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Original Paper

A Smart Insole to Promote Healthy Aging for Frail Elderly Individuals: Specifications, Design, and Preliminary Results

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Abstract

Background: Older individuals frequently experience reversible “frailty syndrome,” increasing incidence of disability. Although physical exercise interventions may delay functional decline, there are difficulties in implementing them and performing seamless follow-up at home. Very few technological solutions attempt to address this challenge and improve individual participation.

Objective: Our objectives are to (1) develop a technological solution designed to support active aging of frail older persons, (2) conduct a first laboratory evaluation of the device, and (3) design a multidimensional clinical trial to validate our solution.

Methods: We conducted a first phase of multidisciplinary meetings to identify real end users and health professional’s unmet needs, and to produce specifications for the architecture of the solution. In a second phase, we performed laboratory tests of the first proposed prototype (a smart insole) with 3 healthy volunteers. We then designed an ongoing clinical trial to finalize the multidimensional evaluation and improvement of the solution.

Results: To respond to the needs expressed by the stakeholders (frailty monitoring and adherence improvement), we developed a prototype of smart shoe insole to monitor key parameters of frailty during daily life and promote walking. It is a noninvasive wireless insole, which automatically measures gait parameters and transmits information to a remote terminal via a secure Internet connection. To ensure the solution’s autonomy and transparency, we developed an original energy harvesting system, which transforms mechanical energy produced by the user’s walking movement into electrical energy. The first laboratory tests of this technological solution showed good reliability measures and also a good acceptability for the users. We have planned an original iterative medical research protocol to validate our solution in real life.

Conclusions: Our smart insole could support preventive strategies against disability in primary care by empowering the older patients without increasing the busy health professional’s workload.

Trial Registration: Clinicaltrials.gov NCT02316600; <https://clinicaltrials.gov/ct2/results?term=NCT02316600&Search=Search>. Accessed: 2015-05-13 . (Archived by WebCite at <http://www.webcitation.org/6YUTkObrQ>).

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KEYWORDS

frail elderly; gait; healthy aging; wearable sensors

Introduction

Many older individuals experience progressive functional decline despite the absence of a clear causal disease. This process has been labeled clinically as the “frailty syndrome” [1], which is characterized by a decrease in the capacities needed by an individual to adequately face stressors. To translate the theoretical concept of frailty into practice, Fried et al [1] proposed a model combining the evaluation of five criteria, namely, muscle weakness, self-reported exhaustion, unintentional weight loss, low physical activity, and slow gait speed. Although frailty is a multimodal syndrome, gait speed is recognized as a global indicator of health in older persons [2]. Several authors have evaluated gait speed as a predictor of future disability, mortality, institutionalization [3-5], and health-related events, even those apparently disconnected to physical function, such as cognitive impairment [6,7].

Frailty is potentially reversible [1], and a number of healthy lifestyle interventions can now be proposed [8-10]. Nevertheless, there are difficulties in implementing long-term preventive interventions, obtaining satisfactory patient adherence, and carrying out seamless follow-up of frail older persons at home.

The use of technology could be relevant for frailty assessment [11], as well as for promoting and monitoring exercise at home [12-14] and predicting health-related events [15]. Computer-based exercise interventions administered via a telecommunications system at home seem to be efficient [16,17], and remote feedback in home-based physical activity interventions seems to be as effective as supervised exercise interventions [18]. Monitoring could potentially, in itself, improve adherence and performances [13]. “Quantified self” devices are already proposed to young robust people to encourage their adherence and motivation (eg, Fitbit, Nike+). By contrast, in current clinical practice, no devices are used to measure activity and gait speed and give feedback to the patient. In fact, follow-up of frail elderly patients is almost nonexistent. However, to reach our goal we need to make more accurate measurements, especially concerning gait speed, and to make it less obtrusive for the end users. Given the importance of the relationship between gait speed at usual pace and risk of adverse events, and because of the amount of change for a 0.1-m/s variation [19], we are seeking 0.1-m/s accuracy, which is not provided by commercial devices and mobile phones. In addition, to ensure long-term acceptability it is important to develop a discreet, transparent, and self-reliable device. Practically, this means that there should be no need for direct human intervention in data transmission and battery charging. That is far from being the case with commercial devices and mobile phones delivered today.

We believe that there is a specific need for the development of a patient-centered device that provides accurate and unobtrusive assessment of physical activity and gait speed, as well as intervention adherence through feedback and self-motivation. Our overall objective is to develop and validate a smart device to support healthy aging of frail older persons (ClinicalTrials.gov identifier NCT02316600).

Methods

We conducted a first phase of medical and technical specifications to develop a device that will address unmet needs of frailty. This first phase involved medical practitioners (gerontologists) from the Toulouse University Hospital (France), who identified unmet medical needs in clinical frailty management. A systematic literature review of technologies for frailty and disability was performed [20], and a focus group was conducted to come to a consensus. The main unmet needs reported from the clinical ward were as follows: the difficulty to follow-up on patients’ frailty indicators in the community setting and to obtain adherence through feedback and motivational coaching. This phase also involved researchers from the Laboratory for Analysis and Architecture of Systems-Centre National de la Recherche Scientifique (LAAS-CNRS) who explored technical opportunities and locks. We then built a consortium to address the device development challenge.

In a second phase, we developed the first prototype of the device (a smart insole) with several partners, including new technologies companies (metrological tools and remote monitoring), podiatrist experts, LAAS-CNRS, and clinical experts on frailty. We were rapidly able to perform laboratory tests of the first prototype with 3 healthy volunteers. This took place in the LAAS-CNRS living laboratory and was part of a multiphased multidimensional trial. The first complete technical laboratory phase, which is not described here, did not include clinical tests and was centered on technical performances of the prototype. The acceptability, security, and performances of the solution are evaluated at each phase of the iterative clinical evaluation, which is fully accepted by the regional medical ethic committee.

Results

Smart Insole Specifications

According to the unmet needs reported from the clinical ward, we were able to resume the medical specifications for the device as follows:

- The device should target the community setting and more specifically the follow-up of the patients;
- The device should measure major physical frailty criteria, such as muscle weakness, unintentional weight loss, low physical activity, and slow gait speed;
- The device should not only perform a seamless follow-up but should also support adherence to recommendations;
- The device should be unobtrusive and need no maintenance;
- The overall solution has to be patient centered, avoiding work overload for the medical practitioner;
- The device should provide patient feedback regarding performances, evolution of health status, and alerts in case of abnormal trends in indicators through existing terminals, such as touchpads or via mobile phones;
- The device should provide a feedback to the medical practitioner through the Internet, including history of health status indicators alerts according to prespecified thresholds and adherence to recommendations.

These medical specifications may express wishes that could not be fulfilled from a technical point of view. This phase also involved researchers from the LAAS-CNRS who explored the technical possibilities and locks. With regard to medical specifications, technical possibilities, and on the basis of previous works [21], we chose to develop a wireless smart shoe insole, which would meet technological specifications, while providing good acceptability and unobtrusiveness for the end users. This device should be able to measure the following:

- Activity periods and their durations over time;
- For each activity period, the number of steps, average speed, and distance covered were calculated;
- Energy expenditure (indirect data);

Unintentional weight loss and muscle weakness will not be directly measured with this first insole prototype. We will have to use other means such as direct questioning via the Web-based interface.

We conducted two sessions with end-user focus group (12 robust old adults) to validate this choice. Given the technical specifications, the consortium—new technologies firms (metrological tools and remote monitoring), podiatrist experts, LAAS-CNRS, and clinical experts on frailty—was able to address the device development challenge.

Prototype Design

In the second phase, we developed the first prototype of the smart insole (Figure 1) including our sensors tag (Figure 2). It was designed by the consortium at the LAAS-CNRS laboratory. Developing an efficient means of powering the device was an important consideration during the design process, thus enabling full autonomy and transparency. Accelerometers and gyroscopes are the most frequently used types of sensors to measure the gait characteristics [22,23]. In our device, we used an accelerometer because it is more compact and consumes less

power than a gyroscope. The printed circuit board embedded in the insole includes the following elements: a low-power 3-axis acceleration sensor, a global system comprising a low-power microprocessor unit and a transceiver, a flash memory for local data logging, and a nano-powered time keeper to activate scheduled data-logging modes. This system measures gait parameters when the accelerometer detects an activity. The dimensions of the system are 3.2 cm × 2.2 cm × 2.0 mm and total weight is 5 g, including the battery. The smart insole will be part of an operational setup illustrated in Figure 3. The following components are included in our system:

- A radio beacon for automatic data collection (when the wireless insole detects the beacon);
- A collection terminal with an Internet connection (touchpad, mobile phone);
- A remote server for database management; and
- A Web application used by the person and his/her physician via a remote access.

In its current version, a lithium battery CR2016 supplies the smart insole with a capacity of 90 mAh. An energy harvesting system is also proposed aiming to produce an unobtrusive self-powered insole. Piezoelectric generators transform mechanical energy produced by the user's walking movement into electrical energy.

This solution monitors several frailty indicators and feedback is given to the user during his/her daily life at home. A screen capture of the end-user Web application is shown in Figures 4 and 5. This will enable the user to be informed about self-adherence with respect to individual physical exercise objectives, personal health status evolution, and a possible alert in case an abnormal trend in indicators occurs. The physician interface is presented in Figure 6. This first prototype does not include weight sensors, which is currently under development but not yet consolidated.

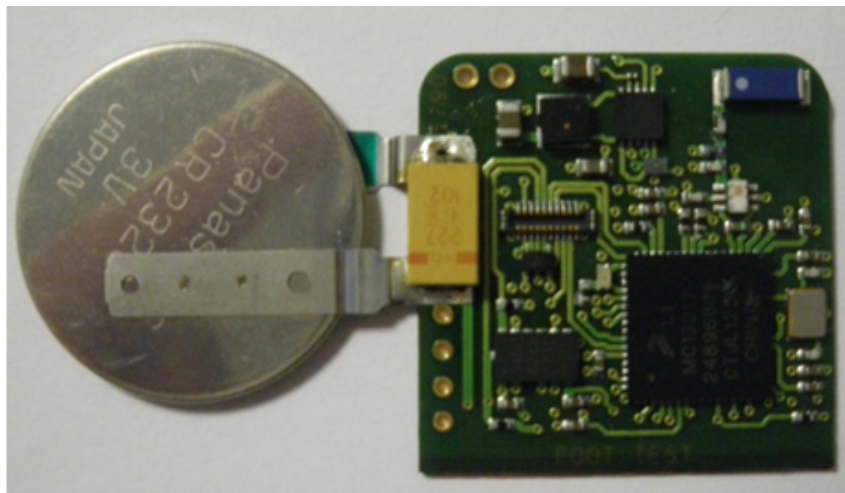
Figure 1. Smart insole.**Figure 2.** Sensors tag.

Figure 3. Operational setup.



Figure 4. End user interface: active minutes.

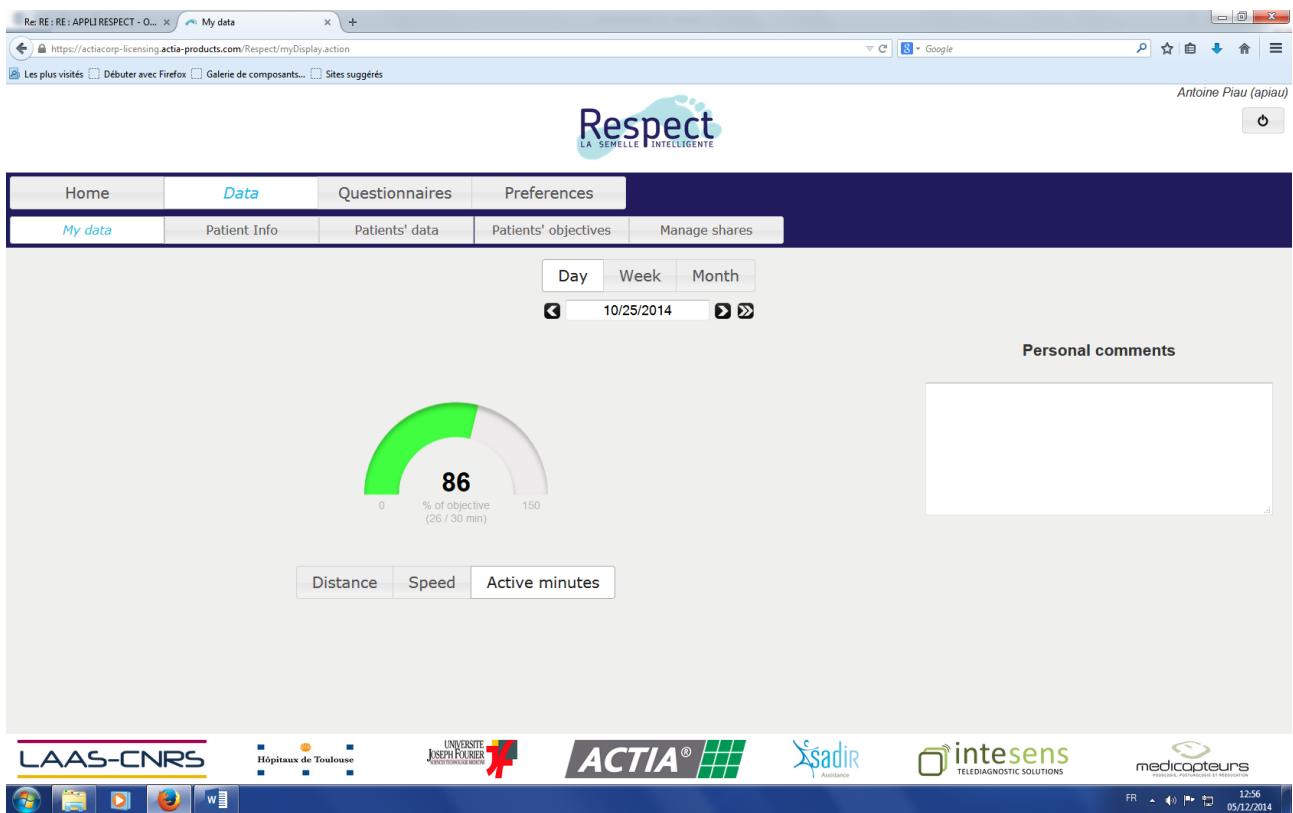


Figure 5. End user interface: distance.

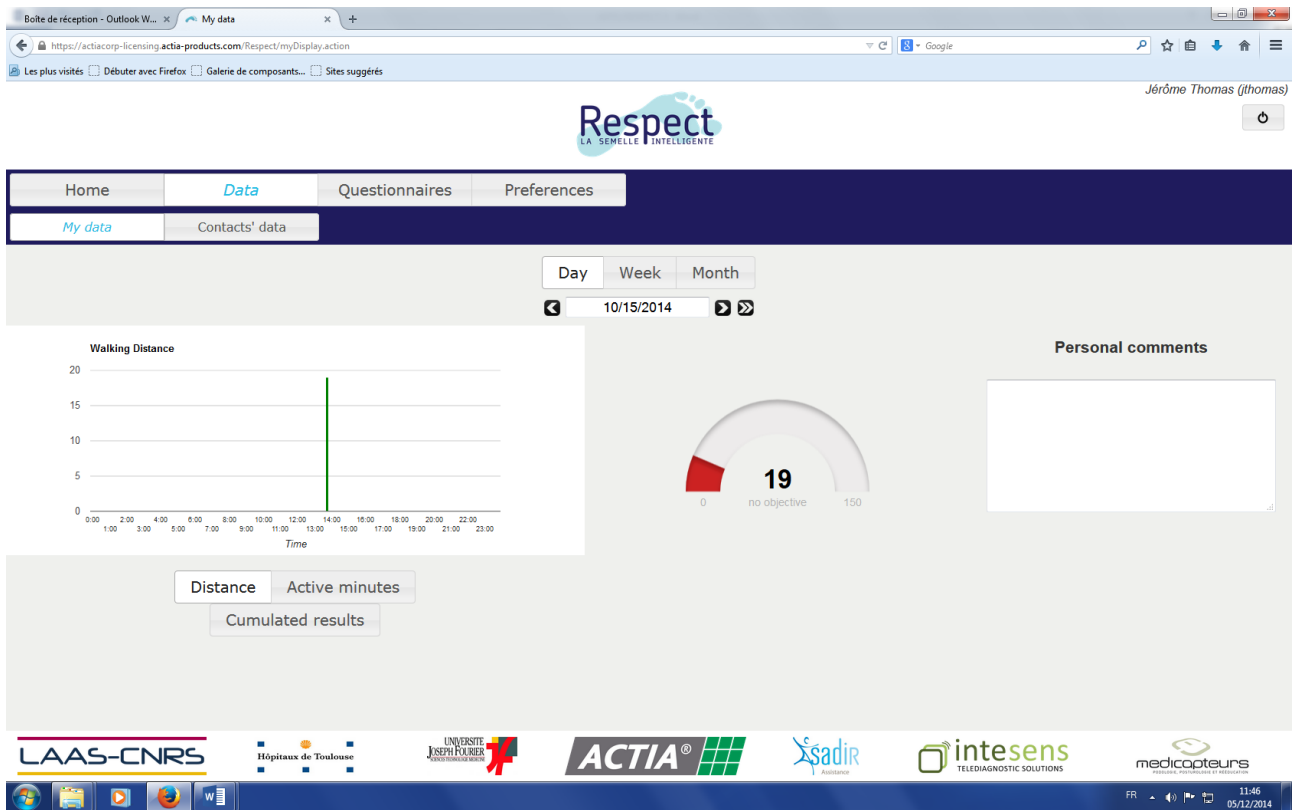
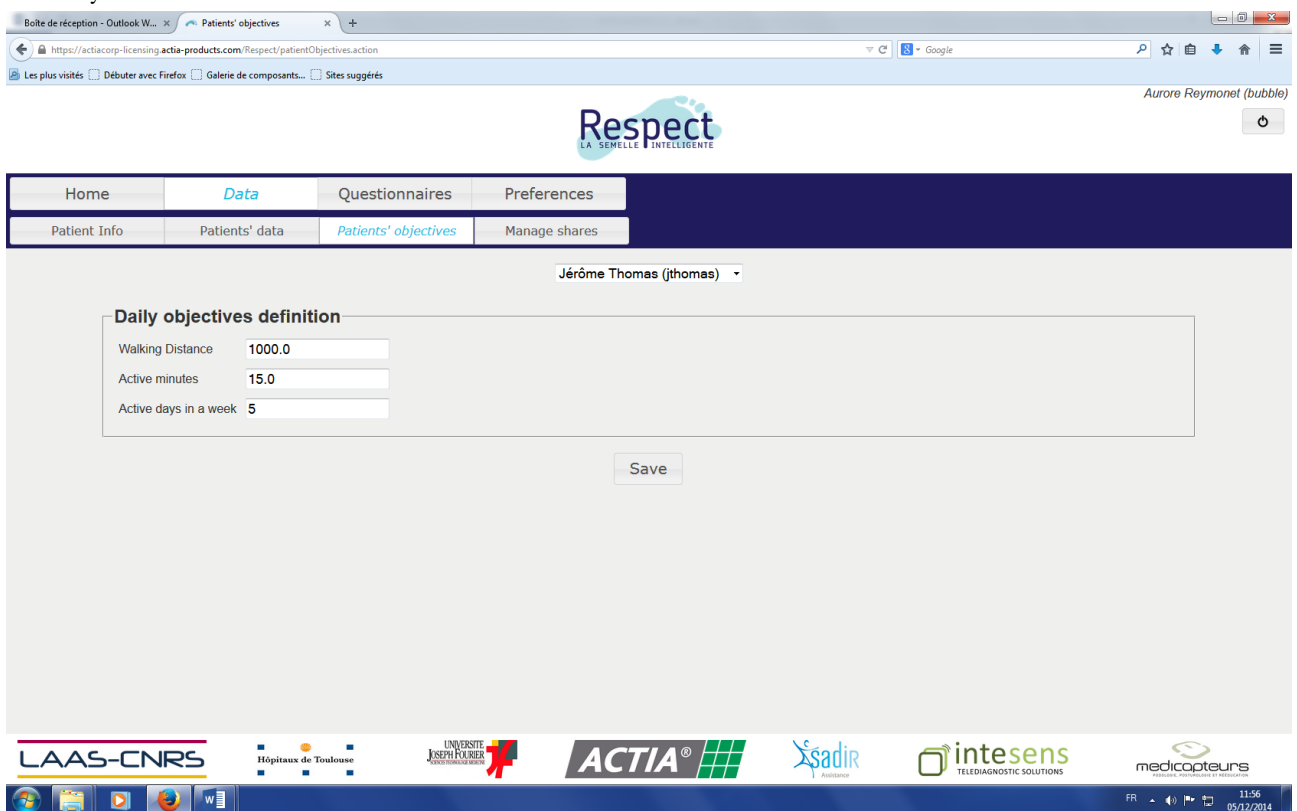


Figure 6. Physician interface.



Preliminary Living Laboratory Findings

Overview

We performed preliminary laboratory tests in 3 healthy volunteers in the LAAS-CNRS living laboratory, to validate the stride detection algorithm for gait speed monitoring before larger clinical trials, as well as to test the energy harvesting system. The volunteers conducted tests on a treadmill by following three-step instructions (slow, medium, and fast).

Gait Speed Monitoring

Accelerometers and gyroscopes are mainly used in the literature [22,24,25] to measure the dynamic characteristics of walking from the foot position. In our device, we used an accelerometer because it is more compact and has more low power consumption than a gyroscope. For stride detection with low-cost accelerometer, Jimenez et al [26] proposed a reliable algorithm with an error of 0.1% for a normal gait speed. We added a method to measure cadence. The accelerometer was set to capture sensor samples at 100 Hz. The algorithm implemented for stride detection and cadence measurement includes the following five steps:

- Compute the magnitude of the acceleration;
- Compute the local mean acceleration value;
- Compute the local acceleration variance, to highlight foot activity and to remove gravity;
- Stride detection with two thresholds on the local acceleration variance: the first threshold detects the rising edge, and the second threshold detects the falling edge (Figure 7); and

- After stride detection, we use it to compute the local cadence expressed in steps/second (1 stride is equivalent to 2 steps) with a sliding windows on the last 3 strides (6 steps).

This stride detection algorithm was implemented in the smart insole. Measurements were performed on a treadmill to determine the robustness of this method. A total of 3 volunteers (men aged 25, 29, and 30 years) were requested to walk at 5 gait speeds on the treadmill, which were fixed (0.5, 0.75, 1.0, 1.25, and 1.5 m/s). For each gait speed, 100 strides were performed. The results for each volunteer are presented in Table 1.

Errors were observed on less than 1% of the number of strides. Less than 1% of error on the number of strides was observed over the entire speed range studied (0.5-1.5 m/s for each step of 0.25 m/s). It was also reported that the measured cadence was relatively stable for a constant gait speed, as cadence variations were approximately 1% for a stable gait speed, over the gait speed range studied. These preliminary tests showed a strong correlation between gait speed and cadence. It seems possible to assess walking speed in an ambulatory setting by measuring cadence, when an individual's specific relationship between cadence and gait speed is established. For this purpose, training would need to be implemented to calculate this relationship. A specific tool was designed to automatically calibrate the measurements of the insole during the training period. This system is based on the use of two light barriers (infrared transceiver combined with an optical reflector and a transmitter) that measure true mean gait speed over a distance of 4 m.

Figure 7. Stride detection process.

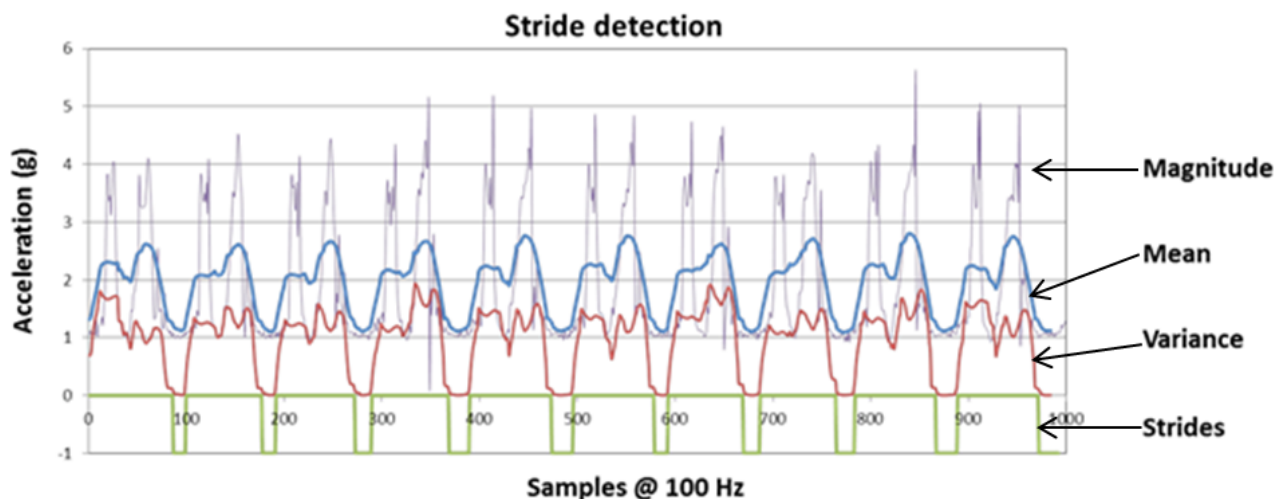


Table 1. Test of the stride detection algorithm.

Gait speed (m/s)	Real number of strides	Number of strides counted by the smart insole	Percentage of errors
Volunteer 1			
0.5	100	102	2
0.75	100	101	1
1	100	100	0
1.25	100	100	0
1.5	100	99	1
Total	500	502	0.4
Volunteer 2			
0.5	100	99	1
0.75	100	99	1
1	100	100	0
1.25	100	99	1
1.5	100	99	1
Total	500	496	0.8
Volunteer 3			
0.5	100	98	2
0.75	100	100	1
1	100	100	0
1.25	100	100	1
1.5	100	99	1
Total	500	497	0.6

Energy Harvesting System

Previous studies have shown that for a 68-kg person walking at a speed of 2 steps/second with a heel movement of 5 cm, the maximum power that can be generated is 67 W [27]. Only thin-film piezoelectric generators can be integrated in the thickness of an insole, such as lead zirconate titanate and polyvinylidene fluoride piezoelectric materials [28]. We tested the feasibility of an energy-autonomous smart insole based on the solution proposed by Smart Material Corporation. For a rapid walking speed (1.5 and 1.75 m/s), energy needs are covered. For a slow walking speed (0.5 m/s), one third of the energy needs are covered. The feasibility stage is conclusive and enables us to launch the design stage of a miniaturized energy harvesting system.

Discussion

Principal Findings

The population is aging rapidly. Yet, added life years are not always lived in healthy conditions and independency. A major goal of aging interventions is not only to extend life, but also to preserve the capacity for independent living. Frailty is considered as a predisability state which, unlike disability, is still amenable for interventions. This new concept of frailty modifies the common geriatric approach by leading it toward the importance of prevention. Nevertheless, we still have

difficulties to implement long-term preventive interventions against disability, to obtain the adequate patient's adherence and participation, and to perform a seamless and efficient follow-up of older persons at home.

Although information and communication technologies (ICTs) have proven their efficiency for monitoring various chronic diseases such as heart failure or diabetes, very limited evidence is available about the application of technologies in early prevention of physical disability [29,30]. According to a review by Marziali et al [31], only 1% of the home health care programs studied focused on this situation. Nevertheless, using technology in this direction does make sense. A review of 2246 publications [32] has demonstrated that quantified self-tools can motivate sedentary individuals to change their habits. ICT, as visiophonic communication, could also be helpful for intervention implementation [33]. Technologies may support intervention at home and prevent negative health-related outcomes by detecting early signs of deteriorating health.

We designed a technological tool to support continuous monitoring of key parameters of frailty. The first version of our unobtrusive insole allowed us to implement the algorithms of the dynamic gait parameters assessment.

In our study, the stride detection method was robust and accurate over the entire speed range studied with healthy young volunteers. A strong correlation was reported between walking speed and cadence and the feasibility of the energy harvesting

system. These tests must be carried out in natural walking conditions with senior end users, which will present walking patterns potentially impeding these results. Even if each individual's specific relationship between cadence and gait speed is established, the relationship could change over time. The uncertainty about the evolution of the relationship between gait speed and cadence in a prefrail and frail elderly population is one of the most important limitations of our project. Scientific data are scarce, but according to a recent review [34], the prominent parameter related to prefrailty is reduced cadence, whereas frailty (vs prefrail status) is characterized by reduced step length in everyday walking. This could potentially drive the necessity to repeat personal calibration process over time. These initial results show the feasibility of an instrumented insole, which is an energy autonomous device (energy harvest and energy generation). Indeed, for a rapid walking speed (1.5 and 1.75 m/s), the energetic needs are covered. In case of slow walking speed (0.5 m/s), one third of the energetic needs are covered. A simple solution to design a more efficient energy harvesting system is to use a piezoelectric generator with a larger active area or to use multiple stacked piezoelectric generators. To cover all the ranges of walking speed, we are also reducing the power consumption of the insole.

Lastly, based on the Toulouse University Hospital method for medical device evaluation, we designed a two-phase original clinical trial to finalize the multidimensional evaluation of the smart insole. Although there is no consensus for health technologies evaluation, several methods have been proposed [35,36]. They all emphasize the multidimensional aspect and the iterative character of the evaluation. The first phase of our testing was centered on gait speed measurement and energy harvesting. We are currently performing two additional phases of multidimensional evaluation thanks to a national grant from the French National Research Agency (Project Number ANR-13-TECS-0007). The first clinical and technical feasibility trial will include 15 healthy old people to evaluate the

acceptability and the technical performances of the first prototype (from October 2014 to December 2015). In parallel with this first clinical phase, we are planning to make technical improvements to the insole by adding an additional frailty parameter measurement: weight monitoring, and by developing a touchpad motivational coaching software through the Internet. Then, the final solution (shoe insole and coaching software) will be evaluated in a larger clinical comparative study to assess its acceptability during field tests in real-life conditions. This phase will include 60 frail individuals living at home (from January 2015 to June 2016). We included a new partner for the acceptability evaluation: Age-Imaging-Modelization Laboratory of the Joseph Fourier University (Grenoble, France), a new research laboratory devoted to the science and technology of aging. We believe that our solution has to be patient centered. Our aim is not to propose telehealth, which would lead to additional costs because of the need for a dedicated helpline. Nevertheless, the solution provides the physician with additional useful information (health status and adherence to recommendations) without interfering with the organization of health care. Access to seamless follow-up could lead to earlier diagnosis and prevention of the high burden of disability. This project also addresses global issues relating to our centralized health system. There is a potential benefit for the frail older persons in adopting this kind of ICT solution, because of their active involvement in a healthy lifestyle project.

Conclusion

Our purpose is to design a technological tool to support continuous monitoring with minimal invasiveness both at home and in the outside environment. This could be potentially helpful to promote healthy lifestyle recommendations in the frail older population. A first prototype has been developed in the living laboratory and has passed through a test phase involving volunteers. We are planning additional phases of multidimensional evaluation in real-life conditions.

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Conflicts of Interest

None declared.

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Abbreviations

ICT: information and communication technology

LAAS-CNRS: Laboratory for Analysis and Architecture of Systems-Centre National de la Recherche Scientifique

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Original Paper

Measurement and Data Transmission Validity of a Multi-Biosensor System for Real-Time Remote Exercise Monitoring Among Cardiac Patients

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Abstract

Background: Remote telemonitoring holds great potential to augment management of patients with coronary heart disease (CHD) and atrial fibrillation (AF) by enabling regular physiological monitoring during physical activity. Remote physiological monitoring may improve home and community exercise-based cardiac rehabilitation (exCR) programs and could improve assessment of the impact and management of pharmacological interventions for heart rate control in individuals with AF.

Objective: Our aim was to evaluate the measurement validity and data transmission reliability of a remote telemonitoring system comprising a wireless multi-parameter physiological sensor, custom mobile app, and middleware platform, among individuals in sinus rhythm and AF.

Methods: Participants in sinus rhythm and with AF undertook simulated daily activities, low, moderate, and/or high intensity exercise. Remote monitoring system heart rate and respiratory rate were compared to reference measures (12-lead ECG and indirect calorimeter). Wireless data transmission loss was calculated between the sensor, mobile app, and remote Internet server.

Results: Median heart rate (-0.30 to 1.10 b·min⁻¹) and respiratory rate (-1.25 to 0.39 br·min⁻¹) measurement biases were small, yet statistically significant (all $P \leq .003$) due to the large number of observations. Measurement reliability was generally excellent ($\rho = .87-.97$, all $P < .001$; intraclass correlation coefficient [ICC] = .94-.98, all $P < .001$; coefficient of variation [CV] = 2.24-7.94%), although respiratory rate measurement reliability was poor among AF participants ($\rho = .43$, $P < .001$; ICC = .55, $P < .001$; CV = 16.61%). Data loss was minimal (<5%) when all system components were active; however, instability of the network hosting the remote data capture server resulted in data loss at the remote Internet server during some trials.

Conclusions: System validity was sufficient for remote monitoring of heart and respiratory rates across a range of exercise intensities. Remote exercise monitoring has potential to augment current exCR and heart rate control management approaches by enabling the provision of individually tailored care to individuals outside traditional clinical environments.

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KEYWORDS

telemedicine; remote sensing technology; telemetry; smartphone; mHealth; rehabilitation; cardiac rehabilitation

Introduction

Cardiovascular diseases remain the leading cause of morbidity and mortality worldwide, accounting for around one third (approximately 17 million) of deaths globally, with the greatest proportion of deaths attributed to coronary heart disease (CHD) [1]. Cardiac rehabilitation (CR) is an essential component of CHD management [2,3], and international guidelines consistently identify exercise training as a central element of CR [4-6]. The beneficial effects of exercise-based CR (exCR) on all-cause and cardiac mortality are comparable with comprehensive CR [7-10], and exercise training can concurrently improve an array of modifiable cardiac risk factors including hypertension, dyslipidemia, insulin resistance, overweight and obesity, and exercise capacity [10-15]. Despite these benefits, many eligible patients are not referred for CR [16], and uptake is low among those who are referred [17,18]. Common participation barriers include transport limitations, work commitments, and inconvenient program scheduling [19]. Among those who do undertake CR, adherence to prescribed exercise is poor with up to 50% of participants dropping out of regular exercise within 6 months of program completion [20-22]. It is clear traditional CR delivery models do not meet the needs of many eligible patients, and innovation is required to enhance participation and adherence.

Home-based exCR has been introduced to broaden access and participation and confers similar improvements in mortality, cardiac events, and cardiac risk factors compared to center-based CR [23]. Home-based programs overcome several traditional participation barriers, but many do not include physiological monitoring that is typical during center-based exCR. In addition to concerns about patient safety, a lack of physiological monitoring also restricts the potential to individualize and optimally manage exercise prescription. As the beneficial effects of exCR are dose-dependent [11,24,25], remote physiological monitoring may help home-based exCR participants to achieve recommended exercise training loads and improve program outcomes.

Physiological monitoring has recently been identified as a particularly important direction for the future development of home-based exCR [26], but to date, most telehealth CR interventions have utilized fixed-line communication tools (eg, telephone, Internet, videoconferencing, transtelephonic electrocardiogram [ECG]) that constrain participants within the home environment. Recent advances in mobile sensor technologies and rapidly growing access to mobile broadband [27] enable real-time remote physiological monitoring outside fixed-line communication networks, and these technologies should be integrated into telehealth CR [28].

A survey of wearable physiological monitoring devices identified several key requirements including measurement validity, data transmission integrity, real-time data processing, ease of use, and scalability [29]. While few existing monitoring systems addressed all requirements the commercially available BioHarness (Zephyr Technology) scored highly [29]. This multi-parameter wireless biosensor quantifies heart rate, single lead ECG, respiratory rate, tri-axial body acceleration, and torso

posture via sensors embedded in a textile chest strap or compression-fit vest. On-board memory and Bluetooth connectivity enable data to be stored locally or transmitted wirelessly to compatible devices such as smartphones, tablets, and computers. The low-profile design, ease of use, and advanced array of sensors make this device well suited for remote exercise monitoring. Early model BioHarness devices have been validated [30-35]; however, the current model has yet to be evaluated in either clinical or non-clinical populations.

Most wearable physiological sensors do not support long-range data transmission to remotely located monitoring stations. Therefore, remote monitoring requires physiological sensors to be combined with devices capable of collating and transmitting sensor data to remote monitoring stations for review and action by health care professionals. Smartphones are a preferable intermediary as, in combination with appropriate mobile or Web apps, they provide a ready-to-use mobile platform capable of logging and transmitting data via ubiquitous wireless data networks (eg, Bluetooth, Wi-Fi, 3G, and 4G). Portability, compatibility with several data networks, substantial computational capability, and routine integration of motion and location sensors further enhance the potential utility of smartphones for remote exercise monitoring. Moreover, continued rapid global smartphone market penetration growth [36] will likely reduce the necessity for health care providers to supply smart phones to would-be remote monitoring system end users. To date, there is a lack of published research combining physiological sensors with mobile data transmission technologies. A system comprising ECG and global positioning system (GPS) sensors, and a smartphone has been evaluated for remotely monitoring cardiac patients during exercise [37]. Remote data transmission was interrupted during 8.6% of completed exercise sessions; however, the amount of data lost and the subsequent impact on real-time remote monitoring were not described.

We have developed a custom mobile app and middleware platform to provide real-time transmission of physiological and clinical data, via smartphones, to remotely located monitoring centers [38]. Bi-directional communication capability enables health care professionals to provide users with instantaneous feedback that could prompt rapid changes in exercise behavior, enhance exercise self-efficacy, deliver educational information and provide support. Frequent access to remotely recorded heart rate data during rest, activities of daily living, and exercise could enable physicians to assess the impact of pharmacological intervention on heart rate control. In combination with the communication capability, this could assist physicians to titrate AF patients' medications in order to achieve optimal heart rate control. Our platform has shown promise in preliminary proof of concept research; however, a robust assessment of wireless data transmission reliability is required.

This study aimed to evaluate the sensor measurement validity and wireless data transmission reliability of a remote physiological monitoring system comprising the BioHarness, custom app, and middleware platform among individuals in sinus rhythm. Given that AF is the most common sustained cardiac arrhythmia and is a common comorbidity in CHD [39], system validity was also assessed in individuals with AF to

determine whether the sensor was robust to a common cardiac dysrhythmia.

Methods

Overview

A dual-phase cross-sectional study was conducted to assess system validity among convenience samples of healthy recreationally active individuals in sinus rhythm (ie, systole initiated at the sinoatrial node and proliferated via normal cardiac conduction pathways; Phase One), and individuals with AF (Phase Two). Phase One participants were recruited via contacts and local sport clubs. Phase Two participants were recruited via outpatient cardiology clinics. This dual-phase approach enabled safe assessment of sensor measurement validity across a broad range of exercise intensities. Phase One participants completed constant, intermittent, and incremental intensity exercise at moderate to maximal levels of intensity. Phase Two participants completed constant intensity exercise and simulated daily activities at low to moderate levels of intensity. Phase One was approved by the University of Auckland Human Participants Ethics Committee (2011/7674). Phase Two was approved by the New Zealand Health and Disability Ethics Committee (CEN/11/11058), respectively. All volunteers provided written informed consent. Procedures common to Phases One and Two are outlined below, followed by phase-specific exercise procedures.

Common Procedures

The remote physiological monitoring system comprised the BioHarness (version 3 with chest strap; Figure 1), a smartphone

(Xperia Arc S, Sony Ericsson Mobile Communications AB, Sweden) utilizing the Android operating system (v2.3.4, Google Inc.), a custom mobile app with integrated middleware platform (Figure 2), and a remote monitoring Internet server (Odin) [38]. Physiological data, transmitted to the smartphone via Bluetooth, were displayed throughout exercise, stored locally, and transmitted to the remote Internet server in near real-time (30-second data packet transmission interval).

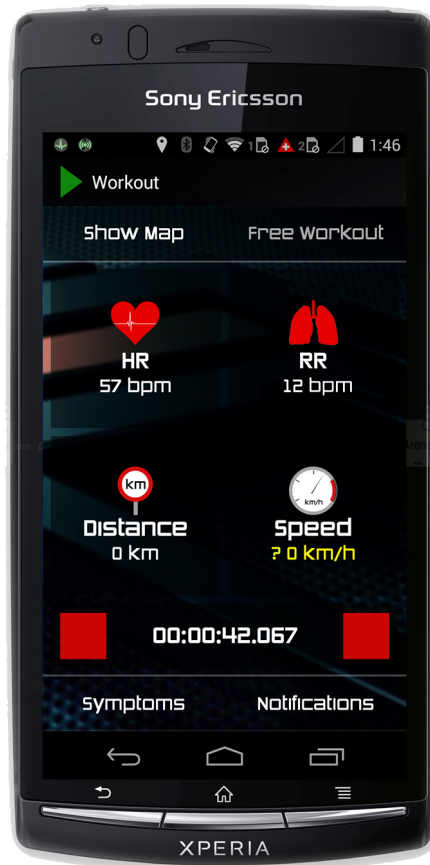
On arrival at the laboratory, participants underwent baseline measurement of stature and body mass, and familiarization with exercise ergometers. Participants were instrumented with a 12-lead ECG (AT-110, Schiller AG), BioHarness, and indirect calorimeter (Metalyzer, Cortex Biophysik GmbH). Adhesive electrodes were applied at standard ECG sites following recommended skin preparation procedures [40], and electrical cables were secured to minimize signal artefact. Calorimeter gas sensors were calibrated via a two-point procedure using gases of known composition, the volume transducer was calibrated using a 3000 mL calibration syringe (Hans Rudolph), and the internal barometer was calibrated against a mercury barometer (SK1256, Sato Keiryoki Manufacturing).

Activation of ECG, BioHarness, and calorimeter data logging followed a standardized procedure to ensure accurate data synchronization. Data were recorded during 180 seconds of seated rest prior to, and throughout exercise. A 60-second transition period was included prior to locomotive exercise to enable treadmill initiation.

Figure 1. Zephyr BioHarness.



Figure 2. Custom mobile app screenshot.



Phase One Exercise Procedures

During Phase One, participants completed three discrete bouts of treadmill running during two laboratory-based trials. During Trial One, participants ran on a motorized treadmill (EX200, Powersport) at 0% incline to determine the velocity eliciting 50% heart rate reserve ($V_{50\%HRR}$). Following instrumentation, participants completed an incremental protocol to assess peak oxygen uptake ($\dot{V}O_{2peak}$), operationally defined as the highest measured $\dot{V}O_2$. Treadmill velocity ($V_{50\%HRR}$) remained constant, and the incline was increased by 1% every 60 seconds until volitional exhaustion. Mean $\dot{V}O_2$ during the final 30 seconds of each workload was plotted as a function of treadmill incline, and inclines eliciting 50%, 66%, 70% and 90% $\dot{V}O_{2peak}$ were derived via linear interpolation. After 30 minutes of rest, participants completed a 30 minute constant intensity treadmill running protocol (C30) at an incline eliciting 66% $\dot{V}O_{2peak}$. During Trial Two, participants completed a 30-minute intermittent intensity treadmill protocol (I30) comprising three repetitions of a 10-minute exercise block. Each exercise block included five sequential 2-minute stages at inclines eliciting 50%, 70%, 90%, 70%, and 50% $\dot{V}O_{2peak}$, respectively. Mean levels of exercise intensity were equivalent in the C30 and I30 protocols.

Phase Two Exercise Procedures

During Phase Two, participants completed three bouts of exercise during a single laboratory-based trial. Participants self-selected light-to-moderate levels of exercise intensity during treadmill and cycle ergometer (Velotron, RacerMate Inc.)

familiarization. Following instrumentation, participants undertook 10 minutes of treadmill walking, 10 minutes of cycling, and sequential 3-minute bouts of simulated daily activities (sweeping and vacuuming). Walk, cycle, and daily activity bouts were separated by 5 minutes of seated rest.

Data Analysis

Reference heart rate measures were manually calculated from synchronized ECG waveforms as the average rate during the final 10 seconds of each minute. Reference respiratory rate was captured by the calorimeter at 0.10 Hz. BioHarness and calorimeter data were downloaded using the manufacturers' software (BioHarness Log Downloader v1.0.24 and MetaSoft v3.9.3, respectively) and exported for manual analysis. BioHarness data were down-sampled to match reference measures. Data outside the manufacturers specified measurement ranges were excluded prior to analysis.

Phase One and Two data were analyzed separately following identical procedures using SPSS v20.0.0. Consistent with guidelines for assessing measurement validity in this field [41], a multi-faceted approach was undertaken to evaluate BioHarness heart rate and respiratory rate measurement accuracy and reliability. Heart rate and respiratory rate data were non-normally distributed, and a nonparametric analytical approach was implemented where necessary. Wilcoxon signed-rank tests for matched pairs were conducted to assess systematic biases between sensor and reference measures. Kruskal-Wallis analyses of variance were performed to assess the effect of Activity (Phase One: rest, transition, run; Phase Two: rest, transition, walk, cycle, sweep, vacuum) on

measurement biases. Statistically significant main effects were explored using Dunn-Bonferroni corrected paired comparisons.

Spearman's rank-order correlation coefficients (ρ) and two-way random effects intraclass correlation coefficients (ICC) for absolute agreement were calculated to describe relative measurement reliability [41]. Absolute measurement reliability was assessed by calculating the standard error of measurement (SEM) and coefficient of variation (CV) [41] and a non-parametric approach to the 95% limits of agreement (LoA) similar to that described by Bland & Altman [42], in which the LoA were calculated as the 2.5th and 97.5th percentile ranked biases. The threshold for statistical significance was set at $\alpha < .05$.

Wireless data transmission reliability was evaluated by determining data loss between the BioHarness, App, and remote monitoring server (Odin). Reference sample sizes were

calculated as the product of exercise duration and sensor sampling frequency. These analyses utilized data logged at the BioHarness' native summary frequency (1 Hz) as the aforementioned down-sampling procedures had potential to conceal intermittent data loss.

Results

Overview

Participant characteristics are summarized in Table 1. Ten and eight participants completed all Phase One and Two activity bouts, respectively. Unidentified trial-wide technical errors affected heart rate and respiratory rate measurements during two separate Phase Two trials. The outlying nature of these datasets was confirmed by 2 independent investigators, and they were excluded from analyses.

Table 1. Participant characteristics (Phase One: participants in sinus rhythm; Phase Two: participants with atrial fibrillation).

	Phase One, mean (SD)	Phase Two, mean (SD)
Sample size/male	10/6	8/5
Age, years	26.68 (3.26)	69.68 (9.53)
Body mass, kg	71.10 (11.53)	77.46 (18.81)
Stature, m	1.73 (0.06)	1.69 (0.12)
Peak oxygen consumption, ml·kg ⁻¹ ·min ⁻¹	50.82 (4.51)	Not assessed

Measurement Accuracy

The BioHarness systematically underestimated heart rate ($z = -3.01$, $P = .003$) and respiratory rate ($z = -21.57$, $P < .001$) during Phase One, although the median biases were small (Tables 2 and 3). A statistically significant effect of Activity on measurement bias was detected for respiratory rate ($H_2 = 40.96$, $P < .001$), but not heart rate ($H_2 = 0.83$, $P = .66$). Dunn-Bonferroni corrected paired comparisons revealed systematic differences in respiratory rate measurement biases between all three levels of Activity (all $P < .001$ to $P = .04$; Table 3).

The BioHarness systematically overestimated heart rate ($z = -3.28$, $P = .001$) and respiratory rate ($z = -4.47$, $P < .001$) during

Phase Two, although negative biases were observed during some activities (Tables 2 and 3). A statistically significant effect of Activity was detected on respiratory rate ($H_5 = 203.07$, $P < .001$; Table 3), but not heart rate ($H_5 = 4.41$, $P = .49$; Table 2). Dunn-Bonferroni-corrected paired comparisons revealed systematic differences in respiratory rate measurement biases between all levels of Activity ($P < .001$ to $P = .02$; Table 3) with the exception of walk and cycle ($P = .12$; Table 3).

BioHarness measurement error was relatively consistent across the measurement ranges, although a degree of heteroscedasticity was apparent among Phase Two respiratory rate measures (Figure 3).

Table 2. Biases between BioHarness and reference heart rate (Phase One: participants in sinus rhythm; Phase Two participants with atrial fibrillation)^a.

		Heart rate				
			Median b·min ⁻¹	Bias b·min ⁻¹	Bias %	
Phase One	Rest	REF	72.00 (18.00)	0.00 (4.45)	0.02 (5.55)	
		BH	70.75 (23.38)			
	Transition	REF	108.00 (30.00)	-0.80 (7.20)	-0.65 (7.38)	
		BH	97.00 (31.18)			
	Run	REF	162.00 (18.00)	-0.30 (4.60)	-0.20 (2.80)	
		BH	163.50 (16.40)			
REF		162.00 (24.00)				
	Total	BH	160.70 (13.40)	-0.30 (4.53) ^b	-0.20 (2.96)	
Phase Two	Rest	REF	84.00 (24.00)	2.10 (4.55)	2.06 (5.77)	
		BH	89.10 (29.45)			
	Transition	REF	108.00 (6.00)	1.10 (9.30)	1.67 (8.78)	
		BH	91.70 (21.30)			
	Walk	REF	126.00 (40.50)	0.65 (9.25)	0.49 (7.82)	
		BH	130.20 (46.58)			
	Cycle	REF	120.00 (60.00)	1.90 (11.50)	1.79 (9.66)	
		BH	121.80 (72.50)			
	Sweep	REF	108.00 (27.00)	-3.60 (12.00)	-3.75 (9.70)	
		BH	103.10 (20.05)			
	Vacuum	REF	108.00 (30.00)	3.20 (13.76)	3.47 (13.46)	
		BH	101.30 (33.34)			
		REF	108.00 (48.00)			
		Total	BH	106.55 (51.68)	1.10 (9.75) ^c	1.23 (8.61)

^aTable reports median (IQR) reference (REF) and BioHarness (BH) heart rates, absolute (b·min⁻¹) and relative (%) biases.

^b*P*=.003.

^c*P*=.001.

Table 3. Biases between BioHarness and reference respiratory rate (Phase One: participants in sinus rhythm; Phase Two participants with atrial fibrillation)^a.

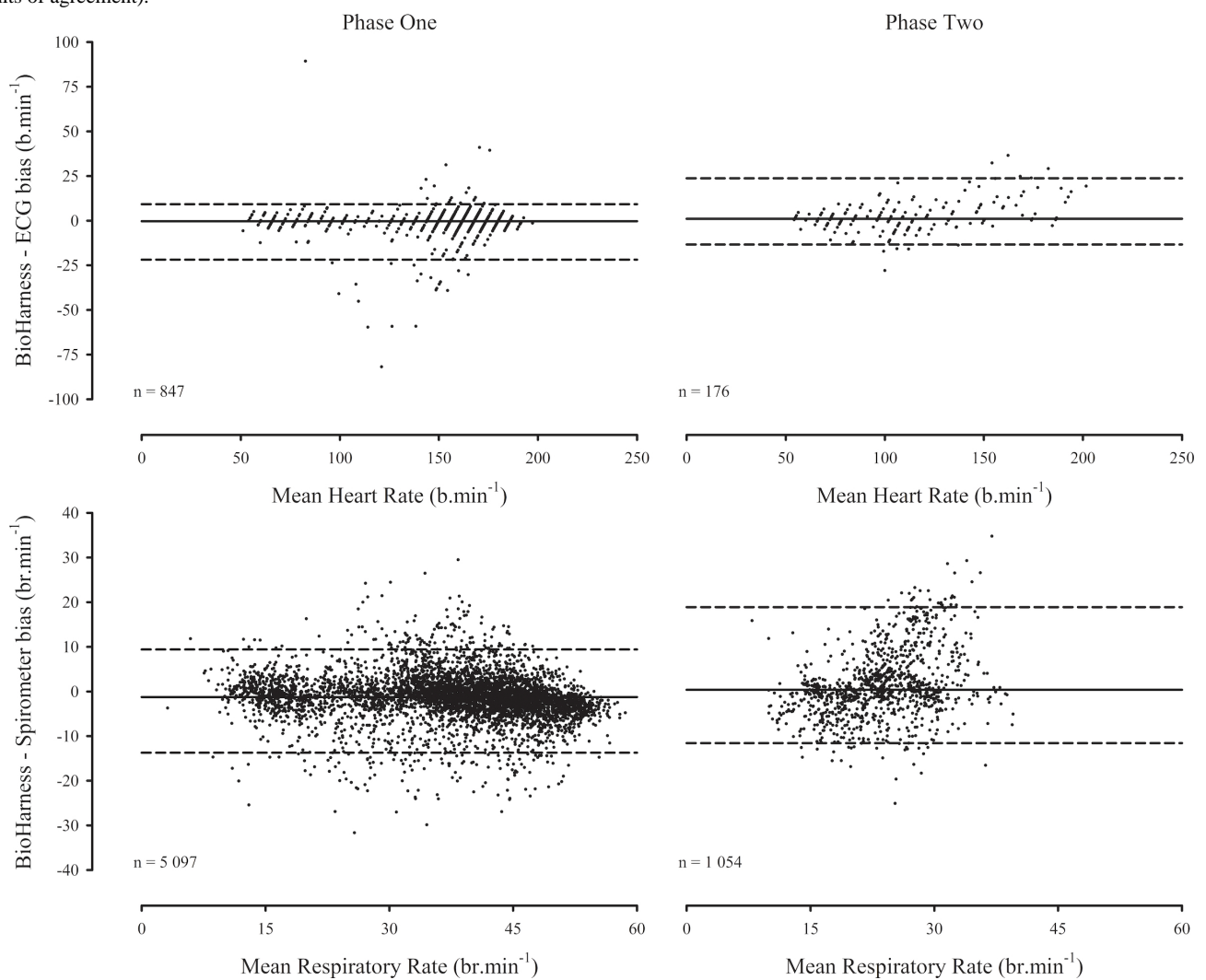
			Median br·min ⁻¹	Bias br·min ⁻¹ ^b	Bias %
Phase One	Rest	REF	17.00 (6.75)	-0.28 (4.00) ^{rR}	-1.56 (23.42)
		BH	16.15 (5.44)		
		REF	19.30 (7.33)		
	Transition	BH	17.65 (6.32)	-2.20 (5.72) ^{rR}	-12.17 (29.52)
		REF	41.70 (12.00)		
	Run	BH	40.80 (10.09)	-1.36 (4.58) ^{rI}	-3.30 (10.65)
REF		39.90 (15.30)			
Total	BH	39.02 (13.40)	-1.25 (4.65) ^c	-3.33 (12.01)	
Phase Two	Rest	REF	18.50 (6.65)	-0.88 (4.30) ^{twcsv}	-4.89 (21.77)
		BH	17.29 (4.80)		
		REF	19.70 (8.30)		
	Transition	BH	14.34 (4.92)	-5.73 (5.97) ^{twcsv}	-28.02 (23.69)
		REF	22.30 (5.85)		
	Walk	BH	25.16 (6.35)	0.81 (6.34) ^{rIsv}	3.12 (30.80)
		REF	25.00 (7.28)		
	Cycle	BH	26.69 (6.94)	0.28 (7.65) ^{rIsv}	1.04 (28.84)
		REF	22.00 (6.05)		
	Sweep	BH	31.03 (11.87)	6.61 (16.35) ^{rtwcv}	27.22 (77.73)
		REF	19.65 (9.33)		
	Vacuum	BH	31.55 (9.72)	9.42 (10.18) ^{rtwcv}	43.89 (67.69)
		REF	22.10 (7.18)		
	Total	BH	24.26 (11.02)	0.39 (7.33) ^c	1.56 (31.88)

^aTable reports median (IQR) reference (REF) and BioHarness (BH) respiratory rates, absolute (br·min⁻¹) and relative (%) biases.

^bThe letters ^r_t^R = rest, transition, run; statistically significantly different compared to Phase One rest, transition, Run ($P < .001$ to $P = .04$). The letters ^r_t^I ^w_c^S^v = rest, transition, walk, cycle, sweep, vacuum; statistically significantly different compared to Phase Two rest, transition, walk, cycle, sweep, and vacuum ($P < .001$ to $P = .02$).

^cStatistically significantly different compared to reference measures ($P < .001$).

Figure 3. Sensor measurement error as a function of mean measurement magnitude (solid reference lines = mean biases, dashed reference lines = 95% limits of agreement).



Measurement Reliability

BioHarness and reference heart rate measures were strongly correlated during both phases (Table 4), indicating excellent relative measurement reliability. The SEM, CV, and LoA for heart rate were similar during both phases (Table 4). Small SEM and CV indicate acceptable absolute heart rate measurement reliability during both phases; however, the non-parametrically derived LoA were relatively wide (Figure 3). Asymmetric LoA reflect the aforementioned non-normal measurement error

distributions. BioHarness and reference respiratory rate measures were strongly correlated during Phase One, but not Phase Two (Table 4). Phase One respiratory rate SEM and CV were small, but the LoA were relatively wide (Figure 3). The respiratory rate SEM, CV, and LoA were substantially larger during Phase Two (Table 4) and reflect poor absolute measurement reliability. While the magnitude of the Phase Two respiratory rate SEM was comparable to the heart rate SEM during both phases, it represents a larger proportion of the total measurement range and therefore, markedly lower absolute measurement reliability.

Table 4. Relative and absolute reliability of BioHarness heart rate and respiratory rate measures^a.

		Relative		Absolute		
		rho	ICC	SEM, min ⁻¹	LoA, min ⁻¹	CV, %
Phase One	HR	.92 ^b	.98 ^b	5.20	(-21.87, 9.26)	2.24
	RR	.87 ^b	.94 ^b	2.78	(-13.73, 9.41)	7.94
Phase Two	HR	.97 ^b	.98 ^b	4.77	(-13.39, 23.79)	4.05
	RR	.43 ^b	.55 ^b	4.60	(-11.58, 18.91)	16.61

^aTable reports Spearman's rank-order correlation coefficient (rho), two-way random effects intraclass correlation coefficient (ICC), standard error of measurement (SEM), non-parametric 95% limits of agreement (LoA), and coefficient of variation (CV) for heart rate (HR) and respiratory rate (RR).

^bStatistically significant $P < .001$.

Wireless Data Transmission Reliability

Zero biases were observed between BioHarness, App, and Odin measurements, indicating sensor measurement validity was unaffected by wireless data transmission. Phase One BioHarness, App, and Odin data loss were 4.1%, 0.2%, and 21.3%, respectively. Failure to record data throughout two $\dot{V}O_2$ peak bouts accounted for all BioHarness data loss. However, these errors did not compromise BioHarness-to-App data transmission. A terminal App crash during one exercise bout accounted for all Phase One App data loss. Outages of the data network hosting the Odin server precluded App-to-Odin data transmission throughout five exercise bouts, and this instability accounted for 15.5% Odin data loss. Unidentified intermittent data capture errors accounted for the remaining Odin data loss (5.9%).

Phase Two BioHarness, App, and Odin data loss were 0.0%, 0.6%, and 1.1%, respectively. Phase Two was unaffected by Odin network stability and data loss occurred as a result of intermittent errors similar to those observed during Phase One.

Discussion

Principal Findings

This study evaluated the sensor measurement and wireless data transmission validity of a remote physiological monitoring system among participants in sinus rhythm and AF. Heart and respiratory rates differed systematically from reference measures across a range of exercise intensities and activities, but the magnitudes of these biases were small. Measurement reliability was generally acceptable, and wireless data capture was excellent when all components of the monitoring system were operational. However, instability of the data network hosting the Odin remote monitoring server resulted in substantial data loss during some exercise bouts.

The small magnitudes of heart rate and respiratory rate measurement biases are unlikely to impair interpretation of physiological stress or workload during remote monitoring. As a caveat, larger biases during simulated sweeping and vacuuming may indicate reduced sensor stability and increased movement artefact during activities requiring substantial upper limb movement. Recent evidence suggests conductive fabric sensors embedded in a textile vest are subject to less movement

artefact than traditional adhesive ECG electrodes [43]. Thus the BioHarness compression-fit vest may improve sensor measurement validity; however, it was not publicly available during this experiment and could not be assessed.

Heart rate and respiratory rate measurement biases were comparable to some, but not all previous evaluations of similar sensors' measurement validity. Biases were smaller than those reported for a previous model BioHarness during laboratory- and field-based locomotion [31,32,34] but comparable to those reported during incremental and constant intensity treadmill running [35]. As it is not possible to determine the extent to which iterative hardware and software development contributes to measurement accuracy, caution should be taken when generalizing our results to earlier model devices.

Relative heart rate measurement reliability was excellent across a range of activities and workloads. Correlation coefficients compare favorably with evaluations of previous model BioHarness devices [32,35] and other wearable physiological sensing devices [44-47]. Small SEM, and CV substantially smaller than a previously established criterion for acceptability [45] indicate good absolute heart rate measurement reliability during both phases. Relatively wide LoA are consistent with previous BioHarness evaluations [34,35] and reflect infrequent large measurement errors. While high frequency data are attractive for real-time remote exercise monitoring, the effect of infrequent outlying measurement errors may unnecessarily confound real-time data interpretation. Many wearable physiological sensors support much higher frequency monitoring than is typically provided during center-based supervised exercise. Thus it may be acceptable to sacrifice some temporal resolution in order to increase measurement reliability. Post-processed down-sampling is recommended to account for the temporal instability of respiratory gas exchange data during exercise [48,49], and a similar approach warrants consideration for real-time monitoring of high-frequency physiological data. Aggregating individual data packets, which were transmitted every 30 seconds during this experiment, may overcome the effects of infrequent outlying measurement errors. However, further investigation is required to determine the optimal balance between temporal resolution and measurement reliability.

Respiratory rate measurement reliability was comparable with evaluations of previous BioHarness models [31,35] and other wearable physiological monitors featuring inductive

plethysmographs during Phase One [45,47,50] but was notably reduced during Phase Two. This was unexpected, but not without precedent [33,34]. The major methodological discrepancies between phases were the inclusion of upper body activities (simulated sweeping and vacuuming), lower levels of activity intensity, and older aged participants of lower exercise training status during Phase Two. Activities requiring substantial upper limb movement could impair the BioHarness respiratory rate sensor; however, post-hoc sensitivity analyses (not presented) did not support this effect. As low intensity activities are associated with small tidal volumes and thoracic wall displacements [51], it is possible the BioHarness respiratory rate sensor may be confounded during low levels of exercise intensity. Again, however, post-hoc sensitivity analyses did not support this effect. Pulmonary mechanics are impaired among older aged individuals (independent of pathophysiological conditions) and those with respiratory muscle weakness [52,53]. However, data describing pulmonary mechanics were not collected during this study, and the mechanism(s) underlying poor Phase Two respiratory rate measurement reliability remain unknown.

Remote physiological monitoring is contingent on reliable data transmission to a remotely located monitoring station. Data capture was generally excellent throughout this experiment; however, several errors were identified. Unresolved data logging errors precluded data storage on the local BioHarness memory during two exercise bouts; however, remote data transmission was unaffected and all data were successfully transmitted to the remote monitoring server during these errors. While local BioHarness data capture was necessary to assess sensor measurement validity, the middleware platform responds to network instability by temporarily caching all data until a network connection is re-established. Thus local BioHarness data capture would not be required in a production-ready remote monitoring system. The institutional network that hosted the Odin server throughout this study was subject to inconsistent power supply and undisclosed maintenance events. Resulting Odin server outages affected five exercise bouts during three Phase One trials. Relocating Odin to a robust host network will resolve this issue and is an immediate priority for future iterations of the monitoring system. After accounting for host network instability, Odin captured 94.7% and 98.9% of data during Phases One and Two, respectively. Iterative development is required to resolve the remaining App and Odin data capture errors; however, data capture reliability was sufficient for real-time remote monitoring given that a stable App-to-Odin connection was confirmed before beginning exercise.

Limitations

A potential limitation of this study was the small sample size. However, as the unit of analysis was the number of sensor observations, rather than the number of participants, the design had sufficient statistical power to detect clinically significant biases between BioHarness and reference measures of heart rate and respiratory rate.

As with all studies evaluating physiological sensor validity, these results may be confounded by factors influencing the quality of data from the BioHarness and reference sensors.

Positional overlap between ECG (V_1 - V_6) and BioHarness electrodes may have impaired BioHarness electrode skin contact, particularly among participants with small chest circumferences requiring ECG electrodes to be closely grouped. Interrupted skin contact could explain the occasional presence of large measurement errors apparent in the relatively wide heart rate LoA.

Similarly, the design of the BioHarness respiratory rate sensor dictated that it was typically located above ECG electrodes V_5 and V_6 . Compression of the respiratory rate sensor against underlying ECG electrodes could impair measurement validity; however, this would be expected to affect both phases and is unlikely to explain the reduced measurement reliability observed during Phase Two.

Implications

Remote physiological monitoring has numerous potential applications in both clinical and non-clinical settings. Remote monitoring has been identified as an important future development in home-based exCR [26] and may help to bridge the gap between center- and home-based programs for individuals who are unable to attend traditional exCR. Real-time remote physiological monitoring could help home-based exCR participants' to achieve and adhere to recommended exercise training loads, and this may optimize beneficial exercise-induced physiological adaptations. Moreover, bi-directional communication capability will enable exercise physiologists to provide instantaneous individualized feedback, educational information, and support based on real-time physiological responses. While remote exCR should not replace center-based programs, it may provide a viable alternative for those who are unable or unwilling to attend supervised exCR. Robust trials are now required to determine the efficacy and safety of remotely monitored exCR. Given that center-based exCR is the gold standard treatment in many countries, it seems prudent to compare remotely monitored exCR with center-based programs.

Remote physiological monitoring also has potential applications outside of exCR and could be used to monitor heart rate control in people with AF. Management of patients with AF involves consideration of either a rhythm control approach (attempt to maintain sinus rhythm) or one of rate control, which is often the preferred approach. Reduction of the rapid heart rate in AF increases the diastolic filling periods and left ventricular stroke volume [39]. Current guidelines recommend an individualized approach to AF rate control, using a combination of pharmacological agents such as beta-blockers, calcium channel blockers, and digoxin [39]. However, heart rate control during exercise remains problematic for many patients with AF, even when receiving medications. Guidelines recommend that patients who experience symptoms associated with AF during exercise should be assessed during exercise and have their pharmacological treatment titrated to achieve a physiological chronotropic response and avoid bradycardia [39]. The most common approach for monitoring arrhythmias during everyday life is Holter monitoring (24 hours to 7 days) [39]. This approach is highly regarded and valuable for clinical decision making; however, it is time and resource intensive to monitor data and can be intrusive for patients. Remote monitoring systems such

as the one described in this paper have several advantages over traditional Holter monitoring. The conductive textile electrodes embedded into wearable physiological sensors overcome the discomfort associated with adhesive electrodes. Moreover, data from integrated motion sensors could be used to delineate periods of rest and physical activity, and these contextual data may augment interpretation of heart rate control among patients with AF. Finally, embedding automated data collation and processing within remote monitoring servers can eliminate manual data handling and improve the efficiency of data processing and reporting. Collectively these characteristics could assist physicians to assess the effects of pharmacological intervention and titrate AF patients' medications in order to

optimize heart rate control at rest and during exercise. Future research is needed to determine the utility of such remote monitoring in this and other translational contexts.

Conclusion

The remote monitoring system evaluated in this experiment has sufficient measurement accuracy for quantifying heart rate and respiratory rate among individuals in sinus rhythm and with AF when gold standard clinical sensors are unavailable. Wireless data transmission reliability was generally excellent. Remote physiological monitoring has potential application as an alternate method for delivering exercise-based cardiac rehabilitation and enhancing the management of heart rate control for individuals with atrial fibrillation.

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Authors' Contributions

All authors contributed to the design, data collection, analysis and interpretation, drafting of the article, and final approval of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AF: atrial fibrillation
C30: constant intensity 30-minute exercise protocol
CHD: coronary heart disease
CR: cardiac rehabilitation
CV: coefficient of variation
ECG: electrocardiogram
exCR: exercise-based cardiac rehabilitation
GPS: global positioning system
I30: intermittent intensity 30 minute exercise protocol
ICC: intraclass correlation coefficient
LOA: limits of agreement
SEM: standard error of measurement
V O₂peak: peak oxygen consumption

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Original Paper

Mobile Functional Reach Test in People Who Suffer Stroke: A Pilot Study

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Abstract

Background: Postural instability is one of the major complications found in people who survive a stroke. Parameterizing the Functional Reach Test (FRT) could be useful in clinical practice and basic research, as this test is a clinically accepted tool (for its simplicity, reliability, economy, and portability) to measure the semistatic balance of a subject.

Objective: The aim of this study is to analyze the reliability in the FRT parameterization using inertial sensor within mobile phones (mobile sensors) for recording kinematic variables in patients who have suffered a stroke. Our hypothesis is that the sensors in mobile phones will be reliable instruments for kinematic study of the FRT.

Methods: This is a cross-sectional study of 7 subjects over 65 years of age who suffered a stroke. During the execution of FRT, the subjects carried two mobile phones: one placed in the lumbar region and the other one on the trunk. After analyzing the data obtained in the kinematic registration by the mobile sensors, a number of direct and indirect variables were obtained. The variables extracted directly from FRT through the mobile sensors were distance, maximum angular lumbosacral/thoracic displacement, time for maximum angular lumbosacral/thoracic displacement, time of return to the initial position, and total time. Using these data, we calculated speed and acceleration of each. A descriptive analysis of all kinematic outcomes recorded by the two mobile sensors (trunk and lumbar) was developed and the average range achieved in the FRT. Reliability measures were calculated by analyzing the internal consistency of the measures with 95% confidence interval of each outcome variable. We calculated the reliability of mobile sensors in the measurement of the kinematic variables during the execution of the FRT.

Results: The values in the FRT obtained in this study (2.49 cm, SD 13.15) are similar to those found in other studies with this population and with the same age range. Intrasubject reliability values observed in the use of mobile phones are all located above 0.831, ranging from 0.831 (time B_C trunk area) and 0.894 (displacement A_B trunk area). Likewise, the observed intersubject values range from 0.835 (time B_C trunk area) and 0.882 (displacement A_C trunk area). On the other hand, the reliability of the FRT was 0.989 (0.981-0.996) and 0.978 (0.970-0.985), intrasubject and intersubject respectively.

Conclusions: We found that mobile sensors in mobile phones could be reliable tools in the parameterization of the Functional Reach Test in people who have had a stroke.

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KEYWORDS

mobile health; reliability and validity; elderly; stroke; postural balance

Introduction

Stroke is the leading cause of severe long-term disability worldwide, and it commonly occurs in people aged 65 years and over [1,2]. Neurological deficits caused by stroke lead to motor, sensory, and/or cognitive limitations [3]. In particular, people who have suffered stroke present deficits in balance. This is the main cause of the increased risk of falls and severe limitations suffered by patients in performing activities of daily living [3-5].

The deficit in balance experienced by patients who suffer stroke is due to loss of muscle strength and coordination and to spasticity and degenerative and neurological disorders [5]. The imbalance is visible in increased postural sway, in asymmetric distribution of weight between the legs at rest position, and in difficulty maintaining the center of mass in the limits of corporal stability during a task [1,3,6]. Due to their inability to recover from a loss of balance, patients who have suffered stroke have a high risk of falls [1,4,6]. Half of the people who have suffered stroke and are living in the community experience at least one fall per year, and about half of them suffer from repeated falls [1,4].

The Functional Reach Test (FRT) is a standardized instrument that assesses anteroposterior stability [7,8]. In recent years, it has been widely used to assess balance and risk of falls in people who have suffered a stroke [9]. It has proved to be an accurate, portable, cheap, and reliable test with low interexaminer variability [7,9,10].

Numerous studies have used inertial sensors as a tool for collecting kinematic data in the analysis of human motion in different functional tests, such as the Romberg test, the Time Up and Go test (TUG), the Sit to Stand test, and the FRT test [11-15]. Incorporating accelerometers and gyroscopes within the functions of mobile phones makes these devices the ideal replacement for inertial sensors as a tool for measuring human movement and imbalance through the instrumentalization of functional testing because of their portability, ease of use with apps, and low cost compared with inertial sensors [16-19]. Furthermore, in recent years, the mobile phone has emerged as an alternative to face-to-face health care for people living in different areas and with different pathologies, specifically in the diagnosis, assessment, intervention, and monitoring of patients (mHealth) [18,20-22].

There are no studies to date in which the FRT has been instrumentalized through a mobile device in people who have suffered a stroke. The aim of this study is to analyze the reliability of mobile phones for collecting kinematic variables in the parameterization of the FRT in people who have suffered a stroke. The hypothesis is that the mobile phone will be a reliable tool in the kinematic study of functional reach.

Methods

Design and Participants

This is an analytical cross-sectional study in which participants have suffered a stroke as defined by the World Health Organization [23]. The sample was selected considering the following inclusion criteria: age over 65 years of age, ability to walk for 10 meters at a speed equal to or higher than 0.8 m/s without help from another person or instrument support, capacity to stand upright without any help for 30 seconds, and moderate severity (score between 0 and 49 on Barthel's Index). Exclusion criteria for this study were being 65 years of age, limitations in ambulation, major communication problems, severe cardiovascular, orthopedic or breathing limitations, having a secondary neurological disease, or failing to provide informed consent.

Ethical approval for the study was granted by the ethics committee of the Faculty of Health Sciences, University of Málaga. This study was conducted in accordance with Ethical Principles for Medical Research Involving Human Subjects (Helsinki Declaration 2008).

Before beginning the study, researchers gave each of the participants an information sheet and a request for informed consent, in which the study was explained, as well as the possibility that they may leave the study at any time, and an assurance of the protection of personal data, according to the Organic Law of Protection of Personal Data 19/55.

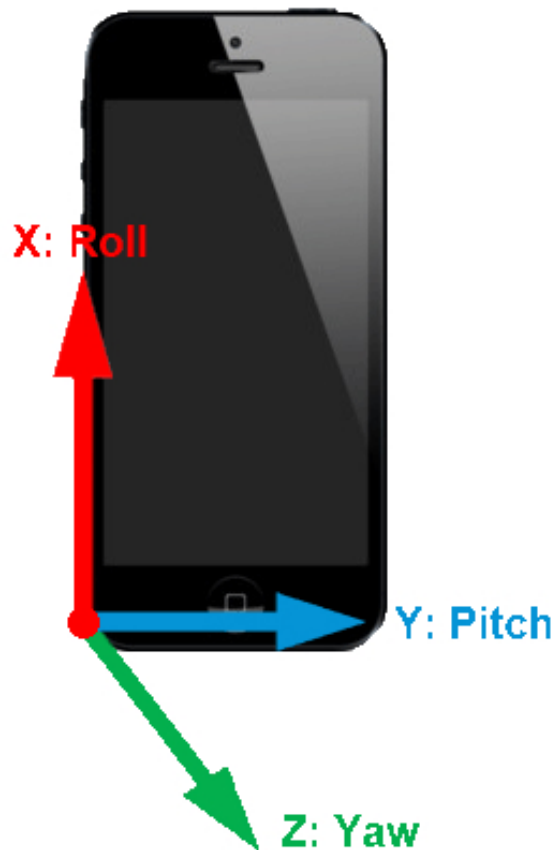
Functional Reach Test

To perform the FRT or Duncan test (1990) [9], a tapeline is placed on the wall. The participant is then asked to situate themselves parallel to the tapeline, so that the axis through the participant's shoulders is as perpendicular to the wall as possible. Their feet are located at the width of their shoulders, which are flexed 90° with elbows and hands outstretched. At this point, the researcher makes a mark on the tape using the metacarpal head of the third finger as a benchmark. From this starting position, the participant begins a movement for maximum anterior reach, before taking a step, lifting the heels, or touching the wall. A second mark on the wall is then made, and thereafter the participant returns to the starting position. The distance in centimeters between the two marks is the functional reach of each participant [7,9,10,24]. The reliability of this functional test is 0.81 [25].

In our study, a blinded investigator extracted the offline variables from each of the graphs generated after the collection of the kinematic data from each of the tests.

During the execution of the FRT in this study, the participants each wore two mobile devices, one located at the L5-S1 (lumbar) level and the other at T7 (trunk). They were placed so that the origin of coordinates (X, Y, Z) (0, 0, 0) were placed in the left posterior-inferior vertex. See [Figure 1](#).

Figure 1. Origin of the coordinates (X, Y, Z) in the mobile.



Mobile Devices

The two mobile devices used for the kinematic registration of the FRT were both iPhone 4s. This device has a triaxial gyroscope, accelerometer, and magnetometer [22,26,27]. The accelerometer was operated at a frequency of 32 Hz during the measurement. These accelerometers have a correlation coefficient of .98 or above [19,22]. We used SensorLog to retrieve sensor data for this study.

Outcome Measures

The following variables were extracted from the FRT:

1. FRT distance: distance achieved by the participant between the starting position and the final position.
2. Maximum angular lumbosacral/thoracic displacement FRT: angular variation that the participant causes on the pitch axis. This amplitude is considered from the starting point until it reaches its peak before the return.
3. Time of maximum angular lumbosacral/thoracic displacement FRT: time it takes the participant to reach the peak.
4. Time for return to starting position: time it takes the participant to return to the starting point.
5. Total time FRT: time it takes the participant from the starting position to return to it.

These variables were taken from the kinematic registration of the mobile phone in the pitch axis.

Using data extracted previously, the following variables were calculated:

1. Average speed FRT: medium speed at which the test is run.
2. Maximum angular lumbosacral/thoracic displacement speed FRT: average speed at which the participant reaches the peak from the starting position.
3. Starting to return position speed: average rate at which the participant returns to the starting position from the peak.
4. Average acceleration FRT: average acceleration at which the participant executes the FRT.
5. Maximum angular lumbosacral/thoracic displacement average acceleration FRT: average acceleration at which the participant reaches the peak.
6. Acceleration average return starting position FRT: average acceleration the participant attained from the peak until the starting position.

The mean and the standard deviation of X, Y, Z were calculated in the maximum, minimum, and average speed and acceleration on both mobile devices. The result was found through the square root of the sum of the squares of the three axes in the displacement, the maximum and minimum speed, and the acceleration of the FRT, and also the mean and standard deviation in the result of the displacement and the result of the maximum and minimum speed and acceleration.

The variables analyzed were those we obtained from the repetition in which the participant achieved the widest functional reach.

Procedure

At the beginning of the study, we explained to all participants what the test consisted of. Each signed the informed consent

and completed the Barthel Index, the Stroke Impact Scale-16, and the Canadian neurological scale to improve the description of the sample. We also collected sociodemographic data on each of the participants via a questionnaire. The reliability of these tools are $\kappa=.93$ [28], $\kappa=.76$ [29], and intraclass correlation coefficient (ICC)=.70 to .92 [30], respectively.

During the execution of the FRT or Duncan's Test [9,25], the participants carried two mobile phones, one placed at the level of L5-S1 (lumbar) and the other at T7 (trunk). Three repetitions

Figure 2. Position of the inertial sensors on the back of patients.



Data Analysis

As noted above, sociodemographic data were collected through a questionnaire and a series of tests designed specifically for people with neurological disorders. Subsequently, the distance achieved in the FRT was recorded and a descriptive analysis of all kinematic variables recorded by both mobiles was conducted (trunk and lumbar).

The Kolmogov-Smirnov test was used to test the normality of the variables. The data obtained in the kinematic record from the trunk and lumbar positions were compared, both the direct variables (time and displacement) and the indirect variables (velocity, acceleration, and result). The Student *t* test was used for parametric variables and Wilcoxon's test for nonparametric. The index of significance was set at $P \leq .05$ values.

By analyzing internal consistency, we calculated the reliability of direct measurements with a confidence interval of 95% for each outcome variable. Correlation coefficients were calculated for interclass and intraclass reliability. Reliability was calculated for the reach achieved by the participant and direct variables measured by mobiles (time and displacement). The reliability of indirect variables (velocity, acceleration, and result) was not

of the test were carried out under the supervision of 2 researchers. The 2 researchers then conducted the analysis of the results independently. See Figure 2.

From the kinematic registration collected by use of the mobile devices, we obtained the direct variables of time and displacement between the three intervals. As indirect variables, calculated thereafter, the velocity and displacement were obtained.

calculated because its value is determined by the reliability of direct measures. Levels of reliability were classified as follows: very low correlation was $0 \leq \text{ICC} \leq .29$, low correlation was $.30 \leq \text{ICC} \leq .49$, moderate correlation was $.50 \leq \text{ICC} \leq .69$, high correlation was $.70 \leq \text{ICC} \leq .89$, and very high correlation was $\text{ICC} \geq .90$ and above [31].

In this study, we used SPSS version 17.0 for Windows for statistical analysis.

Results

Table 1 presents the demographic and anthropometric data collected through the questionnaire. It also shows the results of different specific tests used to obtain the degree of disability.

Table 2 shows the functional reach distance achieved by each participant and the description of the kinematic variables collected during the execution of the FRT depending on the position of the mobile, trunk, or lumbar. Furthermore, the registered movements appear divided into three intervals based on the start of the test, the maximum angular displacement, and the end of the test. This table shows the maximum, minimum, average and standard deviation of time, displacement, speed, and acceleration in each of the intervals.

Table 1. Descriptive values of participants.

	Minimum	Maximum	Mean	SD
Age in years	68	87	75.1	5.22
Canadian Neurological Scale	7.0	9.0	8.1	0.73
Barthel Index	80	100	93.50	5.95
Stroke Impact Scale-16	61	73	66.25	4.18
N valid (according to the list)	7			

Table 2. Description of the kinematic variables of FRT depending on the placement of the mobile device.^a

	Minimum	Maximum	Mean	SD
Functional reach test distance in cm	9.86	16.84	13.15	2.49
Trunk				
Time_A_B (s)	6.76	10.53	8.84	1.29
Displacement_A_B (°)	6.24	18.90	12.62	5.19
Speed_A_B (°/s)	0.49	2.49	1.43	0.79
Acceleration_A_B (°/s ²)	0.04	0.26	0.16	0.09
Time_B_C (s)	4.73	10.55	7.18	2.74
Displacement_B_C (°)	4.37	17.18	10.01	5.41
Speed_B_C (°/s)	0.49	2.28	1.40	0.69
Acceleration_B_C (°/s ²)	0.08	0.22	0.19	0.11
Time_A_C (s)	11.43	22.06	16.04	4.79
Displacement_A_C (°)	14.01	31.82	22.64	7.87
Speed_A_C (°/s)	0.62	2.16	1.36	0.72
Acceleration_A_C (°/s ²)	0.04	0.16	0.08	0.07
Lumbar				
Time_A_B (s)	5.19	12.09	8.71	2.93
Displacement_A_B (°)	6.40	16.02	10.93	4.02
Speed_A_B (°/s)	0.76	1.48	1.25	1.07
Acceleration_A_B (°/s ²)	0.06	0.26	0.14	0.11
Time_B_C (s)	4.24	11.58	7.81	3.16
Displacement_B_C (°)	5.86	13.87	9.43	3.38
Speed_B_C (°/s)	0.58	1.89	1.21	0.56
Acceleration_B_C (°/s ²)	0.06	0.26	0.15	0.08
Time_A_C (s)	10.48	22.97	16.52	5.11
Displacement_A_C (°)	11.59	28.20	20.36	7.20
Speed_A_C (°/s)	0.72	1.68	1.24	1.04
Acceleration_A_C (°/s ²)	0.03	0.12	0.07	0.04
N valid (according to the list)	7			

^aA: beginning of the FRT; B: maximum angular displacement; C: end of the FRT.

Table 3 shows the result of the displacement, of the maximum and minimum speed and acceleration in the FRT; and the average, maximum, and minimum speed and acceleration. The variables were presented as the mean and standard deviation of

the sum of the participants in relation to the three axes of each mobile and the difference between them.

Table 4 presents the intraobserver and interobserver reliability with a 95% confidence interval for each of the direct variables

obtained in the instrumentalization of the FRT by mobile. They are presented according to the placement of the mobile device and divided into three intervals of movement.

Table 3. Mean and standard deviation of the records of each of the sensors and differences between them.

	Trunk (SD)			Lumbar (SD)			Mean difference (SD)		
	X	Y	Z	X	Y	Z	X	Y	Z
Resultant displacement	34.92 (7.02)			37.06 (14.75)			1.86 ^a (23.64)		
Speed mean	1.79 (0.27)	25.44 (7.84)	24.59 (8.73)	1.68 (0.67)	22.39 (7.42)	19.42 (5.03)	0.11 ^a (0.74)	3.05 ^a (1.97)	5.17 ^a (8.43)
Speed maximum	-0.57 (0.70)	10.06 (3.97)	9.38 (1.42)	1.48 (0.94)	9.76 (6.14)	8.11 (1.07)	-2.05 ^a (0.62)	0.30 ^b (3.51)	-1.27 ^b (1.74)
Speed minimum	-2.19 (0.73)	-15.79 (2.81)	-13.10 (7.49)	1.19 (1.16)	-14.18 (4.43)	-12.28 (3.86)	-3.38 ^a (1.19)	1.61 ^b (4.07)	-0.82 ^b (9.21)
Resultant speed maximum	13.80 (4.22)			13.19 (4.70)			-0.61 ^a (4.41)		
Resultant speed minimum	20.55 (5.61)			19.01 (4.18)			-1.54 ^a (2.74)		
Acceleration mean	2.34 (1.21)	3.03 (1.27)	6.53 (1.32)	1.39 (1.01)	0.43 (3.38)	5.27 (1.84)	0.95 ^a (0.98) ^c	2.60 ^b (3.83)	1.26 ^b (1.96)
Acceleration maximum	0.73 (0.81)	2.19 (3.07)	95.40 (8.54)	0.43 (0.29)	2.34 (2.13)	90.94 (5.09)	0.30 ^a (1.43)	-0.15 ^b (3.79)	4.46 ^a (6.05)
Acceleration minimum	-2.42 (2.26)	4.33 (2.72)	88.88 (9.58)	1.84 (1.17)	2.97 (3.07)	84.11 (7.07)	-4.26 ^b (3.18)	1.36 ^a (2.81) ^d	4.77 ^b (6.18)
Resultant acceleration maximum	88.17 (10.23)			89.51 (8.69)			-1.34 ^b (4.84)		
Resultant acceleration minimum	90.19 (9.28)			88.71 (7.91)			1.48 ^a (5.71)		

^aDifferences calculated through Student *t* test (parametric distribution of the sample).

^bDifferences calculated through Wilcoxon's test (nonparametric distribution of the sample).

^c*P*=.02.

^d*P*=.03.

Table 4. Intraobserver and interobserver reliability of variables measured directly during FRT.

Variable	Intraobserver		Interobserver	
	ICC	95% CI	ICC	95% CI
Trunk				
Time				
A_B	.872	.857-.886	.868	.857-.875
B_C	.847	.831-.862	.840	.835-.851
A_C	.884	.873-.892	.864	.853-.876
Displacement				
A_B	.884	.871-.894	.873	.867-.880
B_C	.870	.862-.879	.861	.854-.872
A_C	.880	.869-.887	.869	.857-.882
Lumbar				
Time				
A_B	.883	.874-.891	.871	.864-.878
B_C	.867	.855-.876	.853	.848-.860
A_C	.849	.833-.860	.842	.837-.849
Displacement				
A_B	.874	.862-.887	.861	.853-.869
B_C	.877	.864-.885	.864	.857-.873
A_C	.869	.859-.883	.857	.850-.864
Functional Reach Test	.989	.981-.996	.978	.970-.985

Discussion

Principal Findings

The results show that inertial sensor mobile phones can be an accurate and reliable instrument for obtaining kinematic variables in the instrumentalization of FRT in people who have suffered a stroke.

The reliability of this study can be classed as high correlation [31], with ranges in intraobserver reliability between .831 and .894 and interobserver reliability between .835 and .882 (Table 4). These values are shown to be in accordance with values observed in previous and similar studies. Marchetti et al [12] had test-retest reliability of .87 (.68-.95), Merchán-Baeza et al [15] showed intraobserver reliability of .829-.878 and interobserver of .821-.883, and Mellone et al [14] had intraobserver reliability of .72 (.46-.86) and interobserver of .99 (.99-1.00). In the latter study, the reliability was extracted during the execution of a specific section of the TUG test, namely, from sitting to standing [14]. The differences in reliability between the values of our study and that of Mellone et al [14] could be due to the type of balance analyzed in each test. In our study, the controlled semistatic equilibrium was analyzed, whereas Mellone et al [14] analyzed the coordinated and explosive semistatic equilibrium necessary for carrying out a normal gesture [14]. However, the interobserver reliability cannot be compared between this study and that of Mellone et al because they did not differentiate in the calculation of

reliability distinct values for the mobile device and for the accelerometer [14].

The high reliability observed in the duration of our test (ie, intraobserver reliability of .847-.884 and interobserver of .840-.871) is comparable with the results shown by Mellone et al [14] in the parameterization of the TUG with a mobile device, with an ICC value of .83-.96 for intraobserver and 1.00-1.00 for interobserver. Although in the latter study the value for the accelerometer and mobile device was unified. Merchán-Baeza et al [15] had ICC values of .806-.880 (intraobserver) and .804-.879 (interobserver).

Given the position where the mobile phone is located in our study, the values of intraobserver reliability ranged between .847 and .884 for the trunk and between .849 and .883 for the lumbar position data. These were in accordance with the results obtained from a previous study where there were no observed notable differences in the values of reliability when two inertial sensors were placed in the same segments as our study (trunk and lumbar) for the kinematic record of the FRT. The ICC values observed in that study [15] were .835-.877 (trunk) and .829-.878 (lumbar). In addition, the mobile data are stable not only in primary measures, but also in secondary measures, as shown by Nishiguchi et al [13]: peak frequency ICC=.906, 95% CI .83-.95; root mean square ICC=.902, 95% CI .82-.95; autocorrelation peak ICC=.752, 95% CI .55-.87, and coefficient of variance ICC=.777, 95% CI .59-.89.

Strengths and Limitations

The main weakness in this study is the sample size, which is small, but sufficient to provide evidence for usefulness of mobile devices in the kinematic record of FRT in people who have suffered stroke. However, it would be beneficial to increase the number of participants to consolidate the results. Future studies should make absolute comparisons between healthy people and people with a profile marked by a static, semistatic, or dynamic imbalance during the FRT. However, a particular strength of our study is that it is the first to perform simultaneous kinematic recording using two mobile devices, that is, one placed on the trunk and another in the lumbar position.

Conclusions

Mobile phones have been proven to be reliable, valid, and specific tools to analyze the kinematics in FRT parameterization. Besides these properties, it is important to also note economy, ease of access, ease of use, portability, no computer needed to record the registration, large internal memory, stored data can be sent by email instantaneously, and additionally there are numerous apps to optimize the use of the various elements of the device. For these reasons, it can be argued that mobile devices have greater clinical potential than the inertial sensors (or accelerometers) commonly used in the laboratory. These statements supplement other similar claims made in previous studies [13,14].

We conclude that mobile phones are reliable tools for parameterization of FRT in people who have suffered a stroke.

Conflicts of Interest

None declared.

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Abbreviations

FRT: Functional Reach Test

ICC: intraclass correlation coefficient

TUG: Time Up and Go test

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Original Paper

Rehab on Wheels: A Pilot Study of Tablet-Based Wheelchair Training for Older Adults

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Abstract

Background: Alternative and innovative strategies such as mHealth and eLearning are becoming a necessity for delivery of rehabilitation services. For example, older adults who require a wheelchair receive little, if any, training for proficiency with mobility skills. This substantive service gap is due in part to restricted availability of clinicians and challenges for consumers to attend appointments. A research team of occupational therapists and computer scientists engaged clinicians, consumers, and care providers using a participatory action design approach. A tablet-based application, Enhancing Participation In the Community by improving Wheelchair Skills (EPIC Wheels), was developed to enable in-chair home training, online expert trainer monitoring, and trainee-trainer communication via secure voice messaging.

Objective: Prior to undertaking a randomized controlled trial (RCT), a pilot study was conducted to determine the acceptability and feasibility of administering an mHealth wheelchair skills training program safely and effectively with two participants of different skill levels. The findings were used to determine whether further enhancements to the program were indicated.

Methods: The program included two in-person sessions with an expert trainer and four weeks of independent home training. The EPIC Wheels application included video instruction and demonstration, self-paced training activities, and interactive training games. Participants were provided with a 10-inch Android tablet, mounting apparatus, and mobile Wi-Fi device. Frequency and duration of tablet interactions were monitored and uploaded daily to an online trainer interface. Participants completed a structured evaluation survey and provided feedback post-study. The trainer provided feedback on the training protocol and trainer interface.

Results: Both participants perceived the program to be comprehensive, useful, and easily navigated. The trainer indicated usage data was comprehensive and informative for monitoring participant progress and adherence. The application performed equally well with multiple devices. Some initial issues with log-in requests were resolved via tablet-specific settings. Inconsistent Internet connectivity, resulting in delayed data upload and voice messaging, was specific to individual Wi-Fi devices and resolved by standardizing configuration. Based on the pilot results, the software was updated to make content download more robust. Additional features were also incorporated such as check marks for completed content, a more consumer-friendly aesthetic, and achievement awards. The trainer web interface was updated to improve usability and provides both a numerical and visual summary of participant data.

Conclusions: The EPIC Wheels pilot study provided useful feedback on the feasibility of a tablet-based home program for wheelchair skills training among older adults, justifying advancement to evaluation in an RCT. The program may be expanded for use with other rehabilitation interventions and populations, particularly for those living in rural or remote locations. Future development will consider integration of built-in tablet sensors to provide performance feedback and enable interactive training activities.

Trial Registration: ClinicalTrials.gov NCT01644292; <https://clinicaltrials.gov/ct2/show/NCT01644292> (Archived by WebCite at <http://www.webcitation.org/6XyvYyTUF>).

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KEYWORDS

wheelchairs; telemedicine; self-efficacy; aged; pilot projects

Introduction

Overview

Alternative and innovative electronic and mobile technology strategies are becoming increasingly important as platforms for delivery of health-related services [1]. Emergent research literature has demonstrated effective interventions for health literacy [2,3], self-management [4], and adherence and health behavior change programs [5]. However, mHealth has thus far been limited in its application to motor-skill training and rehabilitation services. Occupational and physical therapists often provide rehabilitation in a hospital setting. However, decreasing resources for continued outpatient rehabilitation has resulted in challenging and costly access, particularly for clients living in rural and underserved communities [6,7]. The literature is beginning to document the benefits of using telehealth and mHealth as augmentative or alternative strategies to traditional in-person, individualized rehabilitation models [8]. In the previous decade, investigators explored in-home video telerehabilitation; however, this involved cumbersome camera equipment and coordination of real-time availability for client and clinician [9,10]. Near-ubiquitous Internet access and the emergence of lower-cost, portable, and powerful mobile devices such as smartphones and tablets have provided new opportunities for delivery of home-based rehabilitation.

One example of potential service delivery is the provision of wheelchair skills training, particularly among older adults. In Canada, there are an estimated 220,000 wheelchair users [11], over half of those being over the age of 65 [12]. Unfortunately, the growing numbers of older adults who require a wheelchair receive little if any training for proficiency with mobility skills [13,14]. This substantive service gap is due to restricted availability and time for clinicians to provide one-to-one therapy, limited content expertise, and challenges for consumers to attend appointments, particularly in rural or remote locations [15].

A tablet-based application, Enhancing Participation In the Community by Improving Wheelchair Skills (EPIC Wheels), was developed to address this issue. The mobile device enables in-chair home training, asynchronous online expert trainer monitoring, and trainee-trainer communication via secure voice messaging. The EPIC Wheels content was developed using a social cognitive theory framework to optimize wheelchair-specific self-efficacy [16,17]. Self-efficacy has a demonstrated link to skill development and participation among

wheelchair users [18]. Furthermore, incorporating self-efficacy strategies produces stronger adherence in home programs [19]. Four principal constructs promoting self-efficacy are integrated into EPIC Wheels content. *Mastery experience*, or the perception of performance achievement, is promoted by grading training activities from simple to complex to ensure early success experiences. Observing success in a comparable peer, or *vicarious experience*, is achieved by using age-appropriate models from both sexes for the demonstration videos. Personalized sessions and voice messaging contact with the trainer engenders *verbal persuasion* or reinforcement from a significant other. Finally, incorporating frequent but short training activities and self-monitoring exertion addresses participants' reinterpretation of their *physiological state*. Principles from adult learning theory, or andragogy, [20,21] were used to structure the delivery of content with the EPIC Wheels program, as these have proven effective with mHealth behavioral interventions [6]. Andragogy theory proposes that adult learners are internally motivated and prefer to direct their learning, they bring life experience and knowledge to the learning process, they are goal-oriented, they desire learning that is relevant to their social role, they prefer practical learning strategies, and they like to be respected in the learning process. As a self-directed mHealth application, EPIC Wheels allows participants to negotiate their own home training schedule and navigate the program to work on the skills and functions that are most personally relevant and important.

The EPIC Wheels program was conceived as a three-phase project. Phase one involved design, evaluation, and revision of the training program content and method of delivery. Before undertaking a clinical trial, it is prudent to conduct a preliminary evaluation of the feasibility of study methods and procedures in a pilot study [22]. This paper reports on phase two, which is a pilot study focusing on administration and acceptability of the intervention processes to ensure components are well integrated and viable [23,24]. Once confirmed, phase three would be a randomized controlled trial (RCT) evaluating the impact of EPIC Wheels on wheelchair mobility skill among older adult novice manual wheelchair (MWC) users.

Program Development and Content

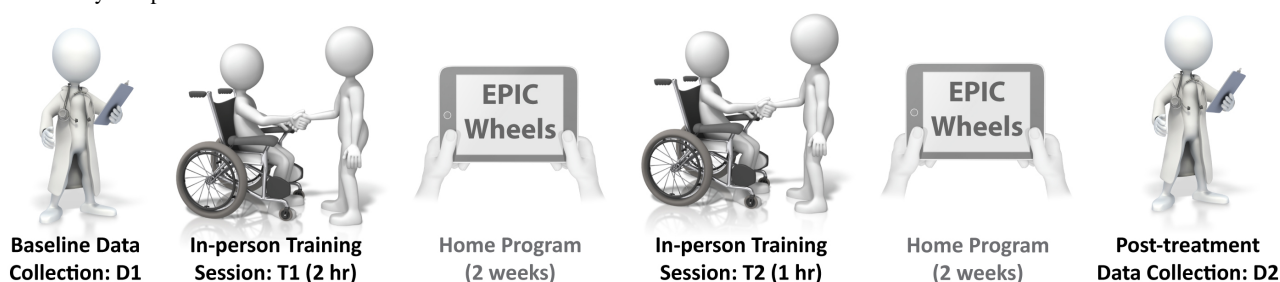
Using a participatory action design approach [25,26], clinicians, consumers, and care providers engaged with occupational therapists and computer scientists on the study team to develop the EPIC Wheels program in phase one. Through an iterative process of design, evaluation, feedback, and revision, the

program prototype progressed through three preliminary versions. A total of eight focus groups were conducted involving 34 participants from six stakeholder groups in two large urban centres. Focus group participants interacted with and critiqued each successful prototype, and the study team made evolving revisions until a beta version was ready for pilot testing in phase two. A detailed description of this development process has been reported in a previous publication [27]. As an extension to the participatory design process, participant feedback from the phase two pilot study further contributed to refinement of the EPIC Wheels program.

Purpose and Objectives

As is often the case with rehabilitation interventions, there is considerable complexity evaluating EPIC Wheels due to the multiple components of administration, various behavioral requirements, and the tailored aspect of the program. The degree of clinical impact may be a consequence of program effectiveness or potentially an issue of implementation; therefore, process evaluation is critical. Best practice suggests that fidelity in the implementation protocol should be established and reported on using a pilot study as part of a systematic framework for evaluating complex interventions in clinical trials [28]. The intent of this pilot study was to run a preliminary version of the EPIC Wheels procedures to ensure integrity and integration of the study components, fidelity of the intervention protocol and methodological integrity [29], viability of participant adherence or engagement [30], and participant acceptance [31]. Rather than a *feasibility study*, which operates as a mini-RCT focusing on recruitment and primary outcome estimates, a *pilot study* addresses study-related issues of procedural administration, data collection, and intervention-specific issues [24]. Given the small scale, absence of a control group, and potential for changes based on the results, there was no intent to conduct hypothesis testing or include the data in the full clinical trial [23,24]. Thabane et al [23] propose the use of a framework for evaluation of process, resource, management, and scientific outcomes in a pilot study. Using this structure, we developed a comprehensive set of metrics by which to evaluate each component, including parameters for confirming feasibility. Consequently, the specific study objectives were to determine whether a wheelchair skills training program could be administered effectively and safely in an mHealth format, whether participants would adhere to the prescribed mHealth training protocol and find the training program acceptable and beneficial, and if additional changes or enhancements to the mHealth program were indicated.

Figure 1. Study components and timeline.



Methods

Participants

Given the purpose of methodological evaluation, a sample size calculation was not indicated. Pilot studies typically involve a small sample, with 2-4 participants generally being sufficient to verify procedural feasibility [31]. We selected a purposive sample of two participants of different skill levels - one experienced and one novice MWC user. The experienced user (participant 1) would provide perspective on the applicability and relevance of the program and bring a larger spectrum of skills, enabling the trainer to anticipate how to adjust the training process accordingly. The novice user (participant 2) would be reflective of the target population. Participant 1 was a 60-year-old single male with a T9 spinal cord injury who had been a MWC user for 485 months and a competitive wheelchair athlete earlier in life. He was recruited through previous contact in phase 1 of the EPIC Wheels project, where he had expressed interest but was unable to participate in the program development. Participant 2 was a 73-year-old married male with left above-knee amputation who had been a MWC user for 3 months and was recruited through public advertisement. Both participants had home computers and a basic level of computer literacy but neither had a tablet device. Approval for the study was obtained from the University of Manitoba Health Research Ethics Board (#H2012:069) and registered with clinicaltrials.gov (NCT01644292). Participants completed a consent form that clearly articulated this was a pilot study to evaluate study procedures and participant acceptability.

Study Overview

Based on clinical consensus during the EPIC Wheels development phase, a four-week timeline was constructed to administer the program (see Figure 1). Acceptable time intervals for each milestone were identified in advance. Participants attended a baseline data collection appointment (D1) and then scheduled the first in-person training appointment (T1) within 7 days. After 14 days (optimal; must be between 12 and 16 days after T1) of home training with the tablet, participants attended a second in-person training session (T2). After another 14 days of home training, the program was complete and post-treatment data were collected (D2) within 42 days of D1. All data collection and in-person training occurred in a centrally located wheelchair-accessible clinic.

Intervention Description

The EPIC Wheels program incorporates two brief in-person education sessions with an expert trainer and four weeks of monitored home training conducted via a computer tablet. The first education session involves one hour of individualized assessment of specific mobility-related wheelchair skills and one hour of orientation to the tablet and software program. The trainee is provided with a password-protected 10" Android tablet configured for single-function use (ie, only the EPIC Wheels program is accessible) along with a pre-synchronized mobile Wi-Fi device to provide Internet access. We intentionally used two different tablets (Motorola XOOM and ASUS TF300) and mobile Wi-Fi devices (Huawei E587 and Sierra AirCard 763S) to ensure a spectrum of device compatibility and functionality. A tablet stand mounted on a cushioned platform rests on the trainee's lap, secured in place with a strap around the thighs for in-chair use (see [Figure 2](#)).

The tablet home program incorporates a variety of training components provided in video format. Participants view videos from one to five minutes in length that provide education and demonstration of specific wheelchair mobility skills. Additional videos require participants to practice demonstrated skills for a prescribed period of time using an on-screen timer with a start/stop function. Other videos incorporate interactive games and activities that require participants to perform maneuvers in response to or synchronous with the displayed video content. The training videos are structured to encourage repetition and variation of skill performance consistent with motor learning principles. Skills are broken down into subcomponents and progress from simple to complex. The initial section contains five chapters beginning with detailed information and instruction related to safety, injury prevention, and caregiver spotting; subsequent sections are locked out until the safety section is completed. The remaining four sections cover wheelchair components and body positioning; propulsion strategies; basic

skills, such as turning around and negotiating obstacles; and advanced skills, such as ascending and descending thresholds and inclines, crossing gaps and soft surfaces, negotiating doorways, and managing curbs and stairs.

Trainees are instructed to practice at home 4 to 5 days per week in 15-30 minute sessions for a total of at least 75 minutes each week. All tablet activity is internally recorded and uploaded to a secure server which the trainer can access online. Two prompting questions are posed when the trainee engages the program (questions only appear once per 24 hours), requiring responses. The first question asks "Did you have any tips or falls?" If the response is yes, trainees receive an additional prompt to contact their trainer. The second question asks "Since your last session, did you do any training on your own?" If trainees select yes, they receive an additional prompt to select the number of minutes spent practicing without the tablet in 5-minute increments. Trainer and trainee can exchange voice messages from their respective computers and tablets at their convenience. Based on the monitored data, the trainer may initiate contact if concerns arise (ie, if there is no training activity for 2-3 days) or adapt the content of the second education session (ie, if the trainee is advancing quickly through the progression of skills). After two weeks of home training, the trainee attends a second in-person education session of 1 hour in length. The trainer reviews home program activities and provides additional, more advanced skills training, and the trainee continues with the EPIC Wheels home program for another two weeks.

As there are inherent safety risks with wheelchair use, primarily related to tips and falls, several safety strategies were employed. Participants were encouraged to bring a care provider to the in-person training sessions and have them supervise higher-risk training activities at home. Safe spotting and supervision instruction were provided at the first training session along with a spotter's strap (to prevent rearward tips) for home use.

Figure 2. Tablet and mounting platform for in-chair training.



Data Collection and Analysis

Dates for completion of each study component were documented and intervals calculated. The study tester administered D1 and D2 in accordance with a detailed protocol binder and corresponding checklist. The first author confirmed procedural

and scoring accuracy via video recordings; any discrepancies or errors were reviewed with the tester and additional training provided if necessary. If procedural issues arose, these were documented and protocols modified. The principal clinical outcomes of the intervention were wheelchair skill capacity and safety as measured by the Wheelchair Skills Test (WST 4.1)

[32], as well as wheelchair-specific self-efficacy as measured by the Wheelchair Use Confidence Scale (WheelCon-M 3.0) [33]. The WST is a standardized, performance-based measure of 32 skills, each evaluated on a capacity subscale and a safety subscale scored from 0 to 32. The WheelCon-M is a 65-item questionnaire in which respondents rate their confidence using a wheelchair in varying activities and environments on a scale from 0 (not confident) to 100 (completely confident), producing a mean confidence score between 0 and 100.

The study trainer administered T1 and T2 in accordance with a detailed protocol binder and corresponding checklist, with the first author again confirming accuracy via video recordings and addressing issues with the trainer or revising the protocol. The study trainer completed a post-treatment evaluation form and interview with the first author.

The EPIC Wheels software documented all tablet interactions with a time stamp and uploaded this data to the trainer website on a secure server. Training activity data (in minutes) were tabulated for each day and imported into an Excel spreadsheet. From this data, we were able to calculate the total number of days and minutes of training, mean number of days per week training, minutes per week training, and minutes per training day. Responses to the daily safety question prompt “Did you have any tips or falls?” were also recorded. When technical issues arose with the tablet or mobile Wi-Fi device, trainees contacted their trainer via the tablet voice-messaging feature. If the trainer was unable to resolve the issue, the first author traveled to the trainee’s home to troubleshoot the problem and document how it was resolved. Based upon the data analysis and feedback from trainer and trainees, the development team explored any further changes or revisions that could improve functionality or feasibility of the program.

After finishing all data collection at D2, trainees completed a 9-item post-treatment questionnaire evaluating elements critical to rehabilitation intervention development [34,35] on a Likert scale from 1 (strongly disagree) to 4 (strongly agree). Following this, the first author conducted an exit interview to obtain additional qualitative feedback about participant experiences. The interviews were conducted in a semistructured format and were 15 to 20 minutes in length. The sessions began with open-ended queries related to overall impressions of the program

and then, following the participant’s lead, more focused questions were asked to elicit details about factors that enhanced or detracted from the training experience. Follow-up questions targeted specific impacts of the program on wheelchair use, impressions of the user interface, and perceptions of the program’s benefit. The first author took detailed notes during the interview and further refined details immediately afterwards. In addition, participant 1 shared written feedback related to program content, which he had brought to the D2 session.

The study trainer completed a post-treatment questionnaire after finishing with each participant which included five dichotomous questions (yes/no) related to clarity, timeliness, and issues with and major/minor deviations from the intervention protocol, with the option for narrative explanation. The first author also conducted an informal exit interview with the trainer after participant 2 had finished the study. The interview was approximately 15 minutes long and employed an unstructured format. The trainer was invited to share her experience with the training intervention and explicate both benefits and shortcomings. Follow-up questions were spontaneous and intended to elicit additional detail or clarification. Experience with and impressions of the monitoring website were one area of specific exploration. General notes were taken during the interview and additional detail constructed immediately afterwards by the first author.

Results

All study components were completed within the prescribed time allocations. Administration of the data collection and in-person training sessions were consistent with protocol guidelines, with minor revisions (see [Multimedia Appendix 1](#)). No adverse events were encountered during any data collection or training sessions. The principal clinical outcomes of wheelchair skill capacity and safety as well as wheelchair-specific self-efficacy are presented in [Table 1](#). Participant 1 (the experienced MWC user) demonstrated no change in wheelchair skill and safety, but his self-efficacy score increased by 5.9 (5.9%). Participant 2 (the novice MWC user) had improved scores in skill capacity (12.5%), safety (3.2%), and self-efficacy (7.2%).

Table 1. Wheelchair skill capacity, safety, and self-efficacy scores.

Measure	Participant 1		Participant 2	
	Baseline	Post-intervention	Baseline	Post-intervention
WST: capacity (%)	24 (75.0)	24 (75.0)	18 (56.3)	22 (68.8)
WST: safety (%)	32 (100)	32 (100)	29 (90.6)	30 (93.8)
WheelCon-M	79.3	85.2	63.9	71.1

With respect to adherence with tablet home program expectations, the frequency of training (days spent training each week) was 4, 3, 4, and 4 (total 15 days) for participant 1 and 6, 5, 3, and 6 (total 20 days) for participant 2. The intensity of training sessions (mean minutes per training day) was 36.9 minutes for participant 1 and 30.4 minutes for participant 2. In terms of training dosage, participant 1 spent a total of 553

minutes in home training (138.3 minutes/week) while participant 2 spent a 608 minutes training with the tablet (152.0 minutes/week). Neither participant reported any adverse events or injuries during home training.

A summary of participant responses to the post-treatment questionnaire is detailed in [Table 2](#). During the post-treatment interview, participant 1 indicated the program was excellent

and would have been beneficial to him during his initial transition to wheelchair use. He stated the training activities were fun and engaging, some of which he had modified on his own to increase the complexity and challenge given his existing level of skill proficiency. One observation he made was the uncertainty around how far he was through a given training video. Videos were limited to play, pause, and stop functions, and the participant didn't know how much running time had

passed or was remaining. Participant 2 reported a number of areas of specific skill improvement including propelling over high resistance surfaces and maneuvering around corners. He highlighted the comfort and ease he now had with "popping his casters" to get over small obstacles in his home and community and reflected on how this had seemed an impossibility to him during the baseline assessment.

Table 2. Post-treatment questionnaire responses by participant 1 and 2.

Item	Strongly agree	Agree	Disagree	Strongly disagree
Training is valuable or important	P1 ^a , P2 ^b			
Method of training was reasonable and appropriate	P1	P2		
Skills taught were reasonable and appropriate	P1	P2		
Trainer was reasonable and appropriate	P1, P2			
Expectations were manageable and practical		P1, P2		
Components of program provided as described	P1	P2		
I was able to perform or improve skills taught	P1	P2		
I did not experience injury or undue physical/mental stress	P1	P2		
Program was successful in improving my skills	P2	P1 ^c		
Total	10	8	0	0

^aP1: Participant 1.

^bP2: Participant 2.

^cThis participant self-modified some of the activities to increase the challenge/difficulty.

The trainer indicated no major/minor deviations or issues with administering the intervention and confirmed satisfactory timeliness and clarity of process with both participants. At T1, set-up of the Wi-Fi device occurred after the tablet program orientation; consequently, the trainer was unable to demonstrate the daily prompting questions, which proved to be problematic for the participants. During the exit interview, the trainer highlighted the value of being able to monitor participant training activities online to identify potential problems (ie, no training activities for several days) and adapt the intervention content and goals based on participant progress. However, the trainer identified that data was collated into daily totals and did not explicate multiple sessions within a given day. In addition, the details of training activity (ie, specificity and frequency of which components participants engaged in) were not available. These shortcomings were identified as a limitation to capturing a full picture of participant training activity. Participant 2 reported several occasions when the voice message function failed to send and receive messages, compelling him to contact the trainer via telephone. The trainer also identified extended time periods between participant practice data uploading to the website. This also proved to be frustrating for the participant because his training time was not included in the progress window. The first author traveled to the participant's home on two occasions before diagnosing an issue with the Wi-Fi timing out, resulting in the tablet losing Internet connectivity. Revision of the tablet and Wi-Fi configuration settings resolved these issues.

Discussion

Evaluation of Program Administration, Adherence, and Acceptability

The results of the pilot study demonstrated that, with several minor revisions, the EPIC Wheels RCT could feasibly be administered as planned. With respect to the administration of the data collection and treatment intervention procedures, these were conducted efficiently within the proposed timeframe of six weeks and consistently within the outlined protocols. While no breaks from protocol were encountered during in-person training sessions, a revision to the T1 session was instituted as a result of the pilot experience. Wi-Fi connectivity is now initiated prior to the tablet orientation to ensure the daily prompting questions appear, allowing the trainer to demonstrate this feature. The trainer also confirmed feasibility of the intervention protocol, including the sufficiency of a 1-hour orientation to the tablet and EPIC Wheels software program with novice users. The trainer website provided useful and relevant data for basic monitoring of trainee progress; however, the trainer identified that additional detail about the specificity of training activities and multiple daily sessions would be desirable. The voice-messaging issue proved to be frustrating for the trainer and trainee because it required coordinating a contact time via telephone. Delays in data upload to the website were concerning as the trainer could not ascertain whether the participant was not actually engaging in any training or whether this data were simply not being reported. Participant 2 identified

the progress window as highly motivating and was upset when completed practice was not recognized. Even small issues such as these with an mHealth user interface could potentially compromise usage and adherence, and this experience was valuable in highlighting the benefits of pilot testing to resolve any issues with seamless delivery.

Viability of the EPIC Wheels program with multiple Android tablet and mobile Wi-Fi device combinations was confirmed. Intermittent connectivity issues with the mobile Wi-Fi devices required troubleshooting during the home training component of the study until a satisfactory configuration was obtained. As a result, tablet/Wi-Fi device specifications were documented to optimize setup for future participants. In addition, printed user guides were created for each tablet/Wi-Fi device combination. Ideally, using a participant's home Wi-Fi would eliminate most potential connectivity problems as well as the cost of renting a mobile Wi-Fi device (approximately \$10/month). However, this requires configuration of tablet settings in-home, which can present several barriers. First, the tablet is configured as a single application device preventing participants from accessing other applications or tablet settings. This restriction can be overridden but would require that a study administrator either visit the participant's home and make these adjustments (potentially requiring participants to reveal a security password) or convey these procedures to the participant. The latter option would necessitate the participant or surrogate possesses the capacity to operationalize the changes or study personnel to provide continuing technical support from a distance and would increase the potential for additional untoward modifications or alternate use of the tablet. Second, home Wi-Fi availability is not ubiquitous, particularly among the target population of older adults. A recent survey estimates that in the United States, only 47% of seniors have high-speed Internet connectivity in their home [36]. An alternative solution would thus be required for individuals without Internet access and for those with connectivity but no Wi-Fi service.

An important objective of this study was to ensure the expectations of the home training program were reasonable and safe and that participant adherence was feasible. Without confirming these elements, valid evaluation of the intervention as intended in the subsequent RCT would be in jeopardy. Both participants met or exceeded the targeted parameters of adherence; participant 1 was slightly under the desired frequency of days practicing but exceeded the minimum session intensity and dosage metrics. Both participants spent nearly twice the minimum recommended time engaged with the mHealth platform, training a total of approximately 10 hours over four weeks. Frequency of practice is a critical component in developing motor skills [37] and using a mobile tablet application rather than a Web-based program accessible only via computer offers greater flexibility to encourage multiple training sessions in varied contexts [2]. Participant 1 had fewer practice sessions and spent slightly less time overall with the home program. However, given his level of proficiency with wheelchair use he may have been less motivated to engage in watching and practicing skills he had already mastered. Neither participant reported any adverse events, including tips or falls; each agreed they did not experience undue mental or physical

stress and the program methods and expectations were reasonable.

In addition to confirming the EPIC Wheels program was reasonable and safe, participant acceptability and perception of program relevance and benefit was paramount. While evaluation of clinical outcomes was not the primary purpose, the results from the pilot study were promising. Participant 1 was an expert MWC user and, as expected, did not improve in skill capacity or safety. However, he did show a small improvement in self-efficacy even after 40 years of experience. Participant 2, who was a novice user and representative of the target population, demonstrated improvements in skill capacity, safety, and self-efficacy. The improved wheelchair skill scores suggest that the EPIC Wheels intervention could be effective in achieving the desired outcome. Furthermore, the improvement seen in self-efficacy among both participants supports the theoretical basis of the training program using social cognitive theory constructs. Current evidence suggests that, in addition to wheelchair skill capacity, higher self-efficacy is positively associated with frequency of participation among older wheelchair users [38].

With respect to the trainee post-treatment questionnaire, our evaluation metric was to have both participants agree or strongly agree with each item, which was confirmed. Both participants confirmed the content was appropriate and beneficial. Both participants described the mHealth platform as engaging and entertaining, as well as providing an appropriate context and delivery strategy for learning new wheelchair skills. These positive evaluations regarding the EPIC Wheels intervention appear reasonable, given that both participants experienced improvement in self-efficacy and the novice MWC user also increased his capacity and safety with wheelchair use. Since most telerehabilitation and mHealth interventions target behavioral or cognitive skills and strategies, this pilot study was particularly useful in providing initial evidence to support mHealth application to motor skill improvement.

Changes and Enhancements to the EPIC Wheels User Interface

While neither trainee identified overwhelming concerns with the user interface, conveying participant practice data and progress was an issue for both trainee and trainer. Improved navigation of the program and individual training videos were also identified as desirable. While both participants rated all components of the post-treatment questionnaire as at least satisfactory, the study team felt that additional information and improved aesthetics could further enhance adherence and usability in the subsequent RCT, which would be reflected in future evaluations. Consequently, several modifications were made to the home program. The user interface was upgraded with a more colorful and dynamic appearance, consistent with other consumer applications (Figure 3). Participant progress information is in constant display, rather than opening in a new window, and includes not just the number of minutes practiced but the number of instructional videos viewed and activities completed as well as a progress bar for the current training week (Figure 4, red highlights). When completed, training components now display a visual check mark (to simplify navigation to the

current training activity) and a gold star (Figure 4, blue highlights). The gold stars cumulatively earn progress awards, which are delivered to the participant and can be viewed in a dedicated awards window (Figure 4, green highlight, and Figure 5).

The window for displaying training information and activities was modified to improve appearance and navigation (Figure 6). In particular, a scrubber bar was introduced to identify progress through the activity and allow trainees to easily navigate forward and backward. For timed training activities, the monochrome Start/Stop button was replaced with a larger, colorful button with more detailed directions and a clock with running time. The study team anticipates these modifications will provide better visibility and comprehension for older adult users and promote greater adherence to the suggested training time.

Based on suggestions from the trainer and discussion among the study team, the format and content of the trainer website was also modified to improve usability and appearance. The

original site displayed a simple table with only the total minutes spent engaged in tablet activity on active training days as well as a running total (see Figure 7). The revised site now displays multiple training sessions on a given day in table format and a quick view graphic breakdown for the types of training done (eg, viewing educational videos, engaging in training activities, practice without the tablet). By scrolling down the page, the trainer can view additional graphic and tabular data explicating trainee usage for each home-training session (see Figure 8). The number of days accessed, time accessed, total views, length of time viewing, and associated time practicing is now available for each training component.

The voice-messaging software was restructured to use a more robust commercial application that does not require extensive configuration to the trainer’s computer and now provides efficient and reliable performance. The trainer website was also revised to incorporate a simple and intuitive voice-message user applet that also includes the option of a subject line (see Figure 9).

Figure 3. Trainee interface pre- and post-pilot versions.

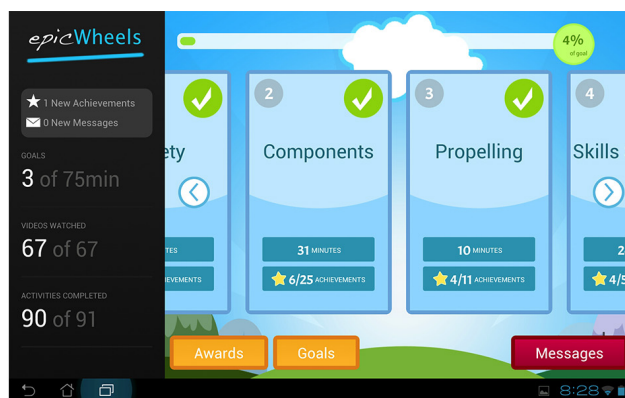
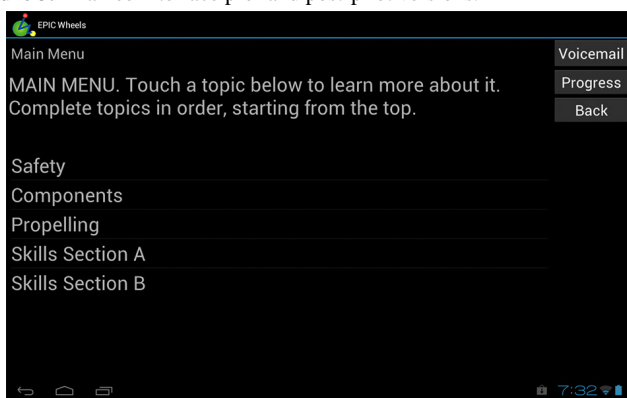


Figure 4. Participant progress display pre- and post-pilot versions.

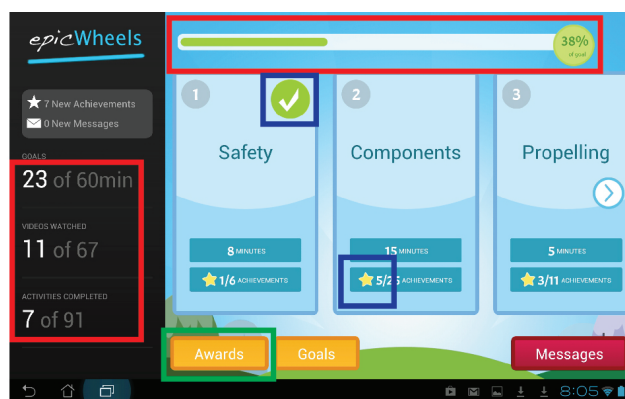
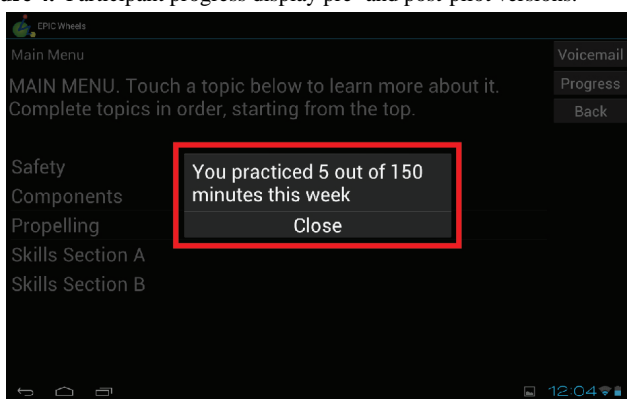


Figure 5. Award pop-up with Awards Earned windows in post-pilot version.

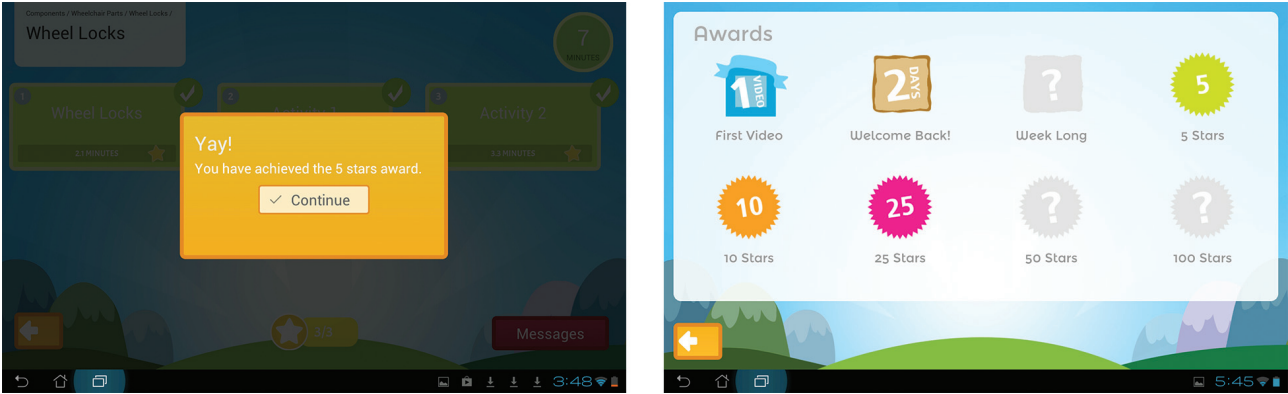


Figure 6. Training activity window with timer pre- and post-pilot versions.



Figure 7. Trainer website pre- and post-pilot testing.

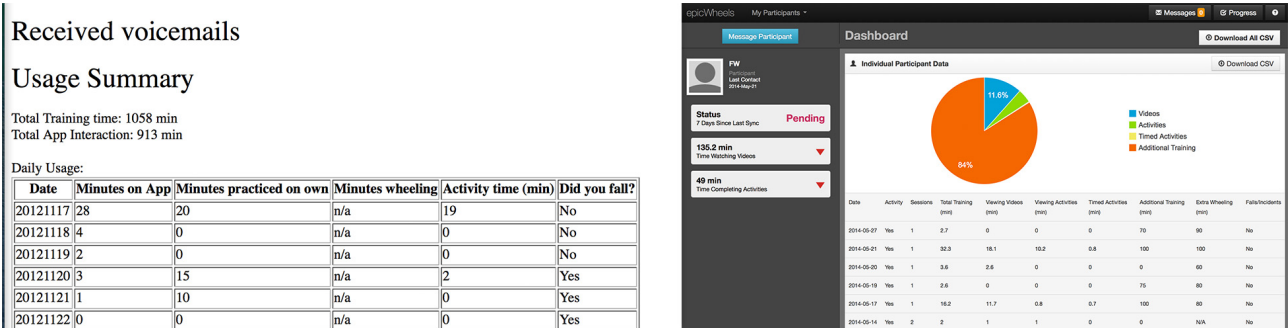


Figure 8. Trainer website features.

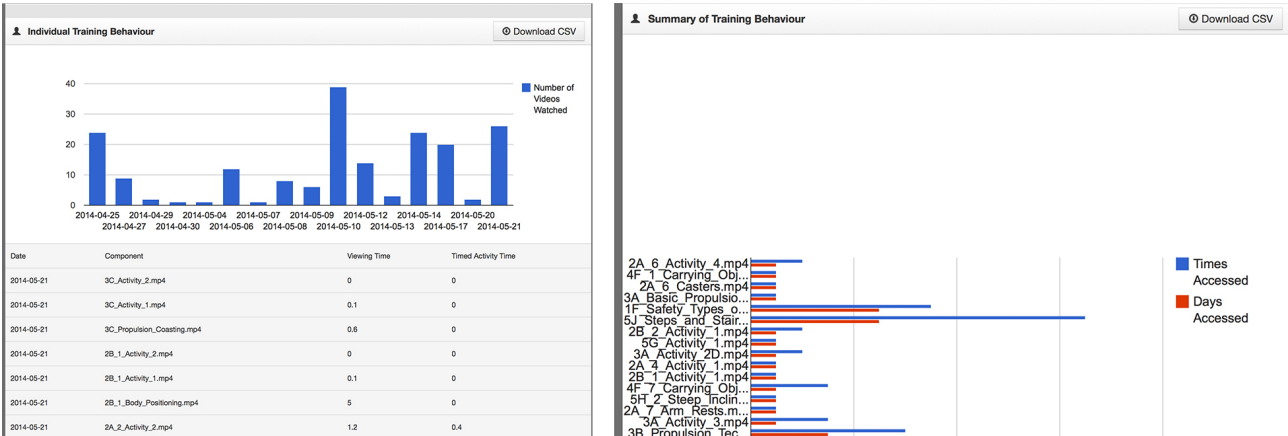
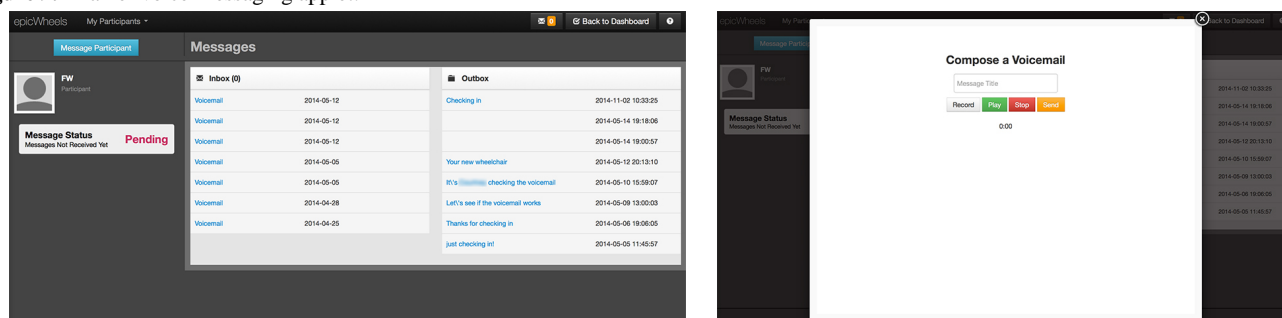


Figure 9. Trainer voice-messaging applet.



Limitations

This pilot study provided sufficient confirmation of the fidelity of study procedures to proceed with a feasibility RCT. The small number of participants may have limited the scope of issues identified in the implementation and acceptability of the mHealth intervention. The investigators developed the evaluation structure and questionnaires with specificity to address usability and implementation issues of concern; however, the use of validated evaluation formats and measures would enhance the generalizability of results, and future studies should endeavor to employ them. The first author conducted the post-intervention interviews with participants, and they may have been reluctant to express concerns or criticism because of the relationship established during the study. A more extended interview with a structured guide or a series of interviews throughout the pilot study might have elicited additional information related to program attributes and factors contributing to success. Participant 2 subsequently provided a separate interview with a public access television station and expressed

a comparably positive evaluation of the EPIC Wheels program [39].

Conclusions

The EPIC Wheels pilot study provided confirmation of the feasibility of our study design to evaluate a tablet-based home program for wheelchair skills training among older adults. Participants reported positive impressions of the intervention and delivery method and the initial treatment effect results are promising. Feedback from participants and trainers resulted in several adaptations to the intervention, including expansion and upgrade of the user interface for both trainee and trainer. Effectiveness of the EPIC Wheels program will be evaluated in an RCT [40]. The program offers considerable potential for expansion and use with various populations and delivery of other rehabilitation training programs, particularly for those living in rural/remote locations having limited access to rehabilitation services, including those in developing nations. Future development will consider integration of built-in tablet sensors to provide performance feedback and enable interactive training activities.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Data on administration of data collection and intervention.

[PDF File (Adobe PDF File), 21KB - [rehab_v2i1e3_app1.pdf](#)]

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Abbreviations

EPIC Wheels: Enhancing Participation In the Community by improving Wheelchair Skills

MWC: manual wheelchair

RCT: randomized controlled trial

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Original Paper

Studying Upper-Limb Kinematics Using Inertial Sensors Embedded in Mobile Phones

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Abstract

Background: In recent years, there has been a great interest in analyzing upper-limb kinematics. Inertial measurement with mobile phones is a convenient and portable analysis method for studying humerus kinematics in terms of angular mobility and linear acceleration.

Objective: The aim of this analysis was to study upper-limb kinematics via mobile phones through six physical properties that correspond to angular mobility and acceleration in the three axes of space.

Methods: This cross-sectional study recruited healthy young adult subjects. Humerus kinematics was studied in 10 young adults with the iPhone4. They performed flexion and abduction analytical tasks. Mobility angle and lineal acceleration in each of its axes (yaw, pitch, and roll) were obtained with the iPhone4. This device was placed on the right half of the body of each subject, in the middle third of the humerus, slightly posterior. Descriptive statistics were calculated.

Results: Descriptive graphics of analytical tasks performed were obtained. The biggest range of motion was found in pitch angle, and the biggest acceleration was found in the y-axis in both analytical tasks. Focusing on tridimensional kinematics, bigger range of motion and acceleration was found in abduction (209.69 degrees and 23.31 degrees per second respectively). Also, very strong correlation was found between angular mobility and linear acceleration in abduction ($r=.845$) and flexion ($r=.860$).

Conclusions: The use of an iPhone for humerus tridimensional kinematics is feasible. This supports use of the mobile phone as a device to analyze upper-limb kinematics and to facilitate the evaluation of the patient.

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KEYWORDS

patient outcome assessment; shoulder; upper extremity; kinematics

Introduction

Upper-limb mobility is of great interest in clinical settings [1] because measuring the range of motion (ROM) is critical when evaluating the musculoskeletal system [2]. Upper extremities

have been measured by manual goniometry for the last 100 years, but measurement methods have recently expanded [3-6]. Besides goniometry, arm ROM has been studied by other methods, such a digital goniometer [5], visual estimation [7], digital inclinometer [8,9], three-dimensional (3D) gyroscope [10,11], polhemus fastrak [12], calibration anatomical system

techniques [13], the Kinect system [14], biplane fluoroscopy [15,16], markers fitted on intracortical pins [17], 3D computerized tomography [18], and the moiré fringe projection technique [19].

Recently, telerehabilitation has provided rehabilitation using Internet communication as a result of emerging contemporary technologies for therapeutic purposes [20,21]. Thus, Internet-based evaluation and goniometry have been accepted as new, valid, and reliable tools for measuring ROM [22]. This drives the use of the mobile phone as a tool for assessing and measuring. Mobile phone apps are being validated as goniometric tools [23] through clinometers [24] or goniometers [25]. Image-based apps have been created for measuring elbow and hallux valgus angles [26,27], and clinometer-based apps have also been created for measuring shoulder ROM [24]. In addition, an inclinometer-based app on a mobile phone has been demonstrated to have an acceptable reliability compared to conventional inclinometers that evaluate the shoulder joint [28]. Furthermore, active shoulder external rotation measures have been validated using inclinometry-based and image-based apps [29]. Recently, a study has analyzed arm motion by inertial variables provided by a mobile phone in five subjects [30].

One of the recently used techniques has been inertial sensors. Their use in human analysis involves a valid and reliable method that provides the potential required for dynamic 3D motion analysis [31]. Their protocol [32] and intra- and interoperator reliability [33] in the upper extremity have been determined. In addition, their operational feasibility in various clinical applications has been studied [34]. Several protocols have also been developed for analyzing the scapulothoracic, humerothoracic, and elbow joints [35], as well as scapula [36]. Very recently, reliability and precision of scapula kinematic through inertial and magnetic measurement systems (IMMS) has been studied in healthy subjects [37]. Advantages and disadvantages of these sensors have been discussed as part of

a variety of motion analysis systems [38]. Thus, inertial sensors embedded in mobile phones have been used for analyzing movement, such as trunk kinematics [39]. More specifically, they have been used for evaluating shoulder movement using kinematic scores to assess the difference between healthy and painful shoulders [30].

Emerging mobile phone use for therapeutic purposes [40] has led to the need for research on arm ROM using mobile phones while incorporating the qualities of inertial sensors that allow clinicians an inexpensive and easy-to-use tool for upper extremity evaluation and outcome assessment.

The purpose of this study was to study humerus kinematics through two physical properties that correspond to angular mobility and acceleration in the three axes of space, obtained by inertial sensors embedded in a mobile phone.

Methods

Subjects

This cross-sectional study recruited healthy young adults from the Faculty of Health Sciences (University of Málaga) who were interested in taking part in the project. Subjects provided inclusion and exclusion criteria. Inclusion criteria included being aged between 18 and 35 years, having a Body Mass Index (BMI) between 18.5 and 28, and being right-handed. Exclusion criteria included consuming analgesics or non-steroidal anti-inflammatory drugs (NSAIDs) and suffering from shoulder pathology.

Ten subjects (7 men and 3 women) were included. Mean age was 24.2 years (SD 4.04 years), and average BMI was 22.59 kg/m²(SD 2.4 kg/m²; see Table 1).

The ethics committee of the University of Málaga, Spain, approved this study. Written consent was obtained following an explanation of the procedures.

Table 1. Values of anthropometric and descriptive variables.

	Minimum	Maximum	Mean	Standard deviation
Age, years	20.00	34.00	24.20	4.04
Size, cm	156.00	184.00	172.20	9.05
Weight, kg	48.00	87.00	66.60	11.88
BMI, kg/m ²	19.72	27.46	22.59	2.40

Apparatus

Mobility angle (degrees) and acceleration were measured along three orthogonal axes using the iPhone4 (LG Electronics INC, Seoul, South Korea) iOS8.2, which has a storage capacity of 20MB. This phone was placed on the right half of the body of each subject in the triceps skinfold site, located on the posterior part of triceps at mid-acromiale-radiale level (defined by ISAK) [41]. The phone was attached by using a neoprene arm belt (Figure 1) and remained attached throughout. The app used to obtain kinematic data was xSensor Pro (Crossbow Technology,

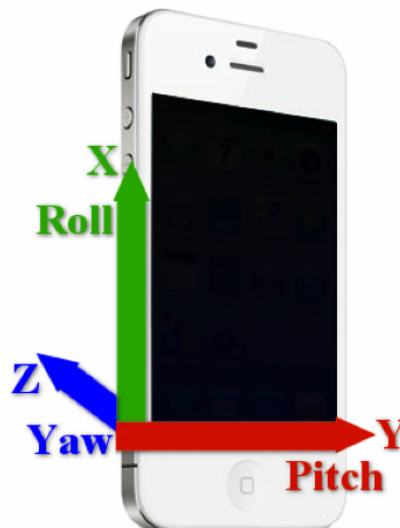
Inc.), available at the Apple AppStore. The data-sampling rate was set to 32 Hz, and the data for each analytical task was transmitted as email for analysis and post-processing. Data from the phone were subsequently sent to a Microsoft Excel 2007 database.

Because of its positioning, axes and planes in the phone corresponded to different planes of anatomical movement: yaw (z) for shoulder flexor-extension plane, pitch (y) for shoulder abduction plane, and roll (x) for humerus rotation plane (Figure 2).

Figure 1. iPhone4 smartphone placed on the right hemi-body of a subject.



Figure 2. Representation of yaw, pitch, and roll axes in the smartphone placed on humerus.



Procedure

Subjects were asked to attend the study in the Human Movement Laboratory, Faculty of Health Sciences (University of Málaga). The analytical task to be performed was explained clearly. The beginning and the end were decided by a verbal order by the researcher, which was identical for all participants. They stood, starting from a neutral position, and performed the following analytical tasks: right shoulder abduction for eight repetitions and, after a break of about three minutes, right shoulder flexion for eight repetitions. Participants were told to perform the movements to the highest position they could reach. Both tasks were performed with the elbow extended, the wrist in a neutral position, and the palm area of the hand toward the midline at the beginning and end of the movement.

Data Analysis

SPSS v15.0 was used for all statistical computations. Descriptive statistics (mean, standard deviation, minimum, and maximum) were calculated for age, height, weight, BMI, angular mobility, and linear acceleration. Standard procedures were used to

calculate means and standard deviations. The Kolmogorov-Smirnov test showed a normal distribution of the data ($P > .05$).

Angular mobility and linear acceleration were calculated in two different ways: calculating each space of motion separately and considering the resultant vector of the three axes of movement, which was understood as: Resultant vector = $\sqrt{x^2 + y^2 + z^2}$

Results

Analyzing angular mobility allowed us to obtain descriptive graphics of analytical tasks performed by each participant (Figure 3).

Means and standard deviations of angular mobility and acceleration were calculated. For that, data from the second repetition of the second series for both abduction and flexion movements in each of the space axes were analyzed.

In terms of angular mobility, the biggest range was found in pitch axis for flexion movement, followed by the same axis in

abduction. However, the smallest range was found in yaw for flexion and in roll for abduction. Considering resultant vector, ROM is bigger for abduction (Table 2).

Regarding acceleration, the largest value was found in the y-axis, followed by the z- and x-axes in both movements. Flexion acceleration was greater in the x-axis when compared to abduction; while, in abduction, acceleration was greater in the

y- and z-axes than flex. With regards to resultant vector, acceleration was greater in abduction (Table 3).

Relationship between angular mobility and linear acceleration was calculated for both tasks in each axes of space and resultant vector. Strong correlation was found in y and x as well as in resultant vector, for both tasks. However, that correlation was not significant in yaw axis. More details are shown in Table 4.

Table 2. Degrees of angular mobility recorded in abduction and flexion movement.

Angles	Abduction, mean (SD)	Flexion, mean (SD)
Yaw	109.96 (39.44)	79.81 (39.69)
Pitch	151.59 (10.21)	156.15 (12.40)
Roll	87.53 (38.46)	80.09 (47.45)
Resultant vector	209.69 (42.01)	197.89 (42.02)

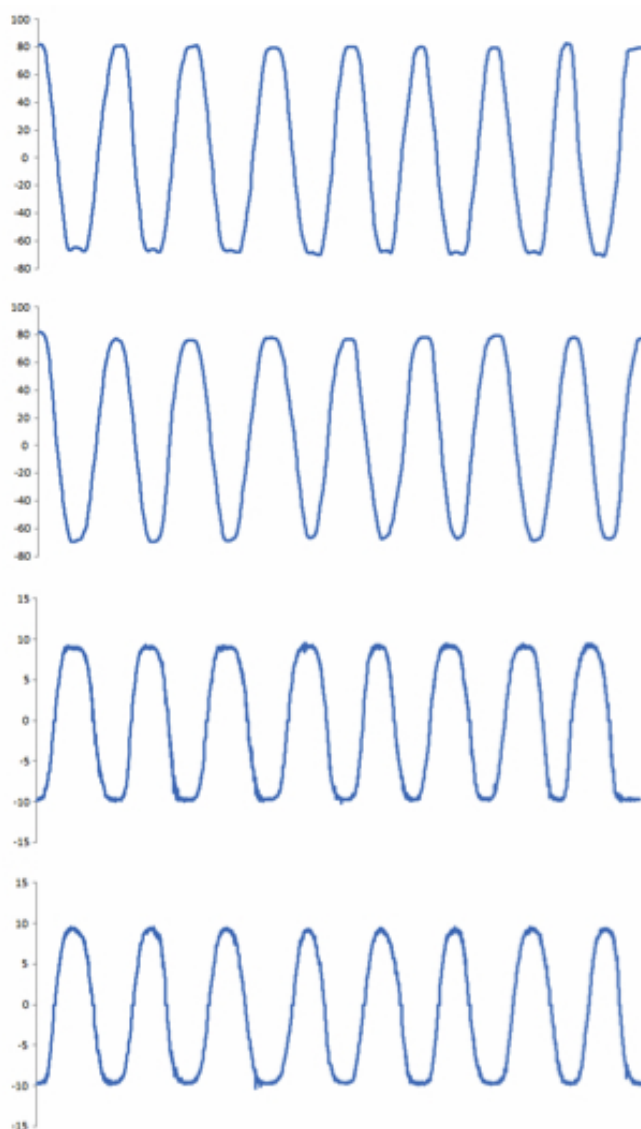
Table 3. Degrees/seconds² of acceleration recorded in abduction and flexion movement.

Axes	Abduction, mean (SD)	Flexion, mean (SD)
X	8.48 (1.76)	8.53 (2.8)
Y	19.48 (0.85)	19.43 (0.77)
Z	9.41 (1.5)	7.09 (1.9)
Resultant vector	23.31 (1.58)	22.55 (1.73)

Table 4. Pearson correlation between angular mobility and linear acceleration.

Task	Abduction, correlation (<i>P</i> value)	Flexion, correlation (<i>P</i> value)
Yaw (z)	.462 (.17)	.380 (.2)
Pitch (y)	.914 (<.01)	.915 (<.01)
Roll (x)	.811 (<.01)	.691 (.02)
Resultant vector	.845 (<.01)	.860 (<.01)

Figure 3. Four examples of kinematic patterns through repetitions shown for angular mobility during ABD (A) and FLEX in pitch axis (B), and the linear acceleration during abduction (C) and flexion (D) in the y-axis.



Discussion

Principal Findings

This study has described and examined upper-limb 3D kinematics using the inertial sensor in the iPhone4 during the performance of shoulder abduction and flexion task in healthy subjects. The biggest range of motion and largest acceleration values varied along each axes. However, taking into account resultant vector from each axes of space, mobility and acceleration were found to be greater for abduction movement. Strong correlation was found between tridimensional mobility and acceleration for both task. The results obtained in this study allow us to obtain descriptive data from upper-limb 3D kinematics, providing an overview of the use of a mobile phone for the study of upper-limb movement.

Previous research has attempted to describe overall upper-limb kinematics through mobile phones. Recently, mobile phone inclinometric measurements of various movements, including abduction and flexion, were performed in 41 affected shoulders.

Results showed an acceptable reliability score when compared to conventional goniometers [28]. Very recently, functional assessments of the shoulder through velocity and acceleration inertial variables provided by a mobile phone were studied in five subjects [30]. The use of a clinometer embedded in a mobile phone has been validated in shoulder abduction and flexion movements in healthy and symptomatic shoulders [24]. Recently, mobile phone goniometric measurements have been validated in five healthy subjects, obtaining 95.2° for flexion and 155.4° for abduction [25], which is similar to the abduction degrees obtained in our study. Furthermore, an inclinometry-based and photo-based mobile phone app has been validated for measuring shoulder external rotation [29].

Upper-limb motion has been studied using several devices from decades ago. However, it tends to be deep in kinematic aspects [31] and 3D kinematics [32,42]. For that reason, inertial devices have played an important role when studying shoulder kinematics in several studies [43,44]. Obtaining different results depending on analyzing one plane/axis or its resultant vector intensifies the importance of taking into account the

three-dimensional component of anatomical movement, whose analysis is allowed through inertial sensors embedded in mobile phones.

Nowadays, because of new technologies, the concept of telerehabilitation has emerged as an attractive opportunity for provisioning rehabilitation at a distance with the Internet, thus improving the quality of rehabilitation health care [20,21]. Providing comprehensive instructions regarding placement and use of mobile phones would allow patients to measure humerus kinematics, facilitating equitable access to all individuals. Regarding upper-limbs, diagnosis and assessment of musculoskeletal shoulder disorders through the Internet have already been studied [45]. As telerehabilitation is a convenient and easy-to-use system, it would help patients and physicians meet health-related goals. Communication technologies as part of telehealth should also reduce health care costs.

Having reference values of humerus kinematics in the future would be potentially desirable for comparing data from new technologies, such as smartphones or smartcameras like Kinect, opening a new world of possibilities in shoulder telehealth assessment.

Tridimensional kinematic tendency, along with the birth of the concept of telerehabilitation, shows the need for mobile phone 3D evaluation of arm movements. The results of this study are in line with other research and show that the use of inertial

sensors embedded in mobile phones for upper-limb kinematic analysis appears feasible.

Limitations

The main weakness of the study is that it is a cross-sectional study, which means cause and effect relationships in kinematic patterns cannot be established. In addition, criterion validity has not been studied because there is no criterion standard.

However, having a sample with a larger number of participants and in which there are also subjects presenting shoulder pathology, we hope to compare our results with those studies reporting on other systems for upper-limb motion analysis. Furthermore, measuring upper-limbs with a gold standard system will allow us to validate mobile phones in upper-limb use as an inertial, easy-to-use measurement. It should be also mentioned that this study estimated only humerus kinematics, while the contribution of other shoulder joints, like sternoclavicular and acromioclavicular ones [46], whose importance has been previously claimed were not included.

Conclusion

This study discusses humerus kinematics and identifies movement patterns. Therefore, it supports using mobile phones as devices to analyze upper-limb kinematics. Thanks to this study, it is possible to develop a simple and accessible-to-all app that facilitates patient evaluation in this area.

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Authors' Contributions

AICV and PB participated in the conception and design of the study; the data collection, analysis, and interpretation of data; and helped to draft the manuscript. CRJ participated in the data collection, analysis, and interpretation of data and drafted the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BMI: Body Mass Index

ROM: range of motion

3D: three-dimensional

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Original Paper

Perceptions of Technology and Its Use for Therapeutic Application for Individuals With Hemiparesis: Findings From Adult and Pediatric Focus Groups

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Abstract

Background: Digital technology is becoming an increasingly popular means of delivering meaningful therapy to individuals with neurological impairments. An understanding of clients' technology use and their perspectives on incorporating technology into rehabilitation can provide researchers and designers with valuable information to inform development of technologies and technology-based rehabilitation programs.

Objective: This study was designed to establish the current use and perceptions of gaming, social media, and robotics technologies for rehabilitative purposes from the perspective of adults and children with upper limb impairments to identify barriers and enablers to their adoption and use.

Methods: We conducted three focus groups consisting of pediatric (n=7, mean age 11.0 years) and adult (n=8, mean age 60.8 years) participants with hemiparesis affecting their upper limb. We applied thematic analysis methods to the resulting data.

Results: We identified three key themes: (1) clients' use of technology in everyday life and rehabilitation, (2) barriers to use, and (3) enablers to therapy. Participants had limited exposure to technology for therapeutic purposes, but all acknowledged the potential benefits in providing motivation and interest for the performance of repetitive task practice. Adult participants requested efficacious, simple, and easy-to-use technology for rehabilitation with programs that could be individualized for them and expressed that they wanted these programs to provide a motivating means of repeated practice of therapeutic movements. In contrast, pediatric participants emphasized a desire for technology for rehabilitation that offered opportunities for social interaction and interactive games involving their whole body and not only their affected limb. Perceived safety and privacy were concerns for both groups.

Conclusions: Our findings highlight that all participants were open to the integration of technology into rehabilitation. Adult participants were more pragmatically motivated by potential recovery gains, whereas pediatric participants were more intrinsically motivated by access to games.

KEYWORDS

cerebral palsy; stroke; hemiplegia; rehabilitation; gaming; social media; technology adoption; qualitative research

Introduction

Therapeutic exercises are an important component of a comprehensive rehabilitation program designed to improve strength, flexibility, mobility, and function of the affected limb(s) in individuals with hemiparesis, including those with cerebral palsy (CP) or stroke. Unfortunately, rehabilitation therapy tends to be terminated when clients shows no marked improvements within a set recovery time frame, or after a critical time period post stroke when rehabilitation is thought to no longer benefit them. As a consequence, any improvements in motor control and functional abilities that may have been acquired during therapy typically deteriorate over time [1]. The importance of maintaining an exercise regimen aimed at improving motor function once rehabilitation therapy ends has been demonstrated in studies examining individuals who showed continued motor function when engaging in repeated motor practice more than a year post stroke [2,3]. Indeed, as repetitive practice is an integral element in the functional retraining of individuals with stroke [4] and CP [5], home-based exercises are routinely prescribed to maintain or to improve functional gains obtained during inpatient and outpatient rehabilitation. Ultimately, these home exercise programs are intended to help individuals assume responsibility for the long-term management of their functional impairments. Despite the demonstrated benefits of these programs [6,7], adherence rates are suboptimal [8]. A number of factors have been identified as barriers to adherence to prescribed home-based exercise programs by individuals with CP and those who have suffered a stroke. These include personal (eg, motivation, time constraints), health (eg, fatigue, musculoskeletal problems), and environmental (eg, equipment, emotional/physical support) factors [9,10]. Studies have indicated that client motivation specifically has an influence on rehabilitation outcomes such that greater motivation is associated with a more favorable result [11-14]. Accordingly, researchers are now investigating methods of motivating clients to practice their therapeutic exercises outside of the clinical setting.

An increasingly popular motivational strategy is the use of computer gaming technologies to augment home exercise prescription (see [15] for a review). However, successful development, design, adoption, and use of these technologies hinge on understanding how clients think and feel about games, technology, and rehabilitation in the home setting [16]. Focus groups provide valuable insight from potential users in the early stages of product development because they identify the specific needs of the targeted user and can highlight to design teams the features of a product that could be problematic for users. For example, Demain et al [17] used the focus group technique to probe the views of individuals after stroke, health care professionals, and family caregivers on assistive technology

and their perceptions of stroke upper-limb rehabilitation. Their study demonstrated that focus groups offer critical insight into the importance of including all stakeholders in the design process of assistive technology and its testing outside of the controlled setting of a laboratory. Other studies have also used focus group discussions to identify the suitability of commercial games as a rehabilitation tool for persons recovering from spinal cord injury, traumatic brain injury, and stroke [18] and to acquire feedback about home-based rehabilitation devices from children with cerebral palsy [19].

The purpose of this study was to explore potential users' perspectives of technology for rehabilitation of the upper limb using information from focus group discussions. Specifically, the study aimed to determine to what extent the participants were currently using social media, computer games, and assistive devices, and their perceptions of these technologies in everyday life and rehabilitation. An additional aim was to explore the perceived relative advantages of incorporating these technologies into a client's own rehabilitation for both adults and children with hemiparesis, and their caregivers, identifying barriers and enablers to use. Clinician perceptions of technology use for rehabilitation of the upper limb were investigated separately [20].

Methods

Participants

Persons with hemiparesis affecting their upper limb were invited to participate in the study by clinicians at two separate facilities within a publically funded child development center and a private clinic providing outpatient therapy for adults with neurological conditions. Two participant samples, an adult group and a pediatric group, were recruited (see [Table 1](#) for the demographic and physical impairment information of all participants). The pediatric participants all attended school at their appropriate grade level. Note that one participant (P4: 12-year-old male with acute brain injury [ABI]) received additional behavior management support. The pediatric participants were required to have the ability to share verbal responses to focus group questions and to provide context-specific answers to those questions. Parents were present during the focus group discussion to help clarify responses when needed or to elaborate on a statement made by their child; however, they were not active participants in the discussion. The wife of one adult participant was present but did not participate in the focus group. All adult participants provided written informed consent. Informed child assent and parental consent were required from the pediatric group. Approval for this study was obtained from the UBC's Research Ethics Board (REB #: H12-00220).

Table 1. Participant demographic information.

Focus group	Participant #	Gender, M/F	Age, years	School grade	Diagnosis	Caregiver present during session
1 (Pediatric)	1	M	13	8	CP, hearing impairment	Y
	2	M	6	1	CP	Y
1 (Pediatric)	3	M	11	5	CP	Y
	4	M	12	Not disclosed	ABI	Y
	5	M	16	11	CP	N
	6	F	8	3	CP, visual impairment	Y
	7	M	11	5	In utero stroke	Y
2 (Adults)	8	M	61	N/A	Stroke	N/A
	9	F	70	N/A	Stroke	N/A
	10	M	45	N/A	Stroke	N/A
	11	M	73	N/A	Stroke	N/A
	12	F	41	N/A	Stroke	N/A
	13	M	60	N/A	Stroke	N/A
	14	M	75	N/A	Stroke	N/A
	15	M	61	N/A	Stroke	N/A

Data Collection

Focus groups were conducted as part of a larger project, Functional Engagement in Assisted Therapy through Exercise Robotics (FEATHERS) (intended to develop a home-based upper-limb rehabilitation platform), to obtain in-depth information from a group of participants representing potential users of the technology [21]. The semistructured focus groups took place in the facilities where the participants were recruited. At the beginning of each group, author MV introduced the FEATHERS project and described the development of rehabilitative technology, which might include gaming systems and/or robotic systems, as the background context for the focus group. During the focus group session, participants were led through a series of questions following a semistructured guide (see [Multimedia Appendix 1](#) for samples of these questions) that was developed in conjunction with a team of qualitative research experts with experience in conducting focus groups. The focus group moderator (ST) is an occupational therapist with extensive experience in the management of individuals with neurological conditions. The moderator facilitated the discussion to allow the participants to enrich the conversation through interactions with each other and with project personnel. The questions probed the participants' views of current therapy and use of technology, desirable features in a future technology designed to rehabilitate the upper limb, and perceived barriers to use of technologies.

The entire conversation was recorded and later transcribed verbatim by a research assistant. One of the research team members (ML) took detailed field notes to complement the transcription. The field notes reported participant characteristics, body language, the consistency between participant comments and observed behavior, and the overall mood of the discussion; they captured details that the audio recording could not.

Transcripts identified participants and field personnel by number so that perceptions/contributions of each individual could be tracked anonymously throughout the conversation.

Data Analysis

Anonymized transcriptions were given to four project personnel (authors KL, KM, ST, and NV) for coding based on thematic analysis [22,23]. The coders for the adult participant group were a cognitive neuroscientist with a specialization in motor learning and control (KL) and a physical therapist with 25 years of experience in the treatment of adults and children with neurological conditions (KM). Coders for the pediatric group were an occupational therapist and researcher in the field of pediatric neurorehabilitation (ST), and a physical therapist and professor in the Department of Physical Therapy with a specialization in developmental neuroscience (NV). Before the analysis, all coders wrote a statement of their personal background and potential biases/assumptions with respect to the general theme of the project. These explicit bias statements were used in later stages of the analysis (namely, reflecting on which codes were generated and how these codes were grouped into themes [24]). In the thematic analysis, the lowest level of information was individual codes (eg, "mirror-box", "personal computer") that were supported by multiple quotes or "extractions" from transcripts and supporting materials. These codes were then organized into categories (eg, "tools used", "purposes for using"), subthemes (eg, "technology for rehabilitation", "technology in the home"), and themes (eg, "client's use of technology in everyday life and rehabilitation").

Thematic analysis was conducted in five stages (based on recommendations by [22]). First, coders independently read the transcripts and the field notes to familiarize themselves with the data. Next, themes were generated based on the recurrence of ideas, topics, or words in the transcripts. Themes were

generated to be semantic rather than latent in nature. That is, the coders attempted to minimize their own inferences, so that the themes were superficial and apparent in the text. Using an inductive approach, themes were generated based on the codes [25]. Coders reviewed the levels of their individual themes, subthemes, and categories prior to meeting together to generate consensus themes, which were refined using an iterative process. The goal of the coders when constructing themes was to provide a rich description of the full dataset. Finally, all coders met as a group led by a researcher with expertise in qualitative research (LH) to explore and refine the specifics of each theme.

Results

Three focus groups (one group of adult participants and two groups of pediatric participants), for a total of 15 participants,

were conducted between November 2012 and March 2013. The focus group data are presented as quotations from individuals. It is important to note that even though these quotes represent individual statements, there was considerable interaction between focus group participants that shaped these statements.

Three major themes emerged as being key to understanding participants' perspectives of technology and its use for therapeutic rehabilitation: (1) clients' use of technology in everyday life and rehabilitation, (2) barriers to use, and (3) enablers to therapy, which includes motivating factors and desirable features discussed by participants. Tables 2 and 3 summarize the features that participants identified as desirable for incorporation in gaming systems.

Table 2. Summary of main barriers to use and main enablers to therapy for adult focus group.

Features	Representative quotes
Main barriers to use	
Cost-efficient	Context: the burden of out-of-pocket expenses for therapy beyond the number of funded rehabilitation treatments they can receive. Adult participant: ...for people without money I don't think that's fair
Assurance of therapeutic improvement	Context: how busy lives make it challenging to commit to a home-based rehabilitation program. Adult participant: We don't have time, but if you said this is going to help you then we would do it...so you have to say I'm going to do this every day for fifteen minutes, say, or whatever. And if it works and someone like me, you see a difference, well it spurs you on, right?
Main enablers to therapy	
Distinct exercises from those practiced in the clinic	Context: technology as motivation for rehabilitation by offering alternative exercises to those performed in the clinic. Adult participant: ...it's so boring to sit there and roll a towel up.
Game-based therapy to generate results	Context: importance of repetition of exercises in stroke rehabilitation. Adult participant: In my exercises I've got a basketball I just play with myself in the garage just trying to use my left hand [the affected limb] back and forth and just, like, do it over and over again...as long as I can tolerate it.
Simplicity of set-up and operation	Context: suggestions for developers of game-based rehabilitation tools. Adult participant: Just to make it simple Adult participant: ...we need things that are very plain, very simple because computers I mean he [his son] had it from kindergarten on. It's so different for all of us right?

Table 3. Summary of main barriers to use and main enablers to therapy for pediatric focus group.

Features	Representative quotes ^a
Main barriers to use	
Privacy and online safety	Context: follow-up conversation between parent and moderator CPP: ...He trusts anyone, strangers, so I don't feel comfortable with opening up a Facebook account for him
Space requirement	Context: video games that support bilateral rehabilitation. CPP: ...we don't have the room in our house to accommodate all of that gross movement
Main enablers to therapy	
Video games with a storyline	Context: what participants enjoy about the video games that they currently play. PP: I like it when you have like you make up like a pod then you get to like make your own city and get like troops... And you get to take over buildings and people and build a community.
Incorporation of both the unaffected and affected limb	Context: potential issues for video games developed for home-based rehabilitation. PP: ...you can't use your hand that works perfectly, you have to control the guy with your affected and... that would be sooo boring
Creates opportunities to connect with others	Context: what video games have to offer beyond rehabilitation PP: You know, if it would mean interacting with others kids who also have the same challenges, I think that would be pretty cool... someone that understands and gets it.
Gaming for therapy vs gaming for leisure	Context: whether video games could motivate pediatric clients to adhere to their rehabilitation programs. PP: And if you want to play the therapy games you can play those therapy games, if you want to you can play your own kind of games

^aPP: pediatric participant, CPP: caregiver of pediatric participant.

Theme 1: Clients' Use of Technology in Everyday Life and Rehabilitation

Technology and Home Use

When asked about the types of technology used within their home, participant responses were quite diverse. Adults and children differed in the types of technology they used. The adult participants reported regularly making use of mobile phones, Apple's iPad, Facebook, email, and the Internet. In contrast, pediatric participants regularly used videogame consoles, such as Microsoft's Xbox and Kinect, Sony's PlayStation 2 and Move, as well as the Nintendo Wii. For the adult participants, the primary purpose for technology use was to acquire knowledge and information. One adult participant stated that, "you go to the doctor and he tells you stuff and you come home and look it up and you really know, you know" (Group 2, Line 580-581).

Technology for Social Interaction

Mobile phones, email, and Skype, which allow users to communicate by voice, video, and instant messaging over the Internet, were identified by adult participants as convenient ways to keep in touch with friends and family. Many of the adult participants reported that their use of technology was motivated by the opportunity to socialize and engage with others. When one adult participant was probed about her gaming experience, she responded that, "I've got two granddaughters so whatever they play, I play" (Group 2, Line 1129).

Technology for Entertainment

The pediatric participants' current use of technology was primarily to play games for purely entertainment purposes rather than for social interaction. One parent reported that their child, "used a computer a lot at home for games" (Group 1, Line 8), but that they restricted the number of hours of play. Despite the popularity of social networking (eg, Facebook), the pediatric participants did not report the use of technology for the purpose of socializing with friends from home. Most pediatric participants were too young to be legally permitted to create a social networking account (eg, Facebook requires a minimum age of 13 years). Privacy and personal safety concerns were identified as barriers by caregivers (as discussed in Privacy Management and Personal Safety).

Therapeutic Use of Technology

All participants reported limited exposure to technology for rehabilitation. Discussion with the pediatric participants revealed that when technology was used during clinic visits, it was used by the clinician to motivate or to reduce boredom during therapy sessions. One parent reported that when their child performed the Superman pose (a floor exercise used in rehabilitation to strengthen back muscles whereby the child lies prone with back and arms extended, a position that resembles "Superman" flying, and one that is held for a short period of time), the physiotherapist placed an Apple iPad in front of their child. According to this parent, "our physio will actually put him in a Superman swing which, you know, so he's on his hands and he'll put an iPad in front of him... so then he has to weight bear on one hand and use the other one to play Ninja or whatever" (Group 1, Line 206-210). Technology was also used to break

up the monotony of performing repetitive movement exercises and to re-engage the child. Another parent stated that it is, “often very motivating when, when they’re tired, and it’s like, okay, I don’t want to go chase that ball anymore but I can, I’ll play those video games for a while” (Group 1, Line 214-216).

Theme 2: Barriers to Use

Privacy Management and Personal Safety

Security and privacy were primary concerns for both groups of participants when asked about combining social networking websites with home-based rehabilitation technology; the nature of these concerns was unique for each group. The parents of pediatric participants voiced that their major concern was the safety of social networking websites, especially if their child had any cognitive impairments. These impairments meant that their child might have difficulty creating appropriate boundaries, making them a target for predators. “He trusts anyone, strangers, so I don’t feel comfortable with opening up a Facebook account for him” (Group 1: follow-up conversation between parent and moderator). In contrast, the adult participants were apprehensive about public access to content available through personal profile page. According to the adult participants, the very nature of social networking encourages its users to reveal personal information. One adult participant stated, “I’m registered for Facebook, I don’t use it, I don’t, I don’t like to have everybody know my business” (Group 2, Line 550-551). They expressed that they did not understand why people choose to post family affairs on social networking websites. One adult participant asserted, “you’re private. You don’t put your stuff, your dirty laundry, out to dry” (Group 2, Line 565). In spite of these concerns, there seemed to be a general consensus among the parents of the pediatric and the adult participants that online games could be an innovative means of motivating clients to practice their therapeutic exercises. However, integrating it with social networking websites, such as Facebook, seemed to dissuade potential acceptance of such rehabilitation programs.

Cost

A potentially limiting factor identified by all the adult participants was the cost of the equipment for the proposed home-based rehabilitation system. The majority of the adult participants expressed that their decision to invest in technologies, such as robotics, would be largely dependent on the financial commitment they would have to make and the support or lack thereof that they might receive from government or other funding agencies. In contrast, the parents of the pediatric participants did not identify cost as a factor that would influence their use of a home-based rehabilitation device.

There was a general consensus among the adult participants that the government’s efforts to reduce health care costs by terminating payment for stroke rehabilitation before they had reached maximum recovery were very frustrating for them. This topic led to a candid discussion about the lack of government subsidy/support for rehabilitative therapy and the adult participants’ worry for those who could not afford the planned development of social gaming programs for home-based rehabilitation. There was also concern about equity of access to these new technologies, with one adult participant expressing

that, “for people without money I don’t think that’s fair” (Group 2, Line 627-628).

Assurance of Therapeutic Improvement

To be convinced to use robotic technology and social gaming programs for rehabilitation, the adult participants wanted assurance that motor function would improve. One adult participant indicated, “We don’t have time, but if you said this is going to help you then we would do it...so you have to say I’m going to do this every day for 15 minutes, say, or whatever. And if it works and someone like me, you see a difference, well it spurs you on, right?” (Group 2, Line 1463-1466). When the moderator followed up asking, “if you see a difference with a therapy, it will keep you going?” (Moderator with Group 2, Line 1468), one of them replied, “Yes. Exactly” (Group 2, Line 1470).

Familiarity With Technology

Some adult participants expressed that their age stopped them from reaping the full benefits of video games and robotics technology aimed at motivating users to practice their daily therapy exercises. However, consistent with the previous theme, other adult participants expressed their willingness to adopt new technologies, especially if technologies were shown to be effective, for example, “If it’s going to help me, I’ll do it” (Group 2, Line 1204-1207). The adult participants reported that another major barrier to readily accepting a home-based robotic exercise program was their general lack of familiarity with social gaming programs and the time they would need to invest to learn about them. Many of the older adult participants expressed that, unlike the younger generation that had grown up with the Internet, they were less comfortable going “online”. They shared that they preferred to “live” their life rather than staying indoors playing “video games”. One adult participant stated, “You have to say, okay, this is my therapy. I think a lot of things about computers, I think a lot of the things, we’re not, we’re too busy living” (Group 2, Line 1458-1459). The adult participants did acknowledge that stroke also affects younger individuals, “I know there’s a lot of young people have strokes but most of us are older and, like, at this time computers are difficult for us” (Group 2, Line 1761-1762). They expressed that this type of rehabilitation technology would probably be valuable for younger people who had suffered a stroke. Despite their initial apprehension, the adult participants agreed that if the benefits of technology intervention for home-based rehabilitation could be demonstrated, they would be willing to invest both the time and the energy into utilizing it.

In contrast, pediatric participants were more uniform in their understanding of robotic technology, therapy games, and social media platforms. When asked about their comfort with technology, one pediatric participant claimed, “No, it’s pretty much, if you want to use it, then you have to get up and use it, figure it out” (Group 1, Line 1224). Another pediatric participant asserted, “I figured a lot of it out on my own” (Group 1, Line 908).

Space

Availability of space to play the games was also raised as an issue by the parents of the pediatric participants. The amount

of room that would be necessary to practice the gross movements that the therapeutic exercises sometimes entail was identified as being potentially problematic. One parent stated, “we don’t have the room in our house to accommodate all that gross movement” (Group 1, Line 1262-1263).

Theme 3: Enablers to Therapy

Overview

Enablers to therapy fell into a variety of subthemes that could be loosely grouped as potential motivators and desirable features for future therapy. Motivation and desirable features are intertwined (eg, desirable features would be motivating). Thus, the subthemes discussed below can be interpreted as motivators in current games, therapy, or technology and would therefore be desirable features for future therapies. All participants described mechanisms that would enhance their motivation and engage them in home-based rehabilitation therapies in which video games were integrated. Both the pediatric and the adult participants stressed the importance of having games that were both entertaining and enjoyable. The following subthemes were identified.

Going Beyond Clinically Prescribed Exercises

The adult participants stressed the need for video games that encourage diverse movement-based exercises from typical home-based exercises prescribed by clinicians (eg, towel rolling exercises) that tend to be the repetitive in nature. One adult participant stated, “it’s so boring to sit there and roll a towel up” (Group 2, Line 1405-1406). When the possibility of using a robotic device in therapy was raised, one of the adult participants responded, “So I think that would be a good idea because it’s hard finding things to do here I think, you know, that’s the problem with therapy, it’s so boring” (Group 2, Line 595-596).

Seeking “Deeper Stories” to Motivate

The pediatric participants were very clear about their desire for video games that were unique from those that social networking websites, such as Facebook, had to offer (eg, Candy Crush). There was a strong voice for video games that required “real time strategy” and offered “deeper stories”. While video games with esthetically pleasing graphics were an important consideration, these participants were also seeking a storyline, not just a game to play. Games previously played by this group that encouraged them to think and made them an active participant were exciting for them. “I like it when you have, like you make up like a pod, then you get to like make your own city and get like troops...And you get to take over buildings and people and build a community” (Group 2, Line 1052-1053). A few participants expressed their desire for games that would provide them with the opportunity to add to their gaming experience. Furthermore, these games should be multiplayer; however, participants were not stringent on whether these other “players” had to be family members, friends, or random opponents found online. They did like the idea of playing therapy games with others who had similar physical challenges.

Desire for Game-Based Therapy to Generate Results

The stance that the adult participants took regarding the entire rehabilitation process also distinguished them from the pediatric participants. They understood that structured exercises and the daily use of their affected limb were essential to achieve maximal functional gains. They also expressed their desire for the ability to adjust their therapy according to their individual needs—provide resistance and/or assistance, different motions, and to practice functional movements rather than single simple joint movements. According to the adult participants, game-based therapy should be competitive, challenging, and encourage the use of their affected limb. They recognized that to regain any degree of function of their affected limb would require intensive repetition of movement. They also accepted that they were accountable for continuing to perform their exercise regimen at home if they wished to make any significant progress toward their therapeutic goals. Finally, they expressed their willingness to put in the time and effort in order to see results. “In my exercises I’ve got a basketball I just play with myself in the garage just trying to use my left hand [the affected limb] back and forth and just, like, do it over and over again...as long as I can tolerate it” (Group 2, Line 1654-1655).

Need for Games to Incorporate the Unaffected Limb

The pediatric participants had a considerably different outlook on challenging themselves to actively engage their affected limb. They were firm in their appeal that video games be designed in such a way that they were not limited to using only their affected limb. Instead, they wanted video games that allowed them to utilize their entire body. One pediatric participant expressed his frustration when playing a video game that forced him to use only his affected limb, “you can’t use your hand that works perfectly, you have to control the guy with your affected and...that would be sooo boring” (Group 1, Line 1443-1444). When it came down to the aim of rehabilitation, the pediatric participants, unlike the adult participants, appeared much less concerned with long-term outcome. Their focus centered on the esthetic experience, enjoyment of gameplay, as well as, games that were not restricted to their affected limb only.

The parents of the pediatric participants expanded on the comments made by their children expressing the need to find ways to motivate their children to practice their exercises outside of the clinical setting to maximize functional ability. They described how any activity that engaged their child to use their affected limb without explicit instruction to do so was welcomed and encouraged: “a little girl taught him how to play a song on the piano, and he’s using his left hand [the affected limb] right now but he’s really into it” (Group 1, Line 355-357).

Technology as a Motivational Therapy Tool

Technology was identified by parents as positively tapping into their child’s motivation to comply with their exercise programs. The most challenging aspect for these parents was knowing that repetitive practice was necessary and getting their child to engage in practice regularly. They acknowledged that technology influenced their child’s intrinsic motivation and made exercising more enjoyable:

I thought it was really good. I think that especially, I can only speak to ReJoyce, but you could get him to do so many repetitions, whereas to do here you might get a child to shut down. They shut down. Whereas when you use the technology, they don't even realize that they are doing the repetitions. [Group 1, Line 1262-1263]

ReJoyce is a commercial therapy device for use in either a clinic or a client's home by Rehabtronics Inc., Edmonton, Canada.

Opportunities to Interact With Peers

The idea of introducing technology to rehabilitation therapy that could be carried out at home was well received by the pediatric participants. Further probing by the moderator revealed that they were motivated by the prospects of connecting with others (ie, peers as well as other children with CP) in multiplayer online video games. There was a general sense that these particular pediatric participants had a harder time interacting with their schoolmates in physical games and activities because of their physical limitations. For them, video games offered a medium that leveled the playing field; they felt they could be equal to their typically developing counterparts. These children also acknowledged that playing with children with similar disabilities (CP) would be exciting, "You know, if it would mean interacting with others kids who also have the same challenges, I think that would be pretty cool...someone that understands and gets it" (Group 1, Line 56-58).

Need for Simplicity

The adult participants identified simplicity as essential when designing technology for home-based rehabilitation purposes. Their adoption of rehabilitation technology would depend on ease of use. It was important that the amount of time invested in setting the system up was minimal and that the games were simple to initiate, understand, and play. "Clear, clear directions and using words that you all know" (Group 2, Line 1757).

Once more, the adult participants felt their unfamiliarity with technology was a disadvantage. As a consequence, they anticipated that it would take them longer to learn to use the technology, and this was time that they did not want to waste. Time was very valuable to the adult participants. One adult participant expressed, "Just make it simple" (Group 2, Line 1732), while another adult participant explained that, "we need things that are very plain, very simple because computers, I mean he [his son] had it from kindergarten on. It's so different for all of us, right?" (Group 2, Line 1738-1739).

Distinction Between Gaming for Therapy and Gaming for Leisure

An issue that was strongly and frequently vocalized throughout the pediatric focus group discussion was the need to develop games that are dedicated solely to supporting rehabilitation. If the purposes of these games were to enhance rehabilitation therapy, motivate clients, and promote adherence, then they needed to be unique from those that were played during their free time. One pediatric participant stated, "I think it would actually be very useful because you can have certain games for therapy and certain games for your own free time. And if you want to play the therapy games, you can play your therapy

games, and if you want to you can play your own kind of games" (Group 1, Line 1128-1130). Another expressed, "if you have your video games to motivate your therapy then you can't play with them much on your own" (Group 1, Line 1117-1118). When the moderator probed this statement by asking, "Do you think that it would stop you from wanting to play them on your own?" (Group 1, Line 1120), the participant responded, "Yeah...because then you'd have to do therapy more often" (Group 1, Line 1122, 1126). The concern that participants expressed appeared to be that game-based therapy would take away from gameplay for pleasure. Furthermore, they were uneasy about being monitored while playing therapeutic video games either in the clinical setting or at home by their parents, "people actually watch what you're doing, that freaks me out because they can watch you, it's kind of creepy like they're basically watching you" (Group 1, Line 974-976). They were concerned that they would be subjected to continual scrutiny not only by their therapist but also by their parents.

Discussion

Principal Results

This study was undertaken to examine how adult and pediatric clients with upper-limb hemiparesis were using technology in everyday life and rehabilitation. It also aimed to explore the perceived benefits and barriers to incorporating technology for upper-limb rehabilitation in two different age groups with similar etiology. These findings provide a descriptive perspective of the generational differences in technology use and highlight the need for well-designed systems that are highly user-specific. Three major themes emerged in this study and were central to understanding the participants' perceptions of technology and its potential use for rehabilitation: (1) clients' use of technology in everyday life and rehabilitation, (2) barriers to use, and (3) enablers to therapy. It was clear from the results that all participants had some degree of experience with technology: the adult group using technologies predominantly for communication and information gathering, while the pediatric group used technology for primarily entertainment purposes. This sample of participants reported minimal exposure to technology for therapeutic purposes, but all acknowledged the potential benefits of technology in providing motivation and interest for the performance of repetitive task practice. Determinants of adoption and use of therapeutic technologies for upper-limb rehabilitation differed between age groups. The adult participants appeared to balance benefits in terms of effectiveness, capacity to provide feedback, customization to their specific requirements and ability to offer differing options to current home exercise programs against the monetary costs, and efforts involved in adoption and use. The pediatric participants reported that they value the quality of entertainment and opportunities to interact with peers. They also expressed maximization of opportunities for success in the gameplay over therapeutic benefit and the desire for a distinction between gaming for therapeutic versus leisure purposes. Privacy and personal safety concerns were raised by both groups in those instances that social media would be incorporated to monitor progress into the therapeutic technology paradigm. The barriers and enablers to the adoption of therapeutic technologies differed

between the user age groups. These findings may assist researchers in targeting the development and design of future technologies for therapeutic use in a home setting to these populations.

Limitations

These focus group data are limited by demographics of the individuals participating. That is, the data do not necessarily represent a range of socioeconomic and cultural views in relation to this topic, and no socioeconomic data/cultural data were obtained from participants. Furthermore, the majority of the pediatric client group were male (6 male, 1 female) and there was a wide age range (6-16 years of age). Another drawback of our study is its small sample size; however, our findings should be viewed as exploratory, offering game developers insights from these two populations (children with ABI and adults post stroke).

All participants were from a public/private health care system in an urban area where long-term care is capped; however, they did have access to a number of resources and supports. Our results may have been different had we run our focus group in a rural community, as it is possible that the motivation to consider alternate means of undertaking upper-limb rehabilitation may be influenced by the availability of resources. Furthermore, all participants were volunteers who knew the general aim of the study. Self-selection on the part of the participants may have biased the results of the focus group.

Comparison With Prior Work

The current uses and perceptions of technology reported in this study are consistent with trends previously published regarding the general population [26]. A recent study by Gell et al [27] examined technology use among older adults and found that as physical capacity decreased, so did usage; however, these results were also influenced by the type and degree of disability. Surprisingly, the participants in this study described minimal use of rehabilitative or gaming technologies in their rehabilitation, which contrasts considerably with some countries, such as Australia, where up to 76% of stroke rehabilitation facilities use commercial gaming systems such as the Nintendo Wii [28].

The determinants and modifiers to the adoption and use of rehabilitative technologies for upper-limb rehabilitation identified in this study are congruent with many of the constructs presented by Venkatesh et al [29] in their Unified Theory of Acceptance and Use of Technology. This theory proposed four categories of determinants for acceptance and use: (1) "performance expectancy" related to identified potential benefits of the technology (eg, effectiveness, quality of experience), (2) "effort expectancy", or how the effectiveness is balanced against the effort and costs, (3) "social influence" (eg, image, social factors, and norms), which is linked to the degree that others' expectations influence a user's adoption of technology, and (4) the "facilitating conditions" (eg, simplicity, training, perceived behavioral control) that support the use of the system. Key modifiers to behavioral intention were the gender, age, and experience of the user and the extent to which use of the technologies was voluntary.

The information provided by participants in this study suggests that age may be an important factor in the determinants of technology adoption and use. Performance expectancy elements differed between age groups. The adult participants placed greater weight on effort expectancy constructs, whereas the pediatric group appears to place greater emphasis on social determinants. This was closely linked to the performance expectancy constructs. Designers should be cognizant of a balance between demanding sufficient practice and allowing pediatric users the opportunities to play using their unaffected limb (or perhaps integrating both through bimanual controls) and to make social connections with others. The pediatric participants saw the technologies as providing a medium where they could engage with and perform equally with typically developing peers.

The modifiers identified by the groups also differed. While not specifically evaluated, the adult participants identified user experience as a potentially influential modifier; however, they suggested facilitators that could counter this modifier, including simplicity of use. Applications should be easy for users to set up, and the games should be relatively intuitive and easy to learn in efforts to minimize inexperienced users' anxiety, increase the likelihood of adoption, and increase the likelihood of protracted use [30,31]. An influential modifier for pediatric participants was perceived behavior control related to differentiating gaming for therapy from leisure gaming time. There was also concern regarding scrutiny by therapists and parents during gameplay.

Conclusions

The application of robotics combined with gaming technology is becoming an increasingly popular means of supporting upper-limb rehabilitation. When designing appropriate devices/systems, it is not enough to simply focus on functionality and cost. Consideration needs to be given to their appropriateness and acceptability to their users, which makes user involvement in research invaluable and essential [32-34]. Both the pediatric and the adult participants were open to the integration of technology into rehabilitation; nevertheless, some differences became evident upon further investigation. The adult participants were more pragmatically motivated by potential recovery gains. The younger participants were more intrinsically motivated by access to play games, especially the potential to use games as a platform for socializing and competing with their typically developing peers. Based on the feedback from the study's participants, a successful gaming system should consider the following: incur low cost, demonstrate improved recovery, be simple to operate, be space-efficient, prescribe unique exercises, offer challenging and motivating games, incorporate the unaffected limb(s), create social connections, and demonstrate a clear distinction between gaming for therapy and for leisure. To understand more clearly the needs of potential users, directions for future research should include clinicians' perspectives of technology and rehabilitation [20], and the development of rehabilitation robotics and refinement to existing prototypes based on the information gathered in this study.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Focus group questions.

[[PDF File \(Adobe PDF File\), 30KB - rehab_v2i1e1_app1.pdf](#)]

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Abbreviations

- ABI:** acquired brain injury
CP: cerebral palsy
CPP: caregiver of pediatric participant
PP: pediatric participant

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