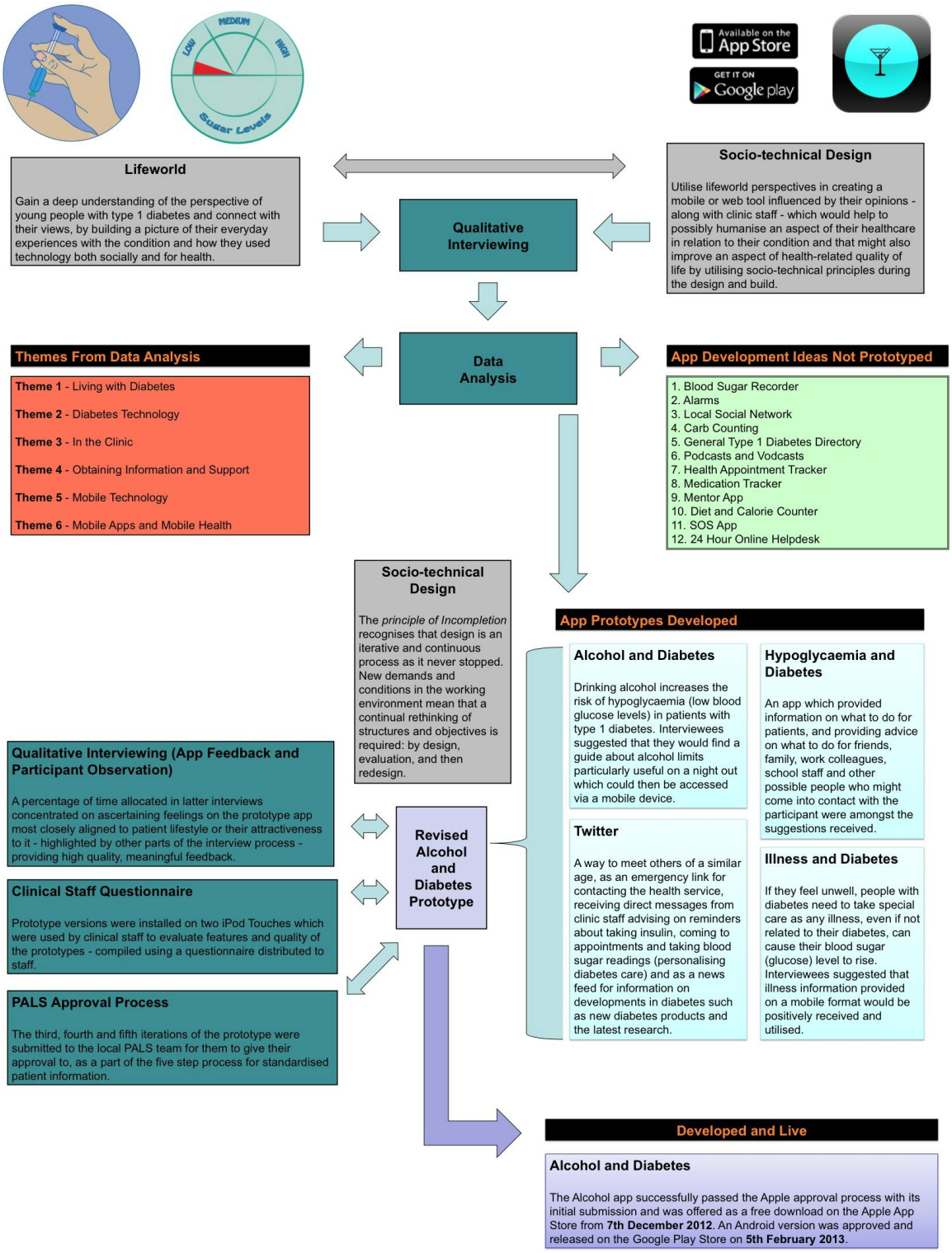
subject being investigated. By spending a substantial period of time in the clinic and observing the day-to-day activities and routines of its staff, it was possible to become immersed in the world of the clinic. During numerous visits there, the researcher was able to build relationships with practitioners, dietitians, and receptionists. By spending longer periods of time with interviewees, they were able to build their trust over the course of interviews. A further method of establishing credibility came from regular supervisory contact, with a requirement to satisfy the supervisory team that research procedures and ethical standards were being followed at all times and also to defend ideas, methods, and analysis during extended questioning on all aspects of this study.

Results

Six main experiential themes were identified providing an understanding of how participants lived with and experienced their condition and how they used technology: (1) living with diabetes, (2) diabetes technology, (3) in the clinic, (4) obtaining information and support, (5) mobile technology, and (6) mobile apps and mobile health apps.

Besides providing an understanding of their day-to-day experiences and how type 1 diabetes affected their HRQOL, interviewing enabled the identification of possible ideas for the development of prototype mobile apps. The suggestions needed to meet SWDC goals, reflect interviewee requirements and comments, and follow local trust guidelines (eg, patient data were not allowed to be recorded). By asking for their suggestions, in collaboration with the clinical team, we were able to focus on four ideas for prototype development [29]. Three of these were created in prototype, with one subsequently chosen by later interviewees (n=5) to be taken to final development [30]. The prototype development used sociotechnical design principles [31]. This approach has recently started to re-emerge in health literature, with examples within diabetes research using it as a means of collecting data for systems designed for both staff [32] and patients [33]. A key characteristic of sociotechnical thinking lies in highlighting the importance of developing new ways of working that significantly meet the needs of clients (patients) and users (service providers) [34]. This developmental work and the final app produced could help contribute to new knowledge and understanding of young people's requirements and concerns, which could then improve their HRQOL. Additionally, a number of other innovative ideas and suggestions for enhancements were made for improving their lifestyle and making a difference in other areas of their lives affected by their condition—these ideas were suggested during the interview process but not taken forward for prototype development (see Figure 1).

Figure 1. Methodological structure.



Blood Sugar Recorder

Capillary Blood Glucose Monitors (CBGM) are capable of holding a large number of historical readings and can sometimes be linked to a computer to transfer data. However, this cannot currently be performed wirelessly. This compares to cloud systems like Apple's iCloud, where data is transferred seamlessly between devices. The constant proximity of the mobile phone to the user makes it an attractive option for use

as a recorder. If it could be linked to the data cloud, information might then be accessed and displayed across multiple devices.

> *Cause again that's something then you're looking at that's more visual, that you can see oh ok, maybe it's not as good as I thought, whereas just doing it, doing your sugars once every day and just seeing the numbers, just seeing it on a chart, seeing how it is over a period of months, that could be quite…* [T1-QOL-05]

> *So maybe an App that could give more advice,'cause coming to the hospital's really good, like they do set you targets, like I came before Christmas and they set me the target of just doing er, my sugars once a day which I've stuck to.* [T1-QOL-05]

> *And then, the personal notifications, I wondered if you could put other things up like erm, like your insulin, or what you've eaten. Sometimes they weigh you, measure your height and things. Maybe you could put that on there.* [T1-QOL-09]

This could then be taken to a clinic to show to staff or also be used for creating historical graphs to pinpoint times of good and bad control, making it easier to see where somebody was going wrong by highlighting higher than normal readings. Historical graphing could also provide a useful incentive for improving control, as it would allow the ability to immediately call up and view the data at any time. This may also be more accessible to a user with pleasing figures and colors. Historical readings are available on newer CBGMs, but they are not as accessible or as attractive to view when compared to a digital display. Personalized goals and targets could also be set, which could then be flagged if they were met or missed. A more interactive diabetes assistant could also be provided to tell users when they were doing well or not. This may be more effective because interviewees view their phone as a friendly device, not automatically associated with their condition [11], as opposed to their CBGM, which might be viewed as more specifically linked to their condition—similar to how interviewees differentiated Facebook usage for health and personal use.

Functionality might also be provided to remind the user to take a reading by using the push function of a mobile device, which could then display alarms and reminders as pop-up SMS text messages. This could also be tailored to include personalized information about insulin, weight, food intake, height, and other useful data. However, some users might not wish to enter the data twice, as it is already on their CBGM, or they might find the task of inputting figures from a blood sugar reading onto a mobile device just too bothersome—even if the task was simple and easy to perform. Some of these suggested features appear on the iBGStar [35], which is the first CBGM that can be used on its own or connected directly to an Apple iPhone or iPod Touch to display, manage, and communicate diabetes information, and which also works in conjunction with a specifically written self-management app. However, no research is available on how this CBGM and app have been utilized to date. It is only available to buy in the United Kingdom (rather than offered for free through clinics), so alternative methods of support could be offered via a free app that worked across a range of different CBGM rather than locking the individual and the clinic into one particular device with its associated costs.

Alarms

Some interviewees had already used the alarm clock function of their mobile phone to remind them to take insulin or to obtain a blood sugar reading. Expanding on this idea and once again applying the principle of utilizing push technology on a mobile device, it would be relatively straightforward to produce a simple-to-use alarm app (see Textbox 1).

This could allow users to set up multiple reminders on insulin, blood sugar level checking, and eating, thus helping individuals to be persuaded or even nagged into doing something specific. However, some users might simply choose to ignore the alarms, which could be addressed by changing the tone of the information contained within the message, received over a longer time period. While acknowledging that some of this functionality already exists within apps like OnTimeRX Pro [36], interviewees had been unable to locate anything that satisfactorily catered to their requirements or their preferences for design and functionality.

Textbox 1. Comments on alarms (I: = interviewer speaking / P: = participant speaking / [T1-QOL-XX] = participant interview number).

I: *Right and does that mean you're occasionally forgetting to look or you might be missing meals or…*

P: *Missing injections and or given too much insulin*

[T1-QOL-01]

I: *Yeah. Ok, so do you think having a reminder or a something on there that sort of nagged you…?*

P: *Yeah, definitely. I definitely need a push with it…*

[T1-QOL-05]

I: *A little box to say "Have you taken it yet?", "Why haven't you taken it yet?"*

P: *Yeah (laughs).*

I: *You need to take it now!*

P: *Yeah (laughs).*

[T1-QOL-09]

Local Social Network

The belief that users of this age group were happy to share every aspect of their personal life on Facebook (including health) was contradicted. Some interviewees wanted to use Facebook only for talking to friends about their life outside of type 1 diabetes, rather than using it for diabetes-related searches and communal group discussions. It is also important to consider how quickly popular opinion in this age range changes concerning different brands and products. Indeed, it seemed as if the amount of discussion in the media about certain social media tools like Twitter was in some cases harming its ability to attract this age group toward using it. Some mentioned the problem of having too much information being constantly tweeted at them by too many people—similar to the Facebook phenomenon of too many people being available to connect with, causing them to exert tight controls on what they looked at and where they visited online.

Consequently, the idea of a small personalized social network was discussed by interviewees (see Textbox 2) in the style of a local, private Facebook or Twitter community, which might encourage communication between clinic attendees and help them to make new friends with the same condition—quite difficult for this age group—in order to address the isolation they sometimes experienced at that age. This could then link into wider regional, national, and international networks. The forum could be split into private and professional areas, with the private area being used for making friends and venting personal opinions in a secure environment with, notably, people of the same age. Establishing this private forum that clinic staff could not access, but which had their patronage, rather than setting up a group administered within Facebook, might even encourage wider participation (interviewees suggested this point). The other part of the forum might be managed by clinic staff, although cost could be an issue, and be accessible to patients for their queries and feedback. Private queries—which users might not want clinic staff to see for whatever reason—could be made within the secure private space. Again, easy access via a mobile phone might encourage some to more actively participate in this type of discussion. Previous research by Pew has shown that wireless connections are associated with deeper engagement in health-related social media, with mobile Internet users more likely than those with tethered access to post comments and reviews online about health and health care [37]. TuDiabetes [38] was praised by one interviewee as being a particularly friendly communal environment that raised general awareness and provided other information related to their condition, as well as for ease of posting personal queries in the discussion forum. However, only 1 out of the 9 interviewees knew about this community, which suggests that awareness of this forum is not currently high with this age group in the United Kingdom.

Textbox 2. Comments on local social networks.

I: *if we wanted to keep it to [clinic location] would you be happy if it went further say if it was used nationally or would you really want it sort of kept specific to [clinic location]*

P: *Yeah, it could be used nationally, but then if you same, in sense under it have like separate departments where you could go to*

I: *Almost like, little mini networks...*

[T1-QOL-01]

P: *But I would definitely use, um, a smartphone to do more for my diabetes with it, even if there was just some specific forum where people could talk…*

[T1-QOL-03]

P: *maybe like erm, a forum, erm, which had erm, both people with diabetes and medical professionals who were part of the forum so if you posted something like if you had a query, you could get feedback from people who possibly have gone through it and from like a medical point of view as well*

[T1-QOL-04]

Carb Counting

While positively viewing Carbs & Cals [39] as a good quality mobile app for diabetes information, interviewees suggested that it was not a perfect product in every aspect. They responded positively to the ability to access more localized information on a mobile platform (see Textbox 3) for their age range and younger, remembering back to just after diagnosis. They valued an app covering items that they had not eaten before, highlighting the importance of a continually updated food database; an app that also provided a better UK perspective on foods, including more detailed information on certain UK restaurants, takeaways, and fast food establishments, more akin to what this age range were actually eating; and one that provided a more practical guide to UK-specific snacks, crisps, biscuits, and chocolate bars. This information could then be presented in a searchable, indexed format within the app, providing a more portable way of carrying around large amounts of information. Or, for simplicity, this information could be made available as a specially tailored eBook or PDF, instead of an app, so that it could be accessed without the need for a constant Internet connection.

Textbox 3. Comments on carb counting.

I: *… say you put that paper booklet of carb values on there er, would you use that? Sort of call that up?*

P: *Yeah, probably. Because every now and then you come across something that you haven't really eaten before so it's quite good to be able to reference somewhere, what, how many carbohydrates are in them…*

[T1-QOL-09]

P: *…I quite liked looking at all like the [fast food chain] and restaurant ones, I think they're the most difficult, because you don't see the ingredients…*

I: *Hmm.*

P: *…so I think an App like that would be useful…*

[T1-QOL-06]

P: *But rather than carrying around a book, if you've got your phone with you, and you've got the app that's the carb counter, the only thing is, most apps require Internet or like a decent signal to get it. It would be better if you got one that you downloaded as maybe a PDF file or something that was constantly on your phone as an e-book or something rather than an app...*

[T1-QOL-08]

General Type 1 Diabetes Directory

When a young person is diagnosed with type 1 diabetes, they need instant access to a vast array of information concerning all aspects of their lifestyle. This is also applicable initially to parent caregivers. Interviewees suggested a general type 1 diabetes app directory to hold information on a number of topics (see Textbox 4). This might include a welcome message to be read in their own time, once they had been initially diagnosed, responding to some of their main fears and concerns in a sensitive, personalized style, and also featuring ways they could deal with some of the most challenging aspects of the condition. In addition to containing the contents of the generally informative patient education pamphlets offered by clinics, which this age range seemed to either throw away or lose and then only wanted to access again when they had a specific query, this directory could also include the specifics of how type 1 diabetes occurred rather than on the mechanics of insulin. It might also provide a tip sheet written for other parents and friends, which could be emailed to them as a PDF prior to a sleepover (like the parental handout that one interviewee's mother had created for them) and could offer more lifestyle-focused information such as exercise, nights out, and alcohol. It would need to be updated regularly to provide the latest information, such as when new policy was formulated on areas like diabetes and driving laws. This would have the advantage of providing up-to-date clinically validated information offered for quick and easy access to users at a particular moment, rather than their having to trawl through different websites.

Textbox 4. Comments on general type 1 diabetes directory.

P: *…if it was kind of like erm, an App which had like, like a contents like, Diabetes, erm, Alcohol, sorry, illnesses, things like that and you could quickly go and it had like Q&A's that would be really handy…*

[T1-QOL-04]

P: *If it was a straightforward, easy to use, I've just done exercise and my bloods have gone high. It would take you to the sports page and give you an explanation why. That would be great…*

I: *Yeah*

P: *You know, if it was, if it was well-organized and um, sort of sub-sectioned so that you could find your problem within the space of maybe 5 minutes, rather than an hour...*

[T1-QOL-08]

Podcasts and Vodcasts

Podcasts were positively received as a potential source for distributing and receiving engaging, good quality, useful information (see Textbox 5). Sometimes this was mentioned as being preferable to reading the information. Although podcasts can be made available for download directly through Apple's App Store or via a website, interviewees preferred they be made available directly through an app to save time when accessing them. Participants were mostly happy to view the information, such as via a vodcast, rather than listen to it. They preferred a less formal style than traditional informational messages from health services, either encouraging users on eating healthily for example or by offering a more serious tone if required. A final important note to consider was the type of presenter; a more professional one might garner the best results and engage the most users in the message being given to them.

Textbox 5. Comments on podcasts and vodcasts.

I: *…thinking back to since eleven, if there was podcast information on particular subjects. Is that something you might listen to?*

P: *Yeah I probably would have listened to it, because I don't really like reading and things so, listening to it would have been much better…*

[T1-QOL-09]

P: *So, I think I would be interested in watching YouTube videos if it was sort of educational. But I wouldn't want to watch them if it was just somebody talking about…*

I: *Ok.*

P: *…you know like a vid- blog or something, er, not a blog a, where they record themselves and talk about their own thing. I don't think I'd watch something like that...*

[T1-QOL-06]

Health Appointment Tracker

The ability to monitor and book appointments over a mobile device via an app was also suggested (see Textbox 6). This app could also feature the ability to immediately record information obtained on the day of the appointment, such as the eyes and feet, which could then be accessed historically by the user.

The app could feature more generic recorded data functions than the idea suggested for recording blood sugar levels but might also have options for ketones and other general information. It would be possible to program this app so that the information entered could be customized and personalized for each user, enabling them to configure it to meet their needs more effectively. However, it should be noted that even within this age group, there were still some young people who preferred using paper rather than digital means for recording information and that some of this functionality already existed on the Diabetes Tracker app [40], although it did not appear to have been well used by those interviewees who had downloaded it.

Textbox 6. Comments on health appointment trackers.

P: *…and then you have your eyes, and then you have your feet, and all things like that, so maybe, erm, something where you could put in when your last one was, what the results were, when your next one was…*

I: *Ok*

P: *…and when you're next due one…*

[T1-QOL-04]

P: *Yeah, just write the appointments, I mean I had a letter with um, recently and I've booked it and I have put it on here as well (on phone) but I, I just find it easier to have on paper in front of me…*

[T1-QOL-06]

Medication Tracker

Although not required by all interviewees, the use of a medication tracker was also suggested as a method of improving daily HRQOL (see Textbox 7). This app could allow the user to simply tick a box once a medication had been taken, perhaps with a date and time stamp attached, and could be customizable to include a number of different medications. Using mobile phone push technology, this could also include pop-up reminders to be configured based on the different medications and the times they were due to be taken.

These warnings could increase in severity if not acted upon, similar to the alarm app idea. Again, this functionality does already exist on other apps [36], but interviewees had not located something usable or found existing products to be designed with them or their condition in mind.

Textbox 7. Comments on medication trackers.

P: *…I've got levemir, I've got a couple of other daily medications as well, just be able to sign and say push, yes I've done my levemir today and if I, um, 'cause sometimes I do my levemir and I'm like, "Have I done my levemir today?" and have this horrible panicky feeling that I might not have done my levemir but I don't want to do more, do it again if I've done it already…*

[T1-QOL-02]

I: *Yeah, so just a little tick thing then, that would sort of say like, right, I've had this and…*

P: *Yes, possibly, probably one that could be customized to a number of medications as well…*

[T1-QOL-02]

Mentor App

Some participants expressed a desire to be able to talk to people younger than themselves who had just been diagnosed, to act as their mentors and help them work through the various aspects of being diagnosed with type 1 diabetes, based on their own experiences post diagnosis. This could include the use of podcasts or vodcasts, where they discussed particular situations,

including times when they had been feeling particularly low and how they had gone about counteracting those feelings. This would not aim to preach, but rather offer supportive understanding from a different perspective, away from their usual group of family and friends. Alternatively, they could offer advice from within a forum on particular questions that other young people just diagnosed might have.

> *I'd like to be like, be able to talk not to, yeah like younger people who are like fourteen, fifteen, sort of, who don't really know where they're going and they can talk to someone who's actually been the worst diabetic, and who probably is the worst diabetic, you know, but who can see the other side of it as well like I've, I'd like to be able to talk to all different people about that I suppose…* [T1-QOL-03]
>
> *Because I like to be able to help the people that don't have such good control* [T1-QOL-06]

The most positive aspect of this suggestion is that it shows how young people with type 1 diabetes are keen on sharing their knowledge, providing information and support, and helping out others in a similar position to themselves or who were just beginning their post-diagnosis journey. There does not appear to be the right set of circumstances or opportunities for this to currently occur according to interviewees.

Diet and Calorie Counter App

While acknowledging that there were a number of existing dietary and calorie counting apps already available, such as My Diet Diary [41], the limitations mentioned with them made the design of a newer, more effective app attractive to interviewees (see Textbox 8).

The new app could help take some of the guesswork out of calculating calorific and carbohydrate values and allow users access at convenient times and in different locations. The major factor for something like this was to be able to replace the vast amounts of literature that would need to be carried around on visits to an external location or restaurant. Enhanced functionality might also include offering advice on healthy eating, weight recording, historical tracking, and offering encouraging messages via SMS text alerts, podcasts, or vodcasts to make the process of controlling weight and eating healthily more attractive and supportive.

Textbox 8. Comments on diet and calorie counter apps.

P: *I have the books at home or in my flat, but I wouldn't carry it around in a bag like this or something to go out for a meal or I'd just try and guess work how much carbs I was eating but whereas if you can just flick it onto, on an app it would be much easier wouldn't it? I think it would be good for accessing it really...*

[T1-QOL-03]

I: *…maybe a little sort of weight related in terms of um, encouraging you to um, sort of put your readings in to keep…*

P: *Yeah*

I: *…to keep going with that, when you've started…*

P: *To stick to healthier eating, yeah.*

[T1-QOL-05]

SOS App

A free BlackBerry app, the Personal Guardian [42], allows a user to summon help with the press of a button in an emergency situation. Users send an SOS by triggering a silent alarm to call 911 in the United States (or any other number entered), in addition to sending an email, text message, or Twitter post with the user's current location, using GPS technology within the device. Users do not have to unlock their phone or wait for the app to open; they simply hold down the convenience button on the side of their BlackBerry. Being able to provide a similar function to this app within a diabetes environment would offer several similar benefits (eg, in the event of a hypoglycemic episode) and might also offer improved HRQOL solutions for other conditions like epilepsy. This was viewed as being a very useful solution because young people with type 1 diabetes were reluctant or often forgot to wear medical alert bracelets as they got older: "…because if you did collapse, you know, they're going to look for your home number or someone to contact it might be really useful to say [laughs nervously] in the event of an emergency you know, just click on that thing on the iPhone or a BlackBerry..." [T1-QOL-03]

24-Hour Online Help Desk

Another beneficial suggestion, though appreciably more difficult to maintain due to the high cost implications, was the production of a 24-hour online help desk that could be accessed via an app, SMS text message, email, Twitter, or real-time chat facility. The challenges may include funding this idea, along with the complexities of the design and programming, rather than the use of specific communication media; any of the above suggestions would provide an improved service to help improve HRQOL. One interviewee noted: "In the event of an emergency, I mean if someone could just tweet on there 'Help what do I do? So and so's got a nose bleed and she's diabetic' or something like that you know". [T1-QOL-03]

It is more likely that this age group would want to engage with these sorts of media rather than older users based on current literature [43,44]. But, by providing this service at a younger age, it could be argued that over time health services would actually benefit, saving money by decreasing the number of complications experienced by this age group, which in some cases led to their hospitalization [2].

Discussion

This research highlights that there are many ways in which the HRQOL of young people with type 1 diabetes could be improved, through the design and implementation of new technological innovations and enhancements that use Web and mobile technology. This research tells us that there is a need to consider three factors before anything is actually developed: (1) considering young people's relationship to technology, (2) reflecting on how this might be able to effectively make a difference to them, and (3) considering when it might not be a suitable mechanism to use.

Young People's Relationship With Technology

The age when most interviewees obtained their first mobile phone was quite young in comparison to previous generations—on average, at the start of teenage years, although some interviewees had obtained them even earlier, in some cases, from the age of 9 or 10. Therefore, from a relatively young age this generation has viewed their phone as a constant companion, accompanying them at play, through school, university, and then work use: "because I wasn't carrying the book around with me, whereas with my phone…it's always with me wherever I go". [T1-QOL-05]

It appears that newer smartphone devices have gradually started to replace other electronic media that interviewees owned like MP3 players, laptops, cameras, and paper-based systems like diaries. As the capabilities of smartphones have increased, they can be viewed as ever more attractive options for use in relation to type 1 diabetes. Indeed, 60% of 16 to 24-year-olds in the United Kingdom now use a mobile phone to access the Internet every day [43], while in the United States, 42% of mobile owners aged 18-29 have looked for health and medical information on their mobile devices [44]. Because this generation of users has become more attached to their mobile device, there are important implications on how future education, awareness, and management of type 1 diabetes could be changed or integrated with technology. For example, it has been noted [45] that the majority of adolescents wished to communicate only by SMS text message for follow-up post education, highlighting the need for health professionals to adapt to the lifestyle and mechanisms of communication adopted by today's adolescents. Literature suggests that there is a thirst for new technology to be applied in the care of type 1 diabetes and on the rare occasions when young patients have been asked [46], they were keen on trying new solutions, although there remain doubts as to whether technology can effectively help them in all aspects of education and self-management [11].

How Technology Can Make a Difference

In some cases, the closeness of technology to the young person had already led to it being used innovatively in relation to their condition, such as using alarm functionality on a mobile phone. It is important to note that some users would be more likely to engage with diabetes-specific, app-related technology if cost were not an issue. The main benefits mentioned by interviewees of using diabetes apps tended to focus on their ability to replace paper-based information, like logbooks and books, which they previously had to carry around with them, in addition to their other diabetes equipment. However, there was a feeling that current apps, although helpful, were not actually worth using. This could be due to the cost, flexibility, design, and usefulness of the apps themselves, or the lack of a cohesive guiding framework for using them, which could involve the clinic in some way. For example, if a CBGM automatically logged blood glucose, what was gained by interviewees having to additionally enter it themselves on their phone? The lack of a decent quality app for blood glucose monitoring was mentioned by one participant directly while others lamented the lack of UK-centric apps; the dietary values on those available were slightly different, making them difficult to use effectively. This was a comment also directed at some of the data held on the Carbs & Cals app [39], even though the app itself was well regarded. Participants could see the value of accessing up-to-date information via some form of technology like Twitter [29] as a means of providing them with support and information, such as increasing awareness of information on new CBGM about to be released and other technological innovations, highlighting news on scientific advances, and helping with support immediately after diagnosis.

Technology could also be used to ease the transition between different clinics and prevent issues such as the lack of notification of changes in guidance [29]. This could help minimize the problems of receiving differing, seemingly contradictory, advice from different parts of the health service. Technological enhancements were suggested for the development of health apps that might be useful to them in the areas of Twitter [29], illness and diabetes [29], hypoglycemia and diabetes [29], and alcohol and diabetes [30]. These were in addition to the many other ideas and suggestions they had for improving their lifestyle and making a difference in other areas of their lives affected by their condition, which were not taken forward to development (see Results).

As can be seen from these suggestions, there are a number of areas where new technological solutions might help to bridge a gap and offer new opportunities to improve HRQOL for this age group and condition. It is a surprising aspect of this research that there were so many areas mentioned that have yet to be adequately addressed, either not existing at all or existing in an inadequate or unsatisfactory product for this age group. It is more surprising in light of the current poor performance of UK diabetes care and the length of time these technologies have now been around for: "There is apps on here but I've never used them because they don't seem that good. Just seems like someone in the back shed's made them". [T1-QOL-01]

Considering When Not to Use Technology

There was a strong feeling expressed by interviewees that although the condition, type 1 diabetes, might be the same, the experience of living with it was completely different for each individual. Just as each person had their own unique perspective and a completely different personal experience of living with type 1 diabetes, so they also required different approaches and suggestions based on their own personal preferences toward technology: "no one, no two people are the same with diabetes, everybody is different". [T1-QOL-08]

This means not assuming that everybody in a particular age group will automatically adopt any new form of social media or technology. It is notable that not all interviewees were drawn to engage with new products if they did not directly appeal to them in some way. For the majority of users, from a mobile perspective, apps were quite a new development even though launched some time ago, and some interviewees had not made much use of them. One of the reasons for this was financial; users were reluctant to try them out because they were frightened about the implications of creating an account or they were reluctant to pay for an Internet connection as a part of their mobile contract. The general theory concerning Web 2.0 and social media suggests that it facilitates and encourages use and collaboration. So, it is in stark contrast that this particular age group does not always feel inclined to use it as a mechanism for obtaining information and support for their condition. It might be that aspects of their character or personal feelings limit them from interaction in online environments with people they do not know. Or they might have conditions precluding certain areas or functions of online activity, like Asperger's syndrome. They may not wish to share information about their condition online—the technological equivalent of Williams' [47] findings on how diabetes is sometimes kept separate from social identity. Aspects of technology use that might be diversive; use the wrong medium to spread a health message; try to manipulate something entertaining into something educational without clear education, explanation or support; or exclude through cost or software system could negatively impact on any technological enhancement implemented. They need to be given clear and careful consideration before any solution is developed.

Limitations

The main limitations of this study are that it was not able to test the impact of the innovative tool that was created [29-30] and that more of the other suggested enhancements were not able to be taken forward for development (see Results). However, future research projects can help to address this, by measuring the impact of the created app locally, nationally and overseas using a validated HRQOL measure. Additional health apps based on this research approach can also be designed, tested, built and implemented using the same approach and then be subsequently measured for any positive or negative impact on HRQOL.

Conclusions

We need to consider in depth the relationship to technology that young people with type 1 diabetes now have and then consider how this might make a difference to them. But we also need to decide when it might not be a suitable mechanism to use. By reflecting on these areas, any technology to be created will be much more usable and suitable for the target users. Reflecting on the tenets of good sociotechnical design related to the creation of new or enhancements to existing health apps, democratic and participative communication and decision making must always be available to give users a voice [22]. Future developments concerning the use of mobile phones and health apps should reflect and focus on how this generation has become accustomed to using them and where they might best fit best in a health context - acknowledging that this will not naturally be successful in every circumstance. This will be a key way to address a broad range of enhancements to improve HRQOL that will be used regularly and make a real difference. For example, a new CBGM app could be tailored to include personalized information about insulin, weight, food intake, height and other useful data, without replicating the functionality of existing CBGM that already have the ability to record these data. Stepping back and taking a more practical, logistical approach to some of the problems users experienced, a tip sheet written for other parents and friends could be emailed to them as a PDF prior to a sleepover. Calorie and carbohydrate counting material could be provided as a specially tailored e-Book or PDF instead of as an app, so that it could be accessed without the need for an Internet connection via a simple and quick indexing system. Another options would be enhancing (based on user requirements) or using existing mobile phone technology in new ways to harness improvements to HRQOL, such as using push technology for pop-up reminders about insulin injecting, blood sugar level checking and having something to eat (but in a more attractive and interactive way for younger users).

The need is there and has been highlighted—we just need to create the proper technological solutions that this user base is asking for. The World Health Organization estimates that more than 80% of diabetes deaths occur in low- and middle-income countries and projects that diabetes deaths will increase by two thirds between 2008 and 2030 [48]. We hope that the dissemination of these innovative ideas and enhancements for possible mobile interventions, education, and support will offer ways to help reduce these figures. It is vital for policy makers, health practitioners, and technicians to take note of and reflect on these ideas and the issues that they raise. Helping to build an enhanced understanding of young people with type 1 diabetes and what they might use, what is not being provided to them in the format and design they require, and what they would like to see in future type 1 diabetes education and support could improve HRQOL and reduce the health care burden.

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

CBGM: capillary blood glucose monitor
HRQOL: health-related quality of life
NHS: National Health Service
PAC: Public Accounts Committee
RCT: randomized control trial
SMS: short message service
SWDC: district hospital in South West England

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Original Paper

Personal Health Technologies in Employee Health Promotion: Usage Activity, Usefulness, and Health-Related Outcomes in a 1-Year Randomized Controlled Trial

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Abstract

Background: Common risk factors such as obesity, poor nutrition, physical inactivity, stress, and sleep deprivation threaten the wellness and work ability of employees. Personal health technologies may help improve engagement in health promotion programs and maintenance of their effect.

Objective: This study investigated personal health technologies in supporting employee health promotion targeting multiple behavioral health risks. We studied the relations of usage activity to demographic and physiological characteristics, health-related outcomes (weight, aerobic fitness, blood pressure and cholesterol), and the perceived usefulness of technologies in wellness management.

Methods: We conducted a subgroup analysis of the technology group (114 subjects, 33 males, average age 45 years, average BMI 27.1 kg/m^2) of a 3-arm randomized controlled trial (N=352). The trial was organized to study the efficacy of a face-to-face group intervention supported by technologies, including Web services, mobile applications, and personal monitoring devices. Technology usage was investigated based on log files and questionnaires. The associations between sustained usage of Web and mobile technologies and demographic and physiological characteristics were analyzed by comparing the baseline data of sustained and non-sustained users. The associations between sustained usage and changes in health-related outcomes were studied by repeated analysis of variance, using data measured by baseline and end questionnaires, and anthropometric and laboratory measurements. The experienced usability, usefulness, motivation, and barriers to using technologies were investigated by 4 questionnaires and 2 interviews.

Results: 111 subjects (97.4%) used technologies at some point of the study, and 33 (29.9%) were classified as sustained users of Web or mobile technologies. Simple technologies, weight scales and pedometer, attracted the most users. The sustained users were slightly older 47 years (95% CI 44 to 49) versus 44 years (95% CI 42 to 45), *P*=.034 and had poorer aerobic fitness at baseline (mean difference in maximal metabolic equivalent 1.0, 95% Cl 0.39 to 1.39; *P*=.013) than non-sustained users. They succeeded better in weight management: their weight decreased -1.2 kg (95% CI -2.38 to -0.01) versus +0.6 kg (95% CI -0.095 to 1.27), *P*=.006; body fat percentage -0.9%-units (95% CI -1.64 to -0.09) versus +0.3%-units (95% CI -0.28 to 0.73), *P*=.014; and waist circumference -1.4 cm (95% CI -2.60 to -0.20) versus +0.7 cm (95% CI -0.21 to 1.66), *P*=.01. They also participated in intervention meetings more actively: median 4 meetings (interquartile range; IQR 4–5) versus 4 meetings (IQR 3–4), *P*=.009. The key factors in usefulness were: simplicity, integration into daily life, and clear feedback on progress.

Conclusions: Despite active initial usage, less than 30% of subjects continued using Web or mobile technologies throughout the study. Sustained users achieved better weight-related outcomes than non-sustained users. High non-usage attrition and modest outcomes cast doubt on the potential of technologies to support interventions.

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KEYWORDS

health promotion; intervention; Internet; mobile phones; device; risk factors; health technology

Introduction

Personal health technologies such as Web services, mobile applications, and personal monitoring devices designed for individuals to manage their own health and wellness, are expected to enable more cost effective health promotion and disease prevention. These technologies thereby can help cut the costs of healthcare, work-related absenteeism, and disability. Personal health technologies could be used to deliver complete health promotion interventions or to support face-to-face interventions.

Various computerized interventions have been used in health promotion for several decades. Portnoy et al [1] reviewed 75 articles on computerized interventions over 20 years and found that they were successful in changing health-related knowledge, attitudes, and intentions; nutrition and smoking, but not physical activity or weight. On the other hand, Norman et al [2] reviewed 47 eHealth intervention studies and found that about half of them had favorable outcomes for eHealth interventions compared to control groups in increasing physical activity, improving diet, and facilitating weight loss.

Mobile health promotion programs have been implemented using text messaging or portable devices such as personal digital assistants [3]. These interventions have produced favorable outcomes in areas such as weight loss, physical activity, smoking cessation, and anxiety [3-7]. Mobile phone applications, running in individuals' personal mobile phones, might improve the usefulness and integration of the interventions into the daily routines of the users. However, the widespread utilization of mobile phone applications is still hindered by the variety of mobile phone operating systems, making it challenging to develop applications and services [8]. There are promising preliminary results on the ability of mobile phone applications to increase physical activity and improve nutrition [9,10].

Personal monitoring devices, such as weight scales, pedometers, and heart rate monitors have also been evaluated in health promotion. Frequent self-weighing has been found to be associated with better weight loss and weight maintenance results [11,12]. A review by Bravata et al [13] found that using pedometers was associated with significant increases in physical activity and decreases in body mass index and blood pressure. Byrne et al [14] found that a weight loss program delivered via a heart rate monitor was superior to standard care weight management advice.

In the United States, the majority of adults have more than 1 out of the 4 main health risks (smoking, risky alcohol consumption, physical inactivity, and overweight) [15], which implies that interventions targeting several risk factors simultaneously may be needed. However, the evidence for this type of intervention is contradictory, especially for primary prevention. Goldstein et al [16] examined several reviews on primary care interventions addressing the multiple behavioral risk factors of diabetes and cardiovascular disease and found that while many gaps in the evidence remained, secondary prevention interventions gave the most promising results. Robroek et al [17] found that programs consisting of multiple components or targeting multiple behaviors produced higher participation rates. In line with this, Portnoy et al [1] found that single-approach interventions were used a median of 3 times, whereas multiple approach interventions had a median of 11 usage sessions. However, interventions targeting multiple behaviors may be more burdening for the participants than single-behavior interventions due to having more content and requiring more time [2].

Key problems in worksite health promotion programs are low participation and high attrition. Robroek et al [17] found that, typically, less than 50% of employees are reached. In a review by Bull et al [18], the median attrition rate in worksite health promotion programs was 28%. Low participation and high attrition also plague eHealth interventions [19]. Combined with low usage rates, this usually means that the participants do not receive the intended dose of intervention, which detracts from the effectiveness, cost-effectiveness, and generalizability of the interventions [20]. Sustained and frequent usage of intervention has been found to lead to better outcomes in terms of physical activity, dietary behavior change, and weight loss [2,21]. However, high attrition may be normal and natural for eHealth interventions for health promotion. Potential explanations are that the intervention is not mandatory or critical to the participants' wellness, a lack of tangible advantages in continuing use, lack of encouragement from health professionals, a lack of reminders, external events distracting attention from the intervention, and ease of discontinuation [19].

Studying the sub-group that uses the intervention may provide useful information on topics such as user characteristics [19]. This may help identify the groups for which the intervention is most applicable and determine the efficacy of the intervention if participants are exposed to it frequently and over prolonged periods. Probably not all individuals will benefit from personal health technologies, but they may serve a useful role when targeted well and provided in an appropriate context.

A 3-arm randomized controlled trial (N=352) was organized to study the efficacy of a group health promotion intervention, targeting multiple lifestyle-related health risks with and without the support of personal health technologies [22,23]. It was expected that personal health technologies would support the face-to-face intervention by improving its efficacy or the

maintenance of the health-related changes. It was also expected that only active usage of technologies would lead to these added benefits and it was also expected that not all the subjects would adopt the technologies.

A subgroup analysis of the technology group was conducted to investigate the role of personal health technologies in supporting the intervention. Our objectives were to investigate the following issues: (1) the usage activity of personal health technologies during the 1-year study period, (2) the associations between sustained usage and the demographic and physiological characteristics of the subjects, (3) the associations between sustained usage and changes in health-related outcomes (ie, weight, aerobic fitness, blood pressure, and blood cholesterol), and (4) the perceived usefulness of the technologies in wellness management.

Methods

Study Set-Up

The intervention was targeted at employees with elevated health risks but who were still relatively healthy and had no immediate risk of disability. They also needed to have sufficient motivation and the ability to make lifestyle changes. In the fall of 2007, the screening of eligible subjects was done via a Web-based health questionnaire sent to all employees of the city of Espoo, Finland. The inclusion criteria were as follows: age of 30-55 years, willingness to participate in the intervention and to make lifestyle improvements in one of the targeted behaviors (ie, weight management, eating habits, physical activity, sleep habits, smoking, or alcohol consumption) within the following 6 months. The included subjects needed to rate their work ability as 7, 8, or 9 on a scale of 0 to 10; 10 being their lifetime best work ability [24]. In addition, they had to have either increased risk of diabetes (score of 12-20 in the Diabetes risk test, [25]) or at least two of the following inclusion criteria: (1) overweight (body mass index; BMI=27-34 kg/m^2), (2) low physical activity level (not meeting physical activity recommendations [26]), (3) unhealthy eating habits (not eating vegetables daily and/or not eating during the working day), (4) sleeping difficulties (at least 2 hours of self-assessed sleep deprivation), (5) risky alcohol consumption (score of 5 or more for men, 4 or more for women in the Alcohol Use Disorders Identification Test [27]), and (6) daily or occasional smoking. Pregnant women were excluded.

In total, there were 4134 employees (37.93%) who responded to the health questionnaire, and 783 fulfilled the inclusion criteria. Out of the 783, 352 eligible respondents were randomly assigned to 1 of 3 groups; (1) face-to-face group intervention, (2) face-to-face group intervention supported by personal health technologies, and (3) a control group receiving standard occupational healthcare. The randomization was done by drawing a random number between 0-1 from a uniform distribution for each eligible respondent. The random numbers were sorted to ascending order and the subjects with the lowest 120 random numbers were assigned to the intervention supported by technologies, the next 120 to the intervention without technologies, and the next 120 to control group. After randomization, it was found that 17 subjects had a BMI over 35. To comply more closely with the original inclusion criterion of BMI, they were excluded from the analyses. As a result, there were 4 excluded subjects in the technology group (Figure 1). Thus in the technology group, there were 114 subjects included in the analyses. The randomized controlled trial has been presented in more detail elsewhere [22,23]. This study focuses on the intervention group supported by personal health technologies.

The trial was registered with a local ethics committee in Finland, but not in any international registry. This was the convention in Finland at the time the study was started in 2007. The ethics committee of Helsinki and Uusimaa Hospital District approved the study and all the subjects gave their written informed consent.

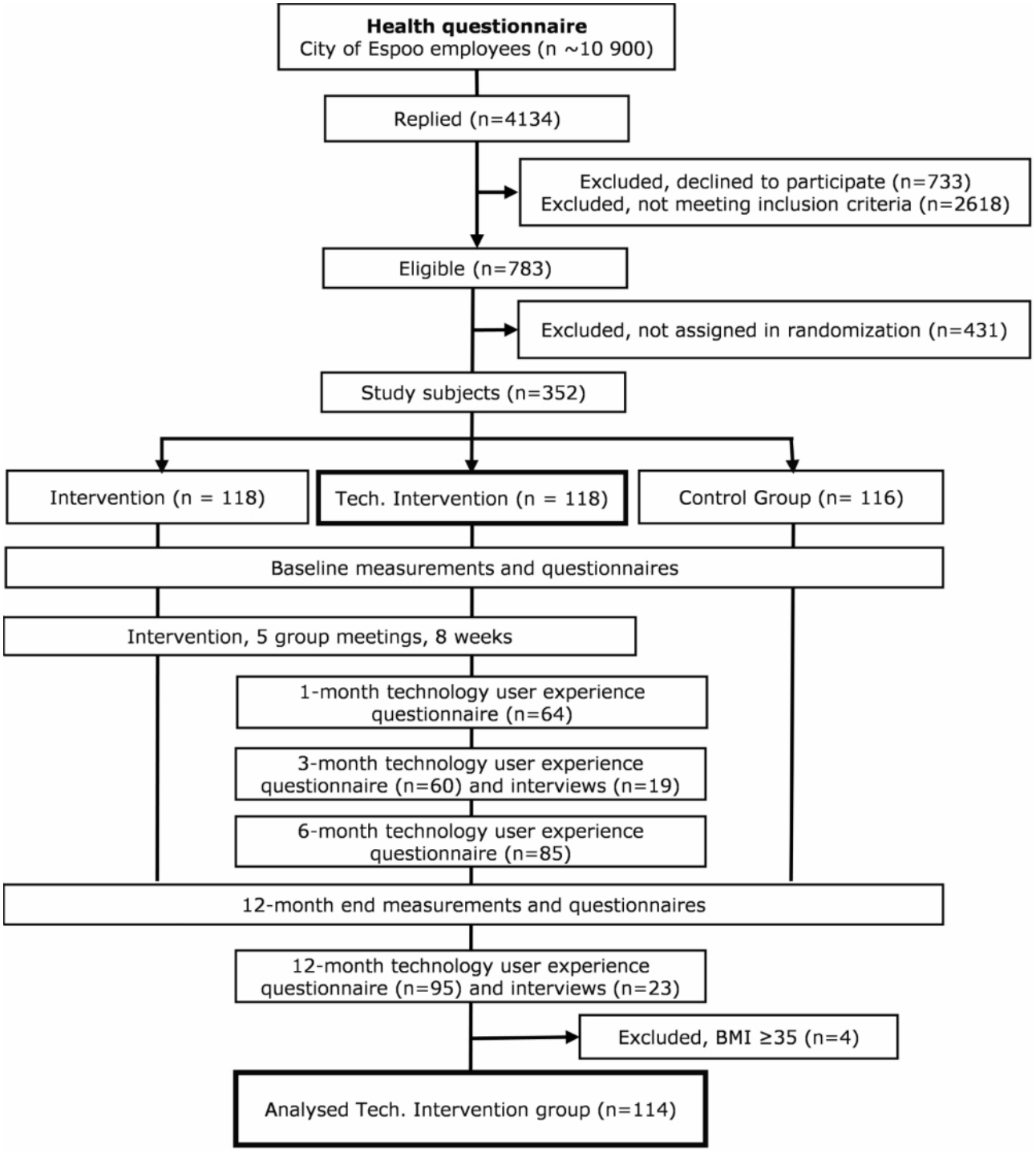
Intervention

A face-to-face intervention program was developed to target several behavioral health risk factors, namely overweight, poor eating habits, physical inactivity, sleep problems, stress, excess alcohol consumption, and smoking. The intervention was designed to motivate and empower individuals by teaching them generic strategies for improving their lifestyles, irrespective of their personal goals and health risks. The intervention was based mainly on the transtheoretical model [28] and acceptance and commitment therapy [29].

The intervention was delivered as 5 bi-weekly face-to-face meetings in groups of 7-12 subjects. The meetings were led by an intervention leader, trained to perform the intervention from a manuscript and with the guidance of the intervention developers. The following topics and strategies were covered during the course of the 5 meetings: personal analysis of values and good life and health and wellness (meetings 1 and 2), mindfulness skills (meetings 1 and 2), self-monitoring (meetings 1-3), problem-solving (meetings 3 and 4), healthy lifestyles and work ability (meeting 3), relaxation (meeting 4), and the transtheoretical model and preparation and planning for the future (meeting 5). The total duration of each meeting for the technology group was 2 hours, including a 90-minute intervention, followed by a 30-minute technology introduction. The subjects also received homework assignments. The intervention took place between February and June 2008 [23].

A toolbox of personal health technologies was developed to support the face-to-face intervention. The aim of the technologies was to provide additional support for behavior change and to help maintain the intervention effects between the meetings and also after the active intervention period. The technology toolbox was designed to address the strategies and health behaviors covered in the intervention meetings. All subjects were provided with the entire technology toolbox, though they were also encouraged to choose the technologies they considered the most appropriate in supporting their personal goals. The subjects were also told they could change technologies at any time; for example, if their needs changed.

Figure 1. Study procedures.



Personal Health Technologies

The technology toolbox consisted of monitoring devices, mobile applications, and Web services (Figure 2). Personal monitoring devices included off-the-shelf weight scales (seca sensa 804, Hamburg, Germany)[30] and a pedometer (Omron Walking style II, Kyoto, Japan)[31]. These devices were provided to support regular self-monitoring of weight and daily physical activity. In addition, the subjects were offered the loan of a heart rate belt (Suunto MemoryBelt; Suunto, Vantaa, Finland)[32] for 3-day heart rate variability measurement periods. At the end of the measurement period, the subjects returned the belt by mail and a researcher downloaded and analyzed the data using commercial analysis software (Firstbeat Health; Firstbeat Technologies, Jyväskylä, Finland)[33]. A report of the subjects' sleep, recovery, and physical activity was generated and sent to them via email or the Web portal.

There were 3 mobile applications in the toolbox. The Wellness Diary (Nokia, Helsinki, Finland) [34] enables manual self-monitoring of 16 health-related variables. The main variables in this study were as follows: weight, steps, exercise, eating, sleep, stress, smoking, and alcohol consumption. The Wellness Diary also provided automatic graphical feedback based on the entries [35,36]. The Wellness Diary is intended

for managing all aspects of wellness through regular self-monitoring and improved self-awareness of behaviors.

Mobile Coach (Firstbeat Technologies, Jyväskylä, Finland) [37] is a mobile exercise training application that creates an adaptive weekly exercise program based on the user's activity level and performed exercises. Mobile Coach allows the manual entry of exercises and provides graphical and numerical feedback on them along with a comparison of the user's progress in terms of set targets [36]. Mobile Coach was provided to support exercise and fitness goals, especially target-oriented training.

SelfRelax (Relaxline, Mantes La Jolie, France) [38] is an audio-guided relaxation application for use in short relaxation sessions. The user can choose the duration, purpose, body position, and background sounds for a relaxation session and the application automatically generates the session based on these parameters and a library of audio fragments. The programs can also be personalized, eg, by choosing specific relaxation techniques[36]. SelfRelax was used to support stress and sleep related goals.

A Web portal (the Portal; Nokia, Helsinki, Finland) [39] was developed specifically for the study. The Portal provided single sign-on access to three integrated wellness services, Wellness Diary Connected, Hyperfit, and Nutritioncode. It also included information on healthy lifestyles, compiled by the project team and based on national health recommendations. The Portal also enabled messaging between intervention leaders and subjects.

Wellness Diary Connected (Nokia, Helsinki, Finland) [40] is a Web-based version of Wellness Diary and was also developed specifically for the study. Wellness Diary Connected contains similar functionality to the mobile version, but it included only the entry and feedback of the main variables related to the study. The subjects could use and synchronize data wirelessly between the mobile and Web versions.

The 2 other services accessible through the Portal were Hyperfit [41,42] and Nutritioncode (Tuulia International, Helsinki, Finland)[43]. Hyperfit is a detailed food and exercise diary for weight management, which provides in-depth information on eating and exercise habits and the quality of nutrition. There were 2 versions of the service provided: a full website and a mobile-optimized website [41]. Hyperfit was provided to support weight management, and nutrition and exercise related goals. Nutritioncode is a commercial service for easy monitoring of the nutritional quality of groceries. The user needs the loyalty card of a Finnish grocery store chain, which is shown at the store check-out in order to transfer the nutrition data of the shopping basket to a Web service. Each transfer cost 0.2€ at the time of the study. Nutritioncode was provided to support goals related to nutrition. Due to the requirement of having a loyalty card, the Nutritioncode was not actively promoted to the subjects, nor was it included in the usage activity analyses.

The technologies were mostly commercial or near-commercial technologies; only the Portal and Wellness Diary Connected were developed specifically for the study. All technologies were frozen during the study; only bug fixes to the Portal were implemented to correct critical errors in the system. User support was available via email and telephone throughout the study during weekdays and office hours.

None of the technologies employed prompts or reminders to encourage their use. The only reminders were given in person at the intervention meetings at the beginning of the study. The subjects received no monetary reward for using the technologies. Each, however, was given a 20 € gift card to cover the cost of synchronizing data between the mobile and Web versions of Wellness Diary.

Figure 2. Toolbox of personal health technologies used in the trial: mobile applications, monitoring devices, and Web services.

Study Procedures and Outcomes

The subjects participated in baseline measurements after randomization and final measurements at the end of the study. The measurements included an electronic questionnaire ("baseline health questionnaire"), blood tests, anthropometric measurements, and an aerobic fitness test. The questionnaires were used to collect data on the subjects' health (eg, self-estimated health on a scale from 1=good to 5=poor) and health behaviors (eg, eating and exercise habits, smoking, sleep, and stress). Blood tests were taken to measure blood lipids (eg, total cholesterol and triglycerides). Anthropometric measurements were made by a research nurse and included data on height, weight, waist circumference, body fat percentage by bioimpedance, and blood pressure. The fitness test was a submaximal bicycle ergometer test for evaluating maximal aerobic capacity. The test was performed in a laboratory on a stationary bicycle ergometer with an initial load of 40/30 W (male/female) that was increased every 2 minutes by 20/15 W with a target of reaching 85% of estimated maximum heart rate. [22] In addition, the data collected with the initial screening questionnaire ("health questionnaire") was included in the baseline data. These data included, for example, the score of the diabetes risk test [25].

The technologies were issued to the subjects during the baseline measurement. The subjects were given the pedometers, weight scales, mobile phones (Nokia E50 [44] or Nokia 5500 Sport [45], Nokia, Helsinki, Finland) with the three applications pre-installed, and user accounts for the Portal. They also

received printed user guides and user support contact information. The subjects were encouraged to test out the technologies before the first intervention meeting and use the mobile phone as their primary phone. The technologies were introduced in detail at the intervention meetings, in the following order: meeting 1, weight scales, pedometer, Wellness Diary, and the Portal; meeting 2, Hyperfit; meeting 3, Mobile Coach; meeting 4, selfRelax; and meeting 5, heart rate belt and analysis. The heart rate belt was not provided for the subjects' personal use, though they could borrow it for three-day measurement periods after the fifth intervention meeting and receive the analysis reports as feedback.

Prior experience of using the technologies (ie, mobile phone and Internet), personal goals, and expectations related to wellness management were gathered using a separate electronic questionnaire ("baseline technology questionnaire") after the baseline measurements.

Usefulness data were collected with electronic questionnaires and telephone interviews. The questionnaires were conducted four times during the study; during the first month of use (1-month questionnaire), after the intervention period (3-month questionnaire), after 6 months (6-month questionnaire), and at the end of the study (12-month questionnaire). Each questionnaire asked the subjects about their usage activity of the technologies and presented 14–17 statements about each technology, rated on a scale from 1 (strongly disagree) to 5 (strongly agree). The statements measured perceived usefulness (eg, "It helps me reach my wellness goals"), ease of use, intention to continue usage, and user satisfaction (eg, "It does not provide sufficient feedback" and "I would recommend it to others"). The subjects were also asked to choose 3 technologies they felt best supported wellness management. Questions on the perceived wellness benefits of the technologies were included in the 6 and 12-month questionnaires. Usefulness interviews were conducted after the intervention period and at the end of the study with a target of interviewing 20–25 subjects per round. For the first interview, interviewees were randomly selected from those who had consented to the interviews. The same subjects were also approached for the second interview, but since not all of them could be contacted, additional interviewees were randomly selected from the remaining consenting subjects. In total, there were 19 subjects (14 female) who participated in the first interview and 23 subjects (13 female) in the second interview. There were 14 subjects who participated in both interviews.

Usage activity of Web and mobile technologies was investigated from the log files. The events stored in the log files included opening an application, logging in to a service, or making an entry. All mobile applications collected log files locally in the mobile phone. The Portal, Wellness Diary Connected, and Hyperfit collected log files to their servers. The usage activity of personal monitoring devices was studied from the usefulness questionnaires.

Analysis

Usage activity of Web and mobile technologies is presented in terms of the number of users (ie, those who had tried the technology at least once), usage days (a day with any log event), and weeks (a week with at least 1 log event). In addition, usage of the main self-monitoring variables is presented to illustrate how actively the various aspects of wellness were monitored. Medians and interquartile ranges (IQR) are reported for usage days and weeks since the data are not normally distributed. The usage activity of personal monitoring devices is presented as the number of subjects reporting use of the technologies in each of the usefulness questionnaires.

The time between the baseline measurement and the first intervention meeting varied between subjects, being 17 (SD 11) days on average. At this stage all the subjects had been given the technologies, but had not yet received detailed instructions and were not expected to start active usage. In the analyses of usage weeks the baseline is counted as one period, for simplicity. The rest of the study period is broken down into "weeks", ie, 7-day periods starting from the first intervention meeting. The duration of the study period also varied among subjects. At week 48, 95% of the subjects stayed enrolled in the study, after which they gradually finished the study. Thus, the baseline period and 48 weeks from the beginning of the intervention program are considered in the analyses.

Classification of usage activity was based on the usage of any mobile or Web technology. "Sustained users" were subjects who used technologies throughout the study. For this classification, the study period was divided into 13 periods, including the baseline period and 12 four-week blocks. If subjects had used any Web or mobile technology even once during a 4-week block, they were considered users during that block. Those who were users on at least 11 of the 13 blocks were classified as sustained users.

To study the associations between sustained usage and demographic and physiological parameters, the following baseline characteristics were explored: age, sex, education, BMI, smoking, self-estimated health, daily amount of exercise, and diabetes risk test score. In addition, the following baseline technology questionnaire parameters were included: prior mobile phone experience (regular user who used only phone calls and text messages vs advanced user who used additional features) and health-related goals (weight management goal and exercise goal). Differences in the baseline status between sustained and non-sustained users were analyzed using Student's *t* test for contiguous variables and chi-square test (or Fisher's exact test in the case where the expected cell frequencies are small) for categorical variables. Each baseline covariate was explored separately to determine if it was associated with sustained usage of technologies.

Health-related parameters measured at baseline and at the end of the study were analyzed and a comparison was made between sustained and non-sustained users. The following variables were included in the analyses: weight, body fat, waist circumference, blood pressure, total cholesterol, triglycerides, and aerobic fitness level (maximal metabolic equivalent value; METmax). Within-group differences were analyzed by paired *t* tests. Repeated measures analysis of variance (repeated ANOVA) was used to investigate the differences between the groups. Further adjustments to other baseline covariates were made if an imbalance between the groups was observed in the baseline

demographic or physiological parameters. There were 13 subjects who did not participate in laboratory measurements at the end of the study, and thus their data were unavailable. No imputations were made but the subjects were excluded from the analysis. Baseline characteristics of the withdrawals were described and compared to subjects who completed the study. No statistical test was conducted because the number of withdrawals was only 13.

Additionally, we calculated the post hoc power for all analyses where sustained and non-sustained users were compared. None of the outcomes was predicted since this is a subgroup analysis of the original trial. Thus, the observed power may provide additional information to support the inference.

Intervention participation was studied by comparing the number of meetings attended by the sustained and non-sustained users. The differences in participation between the groups were examined using the Mann-Whitney Utest. Statistical tests were conducted with risk level α=0.05. Analyses were conducted using SPSS (Statistical Package for Social Sciences) version 19. GPower 3.1.15 was used in the power calculations.

The usefulness questionnaires were used to determine the technologies that the subjects perceived most useful and the health-related benefits they had experienced during the study. The usefulness statements relating to each technology were examined by calculating the percentages of subjects agreeing to the statements in each questionnaire. Negatively worded statements were inverted to positive for this analysis. The interview responses were analyzed using thematic coding; a qualitative content analysis method [46]. There were 7 major themes (ie, ease of use, usefulness, motivation, learning, barriers to use, role of technologies in achieving wellness benefits, and usage habits) identified in the interview responses. The results are presented along with the quantitative questionnaire results to provide more in-depth information.

Results

Baseline Characteristics

The baseline demographics of the subjects are presented in Table 1.

Out of the 108 subjects (94.7%) who responded to the baseline health questionnaire; 72/108 subjects (66.7%) assessed their health as “good” or “fairly good”; 68 subjects (63.0%) reported meeting the criteria of having at least 30 minutes exercise per day. The mean diabetes risk test score was 9.4, which is classified as “slightly increased risk” of developing type II diabetes [25].

Out of 114 subjects, there were 88 (77.2%) who responded to the baseline technology questionnaire. Half of the respondents (44/88, 50%) were classified as regular mobile users using the phone mainly for calling and text messaging and the other half as advanced users using additional features, such as the calendar, camera, or mobile Web browser. Nearly all respondents (80/88, 91%) used computers at home or at work, used email (85/88, 97%), or the Internet (86/88, 98%).

The most typical wellness goal among the respondents was increasing physical activity and improving fitness (68/88 subjects, 77%). Other typical goals were weight and eating management (58/88, 66%), improving sleep duration and quality (33/88, 38%), and managing stress (25/88, 28%).

Nearly all (82/88, 93%) subjects believed the opportunity to consult an expert on health-related issues to be important in wellness management. Similarly, almost all respondents (83/88, 94%) wanted to have personal feedback on their health and wellness from an expert. Most respondents (62/88, 70%) felt that peer group support would be helpful. Technologies were also considered useful, especially mobile and portable technologies (74/88, 84%). Fewer believed in the usefulness of health-related Web services (46/88, 52%).

Usage Activity

Figure 3 presents the percentage of subjects who used Web and mobile technologies during the study. Out of the 114 subjects, 85 (74.6%) had tried out technologies during the baseline period and 57 (50.0%) subjects used technologies on at least 7 out of 8 weeks during the active intervention period. Technologies were used throughout the study by 33 (28.9%) subjects, who were classified as *sustained users*.

Altogether 111 subjects (97.4%) tried some technology during the study. There were 106 subjects (93.0%) who tried Web or mobile technologies at least once during the study (Table 2). The median number of usage weeks in this group was 14 (IQR=7–31). The most actively used technologies were Wellness Diary and selfRelax. The most actively self-monitored variables were weight, steps, and exercise. Table 3 presents the usage activity of the weight scales and pedometer based on usefulness questionnaires.

The heart rate belt was available for loan after the intervention period. The heart rate belt was borrowed at least once by 65 (57.0%) subjects. In addition, 9 (7.9%) subjects borrowed it 2 times and 3 (2.6%) subjects 3 times.

Table 1. Baseline characteristics of subjects

	Technology group, n=114
Sex, male (%)	33 (28.9%)
Age years, mean (SD, min–max)	44.6 (SD 7.1, 30–55)
BMI kg/m^2, mean (SD, min–max)	27.1 (SD 4.0, 19.6–34.3)
Education (% college/university or higher)	67 (58.8%)

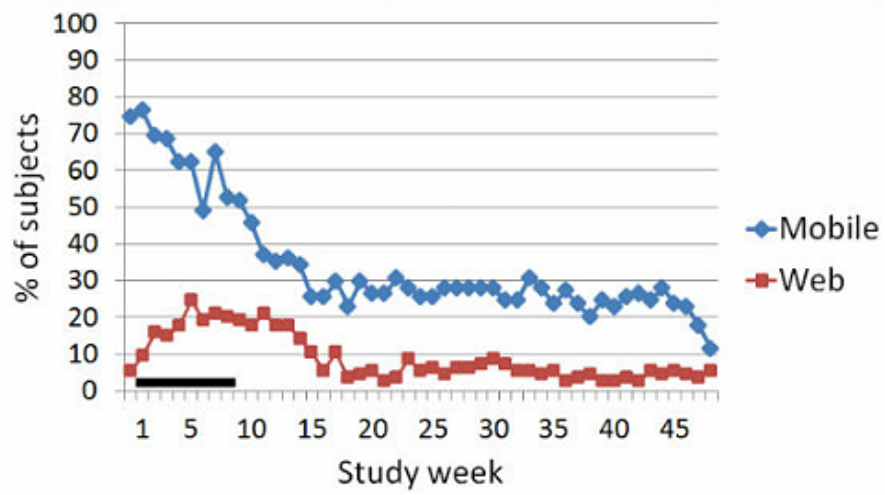
Table 2. Users and usage days and weeks for mobile applications, self-monitoring variables and Web services based on logs, presented as median (IQR), for the subjects who tried the technology at least once.

		Users N tried (%)	Usage days median (IQR)	Usage weeks median (IQR)
Wellness Diary				
	Total	96 (84.2%)	38 (8–95)	10 (4–25)
	Weight	90 (78.9%)	10 (3–46)	5 (2–19)
	Steps	81 (71.1%)	24 (7–67)	6 (2–15)
	Exercise	79 (69.3%)	12 (5–46)	6 (2–18)
	Sleep	65 (57.0%)	8 (2–30)	3 (1–7)
	Stress	44 (38.6%)	3 (2–5)	2 (1–3)
	Eating	66 (57.9%)	2 (1–6)	2 (1–3)
	Alcohol	46 (40.4%)	2 (1–7)	2 (1–3)
	Smoking	31 (27.2%)	1 (1–2)	1 (1–2)
Mobile Coach		53 (46.5%)	2 (1–16)	2 (1–6)
selfRelax		95 (83.3%)	7 (4–10)	5 (3–7)
Portal		86 (75.4%)	4 (2–11)	3 (2–7)
Hyperfit		39 (34.2%)	6 (2–13)	2 (1–5)

Table 3. Users of weight scales and pedometer according to usefulness questionnaires.

Questionnaire (N respondents)	Weight scales	Pedometer
1 month (N=64)	61 (95%)	62 (97%)
3 month (N=60)	46 (77%)	42 (70%)
6 month (N=85)	62 (73%)	39 (46%)
12 month (N=95)	68 (72%)	37 (39%)

Figure 3. Percentage of subjects using Web and mobile technologies during the study (baseline period = week 0) based on usage logs. Horizontal line along the x-axis indicates active intervention period.



Analysis of Sustained Users

Table 4 presents the comparison of sustained and non-sustained users in terms of demographics and baseline health and technology questionnaire responses. The sustained users were slightly older than the non-sustained users (Table 4). No other statistically significant differences were found in these characteristics which may also be partially related to low power in this analysis.

Table 5 presents the measured anthropometric and physiological variables and their changes between baseline and end measurements for both sustained and non-sustained users. The

only difference observed between the groups' baseline status related to aerobic fitness (mean difference in METmax=1.0, 95% Cl 0.39 to 1.39; *P*=.013).

Weight, body fat, BMI, waist circumference decreased, aerobic fitness, and total cholesterol increased among sustained users (Table 5). Among the non-sustained users, aerobic fitness, diastolic blood pressure, and total cholesterol increased during the study. Significant differences between sustained and non-sustained users were found in the average change of weight, body fat, and waist circumference. The analyses were repeated by adjusting for age and baseline level of aerobic fitness for which an imbalance between the groups was observed. This did not affect the results significantly (Table 5).

Sustained users participated in intervention meetings more frequently (median 4, IQR 4–5) than non-sustained users (median 4, IQR 3–4), *P*=.009.

There were 13 subjects (12 of them non-sustained users) who did not attend the laboratory measurements at the end of the study. The completers were more often advanced mobile phone users than the withdrawers (51.2% vs 37.5%). More of the completers also had a good or fairly good self-estimated health (74.7% vs 58.3%). More of the withdrawers than completers had a weight management goal (87.5% vs 62.5%) and had at least 30 minutes of daily exercise (50.0% vs 35.4%).

Table 4. Comparison of baseline demographics and baseline health and technology questionnaire responses between sustained users and non-sustained users as mean (SD) or frequency (percentage).

	Sustained users, n=33	Non-sustained users, n=81	*P* value	Power
Male[a], n (%)	8 (24%)	25 (31%)	.507	.108
Age[a][years], mean(SD)	47 (6)	44 (7)	.034	.566
BMI[a][kg/m^2], mean(SD)	27.7 (4.0)	26.9 (4.0)	.248	.184
Education[a], n high school or higher (%)	18 (55%)	49 (60%)	.675	.09
Diabetes risk test scores[a][25], mean (SD)	10.1 (5.8)	9.2 (5.3)	.391	.137
Smoking[b], n (%)	6 (19%)	21 (28%)	.344	.173
Daily exercise at least 30 minutes[b], n (%)	12 (38%)	28 (37%)	1.0	.05
Self-estimated health[b], n "good" or "fairly good" (%)	27 (84%)	51 (67%)	.099	.419
Familiarity with mobile phone[c], n advanced[d](%)	17 (61%)	27 (45%)	.252	.277
Exercise goal[c], n (%)	23 (82%)	45 (75%)	.588	.114
Weight management goal[c], n (%)	22 (79%)	35 (58%)	.093	.455

[a]Data available for all 114 subjects.

[b]Data obtained from baseline health questionnaire and available for 32 sustained users and 76 non-sustained users.

[c]Data obtained from baseline technology questionnaire and available for 28 sustained users and 60 non-sustained users.

[d]Advanced mobile phone functions (eg, calendar, camera, or Web browser) used at least weekly.

Table 5. Changes in anthropometric and physiological variables as mean change within groups and their 95% confidence interval. n denotes the number of subjects for whom the measurements were available and P values for group x time interaction indicate the significance whether the groups have evolved differently from baseline to end-point.

	Sustained users			Non-sustained users					
	n	Baseline mean (SD)	Within group change	n	Baseline mean (SD)	Within group change	*P* value for *group x time* interaction	Power	Adjusted[a] *P* value for *group x time* interaction
Weight, kg	32	79.9 (15.2)	-1.19 (-2.38 to -0.01) *P*=.048	69	77.5 (14.1)	0.59 (-0.10 to 1.27) *P*=.09	.006	.789	.026
Body fat, %	32	29.9 (6.8)	-0.866 (-1.64 to -0.09) *P*=.03	67	27.4 (8.5)	0.23 (-0.28 to 0.73) *P*=.370	.017	.672	.020
Waist, cm	32	95.6 (13.9)	-1.3969 (-2.59 to -0.20) *P*=.024	69	91.0 (11.1)	0.72 (-0.21 to 1.66) *P*=.127	.009	.751	.012
BMI, kg/m^2	32	27.8 (4.1)	-0.446 (-0.88 to -0.02) *P*=.043	69	26.8 (4.0)	0.12 (-0.11 to 0.35) *P*=.314	.013	.707	.049
Aerobic fitness (METmax)	31	7.3 (1.0)	0.54 (0.29 to 0.78) *P*<0.001	68	8.3 (1.4)	0.42 (0.21 to 0.62) *P*<.001	.477	.109	.390
Systolic blood pressure, mmHg	32	124 (14)	-0.44 (-4.35 to 3.47) *P*=.821	69	121 (13)	1.54 (-1.12; 4.23) *P*=.259	.408	.131	.654
Diastolic blood pressure, mmHg	32	80 (8)	1.06 (-1.48 to 3.61) *P*=.401	69	78 (7)	1.70 (0.18 to 3.21) *P*=.028	.652	.073	.639
Triglycerides, mmol/l	32	1.18 (0.70)	-0.08 (-0.34 to 0.18) *P*=.554	68	1.13 (0.65)	-0.09 (-0.20 to 0.02) *P*=.112	.920	.051	.553
Total cholesterol, mmol/l	32	4.5 (0.8)	0.28 (0.06 to 0.49) *P*=.013	67	4.9 (1.0)	0.27 (0.11 to 0.42) *P*=.001	.962	.05	.912

[a]Adjusted for age and aerobic fitness (METmax)

Usefulness of Technologies in Wellness Management

Response rates to the usefulness questionnaires varied between questionnaires and also between questions within the questionnaires. Of the 114 subjects, there were 64 (56.1%) who responded to the 1-month questionnaire (range for individual questions 33–64 subjects, 28.9–56.1%), 60 subjects (52.6%) to the 3-month questionnaire (range 49–60 subjects, 43.0–52.6%), 85 subjects (74.6%) to the 6-month questionnaire (range 77–85 subjects, 67.5–74.6%), and 95 subjects (83.3%) to the 12-month questionnaire (range 90–95 subjects, 78.9–83.3%).

The interviewees represented different types of technology users, including non-users, moderately active and sustained users. The median number of usage weeks among the interviewees was 16 in the first interview and 13 in the second interview.

The weight scales and pedometer were regarded as the best technologies for supporting wellness management in all post-intervention questionnaires, followed by Wellness Diary and heart rate belt (Figure 4).

According to the usefulness statements, the scales, pedometer, and Wellness Diary were also most often the highest rated (Multimedia Appendix 1). For most technologies, satisfaction decreased slightly over time. Of all respondents, 73–78% felt that the scales motivated them to maintain or improve personal wellness. The same was true for 68–83% of respondents about the pedometer and for 43–59% about the Wellness Diary. The same technologies were also perceived as having useful features by most respondents: 79–83% for the scales, 79–88% for the pedometer, and 45–66% for Wellness Diary. Most of the respondents reported that they would also recommend these

technologies to others: 67–80% would recommend the scales, 71–85% the pedometer, and 38–55% the Wellness Diary.

According to the interviews, the important motivational factors of the technologies were the ability to see one's progress and be reminded to do an activity, such as walking or exercising (Multimedia Appendix 2). The main appeal of the weight scales and pedometer were their simplicity, ease of use, and concreteness. The benefits of the Wellness Diary were the record it provided of personal progress and development in long-term health data through graphical feedback. The heart rate belt and analysis report were valued for the interesting and all-round feedback. The benefits of the Mobile Coach were seen to be its adaptive exercise programs and coaching. The interviewees also noted the benefits of SelfRelax, which provided relaxation programs for specific situations, such as falling asleep, relaxing after work, or unwinding after a challenging encounter.

Typical barriers to using the technologies included problems with the phone or the Portal being down. An unexpected barrier to use reported by some interviewees was a sense of irritation at being pressurized by the technologies to do healthy activities (Multimedia Appendix 2).

At 6 and 12 months, the subjects were questioned on the behavioral and wellness-related benefits gained by participating in the study and using the technologies (Figure 5). Apart from the health insights, willingness to change and lower stress, the perceived benefits decreased somewhat from 6 to 12 months.

Perceived benefits and measured health-related outcomes were correlated. There were 23 respondents who self-reported as having achieved weight loss at the end of the study. Their average measured weight change was -2.9% (95% CI -4.8 to -1.3). There were 17 respondents who had lost at least 0.5% of their baseline weight, 5 who had maintained or gained weight, and 1 respondent who had no end measurement. At the end of the study, there were 51 respondents who reported that they had increased their amount of exercise.Their measured average change in aerobic fitness (METmax) was 0.53 (95% CI 0.32 to 0.74). There were 36 respondents who had increased their aerobic fitness, 13 who had maintained or decreased their fitness, and 2 who had no end measurement. Many interviewees also reported that the technologies had a role in motivating and helping them achieve the health-related benefits (Multimedia Appendix 3).

The interviewees also reported changes in their usage habits during the study (Multimedia Appendix 3). In most cases this meant they had either stopped using certain technologies or started using them less often because they no longer needed them or needed them less. The users also changed technologies during the study. In the case of the pedometer, the most common reason reported was that the user had already learned enough. The reasons for the decrease in usage of the Wellness Diary were a change of routines from daily entries to entering several days' data at a time or stopping usage of certain variables due to a perceived lack of need. The interviewees also reported taking breaks, and recommended that the technologies could better support such intermittent usage. A typical time to take a break was summer holidays. Some of the respondents continued to use the technologies after a break but others did not.

Figure 4. Best technologies for supporting wellness management based on responses to the 3-month, 6-month, and 12-month questionnaires. The bars represent the percentage of respondents choosing the technology among the top 3 best technologies.

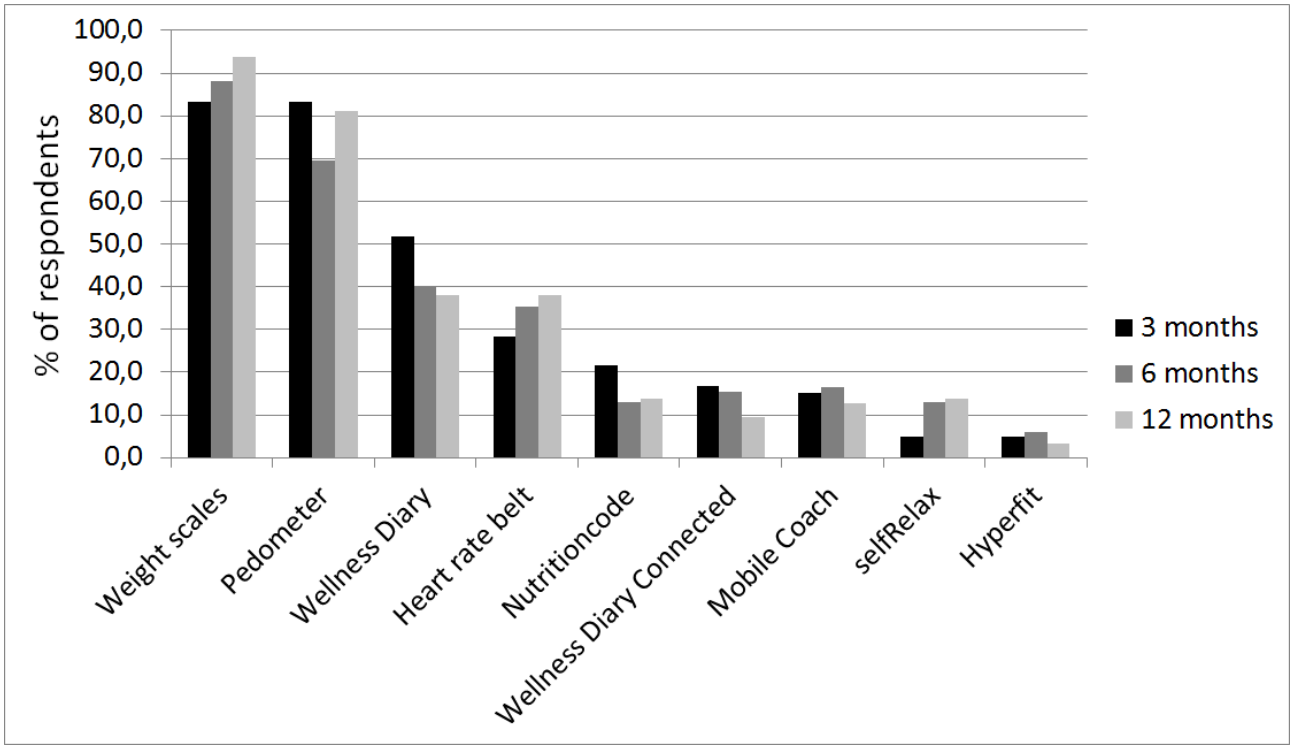
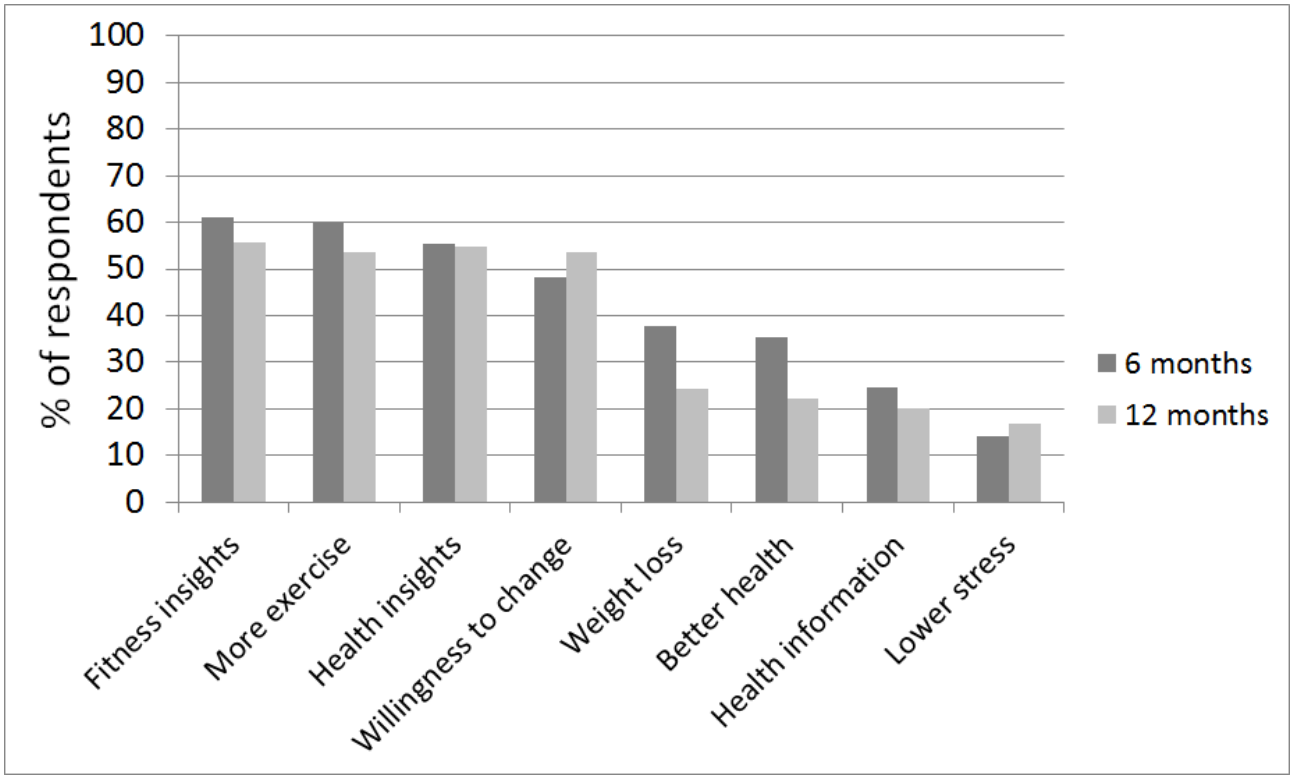


Figure 5. Health-related benefits reported by the respondents.



Discussion

Summary

The study examined the role of personal health technologies in supporting a face-to-face group health promotion intervention with a group randomized to using a toolbox of personal health technologies in a 1 year randomized controlled trial. The technologies included Web services, mobile applications, and personal monitoring devices. The study also investigated the uptake and sustained usage of various technologies as well as their perceived usefulness. The associations between sustained usage and baseline demographic and physiological characteristics as well as changes in health-related outcomes (ie, weight, aerobic fitness, blood pressure, and blood cholesterol) were also considered here. The participants were basic technology users and not early technology adopters. As such, the study provides insights into technology adoption by a fairly typical working population.

Primary Findings

Most subjects, (111/114, 97%), had tried out the technologies at least once. Half of them had used mobile or Web technologies throughout the active intervention period (weeks 1–8), after which the number of users declined, leaving 33 (29%) sustained users. The median number of usage weeks for mobile or Web technologies was 14 (IQR 7–31). The scales and pedometer were the most popular technologies; at the end of the study, 72% of the questionnaire respondents reported continuing to use the scales and 39% the pedometer. Of the Web and mobile technologies, the most actively used technology was the self-monitoring diary, which was provided as a mobile application (Wellness Diary) and a Web service (Wellness Diary Connected).

Low participation and high attrition rates are common drawbacks in occupational health promotion programs. For example, McCarty et al [47] reported 2 employee fitness programs, where participation rates were 17% in the first study and 9% in the second study. Follow-up data were obtained from only 28% of participants in the first study and 43% of participants in the second study. In the case of eHealth, low usage can undermine the effectiveness of the intervention. In a study by Robroek et al [20], 64% of participants visited the intervention website 3 times or more, the median number of visits being 3 (IQR 2-6) over 2 years. In a study of a commercial weight loss service, Neve et al [48] used criteria comparable to ours to define sustained usage. They found that 30% of participants could still be classified as users after 1 year. Potential reasons of non-usage include that the intervention is not mandatory or not critical to wellness, a lack of tangible and immediate advantages, a lack of encouragement and reminders, and distraction due to routine events [19]. These issues should be addressed in the design of future health technologies.

The only statistically significant associations between sustained usage and baseline characteristics were that the sustained users were slightly older and had a lower level of physical fitness at baseline than non-sustained users. As the average age difference between the groups was only 3 years, this tendency may not have practical relevance. The lower physical fitness level may be an indication of technologies being adopted by those who had a real need to improve their wellness. As a summary, we could not predict who would become a sustained user or benefit from the technologies based on baseline data.

Robroek et al [17] report that female employees were more likely to participate in health promotion programs, but they found no other universal predictors. In their study of a Web

intervention, Robroek et al [20] also found that predictors of sustained participation by subjects were as follows: aged 30 years or older, non-smoking, and a higher level of fitness. They also found that individuals with low motivation to change their physical activity level were less likely to participate but more likely to sustain their participation. Neve et al [48] found that older users were less likely to stop using a weight loss service. In terms of behavioral predictors, they found that participants who skipped meals, ate to ease emotional upset, missed breakfast, or exercised less than once a week were more likely to discontinue usage.

Sustained usage was associated with some small but significant changes in weight-related outcomes. Sustained users lost more weight and body fat and decreased their waist circumference more than non-sustained users. Although the results are not clinically significant, maintenance of current weight is in itself beneficial for health if the alternative is continued weight gain. Interestingly, the non-sustained users gained about 0.6 kg during the study, which corresponds to estimates of average yearly population-level weight gain [49,50]. Thus, the usage of technologies may have helped to reverse the trend of gradual weight gain. No other significant differences were found when comparing the health-related outcomes of sustained and non-sustained users. It was found that the sustained users participated in intervention meetings more actively than non-sustained users. Since there were no differences in participation between two intervention conditions at the group level [22], this result may indicate that the technologies improved engagement with the intervention and also partly explain the slightly better health-related outcomes in sustained users as compared to non-sustained users.

The pedometer and weight scales were considered by the subjects as the most useful technologies. Overall, the features appreciated in any of the technologies were ease of use, simplicity, availability, and clear and informative feedback. Post-intervention results on user experiences of mobile applications have been reported by Ahtinen et al [36]. The present study extended the view to long-term, non-supported usage of technologies, and included results on the personal monitoring devices and Web services. The results also highlight the importance of integration into daily life over multifunctionality when a technology is intended for regular long-term use. However, in short-term use, multifunctional technologies that provide a great deal of added value instantly may help to promote awareness, identify problems, and motivate the user to make beneficial behavioral changes.

Limitations and Lessons Learned

There were certain limitations in the study setting, intervention, and technology approach. These limitations and lessons learned are summarized below.

In the trial, the subjects were randomly assigned to intervention groups and a control group with the result that they had no opportunity to express their preferences regarding the type of intervention. Although the subjects enrolled in the study knowing they could be randomized to the technology group, their attitudes toward technologies were not known at the time. As a result, several users might not have selected to use a particular intervention modality, if given a choice. This may partly explain the results on adoption and sustained usage. While these results may be typical of technology uptake for a working age population, the technology intervention would probably be only one option in real-life interventions and individuals would have some degree of choice. This may lead to more efficient usage and cost effective technologies.

There may also be volunteer bias that limits the generalizability of the results. Only about 38% of the employee population responded to the screening questionnaire and only 29% of the subjects in the technology group self-selected to use technologies over the long-term. Furthermore, there was an uneven gender distribution in the study, in which only about 30% of the subjects were male. Although this distribution was fairly close to that of the overall employee population (21% male at the end of 2008 [51]), it is unlikely that the results can reliably be generalized to male employees.

The measurement of health-related outcomes proved to be challenging in this study set-up. Firstly, the subjects were allowed to choose their own wellness goals and modify them during the study. At the individual level, favorable changes in one area of wellness may lead to unfavorable changes in others (eg, quitting smoking may lead to weight gain [52]), which would average out at the group level. The subjects may also have made minor changes in several areas, which may not be considered relevant changes in any single health-related outcome measure when the changes are looked at separately. Secondly, there were few, if any, health-related benefits in any of the study arms [23], which may be linked to the selection of the study population. Although the inclusion criteria required sub-optimally healthy lifestyles, the subjects were in fact generally healthy, and thus had less room to show improvement except for overweight. Healthier and more motivated individuals self-selecting for workplace health promotion programs has been observed in many studies and is a common concern for researchers [18,20,53]. Targeting the interventions to those who need them most would probably be more cost-effective; however, these individuals are not necessarily the most willing to volunteer for such programs.

Several limitations and challenges relate to the technologies. Firstly the technologies were at different stages of maturity; some of them were already at the commercial or pre-commercial stage whereas others were being developed specifically for the study and had undergone limited technical and user testing. This gave rise to technical problems during the study. The Portal, in particular, had problems with relatively frequent down-times that hindered its usage and the usage of the integrated services. Providing a bypass access to the integrated services would have been useful. Some subjects had difficulty adopting the study phone as their primary phone, while others considered the phone screen, font, and keypad to be too small. Ideally, the subjects would have run the applications on their personal mobile phones, but this was not possible at the time of the study.

In addition, the technologies were not well integrated. Similar information had to be entered to several applications, for example, whenever someone wanted to use both the Wellness Diary and Mobile Coach for tracking exercises. Having the

information automatically synchronized across all services would have facilitated usage and also made changing technologies in the middle of the study more seamless.

Usage rates of the personal monitoring devices could not be continuously logged at the time of the study and so they could not be included in the detailed analysis of sustained usage. Self-reporting was used to assess the usage of these technologies, though this gives less accurate results and the likelihood of positive bias. Only Web and mobile technologies were considered in the sustained usage classification, which probably resulted in an underestimation of the number of sustained users. In future studies, this problem can be avoided by using wireless monitoring devices that transmit their data to a server.

In contrast to the original aim of allowing individuals to find the most appropriate technologies for themselves, it became clear that the subjects found the plethora of options confusing. A more personalized approach of pre-selecting and tailoring the technologies to the subjects' needs and wellness goals might have resulted in better outcomes both in terms of adoption and long-term usage. Limiting choice and guiding the user through well-designed procedures may be more effective in encouraging healthy behaviors and technology usage [54,55]. However, our study setting does not allow differentiating whether the positive outcomes would have been achieved by offering just a subset of choices or a broader variety of options.

The technologies remained unchanged throughout the study and were only modified if the users themselves switched from one technology to another or changed the settings (eg, changed self-monitoring variables in Wellness Diary or goals in Hyperfit). Users would probably have welcomed continuous updating of content to maintain their interest but this is hard to do in a randomized controlled trial where the methods need to be standardized throughout the study. Of the current mobile or Web technologies, only Mobile Coach was adaptive in that it updated the weekly exercise program in response to the performed exercises and changing activity levels. Technologies automatically adapting to users' needs and progress might have been more interesting. For example, it might have been useful to provide a "holiday mode" with reminders to continue after a summer break or suggesting new goals after the previous ones had been reached. There were no reminders to encourage usage in this study. As the subjects reported, the distractions of daily life sometimes made them forget to use the technologies. Having reminders could have increased participant involvement.

Finally, the statistical power of our study was only modest or sometimes low due to relatively small sample size as compared to intervention effect. We also note that we have conducted multiple tests without correcting the alpha level. As a consequence the probability of having at least 1 significant result is greater than 0.05. Some of the low P values may have occurred by chance.

Conclusions

Almost all the subjects tried to make use of the Web and mobile technologies but less than 30% of them did so for the entire 1-year period of the study. Sustained usage was associated with slightly older subjects and lower baseline aerobic fitness. Simple technologies, ie, weight scales and pedometer, gained more users than the Web and mobile technologies. The only differences in health-related outcomes between sustained and non-sustained users were seen in weight-related changes. The results highlight the key requirements for personal health technologies: ease of use, simplicity, integration to daily life, and clear feedback. Despite the high expectations placed on personal health technologies to cost-effectively support or deliver health promotion interventions to a broad range of users, high attrition rates, and modest health-related outcomes related to sustained usage may limit their potential. Future research should target interventions and technologies more accurately to overcome these limitations.

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Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

Agreement percentages to usefulness statements in the 3-month, 6-month, and 12-month questionnaire.

[PDF File (Adobe PDF File), 21KB - mhealth_v1i2e16_app1.pdf]

Multimedia Appendix 2

Interview comments on usefulness and ease of use, motivation and learning, and barriers to using technologies.

[PDF File (Adobe PDF File), 16KB - mhealth_v1i2e16_app2.pdf]

Multimedia Appendix 3

Interview comments on the role of technologies in achieving health-related benefits, and changes in usage habits.

[PDF File (Adobe PDF File), 8KB - mhealth_v1i2e16_app3.pdf]

Multimedia Appendix 4

CONSORT-EHEALTH checklist V1.6.2 [56].

[PDF File (Adobe PDF File), 1001KB - mhealth_v1i2e16_app4.pdf]

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Abbreviations

ANOVA: analysis of variance
BMI: body mass index
CI: confidence interval
IQR: interquartile range
METmax: maximal metabolic equivalent

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Original Paper

Mobile Mental Wellness Training for Stress Management: Feasibility and Design Implications Based on a One-Month Field Study

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Abstract

Background: Prevention and management of work-related stress and related mental problems is a great challenge. Mobile applications are a promising way to integrate prevention strategies into the everyday lives of citizens.

Objective: The objectives of this study was to study the usage, acceptance, and usefulness of a mobile mental wellness training application among working-age individuals, and to derive preliminary design implications for mobile apps for stress management.

Methods: Oiva, a mobile app based on acceptance and commitment therapy (ACT), was designed to support active learning of skills related to mental wellness through brief ACT-based exercises in the daily life. A one-month field study with 15 working-age participants was organized to study the usage, acceptance, and usefulness of Oiva. The usage of Oiva was studied based on the usage log files of the application. Changes in wellness were measured by three validated questionnaires on stress, satisfaction with life (SWLS), and psychological flexibility (AAQ-II) at the beginning and at end of the study and by user experience questionnaires after one week's and one month's use. In-depth user experience interviews were conducted after one month's use to study the acceptance and user experiences of Oiva.

Results: Oiva was used actively throughout the study. The average number of usage sessions was 16.8 (SD 2.4) and the total usage time per participant was 3 hours 12 minutes (SD 99 minutes). Significant pre-post improvements were obtained in stress ratings (mean 3.1 SD 0.2 vs mean 2.5 SD 0.1, P=.003) and satisfaction with life scores (mean 23.1 SD 1.3 vs mean 25.9 SD 0.8, P=.02), but not in psychological flexibility. Oiva was perceived easy to use, acceptable, and useful by the participants. A randomized controlled trial is ongoing to evaluate the effectiveness of Oiva on working-age individuals with stress problems.

Conclusions: A feasibility study of Oiva mobile mental wellness training app showed good acceptability, usefulness, and engagement among the working-age participants, and provided increased understanding on the essential features of mobile apps for stress management. Five design implications were derived based on the qualitative findings: (1) provide exercises for everyday life, (2) find proper place and time for challenging content, (3) focus on self-improvement and learning instead of external rewards, (4) guide gently but do not restrict choice, and (5) provide an easy and flexible tool for self-reflection.

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KEYWORDS

stress; mental health; mobile phone; acceptance and commitment therapy; field studies; user experience; design

Introduction

Background

Work-related mental health problems are the most common cause of disability in the countries of the Organization for Economic Cooperation and Development [1]. Stress is strongly associated with mental health problems, such as depression [2]. In 2005, 22% of European workers reported suffering from stress [3], and stress is estimated to be a significant factor in 50-60% of lost working days [4].

Preventative interventions targeted at individuals at risk may be used to contain the costs and suffering related to stress and mental disorders [5,6]. Occupational stress management programs usually focus on teaching individuals techniques to cope with stress, and are delivered in sessions over several weeks [7,8]. Especially interventions based on cognitive-behavioral techniques have been found effective, but as they are usually delivered in group sessions by trained professionals, they are also relatively costly [5,8].

Technology-assisted prevention programs enable easier, earlier, and more flexible access to care at a lower cost, and many of them have been shown to reach equal effectiveness to face-to-face therapies in the treatment of psychological problems [9]. In the past few years, due to the wide availability of smartphones and mobile apps, mobile delivery of interventions has become feasible. Mobile phones facilitate integrating interventions into the daily lives of the citizens, allow unobtrusive monitoring of their activities and contexts, and make it possible to provide interventions at opportune moments, that is, when most needed and desired [10].

Acceptance and Commitment Therapy in Stress Management

Most computerized therapies build on psychological therapy methods, usually cognitive-behavioral therapies (CBT) [9]. The so-called third wave of CBT includes mindfulness and acceptance based behavioral and cognitive therapies, such as acceptance and commitment therapy (ACT). ACT aims to increase the individual's psychological flexibility, which is "the ability to contact the present moment more fully as a conscious human being, and to change or persist in behavior when doing so serves valued ends" [11].

Psychological flexibility can be increased through the six core processes of ACT [11,12]. *Acceptance* means embracing feelings and events without trying to change them. *Cognitive defusion* techniques try to change the way one relates to thoughts, for example, by observing one's thoughts and feelings without being caught up in them. The skill of *being present* helps to experience psychological and environmental events in a non-judgmental way and bringing full awareness to the present moment. The *self-as-context* process aims at becoming aware of the flow of personal experiences with an understanding that they are not one's essence. *Values* determine what is truly important and help choose life directions. *Committed actions* are concrete actions chosen based on personal values. [11,12] To train the skills, an eclectic mix of metaphor, paradox, and mindfulness methods, along with a wide range of experiential exercises and value-guided behavioral interventions are used [11,13].

Psychological flexibility is associated with better mental health and behavioral changes [11,12]. ACT-based interventions have been found effective in reducing work stress and increasing work performance and the ability to innovate [14-17].

Mobile Apps for Mental Wellness

Mobile interventions have been used effectively to promote physical health, but despite increasing activity in the area, mobile mental wellness apps are still in their infancy [18]. Most apps developed thus far are not guided full-length programs, but rather implement a range of intervention techniques, including mood assessments, experience sampling, and small exercises. The trials have mostly been carried out with small samples, making the efficacy of different interventions and generalizability of the results difficult to assess. Still, previous studies yield several useful insights to inform the design of mental wellness interventions that utilize mobile technology in preventative or therapeutic context.

CBT-based interventions commonly use monitoring of symptoms and mood states as a strategy to develop self-awareness and coping abilities [19]. Mood charting with a mobile and online symptom tracking tool, Mobile Mood Diary, has been explored in a series of small studies carried out with teenagers with mental health problems. The findings suggested that mood charting with mobile phones could increase adherence to therapy and improve self-awareness. In addition, coupling mood charts with a diary could help to support recall and to broach difficult topics with a therapist [19].

Several mobile interventions, such as Mood Map and PRISM, have combined monitoring of mental states with brief exercises [20,21]. Mood Map is a mobile app for increasing emotional self-awareness [20]. The app consists of mood-related experience sampling and CBT-inspired psychological exercises that could be completed in a minute or less. The app has been evaluated in a one-month study among 8 working-age adults who reported moderate or high level of stress [20]. The participants increased their emotional awareness and started practicing new strategies to cope with stress, although some of the impact may be due to the weekly interviews conducted during the study rather than the app. The findings indicated that exercises were more likely to be used when experiencing intense emotions.

In therapeutic context, PRISM is a mobile intervention that was evaluated in a two-week study among 10 outpatients with bipolar disorder [21]. The intervention, delivered via a personal digital assistant and based on Life Goals psychoeducation, prompted users to engage in personally selected self-management behaviors as a response to specific self-reported mood states. The trial resulted in a decrease in depressive symptoms and high satisfaction with the intervention. Several improvements to support long-term use were also brought up, including the ability to enter text entries and offering a broad collection of self-management strategies.

Some interventions have combined mobile and Web apps that serve different functions. Mobilyze! is a mobile phone and

Web-based intervention for depression [22]. It uses phone sensors and experience sampling to gather data on users' contexts and moods and to remind them to use the website. The intervention consists of behavioral skills training through 9 weekly 15-minute lessons on an interactive website, and telephone coaching to increase adherence. The system was trialed with 8 participants who had a diagnosis of major depressive disorder [22]. Their depressive symptoms decreased over the course of the intervention and they were generally satisfied with the program. Despite several technical difficulties such as battery drainage and inaccuracy of sensor data, context-aware interventions seem potentially promising in helping a person gain self-awareness and encouraging behavioral changes at right moments.

One of the few larger studies is the trial of myCompass, a mobile phone and Web-based program for stress, depression, and anxiety [18]. The program consists of self-tracking, reminders, and tips on the phone and CBT-based 10-minute self-management modules on the website. Participants of the 6-week trial were 44 adults experiencing a current episode of depression, anxiety, or stress. The results showed a reduction in psychological distress, and improvements in functional impairment and self-efficacy. The participants appreciated the accessibility and convenience of the app, but wished for more personalized instructions.

Randomized controlled studies of mobile mental wellness apps, especially in preventative context, appear to be scarce. One of the few examples is the evaluation of MEMO, a 9-week mobile intervention for preventing teenage depression consisting of mobile messages and a mobile website [23]. The evaluation of the intervention involved 418 teenage participants in the intervention group. Good user acceptance and perceived usefulness were found, but measured outcomes related to depression have not been published yet. A common critique of the intervention was the large amount of messages; the intervention delivered 2 messages per day over 9 weeks, which appeared to be too frequent for most.

To our knowledge, the only ACT-based mobile intervention reported thus far was by Ly et al [24] who presented a program with Web and mobile components, aimed at supporting individuals to live consistently with their values. The Web component includes psychoeducation and exercises for analyzing personal values. The mobile app reminds the user to perform behaviors in line with their values, gives feedback on their progress, and allows them to view other users' actions. The 4-week trial of the app included 11 participants with no diagnosed mental disorders. Increased psychological flexibility and value-based actions were measured at post-test, but no effects were found for depression, anxiety, or stress. The qualitative findings of the study suggest that the mere presence of the icon of the app on the mobile phone screen may have increased awareness of values and behaviors [24].

Conclusive evidence of effectiveness of existing mobile mental wellness apps is not yet available, but the results have been promising and several large-scale randomized controlled trials are currently underway [18,23,25]. Based on the studies so far, mobile phone interventions appear to be feasible and convenient for the users, and the mobile phone might in itself have a small positive effect on self-awareness. Nevertheless, there is insufficient knowledge available of what works in mobile mental health promotion and what makes an app successful in producing a lasting change in the user's wellness. Lessons learned from apps used as a part of therapy may not necessarily translate directly to preventive context.

Guidelines for Mental Wellness Apps

Several guidelines exist for designing technological apps that engage, motivate, and support behavior and attitude changes. Systems "designed to change people's attitudes or behaviors" are called persuasive technologies [26] and some guidelines for their design have been developed [26-28]. Gamification, that is, using game-like elements has also been proposed in the domain of wellness apps to increase adherence and engagement [29,30]. However, the guidelines that are based on apps promoting physical health and thus they may not be directly applicable to the domain of mental wellness.

The guidelines that are more closely related to mental wellness apps include Morris' 7 guidelines for behavior change [31]: (1) remind people who they want to be, (2) foster an alliance (empathy, coinvestigation, joint problem solving), (3) apply social influence, (4) show people what they could lose, (5) put the message where the action is, (6) raise emotional awareness, and (7) reframe challenges. In addition, Doherty et al [32] introduced and explored a set of design strategies to reduce attrition in Web-based interventions and concluded that the interventions need to be: (1) interactive, (2) personal, (3) supportive, and (4) social. Furthermore, using naturally calming elements and providing positive feedback on user actions can minimize stressors for users [33]. Finally, technology should be seen as a tool to assist in the change process; engagement with the treatment rather than with the technology should be the overall aim [34].

Objectives of the Current Study

In this paper, we describe Oiva, a mobile app for stress management, and present results of a one-month field study that was performed to assess the feasibility of Oiva and validate its design choices. To the best of our knowledge, Oiva is the first ACT-based, stand-alone mobile intervention for self-administered preventative training of stress management skills. Most of the previous studies of mobile mental wellness apps have either focused on mood charting or combined mood charting with brief exercises that have been Web-based in some of the studies. Although mood charting appears to increase adherence and improve self-awareness among certain target groups, none of the studies so far have done a detailed analysis of how mental wellness exercises on a mobile platform should be designed to maximize adherence, user satisfaction and outcomes. To shed light specifically on this matter, the current study excluded the mood-charting component and focused on a structured training program with experiential exercises. The detailed objectives of this study were to: (1) investigate how the participants used the app, (2) study the effects of Oiva on the participants' mental wellness, (3) explore the user experiences of Oiva and its functions, and (4) derive preliminary design implications for mobile mental wellness apps.

Methods

Mobile App

Oiva is a mobile mental wellness-training app targeted at working-age people who suffer from stress. Oiva is a stand-alone app for Android mobile phones and tablets, and it was designed in cooperation of experts in psychology, user needs and technology. The content and logic of Oiva were built upon ACT principles and methods, and the app delivers a complete ACT-based intervention program in bite-sized daily sessions.

Oiva contains 4 intervention modules or "paths" named Aware Mind, Wise Mind, Values, and Healthy Body. The first 3 paths teach the user the 6 core processes of ACT and the fourth path focuses on physical wellness, but with an ACT-based approach. The paths consist of altogether 46 text and audio exercises. *Aware Mind* contains exercises on awareness of the present moment, breathing, and observing one's body, mind, and surroundings. *Wise Mind* teaches skills related to observation and acceptance of one's thoughts and feelings. *Values* focuses on clarifying one's personal values and committing to concrete actions to pursue them. *Healthy Body* includes relaxation, mindful eating, and mindful physical activity exercises.

Figure 1 presents examples of the user interface of Oiva. The main screen (Figure 1a) of the app contains a flower-shaped menu through which the different paths can be accessed. The main screen also provides an access to the diary (Figure 1b), list of favorite exercises, and an introduction to the app as text and video (Figure 1c). The introduction video informs the users about the purpose of the app and motivates them to use it. The video features an expert in ACT and thereby aim to increase the credibility of the app, as suggested by the persuasive systems design model [27], and creating a feeling of therapeutic alliance, proposed by Morris [31].

Each petal represents one of the paths, which are numbered according to their recommended order. Each path consists of 1–4 subsections ("steps"), which include 5–8 exercises (Figure 1d). An introduction as text and video is included in each path and step, informing the user about the processes and skills taught in them.

Oiva gently steers the user through the intervention program without restricting free navigation. Paths, steps, and exercises are numbered in the recommended order and the next suggested item is dynamically highlighted (Figure 1a and d). However, all paths and exercises are accessible from the very beginning. This design solution follows the tunneling and reduction principles of persuasion [26,27], but in a non-restrictive way.

Most of the exercises are short and take about 1-3 minutes to complete (Figure 1e-h). This aims at making them easy to perform in any situation. Each exercise begins with an introduction presenting the purpose, duration and instructions of the exercise (Figure 1e). The user can choose to do the exercise by listening (Figure 1f) or reading (Figure 1g). After each exercise, a reflection screen (Figure 1h) summarizes the skills learned in the exercise and enables the user to write notes and reflections in the diary (Figure 1b). The notes are saved in the diary and can be accessed later to encourage self-reflection as well as raise emotional awareness, as suggested by Morris [31]. The user can also mark the exercise as a favorite, thus adding it on the list of favorites, which is accessible quickly through the main view.

Progress in the program is presented in several ways. First, the number of completed exercises is displayed for each step. Second, the background color of steps and exercises changes once they are completed. Each completed exercise is rewarded by a virtual rose (Figure 1d), providing immediate graphical feedback of progress [32]. The visual theme of Oiva draws from nature. The graphics and background images depict nature, animals, and landscapes to provide calming elements, as proposed by Moraveji and Soesanto [33]. Pictures, audio, and video are used to make the experience of using Oiva pleasurable and less demanding, reducing the amount of text in a similar manner as done by Ly et al [24].

Figure 1. Screenshots of Oiva. (a) the main screen, (b) diary, (c) introduction video, (d) top menu of Aware Mind, (e) exercise introduction screen, (f) audio exercise, (g) text exercise, (h) exercise reflection screen.

Study Participants and Recruitment

Fifteen volunteer participants were recruited via email from the staff of the local technical university in Finland. Thirteen of the participants had not encountered Oiva and did not know the researchers prior to the study. Two of the participants had seen an earlier version of Oiva, because they had volunteered in a short usability test in a laboratory. There were no specific inclusion criteria, only that the participants needed to be interested in stress management and willing to use a prototype mobile app. The app was described as an acceptance-, value-, and mindfulness-based self-help program designed to help in, for example, stress management and relaxation, increasing physical activity, and practicing mindful eating.

The 15 participants (9 female) were university staff, including, for example, a human resources manager, a secretary, a researcher, and a laboratory engineer. Five participants were younger than 30 years old, 5 were between 31 and 40 years, and 5 were older than 40 years.

The participants signed an informed consent form prior to the study and were aware of their right to withdraw from the study at any time. Ethics committee approval was not acquired as the study was deemed to involve minimal risk and the focus was on studying mainly user experiences.

Procedures

The participants filled in baseline questionnaires and attended a face-to-face group kick-off session, which consisted of two 10-minute presentations, one on ACT theory and one on Oiva. The aim and process of the study were explained. An Android smartphone with Oiva pre-installed was provided for each of the participants to be used for one month. The phone model was either ZTE Blade (7 participants) or Sony Ericsson Xperia ray (8 participants). A short user guide about Oiva was provided on paper. Active, preferably daily use was recommended, but finding personally appropriate ways of use was also encouraged. The study period was one month in May 2012. At the end of the study, each participant was given two movie tickets to compensate for the time spent in study procedures.

Measures

Data were collected from 3 sources: (1) online questionnaires completed at baseline, after one week's use and after one month's use, (2) interviews conducted after one month's use, and (3) the usage log of Oiva app.

Background information (eg, age and previous experience in using mobile phones and wellness technologies) was collected at baseline. Wellness questionnaires were administered at baseline and after one month's use. Psychological flexibility was assessed with a 7-item Acceptance and Action Questionnaire (AAQ-II, [35]). AAQ-II employs a 7-point Likert scale from 1 (strongly disagree) to 7 (strongly agree) and includes negative statements, such as "Worries get in the ways of my success". AAQ-II is scored from 7 to 49, and higher scores suggest less psychological flexibility. Results across seven samples with a total of 3280 participants have provided promising evidence as to the adequate structure, reliability, and validity of the AAQ-II [36]. The Satisfaction with Life Scale (SWLS, [37]) also employs a 7-point Likert scale and includes five positive statements, for example "in most ways my life is close to ideal". The SWLS is scored from 5 to 35, where higher scores suggest higher satisfaction with life. The SWLS has been found to have good validity and reliability and has been shown to correlate with measures of mental health [37,38]. The single-item stress scale [39] has one statement: "Stress means a situation in which a person feels tense, restless, nervous or anxious or is unable to sleep at night because his/her mind is troubled all the time. Do you feel this kind of stress these days?" The response is recorded on a 5-point Likert scale varying from 1 (not at all) to 5 (very much). The stress scale has shown satisfactory content, criterion, and construct validity for group level analysis [39]. Experienced wellness benefits were measured by user experience questionnaires after one week's use and one month's use. Three questions measured Oiva's perceived usefulness in the maintenance and improvement of wellness, learning new skills, and gaining new insights. These questions were recorded with scales ranging from 1 (completely disagree) to 7 (completely agree).

Qualitative data on user experiences, usage, and usefulness were gathered in individual, semi-structured, face-to-face interviews after one month's use. The interviews were designed among the authors and a discussion guide outlining the themes of the interview was created. Some of the themes included were: the situations where Oiva was used in, whether using Oiva affected the participant's wellness, the user experiences of different features of Oiva, Oiva's ability to persuade and reward usage, and desired new features of Oiva. The first author, who has several years of experience in user experience studies, conducted the interviews. Each interview lasted about 45 minutes and was audio recorded.

The usage log files were collected from the phones after the interview. The usage log contained all user actions and their time stamps. The number of characters in diary entries was also logged, but not the content of the entries.

Data Analysis

The log files of 14 participants were analyzed. One participant was excluded due to unreliable time stamps in her log file caused by a date change in her phone. Individual usage sessions were first detected and counted. Then, usage days were calculated as days containing a usage session. The durations of individual sessions were calculated based on the start and end times of each session, and the total duration of use by summing the durations of all sessions. As the app can be always "on" and running in the background, there were no specific log events that would flawlessly indicate the start of a usage session. Thus, two criteria were used to determine the start of a session. First, if an "app started" event was detected without any prior activity for the past 10 minutes, a new session was considered to have started. Second, if there was at least a 20-minute pause between consecutive log events, a new session was marked. The 20-minute requirement was chosen to avoid marking a new session while the user was listening to or otherwise performing an exercise.

Statistical analysis of the quantitative data from the wellness questionnaires and our custom rating scales for the experienced benefits was performed as follows. First, one female participant was excluded as she omitted some of the questionnaires. Coincidentally, she was the same participant who was also excluded from log file analyses. Then, change in participants' ratings of wellness from before to after using Oiva was analyzed with paired comparisons using Wilcoxon signed rank tests. Finally, we tested if the median ratings of experienced benefits of Oiva (ie, improvement or maintenance of wellness, learning new things, and gaining new insights) were statistically significantly on the positive side (ie, above the mid-point of 4) using Wilcoxon signed rank tests.

The interview audio recordings were transcribed and analyzed with a qualitative content analysis method called thematic coding [40]. The data were categorized under three main themes (usage habits, perceived benefits, user experiences of Oiva and its functions). Under each main theme, several subthemes were identified, for example, usage situations, barriers of use, and benefits.

Results

Participant Characteristics

According to the baseline questionnaire, all except one of the participants used mobile phones daily, and all but one had used mobile phones for more than ten years. Eleven participants were currently using a smartphone. Of the participants, 67% (10/15) had already tried some mobile wellness apps (eg, for exercise tracking), and 73% (11/15) had tried wellness-related Web services (eg, for weight management). Eleven participants (73%) had some prior knowledge of ACT related topics (eg, mindfulness).

Usage

The average duration of the usage period from the first log event to the last was 34.0 (SD 5.3, range 26-46) days. The participants used Oiva, on average, on 11.5 (SD 5.8, range 4-20) days, and there were, on average, 16.8 (SD 9.0, range 5-36) usage sessions per participant during the study. The average duration of usage sessions was 12.3 (SD 5.2, range 4.4-24) minutes. The average total usage time per participant was 192 (SD 99, range 56-339) minutes.

Effects on Wellness

Table 1 presents the participants' average ratings of stress (score of Elo's stress scale), life satisfaction (score of SWLS), and

psychological flexibility (score of AAQ-II). The change from before to after using Oiva was statistically significant for ratings of stress (z=3.00, P=.003) and life satisfaction (z=2.32, P=.02). There was no statistically significant change in psychological flexibility (z=0.06, P=.950).

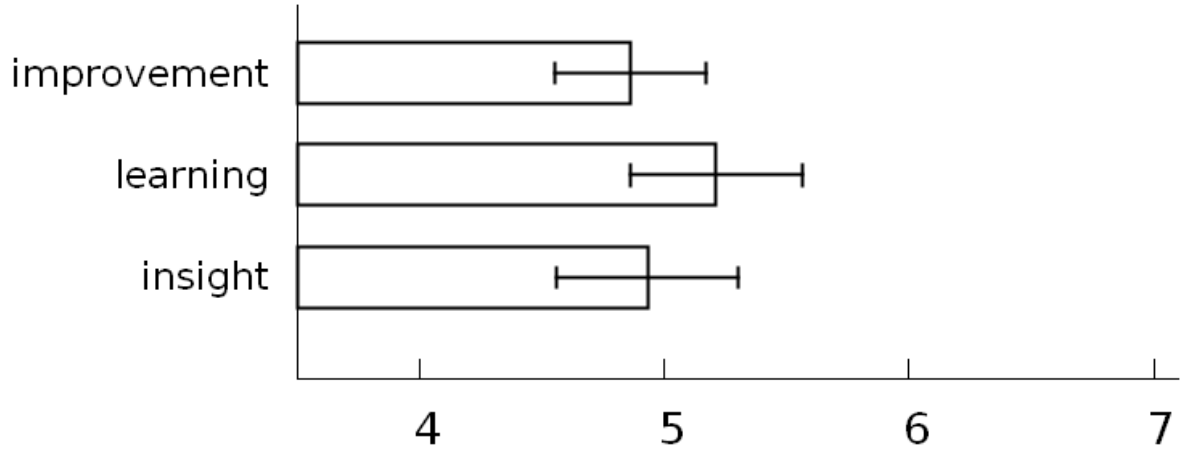
Figure 2 presents the mean ratings of benefits that the participants reported having gained from using Oiva. All mean ratings were on the positive side. Observed medians for each scale were 5 and statistically significantly higher than the mid-point of 4 for all the scales, improvement or maintenance of wellness (z=2.29, P=.022), learning new skills (z=2.67, P=.008), and gaining new insights (z=2.17, P=.03).

Table 1. Ratings of stress and scores in SWLS and AAQ-II questionnaires before and after using Oiva.

	Before mean (SEM[a])	After mean (SEM)	*P*
Stress	3.1 (0.2)	2.5 (0.1)	.003
SWLS	23.1 (1.3)	25.9 (0.8)	.02
AAQ-II	17.2 (1.5)	17.2 (1.6)	.95

[a]SEM=standard error of mean

Figure 2. Mean post-study ratings (± SEM) of the effects attributed to Oiva.



Usage Habits and Barriers

The most common place to use Oiva, reported by 80% (12/15) of participants, was at home. Typical usage contexts at home included: in bed before falling asleep or after waking up (5/15, 33% of participants), in the backyard (2/15, 13% of participants), or in the middle of household routines (3/15, 20% of participants). One participant who used Oiva outdoors commented that the elements of nature (eg, birds singing or fresh air) strengthened the effects of the exercises. Only 27% (4/15) of participants had used Oiva at work. Forty percent (6/15) of the participants had tried performing exercises in mobile contexts, for example, when commuting, and 27% (4/15) of them reported liking this way of use. Mobile situations were often regarded as restless and not providing a possibility for proper concentration.

Despite little actual mobile use, the mobile device was regarded as a good platform for a stress management app. Ten participants (67%) brought up the ease of carrying a mobile phone along as the main benefit. Even at home, the mobile phone was taken along to different places, such as bed, hammock, or living room floor, where the usage of a computer would have been more difficult. Also, being able to open the app quickly and not requiring an extra device to carry were important benefits of the mobile phone for 27% (4/15) of participants (eg, compared to relaxation CDs or laptops). The mobile phone implementation was perceived especially suitable for short and easy exercises (6/15, 40% of participants) and for audio exercises (4/15, 27% of participants). Three participants specifically mentioned that some of the exercises, such as long exercises requiring concentration and tranquility, were less suitable for a mobile phone. However, not having Oiva installed in their personal phone affected use; 60% (9/15) of participants believed that, if Oiva had been installed in their own phone, they would have used it in a more versatile way and also in mobile contexts.

A typical barrier of use was being busy in everyday life (7/15, 47% of participants), which made it difficult to find suitable, peaceful moments for exercises. For example, concentrating on

the exercises in the evening when already tired was perceived challenging (3/15, 20% of participants). Forty percent (6/15) of participants also mentioned that they forgot to use Oiva unless they consciously dedicated a time slot for it in their schedules.

The participants preferred short and simple exercises that were easy to integrate into their everyday life, could be done anywhere and were easy to perform even without Oiva after learning the techniques. Forty-seven percent (7/15) of participants said that these exercises gave them immediate benefits and that they intended to continue doing them also after the study.

The one-month usage period seemed too short to 73% (11/15) of the participants. They felt that establishing profound lifestyle changes and new routines takes longer than a month, and that they only had time to explore the exercises but not to apply the skills properly to their own life. The participants who had learned to apply the skills in their life and perform the exercises even without Oiva had been familiar with the techniques already prior to the study. The short breathing and relaxation exercises were an exception as the techniques were very easy to learn.

Perceived Benefits

According to the interviews, the main benefit of Oiva was being able to take a break in the midst of daily hassles, whether at work or at home (eg, taking care of children or household chores). Especially the short breathing and relaxation exercises were found useful for this purpose. One participant described how differently her day began after doing an exercise compared to her routine mornings: “When I did an exercise in the morning before leaving for work, the day begun in a totally different way. Otherwise I would have just driven to work in a rush”. The participants who had done exercises in bed at night felt that it helped them fall asleep easier.

Four participants (27%) reported gaining more profound benefits, such as changes in their thoughts and attitudes. These included getting a new perspective on their life or starting to consider their values and actions. Two participants (13%) had also discussed their values with their spouses. One of them stated this would not have happened without Oiva. The other one had experienced value-based exercises beneficial in a new life situation, after becoming a parent for the first time. A third participant described that value exercises had helped her realize concretely that she has the power to decide how she spends her time and her life.

Four participants (27%) also reported gaining the ability to let go of their thoughts and feelings, and change their perspective to them. They reported that these skills had helped them deal with negative thoughts and feelings, distance themselves from stressful thoughts and accept setbacks. It had made them question whether some of their issues were as serious as they had thought.

User Experiences of Oiva and Its Functions

Mindfulness was considered a good philosophy for Oiva. Seven participants (47%) commented that Oiva’s exercises concretely demonstrated how they could apply mindfulness in their everyday life. In general, the participants regarded the exercises as interesting, concrete, down-to-earth, and memorable. The stories and metaphors helped them understand the topics. In addition, as Oiva included versatile topics and exercises in a structured form, the participants were able to choose the most suitable exercises.

Audio exercises were preferred over text by 73% (11/15) of participants because they provided guidance through the exercise. They were also perceived to provide a “more personal feeling” and make it easier to concentrate and relax. An unexpected benefit, reported by one participant, was that audio exercises enabled performing them together with other people. However, text exercises were considered useful for recapitulation and therefore both formats were needed.

Eight participants (53%) performed exercises in the order recommended by Oiva. Guidance was perceived to facilitate use, as reflected in a comment: “It does not limit but provides the direction where to go, that works!” If the participants felt that the recommended exercise was not suitable for a specific situation, they skipped it at that moment. The recommended order was not taken by 47% (7/15) of participants, who chose exercises based on interesting topics, names of the exercises, or their own feelings. They did not feel that the guidance limited their freedom of choice. The app “told in a plain enough way, not with exclamation mark, where one is going and what is being suggested next”, as one participant articulated.

Although the participants liked the current guidance in Oiva, they wished for even more guidance. Six participants (40%) would have liked a scheduled program and 67% (10/15) would have liked to receive reminders to use Oiva. They felt that these features would bring order and motivation. However, they stated that scheduling should not be too restrictive. Skipping and choosing different exercises should still be possible.

Skepticism toward gamification was expressed by 60% (9/15) of participants. They thought that collecting points, rewards, and achievements would not sit well with a mental wellness app or fit the philosophy of mindfulness. They felt that the motivation to use Oiva rises from its content and wellness effects and that the real achievements and rewards come from learning and self-improvement. Instead, they wanted to see their progress in the skills they had learned and the positive changes they had accomplished.

Nine participants (60%) made entries to Oiva’s diary. The interviews revealed that the entries mainly dealt with thoughts, feelings, and insights raised by the exercises, and answers to the questions in the reflection screen. According to the participants, one of the main benefits of the diary was that it enabled the follow-up of thoughts when the same exercise was repeated. Two participants used a paper diary, because they wanted to be able to write and draw freely. Three participants wished to have more structured and guided questionnaires with pre-defined response options, as they found it difficult to know what to write. They also felt that a structured diary would enable easier follow-up and comparison of entries. In general, the touch screen text input was regarded as cumbersome, which may have caused some of the problems encountered with the diary.

At the time of the study, Oiva did not offer anything extra when the user had completed all the exercises, which 80% (12/15) of the participants saw as an inadequate end for the program. Nine participants (60%) mentioned that they would have wanted a follow-up program to remind them to continue to do the exercises, preferably focusing on the exercises that were the most beneficial for them or where there still was room for improvement. The follow-up program could also provide new content and exercises. The participants felt that the usage of Oiva should not end after completing the exercises once, but that the exercises should be repeated whenever needed. The skills learned should be integrated to one's life and Oiva could help by guiding in that.

Discussion

Principal Findings

The 4 main goals of this study were: (1) to find out how the participants used the app, (2) to study whether using Oiva improved the participants' mental wellness, (3) to explore how Oiva and its functions were experienced, and (4) to derive preliminary design guidelines for mobile stress management apps.

Oiva was used actively by the participants, on average, every third day. The sessions were relatively long for mobile use, on average 12 minutes. This result is similar to the one reported by Doherty et al [32], albeit their intervention was Web-based. Although daily use of Oiva was recommended to the participants, finding personally appropriate ways of use was also encouraged. Longer sessions may be useful for learning the skills at the beginning, whereas later on, short sessions may be enough to maintain them. This indicates that different phases of use should be identified and supported.

Statistically significant improvements in stress and life satisfaction were achieved during the study. The positive mean ratings on the subjective scales of improvement or maintenance of wellness, learning new things, and gaining new insights suggest that the participants explicitly attributed these positive effects to Oiva, although other factors (eg, changes in common stressors for the university staff) cannot be excluded in this study. Furthermore, as the study sample was small, these results should be considered preliminary and indicative.

The interview data implied that the participants had taken the first steps towards learning the skills related to ACT. Most participants reported increased mindfulness, but also learning other skills, such as skills related to acceptance, cognitive defusion, values, and committed actions. However, we did not observe significant changes in psychological flexibility, which would have been in line with such changes. One of the reasons may be that most of the sample already had some prior knowledge of ACT. Moreover, psychological flexibility has been described as a fundamental basic aspect of health [41], and changes in such basic psychological processes may take a longer period of time to manifest. However, there is evidence that gaining changes in psychological flexibility within such a short time period may be possible by concentrating on specific processes, such as values and committed actions, as in the work by Ly et al [24]. However, in contrast to our results, they did not find any changes in life satisfaction, which may be due to their narrower coverage of ACT processes. In our study, most of the participants started with mindfulness exercises and did not have enough time to properly go through exercises related to acceptance and values, which could have a more direct impact on psychological flexibility. The comparison of the outcomes of these two studies poses an interesting question: does focusing on different processes of ACT influence different aspects of psychological wellness?

Design Implications

It is assumed that mobile devices are well-suited for wellness apps because they enable interventions in mobile contexts. In our study, we found that most of the use occurred, not in mobile situations, but in situations that were peaceful and provided an opportunity for proper concentration. The short breathing and relaxation exercises formed an exception—they were found easy to integrate into everyday life and in some cases even mobile situations. However, the strengths of the mobile platform became evident because the mobile phone was easy to carry along anywhere enabling more freedom in choosing the locations of use. Also, being fast to open for a quick session was an important benefit.

Participants appreciated guidance in both navigation and performing the exercises. They liked to hand over the responsibility of deciding the order of exercises to the app. Thus, guidance may have helped in creating a sense of therapeutic alliance between Oiva and the participants [31].

Based on our findings, we propose the following set of preliminary design implications for mobile mental wellness training apps.

Provide Exercises for Everyday Life

Most, if not all, participants understood that the purpose of Oiva was to learn skills and techniques that improve wellness, and to integrate these skills to everyday life as a process of mental self-development. The main benefit for most participants was the possibility to do exercises to calm down quickly. The short breathing and relaxation exercises were used to take a break, a "moment for me". Such exercises were well-suited to the relatively short one-month study period, since they were quick to absorb, easy to integrate into one's daily habits and everyday life, and did not require much thought or preparation.

Find Proper Place and Time for Challenging Content

The participants perceived some of Oiva's exercises as more challenging, especially the exercises that were longer or related to more challenging skills (eg, values or acceptance). They required more concentration and effort, and therefore had a high threshold to get started with. However, the challenging exercises would probably have stronger effects on psychological flexibility and thus it is essential to lower the threshold for the users to engage in them. One way to approach this could be to utilize context-awareness on mobile platforms to identify appropriate moments to engage the user [42]. In the future, the context-aware system could be able to recognize a suitable time and a peaceful place for performing the exercises requiring more

concentration, and prompt the user at that moment. Another less technical solution would be to provide an opportunity for the user to filter and search exercises for specific contexts and needs.

Focus on Self-Improvement and Learning Instead of External Rewards

Interestingly, the majority of the participants did not wish for extra rewards or game-like elements in Oiva. An achievement-oriented approach is often utilized in the apps for physical activity [30], and it is easy to assume that users would enjoy a gamified approach also in mental wellness apps. However, our participants thought otherwise. Playful interface or hunting for rewards was not seen to fit the philosophy of mindfulness, concentration, and calming down. The participants felt they were rewarded and intrinsically motivated by learning new skills and seeing changes in their lives. This is in line with the notion that it is more important to focus on meaningful experiences than rewards [43]. As argued by Doherty et al [32], the designers should emphasize the engagement with the treatment, rather than with the technology. However, at the same time we note that our participants were working age adults in a university setting. Rewards and a gamified approach might suit other types of user profiles better.

Guide Gently but Do Not Restrict Choice

In general, the preference for guidance as "giving direction but not limiting" was expressed frequently. Oiva's way of gently recommending an exercise while still leaving the user the freedom of choice was appreciated. The participants also liked having audio narration to guide them through exercises. In self-help apps, active guidance is a way to foster a sense of alliance [31]. Even more guidance was wished for in the form of a scheduled program in the calendar and reminders for specific exercises. Furthermore, some implied that a follow-up program would be useful to integrate the skills learned in the intervention as a part of life. Based on these findings, it seems that the participants wanted to have a feeling of being guided through the program, but they did not want to follow too strict tunnels without an option to skip exercises or select more suitable ones. Therefore, the persuasive design principle of tunneling (narrowing down the choices available for the user) [26,27] should not be used excessively.

Provide an Easy and Flexible Tool for Self-Reflection

Many participants used the diary as a self-reflection tool, as they wrote down feelings and thoughts related to exercises, as well as responded to the questions that were asked at the end of the exercises. The participants emphasized the importance of raising emotional awareness through self-reflection [31]. Some of them desired a diary with structured questionnaires and pre-defined answers, revealing the need for a wider range of interactivity [32]. Not surprisingly, a mobile device was not considered ideal for free text input. Considering the successful use of self-tracking and mood monitoring in previous studies [19,20], a structured manner of recording feelings and emotions as well as ability to view historical data could be useful.

Limitations

This study was an uncontrolled field trial involving a small number of volunteer participants, which must be taken into account in interpreting the results. Many of the participants were already somewhat familiar with ACT-based methods, which may have facilitated the adoption of the app and learning the skills. Due to the lack of a control group, common confounding factors affecting the wellness of university staff at the time of the study cannot be assessed. Also the usage patterns observed in the study may not fully reflect realistic usage patterns, as the participants were not able to use Oiva in their own mobile phones.

The study participants were not the direct target group of the app. For ethical reasons, we did not want to present a prototype app to people suffering from severe stress, and thus chose a healthy group of participants for this feasibility study. This choice limits the generalizability of the results.

Conclusions and Future Work

This article presented Oiva, a mobile stress management app based on acceptance and commitment therapy methods. We studied the usage, impact, and user experiences of Oiva in a one-month field study with 15 participants. The active usage, observed positive effects on wellness, and the generally positive user experiences of Oiva suggest that it is possible to develop engaging mobile apps that are experienced as beneficial for personal mental wellness. Our present results establish Oiva as a good starting point for continuing research on mobile support for mental wellness. We believe that the insights gained from our in-depth interviews with the participants may help future researchers to create effective and engaging mental wellness apps.

Oiva is currently being studied in a randomized controlled trial with working-age subjects suffering from stress and features of metabolic syndrome. In the study, Oiva is compared to an ACT-based face-to-face intervention with similar content, delivered as 6 group meetings during an 8-week period, and a control group. Each study condition will involve about 80 subjects. The impact of interventions will be measured by psychological, physical, and anthropometric questionnaires and measurements at baseline, after the intervention, and at 6 months after the intervention.

In future versions of Oiva, we aim to enable easier tailoring of programs to different target groups as well as individual needs and explore the possibilities of context-sensitivity in supporting better integration into the daily life. We will also study the opportunities of adding social features to the app [31,32]. However, our aim is to continue to develop and study Oiva in an iterative way, making sure that the existing features are successful before adding new ones.

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

AAQ-II: acceptance and action questionnaire
ACT: acceptance and commitment therapy
CBT: cognitive behavioral therapy
SEM: standard error of mean

SWLS: satisfaction with life scale

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Original Paper

A Text Message Delivered Smoking Cessation Intervention: The Initial Trial of TXT-2-Quit: Randomized Controlled Trial

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Abstract

Background: Mobile technology offers the potential to deliver health-related interventions to individuals who would not otherwise present for in-person treatment. Text messaging (short message service, SMS), being the most ubiquitous form of mobile communication, is a promising method for reaching the most individuals.

Objective: The goal of the present study was to evaluate the feasibility and preliminary efficacy of a smoking cessation intervention program delivered through text messaging.

Methods: Adult participants (N=60, age range 18-52 years) took part in a single individual smoking cessation counseling session, and were then randomly assigned to receive either daily non-smoking related text messages (control condition) or the TXT-2-Quit (TXT) intervention. TXT consisted of automated smoking cessation messages tailored to individual's stage of smoking cessation, specialized messages provided on-demand based on user requests for additional support, and a peer-to-peer social support network. Generalized estimating equation analysis was used to assess the primary outcome (7-day point-prevalence abstinence) using a 2 (treatment groups)×3 (time points) repeated measures design across three time points: 8 weeks, 3 months, and 6 months.

Results: Smoking cessation results showed an overall significant group difference in 7-day point prevalence abstinence across all follow-up time points. Individuals given the TXT intervention, with higher odds of 7-day point prevalence abstinence for the TXT group compared to the Mojo group (OR=4.52, 95% CI=1.24, 16.53). However, individual comparisons at each time point did not show significant between-group differences, likely due to reduced statistical power. Intervention feasibility was greatly improved by switching from traditional face-to-face recruitment methods (4.7% yield) to an online/remote strategy (41.7% yield).

Conclusions: Although this study was designed to develop and provide initial testing of the TXT-2-Quit system, these initial findings provide promising evidence that a text-based intervention can be successfully implemented with a diverse group of adult smokers.

Trial Registration: ClinicalTrials.gov: NCT01166464; http://clinicaltrials.gov/ct2/show/NCT01166464 (Archived by WebCite at http://www.webcitation.org/6IOE8XdE0).

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KEYWORDS

smoking cessation; tobacco; texting, text messaging; mobile health; mHealth; health communications

Introduction

It is estimated that 19.3% (45.3 million) of US adults are smokers, with higher rates among younger adults and individuals with lower socioeconomic status [1]. Smoking or exposure to second-hand smoke kills more than 440,000 people in the USA every year, and is associated with numerous chronic health conditions, which results in nearly $100 billion in healthcare costs and productivity losses annually [2,3]. Estimates suggest that 69% of smokers want to quit, and in 2010, more than half of all smokers attempted to quit [1]. Although evidence-based behavioral smoking treatments exist, research suggests that these resources are used by less than 10% of smokers attempting to quit [4,5]. Frequently cited barriers to utilizing behavioral interventions include the cost, time commitments, and logistics (eg, travel, scheduling appointments) associated with these treatments [6]. To effect significant reductions in smoking rates, innovative interventions and delivery systems are needed that reach smokers effectively and efficiently [7].

One emerging method that may help overcome these barriers to treatment is the use of mobile communication technologies, or mHealth treatment programs. The use of mobile technology, such as mobile phones, smartphones, and tablet devices to deliver health-related interventions is a rapidly expanding area of research and practice [8-11]. With more than 80% of adults in the USA-across various demographic groups-owning mobile phones [12], the majority of smokers can be reached for smoking cessation treatment using mobile technology. Previous research suggests ("landline") telephone counseling for smoking cessation is efficacious [13], is acceptable to smokers, and in many cases is the preferred mode of treatment as compared with face-to-face behavioral counseling [13,14].

As with landline telephones, mobile phones can be used to provide behavioral counseling, but offer the additional benefit of allowing for SMS text messaging (short message service, SMS) as well. SMS text messaging-based mHealth interventions that use texting are becoming popular because of the ease-of-use and low cost of SMS text messaging. This intervention modality also offers several benefits over face-to-face or telephone-based behavioral interventions, primarily because mobile technology allows interventions to be delivered to people in everyday settings and in real-time. This allows for the content and timing of messages to be individually tailored to individuals. For example, text messages encouraging continued abstinence from smoking can be provided at times when patients report they are in need of additional support (eg, when having cravings, at times when they typically smoke). The use of mobile technology can allow for multiple daily contacts over longer periods of time (ie, several text messages per day). This increased intensity and tailoring of interventions may improve adherence to self-help materials, resulting in higher quit rates [15-18].

To date, there have been several interventions designed using SMS text messaging to deliver smoking cessation interventions. Although many studies have evaluated short-term treatment outcome for smokers either using single group [19,20] or randomized designs [21-23], there are fewer SMS text messaging-based smoking cessation programs that have carefully examined long-term outcome data (≥6 months) in randomized trials [24,25]. In the past several years, two Cochrane reviews have been conducted evaluating the short-term [26] and longer-term [27] efficacy of SMS text messaging-based smoking cessation interventions. The authors have concluded that although there is heterogeneity among study results, overall there is a benefit of mobile phone-based smoking cessation interventions.

The goal of the present work was to develop and evaluate the feasibility and preliminary efficacy of a smoking cessation intervention program delivered through SMS text messaging. The content and structure of this program was designed based on evidence-based intervention guidelines for smoking treatment programs, while also incorporating feedback from potential end users regarding their preferences. Formative work was conducted to assess user preferences for the intervention features, content and delivery schedules, and is reported elsewhere [28]. In the present study, we report on the intervention feasibility and acceptability of this intervention method, and present data from an initial study that included follow-up assessments thorough six months post-treatment.

Methods

Participants

Adult smokers were recruited to participate in this study. To be eligible for this study, individuals had to meet the following inclusion criteria: (1) current daily smoker, (2) interested in quitting smoking in the next 30 days, (3) have a mobile phone with SMS text messaging capability, and (4) use SMS text messaging at least once monthly.

Measures

Baseline Measures

Smoking history variables were assessed, including age when started smoking, current number of cigarettes smoked per day, number of quit attempts in the last year, and methods used to attempt to quit. Nicotine dependence was measured using the 6-item Fagerstrom Test for Nicotine Dependence (FTND) [29]. Scores can range from 0-10 with higher numbers indicating greater levels of nicotine dependence. Symptoms of nicotine withdrawal were measured using the Mood and Physical Symptoms Scale (MPSS) [30]. The MPSS uses a 5-point rating scale assessing mood, irritability, restlessness, difficulty concentrating, and hunger, and has an additional item using a 6-point scale to assess urges to smoke. We also used a 16-item instrument derived from work by Hughes and Hatsukami [31]

that assessed the degree to which participants had experienced typical symptoms of nicotine withdrawal during previous quit attempts. Readiness and confidence in ability to quit smoking were assessed using two items. Participants used a 10-point scale to rate readiness to quit (1=not ready at all, 10=extremely ready) and confidence (1=very low confidence, 10=extremely confident). Readiness to quit smoking was also assessed using the stages of change measure, with participants indicating their number of quit attempts in the last year and how seriously they are considering quitting (within next 30 days, within next 6 months, not thinking of quitting). This measure was used to identify a person's current stage of change for quitting smoking [32]. The Center for Epidemiologic Studies Depression Scale (CESD-10) [33] was used to measure depressive symptoms. Participants rate the extent to which they experience specific feelings or engaged in behaviors during the previous week with responses ranging from rarely (0) to most or all of the time, 5-7 days (3). Scores range from 0 to 30 with higher scores indicating greater depressive symptoms.

Outcome Measures

Outcome measures were administered mid-intervention (week 4), post-intervention (week 8), and at 3 and 6 months follow-up assessments. During these times, participants reported their smoking status, readiness, and confidence in quitting (or remaining quit), and symptoms related to nicotine withdrawal. Smoking status included 7-day point prevalence abstinence, the primary outcome variable, and 24-hour point prevalence abstinence. Readiness and confidence in quitting and nicotine withdrawal symptoms were assessed using the measures described above. Feasibility and acceptability of the program were assessed by recruitment numbers, participant retention through the treatment program and final follow-up assessment, and results of a program satisfaction survey.

Intervention Design and Components

Formative work which included several focus groups with young adult smokers was conducted to inform the development of the intervention design and content [28]. The intervention, including both the SMS text messaging and individual counseling session, was modeled after national treatment guidelines [34], and guided by Social Cognitive Theory [35,36] and the stages of change model [37]. All intervention content (including the text message and counseling session content) was developed and reviewed by PhD-level clinical psychologists with expertise in smoking cessation treatment.

Individual Counseling Session

At study enrollment, all participants also took part in an individual 30-minute counseling session, led by a PhD-level clinical psychologist. Participants chose the format of the session (ie, in-person, telephone, Google chat, or Skype), and were provided a copy of a quit smoking guide published by the American Lung Association [38]. During the session, the counselor led a discussion based upon key sections of the guide, including reasons for quitting, perceived importance of quitting, and confidence in one's ability to quit, identifying obstacles to quitting, preparing for quit day, and planning strategies to aid quitting. Participants were encouraged to continue using the guide during their participation in the intervention.

Text Message Intervention Content and Design

The intervention was designed to accommodate participants who were at various stages of quitting and to allow for different trajectories to abstinence. Four tracks were created that included "Not Ready", "Prepare", "Quit", and "Relapse". The "Not Ready" track was designed for individuals who wished to quit smoking in the next 30 days, but who were not ready to set a quit date. Messages in the "Not Ready" track consisted of once daily messages delivered for up to 14 days and were aimed at enhancing motivation to quit. The "Prepare" track was designed for individuals who set a targeted quit day within the next 14 days, and consisted of twice daily messages that included tips and advice on obtaining support for quitting, medications to aid quitting, dealing with nicotine addiction, coping with stress, problem solving and self-monitoring, and motivational messages. More than 200 messages were generated to address the following categories: social support, problem solving, decision making, motivational support, behavioral tips, information about smoking cessation medications, and addiction education. Participants received messages that spanned these categories to provide broad coverage of topics, and to ensure messages were not duplicated.

To avoid redundancy, variations on these messages were created for a "Prepare-2" track, which was delivered to those who failed to quit on quit day or relapsed. The "Quit" track contained messages delivered 4 times daily for 2 weeks, then twice daily for 4 weeks (6 weeks in total). These messages addressed the same general topics noted above, but were tailored to be appropriate for individuals who were currently engaged in quitting smoking.

At study enrollment, participants randomized to the intervention (TXT) were assigned either to the "Prepare" or "Not Ready" tracks depending on whether they set a target quit date. Those who remained in the "Not Ready" track for all 14 days without setting a quit date were called by the study counselor and encouraged to set a quit date. At an individual's designated quit day, participants were moved into the "Quit" track. During the first week following the quit day, participants answered texted questions regarding whether they had been able to quit. Those who did not quit on their quit date or who relapsed were asked whether they wished to set a new date. Those setting a new quit date within 14 days were moved into the "Prepare" track, the remaining participants were moved into the "Not Ready" track. Participants could text the key words "Prepare", "Quit", "Not Ready", and "Relapse" at any time during the program to move themselves into the appropriate track for their experience with quitting. For example, an individual in "Prepare" track who decided to quit several days before his/her designated quit day could text "Quit" to move himself/herself immediately into that part of the program. A participant in the "Quit" part of the program could text "Relapse" if he/she was smoking again and could then choose to begin the "Not Ready" or "Prepare" track.

Additional Intervention Features

In our formative work, focus group participants strongly supported being able to receive messages "on demand" at times when they were experiencing a craving. This feature was included in the intervention; participants could text "Crave" and would receive an SMS text message back with a tip for coping with cravings. In addition, after quitting, participants reporting that they had "slipped" and smoked a cigarette, would receive SMS text messages immediately and twice daily for 3 days targeting coping and getting back on track with quitting. After a "slip" they were texted to report on their abstinence status and received tailored messages depending on their response.

Control Condition

The SMS text messaging intervention was compared to a control condition. Participants who were randomly assigned to the control group (Mojo) received the same initial counseling session followed by 8 weeks of daily non-smoking-related motivational texts (eg, "It takes just one positive step to begin the journey out of a difficult rut. Step out today!").

Procedures

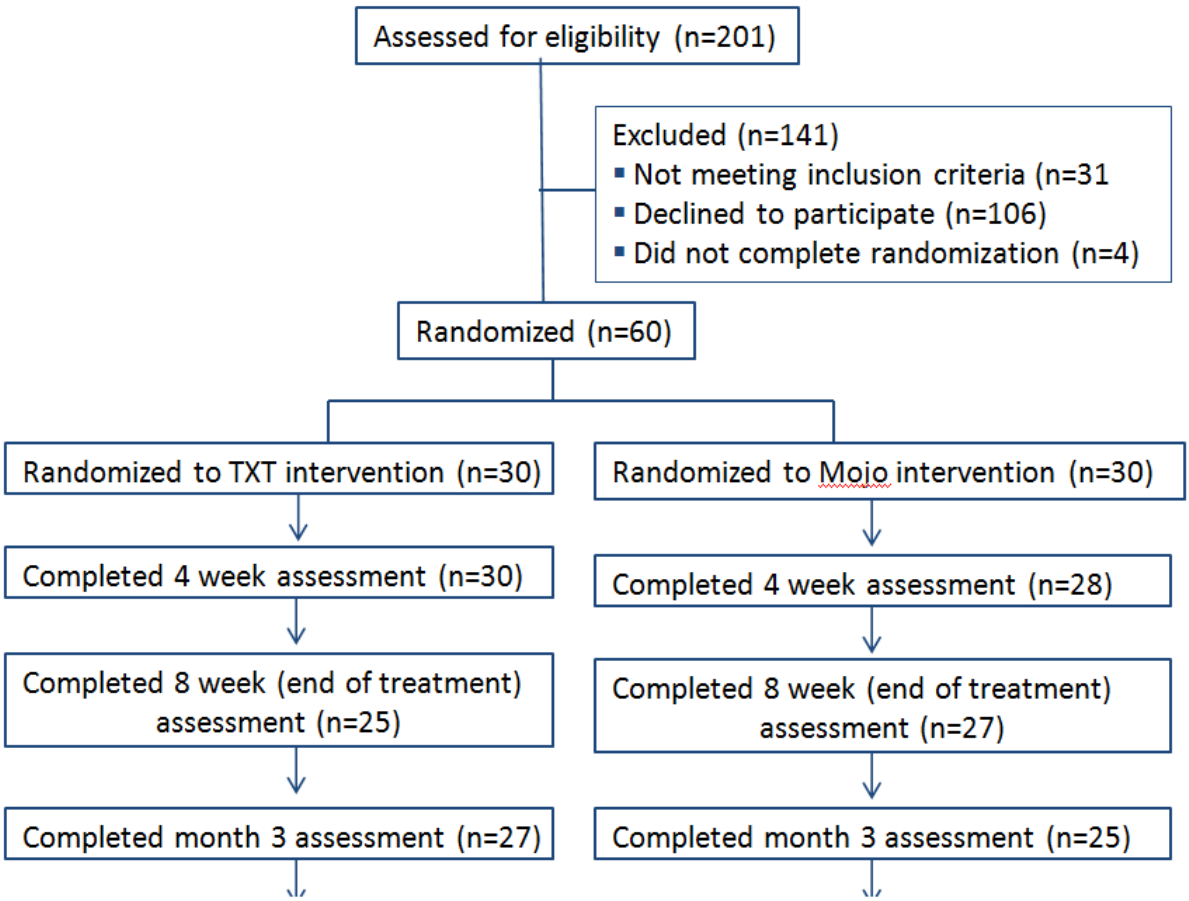
This study was conducted in the research facilities of the Miriam Hospital, which is affiliated with the Alpert School of Medicine at Brown University, and was approved by the Institutional Review Board prior to initiating recruitment. Participants were recruited between January and June 2011 through advertisements in local media outlets (Internet sites, radio programs). Interested individuals called or texted our study phone number for more information. The study research assistant (RA) reached callers by voice phone, provided a brief description of the study (pre-screening introduction), and screened potential participants for eligibility (see Participants section above for eligibility criteria). Eligible individuals were then scheduled for an in-person orientation visit during which they were given more information about the program, provided written informed consent, and took part in a single in-person smoking cessation counseling session. Simple randomization was used to assign participants to each group via a computerized random number generator. Random assignments were placed in a sealed envelope by the study RA prior to each counseling appointment. The RA delivered the randomization assignment to the study participant immediately after completion of the counseling session.

Over a period of 3 months, a total of 7 participants were enrolled and randomized using these procedures. Slow recruitment and high attrition rates prior to attending orientation prompted a change in recruitment methods.

We developed a Web portal that provided the pre-screening introduction to the study. Interested individuals clicked through to a second page that presented an online screener to determine the individual's eligibility. Eligible individuals were then presented with an online consent form to sign electronically. The online consent included a brief quiz to ensure that individuals understood the primary points of the trial. After signing consent, the participant provided identifying and contact information, and completed an online baseline assessment. At the conclusion of the assessment, the program used simple randomization to assign individuals to the study arms and then presented an online Google calendar to schedule their counseling session. Study staff ran a series of 10 mock participants with differing answers to questions in order to test the accuracy of data collected on the Web portal before launching. New advertisements were developed to include the option of accessing the study website directly, in addition to calling or texting our staff. After implementation, 51 participants were recruited and randomized over 21 days using these website-based procedures.

Once enrolled, participants completed the individual counseling session and began receiving either the intervention or control SMS text messages on their personal mobile phones for the following 8 weeks. At the mid-point (week 4) and end (week 8) of the intervention, all participants completed the outcome measures described above using the website. The study RA sent email reminders to participants when assessments were due reminding them to complete the online questionnaires and provided a link to the online questionnaires. The study RA conducting assessments and the counselors were blind to participant randomization assignment. Participants completed the outcome measures 3 and 6 months after completing the intervention (see Figure 1, Consort Diagram).

Figure 1. Recruitment Flow Diagram.



Statistical Analyses

Frequency distributions, means, and standard deviations were used to characterize the overall sample. Chi-square tests and analysis of variance was used to compare groups for comparability on baseline demographic and smoking history variables. The primary smoking outcome analysis examined the 7-day point prevalence abstinence from smoking using the generalized estimating equations (GEE) approach of Zeger and Liang [39] with robust standard errors, using Proc GENMOD within SAS 9.3 for Windows. The model for this outcome analysis was a 2 (treatment groups)×3 (time points) repeated measures design that was fit using an autoregressive working correlation structure on data analyzed from an intention-to-treat (ITT) perspective in which missing participants were counted as smoking. Smoking outcomes were analyzed using odds ratios comparing TXT and Mojo (control) groups. A secondary smoking outcome analysis also used the GEE methodology to examine 24-hour point prevalence abstinence. Further secondary analyses used analysis of variance to evaluate for change in several potential mediating variables at 8 weeks, 3 months, and 6 months follow-up, among respondents who provided complete data at those assessment points.

Results

Participant Characteristics

Randomized participants (N=60) averaged 30.7 years of age (SD 9.0; range 18-52), and 43% (25/60) of them were male participants. Participants were primarily non-Hispanic white (39/60, 66%) or Black (11/60, 19%), with 7% (4/60) bi/multi-racial or unsure, 2% (1/60) Hispanic White, and 7% (4/60) did not respond. With respect to ethnicity, 19% (11/60) were Hispanic/Latino. Most had completed some college education (21/60, 36%) or had graduated from college (15/60, 26%), with 21% (12/60) graduating from high school, while 9% (5/60) had not graduated from high school, and 9% (5/60) did not respond. Most participants worked part time (21/60, 35%) (≤35 hours/week) or full time (18/60, 31%), while 26% (15/60) were unemployed and 9% (5/60) did not respond. Total household income was less than $25,000 for half (50%) of the participants.

On average, participants were 16 years old (SD 2.9) when they first started regular (daily) cigarette smoking. At the start of the study, participants smoked on an average of 16.3 cigarettes/day (SD 8.3; range 4-40). Participants had made an average of 4.1 (SD 3.8) serious quit attempts in their lives. Of the 53 participants who responded to a temporal intention to quit item,

94% noted at baseline that they were planning to quit in the next 30 days. Baseline FTND scores averaged 4.9 (SD 2.5), suggesting moderate nicotine dependence. Baseline CESD scores averaged 10.4 (SD 5.9), and over one third of participants (35%) had CESD scores above 11, indicative of significant levels of depressive symptoms [33]. There were no significant differences between treatment groups on any demographic or baseline smoking history variables.

Smoking Outcome

Table 1 presents the percent of participant who quit smoking by group at each assessment time point.

A 2 (treatment groups)×3 (time points) GEE repeated measures analysis examined the effects of the TXT intervention versus Mojo for differences in 7-day point prevalence abstinence. There was a significant main effect for treatment group (*P*=.02) with higher odds of 7-day point prevalence abstinence for the TXT group compared with the Mojo group (OR 4.52, 95% CI 1.24, 16.53). There were no significant effects for time (*P*=.34) or the time × treatment group interaction (*P*=.60). While the overall main effect was significant, contrast estimates did not find specific differences between TXT versus Mojo at week 8 (23.3% vs 10.7%, OR 2.54, 95% CI 0.59, 10.99), month 3 (16.7% vs 3.6%, OR 5.40, 95% CI 0.59, 49.47), or month 6 (20.0% vs 3.6%, OR 6.75, 95% CI 0.76, 60.15), likely due to reduced statistical power at any individual time point. We also evaluated for treatment group differences in 24-hour point prevalence in a similar manner, using a 2 (treatment groups)×3 (time points) GEE repeated measures analysis, but found no significant effects for group (*P*=.11), time (*P*=.23), or the time × treatment group interaction (*P*=.88).

Secondary Smoking-Related Outcome

Although this was an initial (ie, pilot) study and was not powered to detect mediation effects, we conducted hypothesis-generating exploratory analyses of additional smoking-related variables. Analysis of variance was used to examine for change in participants' confidence to remain quit, readiness for change, level of depression, and nicotine withdrawal symptoms at the 8-week, 3-month and 6-month follow-ups. From baseline to the end of treatment (8 weeks), individuals in the TXT group tended to show increase in confidence in remaining quit (M 0.19, 3% increase) compared with those in the Mojo group (M -0.89, 12% decrease), although this difference was not significant. At 3 months follow-up, there was a trend (*P*=.07) for the MPSS Urge scale to be reduced among TXT participants compared with Mojo participants. During the 6 months follow-up, there was a significant improvement in MPSS mood symptoms of nicotine withdrawal (*P*=.03) among the TXT participants as compared with Mojo participants. No significant changes were seen in readiness to change or depression (CESD) scores.

Table 1. Smoking status by group for 7-Day and 24-Hour ITT at 8 weeks, 3 months, and 6 months.

	Total n (%)	Txt2Quit n (%)	Mojo n (%)
Sample size	60	30	30
7-Day quit: 8 Weeks			
Yes	10 (17.2%)	7 (23.3%)	3 (10.7%)
No	48 (82.8%)	23 (76.7%)	25 (89.3%)
7-Day quit: 3 Months			
Yes	6 (10.3%)	5 (16.7%)	1 (3.6%)
No	52 (89.7%)	25 (83.3%)	27 (96.4%)
7-Day quit: 6 Months			
Yes	7 (12.1%)	6 (20.0%)	1 (3.6%)
No	51 (87.9%)	24 (80.0%)	27 (96.4%)
24-Hour quit: 8 Weeks			
Yes	12 (20.7%)	8 (26.6%)	4 (14.3%)
No	46 (79.3%)	22 (73.3%)	24 (85.7%)
24-Hour quit: 3 Months			
Yes	7 (12.1%)	5 (16.7%)	2 (7.1%)
No	51 (87.9%)	25 (83.3%)	26 (92.7%)
24-Hour quit: 6 Months			
Yes	8 (13.8%)	6 (20.0%)	2 (7.1%)
No	50 (86.2%)	24 (80.0%)	26 (92.7%)

Intervention Feasibility and Acceptability

One of the goals of this trial was to establish the feasibility and acceptability of a text message-based smoking cessation intervention. During the first 3 months of recruitment for this study, we used traditional recruitment and intervention delivery strategies (telephone screening, in-person orientation, face-to-face counseling), but found that with these methods less than 8% of individuals who were screened were eligible and enrolled, and we were only able to randomize 7 participants during this 3 months period (see Table 2). This very low recruitment yield prompted us to switch to online recruitment methods as described previously. Although approximately half (50.8%) of individuals who accessed the website abandoned it before providing consent, 92% of the remaining individuals completed study enrollment and were randomized, resulting in a 41.7% yield from all initial contacts and screens, as shown in Table 2.

Another unique aspect of this intervention was that we provided participants with a choice regarding the mode of delivery of the initial counseling session. We found that counseling visits were accomplished by voice-phone (56/100, 56%), in-person (18/100, 18%), Google chat (20/100, 20%), or Skype (6/100, 6%). Over half (61/100, 61%) of all participants used the online Google calendar to schedule their counseling session. End of treatment (week 8) satisfaction ratings showed that nearly all participants said they were *satisfied* (41/100, 41%) or *very satisfied* (48/100, 48%) with the program, and 63% (63/100) of participants said that the program met their expectations. Most participants said that the program was helpful (40/100, 40%) or very helpful (45/100, 45%). However, 60% (60/100) of participants did not use the group messaging ("help") feature. Of those who did, 72% (72/100) said it was *easy* or *very easy* to use. Participants' feedback indicated strong appreciation of the social networking feature. As an illustrative example, one participant reported: "Yes, I think that it helps me a lot…people to talk with when you would have normally smoked a cig." Nearly one third of participants (n=17) used the peer-to-peer network for social support during their quit attempt. The number of messages sent by any one participant ranged from 2 to 177 (M 39.7, SD 54.0).

Table 2. Recruitment yield using traditional voice phone, SMS text messaging, and online methods (N=60).

	Standard recruitment 3 months		Online recruitment 21 days
	Voice phone, n	Txt Msg, n	Online, n
Total inquiries	96	51	155
Unable to contact	36	28	0
No longer interested	9	0	28
Screened	51	23	127
Ineligible	11	9	11
Eligible	40	14	116
Not interested, in-person orientation	16	11	-
Attended orientation	24	3	-
No-show for orientation	18	0	-
Lost before consent	2	0	59
Enrolled/signed consent	4	3	57
Randomized	4	3	53
Yield from initial contacts (%)	4.1	5.8	34.1
Yield from total screened (%)	7.8	13.0	41.7
Percentage of total sample (%)	6.7	5.0	88.3

Discussion

Principal Findings

Although this study was designed to develop and provide initial testing of the TXT-2-Quit system, significant differences were found between treatment groups, with individuals randomized to the intervention group showing higher point-prevalence abstinence rates vs the comparison group. These results are especially encouraging given that all control participants received an individual smoking cessation counseling session and at least one daily SMS text message for the duration of the 8-week intervention. Although participants in the TXT condition received more "contact" with researchers via multiple daily SMS text messages (albeit through an automated system, not direct personal contact), this well-matched control condition provided a more rigorous test than usual care. As such, finding significant treatment effects indicates that the effects of this intervention are potentially quite robust. Although preliminary, there was also an indication that participants receiving the text message intervention reported lower levels of nicotine withdrawal symptoms than those in the control condition. Future work that is statistically powered for secondary outcome variables should more vigorously evaluate factors that could serve as mediators or moderators of treatment efficacy, including

self-efficacy for quitting, nicotine withdrawal symptoms, readiness for change, and depression.

One of the strengths of this study is that a relatively diverse sample was recruited to participate and found the intervention appealing, including a substantial number of ethnic and racial minorities and participants of many education levels. While over half of participants had at least some college (13-16 years formal education) education, over one-quarter had 12 years or less formal education. These statistics speak to the potential of mobile phones and SMS text messaging in the United States and many other countries for overcoming barriers to treatment access and usage.

While we initially sought to develop and test this intervention with younger adults (age <35 years), we eliminated the upper age limit after receiving many enquiries from individuals in their 40s and 50s. According to the Pew Internet and American Life Project, SMS text messaging is increasingly common among middle age and older adults, with 72% (72/100) of mobile phone owners aged 50-64 and 34% (34/100) of those aged 65+ years reporting using their mobile phone to send or receive SMS text messages [40]. We were unable to examine the extent to which age may act as a moderator of intervention efficacy because of the relatively small sample size for this initial study. However, it is possible that as SMS text messaging is becoming a more acceptable mode of communication among middle age and older adults that age may have a smaller moderating effect that in the past, although this remains an important area for future research.

Recruitment for this intervention was far more successful when the entire recruitment and treatment process was mobile phone and Web-based. Use of our traditional method of recruitment including in-person visits for orientation and consent together with an initial face-to-face smoking cessation counseling visit resulted in very slow recruitment and high rates of loss of eligible individuals. Both recruitment yield and speed were greatly improved when all processes were revised to be congruent with the way that the target audience uses technology.

This intervention was developed based on feedback from focus groups consisting of likely end users (ie, smokers who use SMS text messaging) [28]. A peer-to-peer network, which allowed participants to communicate and encourage each other, was created at the behest of focus group participants. However, we found that this feature was used by less than half of study participants. As designed, the social support feature was only accessed by individuals who requested “help” from others. It may be that some individuals do not need additional social support through this type of intervention or that they already receive (or think they receive) sufficient support from other social networks. Some people may also be hesitant to admit they need help, or tend to underestimate the degree to which seeking help from peers would improve their chances of quitting. This may need to be tested by making the social support network a more integrated (non-optional) part of the intervention in order to better evaluate the utility of including peer networks in SMS text message-based smoking cessation programs.

Limitation

This study built upon previous interventions using SMS text messaging by using less study staff support, greater reliance on participants for providing group support, having a rigorous control condition which received daily SMS text messaging (non-smoking related) and the same individual smoking cessation counseling session as the intervention group. At the same time, there were also limitations that can be addressed by future research. First, results from pilot studies are inherently less reliable due to the small number of participants [41]; therefore, these findings will need replication in a larger trial to verify reliability of the results. Second, given that this was a pilot study, we did not biochemically verify abstinence from smoking, but instead relied on self-report. When this and other interventions are tested in larger clinical trials, objective measures of outcome should be used in order to reduce biases associated with self-reported abstinence from smoking. Third, larger scale studies are needed to provide sufficient statistical power to examine factors that may act as mechanisms of action as well as factors that may moderate intervention efficacy. Fourth, more thorough integration of peer-to-peer social networking within an SMS text message intervention could further enhance engagement with and benefits resulting from this type of treatment.

Conclusions

Despite limitations, these findings add to the small but growing body of literature on text messaging interventions. Several studies have examined using SMS text messaging for smoking cessation, either as a stand-alone intervention [24,25] or as part of a multi-component intervention [21,42], or as part of a relapse prevention intervention [23]. In general, these studies have shown efficacy for smoking cessation interventions delivered by SMS text messaging. However, existing studies have been quite diverse in the intensity and length of the intervention as well as use of additional features (eg, face-to-face counseling and use of website or phone counseling to supplement the SMS text messaging intervention). As with computer and Web-based programs [43], it seems likely that programs using text messaging, either exclusively or as part of a larger intervention, will provide some level of efficacy for some smokers. Much work is needed to determine the effects that can be achieved with text alone versus text as a support to a larger intervention, as well as for which populations and under what circumstances these programs will be efficacious.

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Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [44].

[PDF File (Adobe PDF File), 1019KB - mhealth_v1i2e17_app1.pdf]

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Abbreviations

CESD: Center for Epidemiologic Studies Depression Scale
FTND: Fagerstrom Test for Nicotine Dependence
GEE: generalized estimating equations
ITT: intention-to-treat
MPSS: Mood and Physical Symptoms Scale

RA: research assistant

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Viewpoint

Regulatory Barriers Blocking Standardization of Interoperability

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Abstract

Developing and implementing a set of personal health device interoperability standards is key to cultivating a healthy global industry ecosystem. The standardization organizations, including the Institute of Electrical and Electronics Engineers 11073 Personal Health Device Workgroup (IEEE 11073-PHD WG) and Continua Health Alliance, are striving for this purpose. However, factors like the medial device regulation, health policy, and market reality have placed non-technical barriers over the adoption of technical standards throughout the industry. These barriers have significantly impaired the motivations of consumer device vendors who desire to enter the personal health market and the overall success of personal health industry ecosystem. In this paper, we present the affect that these barriers have placed on the health ecosystem. This requires immediate action from policy makers and other stakeholders. The current regulatory policy needs to be updated to reflect the reality and demand of consumer health industry. Our hope is that this paper will draw wide consensus amongst its readers, policy makers, and other stakeholders.

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KEYWORDS

medical device regulation; device interoperability; personal health device; standardization

Introduction

The utilization of an interconnected mechanism to deliver personal health services has been widely recognized as an efficient way to improve people's quality of life and reduce overall health care cost. By leveraging the latest consumer technologies from the information computer and telecommunication (ICT) domain, individuals are empowered to better manage their health and wellness, more effectively communicate with their service providers and ultimately, improve their personal health status and clinical outcomes while reducing their health care cost. To achieve this goal, we have to cultivate a healthy global industry ecosystem for the technology providers, its users, and operators, enabling them to create innovative personal health services. Due to the multidisciplinary nature of this ecosystem, developing a set of personal health device interoperability standards to ensure seamless cooperation between multiple stakeholders becomes a key prerequisite for this ecosystem.

International standard developing organizations (SDO) and industry alliances, such as Institute of Electrical and Electronics Engineers 11073 Personal Health Device Workgroup (IEEE 11073-PHD WG) [1], Bluetooth Special Interest Group (Bluetooth SIG) [2], and Continua Health Alliance (CHA) [3], are striving to develop, certify, and market the global interoperability standards for personal health devices and services. The outcome of this work has resulted in the publication of more than 20 international standards and more than 90 CHA-certified products available in the global market.

However, due to the lack of synchronization between personal health technology and the development of regulation and health policy, industrial experts in those SDOs have confronted non-technical barriers, which are difficult to achieve consensus within the SDOs. This has significantly delayed the massive

market adoption of these health standards. Any inappropriate technical decision regarding these barriers may lead to insufficient-regulation or over-regulation towards personal health devices, both of which can impair the motivation of stakeholders and the health of the personal health industry ecosystem. This has become a global issue, recognized by several international industry alliances [3-6]. Policy makers, policy advisors, and vendors in many countries and regions are actively working on this policy gap, but with little success [7-9].

In this paper, we will discuss five topics. The first three topics mainly affect the market adoption of those interoperability standards; the remaining two topics have a direct impact on the content of those standards. Working together to achieve balanced solutions on these topics will significantly help SDOs to develop widely-adopted standards.

Granularity of Regulation Policy

Currently, regulators mainly use "intended use" to determine whether a device is a medical device under regulation, based on the claims a device vendor makes about its product. This policy was introduced for traditional health care practices where the user of medical device is always the health care service provider. However, that is not well-suited to the current reality where individuals are empowered by personal health devices to become more active in managing their health. The same device has the potential to support both the health-oriented and medical-oriented use cases, depending on who uses it and how it is used. The boundary between them is blurred. From our perspective, the main differentiators between health- and medical-oriented use include the type of user, the environment, and purpose for using the devices. In fact, most of health devices currently available in the market fall into the definition of a medical device while others are in a gray area. For example, nearly all the publicly-marketed home-use blood pressure meters are registered medical device; however, the individuals who use them only use them to monitor their own health status and do not send their health data to their service provider. In this case, the device is a medical device but the operator of the device is not a clinician, the environment is not a clinical environment, and there may be hardware (eg, a mobile phone or tablet) and software (eg, a self-assisted health management app) associated with this blood pressure meter. Applying the same regulation policy that is usually applied to the traditional clinical-oriented medical devices over such type of health-oriented device and its associated software without properly differentiating its intended use may cause the situation where the increased cost cannot justify the benefit it brings. In order to fulfill the regulatory requirements, vendors need to dramatically increase their research and development (R&D) and productization cost to ensure their product is risk-free or risk-minimized as a traditional medical device. However, such type of health-oriented hardware and software are usually low acuity in terms of the risk it may cause to consumers. Many vendors believe such regulation is a kind of over-regulation, which may push up the product price, thus slowing down the market adoption. The ambiguity in the definition of a medical device and/or the words in the product's claims themselves results in a lack of regulatory clarity and predictability for many personal health products. To solve this, granularity in the regulation policy is needed to distinguish the different types of uses.

As far as the device interoperability standard is concerned, the granularity about "intended use" alone is insufficient to eliminate ambiguity.

1. Devices for medical- and health-oriented use have quite dynamic requirements about the quality of service (QoS) of the underlying communication technology. "Realtime" data transmission is often required in clinical environment, and that is usually achieved via wired connection. In contrast, health devices often leverage communication technologies in consumer market, both wired and wireless. In the extreme case, some personal health applications (eg, a health watch connected to heart rate belt) may even work with connectionless broadcasting technology (eg, a sub-type of Bluetooth Low Energy (BLE) technology [2]), which basically provides no guarantee of data integrity, safety, or privacy. In this case, the benefit is the smaller implementation complexity, device size, power consumption, and R&D cost. Failing to acknowledge such differences may result in over-regulation.
2. Many countries and regions apply the same rule that an accessory of a medical device is subject to the same level of regulation as its "parent" device. The stack of interoperability standard is designed to carry medical data, thus is potentially regarded as an accessory of the medical device, and falls under the same regulation category of its associated device (eg, a glucose meter). However, the reality is the implementation of such standard (in hardware or software) only passively transmits health data, and such implementation is unlikely to cause similar risk as its associated device does. Applying the aforementioned rule over such accessories without enough differentiation will again introduce over-regulation, which may turn the chip vendors into medical device vendors.
3. Many consumer communication technologies are designed for general data transmission purposes. It is this dedicated application-level protocol (eg, IEEE 11073-PHD) that is running on top of the transport channel that turns the software stack into a health-oriented use. The simple wording like "data transfer" and "data conversion" in current regulation policy do not really cover such granularity, but this is crucial for consumer device vendors who implement platform for general purpose. These vendors may suddenly become vendors of medical device components and must go through, at least partially, the medical device regulation processes, which are generally considered as burdensome for them.

SDOs are expecting guidance with enough granularity from regulators, so as to tailor interoperability standards to better satisfy the technical, business, and regulatory requirements in each segment.

Command and Control

One of these key barriers in question is the command and control (C&C) of personal health device. Many disease management

services require, for example, that health device A sends a command to health device B in order to control B's behavior. For example, a mobile phone sends command to Continuous Glucose Monitor to calibrate its glucose value, or a mobile phone sends commands to thermometer to change its measurement frequency from once per minute to once per five minutes. Depending on how it changes the behavior of the health device and how big the potential risk is, the devices (and associated software) supporting various C&C functionalities may be classified into different classification under medical device regulation. There is a general fear among consumer health device vendors with regard to the liability associated to such classifications, especially when something goes wrong during the data transmission and device operation.

So far, personal health device vendors only use proprietary methods to implement C&C. Vendors have differing opinions regarding whether they should or, if they agree, how to define C&C in a standard. Some vendors and users believe the current wireless communication technology cannot absolutely guarantee security. They believe that if C&C is standardized and implemented, the amount of adverse events will increase, and the regulation burden of these types of devices will be aggravated. There are however vendors and users who believe that standardizing C&C brings more benefit than risk, at least for a portion of personal health services. It's unwise to block the beneficial portion just because the other portion may have risky components. In addition, the standardized technical solution generated based on collective wisdom of an entire industry is likely to be more secure and more sustainable than a proprietary solution. From a regulation authority's perspective, regulating a proprietary technical solution has more opacity than a standardized one.

Currently, the consumer device vendors are eager to, but dare not to, use C&C functionality via standardized way due to the lack of clear regulatory guidance. In fact, both BLE and IEEE 11073 Point-of-Care standard series have already defined such functionalities, and similar work in IEEE 11073-PHD is also under going. But it is not likely that we will see this appear on the market in the near future. The large-scale field pilots probably will not begin in the market until the relevant regulation policy and public laws are defined and a complete legal framework dealing with these liability issues is established.

The Selective Connection Between Peer Devices

The goal of building interoperable technical standards is to allow health devices to work together seamlessly in a plug-and-play manner. However, based on the market practice, some device vendors propose to standardize the functionality of selective connection complaining that when their devices get connected to a device manufactured by another vendor (especially some white-label device), the overall user experience may become very poor. One possible reason for that is the poor usability design from the questioning vendor. The way those vendors implement their products does follow the interoperable standards and guidelines, but unfortunately, in an inefficient or inappropriate way. One typical scenario is where the device repeatedly and unnecessarily sends connection requests to the peer device, which drains the peer device's battery power quickly or disables the device's ability to serve other devices normally.

In fact, it is technically feasible to define such functionality in current technical standard. But this is contradictory to the plug-and-play principle that these standards organizations are actively promoting. Consumers may easily get confused when two devices with same logo and cannot connect to each other. However, if the SDOs do not define this functionality, the user experience may become poor in certain scenarios, or this may further cause some technical risks. Lower layer communication standards often contain device filtering functionalities called the "white list" and "black list". Such functionalities are usually requested by user, and are implemented by chip vendors. The health device vendors are not involved in this decision making process, thus their problems cannot be solved by the "white list" and "black list" functionality.

The user demand for customizing devices and services is another possible reason for selective connection. This is needed when particular health service providers wish to customize the health devices, so that these customized devices send health data only to certain designated service networks, rather than other service networks. Such customization can simplify the technical operation for aging people, and can ensure their personal health data goes directly to the designated service provider. However, if such functionality becomes a mandatory content of a standard, other users or service providers may be restricted from using the same health device. Given the competitive relationship between different vendors or service providers, the SDO is not likely to define functionality like "unconditional data redirection" in standards, even though it is technically feasible. What they can do is to standardize an attribute like "Preferred Destination" which may suggest a data flow direction. And this has to be an optional functionality that vendor may choose to not support.

Identifiers of Device and Users

An end-to-end information system for personal health service often contains multiple health devices and different types of users. These devices and users are uniquely identified via identifiers (ID) within the system. These IDs identify the source of data; allowing the service provider to provide personalized service for clients via a set of devices, and the regulatory agency to backtrack all the devices and people involved in the information flow. This is quite useful when investigating medical adverse events. These IDs, typically device IDs (DID) and user IDs (UID), are important and necessary components of personal health device interoperability standards. Defining a proper way to use them in standards has significant impact to R&D cost, user experience, market entry, and regulation.

Nowadays, the DID defined in some mainstream communication standards (eg, the widely used IEEE EUI-64 identifier) actually identifies a particular piece of hardware providing the communication interface, thus indirectly identifies the entire device that embeds this communication hardware. There can

be a device (eg, cpersonal computer) contains multiple communication interfaces, thus is associated to multiple DIDs.

In contrast, the DID usually identifies an entire device in medical device industry. It actually represents a combination of hardware, firmware, and application software. The Food and Drug Administration recently published the proposed rule for unique device identification (UDI) [10] , which aims to establish a UDI system for medical devices. But the UDI registration process seems to be inflexible and slow with regard to the evolving speed of consumer health products and services, because it requires each new version of device to have a new UDI. Software updates may happen frequently in consumer health devices and services. When a firmware update is urgently needed due to business or safety reason, vendors often cannot afford the waiting time to apply for a new UDI. This becomes more challenging when dealing with the international market where different types of DID exist. Therefore, the current IEEE 11073-PHD standards still rely on the EUI-64 being as its DID. SDO and vendors are expecting some harmonization of DID in the future. Ideally, that would be an “e-solution” which can balance above conflicts.

In personal health device use cases, scenario where multiple users share a single device (eg, weighing scale in home) often occurs. This requires the peer health device (eg, a mobile phone connected to that weighing scale) to process the mapping between DIDs and UIDs at application level. Due to this fact, that mobile phone and its mobile application involve deeply into the data flow, resulting in a higher level of medical device regulation. The regulation policy towards such ID-mapping case has not been explicitly clarified yet, which becomes one potential barrier for market entry. Both vendors and SDOs are expecting clear guidance about this issue from regulation authority.

Duplicate Data

After the measurement channel has completed the measuring process, the captured health data is often stored in personal health device before uploading or clearing. For data transmission purpose, one measurement channel of a device can be associated to multiple logical transmission channels. The end result of that is the peer device may receive multiple copies of a single measurement data, either by duplicated transmission via the same channel, or by overlapped transmission via different channels. Some SDOs call this phenomenon as “duplicate data”.

According to current IEEE 11073-PHD standard, after the peer device (eg, a mobile phone) acknowledged the data reception, the personal health device (eg, a thermometer) can decide by itself whether to remove the successfully transmitted health data. This may happen when the device or device user delete data due to limited size of storage memory. While in BLE standard, health data is only transmitted once, thus it does not produce any duplicate data. Some vendors believe the peer device (which is receiving data) should be given the freedom to decide whether to merge the duplicate data. Another group of vendors believe the data merging process may aggravate the regulatory burden of the peer device, and may complicate and delay the data processing.

In fact, what is embedded in this data transmission process is an issue of transferring liability. So far, there is no regulatory policy which explicitly defines guidance for such duplicate data scenarios and the corresponding hand-over of responsibility of maintaining health data. The current consensus within PHD WG is: once the personal health device received the acknowledgment sent from the peer device, the peer device takes the responsibility to store and maintain the transmitted data. After that moment, any data lost or change in the uploading link has nothing to do with the personal health device that sent original data. Again, vendors and SDOs are expecting a clear guidance from regulation authority.

Conclusion

Developing a set of personal health device interoperability standards is a mandatory prerequisite toward cultivating a healthy global industry ecosystem. However, the existing gaps between current regulations, health policies, and the resulting market reality hinder such progress. Policy makers must provide a predictable, risk-based regulatory framework that covers the issues arose from new market segment.

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Conflicts of Interest

None declared.

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Abbreviations

BLE: Bluetooth Low Energy
C&C: command and control
DID: device identifier
ICT: information computer telecommunication
ID: identifier
IEEE 11073-PHD WG: Institute of Electrical and Electronics Engineers 11073 Personal Health Device Workgroup
QoS: quality of services
R&D: research and development
SDO: standard developing organizations
UDI: unique device identification
UID: user identifier

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Original Paper

Acceptability of Delivering and Accessing Health Information Through Text Messaging Among Community Health Advisors

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Abstract

Background: Communication technologies can play a significant role in decreasing communication inequalities and cancer disparities by promoting cancer control and enhancing population and individual health. Studies have shown that technology, such as the mobile phone short message service (SMS) or text messaging, can be an effective health communication strategy that influences individuals' health-related decisions, behaviors, and outcomes.

Objective: The purpose of this study was to explore usage of communication technologies, assess the acceptability of mobile technology for delivery and access of health information, and identify cancer and health information needs among Deep South Network for Cancer Control trained Community Health Advisors as Research Partners (CHARPs).

Methods: A mixed-method design was used, and a triangulation protocol was followed to combine quantitative and qualitative data. Focus groups (4 focus groups; n=37) and self-administered surveys (n=77) were conducted to determine CHARPs mobile phone and text message usage. The objective was to include identification of barriers and facilitators to a mobile phone intervention.

Results: All participants were African American (37/37, 100%), 11/37 (89%) were women, and the mean age was 53.4 (SD 13.9; focus groups) and 59.9 (SD 8.7; survey). Nearly all (33/37, 89%) of focus group participants reported owning a mobile phone. Of those, 8/33 (24%) owned a smartphone, 22/33 (67%) had a text messaging plan, and 18/33 (55%) and 11/33 (33%) received and sent text messages several times a week or day, respectively. Similar responses were seen among the survey participants, with 75/77 (97%) reporting owning a mobile phone, and of those, 22/75 (30%) owned a smartphone, 39/75 (53%) had a text messaging plan, and 37/75 (50%) received and 27/75 (37%) sent text messages several times a week or day. The benefits of a text messaging system mentioned by focus group participants included alternative form of communication, quick method for disseminating information, and privacy of communication. The main barriers reported by both groups to using mobile technology to receive health information were cost and not knowing how to text message. Ways to overcome barriers were explored with focus group participants, and education was the most proposed solution. Majority of CHARPs were in favor of receiving a weekly text message that would provide cancer/health information.

Conclusions: The findings from this study indicate that CHARPs are receptive to receiving text messages focusing on cancer/health information and would be likely to engage in mobile health research. These findings represent the first step in the development of an interactive mobile health program designed to provide cancer/health information and a support network for the Deep South Network Community Health Advisors as Research Partners (DSN CHARPs).

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KEYWORDS

community health workers; mobile health; text messaging; cancer

Introduction

The American Cancer Society cites cancer as the second leading cause of death in the United States, with an estimated 1.7 million new cancer cases diagnosed and over half a million people expected to die of cancer in 2013 [1]. Studies have found that states in the southeastern United States exhibit much higher rates of new cancer diagnosis when compared with the national average. According to the most recent data, newly diagnosed cancer cases in the state of Alabama alone were expected to reach over 25,500, with lung, breast, prostate, and colorectal cancer being the four most common cancer types [2].

Cancer mortality has continued to decline in the United States in the past decade. However, certain racial and ethnic groups and people with low income and/or education continue to have the highest rates of both new cancers and cancer deaths [1]. African Americans have been shown to have the highest death rate and shortest survival of any racial and ethnic groups in the United States for most types of cancers [3]. In 2007, the death rate for all cancers combined continued to be 32% higher in African American men and 16% higher in African American women compared to Caucasian men and women, respectively [3]. Factors contributing to these disparities may include income, education, economic and social barriers to quality cancer prevention, and early detection and treatment services [3].

There are many diverse sources for seeking health information, with different populations and different ages using different strategies [4]. Studies have found people used personal sources, such as doctors, friends, and family members, to obtain most of their health information [5,6]. Gollop found that older African American women received health information from their physicians, the mass media, and members of their social networks [7]. James et al assessed preferences for seeking cancer information in the future among cancer patients, family/friends of cancer patients, and noncancer patients and found that all groups most frequently cited human sources (eg, health professionals and lay people) [8].

Communication technologies can play a significant role in decreasing communication inequalities and cancer disparities by promoting cancer control and enhancing population and individual health [9]. Mobile phones may be an appropriate means for addressing communication inequalities. Mobile phones are ubiquitous, and are becoming increasingly important in the delivery of health information. Mobile health (mHealth), as defined by the National Institutes of Health (NIH) Consensus group, is the use of mobile and wireless devices to improve health outcomes, health care services, and health research [10]. Furthermore, the short message service (SMS; also known as text messaging or texting) feature of the mobile phone is rapidly increasing in popularity. SMS allows for instantaneous delivery of messages to individuals at any time, place or setting, and are asynchronous, meaning messages can be accessed at any time by an individual [11]. The use of SMS permeates all age groups, cultures, and socioeconomic backgrounds [11]. According to a survey conducted in 2012 by the Pew Internet and American Life Project, 85% of US adults own a cell phone and 80% indicated they send and receive text messages [12]. People from racial/ethnic minorities were found to text message more than Caucasians, and African Americans were more likely than other cell phone owners to sign up for health text alerts and text with others in their neighborhood about community issues [12,13].

Recent studies have shown that text messaging can be an effective health communication strategy that influences individuals' health-related decisions, behaviors, and outcomes [14-24]. There has been an increase in the development of health promotion programs that use the SMS feature of the mobile phone, either as an independent intervention, or in combination with other technologies or approaches. One approach used in health promotion programs is incorporating the assistance of community health advisors (CHAs). CHAs are lay community members who are seen as natural helpers and recognized by their friends, families, and neighbors as reliable sources of health information, help, and referrals [25]. Through formal training, CHAs help raise awareness, spread knowledge, and improve the health of their communities [25]. Studies have shown CHAs to be effective as they provide culturally appropriate, informal, and spontaneous assistance to community members [26]. Furthermore, they have been proven to be a useful method of overcoming barriers in the community because they are familiar with the local culture, local resources, and local health concerns [27].

The Deep South Network (DSN) for Cancer Control was created in early 2000 to establish a sustainable community infrastructure to promote cancer awareness among African Americans in the Alabama Black Belt and the Mississippi Delta [28]. To develop this infrastructure, "natural helpers," who are defined as trusted and caring individuals who offer help to the community and/or its residents, were identified, recruited, and trained to become DSN Community Health Advisors as Research Partners (CHARP) [29]. The DSN program has trained and retained over 500 CHARPs in Alabama and Mississippi to educate and answer questions about breast, cervical, and colorectal cancer as well as address issues related to the health and health care access and resources in their community [30]. These CHARPs serve as a vital link between community members and community health agencies and resources. They bridge the gap between individuals and health care resources/cancer information by providing health education, explaining cancer screening tests, and enhancing community participation in clinical trials [29].

The development of an SMS-based program could enhance the CHARPs' ability to reach a large number of people in the community and expand their outreach efforts with the convenience of using a mobile phone. The addition of an SMS system could support the delivery of accurate and up-to-date cancer health information through synchronous, real-time communication to community members. Furthermore, the SMS system could be used to overcome barriers in obtaining cancer health information across socioeconomic groups. In order to

develop strategies to optimize the dissemination of cancer prevention and control information to CHARPs, formative research needs to be conducted to assess the feasibility and acceptability of a mobile phone-based program.

The purpose of this study was: (1) to explore the communication technologies used by the DSN CHARPs, (2) to assess the acceptability of an SMS-based mobile phone intervention, and (3) to identify cancer and health information needs.

Methods

Design

A two-part mixed methods study was conducted. First, the qualitative portion of the study involved focus groups conducted with DSN CHARPs in Alabama. Second, the quantitative, component involved collection of self-administered surveys completed by CHARPs in Alabama and Mississippi. The combination of qualitative and quantitative methodologies strengthened the interpretation of the data regarding feasibility and acceptability of using mobile phones for obtaining health information. By examining information collected by different methods and in different groups, the study findings can be corroborated across datasets, thereby reducing the impact of potential biases that can exist in a study [31].

Study Population

Participants were recruited from DSN CHARPs residing in seven counties in Alabama and four counties in Mississippi. This study was approved by the Institutional Review Board at the University of Alabama at Birmingham.

Data Collection

Focus Groups

DSN CHARPs from two Alabama counties were invited to participate in the focus groups through recruitment flyers, word-of-mouth, and the county coordinator. Four focus groups were conducted with a total of 37 participants, and the groups were divided by age (19-50 and 51 and older) based on evidence that different age groups may have different perspectives on technology [32]. At the start of each focus group, we obtained consent from the participants after study protocols and risks were explained. Following this, the participants completed a brief demographic and mobile phone usage questionnaire. The sessions lasted approximately 90 minutes, were digitally recorded, and were led by a trained moderator and co-moderator. Participants were paid $25 for their participation.

A semistructured interview protocol (see Multimedia Appendix 1) guided the discussion and ensured consistency between focus groups. The interview guide focused on current sources of cancer information, existing knowledge of cancer information and screening services, skills, and availability of resources relative to health information technology including mobile phones, feasibility and acceptability of using mobile phones to access health information, current use of mobile phones, knowledge and use of text messaging, and preference of information to be included in a text messaging database (eg, locations of cancer screenings based on zip code, free community cancer screenings). Participants were also asked what they perceive as barriers and facilitators to acceptability of a mobile phone intervention and what suggestions they may have for addressing the barriers.

County Survey

Based on a review of the literature and results from the focus groups, a 25-item questionnaire was developed by the study investigators with the purpose of assessing demographics, communication technologies usage, attitudes toward SMS usage, intention to use an SMS system, and social influences that predict SMS use. Questions included current cell phone ownership, type of cell phone (eg, iPhone, Blackberry, etc), text messaging plan (none, limited, unlimited), how often they send or receive text messages, purpose of text messages, and reasons for not using text messaging.

Survey packets were sent to the County Coordinators of nine DSN counties in Alabama (n=5) and Mississippi (n=4). The number of surveys sent was based on the number of active CHARPs within each county (n=119). A cover letter was attached to each survey. The cover letter included information about the research study, voluntary nature of participation, and a number to call if there were any questions about the study. By completing the survey, the individual agreed to participate in the study. The County Coordinators read aloud the cover letter and then distributed the surveys to the CHARPs during their monthly meeting. No identifiers were included on the survey other than the county.

Analysis

The digitally recorded focus groups were transcribed to capture participant responses verbatim. The transcriptions were analyzed in two stages by qualitative content analysis [33]. In the first stage, two experienced coders independently read the original transcript and identified themes that were central to areas of discussion both within and across groups. Transcripts were coded using (1) codes and themes derived from the research questions and the moderator guide and (2) codes and themes that emerged from the data. Independent interpretations were discussed and the raters jointly decided upon a final coding scheme of relevant themes. The second stage of the analysis involved summarizing the data within and across groups and included a review of how the themes are interrelated. Themes that were considered relevant appeared within a topic of discussion by a minimum of three group members.

Descriptive analyses were used to report the demographic and mobile phone usage variables of the participants. Statistical analysis was carried out using SPSS version 20.

Results

Focus Groups

Descriptive statistics were used to generate a profile of focus group participants based on demographic information (see Table 1). All participants were African American (37/37, 100%), 11/37 (89%) were women, mean age was 53.6 (SD 13.9), and 26/37 (70%) of participants had been a DSN CHARP for over 5 years. Nearly all participants reported owning a mobile phone (33/37, 89%). Of those, 8/33 (24%) indicated they had a smartphone

(eg, Blackberry, iPhone) and 22/33 (67%) had a texting plan (limited/unlimited). A total of 18/33 (55%) received text messages either several times a week (7/33, 21%) or day (11/33, 33%), and 11/33 (33%) sent text messages either several times a week (2/33, 6%) or day (9/33, 27%) (see Figure 1).

County Survey

A total of 77/119 surveys were completed for a response rate of 65%. All participants were African American (77/77, 100%), 69/77 (90%) were women, the mean age was 59.9 (SD 8.7), and 62/77 (81%) of participants had been a DSN CHARP for over 5 years (see Table 1). Similar to the focus groups, nearly all participants reported owning a cell phone (75/77, 97%), and of those 22/75 (30%) indicated they had a smartphone (eg, Blackberry, iPhone) and 39/75 (53%) had a texting plan (limited/unlimited). A total of 37/75 (50%) received text messages several times a week (20/75, 27%) or day (17/75, 23%), and 27/75 (37%) sent text messages several times a week (14/75, 19%) or day (13/75, 18%), and 22/75 (29%) never sent or received a text message (see Figure 1).

Qualitative and Quantitative Results

General

The major themes that were identified from the focus group discussions are summarized in Table 2. The telephone was reported by focus group participants as the most common method community members used to contact CHARPs for health information. In-person and telephone were the most common methods community members used to contact CHARPs for health information as reported by survey participants.

Table 1. Focus group and county survey participants' demographic information.

Variable	Focus group[a] n=37	County survey[b] n=77
Gender, n (%)		
Female	33 (89)	69 (90)
Male	4 (11)	8 (10)
Age		
Mean (SD)	53.4 (13.9)	59.9 (8.7)
Range	25-79	36-84
Race, African American, n (%)	37 (100)	77 (100)
Marital status, n (%)		
Married	17 (46)	28 (36)
Widowed/Divorced/Separated	12 (32)	37 (48)
Never Married	8 (22)	11(14)
Educational level, n (%)		
Less than high school	7 (19)	5 (6)
High school or GED	14 (38)	12 (16)
Some college	8 (22)	26 (34)
Bachelor's degree or higher	8 (22)	34 (44)
Employment, n (%)		
Employed	19 (52)	39 (50)
Retired	12 (32)	23 (30)
Other[c]	5 (13)	15 (20)
Has children < 18 years old, n (%)	15 (41)	19 (25)
CHARPs with DSN > 5 years, n (%)	26 (70)	62 (81)

[a]One missing value for employment.

[b]One missing value for marital status.

[c]Other = homemaker, unable to work, out of work.

Figure 1. Smartphone ownership and SMS usage among participants owning a mobile phone.

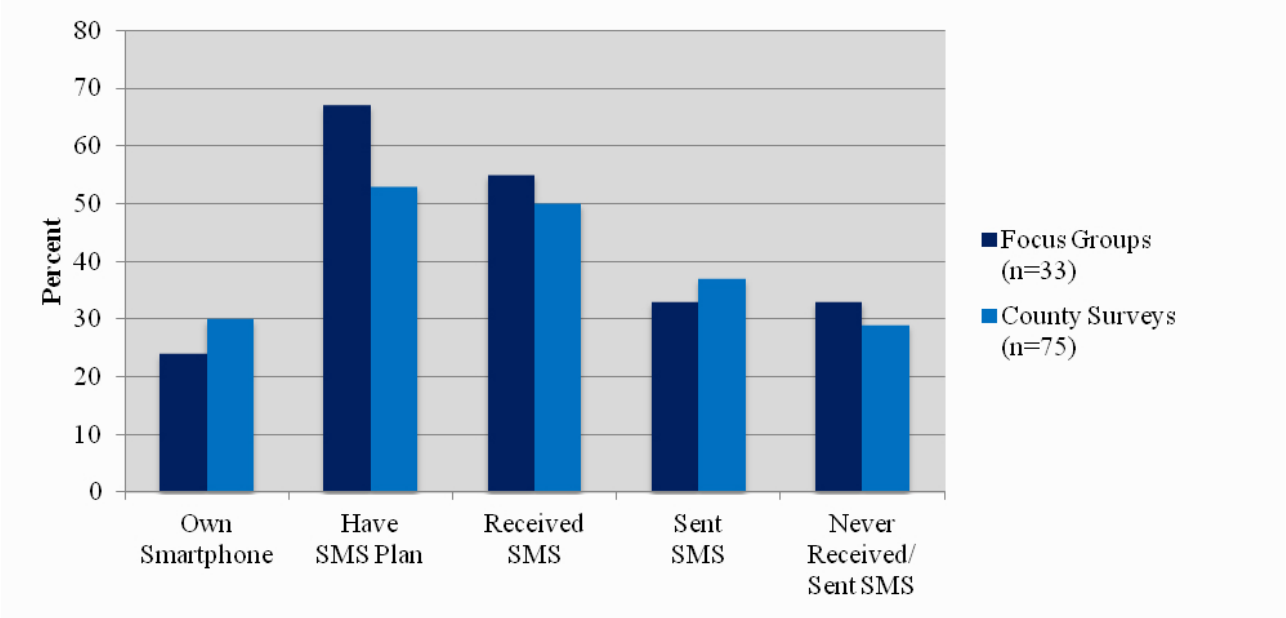

Table 2. Focus group themes.

Theme	Number of comments (%)
Request information (n=20)	
Cancer information	6 (30)
Low-cost/free health care services	5 (25)
Transportation services	2 (10)
Miscellaneous	7 (35)
Text messaging	
Facilitators for text messaging (n=18)	
Alternate form of communication	7 (39)
Quickness	5 (28)
Personal	3 (17)
Privacy	3 (17)
Facilitators for text messaging to receive health information (n=16)	
Dissemination of information	6 (38)
Awareness	4 (25)
Other[a]	6 (38)
Barriers for text messaging (n=21)	
Not knowing how to text	6 (29)
Cost	5 (24)
Confidentiality	4 (19)
Other[b]	6 (29)

[a]Other = prevention, communication, quickness, popular.

[b]Other = age, no reason to text, spam text messages, multiple messages.

Requested Information

Focus group participants mentioned low-cost or free health care services, cancer information (eg, screening, general information, survivorship), and transportation services as the most commonly requested information. For example:

I get calls from family members, like questions about different health problems especially about high blood pressure, diabetes, diabetic.

I have friends calling asking me for information about the free services, if they don't have the money to have a mammogram.

Anywhere they can go and you know have screening done for free or do you know of anybody that could give a discount or something, transportation.

For me they want to know how did I felt when I first found out, you know, I had cancer and how did I handle it, you know, during that period and until after, you know, my breast was removed.

I have friends call and ask me about colonoscopy, a lot of people afraid to take it and when they ask me I tell them there's nothing to it, there's not.

Survey participants' most commonly requested information included breast cancer, nutrition, and physical activity.

Text Messaging

Facilitators for Text Messaging

Focus group participants identified alternate form of communication (7/18, 39%), quickness (5/18, 28%), personal (3/18, 17%), and privacy (3/18, 17%) as the main reasons for text messaging.

It's a quick response to a question, to get information to a person.

You don't have to worry about if you're in a crowded place and somebody else hears your conversation.

This is another way of having close contact with a person, you know. They have unlimited calling, you know, but a lot of times now you can save the amount of time on the phone by just using your text.

Sometimes you're in a place where you can't talk to somebody or you need to send a message to somebody and you don't. You need to be quiet and you need to get a message out.

Has a certain degree of privacy.

Survey participants reported personal (46/75, 62%) and work-related (20/75, 26%) communications were the main reasons for sending/receiving text messages.

Facilitators for Text Messaging to Receive Health Information

Focus group participants also mentioned the ability to disseminate information (6/16, 38%) and awareness (4/16, 25%) as key reasons for using text messaging to receive health information.

Then you can immediately get them information of where they need to go I also think that text messaging, like you said, it's to help each other. If you have some friends out there in the community that you know the phone number, you could now get the information out in different homes, you know, if they have cell phones. Even though you might have people's numbers and just spread the news about cancer, you know, in the community if you know the people's phone numbers.

Maybe if your family needs to go, like if say for instance you text me something, and I can text them to everybody in my phone. I can just forward it to everyone, and so you forward it to me and I could forward it to ten more. They could forward it to ten more, and so there are 20 people that have been told, you know?

Barriers for Text Messaging

Cost, not knowing how to text, and confidentiality were the most frequently mentioned barriers to texting. For example:

I don't know the first thing about it.

I don't know how to and I've never taken the time to learn.

Of course one for most people would be not having a plan because if you don't have a plan it could get costly.

I would think not having the texting knowledge or know-how.

Maybe someone else might see the information on the phone, and they really didn't want anybody else to see it. No cell phone.

Survey participants' most frequently mentioned barriers to texting included: cost (23/77, 30%), not knowing how to text (11/77, 15%), and not wanting to receive too many messages (21/77, 27%).

Almost half of the focus group participants (9/20, 45%) viewed education as the best solution to overcome barriers. The majority of the focus group participants and nearly half of the survey respondents were in favor of receiving a weekly text message that provided cancer/health information.

Discussion

Principal Findings

Our findings suggest that DSN CHARPs are receptive to the use of mobile technology for access and delivery of information, such as health issues (eg, cancer, nutrition, and physical activity), location of health care services, and availability of local transportation services. Furthermore, they are likely to engage in mHealth research because texting provides an alternative form of communication and dissemination as well as social support. To date, there is only one study that has identified projects utilizing mobile technologies for community health workers [34]. Kallander et al [34] conducted a thematic review with the focus on low- and middle-income countries. They found only a limited number of mHealth projects and very few formal outcome evaluations.

The combination of qualitative and quantitative data collection and analysis methods allowed for a rich understanding of the role of DSN CHARPs in the community and their perceived barriers and facilitators to mobile technology. Although the cost of texting and not knowing how to text were the most frequently cited barriers to an SMS-based program, over half of the

CHARPs had a text messaging plan (limited or unlimited). In order to overcome barriers, participants indicated they can be taught how to access and read the texts, which is similar to a study conducted by Pfaeffli et al [32] that found participants in their senior years were interested in taking part in a mobile phone-based exercise intervention, but said they would need assistance. Therefore, participants were taught how to open texts, view messages, and assistance was provided to those who encountered difficulties. These results show that barriers to an SMS-based program can be overcome by providing education to those initially reluctant to texting.

Majority of CHARPs have been volunteers for the DSN Program for over five years, and have been exposed to and have adopted different methods to deliver health information, such as local media messages, town hall meetings, cancer awareness walks, and one-on-one meetings [30]. The addition of mobile technology as a tool has potential to support the performance of CHARPs by disseminating information and prevention messages and by directing individuals to local health care services. It can also be used to keep CHARPs informed of upcoming community events and of recent developments in health or cancer research. Furthermore, CHARPs can communicate directly with one another and provide social support. Our findings demonstrate an important role in developing an SMS-based program as a tool to support community health workers. The next steps are to collaborate with the CHARPs to develop and evaluate a culturally relevant SMS-based project.

Limitations

This study has some limitations. First, the view of African Americans in the rural Deep South may not be generalizable to those in urban areas. However, research has shown that African Americans are more likely to sign up for health text alerts as well as text with others in their neighborhood about community issues [12,13]. Second, the focus group discussion and the county survey may have elicited different responses. Although the questions for both the focus group and county survey were written in the second person, focus group participants answered questions in reference to both themselves and others they knew, whereas the county survey participants most likely answered questions in reference only to themselves. Also, the focus of this study was on SMS use, so there may be opportunities to explore other information and communication technologies, such as social media, as this is constantly growing and ever-changing field [35].

Conclusions

The findings from this study represent the first step in the development of an interactive mobile health program designed to provide cancer/health information and a support network for the DSN CHARPs. This program could be used to increase the accessibility of cancer/health information, thereby increasing the effectiveness of the DSN CHARPs. Health disparities exist not only in health care but also in the ability of different population groups to access and use health information. In order to reach population subgroups with important health information, it is necessary to use the channels through which they seek such information. Our findings suggest the combination of CHARPs and mobile technology may improve access and delivery of information and services, particularly for rural and underserved populations.

Future studies are needed to determine the acceptance of receiving and accessing cancer health information and participating in studies related to mobile research with community health workers beyond low- and middle-income countries.

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Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

Focus group topic guide.

[PDF File (Adobe PDF File), 47KB - mhealth_v1i2e22_app1.pdf]

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Abbreviations

CHAs: community health advisors
CHARPs: community health advisors as research partners
DSN: deep south network
mHealth: mobile health
NIH: national institutes of health
SMS: short message service

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Original Paper

iMHere: A Novel mHealth System for Supporting Self-Care in Management of Complex and Chronic Conditions

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Abstract

Background: Individuals with chronic conditions are vulnerable to secondary complications that can be prevented with adherence to self-care routines. They benefit most from receiving effective treatments beyond acute care, usually in the form of regular follow-up and self-care support in their living environments. One such population is individuals with spina bifida (SB), the most common permanently disabling birth defect in the United States. A Wellness Program at the University of Pittsburgh in which wellness coordinators supervise the care of individuals with chronic disease has produced remarkably improved outcomes. However, time constraints and travel costs have limited its scale. Mobile telehealth service delivery is a potential solution for improving access to care for a larger population.

Objective: The project's goal was to develop and implement a novel mHealth system to support complex self-care tasks, continuous adherence to regimens, monitoring of adherence, and secure two-way communications between patients and clinicians.

Methods: We developed and implemented a novel architecture of mHealth system called iMHere (iMobile Health and Rehabilitation) consisting of smartphone apps, a clinician portal, and a two-way communication protocol connecting the two. The process of implementing iMHere consisted of: (1) requirement analysis to identify clinically important functions that need to be supported, (2) design and development of the apps and the clinician portal, (3) development of efficient real-time bi-directional data exchange between the apps and the clinician portal, (4) usability studies on patients, and (5) implementation of the mHealth system in a clinical service delivery.

Results: There were 9 app features identified as relevant, and 5 apps were considered priority. There were 5 app features designed and developed to address the following issues: medication, skin care, bladder self-catheterization, bowel management, and mental health. The apps were designed to support a patient's self-care tasks, send adherence data to the clinician portal, and receive personalized regimens from the portal. The Web-based portal was designed for clinicians to monitor patients' conditions and to support self-care regimens. The two-way communication protocol was developed to facilitate secure and efficient data exchange between the apps and the portal. The 3 phases of usability study discovered usability issues in the areas of self-care workflow, navigation and interface, and communications between the apps and the portal. The system was used by 14 patients in the first 6 months of the clinical implementation, with 1 drop out due to having a poor wireless connection. The apps have been highly utilized consistently by patients, even those addressing complex issues such as medication and skincare. The patterns of utilization showed an increase in use in the first month, followed by a plateau.

Conclusions: The system was capable of supporting self-care and adherence to regimen, monitoring adherence, supporting clinician engagement with patients, and has been highly utilized.

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KEYWORDS

mobile health; mhealth; self-care; clinician-directed self-care; self-management; telehealth; telemedicine; smartphone; chronic disease management; spina bifida; patient-clinician communications

Introduction

Individuals with chronic conditions account for 75% of health care expenditures in the United States [1-3]. Globally, chronic conditions currently account for 60% of the global disease burden, and this figure is expected to reach 80% by 2020 [4]. The global shortage of health care workers coupled with increasing life expectancy have made it a high priority of health care systems worldwide to develop innovative strategies to improve care for chronic conditions and to prevent secondary complications [4]. Innovative approaches to chronic care have been seen as key to improving health care and reducing cost. Individuals with chronic conditions are vulnerable to such secondary complications as infections, amputations, wounds, and depression. A recent prospective study has identified those secondary complications as the strongest predictors of risk for premature death for people with chronic conditions [5]. Evidence from around the world suggests that people with chronic conditions benefit most when they receive effective treatments beyond acute care, usually in the form of regular follow-up and self-management support in their living environments. Patients with effective self-management skills make better use of health care services, have improved health behaviors, and health status [6].

Individuals with spina bifida (SB) make up one of the chronic condition populations that is susceptible to hospitalization due to problems related to sepsis from urinary tract infections (UTIs) and skin wounds. People with SB are also susceptible to high readmission rates within 30 days of discharge [7,8]. These secondary complications may be partially preventable with appropriate support and interventions to improve self-care skills [7]. Proactively, the Spina Bifida Association of Western Pennsylvania (SBAWP) initiated an in-person Wellness Pilot Program in which 2 wellness coordinators (WC), both registered nurses, supervised the care of 35 individuals with complex medical needs [9]. The WC identified the issues that a given patient faced and then designed an individualized plan of care by actively engaging the patient in the process. They helped to ensure that patients scheduled medical appointments, taught patients how to fill their own prescriptions, encouraged self-examinations for problems such as skin breakdowns, communicated health care provider recommendations to patients with cognitive impairments, activated needed community resources, and "checked in" on patients with home visits in order to identify new problems early. The WC role as the liaison and the director of care empowered the individuals to be responsible for their own care [9].

The program produced remarkably improved outcomes with respect to medical complications and health care utilization measures. Individuals in the SBAWP Wellness Program had shorter lengths of hospital stay, with admission rates of only 12.9% compared to the national rate of 26.9 % [10]. SBWAP Wellness participants also had lower rates of skin breakdown (9.7%) and UTIs (16.1%) compared to those in the general SBAWP population (35.5% and 35.2% respectively). As the cost of treating 1 Stage IV wound for community dwelling adults can exceed $124,000 per wound [11], this program's reduction in the incidence of wounds alone would allow for a significant overall decrease in health care costs. Unfortunately, travel and time constraints prevented the program from including larger groups of patients or those in remote locations [9].

A mobile health (mHealth) system is one way to reduce these constraints. mHealth would allow WC to serve a larger number of patients and would make the Wellness Program not only cost-effective but also scalable. It would also improve access to health care by allowing WC to reach underserved patients, who may benefit most. Mobile phones are the most commonly carried devices for people with disabilities [12]. Portability of mobile phones into almost any environment makes them an ideal tool for self-management, monitoring, and two-way engagement with the clinician.

Although currently there is no mobile or Web framework for the management of SB, the issues related to managing SB are similar to those of other chronic conditions. The current approaches to mHealth in managing chronic conditions fall into 5 categories:

1. *Stand-alone local apps* [13,14]. This first type includes self-monitoring apps such as diet or nutrition tracking apps that are used by consumers but do not connect the user with a clinician [15].
2. *Monitoring and recording apps using store-and-forward data transfer* [16,17]. The second type includes mobile remote health monitoring, such as blood pressure or heart monitor [18], or other store-forward monitoring apps [19].
3. *Consumer referential medical apps.* The third type includes educational apps that aim to help consumers manage chronic conditions through early self-identification and management of symptoms. This type may include access to Web-based disease management systems from a smartphone [20].
4. *Text messaging for engaging patients* [21-26]. The forth type is the most widely used method to engage patient, using both the original type of cellphone as well as a smartphone [27].
5. *Simple voice call, either in person or using interactive voice response (IVR)* [28]. The fifth type is a more traditional way of engaging patients by calling their cellphones.

The interactive Mobile Health and Rehabilitation (iMHere) system is an innovative advancement to the existing systems on the market and will be a significant contribution to current research literature on mHealth. It will support self-care that is initiated by patients or is directed by clinicians. Chronic condition management requires self-care, frequent communications between patients and clinicians, and continuous adherence to and adjustment of complex treatment regimens [29]. Certain conditions such as wounds and infections can worsen in a matter of hours and the ability to understand potential causes often requires a two-way real time dialog and image exchanges between the patient and clinician. These requirements cannot be supported by current mHealth architecture. The seamless two-way communication offered by the iMHere system will allow the clinician to provide a personalized treatment model, address major weaknesses of already existing apps, and mHealth systems for chronic conditions [30].

Methods

Overview

The project objective was to develop a novel mHealth system to support self-management and personalized care delivery for individuals with chronic conditions. The iMHere system consists of smartphone apps, a Web-based clinician portal, and a two-way communication connecting the patients and clinicians. The apps were designed to empower patients to perform preventive self-care activities and can be tailored to each patient's needs and daily routine. Instead of existing as isolated local apps, the apps were designed to send monitoring data to the portal and also receive self-care regimens being pushed from the portal. In this study, using a Web-based portal, the clinician (typically a nurse coordinator, social worker, case manager, or patient advocate) could monitor patients' compliance with regimens and send self-care regimens that would then be delivered to the patient via the apps. This allowed the clinician to monitor a patient's status and intervene as needed. Clinicians could use the portal to tailor a regimen or treatment plan for each and every patient (eg, scheduled medication, wound care instructions, etc) and the portal would push the plan to the smartphone apps in real time, an advancement over existing health portals, which cannot push data to the apps. Real-time interactive medical monitoring of patient self-care offers a powerful unique solution for patients living with chronic conditions, where cognitive as well as physical disabilities present significant barriers to effective self-care. This innovative and unique two-way data exchange protocol was also designed to work in rural or low-resource areas with a spotty data connection. Moreover, the system supports an innovative security mechanism which will erase data in the event of the phone being lost and meets all Health Insurance Portability and Accountability Act (HIPAA) regulations.

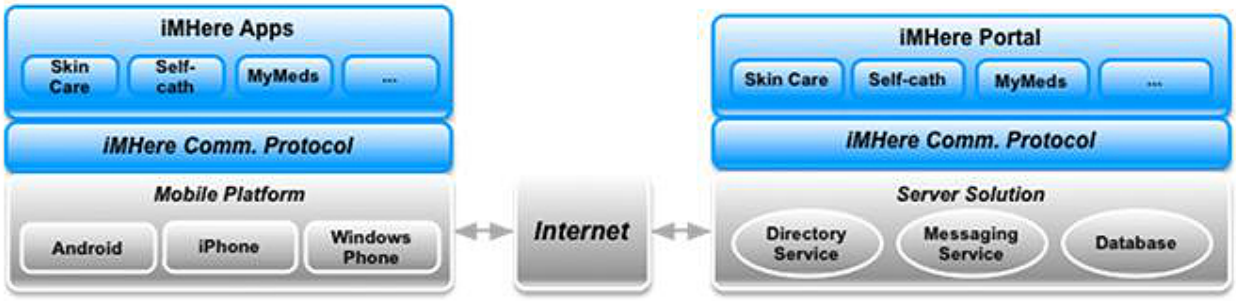
Architecture

The architecture of iMHere consisted of smartphone apps on one side, a clinician portal on the other, and a two-way communication connecting the two, as illustrated in Figure 1. The upper layer of the architecture consists of the apps on the smartphone side and the portal application on the server side. Each app on the smartphone side had a corresponding application on the server portal side. For example, the MyMeds medication app had a corresponding application on the server side. The middle layer of the architecture consisted of the iMHere two-way communication protocol, which allowed real-time data exchange between the patient apps and clinician portal. The lower level of the architecture consisted of the operating systems on the smartphone and server, as well as the Internet protocol connecting the smartphone to the server. The architecture was designed to work with 3 major smartphone operating systems: Android, iOS, and Windows 8. However, since the apps needed to be rewritten for each OS, we implemented it only on an Android platform due to its open architecture, comparatively lower cost, and popularity. The apps and the clinician portal were developed using Java. Since the apps need to be available continuously for support, even if there is no Internet connection, the regimen data were also stored locally in the smartphone's database. The communication protocol connected patients' apps with the clinician portal and was used by the apps to send data to the portal and vice versa.

Smartphone Apps

The purposes of the smartphone apps were three-fold: to support patients' self-care tasks; to send adherence data to the clinician portal; to receive personalized regimens and education from the portal. In a series of meetings among the members of our team, including a physician, an occupational therapist, and software engineers, we identified important smartphone apps for patients based on our experience with the Wellness Program. There were 9 apps identified: medication management, skin care, appointments and scheduling, bowel management, bladder self-catheterization, exercise, mental health, nutrition and medical supplies. Of these 9, we selected the 5 apps that were considered crucial to decrease morbidity and mortality in the SB population apps: medication management, skin care, bowel management, bladder self-catheterization, and mental health.

Figure 1. iMHere Architecture.



Medication App

MyMeds helped patients follow their prescribed medication regimens by providing a reminder for every medication the patients were taking. Patients with SB are frequently prescribed several medications for the management of urinary incontinence, seizures, bowel management, depression, et cetera. Taking medications 3 or 4 times a day and consistently following the prescribed regimen is always challenging. This app helped patients keep track of all the medications they were currently taking or had taken in the past.

Skin Care App

Skin Care enabled patients to keep track of their skin problems and to communicate with clinicians on how to care for the skin problems. Loss of sensation in the lower body associated with the lesion of the spinal cord means there is no trigger that indicated a need to reposition oneself and to reduce the pressure on a particular part of the body. Therefore, people with SB had to be constantly vigilant for skin injury and breakdown over the lower body resulting from pressure ulcers. Poor circulation below the waist and improper functioning of the lymphatic system also cause the lower extremities to receive an inadequate supply of nutrients and oxygen, and to have a buildup of fluid. These combined issues mean that pressure ulcers can develop very quickly in people with SB, but they tend to heal very slowly [31]. Using the Skin Care app, patients could continuously monitor the progress of their skin conditions and report new wounds.

Mental Health App

Mood App allowed the patients to let the clinician know what type of mood related symptoms they were exhibiting and allowed the clinician to provide timely intervention for mental health problems. Studies have shown that, in comparison to the general population, people with SB are at a higher risk of depressed mood and lower self-worth, and they are more likely to think about suicide [32]. In a recent cross-cultural study [33], the incidence of depression was above 40%, while the incidence of anxiety was around 20%.

TeleCath

TeleCath is an app for bladder self catheterization management. This app reminded patients when it was time to perform bladder self-catheterization and to report potential problems encountered. Most people with SB have a neurogenic bladder. This means they are unable to perceive the sensation of bladder fullness, and they lack the neurologic integrity to have coordinated contraction of the bladder muscle and opening of the bladder sphincter [34]. Many people with SB have uninhibited bladder contractions, which may be accompanied by high bladder pressure. Some people may be able to empty their bladders partially by straining, but the emptying is incomplete. Even small amounts of residual urine in the bladder can lead to urinary tract infections. The combination of high bladder pressure and infection can place the kidneys at risk. A technique called Clean Intermittent Catheterization (CIC) prevents these problems by emptying the bladder several times a day via a tube inserted through the sphincter and into the bladder. CIC should occur 5 to 6 times during waking hours, which is every 3 to 4 hours throughout the day. Problems encountered during CIC are indicators of medical issues such as infection or injury. These are symptoms that can be reported via use of the app, including odor, pain, discoloration, or blood in the urine. UTIs and kidney infections require prompt medical attention, and the person will frequently need to follow up with antibiotics.

Bowel Management App

The Bowel Management App (BMQ) is an app for bowel management. The BMQ app helped to remind patients to perform their bowel program and report problems encountered. Bowel continence is important for maintaining skin integrity and is related to mental health issues (self-esteem), and social issues (quality of life and social isolation). Constipation can be a serious health concern as well. People with high spinal lesions have low internal sphincter pressure and rarely experience rectal sensation, while people with low spinal lesions have increased internal sphincter pressure and experience some rectal sensation [35]. Constipation is a result of having a neurogenic bowel and can also be attributed to inadequate intake of fluids, limited physical activity, lack of fiber in the diet, or as a side effect of a medication. Constipation can lead to impaction with overflow incontinence or simply constant elimination of hard stool with physical movement. Treating the constipation aggressively is the first step in continence management. An effective bowel maintenance program needs to be completed at regular, consistent times as part of the person's routine. Forgetting to perform any portion of a bowel program on time or at regular intervals will make it ineffective, and incontinence may likely occur. The app reminds patients to use their medications, enemas or other interventions important for maintaining bowel health. The app's display allows the patients to input what type of problems they are currently having with their bowel movements,

such as diarrhea, abnormal color, blood, pain, no production of stool, or the option to enter free text for another problem.

Clinician Portal

The clinician portal is a Web-based portal system designed for clinicians to engage and monitor patients. In this study, the clinician portal served 3 primary purposes: monitoring patients' conditions and adherence to regimens, prescribing regimens or treatment plans, and communicating with patients. The primary users of the health portal were the WC's directly supporting patients (typically social workers, nurse coordinators, case managers, and/or patient advocates). The secondary users of the clinician portal were physicians, who were consulted by the WC's when interventions required their direction or clinical supervision. Clinicians used desktops, laptops, or tablet computers to access the health portal. Using the health portal, the WC could engage and monitor patients from her desk at the clinic, at the office, or at home. A typical work day of the WC would start with accessing the dashboard in the health portal to get the latest status of the patients under her care. The dashboard would provide a graphical overview of all patients and provide highlights of the small group of patients that require attention (low adherence to regimens, new wound, refill of medications needed, etc), prioritizing tasks. The WC would subsequently focus on this group of patients by looking at the detailed monitoring data of the individual patients. After evaluating the individual monitoring data, the WC could engage patients by prompting the patient via apps, secure messaging, or phone. The WC and physician can regularly discuss patient cases and update the regimens, self-care schedules, and medications. The update of self-management tasks or medications can be conducted using the health portal and then pushed to the smartphone apps in real time.

Bi-Directional Data Exchange Between the Apps and the Clinician Portal

The key to a successful self-management program is the clinician's ability to engage patients by monitoring progress and sending regimens to the patients' apps. A two-way data exchange protocol was needed to support this health care and self-care model and address major weaknesses of the existing apps and mHealth for chronic conditions [30]. The focus of interactions between patients and clinicians in the iMHere system was to promote self-care and adherence to regimens. The novel protocol needed to have apps with the capability to work independently when a data connection was not available. This feature was necessary for those in rural or low-resource areas who had a spotty data connection and necessary for users with no data plan. The protocol also needed to support an innovative security mechanism which would erase data if the phone were lost, because security and confidentiality are of paramount importance in a mobile health application. The smartphone apps were designed to work as independent local apps, yet they were able to synchronize with the health portal in real time when an Internet connection was available. The protocol enabled a seamless exchange of monitoring data from apps to portal and of treatment regimens from portal to apps.

Usability Study

The usability study was conducted in 3 phases. The objective of the usability study was to find usability problems and refine the design of the system to address the problems found. Previous studies from the human-computer interface (HCI) literature found that 80% of usability problems can be found with only 5 subjects [35-38], with almost all of high-severity usability problems uncovered with only 3 subjects [35]. The estimated required sample size for a usability test depends on the problem space [39]. Since the self-care tasks in iMHere apps are well-defined, the problem space is not as large as that of common software systems. Due to the existence of well-defined tasks [39], the involvement of more than 1 evaluator (all co-authors) in the studies [40], and the fact that the study had 3 phases [35,37], the sample size of 14 participants (8 in Phase 1, and 3 in Phases 2 and 3 respectively) can be considered sufficient for discovering usability problems in the system.

The first phase was conducted in a natural environment by giving smartphones to patients for a few weeks and asking patients to use the apps, which were not yet connected to the portal. The purpose of the first phase of the study was to evaluate the usability of the apps in supporting self-care, focusing on the issues related to self-care workflow. The second phase was conducted in a controlled (lab-like) environment where patients were asked to perform specific tasks while their performance was observed and measured. The third phase was conducted in a natural environment like phase 1 but focused instead on the communication between the apps and the portal.

Phase 1 involved 8 participants, while phases 2 and 3 involved 3 participants. All participants in the usability study were individuals with SB, who are potential users of the iMHere system. More specifically, participants were 18-40 years of age with SB and hydrocephalus but no diagnosis of intellectual impairment or serious mental illness. None of the subjects reported or demonstrated sensory (eg, vision, hearing) or motor deficits, which would interfere with operation of the smartphone device. All subjects were cell phone users prior to participating in the study. These subjects had already participated in the in-person SBAWP Wellness Program. Therefore, these participants had experience participating in a preventative wellness program and performing self-care tasks to reduce secondary conditions. This prior knowledge enabled them to better understand the concept of using proactive measures to avoid and manage health problems.

Results

Smartphone Apps

The first result of the study is a complete iMHere system that is ready for clinical trial. The iMHere on the smartphone is a suite of apps, currently consisting of 5 apps, as illustrated in Figure 2. Every app included in iMHere allowed patients to schedule reminders, sound alarms, and collect information when reminders are scheduled. Scheduling and responding to these reminders work the same way across all of the apps, simplifying operation. Similarly, most other tasks within iMHere started through a common set of Action Buttons with consistent behavior across the 5 iMHere apps.

The home screen of the iMHere suite consists of 2 main areas: the action bar and the app selection area. The action bar is located at the top of the home screen, as well as all app screens, and contains action buttons that access most of the functions of iMHere. The area to the left of the action bar contains current location (main screen, apps, etc), and the area to the right of the action bar contains the action buttons that control the tasks. The individual apps from within iMHere are launched from the home screen by clicking their respective icons in the app selection area. Clicking on an icon in the app selection area takes the user to the respective app's main screen. Each app in turn behaves in a familiar way through the common set of Action Buttons located on the Action bar. The following is a description of the apps in the apps suite.

MyMeds: An App for Medication Management

MyMeds keeps track of medications and their schedules, and provides reminders of the medication schedules. The medications and their schedules can be entered by patients from the apps or can be sent by the clinician from the portal. The app allows for complex, multiple-drug schedules, and also allows users to keep drugs on the list that they are no longer taking. This unscheduled drug feature is useful when a patient stops taking a certain medication for a period of time, but expects to return to using it. The reminder shows the name of the drug, the dosage, its purpose (such as "for pain"), how many tablets to take, how frequently to take the medication, and any notes that might help the patient identify the specific drug. Please refer to Figure 3.

Entering drug names can be fraught with mistakes. To help avoid errors in drug name and dosage, we use the drug database from National Drug Code (NDC) of the US Food and Drug Administration (FDA) [41] and provide users with autocompletion and auto correction when a user enters drug data. The result is that the drug and its dosage are from the known entity in the NDC database, unless prescribed differently by the clinician from the portal.

Skincare App: An App for Prevention and Caring for Wounds

The Skincare app provides reminders to perform the task of visual inspection of one's skin as a preventative measure, often termed a "skin check." Persons with insensate areas of the body should perform skin checks at least twice per day. The Skincare app also allows patients to track the progress of skin problems when detected (such as pressure ulcers or lacerations) by taking pictures with the smartphone's digital camera. Pictures can be taken periodically for comparison, and photos are stored on the phone for the patients' reference, as well as synched through the secure portal for clinician review (illustrated in Figure 4). Skincare can track as many skin problems as needed, keeping photos from each separate skin problem organized together as a single case. Daily reminders can be set to perform skin care checks and to take additional photographs for comparison.

A human body graphic provides the user a way to indicate which body part is affected by a wound (illustrated in Figure 5). After the user clicks the body part, the app lets the user upload a picture of his or her skin condition and update the problem as needed. After the user takes a picture of his or her skin condition, there are questions about the condition that need to be answered so that the clinician can have more detailed information about the problem. This detailed information is also used to flag photos that warrant immediate attention from clinicians. Some of the questions include: color of the wound, size of the wound, amount of drainage, or visual details about how the wound looks.

The app also provides a tool to help the clinician and patient track changes in skin care problems. The skincare app organizes the pictures into cases and records them to facilitate the tracking of multiple problems. Each skincare problem is a case. Within each case there may be many records or pictures. The organization of pictures into cases allows the clinician and patient to easily track progress by comparing the pictures in each case. Related pictures from a problem are organized together, in a sequence over time, so that changes can be noted by the clinician and patient. The Skincare app main screen shows all cases, with a picture of the most current record from each case. The patient can click a case and the app will show all of the records for that skincare case, starting with the most recent.

Mood: An App to Track Mental Health Status

This app lets a patient or clinician schedule routine mood questionnaires or take them on demand. The questionnaire is based on the depression screening developed by Mental Health America, formerly known as the National Mental Health Association [42]. This 10 items survey asks questions to determine the patient's mood, including whether the patient has: been sleeping too little or too much; had thoughts of death or suicide; had a hard time concentrating, remembering, or making decisions; had a loss of appetite and weight loss; or increased appetite and weight gain; et cetera. The app records the results of the questionnaire and sends them to the clinician. The Mood app gives an immediate warning to the patient, and provides quick access to a patient's local mental health crisis line if the score on the questionnaire gives cause for immediate concern. Please refer to Figure 6.

Figure 2. Home screen for suite of apps. App selection area launches individual apps and common action bar initiates tasks within all apps.

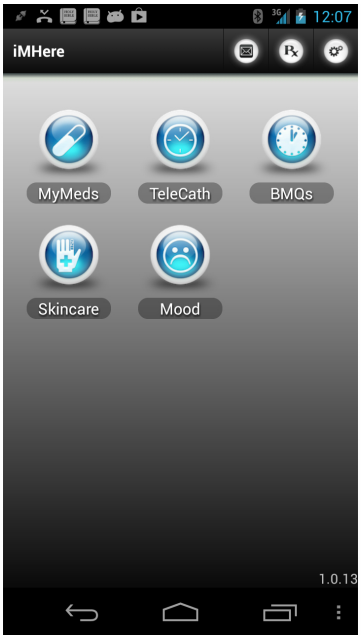


Figure 3. MyMed app with 650 mg Tylenol scheduled every 4 hours.

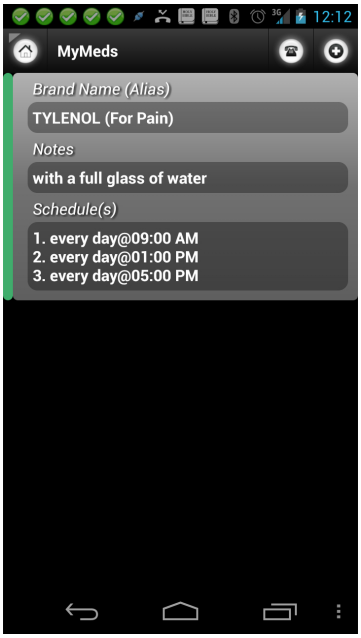
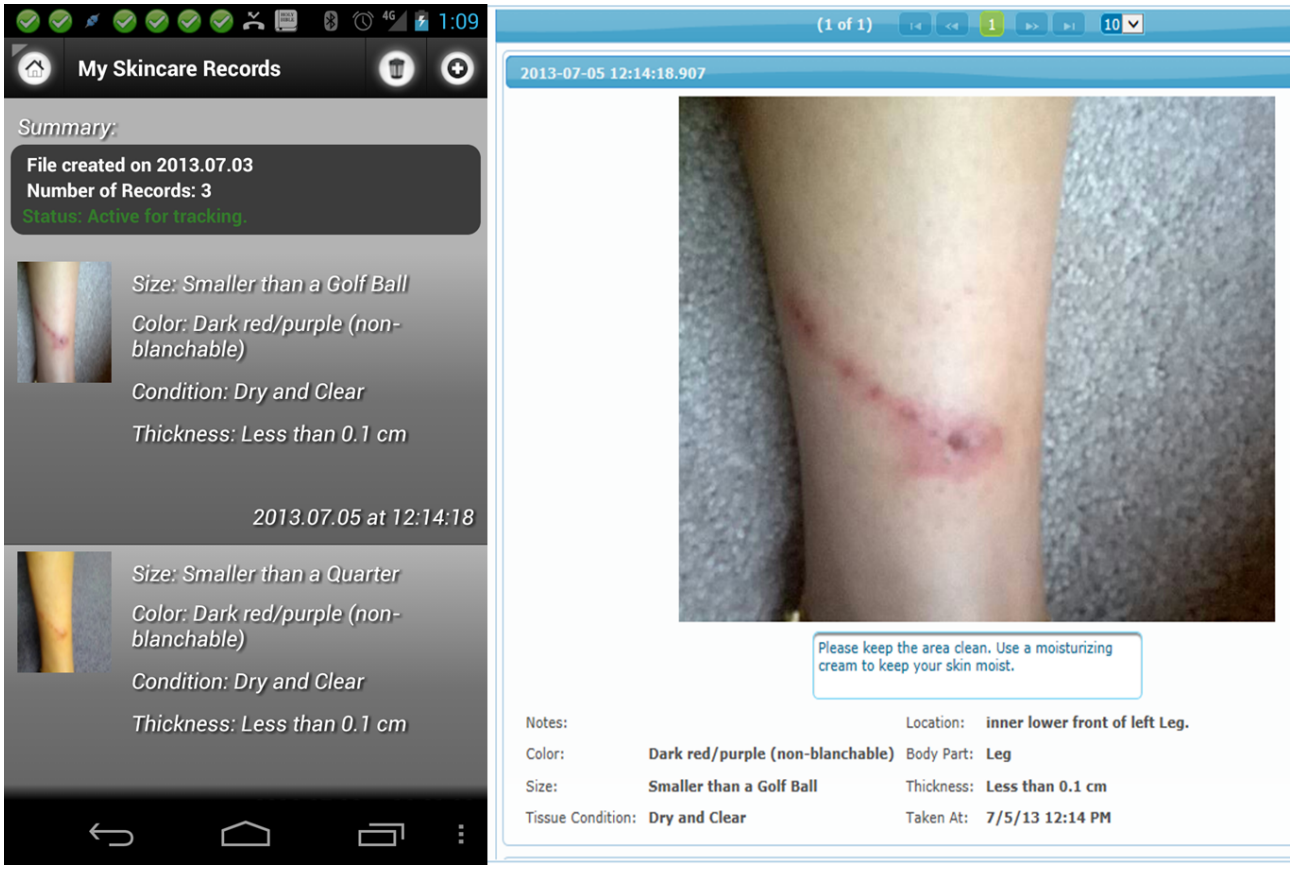


Figure 4. Skincare app and portal side by side.



TeleCath: An App for Bladder Self-Catheterization Management

TeleCath allows a patient or clinician to set daily reminders for bladder catheterization and to schedule daily inquiries about urinary incontinence. Any problems with catheterization (such as pain, difference in urine color, cloudiness, blood in the urine, or lack of urine output) can be reported along with the patient's response to the reminder to catheterize. All information regarding catheterization problems or incontinence are synchronized through the clinician portal and made available for review by clinicians.

BMQ: An App for Bowel Management

BMQ allows a patient or clinician to set daily reminders for performing bowel management (defecation) and to schedule

daily inquiries about defecation or incontinence. Any problems with bowel management (such as diarrhea, blood, pain, etc) can be reported along with the reminder. All information regarding defecation problems or incontinence are synched through the clinician portal and made available for review by clinicians.

Clinician Portal

We developed the clinician portal to allow clinicians to send information to patients' apps, including personalized self-care plans, medication data, and phone numbers of pharmacies to call for refills. The portal is illustrated in Figure 7. The main components of the portal are the patient roster, dashboard, and utility bar. The roster was designed to mirror the smartphone apps. It allows the clinician to create self-care plans for the patients (prescribe medication, schedule skincare, and TeleCath, etc), and review data sent from the apps. The dashboard was designed to provide the clinician with a decision support system and with analytics that can enable the clinician to triage the needs of a large caseload of patients. The utility bar is used for tasks not directly related to patient care, such as client (patient smartphone) management and authentication management.

The Patient Roster is a list of all the patients registered for the clinician. Role-based access is used to give clinicians access to only those patients for whom the clinician is providing care. The patient roster provides information about the patients' smartphone connectivity, with a green check indicating that a patient's phone is currently connected, and a cross indicating that it is not connected. The roster provides clinician access to the detailed patient data. The dashboard is a grid that allows an "at a glance" review of clients' activity and allows the clinician to quickly navigate to areas that need attention. All registered clients are shown on the dashboard, and their activity for each app is classified as: no attention required, needs attention, needs immediate attention. The clinician can review the corresponding patient by clicking an icon on the grid.

Two-Way Communication Protocol

The iMHere two-way communication protocol was developed by extending the Extensible Messaging and Presence Protocol (XMPP) standard [43]. The XMPP protocol was designed with the assumption that the Internet connection would be constantly stable and always available. A mechanism in the application layer to deal with unstable connections in the wireless network was developed in the iMHere protocol to make it usable by patients living in areas where the connection is not always stable. The first major extension is the capability to support efficient and reliable communication that can work under various connection qualities, including when connection is poor or completely unavailable. The communication protocol allows the portal to detect if the mobile device is active and report it to the patient roster.

The second extension is the implementation of advanced security features. Security and confidentiality in a mobile health application is of paramount importance. The authentication process requires a combination of the device's phone number and the device's unique equipment number. All the traffic between the smartphone and the portal is encrypted. The Advanced Encryption Standard (AES) established by the United States National Institute of Standards and Technology (NIST) [44] 128-bit is used for all data communications between the smartphone and the clinician portal. No identification is attached to the data in the smartphone. The communication protocol also allows the clinician to lock the apps and to delete all data in the smartphone in the event that a smartphone is lost. The data will still be preserved in the portal and can then be reconfigured to the apps. HIPAA has not specifically designated guidelines or compliant regulations for telehealth technology. In accordance with existing HIPAA regulations for other technological use and exchange of health information via Internet technology, iMHere is considered HIPAA compliant due to its security measures, privacy precautions, and use of a covered entity to store encrypted data.

Usability Study

The initial design and implementation of iMHere at the first stage was based on clinicians' predictions and developers' understanding of what patients need to encourage self-care. Extensive testing had been conducted with a research group to simulate real use by patients. However, the predicted scenarios from a research perspective may not have been adequate to cover all activities in real use. In order to address any unknown issues with the meaningful use of iMHere, a group of target users (patients with SB) were introduced to usability study phase 1. The first 2 phases of the usability studies uncovered a few usability issues related to the self-care tasks and navigation.

Phase 1: Focus on Self-Care Workflow

The first problem was related to the scheduling, which was originally designed to be object-centered (such as medication) instead of patient-centered. In the medication app, a separate alarm would ring for every medication because each medication is entered and scheduled separately. It was not convenient to have multiple alarms ringing at the same time. We discovered that a better design is patient-centered: all medications included in a person's regimen should be scheduled using a reminder for all medications that need to be taken at a specific time. For example, a patient who needs to take 3 medications 3 times a day can set up reminders for Morning (8:00 AM), Afternoon (1:00 PM), and Evening (7:00 PM), with each reminder applied for all 3 medications. The same concept should also be applied to the response to a reminder. When the patient accesses the app after receiving the reminder, the patient should see a list of medications to take. The patient could respond by pressing a check box next to each medication to indicate that the dose was taken. If the patient does not or cannot take the medication, a place to indicate the reason why can be included and this information could then be immediately reported back to the WC through the portal. In relation to the scheduling and reminders, the snooze function and repeated alerts have been removed. Instead, if the patient does not respond to a reminder, it will be put into a missed schedule list that the patient can access. The missed schedule list will appear as a notification, similar to a "push" notification in email or digital calendar.

Figure 5. Skincare app affected area selection.

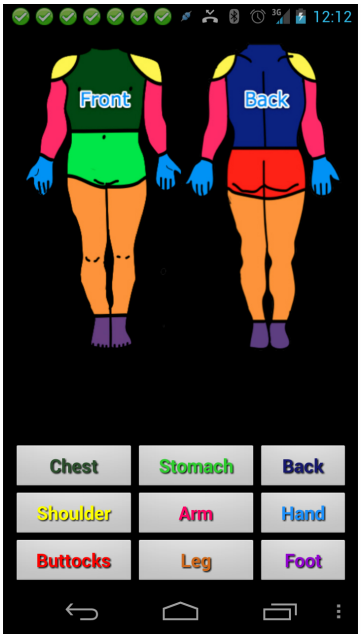


Figure 6. Mental health app mood survey.

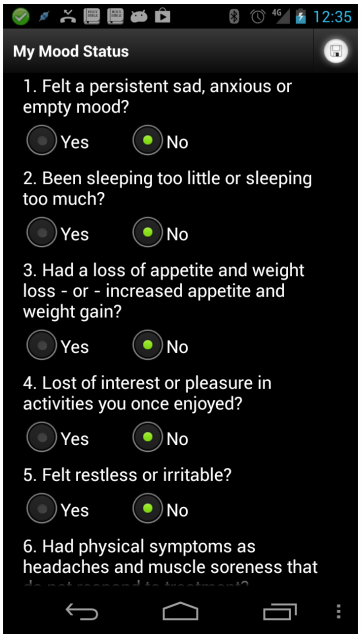


Figure 7. Clinician portal: roster table displays a list of registered patients and their connection status. Dashboard displays priority flags for each patient and application.

The second problem was related to the frequency of self-care tasks. This problem was uncovered as a result of more intense discussions with the clinicians, not from the patient studies. The apps for BMQ, Mood, and medication were originally designed with daily schedules in mind, but some of the self-care tasks are not performed on a daily basis. Patients who complete bowel program regimens typically perform this self-care task every other day or every third day. The mood questionnaire is typically needed only 1 time per week. There was also a need for the ability to take medication less frequently than on a daily basis; on certain days of the week, once per month, et cetera. A patient may also need to vary the time of day to perform bowel management program if it interferes with other activities or is reliant on a caregiver to assist them with performing this task in some way. Appropriate changes in alerts were made to accommodate these needs.

Phase 2: Focus on Navigation and User Interface

We also found issues related to navigation and the user interface during the first phase of the usability study. We conducted a second phase of the usability study to focus on these issues. The term “user-interface” in this study is used to refer to the presentation of elements that are directly accessed by users; such as button size, text size, and colors. The usability study was conducted in a controlled environment where patients were asked to perform tasks and detailed problems were observed.

Due to the narrow width of the scrollbar, it was not obvious to the patients that they needed to scroll down, leading to under-completion of the data. Related to this problem was the fact that the green "+" button, used throughout the app suite to add items such as new schedules, also required patients to scroll down the screen to use it. Another issue was found with the Skincare app, where an on-screen button was used for taking wound pictures. This button was difficult to use for patients attempting to photograph a wound on a less accessible area of their body. Instead of using an on-screen button to take the picture, patients could more easily utilize the physical control button on the device that is already built in to perform this function. We also found minor issues related to the use of a light text color on top of a grey background making text difficult to read; also an activity button at the top of the screen was too small for some users to access.

In addition to addressing these issues by redesigning the apps, we also identified the need for more user training for some of the apps. MyMeds and Skincare are relatively complicated apps that accounted for 90% of the errors (25 out of the 28) that the users made during usability study phase 2.

Phase 3: Focus on Patient-Clinician Communications

Phase 3 of the usability study was conducted to focus on the two-way communications between the apps and the clinician portal. The goal of this implementation was to evaluate problems in the clinical service delivery model and to address the problems before moving on to a full-scale clinical implementation. We encountered problems with the implementation of XMPP protocol in a 4G wireless connection. The 4G wireless signal is not always stable, and the signal can be lost or work only intermittently in some areas. The iMHere protocol was designed to handle an unavailable connection. However, a problem that we encountered was the inability of the XMPP protocol to accurately detect the availability of a connection. This situation led to packet loss when the app would attempt to send data despite the absence of a connection. We added 2 mechanisms to improve on the reliability of the XMPP protocol:

1. *App to portal transmission.* The first mechanism was to verify the connection's availability before sending data. This mechanism was to ensure that the data would be sent only when the connection was definitely available or otherwise be stored locally for later transmission.
2. *Determining wireless signal strength.* The second mechanism was developed to inform the portal about the device's actual signal condition (portal to app transmission). This mechanism ensures that the portal would send data to the device only when the device was receiving a good wireless signal. When the device was receiving poor signal strength, it would notify the portal to hold the data until the signal strength improved.

Extensive testing in various signal conditions was conducted by having smartphone apps send data to the portal and by having clinicians send treatment plans to the patients. The result is a reliable two-way protocol that works under any signal condition and in any version of the Android operating system.

Clinical Implementation

We implemented the system on a rolling basis. In the first 6 months of the clinical implementation, 14 patients used the system, with the length of participation varying between 3 months (1 patient) to 6 months (10 patients). Figure 8 shows the duration of usage for each patient. The patients were located in a tri-state area (Pennsylvania, Ohio, and West Virginia) around Pittsburgh. More than half of the patients were located in rural areas with the furthest distance being a 2.5 hour drive from Pittsburgh. There was 1 patient who dropped out because of a very poor cellular phone signal in the area where the patient lived (a basement apartment in a rural area). There was no drop out for reasons other than a poor signal.

The smartphones and the data plan were provided by the study. The Android operating systems used include versions 2.3 to the latest, 4.1. During the implementation, we did not find serious problems with the fragmentation of the Android operating system other than glitches with the picture-taking function of the Skincare app. We found that picture-taking in the Skincare app did not work in the Android 4.x, despite working well in Android 2.x. After debugging, we found that Android 4.x has faster threads in the operating system, which are not synchronized with the components related to the smartphone camera. The result is that the picture object could not be captured by the apps. We made changes in the Skincare app's code to solve this issue. In order to deal with the operating system fragmentation, the iMHere system is designed to use only the core libraries from Android 2.3 (the first Android version that was widely used). The libraries run on any later Android versions without any problem. Implementing bi-directional communication between smartphone apps and a portal in a clinical setting is a complex process, more complex than implementing a smartphone app or a clinician portal on its own. This is because any change in the apps has to be coordinated with the related change in the portal, and this requires the involvement of both patients and clinicians. With respect to connection type, we found that the 4G wireless connection is still not as reliable as a WiFi connection, but we anticipate that the situation will improve with time. Overall, we developed a robust protocol that is efficient and capable of handling unreliable connections.

Usage of the iMHere System

A patient may use any number of app features from those available in iMHere. Figure 8 provides a matrix showing patients and the apps features used by the patients. There were 5 patients who used all the app features, 3 patients used all except 1 of the app features, while 4 patients used only 3 app features. Patients were trained on how to use the apps, how to set up regimens, and how to manage self-care regimens on their own. Patients knew how to revise their regimens if something changed in their personal plans or if they received recommendations from a physician outside the spina bifida clinic. For instance, a patient may choose to modify the app for their bowel program so their schedule may fit better with a family gathering for that particular week. Figure 8 illustrates the features used by patients at the start of the implementation. Since patients have all the app features on their phones and were trained to use all the features,

patients could decide to change the usage along the way. Patients were able to add features or drop features at any time, although the frequency of change was low in the first 6 months. For example, Patient #8 started to use the BMQ app feature on the fourth month of the implementation.

The average daily usage per patient of the iMHere system is illustrated in Figure 9. This figure includes the usage of all app features (from MyMed to Skincare). We observed that the daily usage increased significantly in the first 2 months (from approximately 1.3 times a day to over 3 times a day). This is consistent with how patients began using the apps. Not all apps were in full use until the second month because the patients were trained one app at a time until it was being utilized properly in the first month. The usage did plateau after 2 months, at around 3.5 times a day per patient. This pattern of increasing usage in the first 2 months and the subsequent plateau is relatively consistent in all patients. The pattern holds when data from all patients are included, as well as when the 2 outliers are excluded. The data shown in Figure 9 are data with the 2 outliers (patient with the highest usage and patient with lowest usage) excluded. Patient #10 had the highest usage, with an average usage of 13 times per day, while Patient #6 had the lowest usage with an average usage of once every 3 days. Patient #10 had the highest usage because of the number of medications that needed to be tracked (15 medications), while Patient #6 had the lowest usage because the patient had social issues not related to the clinical intervention. As mentioned above, after the second month, the usage of every patient was relatively consistent.

Utilization by App Feature

The breakdown of utilization per day is illustrated in Figure 10. The first bar in the bar chart is a utilization per day per patient for those who used it (patients who were not provided with the app were not included in the calculation), while the second bar is the average utilization of the app feature for all patients in the study (including those who did not use it). It is important to note that patients were given only those apps which were relevant to their medical problems (eg, if patient did not need a bowel program, he was not given BMQ app). The second bar is shown to make the numbers consistent with the average daily usage per patient in Figure 9.

The MyMed app was the most frequently used app, with a usage of more than twice a day. This feature was used by all but 2 patients to manage their medications. Of the 11 patients who took medication, 6 used only 1 medication, 5 used 2 medications, and 1 patient each used 5 and 15 medications. The app feature used least frequently was the Mood app, at about once every 4 days. This is to be expected because the Mood feature that measures depression is usually administered once a week. The second most frequently used was the Telecath app feature, used about 1.7 times per day. This app feature includes a once-per-day questionnaire asking whether the patient is having any problem with incontinence and, if so, how many times it happens in 1 day. The BMQ was used less frequently than TeleCath because the bowel program is done less frequently than bladder self-catheterization. It is interesting that the Skincare app feature was used quite frequently. Most patients used the Skincare app feature as a reminder to conduct skin self-care tasks because they did not have serious skin conditions. However, there were 4 patients who had serious skin conditions that necessitated their taking pictures of the wound and sending them to the clinicians. The clinical phase of this study is still on-going and additional clinical outcomes will be reported at the conclusion.

Figure 8. Apps features used by patients.

Feature Utilization

Client	MyMeds	TeleCath	BMQs	Mood	Skincare	Duration
Patient 1		○	○	○	○	6 months
Patient 2	○	○		○	○	6 months
Patient 3	○	○	○	○	○	6 months
Patient 4	○	○	○	○	○	6 months
Patient 5	○	○			○	6 months
Patient 6	○			○	○	6 months
Patient 7	○	○	○	○	○	6 months
Patient 8	○	○		○	○	6 months
Patient 9		○		○	○	3 months
Patient 10	○			○	○	6 months
Patient 11	○	○	○	○	○	6 months
Patient 12	○	○	○		○	4 months
Patient 13	○	○	○	○	○	4 months
Total	**11**	**11**	**7**	**11**	**13**	

Figure 9. Average daily usage per day per patient.

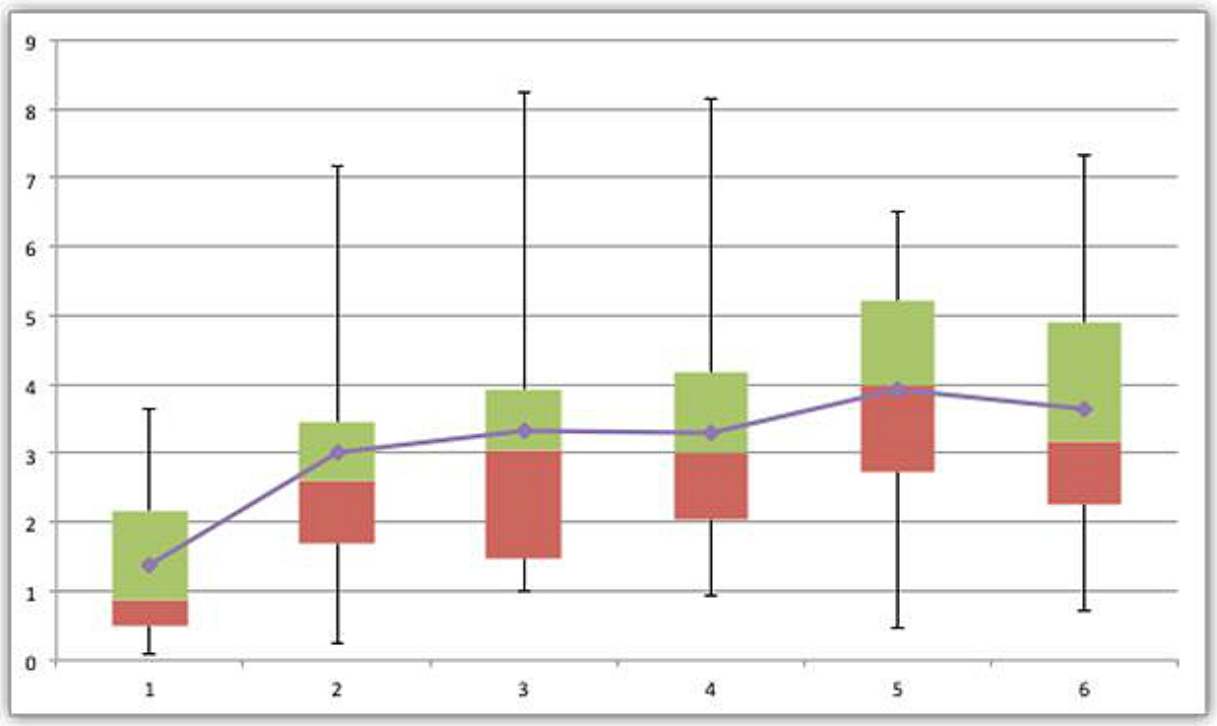
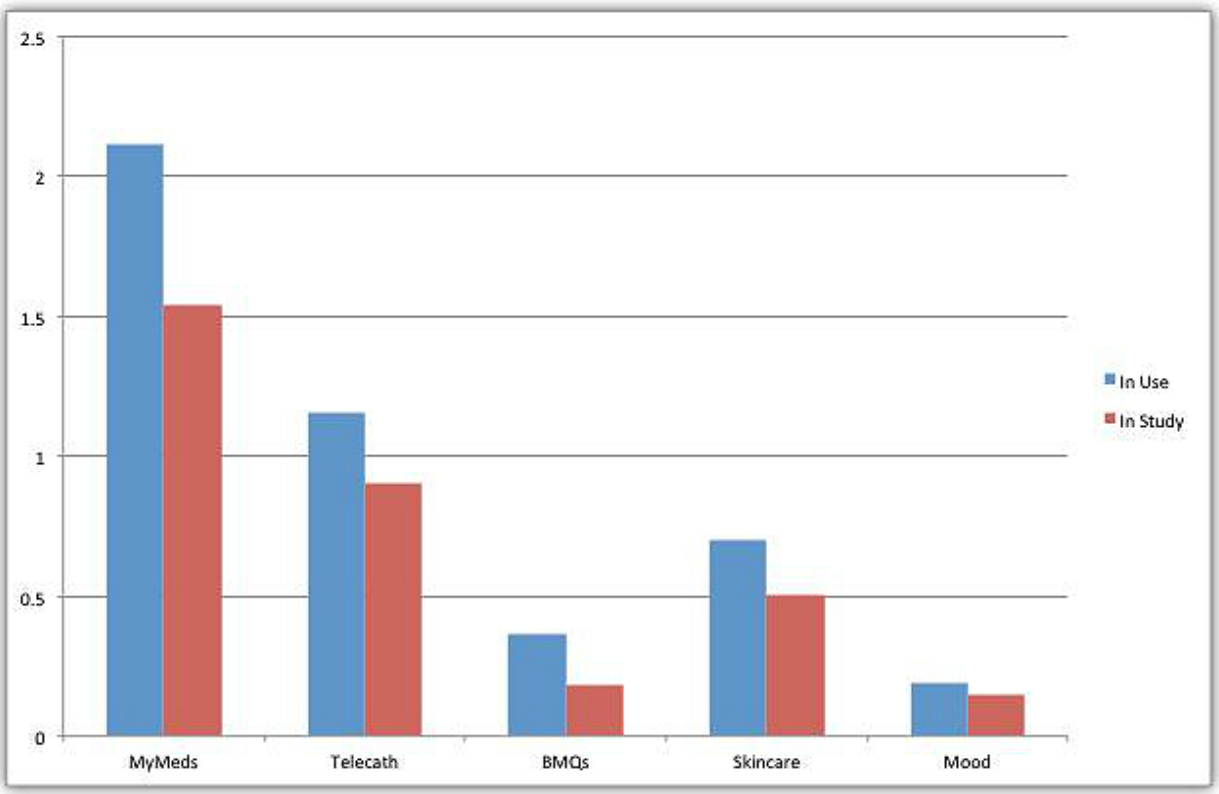


Figure 10. Average daily usage of app features.



Discussion

All patients from the usability and clinical intervention studies were interested in using iMHere and making the apps part of their daily routine. Other than the minor usability issues, they were satisfied with the user interface and felt comfortable using the application. The patients stated that it required only a small amount of training time before a user is able to use the system. This result suggests that the goal of developing iMHere as a self-care tool has been accomplished. This acceptance also provides a good base for allowing clinicians to monitor patients' conditions and intervene sooner to prevent secondary complications. The results of the implementation indicate that the iMHere system has been used as expected. Patients used the system consistently and actively during the first 6 months of the clinical implementation. The full study is a year-long in duration.

The innovative iMHere system can potentially reduce the burden of care for providers, reduce the cost of supporting the wellness service, and empower patients to conduct effective, timely, preventive self-care. The iMHere system allows clinicians to send self-care regimens and adjust existing treatment regimens without having patients come to the clinics. These innovations may help reduce the cost of care for people with chronic conditions and improve health outcomes by reducing secondary complications such as wounds or infections. The iMHere system was designed using concepts found to be extremely effective in managing patients with complex chronic conditions within a medical home model [9]. The iMHere platform was designed to be scalable to allow support service delivery for patients with various types of chronic conditions, but it can also be implemented in clinics for patients with other chronic conditions and cognitive deficits, such as cerebral palsy, multiple sclerosis, traumatic brain injury (TBI), or those with medically complex conditions such as diabetes or HIV/AIDS.

The data in the iMHere portal can potentially be integrated with the electronic health record (EHR) system of medical centers or clinics. This integration would allow health information pertinent to self-care, such as lab results, to flow to smartphone apps, and allow a summary of patient conditions to flow to the EHR system. In the future, health records will not only contain data generated by providers (doctors office, lab, hospitals), but also data generated by patients. The iMHere system collects this new patient generated data. This is a challenge for future EHR systems since the amount of data and frequency of data will be much larger than that of the existing EHR. We envision that only a summary of the patient generated data will be integrated into the EHR system, since clinicians who are not directly involved in managing patients with chronic conditions will not be using detailed monitoring data from patients. The challenges in managing large amounts of high-frequency data generated, by patients (including monitoring data) and in summarizing the large data for integration with the EHR system are potential areas of research opportunity for big data analytics.

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

AES: advanced encryption standard
BMQ: Bowel Management App
CIC: clean intermittent catheterization
EHR: electronic health record
FDA: US Food and Drug Administration
HCI: human-computer interface
HIPAA: Health Insurance Portability and Accountability Act
mHealth: mobile health
NDC: National Drug Code
NIDRR: National Institute on Disability and Rehabilitation Research
NIH: National Institutes of Health
NIST: US National Institute of Standards and Technology
SB: spina bifida
SBAWP: Spina Bifida Association of Western Pennsylvania
TBI: traumatic brain injury
UTIs: urinary tract infections
WC: wellness coordinators
XMPP: Extensible Messaging and Presence Protocol

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Review

Mindfulness-Based Mobile Applications: Literature Review and Analysis of Current Features

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Abstract

Background: Interest in mindfulness has increased exponentially, particularly in the fields of psychology and medicine. The trait or state of mindfulness is significantly related to several indicators of psychological health, and mindfulness-based therapies are effective at preventing and treating many chronic diseases. Interest in mobile applications for health promotion and disease self-management is also growing. Despite the explosion of interest, research on both the design and potential uses of mindfulness-based mobile applications (MBMAs) is scarce.

Objective: Our main objective was to study the features and functionalities of current MBMAs and compare them to current evidence-based literature in the health and clinical setting.

Methods: We searched online vendor markets, scientific journal databases, and grey literature related to MBMAs. We included mobile applications that featured a mindfulness-based component related to training or daily practice of mindfulness techniques. We excluded opinion-based articles from the literature.

Results: The literature search resulted in 11 eligible matches, two of which completely met our selection criteria–a pilot study designed to evaluate the feasibility of a MBMA to train the practice of "walking meditation," and an exploratory study of an application consisting of mood reporting scales and mindfulness-based mobile therapies. The online market search eventually analyzed 50 available MBMAs. Of these, 8% (4/50) did not work, thus we only gathered information about language, downloads, or prices. The most common operating system was Android. Of the analyzed apps, 30% (15/50) have both a free and paid version. MBMAs were devoted to daily meditation practice (27/46, 59%), mindfulness training (6/46, 13%), assessments or tests (5/46, 11%), attention focus (4/46, 9%), and mixed objectives (4/46, 9%). We found 108 different resources, of which the most used were reminders, alarms, or bells (21/108, 19.4%), statistics tools (17/108, 15.7%), audio tracks (15/108, 13.9%), and educational texts (11/108, 10.2%). Daily, weekly, monthly statistics, or reports were provided by 37% (17/46) of the apps. 28% (13/46) of them permitted access to a social network. No information about sensors was available. The analyzed applications seemed not to use any external sensor. English was the only language of 78% (39/50) of the apps, and only 8% (4/50) provided information in Spanish. 20% (9/46) of the apps have interfaces that are difficult to use. No specific apps exist for professionals or, at least, for both profiles (users and professionals). We did not find any evaluations of health outcomes resulting from the use of MBMAs.

Conclusions: While a wide selection of MBMAs seem to be available to interested people, this study still shows an almost complete lack of evidence supporting the usefulness of those applications. We found no randomized clinical trials evaluating the

impact of these applications on mindfulness training or health indicators, and the potential for mobile mindfulness applications remains largely unexplored.

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KEYWORDS

mobile health; mHealth; mindfulness; social networks; personalized education; health informatics; evidence-based medicine

Introduction

Mindfulness-Based Therapies

Mindfulness techniques have emerged in the Western world in the fields of health and education as the application of ancient meditative practices from Buddhist tradition. It is from this tradition that they draw inspiration and take their basic technical features. Since its introduction, interest in mindfulness has increased exponentially particularly over the last two decades in the psychology and medicine fields [1]. Several types of approaches have been tested from secular (mindfulness-based therapies-MBTs) to Eastern meditative traditions (such as Zen and Vipassana), and scientific evidence of their effectiveness is rapidly accumulating [2,3].

The psychological trait or state of mindfulness refers to an awareness that emerges by way of paying attention intentionally and nonjudgementally, in the present moment, to the unfolding of the moment-by-moment experience [4,5]. Mindfulness is a skill that can be obtained using several training techniques, and group and individual interventions have been designed for this purpose [6]. Generally, two main complementary approaches have been used for mindfulness training (1) exercises in focused attention, and (2) open monitoring of experiences in the present moment.

Mindfulness is significantly related to several indicators of physical and psychological health such as improved immune and autonomic nervous systems, higher levels of positive affect, life satisfaction, vitality, and adaptive emotional regulation, and it has been linked to lower levels of negative affect and psychopathological symptoms [2,3,7]. Furthermore, MBTs have demonstrated effectiveness in treating many disorders, including chronic pain conditions [8-10].

The mechanisms underlying the effects of mindfulness training on health are diverse and include improvements in attention control, coping and management of life stressors, descriptions of inner experiences, thoughts and emotional awareness and regulation, and changes in the concept of the self or body awareness [11]. One of the main limitations of MBTs is the need for regular practice. Psycho-technology mobile apps have demonstrated effectiveness as a complementary tool in many psychotherapies [12], and they would be expected to be useful in MBTs as well.

Information and Communication Technology

Information and communication technology (ICT) concerns the elements and techniques related to manipulating and transmitting information, specifically, computers, the Internet, and telecommunications. This concept is dynamic and shows rapid growth and evolution. Thus, new related paradigms are appearing, for instance, the “Internet of Things” (IoT). According to Atzori [13], the basic idea of IoT is the pervasive presence around us of a variety of things or objects—such as tags, sensors, actuators, and mobile phones—that are able to interact with one another and cooperate with their neighbors to achieve common goals. The main strength of the IoT is the large impact it will have on several aspects of everyday life including the behavior of potential users.

In this context, “smart devices” play an important role. They can perform intelligent operations and are capable of communicating to jointly deliver a service to the user [14]. Primary among these devices are “mobile devices.” They are portable, allow access to information and data anywhere, and can be carried and used during their transport. Presently, this concept includes a very large number of devices-smartphones, PDAs, MP3 players, and laptops. Most current mobile devices contain wireless communication capabilities. The common characteristics of mobile devices are their small size, portability, processing capability, network connection, and limited memory. Specifically, smartphones and small tablets allow access to a large number of apps (mobile-based software). Additionally, they can be incorporated into daily activities in a nonintrusive way.

The use of mobile devices is increasing continuously. In 2012, global smartphone shipments grew 46% to 722 million units, (ie, smartphone shipments have more than tripled since 2009 when 174 million units were shipped). The tablet market also did very well in the past year. Total shipments reached 128 million units, which was a 78% increase over 2011. Conversely, the personal computer (PC) industry continued to struggle in 2012. Shipments of laptop and desktop PCs declined 3% and 4%, respectively, as consumers switched to mobile connected devices (Figure 1 shows the growing tablet market for 2011 and 2012) [15,16].

According to Milosevic et al [17], users of today’s ever-increasing number of mobile phones expect to have their favorite desktop apps on smartphones. In addition, a number of new apps are taking advantage of the specific features and sensors on smartphones. This tendency also has been observed in healthcare. A study of the Healthx Team concluded that the most recent growth in mobile apps usage has not proliferated at the expense of browsing the traditional Web; people are simply using mobile apps more [18]. Medical/health care is the third-fastest-growing app category for both the iPhone and Google Inc.’s Android phones based on information from Float Mobile Learning [19].

Currently, it is possible to search the App Store and find 21,227 apps using the criteria “Healthcare & Fitness”, 17,148 using the criteria “Medical”, or 65,128 using the criteria “Lifestyle”

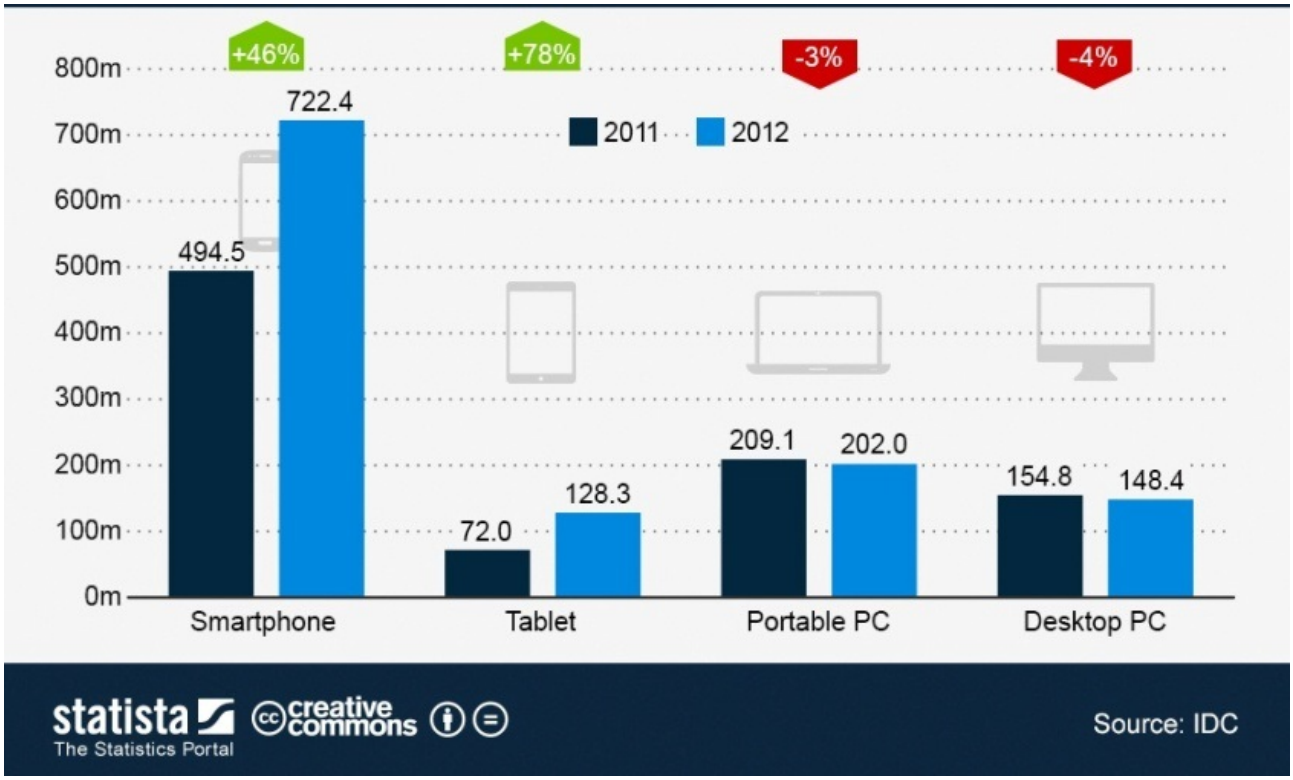
[20]. To design their apps, developers can choose among different platforms. The most popular are Google Android, Windows Phone, Apple iOS, BlackBerry, and Nokia's Symbian; reference [21] gives a complete comparison of the first four.

The usability and ubiquity of mobile devices have resulted in great interest in the development of features for healthcare apps. Research has shown that disease management and health education are areas with broad potential for apps in which mobile devices could enhance the quality of life for people in general and for those living with chronic illnesses in particular [12,22]. For example, well-designed mobile apps with decision support features such as personalized education have demonstrated potential to enhance self-management outcomes in diabetes patients [22].

Healthy patients or professionals interested in MBTs or their practice may benefit from mindfulness-based mobile apps (MBMAs). The potential use of these apps could include online and offline training, practice for daily adherence and maintenance, mindfulness-based group management (for professionals), and information exchange through social forums [12].

Thus, the objective of this study is to present an in-depth analysis of the functionalities and features of current MBMAs in the most-used mobile platforms and to compare them to the current evidence-based literature regarding health and clinical settings. Comparing current with potential features and with scientific-based recommendations from the literature, we discuss a future agenda to improve the usability and utility of MBMAs.

Figure 1. The global tablet market.



Methods

Review of MBMAs

Similar to the study of Chomutare et al [22], our goal was to review MBMAs both in the scientific literature and in the most-used commercial markets and platforms. We independently searched two types of sources: (1) online journal databases, and (2) online markets. In the literature, we searched for apps that have a basis in research. In the online markets and grey literature, we searched for mature and emerging apps, new trends, and novel functionalities and features.

The main inclusion criterion for mobile apps was that they include an explicit mindfulness component. We considered the "mindfulness component" to be either secular mindfulness-based interventions with their related main techniques such as mindfulness of breathing, body scanning, walking meditation, mindful movements, and compassion-based practices or traditional mindfulness practices, such as Zen and Vipassana meditations. Regarding the MBTs, we considered all possibilities including mindfulness-based stress reduction (MBSR), mindfulness-based cognitive therapy (MBCT), acceptance and commitment therapy (ACT), and dialectal behavioral therapy (DBT).

Review of the Literature

Selection Criteria

The only literatures included in this study were original research papers that addressed any mobile app with an explicit mindfulness component. We aimed to include all types of study participants including the general population, patients, and professionals. This broad inclusion criterion was settled upon after a preliminary search identified only a limited number of potential articles for inclusion. We excluded opinion-based

articles and those in languages other than English, Spanish, or Portuguese.

Search Strategy

We searched online journal databases, indexes, and reference lists using the search terms “mindful”, “meditation”, “mobile”, “PDA”, “cell”, “phone”, and “application” from the study’s inception to April 30, 2013. We constructed a general search string with logical operators using both the conjunction “AND” and the disjunction “OR” (mindful OR meditation OR acceptance-based) AND (mobile OR PDA OR cell OR phone OR application). We adapted the search string to each database, and the search was performed on the available metadata–that is, title, abstract, and keywords.

We targeted both original research papers and review articles indexed by Medline, ScienceDirect, Embase, Psychinfo, the Association for Computing Machinery (ACM) Digital Library, the Institute of Electrical and Electronics Engineers (IEEE) Xplore Digital Library, Google Scholar and the Digital Bibliography and Library Project (DBLP) Computer Science Bibliography, and ACM Computer-human interaction (CHI) proceedings. These databases reflect the multidisciplinary nature of the research, which involves the medical, psychological, and computer science fields. We screened the reference lists of all review articles that we identified to crosscheck for missing articles of interest.

The duplicate entries from multiple databases were removed. Only original research papers were eligible for inclusion after reviewing the metadata. Any potential MBMAs not clearly reported in the metadata were explored, with assessment made of the full article. Two authors (MD and PHM) independently assessed all potentially eligible reports that were identified by the search strategy. In the case of disagreements, the matter was resolved through discussion with a third author (JGC). After the metadata screening, the eligible reports were more thoroughly analyzed by two independent reviewers (MD and PHM) who examined their full text in detail before they could finally be included. Two authors (MD and PHM) extracted the data from an included report using a predefined data extraction sheet. They also screened the reference list of all eligible reports to crosscheck for missing articles of interest. Any persistent disagreement was referred to a third author (JGC) for discussion and resolution.

Data Extraction and Coding

Two authors (MD and PHM) extracted data from each included report using a predefined data extraction sheet. Any persistent disagreements were referred to a third author (JGC) for discussion and resolution. All studies were coded for country and year of publication, type of study and participants, intervention characteristics, MBMA functionalities and features (as detailed below), explicit mindfulness component of the intervention, outcomes in terms of health and app usability evaluation, summary of main results, and future directions (if indicated by the authors).

Evaluation and Assessment of App Features and Functionalities

User Evaluation

We found that the evaluation of the apps is better done by the users themselves in the form of a trial or, at least, a survey. We contacted several of the most important meditation associations in Spain (including the Soto Zen Spanish Association, Kagyu and the Gelug Tibetan Buddhist Association, and Mindfulness and Health Association) and found that no one in these groups made regular use of such apps. For this reason, we ruled out the possibility of a survey and decided to revise the characteristics of the present apps. On this basis, we are developing a catalogue of possible utilities of meditation apps and, in a future research that is now in preparation, we will assess the opinion of “professional” or long-term meditators on these utilities.

Thus, we aimed to analyze the following potential MBMA features and functionalities, where available.

App Technology and Design

ICT features included:

1. Smartphone features and operating system
2. Text messaging or short message service (SMS); reminders or similar
3. Camera and other device for collecting and monitoring data
4. Communication tools to other mobile phone features and existing apps
5. Programming interfaces suitable for users
6. Automated sensing through sensing devices
7. Web interface for connectivity and data exchanging, and
8. Other available technology features.

Design and characteristics of functionalities included:

1. Type of mindfulness practices or interventions provided (self- and/or supervised-training; content and characteristics)
2. Tracking and monitoring personal mindfulness practice and health information (through journaling of mindfulness practicing and health-related behaviors and measures; text messaging; automated sensing and recording; online scale and questionnaires; charters and statistics; automated feedback, data export and communication with other devices or apps, synchronization with personal health record systems or patient portals)
3. Online or remote accessing to trainers or health professionals for personalized monitoring and coaching
4. Leveraging social influence (by facilitating peer-to-peer support, influence and/or modelling, integration of social media functions)
5. Increasing the accessibility to mindfulness and related health information (by informational general and/or tailored messages, reminders–content and frequency pattern, glanceable displays)
6. Utilizing any kind of entertainment as an educational tool or approach (messages with fun content, mobile phone-based video games to support mindfulness practice or related healthy behaviors)
7. Declaring “best practice” principles [23], and
8. Other available functionality.

These features and functionalities were chosen based on the relevant literature [12,22-24], mainly on the study of Klasnja and Pratt [24], and from a brainstorming and consensus process among all of the authors with two of them (MD and JGC) being experts in and teachers of MBTs. We created this list with multiple features and functionalities that we believe has the potential to enhance future MBMAs.

Analysis of the Current Apps Available in Online Vendor Markets

Selection Criteria

Platforms

In the Introduction five operating systems were mentioned-Google Android, Windows Phone, Apple iOS, BlackBerry, and Nokia Symbian. Surveys using the latest statistics predict that Apple iOS will remain the second biggest platform worldwide, after Google Android [25,26] (Figure 2 shows this data; Figure 3 shows further data), until 2015, when Windows Phone will surpass it.

In January 2013, the number of Google Android apps overtook those of Apple iOS-800,000 apps are now available on Google Play. In October 2012, Google announced that the total number of apps in its store numbered 700,000. According to a recent press release, 775,000 apps are available in Apple's App Store. Currently, the Windows Phone Store offers 150,000 apps [27] (Figure 4 shows Google apps, Apple apps, and Windows Phone Store apps) [27].

Another important factor is the price of the smartphones that use each operating system. In terms of different models and brands, the Apple Store [28] offers the following models to users (as of March 2, 2013)-iPhone5 from €669 (iOS), iPhone4S from €569 (iOS), and iPhone4 from €389 (iOS).

At the website of the company Phone House, several mobile phones are compared and sold. Following is a sampling of several examples from different brands [29] (as of March 2, 2013)-Android (LG Optimus L3 Black €99; Samsung Galaxy Mini €119; Motorola Defy Mini Black €129; Sony Xperia Tipo Black €149; HTC Desire C 179 €179; Samsung Galaxy S III €479), Other operating systems (Nokia C2-02 Black runs on Symbian €75; BlackBerry Curve 9220 Black runs on Blackberry €179; Nokia Lumia 620 runs on Microsoft Windows Phone 8 €249), and iOS (Apple iPhone5 16Gb White €660).

In conclusion, Google Android should be considered the biggest platform worldwide for the next several years. In addition, mobile phones that use Android are less expensive than those using iOS, which contributes to that operating system's continuous growth. Thus, this study focused on apps for Google Android smartphones. Data were obtained from the Google Play website [30] and from the selected apps.

Figure 2. Worldwide smartphone market share forecast for 2010-2015 based on data from Gartner.

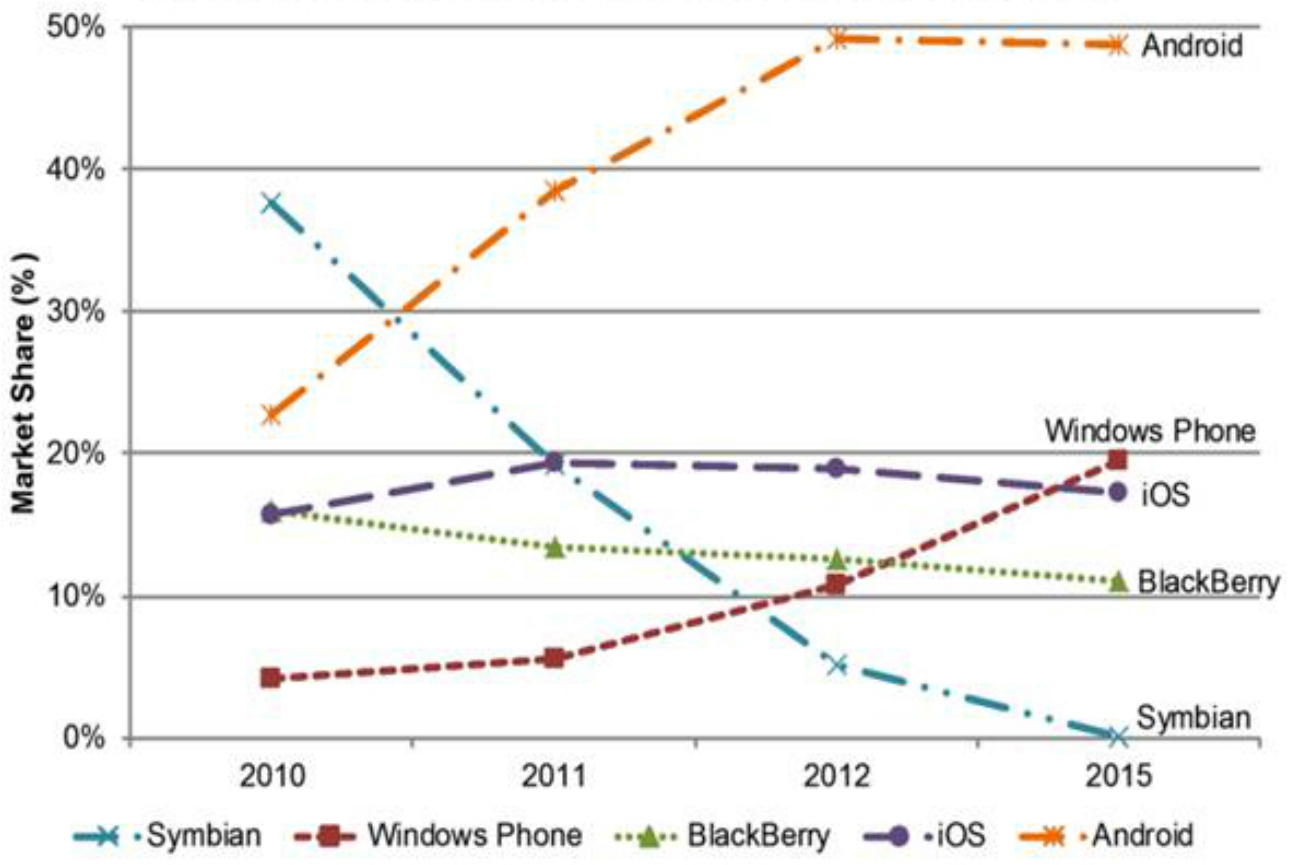


Figure 3. Worldwide smartphone market share forecast for 2015 based on data from IDC.

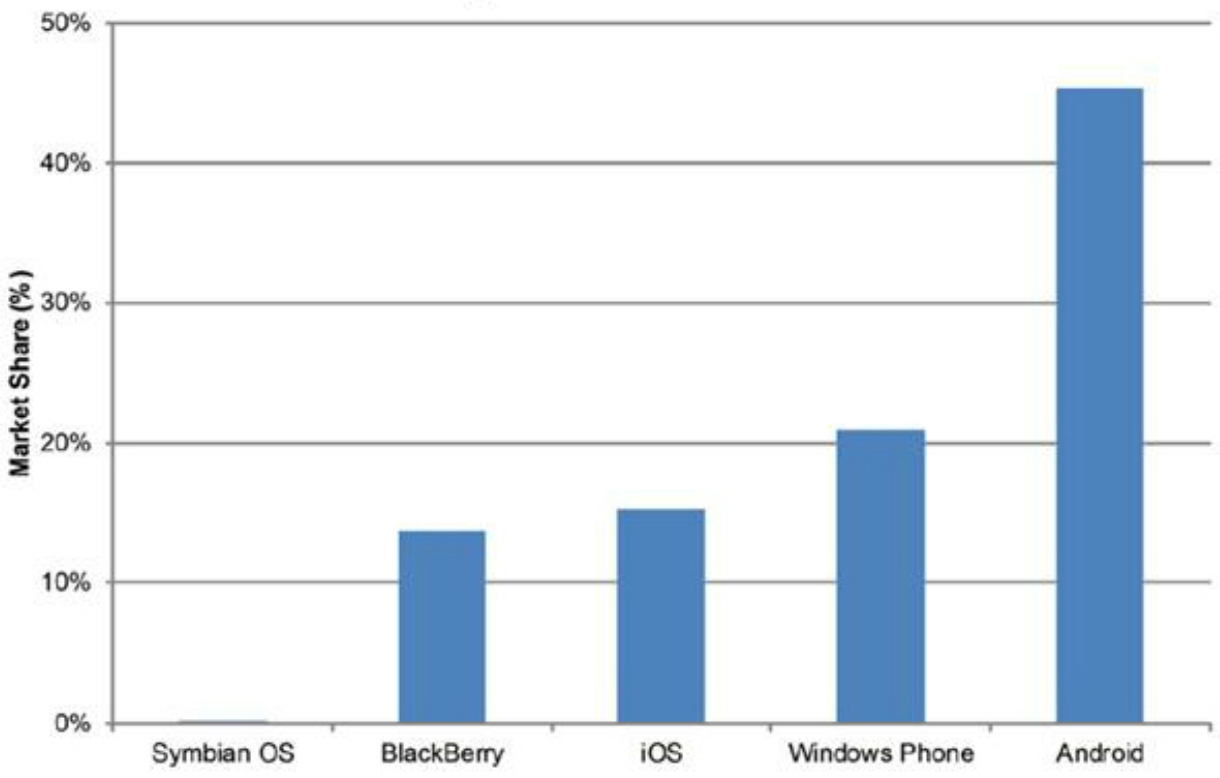
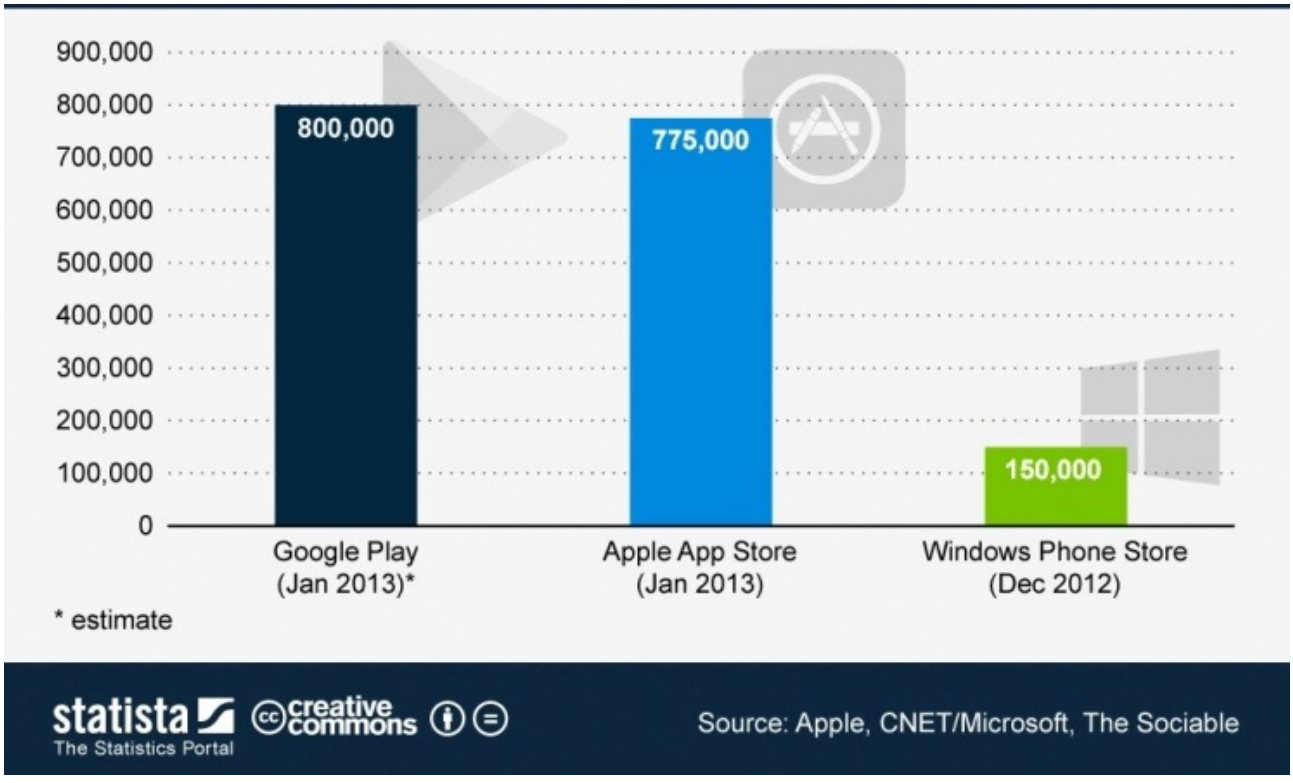


Figure 4. Number of apps in Google Play, Apple's App Store, and Windows Phone Store.



Users

No restriction was applied regarding the types of users of the apps, and we aimed to include any populations, including the general population, patients, and professionals.

Free Apps and Paid Apps

Both free and paid apps were considered, (eg, the Mindfulness free Android and Mindfulness paid Android apps).

Possible Interventions or Use Cases

All possible intervention or use cases were considered including when the user is walking, sitting, or running, and at the gym, at home, or in the office.

Search Strategy and Data Extraction

According to the "Selection Criteria," this study focused on apps for Google Android smartphones. Thus, data were obtained from the Google Play website. The Google Play Store classifies apps according to two main criteria: (1) "popularity" and (2) "relevance." These criteria are based on algorithms that consider items such as the number of download, the number of uninstalled apps, and reviews from users. In this study, the "relevance" criterion was used to filter the most significant apps in two categories: (1) free and (2) paid. Finally, the research was completed in each category using the "popularity" criterion.

Evaluation and Assessment

As previously explained (subsection "Review of the Literature"), we contacted several of the most important meditation associations in Spain and found that no one made use of such apps on a regular basis. Thus, it was not possible to obtain the evaluation of apps either in the form of a trial or a survey. However, the Google Play Store allows users to value apps from 1 to 5. In this case, it was possible to obtain the evaluation made by users themselves based on the public Google Play results.

Features and Functionalities

We aimed to analyze the following potential MBMA features and functionalities for available online apps, where available: (1) number of apps, (2) number of downloads and prices, and (3) characteristics. Between characteristics: (4) main function, (5) possible interventions or use cases, (6) resources, (7) social networks, (8) contents, (9) special features, (10) outcomes: statistics and reports, (11) language, and (12) usability. Finally, (13) global assessment was chosen.

These features and functionalities were chosen based on relevant literature [22,23], our previous analyses of the possibilities that apps offer to users, and consensus process among several members of the research group EduQTech who have experience in developing mobile phone apps [31].

Results

Review of the Literature

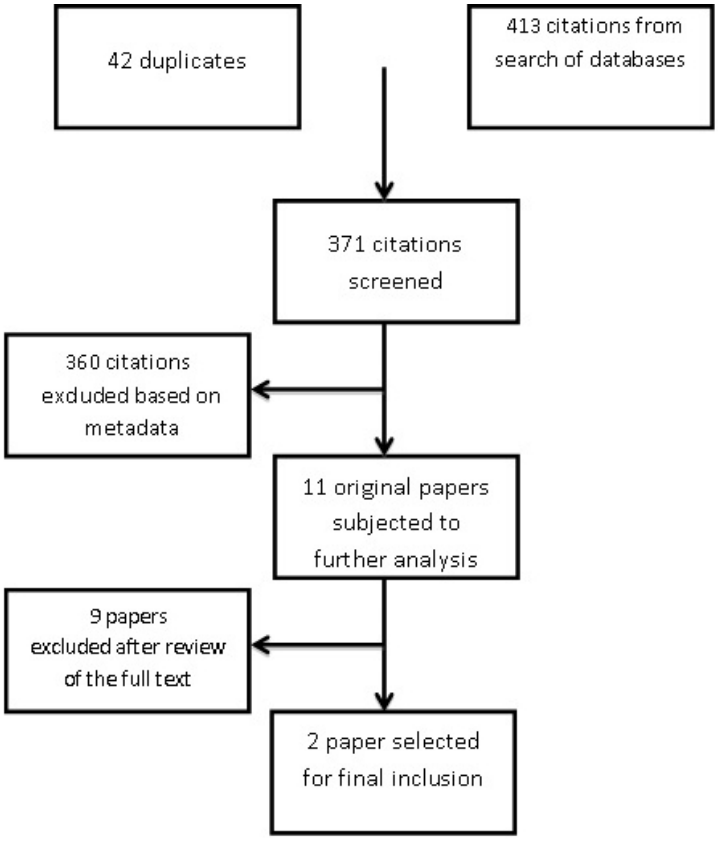
We retrieved 413 citations from our database search (42 were duplicates) and excluded 360 of them based on metadata only, which left 11 eligible original papers for further analysis. We did not identify any relevant systematic review article or international guidelines related to MBMAs, and neither did we identify any new eligible reports by screening the reference lists of these 11 reports (Figure 5 shows the study selection flow diagram).

In the end, we included two original papers [32,33] in our study after excluding nine of the eligible reports after conducting a detailed analysis of their full text. The main reasons for exclusion were as follows:

1. The subject was not a true mobile app, but was instead the use of a mobile or smartphone to send and/or receive information or to access a remote website [34-37].
2. There was no explicit mindfulness component delivered [38-40].
3. The topic was mainly a computer-delivered intervention [41,42].

Multimedia Appendix 1 summarizes the general information extracted from included papers, which were: (1) a pilot study designed to evaluate the feasibility of a mobile app containing a multimedia-assisted system to support the practice of walking meditation, a type of mindfulness technique [32], and (2) an exploratory study of an app consisting of mood reporting scales and mindfulness-based mobile therapies [33]. Multimedia Appendix 2 presents a detailed description of the features and functionalities of apps, focusing on the technology and design characteristics reported in the included studies.

Figure 5. Study selection flow diagram.



Current Apps Available in Online Vendor Markets

Number of Apps

Table 1 shows the number of Android apps found in the Google Play App Store related to meditation, mindfulness, or similar criteria (as of February 25, 2013) [30].

To develop an in-depth analysis of all 203 available apps related to mindfulness would surpass the scope of this study. According to the "Selection Criteria" and "Search Strategy and Data Extraction" subsections, the "relevance" criterion was used to filter the 20 most significant apps in two categories: (1) free and (2) paid. Finally, 5 more were added in each category using the "popularity" criterion. Thus, 50 apps in total were analyzed in depth in this study, which is 24.6% (50/203). Multimedia Appendices 1 and 2 show the names of and relevant data for these apps. There were two free and two paid apps that did not work, thus it was not possible to develop a deep analysis of them and we only gathered information about external features (ie, language, downloads, or prices).

Because data such as number and popularity of these apps are continuously increasing and changing, February 15, 2013 was chosen as the final date for data collection. Figure 6 shows the evolution in the number of Android apps.

Downloads and Prices

To compare the free versus paid apps, the number of downloads was studied. Figure 7 shows it is possible to compare the download rates among the 25 apps analyzed in each case. Figure 8 shows the most recent update of these apps.

Approximately 30% (15/50) of the analyzed apps have both a free and paid version. For example, the developers of "Relax Lite: Stress Relief-Free" and "Relax: Stress & Anxiety Relief" provided interesting data about the usage of both versions [43], which are summarized in Table 2.

In this specific case, users of the paid app showed more loyalty and the number of downloads was greater than the average app. This is the only company that has provided this type of information publicly.

The prices of paid apps varied between €0.75 (in the range of 10-50 downloads) to €5.67 (in the range of 1000-5000 downloads). However, there is not a high correlation between the price and the range of downloads in general (the Pearson coefficient is only 0.34).

Conversely, approximately 52% (12/23) of the free apps offer more options after payment, and 9% (2/23) ask for donations or voluntary economic help. The most common options after payment are the following: support, additional audio, music, videos or exercises, longer meditations, subscriptions, ability to determine the duration of your session by setting a timer, removal of ads, mantras, and breath counts.

Table 1. Number of Google Play apps related to meditation, mindfulness, or similar criteria (as February 25, 2013).

	Apps	Free app	Paid apps
Meditation	>1000	>1000	>1000
Meditation timer	>1000	>1000	>1000
Conscience	>1000	>1000	>1000
Quality of life	>1000	>1000	>1000
Concentration	>1000	>1000	>1000
Health, healthy, health tips, health food	>1000	>1000	>1000
Breath, breathe, breathing	>1000	>1000	>1000
Health tap	>1000	>1000	325
Meditation music	>1000	>1000	46
Mindfulness	203	99	104
Meditation helper	27	15	12

Table 2. Information about free and paid apps from the same developer [44].

Relax Lite: stress relief–free	Relax: stress and anxiety relief
Has been downloaded over 150,000 times worldwide.	Has been downloaded over 500,000 times worldwide.
Over 25% of our users still use our apps regularly after 1 year.	Over 50% of our paid app users still use our apps regularly after 1 year.
Most apps are used by less than 5% of users after 20 days.	Most apps are used by less than 5% of users after 20 days.

Figure 6. Example of the continuous evolution in the number of Android apps related to “Mindfulness.”.

Figure 7. Comparison of the number of downloads among free and paid Android Mindfulness apps.

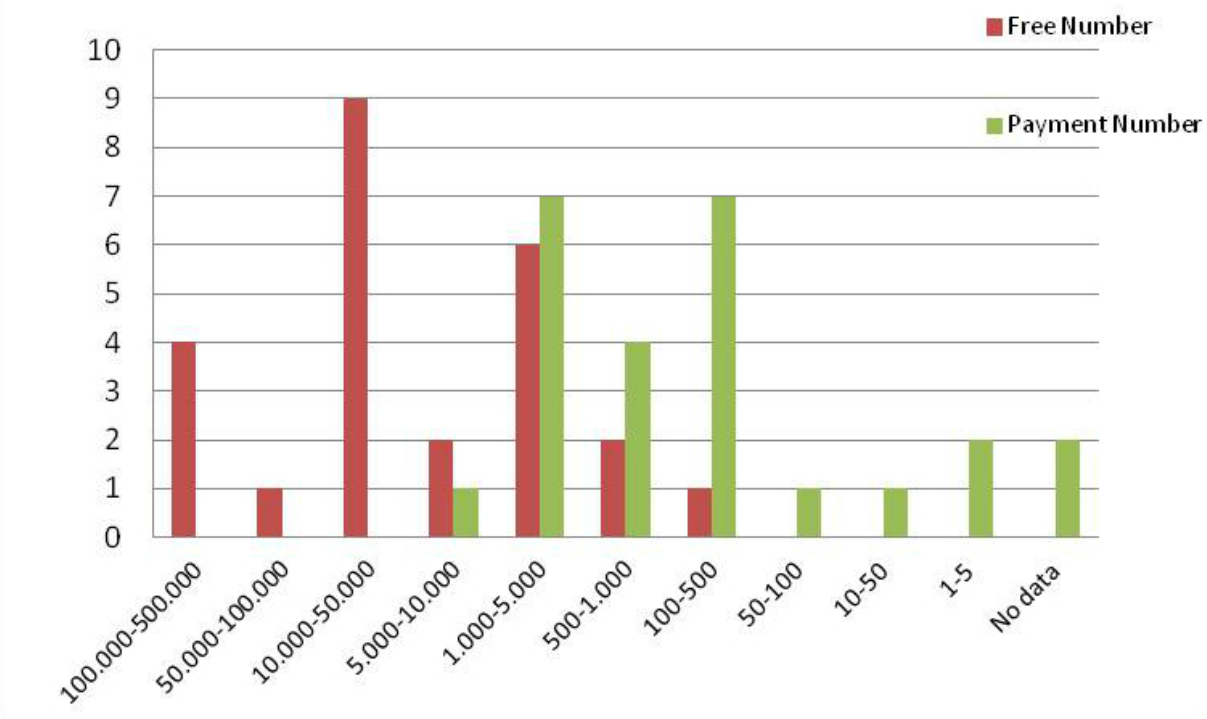
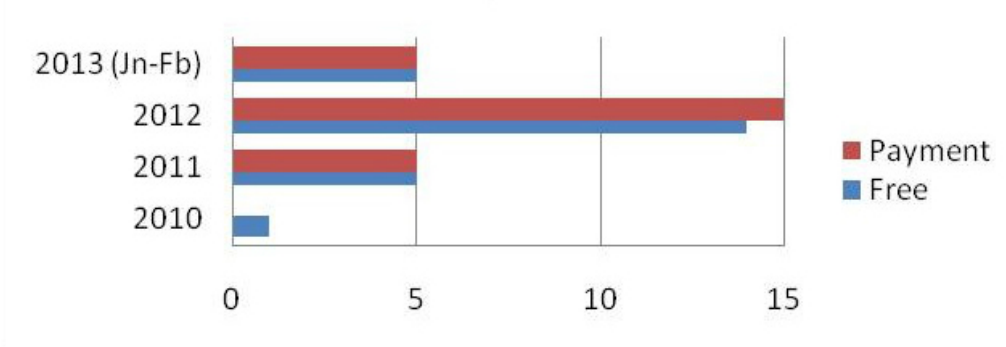


Figure 8. Distribution of time of most recent update.



Characteristics

Main Function

The term “mindfulness” or meditation was not well clarified in most of the apps. The analyzed apps had several primary functions.

Among the free apps–61% (14/23) are devoted to meditation, 13% (3/23) concern training, 9% (2/23) concern tests/questionnaires to know, for instance, the level of stress or types of stress users are experiencing, 9% (2/23) try to help focus the user’s attention, and 9% (2/23) have another main objective.

Among the paid apps–56% (13/23) are devoted to meditation, 13% (3/23) concern tests/questionnaires, 13% (3/23) concern training, 9% (2/23) are related to eating, and 9% (2/23) have another main objective.

In summary, only 56%-61% (13/23-14/23) of the apps are devoted to meditation, the core technique to develop mindfulness. The remaining apps would be best characterized with other words.

Possible Interventions or Use Cases

A small number of apps enabled the user to choose from among several use cases–moving, sitting, or body scan, travelling, walking, gym, or home.

All the apps are devoted to practitioners. They are not specific apps for professionals or, at least, with functionalities useful for each of the profiles.

Resources

Although the design of the apps was very different, most of them used the same resources-reminders (bells, alarms, or similar), audio tracks, and text. The item “Statistics” will be explained in the statistics section. “Quotes” or “everyday tips,” “pictures or photos,” and “music or relaxing sounds” are used in a similar number of apps. Figure 9 shows the percentages of apps that utilized these types of resources. It is important to note that the video resources in several apps are links to YouTube [44].

Social Networks

Approximately 28% (13/46) of the apps interact with social networks. Facebook [45] and Twitter [46] are the most common

according to the extracted data (see Tables 3 and 4). In addition, most of the developers provided a website.

Contents

In addition to the use of previously described resources, Android apps offer additional types of resources, for instance, articles, book information, events, links, personal journals, tutorials, notices, or evaluations.

Special Features

Several apps contained special features. Examples include breath detection, holographic theming (ie, the background and visual aspect can be changed), dieting, single (headphones) or multiple users, skill lists, and review questions about the user's feelings after the audio and "difficulty" levels, (eg, beginner, intermediate, or advanced). However, assessments of psychological and biological variables related to mindfulness or analyses of body statics and kinetics with social interaction were not included in any app studied. The possibility of teaching or practicing for large groups via the Internet was also absent.

Outcomes: Statistics and Reports

Approximately 37% (17/46) of the apps present some type of statistics or reports. Usually, these reports are graphic resources or text. In Table 5, we list the graphic resources and examples of represented measurements.

The temporality is nearly always the same: daily, weekly, and monthly as well as the special case of fully customizable.

Language

English is the language for 41 apps. There are 11 apps that allow the use of or are developed in other languages. There are 3 apps that use Spanish, and only one app provides several videos in this language.

Usability

Thirteen percent (6/46) of the apps lacked an exit button and readability of the text was limited in 6% (3/46) because of the background color (4%, 2/46) or letter format (2%, 1/46).

Figure 9. Percentages of apps that utilized different resources.

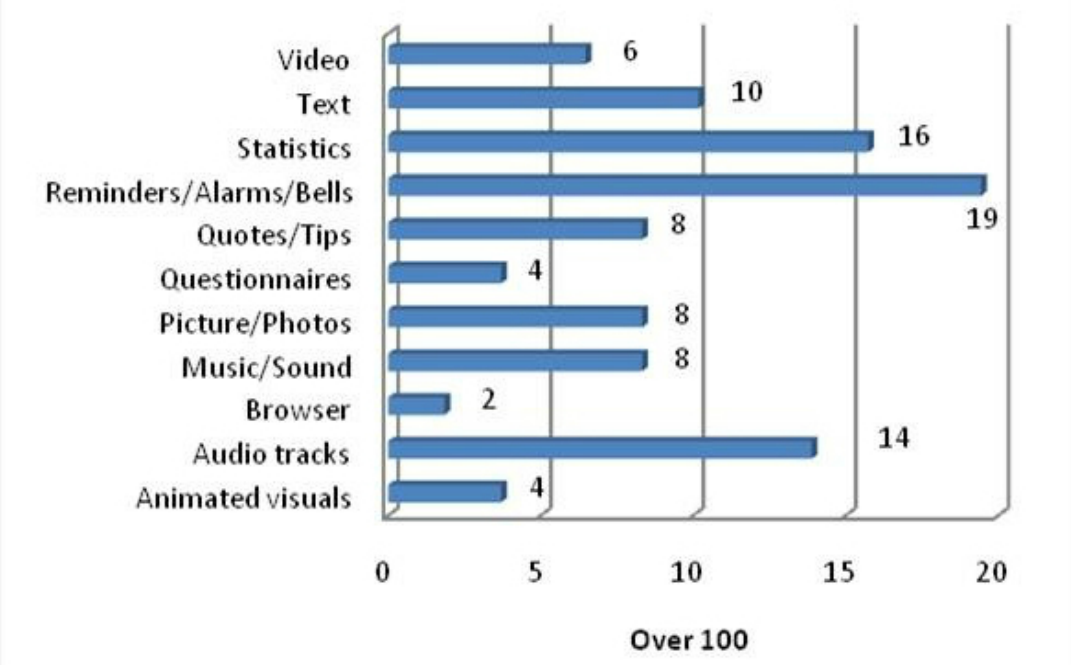


Table 3. Use of Facebook.

Creation year	Followers	Social networks used together with Facebook
1996	201,290	Twitter and Pinterest
2008	643	Twitter
2009	12,742	Twitter
2010	9	Twitter (more used-768 followers)
2010	252	Twitter
2010	453	LinkedIn
2010	523	-
2011	1010	Twitter
2013	105	Google+Community and Google+Page

Table 4. Use of Twitter.

Tweets	Followers	Social networks used together with Twitter
1874	4137	Facebook
3524	768	Facebook
140	100	Facebook
603	936	Facebook
740	581	Facebook
264	([a])	([a])
7795	625,772	Facebook
41	28	The website does not work

[a]Last use: 2011. The access is directly through the app. For mindfulness, 45 Tweets were made in 3 days; for meditation, 14 Tweets were made in 1 hour; for relaxation, 15 Tweets were made in 1 hour; and for mindful, 15 tweets were made in 10 hours.

Table 5. Resources and measurements in statistical reports.

Graphic resources	Measurements
Number	Number of meditations/sessions completed
Bar chart	Time of meditation
Symbols + legend	Time versus test date/goal
Chart type and chart data	Number of consecutive days with at least one recorded session
Comments	Stress level over time or stress score out of 100 points + comments
List of choices	Time spent at each level
Use of Google	Diet: date/time/meal/snack type
Analytics	Record of the ratings: correlation analysis, performance satisfaction by intensity level, performance satisfaction by focus level, and determination of whether the intensity level has positive or negative impact by comparing with the focus.

Global Assessment

Valuing Mobile Apps

To study the global assessment by users of the analyzed apps, we were able to employ the data that Google Play Store offers online. As explained in the Methods Section, users can value mobile apps from 1 to 5.

Multimedia Appendices 3 and 4 show the global score and the number of votes for each analyzed app. In total 10,984 assessments were found, 10,309 corresponding to the free versions and 675 to the paid versions of the apps.

In the free versions the scores ranged from 1.2 (lowest) to 5.0 (highest). There were 10,309 users that had assessed the apps, and the average was 4.6. In the paid versions the scores ranged from 1.7 (lowest) to 5.0 (highest). There were 675 users that had assessed the apps and the average was 4.0.

Users experienced higher satisfaction with the free apps.

A Case

The most relevant free app has a score of 4.5 (88 voters). The app allows users to utilize its Facebook Page (created in 2013 and had 105 followers in January 2013), Google+Community and Google+Page. The developers also provide a "Journal" where users can score their "Conscious level" (from 1 to 7), add comments about the practice (challenge), and know at any time the number of people using the program.

In Table 6, the number of "conscious people" is shown together with the number of people that completed a challenge. Sunday data are not shown because of technological problems.

It is interesting to note that Thursday and Saturday are the days with lower numbers of users, but higher percentages of completed challenges. On the rest of the days, the percentage of users who completed the challenge was approximately 37.22% (590/1585). In other words, only one-third of the followers completed the challenge.

Table 6. Average of the maximum number of users and the percentage who completed the daily challenge.

	Average number of simultaneous users	% of users who completed the daily challenge journal
Tuesday	434	39
Wednesday	407	38
Friday	390	33
Monday	354	39
Thursday	271	65
Saturday	228	58

Discussion

Usefulness of MBMAs

Mobile apps may be useful at facilitating mindfulness accessibility, training, and daily practice adherence [39], which could enhance the impact of MBTs on health indicators worldwide. While a wide selection of MBMAs seems to be available in the market, this study finds a complete lack of evidence to support the usefulness of those apps. We did not find any randomized clinical trials that evaluate the impact of mobile apps and its features and functionalities on mindfulness training or health indicators. In fact, we found only two small-sample pilot studies [32,33]. The study by Yu et al [32] was designed to evaluate the feasibility of an MBMA with a multimedia-assisted system to train and support the practice of walking meditation, a type of mindfulness technique. As that multimedia-assisted system uses a complex net of sensors, it will most likely remain useful only for mindfulness research rather than for the general population. Another study, by Morris et al [33], whose MBMA is probably more suitable to the general population, explored the feasibility of an app consisted of mood reporting scales using touch screen, and self-guided and -demanded mindfulness-based mobile therapies. Both MBMAs were developed for the Android operating system, following the tendency observed in the online vendors market.

The lack of evidence we have found is probably because both MBTs and their related mobile apps are in their early technological development phase, and because developers in the vendors market are not involved in academic or health settings. In our opinion, present apps are not aimed to usual meditators but to nonmeditators that want to become introduced to this technique, because the market is wider. Most of the features and functionalities expected and required for meditators were absent from existing MBMAs. There is ample room to explore in regard to the usability and effectiveness of mobile apps [47]. The way to do this is to identify present functionalities, as we have done in this manuscript, suggest new functionalities available with present technology, and ask meditators about their feasibility and usefulness, which is part of a new project.

We identified 203 eligible MBMAs in the online market (February 25, 2013). It is interesting to note that the number of mindfulness apps is much lower than the number of apps found using other related criteria. As expected, it is clear that the number of free downloads is several orders of magnitude higher than paid downloads. It is also worth pointing out that free versions obtain better scores than paid apps. The current time is exciting as the number of apps is increasing quickly, as shown by the data from 2011 versus the data from two months in 2013 (Figure 8). Looking at the same figure, it is also possible to predict a trend towards the development of more paid apps. In this category (paid apps) a more expensive app does not lead to a lower number of downloads (see Results section, subsection Downloads and Prices).

"Mindfulness" terms and definitions that apps use to self-classify as MBMAs were not always well clarified. Thus, nearly half of the analyzed apps presented different main functionalities and features that were not necessarily related to mindfulness/meditation. It will be necessary for developers to clarify the mindfulness concept and the main objectives of mindfulness apps to better meet the expectations of potential users, as satisfaction can be considered one of the most important parameters for usability [35]. It is interesting to note that the term "mindfulness" was absent in the metadata of the paper from Morris et al [33]; in fact, it is absent throughout the article. This means that terms and definitions for mindfulness are also an issue in the scientific literature, and future systematic reviews on this subject should perform an exhaustive search to prevent this potential bias in selection. In addition, authors should also include the term "mindfulness" or similar in the metadata whenever this is appropriate and relevant.

Some aspects of usability deserve some comments–a minor percentage (about 20%, 9/46) of the apps would benefit from improvements to the design of the interface, (eg, clear exit buttons, changes to the background color or legibility in order to facilitate reading the text, etc). As these pitfalls are subjective and rather difficult to evaluate, two authors, to increase reliability, assessed them. They are easy to improve and would make these apps friendlier.

The question of the language used bears a relation with usability. As 78% (39/50) of the apps studied were only available in English, users speaking other languages would have more difficulties with these apps. This is an important feature because mindfulness decreases conceptual language [5], and it could be more difficult to practice mindfulness while thinking in a language different from the user's native tongue.

As regular practice is a key element in obtaining health benefits from MBTs, it is considered a very important issue among available MBMAs, as approximately 37% (17/46) of them presented some types of statistics or reports of the user's mindfulness practice. Another key element appears to be the

use of social networks as a tool to promote contact among users, to create a sense of community and to permit the exchange of mindfulness practice experiences between users. Therefore, "tracking and monitoring personal mindfulness practice and health information" and "leveraging social influence" seem to be important functionalities for the MBMA developers in the market.

Assessments of psychological and biological variables related to mindfulness or analyses of body statics and kinetics with social interaction are not included in any app studied, except the study of Morris et al [33], which evaluated users' mood reporting. The lack of these functionalities, which are relevant for research studies and for feedback from users, might be one of the reasons for the absence of randomized clinical trials to evaluate the impact of mobile apps on mindfulness training. The improvement of health outcomes produced by apps is probably linked to empowerment and interactivity with the smartphone [47], and psychological and biological feedback could be one of the most important rewards to encourage users to continue to practice mindfulness.

Finally, no app offers a relevant functionality for instructors of mindfulness-the possibility of teaching or practicing for large groups via the Internet. It is widely accepted that the future of psychotherapy is linked to smartphones [12], so this functionality is expected to be one that generates the most demand from trainers and trainees of mindfulness.

Limitations

A limitation of this review is that we did not include an extensive evaluation of websites related to mindfulness training in our method because that would be beyond the scope of this work. As a result, it is possible that we are missing some MBMAs not currently available in online markets or in scientific databases. Furthermore, some functionalities and features may be underreported as we did not thoroughly evaluate all of the MBMAs available in the online vendor markets.

Existing MBMA Versus Real Needs: Future Agenda for Research

Mobile phones and apps are widely used to enhance the delivery of mental health prevention and treatment interventions [48], and they will be a key element in future research on health behavior, according to the experts [12]. These devices are ubiquitous, well accepted in society, relatively inexpensive, programmable and capable of recording media, are already owned by a large number of people, operate almost continuously, allow the input and output of data, and provide content that is more user-friendly and condensed than regular Web pages [39]. With a specific focus on apps that increase the adherence and efficacy of mindfulness practices, there are important limitations in the current apps that future research should address. Some improvements in new apps that would facilitate mindfulness training, practice, and research are the following.

Monitoring psychological variables related to mindfulness would be feasible with present technology and quite useful to meditators that wish to periodically assess their levels of mindfulness or other psychological constructs, such as acceptance, psychological flexibility, and resilience. The user's emotional state could even be assessed, for example, with emotion recognition by voice or photographs obtained with mobile microphones and cameras [49].

Monitoring of biological variables through internal and external sensors could give useful psychophysiological data. Consumer electroencephalogram (EEG) headsets and electrocardiogram (ECG) monitors have already been developed [50,51] and could allow monitoring of brain and heart activity during formal and informal mindfulness practices. Changes in EEG and ECG can be expected as a consequence of mindfulness practice over the acute/medium/long term. Experts consider [12] that, in the future, many people will have a set of wearable wireless biosensors that will monitor not only basic vital signs (temperature, blood pressure, pulse, respiratory rate, pulse ox, and ECG), but also other variables relevant to mindfulness (hormone levels, immune system activity, and inflammation) [52].

Monitoring of physical movement and the psychological state with MBMAs associated with 3-axis accelerometers (to detect linear acceleration in all directions) could reveal whether people are practicing while standing, moving, or walking and whether they feel calm or nervous [53,54].

The analysis of body statics and kinetics could be possible in the near future. Devices for full-body gaming such as the Xbox 360 Kinect will soon be connectable to mobile devices, which would make possible studies of nonverbal behavior according to body position, posture, and motor skill learning. It may also be possible to record limb and torso movements continually to detect changes in body statics and kinetics due to mindfulness practice [12].

The analysis of social interactions could be used by trainers. Devices with Bluetooth routinely scan the identity codes of all other Bluetooth devices nearby. As most people now carry a Bluetooth-enabled mobile phone, the density of local Bluetooth devices is a good proxy for the number of people nearby [55]. This information and call log data allow the inference of social networks associated with mindfulness practice [56] and could be useful for trainers to control individual presence during group activities related to mindfulness training.

Improving adherence to practices can be done online. Achieving individual improvements through online "situational feedback" delivered by trainers, automatic SMS alerts, or a reminder is a functionality that already exists and may improve adherence to a regular mindfulness practice [24,36].

Context-specific and customized behavior activation can help app users. Context-specific alerts, SMS, reminders, tips, and educational content probably will make these functionalities more effective, and customized feedback will improve users' skills to be more mindful during, or to practice mindfulness exercises just before well-known stressful moments or unhealthy behavior daily triggers (for example, preventing psychological overreaction to a known stressful social event) [24].

Conclusions

While a wide selection of MBMAs is available in the online market, this study found that there is still a lack of scientific evidence to support the use and effectiveness of those apps.

Recommendations

According to the results of this study, we provide the following recommendations for future apps.

It is necessary to clarify the concept of mindfulness and the principal aim of any mindfulness app to better meet the expectations of potential users. About 41% (19/46) of the apps that include mindfulness in the title develop some form of a mind-body approach, but not specifically mindfulness.

About 20% (9/46) of the apps have interfaces that are difficult to use, for instance, there is no clear exit button or the background color makes reading the text difficult. To solve these problems, published guidelines for app design could be developed (see, for instance, Google, Apple, and Windows) [57-59] or [17]. Smartphone apps must be intuitive to increase everyday use and generate confidence.

No specific apps exist for professionals or long-term meditators or, at least, for both profiles (users and professionals) and contain functionalities useful for each.

The functionalities of the apps available at present are limited. Assessments of psychological and biological variables related to mindfulness or analyses of body statics and kinetics with social interaction are not included in any app studied, except one. Another relevant functionality for instructors of mindfulness, the possibility of teaching or practicing for large groups via the Internet, is also absent.

It is necessary to develop apps in languages other than English (only 22%, 11/50 of the apps studied allow any other language) to make them friendlier to non-English-speaking users.

In summary, apps are expected to be an important additional tool to increase adherence in MBTs, but some improvements to the present models are advisable to improve their efficacy. The potential for mobile mindfulness apps remains largely unexplored.

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Authors' Contributions

Authors' Contributions: IP and JGC had the initial idea for the review and drafted the first protocol. All authors commented and advised on this draft. All authors devised the search strategy that was conducted by IP and PHM (online vendors), and PHM and MMPD (scientific databases). All authors participated in the screening of the results of the searches and agreed on the final list of included articles and mobile app. IP, MMPD, and PHM carried out the data extraction. IP, JGC, and MMPD wrote the first draft of the final papers with contributions and edits from all remaining authors. All authors contributed to the final draft.

Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

General characteristics of studies.

[PDF File (Adobe PDF File), 136KB - mhealth_v1i2e24_app1.pdf]

Multimedia Appendix 2

Apps features and functionalities (technology and design characteristics) from the included studies.

[PDF File (Adobe PDF File), 14KB - mhealth_v1i2e24_app2.pdf]

Multimedia Appendix 3

Mindfulness free Android apps.

[JPG File, 236KB - mhealth_v1i2e24_app3.jpg]

Multimedia Appendix 4

Mindfulness paid Android apps.

[JPG File, 199KB - mhealth_v1i2e24_app4.jpg]

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Abbreviations

ACM: Association for Computing Machinery
ECG: electrocardiogram
EEG: electroencephalogram
ICT: Information and communication technology
IoT: Internet of Things
MBMAs: mindfulness-based mobile apps
MBTs: mindfulness-based therapies
PC: personal computer
SMS: short message service

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Review

Mobile Apps in Cardiology: Review

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Abstract

Background: Cardiovascular diseases are the deadliest diseases worldwide, with 17.3 million deaths in 2008 alone. Among them, heart-related deaths are of the utmost relevance; a fact easily proven by the 7.25 million deaths caused by ischemic heart disease alone in that year. The latest advances in smartphones and mHealth have been used in the creation of thousands of medical apps related to cardiology, which can help to reduce these mortality rates.

Objective: The aim of this paper is to study the literature on mobile systems and applications currently available, as well as the existing apps related to cardiology from the leading app stores and to then classify the results to see what is available and what is missing, focusing particularly on commercial apps.

Methods: Two reviews have been developed. One is a literature review of mobile systems and applications, retrieved from several databases and systems such as Scopus, PubMed, IEEE Xplore, and Web of Knowledge. The other is a review of mobile apps in the leading app stores, Google play for Android and Apple's App Store for iOS.

Results: Search queries up to May 2013 located 406 papers and 710 apps related to cardiology and heart disease. The most researched section in the literature associated with cardiology is related to mobile heart (and vital signs) monitoring systems and the methods involved in the classification of heart signs in order to detect abnormal functions. Other systems with a significant number of papers are mobile cardiac rehabilitation systems, blood pressure measurement, and systems for the detection of heart failure. The majority of apps for cardiology are heart monitors and medical calculators. Other categories with a high number of apps are those for ECG education and interpretation, cardiology news and journals, blood pressure tracking, heart rate monitoring using an external device, and CPR instruction. There are very few guides on cardiac rehabilitation and apps for the management of the cardiac condition, and there were no apps that assist people who have undergone a heart transplant.

Conclusions: The distribution of work in the field of cardiology apps is considerably disproportionate. Whereas some systems have significant research and apps are available, other important systems lack such research and lack apps, even though the contribution they could provide is significant.

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KEYWORDS

apps; cardiology; heart; m-health; mobile applications

Introduction

According to reports from the World Health Organization, an estimated 51 million people died in 2008 from any type of disease, communicable and noncommunicable, with the latter causing the most deaths. Among them, the worldwide leaders in mortality are cardiovascular diseases (CVDs), with 17.3 million deaths in 2008 alone, representing 30% of all deaths globally. Moreover, these deaths occur in a disproportionate way, with more than 80% occurring in low- and middle-income countries. Regrettably, no better outlook is expected, since it is estimated that more than 23 million people will die annually from CVDs by 2030 [1-5].

Ischemic heart disease (or coronary heart disease) is especially fatal among CVDs, responsible for 7.25 million deaths in 2008. Further, there are more heart-related diseases with a significant fraction of deaths, such as hypertensive heart disease and inflammatory heart disease. In fact, more people die of heart malfunction than of AIDS and all cancers combined. The contribution of these diseases to disabilities is notable—62,587 million Disability-Adjusted Life Years (DALYs) are due to coronary heart disease. These data mean massive costs to the economy of all countries, being estimated at US$448.5 billion in the United States alone in 2008 [2,6-8].

In light of such statistics, it is imperative that we reduce these numbers, not only in health care environments such as hospitals or primary health care facilities, but also in patients' homes and workplaces. To meet this objective, mHealth, defined as "the use of mobile computing and communication technologies in health care and public health" [9], is of utmost importance. For that same reason, the latest advances in mHealth [10-13] and wireless technologies [14-16] have been used, resulting in improvements in several different aspects, from health to financial [17,18].

To aid in this initiative, it is important to acknowledge the use of smartphones and tablets as devices that have become essential to users in recent years. In numbers, there were more than 6 billion mobile subscriptions and more than 1.7 billion mobile phones sold in 2012 alone, of which 712.6 million were smartphones [19-21]. The International Data Corporation (IDC) estimated 70.9 million shipments of tablets globally in 2011 and predicted 117.1 and 165.9 million in 2012 and 2013 respectively [22]. With such growth, it was only a matter of time before the use of these devices would be adopted for mHealth, in the form of mobile applications or apps. Focusing only on the most important app stores, in terms of the market share of smartphone operating systems [23,24], the App Store [25] for Apple iOS has close to 20,000 apps in the category of Health & Fitness and more than 14,000 in Medicine. Android's Google play [26] has more than 11,000 apps in the Health & Fitness section and roughly 5000 in the Medical apps section [27].

The aim of this paper is to conclude research on mobile applications for the most important diseases and health conditions, which we began previously with a study about mobile applications for the most prevalent health conditions [28]. This time we focus on the deadliest illness: heart disease. The main objective of this paper is to study the literature on existing mobile systems and applications, as well as cardiology apps currently available on the cited app stores. In the first part of the research, a review of published articles was performed across several systems and databases and was complemented in the second part with a search of apps in the Apple and Google app stores. The objective was to classify the results in order to see the progress as well as the lack of applications and systems, focusing specifically on commercial apps (ie, those apps available on app stores). Other secondary objectives were to obtain information regarding the prices of these apps and their target users. Since there are no published reviews on this specific topic, the results may be of considerable interest for developers and researchers wanting to investigate further or to create a new app.

Methods

Two reviews were developed and took place up to May 2013. The first was a review of existing mobile systems and applications in the field of cardiology found in the literature, and the second, a study of commercial apps related to cardiology found in the leading app stores.

Review of Mobile Systems and Applications for Cardiology in Literature

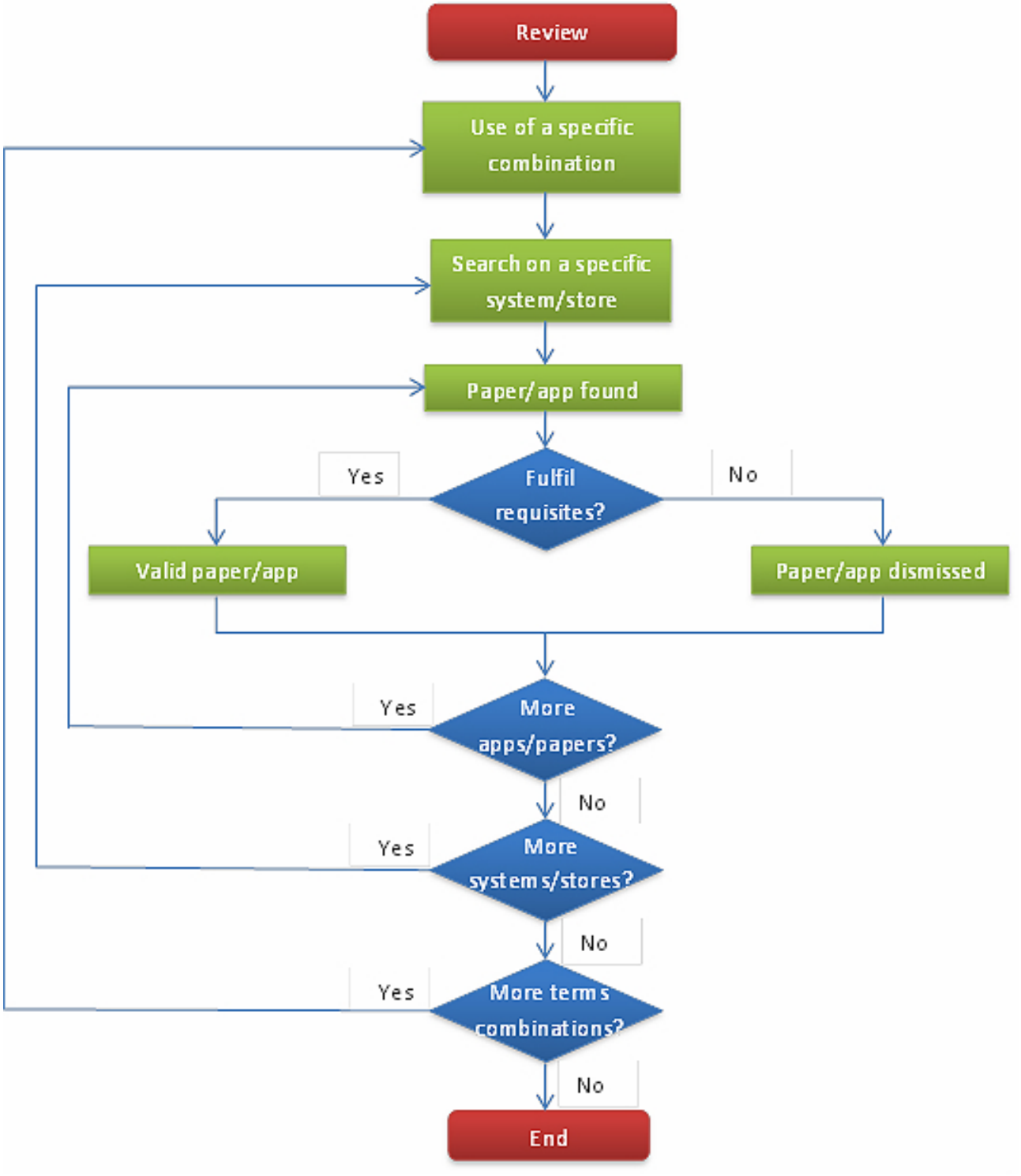
To perform the literature review, the following systems and databases were used: Scopus, IEEE Xplore, Web of Knowledge, and PubMed. The methodology followed is presented in Figure 1 and also applies to the commercial apps review. In this section, the objective was to search for relevant papers in different systems. The following combinations of search terms were used in the metadata field: "term1" AND mobile AND (application OR app); "term2" AND mhealth; "term2" AND smartphone; and "term2" AND "mobile phone", where "term1" and "term2" could be different words. The words used for "term1" were heart disease, heart failure, infarction, arrhythmia, heart attack, coronary disease, angina, fibrillation, cardiology, hypertension, heart transplant, and heart transplantation. For "term2", the terms used were cardiology and heart.

The results were limited to the last 10 years, from 2003 to the present day, and the eligibility requisites used were the following: only papers published originally in English were studied. Publications about mobile systems or applications not focused on cardiology or designed for more than 3 different fields were dismissed, but if the application was intended for 3 disciplines or fewer with being cardiology one of them, then it was included in the review. Similarly, papers regarding systems for many diseases (not only cardiac diseases) were rejected. Articles with algorithms for classification, detection, compression, encryption, or authentication of ECG data (or other types of heart signs) were studied, but publications about the possible influence of the electromagnetic fields irradiated by mobile phones in the heart rate or in implanted cardiac devices were dismissed.

When the selection of papers was finished, the authors convened in order to classify the articles in different categories by reading their abstracts as well as the whole article when required. Once

this process was completed, a revision was done and similar categories were merged to obtain a more condensed classification.

Figure 1. Flow chart of the methods followed in the literature and the commercial reviews.



Review of Apps for Cardiology in Commercial App Stores

The second review was a search of apps related to cardiology in the two leading commercial stores for smartphones [23,24]: the Apple App Store and Google play.

The methodology used in this review is the same used in the previous one, shown in Figure 1, although in this case exploring apps in commercial stores, instead of papers in databases. The search terms used for both stores were heart and cardiology. The eligibility requisites used for this review were the following: apps not in English or in the language of the place where the search was executed (Spanish) were dismissed, the same as those with their summary in a different language from the two mentioned. Only applications focused on cardiac issues were studied. Games, music, apps for cholesterol management or

losing weight, apps for animals, and apps for congresses or conferences were dismissed, but apps related to hypertension were included in the study.

In the App Store, since the apps are separated for iPod and iPhone and for iPad, only the first ones were searched, although in many cases they were also available for iPad. During the search on Google play, some problems arose. When searching by "cardiology" or "heart", the store indicated that there were at least 1000 results, although it showed only 480. Google was asked about this discrepancy and the issue is still under investigation; hence, it was decided to use other search words in order to obtain the highest number of apps related to cardiology in this store. These words were infarction, heart attack, heart failure, heart disease, fibrillation, coronary heart, angina, and arrhythmia. Additionally, in some of these new searches on Google play, it was indicated that a certain number of results has been found but, when exploring the pages of the results found, the last pages (usually between one and three) were blank. This issue did not affect the review since the apps studied are the ones shown, although it is not known if there were more apps that were not visible due to this error.

Once the selection of cardiology-related apps was complete, the authors convened again to sort the apps by their purpose in different types, by reading the summary and explanation given by the stores and downloading them when the explanation specified was not clear enough. In these cases, the smartphones used were an iPhone 4 if the app was designed for iOS and a Samsung Galaxy S SCL GT-I9003 in the case of an app for Android. Finally, revisions were done in order to shorten the classification, similar to the process followed in the literature review.

Results

Mobile Systems and Applications for Cardiology in Literature

A total of 406 relevant papers were found in all the databases and systems used. The classification of the papers by their content is shown in Table 1, which also shows the number of articles for each category.

In Figure 2, the percentage of papers found by their year of publication, from 2003 to 2012, is shown. It can be seen that the publications increased every year until 2011, decreasing slightly in 2012.

Apps for Cardiology in Commercial Stores

A total of 710 relevant apps were found in the App Store and Google play, although we note that some apps are available in both stores. In this study, these apps are counted separately. Hence, 439 apps are available for iOS and 271 for Android. The majority of the apps for iOS are found in the categories of Medicine (303) and Health & Fitness (111), whereas the remaining are included in Utilities (8), Education (7), Entertaining (3), Lifestyle (2), Sports (2), Books (1), Reference (1) and Social network (1). The apps for Android are found in the categories of Medical apps (188), Health & Fitness (65), Education (8), Lifestyle (7), and Books & Reference (3). The classification of these apps sorted by their functions and in decreasing order are shown in Table 2.

If the classification was performed taking into account the target public to whom the app is destined, another sort was conducted. Figure 3 shows the number of apps sorted by target users for each app store.

To understand Figure 3, it is necessary to explain the difference between the "general public" and "everyone". General public is used for common users—normal people not necessarily affected by heart disease. It does not include health care professionals. On the other hand, everyone includes all groups. It is used for apps intended for a specific type of user, such as medical students but that can also be used by other users, such as professionals or the average person for example.

Finally, statistical values on the prices of the apps separated by commercial store are summarized in Table 3. For the mean, mode, and median values, the study is divided into two groups: one group shows all the apps found and the other shows only the apps that are not free.

Table 1. Classification of the results of the literature review.

Type of system/application	Articles
Vital signs monitoring system	55
ECG (electrocardiography)/cardiac signal detection/classification algorithms	44
Heart monitoring system	37
ECG/heart monitoring system trial/evaluation	28
Remote heart monitoring system	25
Heart monitoring system with alerts	17
Cardiac rehabilitation mobile system	16
ECG data transmission	14
Blood pressure measurement/monitor system	13
Remote management/monitoring of implanted pacemakers/cardiac devices	11
Teleconsultation system	10
Remote and local heart monitoring system	8
Exercising/sports related heart monitoring system	7
Innovative heart rate monitor	7
Arrhythmia detection system	7
Sensors evaluation/state of the art	6
Surveys/states of the art of cardiology systems	5
Heart rate & blood pressure monitoring system	5
Remote heart monitoring system with alerts	5
Atrial fibrillation detection system	5
Heart failure detection system	5
Phonocardiography mobile system	5
Remote and local heart monitoring system with alerts	4
Breath monitoring system	4
ECG data compression technique	4
Automatic music selector to maintain a target heart rate	4
Alerts and location of heart attacks	4
CPR instructions through mobile phone trial	4
CPR instructions/reminder through mobile phone	4
Applications for promotion of healthy behaviors	4
System for measuring/reducing stress	3
Personal lifestyle and health management system	3
Fetal heart monitoring system	3
ECG data encryption/authentication/privacy	3
Cardiac rehabilitation mobile system trial	3
Exercising/sports related heart monitoring system evaluation	3
Mobile medical applications for chronic diseases	2
Pocket-size images interpretation	2
First aid/resuscitation app evaluation	2
Apps for hypertension in smartphones	2
Emotional states detection through measuring heart rate differences	2
Weight control in high-risk heart failure population	2

Type of system/application	Articles
Medications management	2
Telemetry-based system for monitoring rats' vital signs	1
Heart attack self-test app	1
Trial for comparing follow-up of hypertensive patients	1
Study about the correlation music-heart rate variability	1
App for improving basic life support (BLS)	1
Non-invasive tissue classifier	1
Share of vital signs in a social network	1

Figure 2. Percentage of papers found per year of publication.

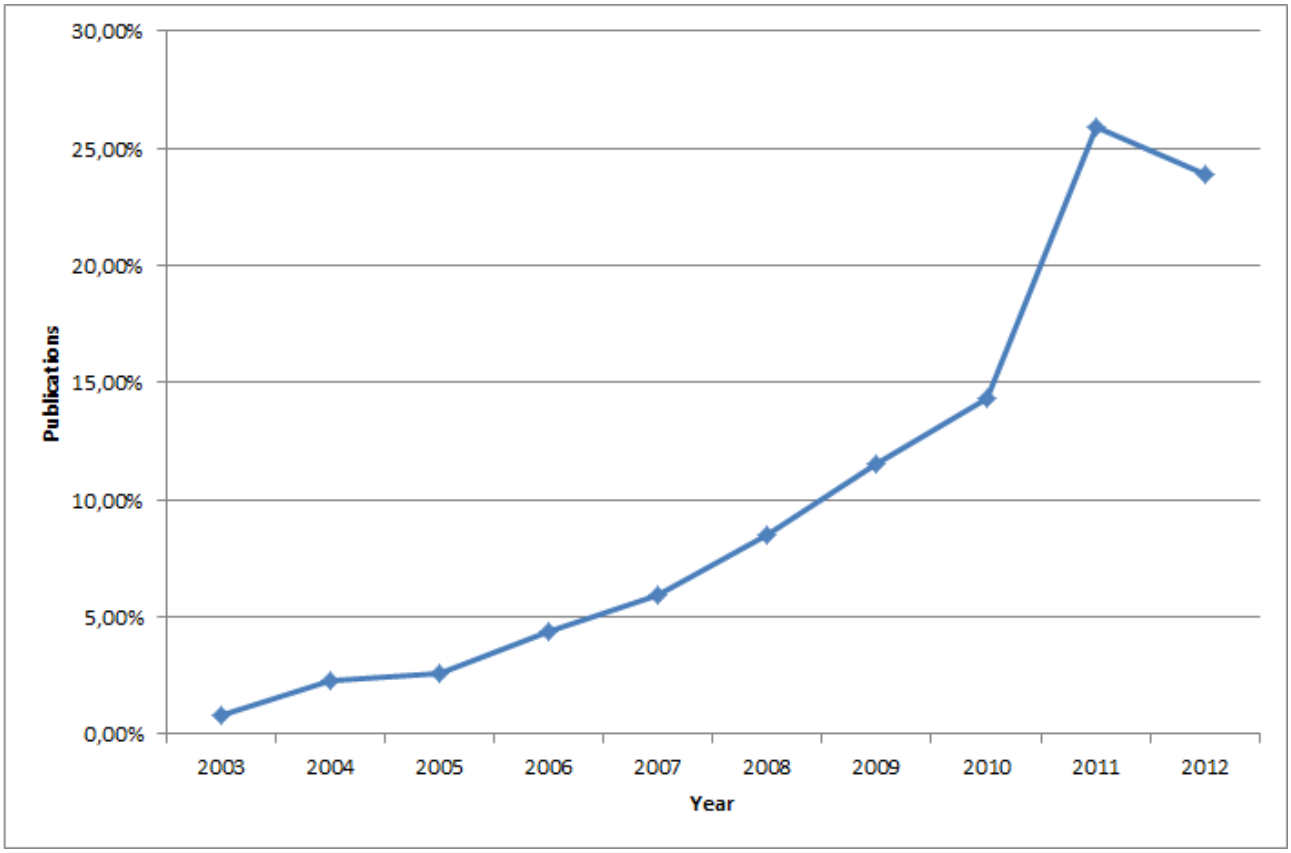


Table 2. Classification of apps in the commercial review by function.

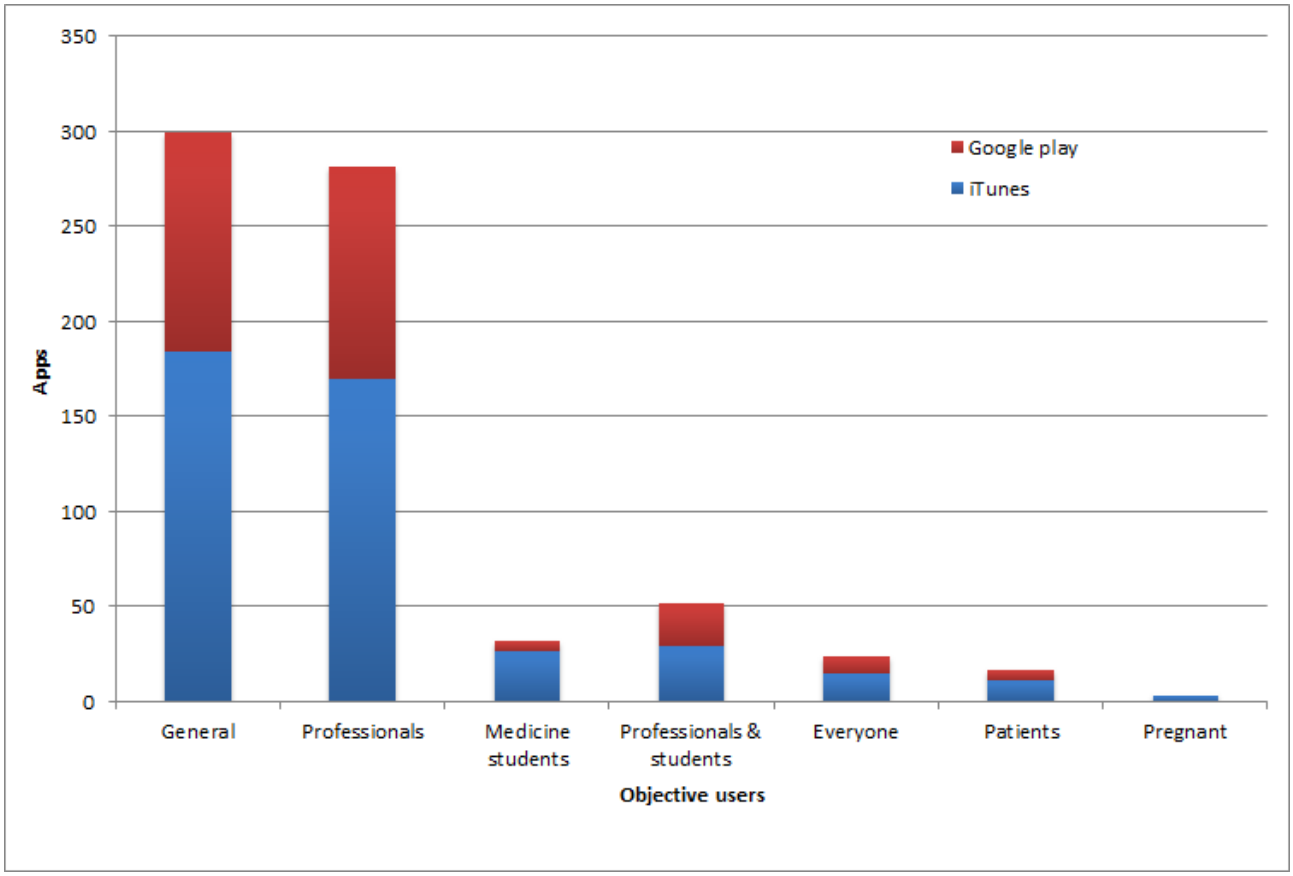
Type of app	Number
Heart rate monitor	94
Algorithm/calculator/predictor	85
Informative guide	41
Educational ECG/interpretation aid of ECG	37
News/journal	34
Blood pressure tracker	30
External devices heart rate monitor	22
CPR (cardiopulmonary resuscitation) instructions	21
Educational anatomy	17
Medicine students education	17
Guide/book	17
Health tips	17
Diagnosis & treatment guidelines	14
Echocardiography reference	14
Professionals & students education	14
Medicine exam preparation	13
General education	11
Diagnosis aid	10
Animated guide	9
Heart sounds reference	9
Blood pressure & heart rate monitor	9
Cardiology medical reference	8
Medical images reference	8
Catheter reference	8
Guide of professional commercial devices	7
Stethoscope/educational stethoscope	7
AED (automated external defibrillator) location	6
Professionals education	6
Clinical trials	6
ECG cases reference	5
Hypertension reference/guidelines	5
Procedures in emergency cases	5
Patients' history/ECGs/images	4
Surgeon aid/training	4
Professionals connections, knowledge/cases share	4
Angiography reference/guide	4
Auscultation reference	4
Heart rate monitor for exercising	4
Fetal heart rate monitor/interpretation	4
Heart rate calculator	4
Ultrasound video reference	4
Resuscitation instructions/guide	4

Type of app	Number
Educational/explanations for patients	3
ECG sending	3
Log procedures	3
Diseases prevention guide	3
Heart rate monitor with external devices for exercising	3
Professionals guidelines	3
Audio reference	2
ECG signal transformer	2
Location of cardiac emergencies	2
Blood pressure measurement with external devices	2
CPR and AED instructions	2
Prescribing drugs	2
AED training	2
Pulse measurement aid	2
Hospitals	2
Instructions/training CPR & AED location	2
Perfusion reference	2
Arrhythmia reference	2
Acute coronary syndrome reference	2
Stent guide/reference	2
Prosthesis guidelines	1
Teleconsultation	1
Upload ECG from a commercial monitor	1
Medications reminder	1
Treatment guide	1
Stand-alone or with external device heart rate monitor	1
Auto-diagnosis	1
Cardiac rehabilitation guide	1
Anesthesia management	1
Social network	1
Atrial fibrillation guidelines	1
AED training with simulation of external device	1
Blood pressure prevention & treatment exercises	1
Condition management	1
Congenital heart defects reference	1
Clinical examination guide	1
Blood pressure measurement	1
Driving guidelines for cardiac patients	1

Table 3. Statistical data on the prices of apps in the commercial review.

	Min.	Max.	% free apps	Mean		Mode		Median	
				Total	Not free	Total	Not free	Total	Not free
iTunes	0	129.99	43.28	2.89	5.10	0	0.89	0.89	1.79
Google play	0	100	49.82	3.45	6.87	0	1.04	0.71	2.17

Figure 3. Classification of the apps of the commercial review by target users.



Discussion

Principal Findings

In light of the results presented in the previous section, several interesting findings can be extracted. Focusing on the literature review, the majority of the 406 articles found are about systems that normally use a mobile phone or smartphone and only a small percentage concerns mobile apps exclusively. In addition, as Table 1 shows, 4 of the first 5 types of applications with more papers are directly related to heart monitoring systems (including vital signs) while the remaining one is related to algorithms for selection/classification of ECGs or other measurable heart signs. At the same time, other different types of heart monitoring systems can be found in the classification. There were 198 papers about those systems, which is almost half of all the publications found. This indicates that the most researched area associated with cardiology is related to mobile heart monitoring systems and the techniques involved in the classification of heart signs in order to detect malfunctions.

An example of a heart monitoring system is the one proposed by Yap et al (2012), which uses a chest-belt wireless ECG measurement system in combination with an Android app for monitoring ECG in real time [29]. In this case, there is an app involved in a whole system, but, as mentioned above, there are few articles focused exclusively on apps, such as the one written by Leijdekkers and Gay (2008) about a heart attack self-test app that allows possible victims to assess whether they are suffering an infarction [30]. De Vries et al (2013) evaluated the actual use and goals of telemonitoring systems [31], whereas Seto et al (2012) developed a randomized trial of mobile phone-based telemonitoring systems [32] to examine the experience of heart failure patients with these systems [33]. An algorithm for improving the classification of ECGs was developed by Jekova et al (2011), which scores the noise corruption level of ECG data by evaluating several features [34]. It is important to indicate that most of these systems cited were designed for patients' use with the knowledge and consent of their professional caregivers, since they have an important role in the correct functioning of the applications, either monitoring remotely the patients' heart or receiving alarms when a heart problem occurs.

Other systems with a number of papers are the following: cardiac rehabilitation mobile systems [35,36], extremely

important in the recovery of heart attacks or in their prevention in people with heart problems [37,38]; systems for measuring blood pressure combined or not with heart rate monitors [39,40], in order to avoid possible problems derived from hypertension (or raised blood pressure), an important risk factor for coronary heart disease or ischemic stroke and indirectly the cause of 9.4 million deaths every year [41,42]; and systems for the detection of heart malfunctions, sometimes focused on certain problems such as arrhythmia or atrial fibrillation [43] and sometimes considering more than one disease [44]. Other important contributions are done in the remote management or monitoring of cardiac devices such as pacemakers, in order to assess their correct operation and to perform periodic checks, which is currently very common in modern health care facilities [45].

Examining the dates of publication of these papers, shown in Figure 2, it is clear that research in mobile systems in the field of cardiology has gained more and more importance in recent years, beginning in 2003 and with many more published articles by 2011 and 2012. This fact shows that the part of cardiology associated with mobile technology has become the recent focus of investigations—quite logically since cardiovascular diseases and especially heart diseases are the leading causes of death worldwide.

In the review of cardiology-related apps, many outcomes were observed. The first notable conclusion from classification (Table 2) is the difference between the first two positions (ie, heart rate monitors and calculators) and the rest, when taking into account the number of apps for each category. There are far more apps for heart rate monitoring and medical calculators or predictors than for informative guides, which is in the third position. In addition to these heart monitoring apps, there are those that use an external device as well as those focused on exercising. Figures 4 and 5 show snapshots of two examples of heart monitoring apps: Runtastic Heart Rate & Pulse Monitor [46] for iOS and Instant Heart Rate [47] for Android. Of the more than 20 apps, we found the following types: apps for ECG education and interpretation, cardiology news and journals, blood pressure tracking, heart rate monitoring using an external device, and apps with instructions about CPR. These categories equal a total of 364 apps, which is more than half of the total apps found.

Despite the fact that the classification shown in Tables 2 and 3 is subjective, we believe we obtained the most realistic classification, performing several iterations until arriving at the final one. As a result, those categories with similar patterns and characteristics have been merged, whereas others with unique features were not, in order not to lose information in the process. As a result, there are many categories with few apps, some of them highly useful and interesting, such as apps related to resuscitation procedures, including apps with CPR and/or AED instructions, essential for properly performing a resuscitation and, hence, saving lives. There were also AED location apps, which indicate the position of nearby AEDs for cardiac emergencies with the help of the GPS (Global Positioning System) included in every modern smartphone. Other compelling apps are those designed to locate cardiac emergencies, through the help of the users, either sending an emergency alarm or receiving it in order to assist them on site. The majority of these types of apps are free; therefore, their use has no additional cost to the user. Since the outcomes they can achieve are significant (eg, saving the life of a person suffering a heart attack), it would be better if there were more available and they were also free.

There are other categories with very few apps (or even no apps), which could provide significant assistance and help. Examples are guides for cardiac rehabilitation and apps for the management of a cardiac condition, with only one app of each type.

Since a rehabilitation program for people who have suffered or suffer heart problems (or have had a heart surgery) is vital [37,38] in order to avoid more worrisome consequences, it would be beneficial for these individuals to have a guide with exercises and instructions for complete rehabilitation of their hearts. Similarly, apps for the management of heart conditions can be useful for people suffering congenital heart defects involving arrhythmia, angina, fibrillations, etc. In addition to this, it is surprising that there are no apps for aiding people who have undergone a heart transplant, since guidelines, exercises, or even medication management would be of help.

Figure 3 shows the numbers of apps for a specific target public, where it is clear that the users preferred by developers are general users and health care professionals. Typical apps for the general public are heart rate monitors, blood pressure trackers, apps with health tips, educational apps, and resuscitation (CPR and AED) guides. Common apps for professionals are calculators and predictors useful for diagnosis or treatment, specific educational apps and references (angiography, catheters, surgery, etc), and guides, books, and apps for assisting in the diagnosis. Educational apps about medicine and apps for the preparation of medical exams are usually designed for students. The apps intended for common people, medical students, and professionals (category “Everyone”) are usually educational and informative apps while typical apps for patients are those for the care of their condition, some with calculators to assess their state and informative guides. The apps for pregnant women are fetal heart rate monitors. Here we note that there are few apps designed exclusively for patients. Nevertheless, there are many general informative applications that can be used by patients; hence, these apps can compensate for the lack of specific apps for patients. However, a preferable option would be the creation of a specific app for the treatment of a determined condition in order to help the affected in a more appropriate way.

Figure 4. Snapshot of Runtastic Heart Rate.

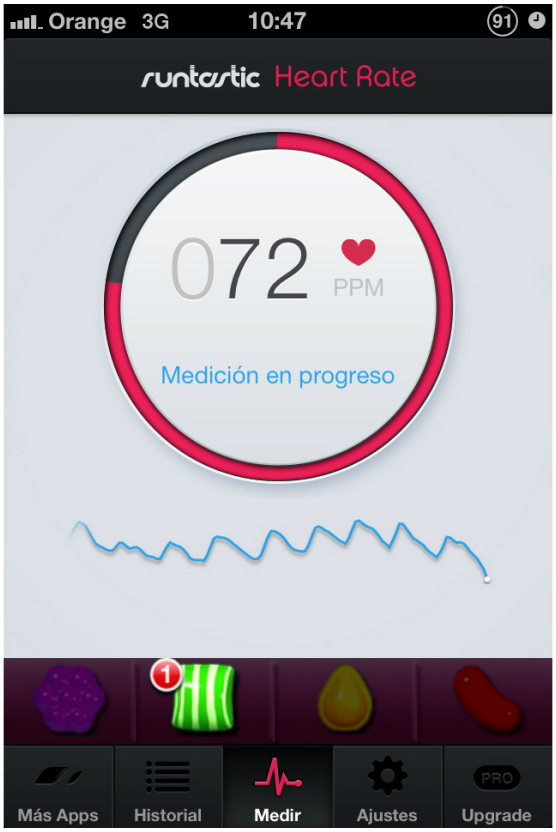
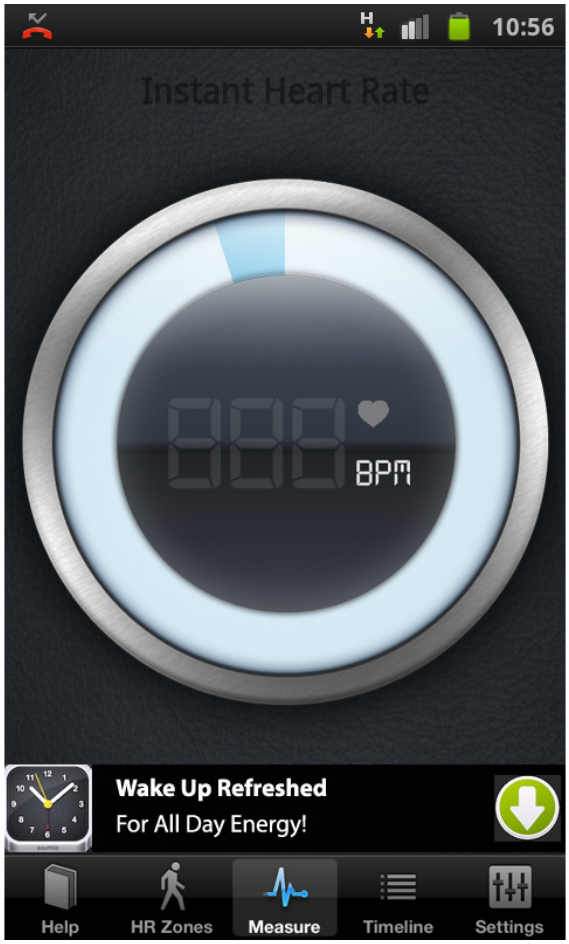


Figure 5. Snapshot of Instant Heart Rate.



Conclusions

Comparing the results for each store, several conclusions can be made. First, there are more apps related to cardiology in the App Store, despite the fact that Android is more prevalent than iOS [23,24]. Figure 3 shows that the numbers related to target users obtained for Apple are consistent with the numbers for Google play, suggesting that the developers for both stores have similar approaches and ideas. The data shown in Table 3 reveal interesting findings. Google play exceeds the App Store only in the number of free apps. Despite the fact that the highest-price app on the App Store is more expensive than the corresponding on Google play, the mean price is lower than the one in Google play, whether free apps are included or not. This was unexpected, since there is a collective belief that iOS devices (especially iPhones and iPads) are more exclusive (usually used in the business environment) and expensive than Android devices [48,49], and their apps are also considered to be higher quality than apps for Android [27,50]. This seems not to be the case in the cardiology field.

There are various lines of investigation for further research. New applications are needed for the management and monitoring of specific cardiac conditions, designed for the patients affected by them, since there are few currently available. The development of applications with this aim could be rather valuable. Another potential field of research could be the creation of an app with guidelines and information for people who have undergone a heart transplant. Such an app could assist them in their new condition and facilitate their new state. Another field to supply is related to resuscitation guides and instructions. Although there are several useful apps with such functions, the creation of an app with different functionalities parallel to the existing ones could be another beneficial field of research, perhaps developing the idea of the location of cardiac emergencies for people trained in resuscitation skills.

Acknowledgments

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

AED: automated external defibrillator
BLS: basic life support
CPR: cardiopulmonary resuscitation
CVDs: cardiovascular diseases
DALYs: disability-adjusted life years
ECG: electrocardiography
GPS: Global Positioning System
IDC: International Data Corporation
WHO: World Health Organization

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Original Paper

Development of a Smartphone App for a Genetics Website: The Amyotrophic Lateral Sclerosis Online Genetics Database (ALSoD)

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Abstract

Background: The ALS Online Genetics Database (ALSoD) website holds mutation, geographical, and phenotype data on genes implicated in amyotrophic lateral sclerosis (ALS) and links to bioinformatics resources, publications, and tools for analysis. On average, there are 300 unique visits per day, suggesting a high demand from the research community. To enable wider access, we developed a mobile-friendly version of the website and a smartphone app.

Objective: We sought to compare data traffic before and after implementation of a mobile version of the website to assess utility.

Methods: We identified the most frequently viewed pages using Google Analytics and our in-house analytic monitoring. For these, we optimized the content layout of the screen, reduced image sizes, and summarized available information. We used the Microsoft .NET framework mobile detection property (HttpRequest.IsMobileDevice in the Request.Browser object in conjunction with HttpRequest.UserAgent), which returns a true value if the browser is a recognized mobile device. For app development, we used the Eclipse integrated development environment with Android plug-ins. We wrapped the mobile website version with the WebView object in Android. Simulators were downloaded to test and debug the applications.

Results: The website automatically detects access from a mobile phone and redirects pages to fit the smaller screen. Because the amount of data stored on ALSoD is very large, the available information for display using smartphone access is deliberately restricted to improve usability. Visits to the website increased from 2231 to 2820, yielding a 26% increase from the pre-mobile to post-mobile period and an increase from 103 to 340 visits (230%) using mobile devices (including tablets). The smartphone app is currently available on BlackBerry and Android devices and will be available shortly on iOS as well.

Conclusions: Further development of the ALSoD website has allowed access through smartphones and tablets, either through the website or directly through a mobile app, making genetic data stored on the database readily accessible to researchers and patients across multiple devices.

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KEYWORDS

ALSoD; amyotrophic lateral sclerosis; frontotemporal dementia; Web-bases; database; genetics; bioinformatics; mobile website; app

Introduction

Amyotrophic lateral sclerosis (ALS) is a neurodegenerative disease of motor neurons resulting in progressive weakness of voluntary muscles. Death usually follows 2-5 years after the first symptoms appear, due to respiratory failure [1]. The causes of ALS are largely unknown, but a genetic component is present even in those without a family history of the disease. The gene variants contributing to risk have been identified in about 15% of the affected population, and the proportion is increasing rapidly. The ALS Online Genetics Database (ALSoD) [2] is a freely available database funded by major ALS charities (the ALS Association, the Motor Neurone Disease Association, ALS Canada, and MNDA Iceland) and sponsored by the European Network for the Cure of ALS and the World Federation of Neurology. It is aimed at researchers and clinicians and is designed for collation and bioinformatics analysis of ALS gene and phenotypic information. It typically receives about 300 unique visits a day [3,4].

Like most websites, ALSoD was initially built to display information to users of desktops and laptops, and the pages are configured to suit the height and width of those screens. With changes in browsing habits, website access is now often through a small portable device like a smartphone or tablet computer. It is therefore essential to ensure data will display correctly on a small device [5,6]. Mobile device data traffic has overtaken desktop traffic in the last decade, and data traffic on mobile devices for browsing alone has risen more than four times in 2008 [5]. According to NetMarketShare, the introduction of the Apple mobile device operating system, iOS, for the Apple iPad and iPhone for mobile browsing between March and October 2010 doubled Internet traffic [7], leading to a projection that, by 2014, mobile Internet usage will overtake desktop Internet usage [8]. Although the target community for ALSoD is mainly university or hospital-based users where desktop and laptop computers are common, such users are increasingly likely to use a portable device for use in clinic settings, conferences, or the laboratory, where fast access away from an office may be needed. Thus, it is essential that the ALSoD website is accessible not just from a desktop or laptop computer, but also from portable devices.

Mobile phone displays have greatly improved from the early monochrome screens for sending SMS messages to colorful graphical touch screens for mobile browsing [9]. Issues of low bandwidth and low resolution screens have been resolved, and smartphones and tablets should be regarded as "mobile computers" [10-13]. It therefore makes sense to write webpages specifically for portable devices. Mobile webpage content is similar to desktop webpage content and uses HTML connected and accessible over the Internet, even though mobile websites are typically accessed through Wi-Fi, 3G, or 4G networks [14]. Furthermore, portable devices are able to use applications (apps) specific to a website for access, rather than a generic browser, with the advantage of offline access to some information. Apps are generally platform-specific and downloaded from company portals, for example, BlackBerry App World, Apple App Store, and Google Play [14]. Thus, as well as writing ALSoD webpages specific for mobile devices, we also aimed to design a platform-specific app to enable some offline content and improve the user experience.

Methods

Optimization of Webpages

Our first focus was on the development of a mobile Web-based platform because we wanted the content to work across all mobile platforms [6]. Identification of the most viewed information was carried out using in-house analytic data coupled with the Google Analytics service configured for the ALSoD website. The Google Analytics tool was configured in August 2012. We based our data analysis on the 3 subsequent months (August, September, and October). These represent the period from when the Google Analytics tool was implemented to the point where we started the development of the mobile website and will be referred to as the pre-mobile website period. The 3-month period from November 2012 to January 2013 with the mobile website fully developed and the app implemented will be referred to as the post-mobile website period. In the pre-mobile website period, page views (the total number of pages viewed) were analyzed to discover the commonly visited pages on the website, including repeated views of a single page.

Design Heuristics

Designing a mobile website that works on several platforms does not mean shrinking a complete webpage into a mini-sized webpage; the aim is to eliminate very small type, scrolling left or right, and typing, and to achieve the outcome required with a single click [6,15]. We therefore created a separate style sheet, retained some original images, reduced the size of images by a fixed percentage, configured the content layout of the screen to wrap text, and summarized the information on the desktop version to fit a smaller screen.

Mobile Device Detection

To detect if the request comes from a mobile device, the .NET Framework provides the "isMobileDevice" property, which returns a true value if the browser is a recognized mobile device. This does not always work because some mobile device browsers disguise themselves as desktop browsers [16]. We therefore use "UserAgent" strings sent by the mobile device browser to the server in conjunction with the "isMobileDevice", as described in Multimedia Appendix 1 and with an overview in Figure 1.

Requesting Responses

Text messages and BlackBerry Messenger messages were sent to a selection of individuals known to the authors, asking them to view the ALSoD Web address on their phones and tablets. After the app was developed, additional users were asked to download the app via Google Play. Since ALSoD has a Facebook [17] account, a Facebook "Recommend" Button was embedded on the mobile master page. All users were asked to click on the Facebook Recommend button so as to have an estimate of the number of users who were satisfied with the outcome of the display on their phone, as seen in Figure 2.

Figure 1. Overview of mobile website development.

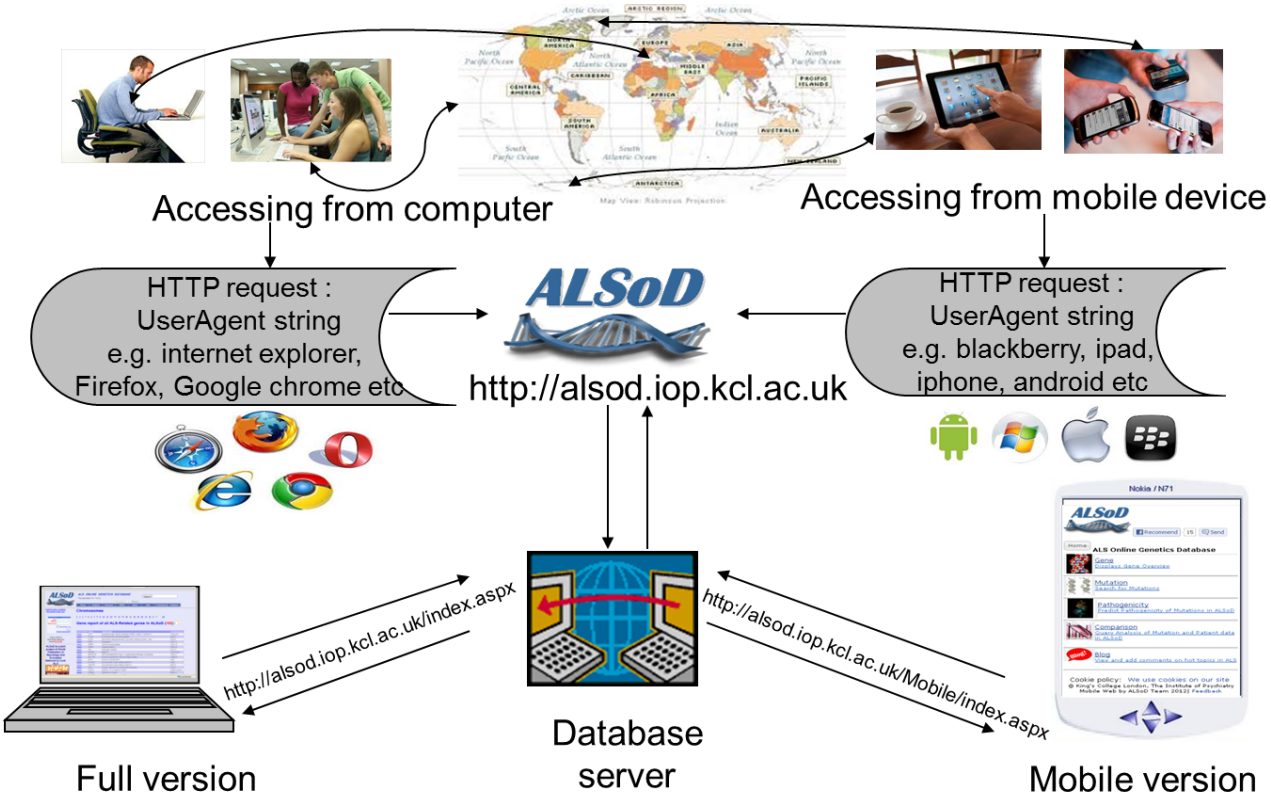
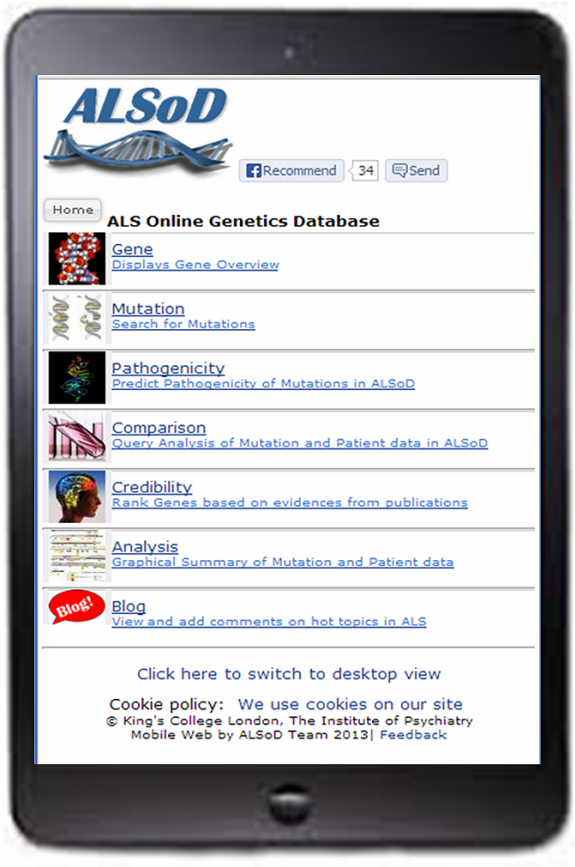


Figure 2. Mobile view of website.



App Development

The most commonly used smartphone platforms are iOS, BlackBerry, Android, and Windows Mobile. We used Eclipse software as the integrated development environment (IDE), with the Android software development kit (SDK), Android development tools (ADT) plugin, BlackBerry plugin, and the latest SDK tools and platforms, downloaded using the SDK Manager [18-22].

App Submission

From Eclipse, the application was compiled producing an .apk file (Android application package file format). This file was submitted to a registered Google Play account with a generated keystore containing a private key [23]. The ALSoD app can be downloaded from Google Play and currently, our Google app account confirms that the ALSoD app has had more than 100 downloads. The app then displays the website (designed using the Microsoft ASP.NET framework) with no status bar or URL navigation on the screen.

Creating Awareness

A marquee function scrolling text from right to left was inserted on the desktop master page to create an alert for regular users of the website, as seen in Figure 3. At symposiums and seminars, researchers were exposed to the recent development of the mobile app, which has contributed to increased Web traffic to ALSoD.

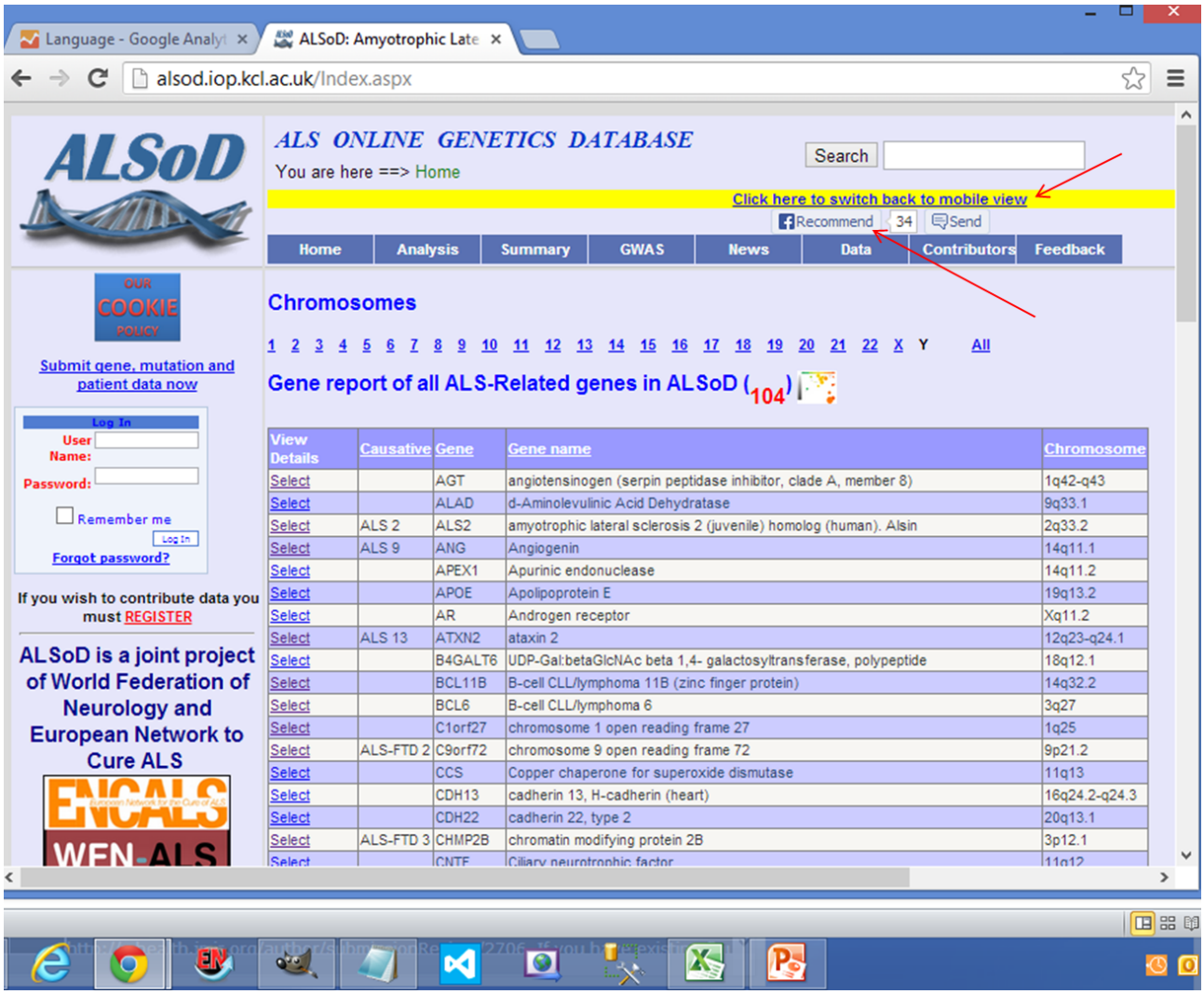
Feedback From App Users

During the various presentations of the mobile app development through posters and seminars, practical assessment of the website on mobile phones was carried out by attendants. Responses, questions asked, concerns raised, and critical analysis given by the audience were recorded and considered.

Analysis of Visits

The Google Analytics account for ALSoD was created in August 2012 to compare results generated by the two tools (mobile website and app) and to gain insight into the changes of the design and content of the website [24]. Visits were compared for the period before mobile website development, from August 2012 to October 2012, with the period after, from November 2012 to January 2013.

Figure 3. Desktop view creating awareness using Facebook and a marquee.



Results

Optimization of Webpages

In the 6-month data analysis period from August 2012 to January 2013, there were 5051 visits to the website, of which 2698 were unique (53%). There were 19,785 page views, of which 8883 (45%) were to 4 sets of pages. These pages focused on the pathogenicity of mutations, gene information, data analysis of mutations, and patient data.

Design Heuristics

Pages were optimized for mobile browsing by reducing image size to 5% of the original size, creating a mobile master page different from the desktop master page, and creating a link page to allow users to switch seamlessly between the mobile and desktop views.

Mobile Device Detection

If the UserAgent string contained keywords suggesting a mobile platform, for example, BlackBerry, Palm, mobile, iPhone, or iPad, then the user's device was redirected to the mobile site [25] displaying the compact version (Figure 2) of the website instead of the full version (Figure 3) [11].

Requesting Responses

To test this, we sent the mobile site URL to mobile phones of 14 users (colleagues and friends from whom we could easily obtain verbal feedback): 3 on the Android platform, 1 on the Windows Phone, 5 on BlackBerry OS, and 5 on iOS (2 iPhone and 3 iPad). All users gave positive feedback except for the Windows Phone user who could not utilize the pages with dropdown boxes.

App Development

Following successful implementation of the mobile website, we began app development. One straightforward method to achieve this is to automatically convert an already-built mobile website into a native app. This is done through the "WebView" object, which is an in-app Web browser used to display a website as if viewed on the browser of an Android smartphone [11]. For testing, we downloaded and used Android simulators. The plugins allow programmers to develop, test, and debug a Java application using the Eclipse IDE, but it requires a high level of programming skill [26]. We also tested and manipulated the .apk file on a real Android phone before submitting to Google Play.

Creating Awareness

Following the development of the mobile version, on the ALSoD Facebook page, 34 users recommended the website by May 29, 2013, using the Facebook "Recommend" button embedded on the website. Current tabular data are available on the website [27], displaying the growth of visits to the genetic database, as seen graphically in Figure 4.

Feedback From App Users

After the creation, testing, and publicity of the app, we received feedback from users about: caching for offline viewing [28-30], which would enable users to continue work; having a "page loading" icon when connecting; making users aware of the cookies policy; using an option menu button [31] to display analysis webpages (interaction.aspx, credibility.aspx, analysis.aspx); and creating a link to allow users to switch from mobile view to desktop view, as this would be useful on tablets like the iPad. We were able to implement all changes except for the offline viewing, which is difficult to implement because the database is large and held online.

Analysis of Visits

Our Google Analytics account showed that visits to the website increased from 2231 to 2820, yielding a 26% increase from pre-mobile period to post-mobile period and a 230% increase on the use of mobile devices (including tablets) to access the ALSoD website. On average, there were 300 unique visitors a day suggesting a high demand from the research community. A total of 1595 unique visitors in the post-mobile era accessed 11,376 page views on the website as opposed to 1220 unique visitors in the pre-mobile period (an increase of 31%), showing the relevance of a mobile-friendly website. Five mobile operating systems (Android, iOS, BlackBerry, Windows Phone, Symbian) were detected to have accessed the website within 6 months. Although BlackBerry OS visits declined from 34 to 14 visits (58%), iOS for iPhones and iPads increased from 40 to 105 visits (162%), and visits by Android devices increased from 29 to 213 visits (634%) (see Table 1). The Google search engine was the most used to search for the website (see Table 2). The likely explanation for the great increase in the use of Android devices is the development and introduction of the Android app submitted to Google Play.

Table 1. Comparison of website visits between the pre-mobile and post-mobile development.

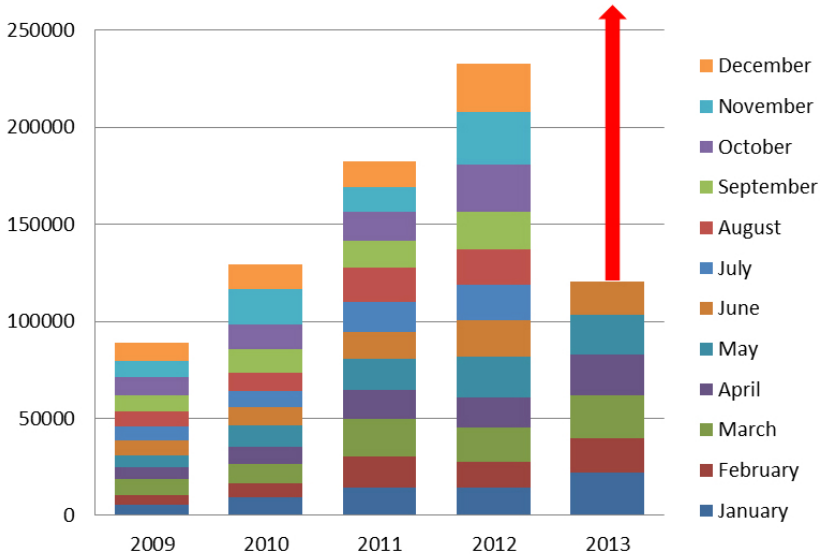
Operating system		Visits	Pages per visit	Avg visit duration	% new visits	Bounce rate, %
Totals						
		26.40%	7.03%	1.48%	4.25	2.98
		2820 vs 2231	4.03 vs 3.77	00:03:55 vs 00:03:58	52.45 vs 54.77	47.45 vs 48.90
Windows						
	01/Nov/2012-31/Jan/2013	1945	4.25	00:04:20	49.56	44.78
	01/Aug/2012-31/Oct/2012	1564	3.85	00:04:13	56.46	48.34
	% Change	24.36	10.47	2.71	-12.21	-7.36
Macintosh						
	01/Nov/2012-31/Jan/2013	435	3.26	00:02:36	51.26	53.33
	01/Aug/2012-31/Oct/2012	490	3.27	00:02:50	51.02	54.08
	% Change	-11.22	-0.28	-8.71	0.48	-1.38
Android						
	01/Nov/2012-31/Jan/2013	213	2.35	00:01:29	76.53	63.85
	01/Aug/2012-31/Oct/2012	29	4.93	00:03:12	65.52	44.83
	% Change	634.48	-52.30	-53.69	16.80	42.43
iOS						
	01/Nov/2012-31/Jan/2013	105	4.52	00:02:31	82.86	48.57
	01/Aug/2012-31/Oct/2012	40	4.55	00:02:06	87.50	50.00
	% Change	162.50	-0.58	19.77	-5.31	-2.86
Linux						
	01/Nov/2012-31/Jan/2013	85	6.51	00:08:11	28.24	29.41
	01/Aug/2012-31/Oct/2012	61	3.23	00:03:13	34.43	32.79
	% Change	39.34	101.45	154.08	-17.98	-10.29
Other systems						
	01/Nov/2012-31/Jan/2013	15	1.07	00:00:28	100.00	93.33
	01/Aug/2012-31/Oct/2012	13	1.92	00:00:43	92.31	84.62
	% Change	15.38	-44.53	-35.61	8.33	10.30
BlackBerry						
	01/Nov/2012-31/Jan/2013	14	8.14	00:11:10	0.00	28.57
	01/Aug/2012-31/Oct/2012	34	7.12	00:14:12	5.88	17.65
	% Change	-58.82	14.40	-21.31	-100.00	61.90
Windows Phone						
	01/Nov/2012-31/Jan/2013	4	6.75	00:08:02	50.00	50.00
	01/Aug/2012-31/Oct/2012	0	0	00:00:00	0.00	0.00
	% Change	∞	∞	∞	∞	∞
LG						
	01/Nov/2012-31/Jan/2013	3	1.33	00:00:11	0.00	66.67
	01/Aug/2012-31/Oct/2012	0	0	00:00:00	0.00	0.00
	% Change	∞	∞	∞	0.00	∞
Samsung						
	01/Nov/2012-31/Jan/2013	1	1	00:00:00	100.00	100.00

Operating system	Visits	Pages per visit	Avg visit duration	% new visits	Bounce rate, %
01/Aug/2012-31/Oct/2012	0	0	00:00:00	0.00	0.00
% Change	∞	∞	0.00	∞	∞

Table 2. Referral traffic from search engines from August 2012 to June 2013.

Source	Visits	Pages per visit	Avg. visit duration	% new visits	Bounce rate, %
Google	4339	4.06	00:04:54	42.73	46.58
Yahoo	62	3.63	00:02:42	51.61	41.94
Bing	32	5.53	00:07:11	62.50	31.25
Baidu	21	6.19	00:12:50	23.81	23.81
Daum	13	3.46	00:06:35	30.77	30.77
Ask	10	4.9	00:08:33	20.00	20.00
Conduit	8	17.62	00:08:27	37.50	25.00
AOL	7	1	00:00:00	71.43	100.00
Other search engines	5	6	00:04:24	0.00	0.00
Yandex	4	1.25	00:00:04	100.00	75.00
Babylon	3	1.33	00:00:33	100.00	66.67
AVG	1	1	00:00:00	100.00	100.00
Comcast	1	1	00:00:00	100.00	100.00

Figure 4. Graphical display of increased Web traffic on ALSoD.



Discussion

Principal Findings

ALSoD was developed as a disease-specific database for ALS, focused on genetics and phenotype, with planned incorporation of environmental and other risk factors in the future. We have shown that development of the website to facilitate smartphone access has greatly increased access.

In broad terms, there are two strategies for development of an app like this. Either the app can be developed as stand-alone software or it can be developed as a means to access an existing mobile website. We chose access to a mobile website for several reasons. First, we used this approach because mobile websites are immediately accessible to users through a browser, more compatible across devices, have easier content updates, are faster to find on search engines, make it easier to share content via a link, have a longer lifecycle on a user's device, are easily convertible to an app, and are more cost-effective [14,32]. Second, the database is regularly updated with data, which would require the release of weekly updates to an app if the website was not the primary content holder. Third, although third-party automated app development tools exist [33,34], it

was simple for us to convert the mobile website into an Android app using the WebView object.

A limitation to this approach is that the website recognizes a mobile device based on the information held in the list in the UserAgents string. Although software exists to automatically update the list, there is a financial cost involved and we have therefore chosen to update the list manually. Furthermore, UserAgents strings are limited in the kind of information sent to the server. Specific information such as the size of the screen, the manufacturer, the format of image supported, and the model of phone are not sent. This is an issue because some mobile devices allow portrait and landscape views when repositioned while others have unique width and height dimensions. It is therefore difficult to have a perfect display on all devices.

There are 3 main methods by which users access the website (Table 2). Roughly 39% of the traffic is organic from the Google search engine, 37% is direct by typing the ALSoD URL directly on a browser, and the rest are referrals through external sites collaborating with ALSoD.

More than 100 interactive, downloadable widgets and mobile applications have been submitted to the NHS Choices Health Apps library [35]. Some of these apps are commercial apps and the freely available ones range from calculating alcohol consumption to weight tracking. There are no specific genetics disease apps that concentrate on combining genotype, phenotype, and geographical information with associated analysis tools, although ALS database apps do exist. For example, the PatientsLikeMe app was initially developed to help United Kingdom-based ALS patients find clinical trials that are right for them and organizations find patients right for their trials [36,37]. The ALSoD app has direct relevance to clinicians working in ALS and therefore relevance to the NHS Choices Health Apps library. It includes a comparison tool to evaluate information for different genes side by side or jointly with user configurable features, a pathogenicity prediction tool using a combination of computational approaches to distinguish variants with nonfunctional characteristics from disease-associated mutations with more dangerous consequences, and a credibility tool to enable ALS clinicians and researchers to objectively assess the evidence for gene-causation in ALS. A checklist, as seen in Multimedia Appendix 2, was used to report the web-based intervention of users [38]. Furthermore, integration of external tools, systems for feedback, annotation by users, and two-way links to collaborators hosting complementary databases further enhance the functionality.

Conclusions

Development of the mobile website and associated app has increased access to this disease-specific database and facilitated access through a wide range of devices. Visitor analysis has shown the importance of collaborating with other relevant databases through hyperlinks. Our future work will concentrate on further integration with other databases, adding in nongenetic risk factors, and increasing access and relevance for related research disciplines.

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Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

Script for redirecting views.

[PDF File (Adobe PDF File), 20KB - mhealth_v1i2e18_app1.pdf]

Multimedia Appendix 2

CONSORT-EHEALTH checklist V1.6.2 [38].

[PDF File (Adobe PDF File), 982KB - mhealth_v1i2e18_app2.pdf]

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Abbreviations

ALSoD: Amyotrophic Lateral Sclerosis Online Genetics Database
ASP.NET: active server page network
IDE: integrated development environment
Master page: provides automatic layout, pagination, headers and footers, and graphic elements for multiple pages.
OS: operating system
SMS: short message service
UserAgent: a user agent is software (a software agent) that is acting on behalf of a user.
Wi-Fi: wireless local area network

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Corrigenda and Addenda

Metadata Correction: Usage of Multilingual Mobile Translation Applications in Clinical Settings

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The authors of "Usage of Multilingual Mobile Translation Applications in Clinical Settings" (JMIR Mhealth Uhealth 2013 (Apr 23); 1(1):e4) inadvertently omitted Regina Schmeer (Nursing Department, Hannover Medical School) from the list of authors during the submission process. The author Schmeer should have been added after Marianne Behrends in the originally published manuscript. The footnote "all authors contributed equally" extends to the omitted author. The omitted author certified that there are no conflicts of interests to add. This error has been corrected in the online version of the paper on the JMIR website on August 7, 2013, together with publishing this correction notice. This was done before submission to PubMed or Pubmed Central and other full-text repositories.

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