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Original Paper

Application of Inertial Measurement Units and Machine Learning Classification in Cerebral Palsy: Randomized Controlled Trial

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Abstract

Background: Cerebral palsy (CP) is a physical disability that affects movement and posture. Approximately 17 million people worldwide and 34,000 people in Australia are living with CP. In clinical and kinematic research, goniometers and inclinometers are the most commonly used clinical tools to measure joint angles and positions in children with CP.

Objective: This paper presents collaborative research between the School of Electrical Engineering, Computing and Mathematical Sciences at Curtin University and a team of clinicians in a multicenter randomized controlled trial involving children with CP. This study aims to develop a digital solution for mass data collection using inertial measurement units (IMUs) and the application of machine learning (ML) to classify the movement features associated with CP to determine the effectiveness of therapy. The results were calculated without the need to measure Euler, quaternion, and joint measurement calculation, reducing the time required to classify the data.

Methods: Custom IMUs were developed to record the usual wrist movements of participants in 2 age groups. The first age group consisted of participants approaching 3 years of age, and the second age group consisted of participants approaching 15 years of age. Both groups consisted of participants with and without CP. The IMU data were used to calculate the joint angle of the wrist movement and determine the range of motion. A total of 9 different ML algorithms were used to classify the movement features associated with CP. This classification can also confirm if the current treatment (in this case, the use of wrist extension) is effective.

Results: Upon completion of the project, the wrist joint angle was successfully calculated and validated against Vicon motion capture. In addition, the CP movement was classified as a feature using ML on raw IMU data. The Random Forest algorithm achieved the highest accuracy of 87.75% for the age range approaching 15 years, and C4.5 decision tree achieved the highest accuracy of 89.39% for the age range approaching 3 years.

Conclusions: Anecdotal feedback from Minimising Impairment Trial researchers was positive about the potential for IMUs to contribute accurate data about active range of motion, especially in children, for whom goniometric methods are challenging. There may also be potential to use IMUs for continued monitoring of hand movements throughout the day.

Trial Registration: Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12614001276640, <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=367398>; ANZCTR ACTRN12614001275651, <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=367422>

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KEYWORDS

inertial measurement unit; wearable sensors; biomedical sensors; machine learning; human joint measurement; occupational therapy; range of motion; wearable; sensor; children; cerebral palsy; therapy; disability;

Introduction

Background

Cerebral palsy (CP) is a condition that affects a person's ability to move [1,2]. It occurs as a result of injury to the developing brain during pregnancy or a short time after birth [3]. CP presents with different characteristics in different people, as the damage to the brain is not identical in every person [1]. The movement difficulties experienced by people with CP are divided into three main categories: spastic motor type, in which muscles appear stiff and tight (most common); dyskinetic type, which involves involuntary movement patterns; and ataxic type, which involves uncoordinated muscle movements that can affect balance and sense of positioning in space [3,4]. The level of severity and combination of symptoms can differ from person to person [5]. For example, one person could have weakness in one hand, which can lead to difficulty in writing or tying shoelaces, whereas another person may have little control over their movement or speech because CP can also affect the person's ability to coordinate the muscles around the mouth and tongue [5].

There are many different clinical classification systems for upper limb function in children with CP with different levels of complexity. In a review by McConnell et al [6], 18 different clinical classification systems were identified and reviewed according to whether they classified function or deformity and by considering the quality of psychometric evidence for each method. These methods were rated based on the clinical utility of each system using previously published tools [6]. An example of clinical classification system is House [7] classification, which contains four categories of thumb deformities. Another example of clinical classification is that by Green and Banks [8], which contains four subgroups of poor, fair, good, and excellent based on the use of the hand by the individual with CP. These classification methods demonstrate the complexity of clinical classification of hand movement in children with CP and the diverse approaches taken to achieve it.

As of early 2021, there is no single method for completely curing or preventing CP. Public health measures such as mandatory seatbelts, pool fencing, and rubella vaccinations are among the prevention methods currently in use [9]. Physiotherapy and occupational therapy focus on encouraging a person's day-to-day movement skills and abilities, such as sitting, walking, dressing, and toileting, and use a range of specialist interventions such as movement and goal-directed training and provision of equipments, such as walking frames, wheelchairs, supportive seating, footwear, and orthotics [9]. When studying children with CP, range of motion, which is the capability of a joint to go through its complete spectrum of movement, may become a crucial component of research. Passive range of motion can be defined as the range of motion when an external force causes movement of the joint and is the maximum range of motion, whereas active range can be

achieved when opposing muscles contract and relax, resulting in child- or person-initiated joint movement [10].

Occupational therapists use upper limb orthoses for children with CP who have muscle overactivity caused by spasticity, but there is little evidence of the long-term effects of these methods [11]. The clinical rationale is that the orthoses help preserve the range of movement; however, they are complex to construct, expensive, and can cause discomfort for the children wearing them [11]. To address the need for robust evidence, a multicenter randomized controlled trial (RCT) is being used to evaluate the effectiveness of wrist hand orthoses to prevent loss of range of movement in children with CP (see *Experiment Setup and Data Collection* for details). This RCT used inertial measurement units (IMUs) to measure active movement in children with CP, to address two measurement problems: (1) the complex movement patterns of children with CP make it difficult for therapists to accurately apply typical clinical measures, such as a goniometer (an instrument that measures the available range of motion at a joint) and (2) young children's small hands and difficulty following detailed movement instructions make it difficult to achieve reliable measurements.

Existing Methods

General movement assessment is used, which is a noninvasive and cost-effective method for identifying babies at risk of CP [12]. This assessment is done by recording a 3- to 5-minute video of an awake infant lying on their back while they were calm and alert without the presence of toys and pacifiers. Parents can be present and record the video, but they should not interact with their babies. This video is then observed and assessed by trained health professionals to detect signs of the disorder [3,12]. This process becomes easier when infants grow older, as they can follow the instructions of the medical professionals to perform different tasks so that their movement can be monitored. This assessment is mainly used as a diagnostic tool for the early detection of CP, and it is not used to quantify the range of movement or motion.

In clinical research, the goniometer and inclinometer are used to measure joint angles in children with CP [13]. A goniometer is an instrument that measures the joint angle, and depending on the nature of the experiment, it can measure the available range of motion at a joint. It can be used to monitor changes in joint angles in clinical settings [14]. The traditional method of using angle-measuring tools is not accurate and reliable, according to some recent studies [13]. Accurately measuring range of motion (ROM) is an important part of clinical assessment as this information is used to guide treatment plans, determine treatment efficacy, and monitor individual's response to treatment [15]. Goniometric measures rely on the ability of the clinician to accurately palpate bony landmarks and visually estimate the alignment of the axis and arms of the goniometer to the joint that is being measured. Goniometers are versatile, reliable, and widely used, irrespective of their measurement errors of up to 15 degrees. However, for active movement, the

use of goniometers is very difficult, and their use may not be possible in populations that are unable to respond to instructions reliably [15].

A general approach for capturing movement is the use of digital technologies, such as motion capture. Motion capture (also referred to as mo-cap or mocap) is the process of digitally recording the movement of people [16]. It is used in entertainment, sports, medical applications, ergonomics, and robotics. In filmmaking and game development, it refers to the recording actions of actors for animations or visual effects. It is also referred to as performance capture when it includes a full body, face, and fingers or captures subtle expressions [16]. The equipment required for motion capture is extremely costly and is not commonly available in a typical hospital; for example, according to Thewlis et al [17], a simple Vicon system [18] cost approximately Aus \$250,000 (US \$268,605.52) in 2011 [17]. Even if the equipment is available, it may be difficult to take children to these motion analysis laboratories to conduct measurements. Another limitation is the need for expert staff to run the laboratories for the motion analysis of hand movement.

Another approach is to measure gesture control using electronic sensors, such as infrared (IR) light-emitting diodes. Gesture recognition software for advanced smartphones was presented in the paper found in the study by Kong et al [19]. The leap motion sensor uses IR sensors to scan finger movements with a typical field of view of 140°×120° [20]. This method is mostly applied in the entertainment industry, so it does not meet the need for accuracy in capturing the movement of people with CP.

With the development of inertial sensor technologies, IMU-based motion capture systems have been introduced in the study of human motion. IMUs comprise an accelerometer, gyroscope, and magnetometer that are connected to a microcontroller and can be used to capture orientation. In recent years, there have been several IMU-based motion capture research studies, such as studies of gait modulation in patients with foot drop problems [21] and human activity recognition using thigh angle derived from a single thigh-mounted IMU data [2]. The use of IMUs for hand movement in free space is currently underdeveloped, primarily due to the lack of a clear calibration reset point compared with gait analysis. Another benefit of IMU solutions is flexibility in the collection window. From a practical point of view, the data measured during any session using motion capture technologies or any nonportable devices that require the patient to be at a certain location at a certain time, which may not be a period when certain movement characteristics are present or typical. For example, the patient could be *having a good day* or fatigued coincidentally during the clinic visit. IMU measurements outside the predefined time may avoid errors in the data collection. In addition, patient's compliance would potentially increase in the case of children, where their movement is taking place in their home environment compared with organized clinic visits. The challenge would then be to filter a larger data set to remove outliers, which is already a problem even when clinicians are involved. Therefore, the IMU data collection needs to be streamlined so that data can be captured easily without any need for clinical or technical expertise.

An overview of all the relevant existing methods, including their advantages and disadvantages can be seen in Table 1.

Table 1. Evaluation of existing methods.

Type of approach	Advantages	Disadvantages
Goniometers [14]	<ul style="list-style-type: none"> • Low cost • Can provide measurements very quickly 	<ul style="list-style-type: none"> • Lack of accuracy • Does not provide long-term tracking of movement unless repeated multiple times • Difficult when children are involved
Video capture [16]	<ul style="list-style-type: none"> • Very accurate • Can provide real-time orientation and active movement 	<ul style="list-style-type: none"> • Very costly • Continued monitoring is not possible outside the motion capture studio • Long set up time • Facilities are not available to everyone
IR ^a LED ^b gesture recognition [20]	<ul style="list-style-type: none"> • Low cost • Portable 	<ul style="list-style-type: none"> • Lack of accuracy • Not possible for continued monitoring • Mostly developed for entertainment use
IMU ^c [22]	<ul style="list-style-type: none"> • Low cost • Can provide a reasonably accurate orientation frame • Low power consumption • Portable 	<ul style="list-style-type: none"> • IMUs drift over time • The postprocessing of IMU data can be lengthy

^aIR: infrared radio.

^bLED: light-emitting diode.

^cIMU: inertial measurement unit.

Contribution of the Paper

This paper presents collaborative research between the Department of Electrical Engineering and Computing at Curtin University and the investigator team of a multicenter RCT involving children with CP [11]. The novelty of this work is the mass data collection and application area of the sensor system. To achieve this goal, 2 small, low-cost, custom-built IMUs were developed to capture the hand movements of participants in 2 age groups. The first age group had participants approaching 3 years, and the second age group had participants approaching 15 years. Both groups comprised participants with and without CP. Custom sensors were needed because commercial sensors are costly and do not provide raw sensor data. This means that validation cannot be performed easily. In addition, the use of custom sensors will avoid preprocessing by a third party. The designed sensors were capable of measuring wrist joint movement as the angle difference between 2 parallel sensors, which simplifies a 3D system problem to a 2D one. Therefore, only the relative motion was used, and the impact of the environment was ignored. This approach facilitates a reliable and valid method to capture changes over time. Capturing ROM over time is important because children with CP have secondary musculoskeletal complications, which means they are at risk of losing movement range. The proposed low-cost sensor system could also provide the means for active and continuous tracking of wrist joint movement during usual or predetermined tasks and actions that are currently not possible using traditional goniometric methods.

A second contribution of this paper is the application of ML to raw IMU data to classify the movement features associated with CP without the need to measure Euler, quaternion, and joint measurement calculations. This means that the processing time will be reduced because of using raw data for classification. This classification aims to investigate the existence of characteristics of CP movement, which is different from the clinical classification used for CP as a condition. This

classification can also confirm if treatment (in this case, the use of wrist extension) is effective. After the initial data collection, 9 different ML algorithms were used to classify CP as a feature: the Random Forrest algorithm achieved the highest accuracy of 87.75% for the age range approaching 15 years, and C4.5 decision tree achieved the highest accuracy with 89.39% for the age range approaching 3 years. The result of this classification aligns with existing research work in which ML is applied to classify footdrop using IMUs [23]. The results of this project showed that decision tree-based ML algorithms were the most accurate compared with other methods, which could be used as a guideline for similar human joint measurements.

Methods

Sensor Development

A custom-built IMU was developed to capture the hand movements of children with CP for this project. The IMU consisted of an MPU 9250, a custom-built Arduino Pro Mini, and a 2.4-GHz radio frequency (RF) radio. Each sensor was powered by a small 90 mAh, 3.7-V rechargeable lithium battery and could support up to 3 hours of nonstop measurement. The custom Arduino Pro Mini was previously designed by Dr Weiyang Xu as part of his thesis titled *Design and Validation of a Portable Wireless Data Acquisition System for Measuring Human Joint Angles in Medical Applications* [24]. The IMU data were captured using a simple receiver dongle that used an RF radio transceiver connected to an Arduino Uno and was read from the serial communication link. Both RF modules were connected using a serial peripheral interface (SPI), and the IMU was connected using an interintegrated circuit (I²C) connection. The designed IMU is shown in Figures 1 and 2. A summary of the specifications of the IMU is presented in Table 2. These sensors were validated against a goniometer and Vicon motion capture system, the results of which can be found in the studies by Walmsley et al [15] and Xu et al [25].

Figure 1. The MPU9150 (blue printed circuit board [PCB]), custom-built Arduino Pro Mini (green PCB), and RF Module (red PCB); a comparison of the inertial measurement unit with an Australian five-cent coin; and the 3D printed case for the sensor [24].



Figure 2. The receiver dongle in the 3D printed case [24].



Table 2. Specification of the inertial measurement unit (IMU).

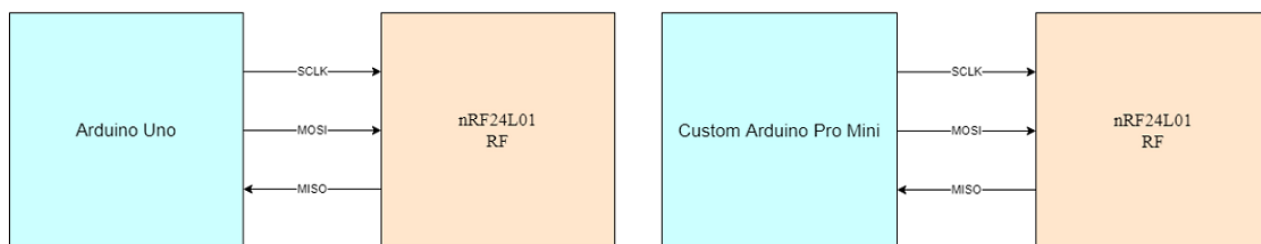
Electronic Module	Parameter	Value
MPU 9250 IMU	• Accelerometer FS range	• Range of ± 2 g, ± 4 g, ± 8 g and ± 16 g
	• Gyroscope FS range	• Range of ± 250 , ± 500 , ± 1000 and $\pm 2000^\circ/\text{sec}$
	• Magnetometer FS range	• Range of ± 1200 μT
nRF24L01 Transceiver	• ISM ^a band operation	• 2.4GHz
	• Air data rate	• 250 kbps, 1 and 2 Mbps
	• Programmable output power	• 0, -6, -12 or -18 dBm
Arduino Pro mini	• Circuit operating voltage	• 3.3 V or 5 V
	• Clock Speed	• 8 MHz (3.3 V version) or 16 MHz (5 V version)
	• Flash memory	• 32 KB
Arduino Uno	• Circuit operating voltage	• 5 V
	• Clock Speed	• 16 MHz
	• Flash memory	• 32 KB

^aISM: Industrial, Scientific, and Medical.

The SPI is a synchronous, full-duplex serial bus standard that was introduced by Motorola to support communication between a master processor and multiple slaves [26]. This protocol used Serial Clock sent by the master to synchronize master and slave; Serial Data Out to stream from the device; Serial Date In to stream into the device; Slave Select to enable slave, which is omitted in point-to-point connotations [26]. The master–slave connection for the RF module is shown in Figure 3. SPI was used to connect the RF module to the custom build module, where Arduino was the master and the RF module was the slave. The same connection was used on the receiver to connect the

RF module and Arduino Uno with the Arduino acting as the master and the RF module acting as the slave. This decision was made because of the inclusion of Master In Slave Out and Master Out Slave In data lines that facilitate full-duplex communication, a fast communication speed that can go to 10 Mbps or more; inclusion of push-pull drivers that provide good signal integrity, not limited to 8-bit words for bits transferred; use of master's clock by the slave, which removed the need for precision oscillators, and lower power requirements compared with other serial buses because of less circuitry.

Figure 3. The left diagram shows the serial peripheral interface (SPI) connection between Arduino Uno and the RF module, and the right diagram shows the SPI connection between the custom Arduino Pro mini and the RF module. MISO: Master In Slave Out; MOSI: Master Out Slave In; RF: radio-frequency; SCLK: Serial Clock.



The designed sensors needed to wirelessly transfer data to avoid hindering the hand movements of the participants in the project. Popular wireless communication technologies include Bluetooth, RF, WiFi, and infrared. The popular frequency range for wireless communication includes subGHz below 1 GHz (for long-range) and 2.4 GHz (for short-range). The proposed joint movement calculation system uses an nRF24L01 RF transceiver [27] (transmitter-receiver integrated on the same chip) module, which operates on a 2.4-GHz frequency band using 125 channels in the frequency range of 2.4 GHz–2.525 GHz. The module uses a license-free industrial, scientific, and medical frequency and can cover a distance of up to 1000 m. To improve the data loss at this crowded frequency band around 2.4 GHz, the nRF24L01 RF transceiver module uses a low noise amplifier [27]. The data rate requirement of the proposed joint movement calculation is not very high. This RF transceiver module is an improvement as it supports data rates in the range of 250 kbps–2 Mbps. The RF transceiver module connects with the Arduino module using SPI through Serial Clock, Master In Slave Out, and Master Out Slave In pins. The nRF24L01 RF transceiver is an ultralow

power drawing of 26 μ A of current in standby mode and 900 nA of current under down mode [27].

The I²C bus is a synchronous serial protocol originally developed by Philips Semiconductor (now known as NXP semiconductors) in the early 1980s [26]. The main aim of I²C was originally to support the board-level interconnection of ID modules and peripherals [26]. This protocol used serial data, and Serial Clock and ground for a half-duplex connection, which is capable of handling multiple masters and slaves. Serial Clock synchronizes all bus transfers, and serial data carries the data being transferred [26]. The connection of the MPU 9250 module is shown in Figure 4. The structure of the timing diagram for I²C is shown in Figure 5. The I²C was used to connect the IMU module to the custom-built IMU, with the Arduino acting as the master and the IMU acting as the slave. This decision was made because of the incorporation of Acknowledgment and No Acknowledgment functionality that improves error handling, flexible data transmission rates, addressability of each devices bus, and requiring only 2 signal lines.

Figure 4. Schematic of the I2C connection between the custom Arduino Pro Mini and the inertial measurement unit. SCL: Serial Clock Line; SDA: Serial Data Line.

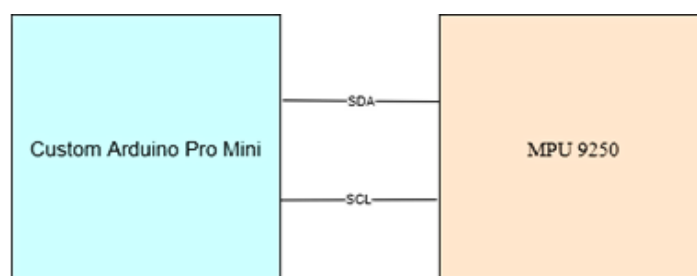
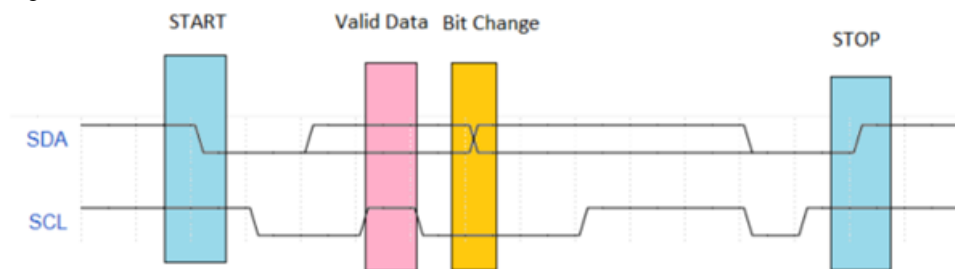
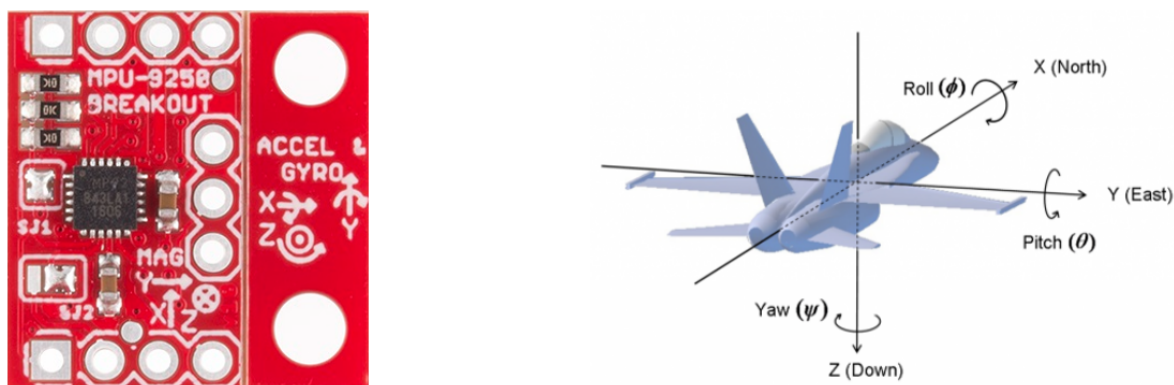


Figure 5. I2C timing diagram. SCL: Serial Clock Line; SDA: Serial Data Line.

The IMUs comprise an accelerometer, gyroscope, and magnetometer. Using sensor fusion techniques, an object's orientation can be captured using differential equations describing its dynamic behavior, which can be derived from the Newton-Euler by means of the Euler angle parametrization [28]. Quaternion is another method for capturing the orientation of an object, which is a four-element vector that can be used to encode any rotation in a 3D coordinate system [28]. In this study, to simplify calculations, raw acceleration and angular velocity were captured and used to measure the wrist joint angle. The requirements and specifications of this research lead to the selection of IMUs owing to their low cost, low power consumption, and ability to provide orientation with the relevant update rate.

Joint Angle Calculations

The sensors collected raw acceleration and angular velocity in the X-, Y-, and Z-axes, and the results were postprocessed in MATLAB using a 2-sensor-based joint orientation algorithm. This algorithm shows the difference in relative movements between 2 sensors when they share the same frame and zero position [24]. The Z- and Y-axes of both sensors need to be parallel to each other, so the X-axis of both sensors merge into the wrist center. This means that the wrist joint movement can be measured as the angle difference between the 2 sensors. The use of 2 parallel sensors for joint calculation simplifies the 3D system problem to a 2D one. The orientation of the MPU9250 is shown in Figure 6 [29] and the placement of the sensors is shown in Figure 7.

Figure 6. Orientation of the MPU9250 inertial measurement unit chip, where X is Roll, Y is Pitch, and Z is Yaw [29].**Figure 7.** Sensor placement showing sensor 1 connected to the back of the hand and sensor 2 connected above the wrist.

Using 2 sensors creates a relative system, so the rotation on the Y-axis or the orientation on the X-Z plane can simply be calculated using the following formula:



According to the tangent function, the angle of β can be initially calculated using the acceleration from the X- and Z-axes, where x is the angle between the net acceleration and the acceleration on the X-Z plane. Therefore, the tangent of β can be calculated as follows:

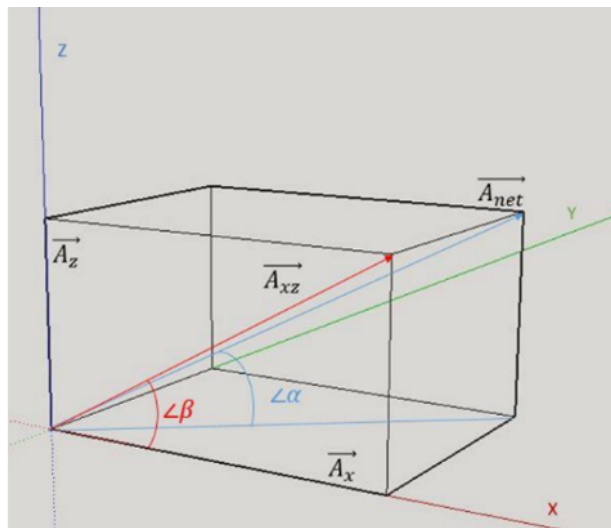


The angles used in equation (2) can be seen in Figure 8.

The data sample rate for both sensors was set to 100 Hz, which reduced the difference in angular velocity measurements between each sample.

Unlike traditional yaw, pitch, and roll orientation systems, a reference plane was unnecessary in the present algorithm as both sensor axes were aligned so that the joint movement was

Figure 8. 3D system for acceleration.



As the desired accuracy cannot be achieved by using only the acceleration, sensor fusion was used to increase the measurement accuracy by combining the data from both the accelerometer and the gyroscope. The accelerometer output was independent of each sample during the measurement period; therefore, θ_{zx} , θ_{yz} , and θ_{zy} , which are the projected orientation angles on the X-Z, Y-Z, and Z-Y planes, respectively, were used as rough measurements. The gyroscope's angular velocity ω_{gf} was added to describe the actual change between samples and can be calculated after subtracting the average static drift and using a Savitzky-Golay filter to calibrate the moving average drift [24]. The gyroscope's angular velocity can be calculated using the following formula:



Here, $\bar{\omega}_{gf}$ is the average static drift, which can be calculated using the following equation:



In the formula given above, n , m , and r are random integers and m is larger than 3. The total number of samples needs to be larger than $n + (m-1)r + 100m$. These calculations lead to the following sensor fusion algorithm, which is based on a complementary filter:



equivalent to the orientation difference between the sensors. Therefore, only relative motion was used, and the impact from the environment was ignored [24].

The orientation of each individual sensor was calculated using the orientation reading and angle movement during each sampling period, and a complementary filter introduced a high-pass filter to the main orientation tracker and adjusted with a low-pass value from the accelerometer's orientation measurement [24].

where a , b , and c are the names of the measurement axes and $n+1$ is the current order of the sample. $\sigma_c(n+1)$ is the filtered angle along the c -axis. Therefore, ω_{gf} represents the rotation on the c -axis, and θ_{ab} is the current angle on the a - b plane, which is based on accelerometer measurements. Finally, the combination of high-pass factor h and low-pass factor l is 1 [24].

The results of these joint calculations were validated in the study by Sharif Bidabadi et al [30] against a 3D Vicon video capture setup. The accuracy of the setup was written in a different paper found in the study by Walmsley et al [15], where a custom-made robotic device with predetermined angles was designed, where the sensors detected peak angles with mean errors ranging from -0.95° to 0.11° when one wearable sensor was static and the other dynamic. When 2 wearable sensors were moving, movement at a higher speed ($90^\circ/\text{s}$) had a mean error range of -2.63° to 0.54° and movement at a slower speed ($30^\circ/\text{s}$) had a mean error range of -0.92° to 2.90° [15].

Data Preprocessing

The IMU sensors generated time-series data from the accelerometer, gyroscope, and magnetometer around the 3 axes. First, small sections were removed from readings taken at the beginning of the experiments when the IMU sensors were not stabilized. Then, the remaining data collected by each sensor from each experiment in 3 orientations (ie, pitch, roll, and yaw) were converted into frequency-domain representations by performing fast Fourier transform. Converting data to the frequency domain can successfully capture the characteristics of gait motion, as shown by similar experiments in [23,31,32],

the interval between adjacent readings was approximated as 0.1 seconds and the fundamental frequency was calculated as $1/t_{\text{total}}$, where t_{total} is the total time of the experiment. The amplitude A , phase shift P , and peak frequency F of the first 5 harmonics were collected into a feature vector. The feature vector for each experiment was 1×270 , and the 270 features were as follows:



Each experiment was then labeled 0 for a typically developing child and 1 for a child with CP.

Classification by ML Algorithms

The problem of distinguishing typical hand movements from hand movements of children with CP constitutes a binary classification problem, that is, classification between two classes. Various algorithms can be constructed using different ML methods based on existing data that can be used to classify unseen data. This process is called *training*. Some classical ML algorithms commonly used in engineering problems include linear classifiers such as Naïve Bayes and logistic regression, decision trees such as the C4.5 decision tree and random forest, support vector machine, k-nearest neighbors, and neural networks such as multilayer perceptron and convolutional neural networks. More sophisticated deep neural networks can also be designed for classification problems; however, the size of training data sets is a major concern. Other problems include data bias, overfitting, a lack of computational resources, etc.

To decide between the 2 classes, ML algorithms for binary classification establish decision boundaries that separate the data points in the training data set from the 2 classes. This process relies on optimizing a cost function that varies between the algorithms. Most algorithms, such as logistic regression, support vector machine, decision trees, and neural networks, aim to construct a model with parameters that are learned from the training data set, whereas some algorithms operate directly on the data set, for example, k-nearest neighbors. Although there are numerous libraries and tools offering implementations of ML algorithms [33,34], the performance of the individual algorithm depends on the nature of the problem and the properties of the data set. Choosing the algorithm that performs best for a particular problem is subject to investigation.

Experiment Setup and Data Collection

As a part of an Australia-wide CP research study called the *Minimising Impairment Trial* (MIT) and *Infant Wrist Hand Orthosis Trial* (iWHOTs), the IMU sensors were used to capture the wrist movements of 2 groups of participants. The MIT trial included children with and without CP aged 5-15 years, and the iWHOT included children aged 6 months to 3 years. These studies were multisite RCTs that aimed to evaluate whether long-term use of rigid wrist or hand orthoses in children with CP, combined with usual multidisciplinary care, could prevent

or reduce musculoskeletal impairments, including muscle stiffness or tone and loss of movement range, compared with usual multidisciplinary care alone [11]. IMUs were used as an outcome measure to capture the active wrist ROM. During each assessment session, the participants completed several wrist movement activities such as making a stop sign motion, picking up small objects, playing with toys, pressing a big button, and so on. The aim of these activities was to assess the ROM used during active movement and task performance while data were collected via sensors. In addition, goniometric measurements of the joint movement was collected. The detailed protocol of this research has been published [11] if the reader is interested in more information about the clinical aspects of this trial.

For this project, the aim was to capture CP movement as a feature by ML on the raw IMU data by focusing on the data collected during the stop sign task in the MIT and iWHOT. Each participant was asked to perform a simple stop sign motion to capture the maximum wrist joint angle as well as the maximum range of movement. To achieve this study's aim, two separate experiments were run using participants who were approaching the age of 3 years from iWHOT and participants who were approaching the age of 15 years from MIT. From MIT, 263 samples from 89 participants with CP and 199 samples of typical movement data captured from 30 participants without CP were used. The participants without CP simulated typical movements to reach 199 samples. From iWHOT, 171 samples from 51 participants with CP and 149 samples from 20 participants without CP were used.

Cross-validation, which is 90% training and 10% testing, were used 10 times to train and test the classifier, which can be seen in the next section of this paper. The CP data were collected by the research teams working on the MIT and iWHOT trial according to ethically approved procedures (HREC REF 201406EP) and with signed, informed consent from all the participants' parents or guardians. Deidentified data were used to produce ML results, which are analyzed in the *Discussion* section of this paper.

Results

Figures 9 and 10 show the raw data captured for a stop sign motion trial of a participant without CP, starting from the stationary position to a stop sign and again to a stationary position. These data included the accelerometer and gyroscope in 3 axes. Figure 11 shows the placement of the sensors on the hand and above the wrist.

After the data were captured, they were processed and run through the different equations described in the joint calculation section of the report. Through these calculations, the drift was removed, and the joint angle was calculated, the results of which are shown in Figure 12.

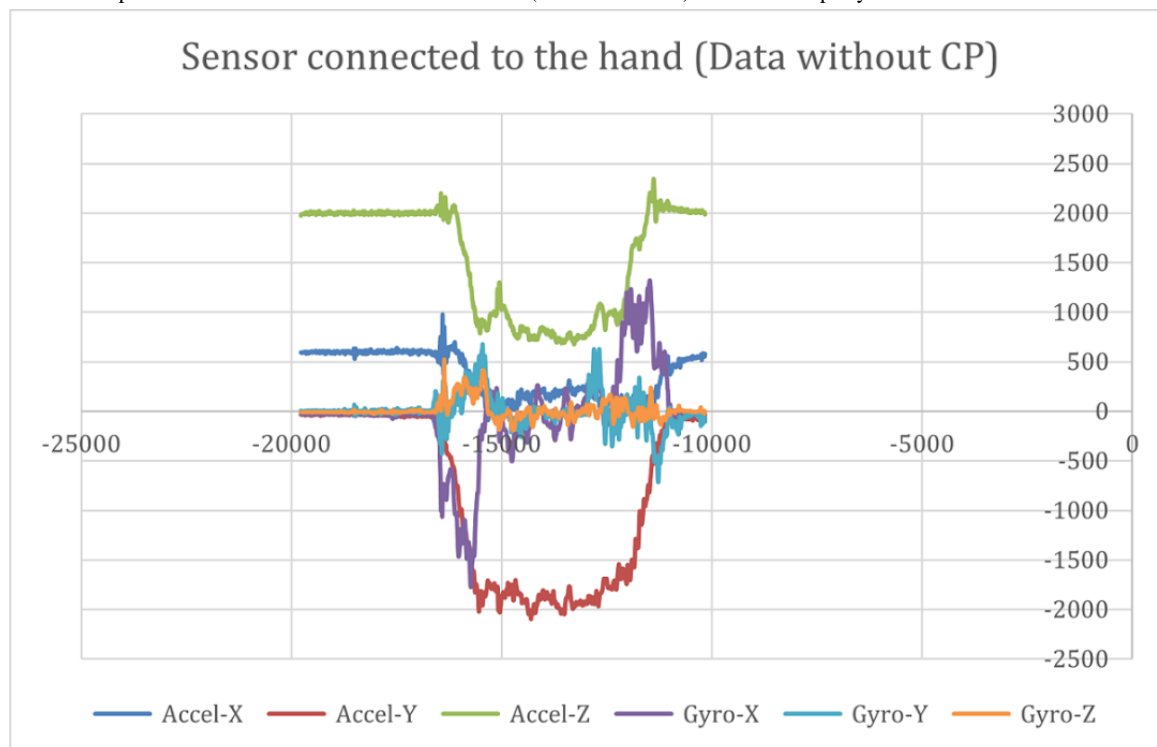
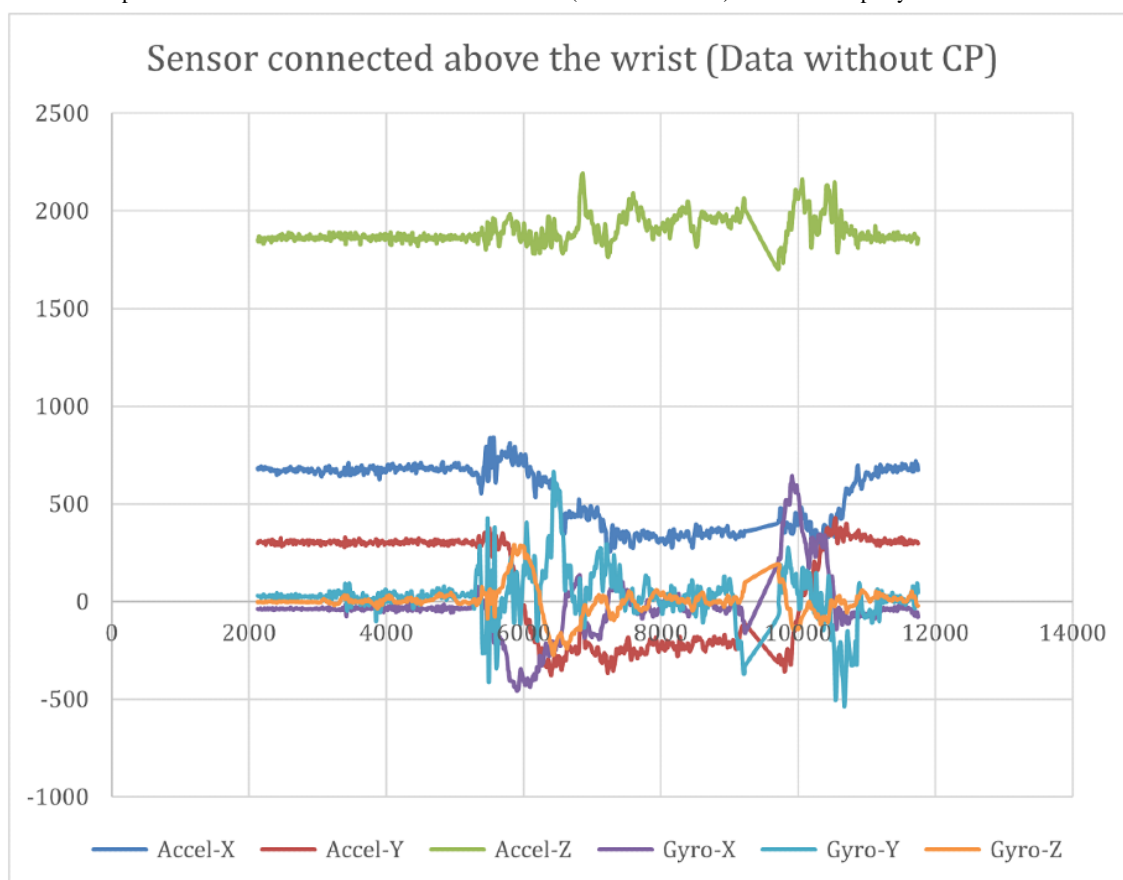
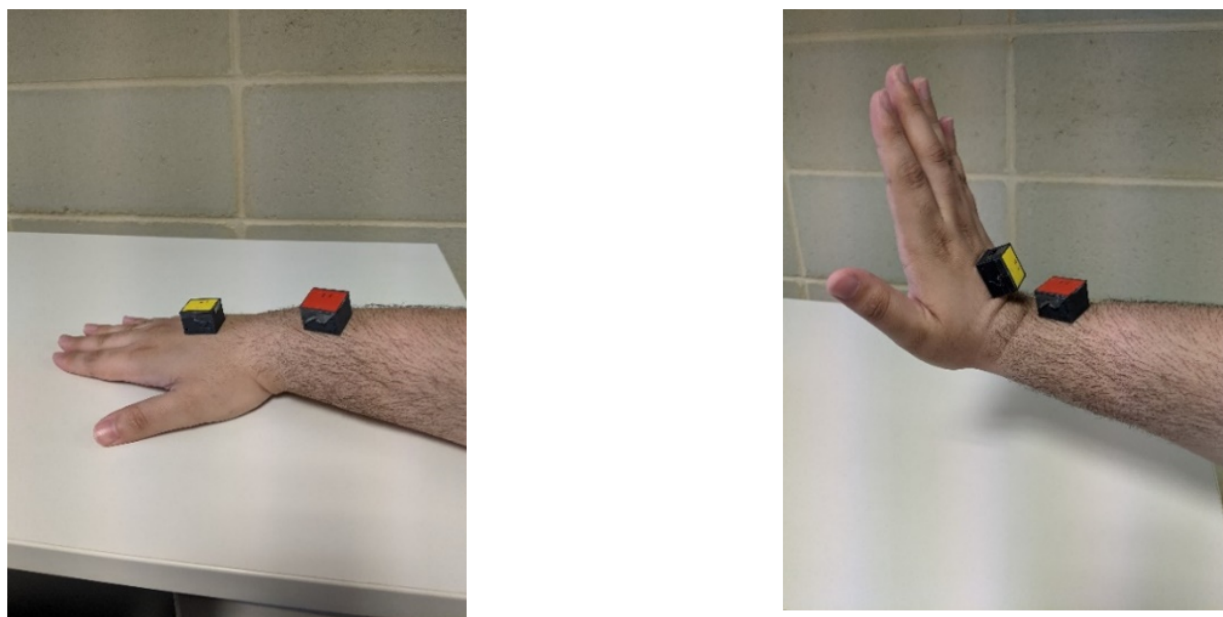
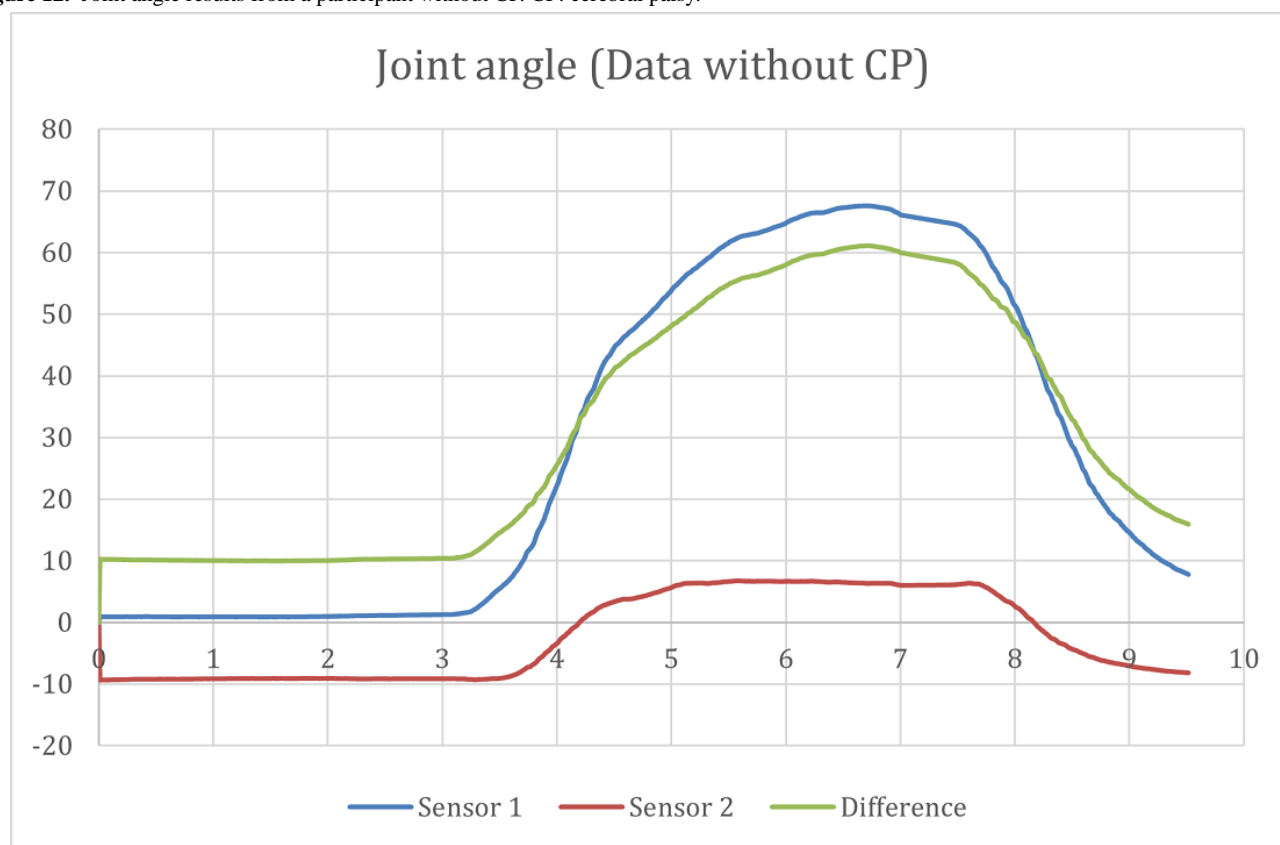
Figure 9. Raw data captured with the sensor connected to the hand (data without CP). CP: cerebral palsy.**Figure 10.** Raw data captured with the sensor connected above the wrist (data without CP). CP: cerebral palsy.

Figure 11. Stop sign motion required by the participants.**Figure 12.** Joint angle results from a participant without CP. CP: cerebral palsy.

The stop sign trials from participants with CP were captured using the same IMUs as those used in the previous group. The results of the raw data captured from the CP participants are shown in Figures 13 and 14. The results of the calculated joint angles are shown in Figure 15.

Anecdotal feedback from MIT and iWHOT researchers was positive about the potential of IMUs to contribute accurate data

about active ROM, especially in children for whom goniometric methods are challenging.

After the initial angles were calculated, several classical ML models were trained to create a classifier for the captured data. The Waikato Environment for Knowledge Analysis platform [34] version 3.8 was chosen as the platform for these experiments. Waikato Environment for Knowledge Analysis is a collection of open-source ML algorithms and contains tools

for data preparation, classification, regression, clustering, association rule mining, and visualization [34]. The algorithms used consisted of ZeroR, OneR, Bayes Net, Naïve Bays, logistic regression, C4.5 decision tree, random forest, support vector

machine, multilayer perceptron, and k-nearest neighbors. The authors analysis of the produced ML results can be found in the *Discussion* section of this paper.

Figure 13. Raw data captured with the sensor connected to the hand (data with CP). CP: cerebral palsy.

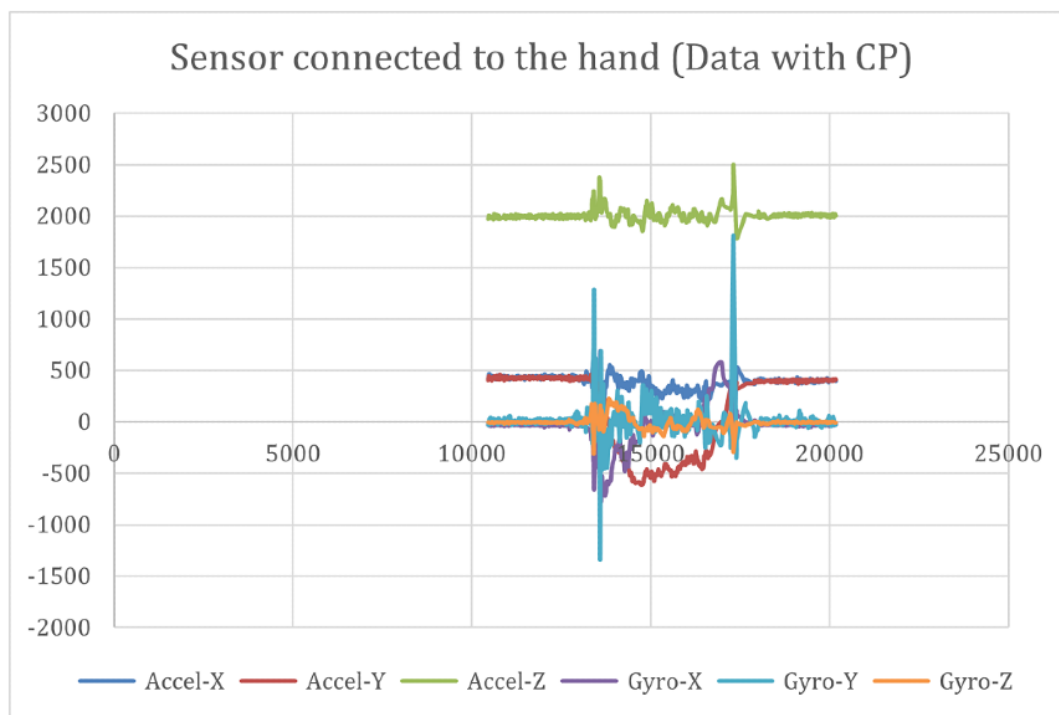


Figure 14. Raw data captured with the sensor connected above the wrist (data with CP). CP: cerebral palsy.

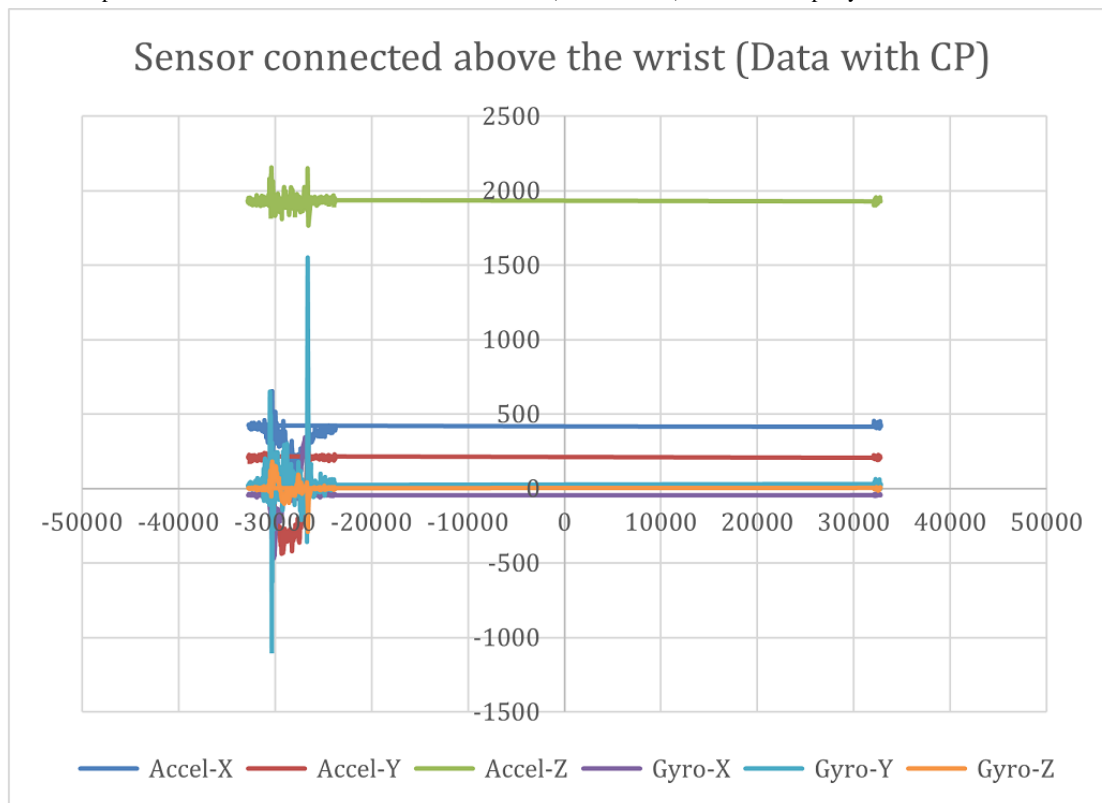
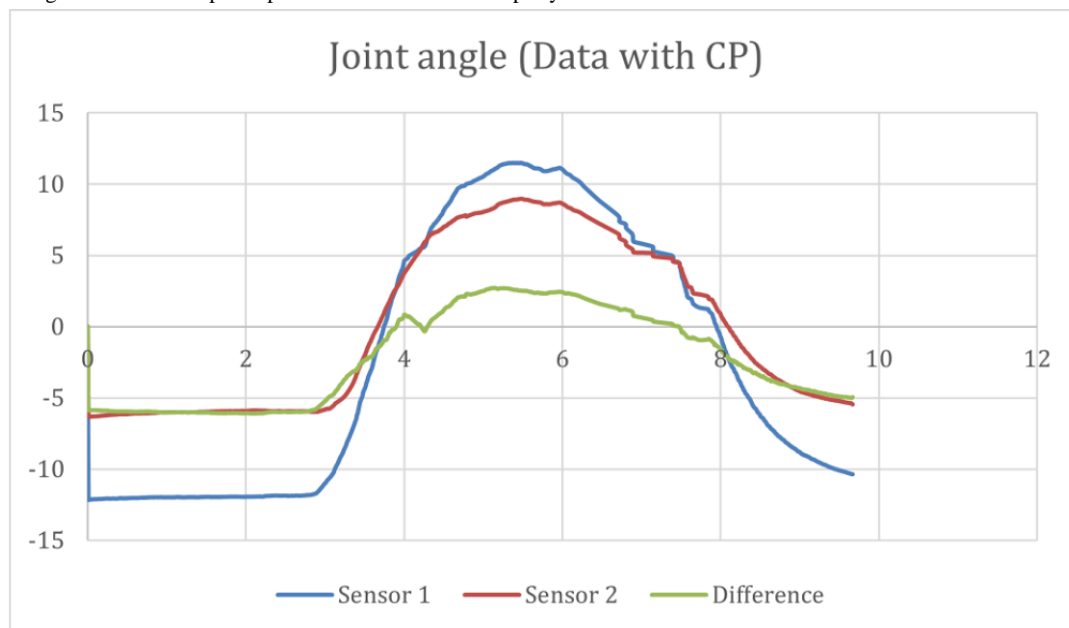


Figure 15. Joint angle results from a participant with CP. CP: cerebral palsy.

Discussion

Principal Findings

The resultant evaluation metrics are accuracy, the number of correctly classified instances over the total number of instances, the area under the curve (AUC), and the area under the receiver operating characteristic (ROC) curve. The ROC curve maps the true positive rates as the x-coordinate and false positive rates as the y-coordinate. Ten-fold cross-validation was adopted, splitting the data set into 10 parts, training the models with 9 parts, and testing with 1 part each time for a total of 10 times. The accuracy and AUC were obtained by averaging the 10 sets of results and taking the weighted average of the 2 classes. The baseline of the experiments was obtained from ZeroR, a

classifier that predicts the class that occurs most often in the training data set as the label without considering other features.

Table 3 presents the results of the 9-ML algorithms on the classification using the MIT data. The baseline obtained from ZeroR showed 57.02% accuracy and 0.493 AUC. The best accuracy was 85.75% yielded by random forest, and the best AUC was 0.890 yielded by k-nearest neighbors. Figure 16 shows the ROC curves of the 9 ML algorithms and the baseline. OneR, k-nearest neighbors, multilayer perceptron, and random forest all produce reasonable ROC curves and are expected to perform well for the problem. Naïve Bayes performs better than the other algorithms owing to the conditional independence assumption it makes. Because the frequency space features are interrelated, it is unreasonable to make this assumption.

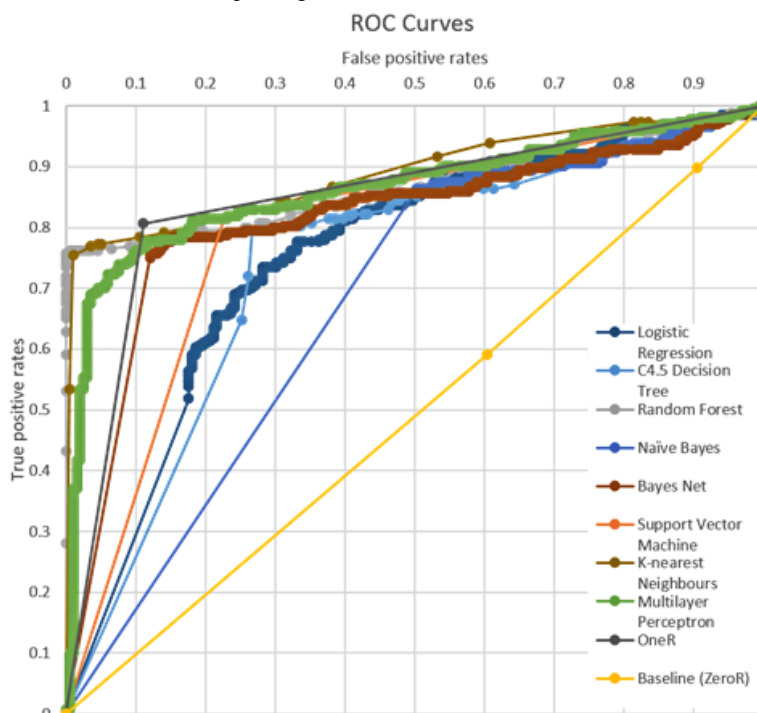
Table 3. Machine learning result using minimizing impairment training data, showing the best accuracy.

Algorithm	Accuracy (%)	AUC ^a
OneR	84.23	0.848
Logistic regression	72.79	0.749
Naïve Bayes	65.23	0.752
Bayes Net	80.99	0.832
C4.5 decision tree	74.95	0.740
<i>Random forest^b</i>	85.75	0.867
Multilayer perceptron	80.35	0.865
Support vector machine	79.70	0.794
K-nearest neighbors	82.07	0.890
<i>Average</i>	78.45	0.815

^aAUC: area under the curve.

^bThe best accuracy and area under the curve values are italicized.

Figure 16. The ROC curves of 10 classification algorithms using the Minimising Impairment Trial data. The area under the curve values are the areas between the ROC curves and the x-axis. ROC: receiver operating characteristic.



Curiously, OneR uses only a single feature and achieves 84.23% classification accuracy. The algorithm uses the 91st feature, which is the phase shift corresponding to the second harmonic obtained from the hand sensor. This phenomenon may indicate that the most useful information for classification is recorded by the hand sensor and that omitting one sensor may be possible in the future.

Table 4 presents the results of the 9-ML algorithms in binary classification using the iWHOT data. The baseline obtained from ZeroR showed 53.44% accuracy and 0.494 AUC. The best accuracy was obtained by the C4.5 decision tree at 85.75%, and the best AUC was obtained by Naive Bayes at 0.890. Figure 17

shows the ROC curves of the 9-ML algorithms plus the baseline. Although all models appear to be reasonable classifiers for the problem, it is worth noting that OneR, which classifies based on one feature alone, already achieves 88.13% accuracy and 0.886 AUC. The deciding feature is the amplitude of the acceleration in the row direction on the hand sensor, which corresponds to the most important piece of information in a real-world scenario. The relative underperformance of the more sophisticated algorithms, in contrast, may be due to the observed noises in the training data that lead to biases in the learned models. Such noises include the sensors falling off the participant, the participant not following instructions, etc.

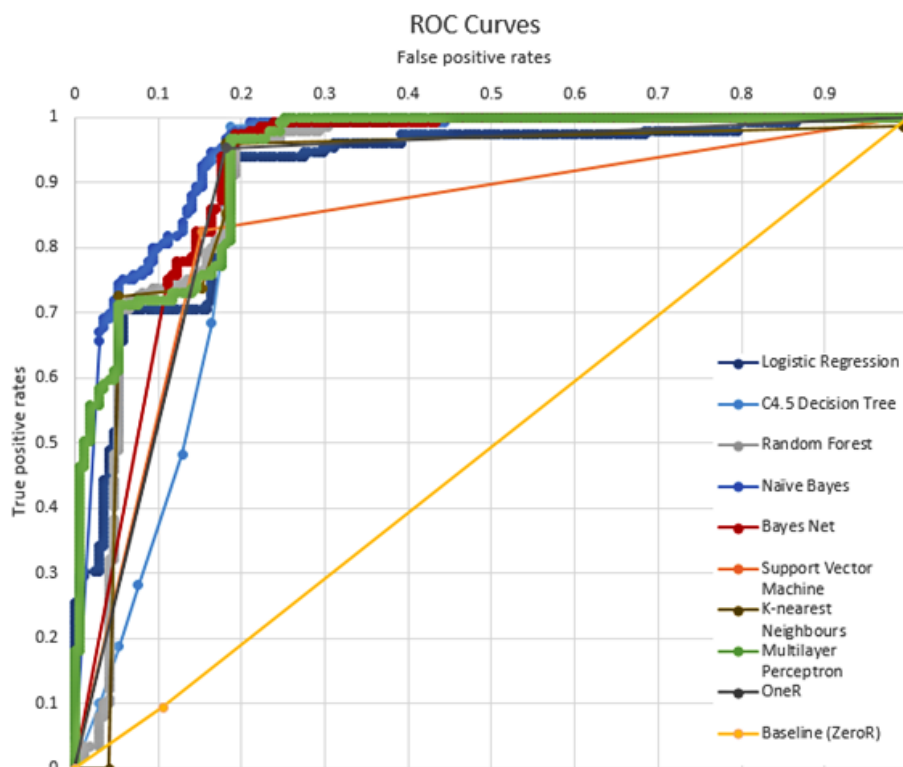
Table 4. Machine learning result using Infant Wrist Hand Orthosis Trial data.

Algorithm	Accuracy (%)	AUC ^a
OneR	88.13	0.886
Logistic regression	80.94	0.906
Naive Bayes	86.88	<i>0.943^b</i>
Bayes Net	88.43	0.921
<i>C4.5 decision tree</i>	89.38	0.858
Random forest	81.88	0.917
Multilayer perceptron	81.25	0.937
Support vector machine	83.75	0.783
K-nearest neighbors	83.44	0.896
<i>Average</i>	<i>84.90</i>	<i>0.894</i>

^aAUC: area under the curve.

^bThe best accuracy and area under the curve values are italicized.

Figure 17. The ROC curves of 10 classification algorithms using the Infant Wrist Hand Orthosis Trial data. The area under the curve values are the areas between the ROC curves and the x-axis. ROC: receiver operating characteristic.



Conclusions

Upon completion of the project, the wrist joint angle was successfully calculated, and CP movement was classified as a feature using ML on raw IMU data. Anecdotal positive feedback from MIT and iWHOT researchers was also received regarding the potential for IMUs to contribute accurate data about active ROM, especially where the use of goniometers can be challenging. There may also be the potential to use IMUs for continued monitoring of hand movements throughout the day. The sensor size needs to be reduced to make it more comfortable to wear. Examples of ML and IMU data captured for medical purposes can be seen in the paper titled *Classification of foot drop gait characteristic due to lumbar radiculopathy using machine learning algorithms* [23]. This paper looks at the classification of IMU data captured from hospital patients with foot drop issues using supervised learning and uses 11 different ML classifiers and shows that random forest was the most accurate method with an accuracy of 88.45% for a specific data set [23]. Some of the other ML algorithms used were SVM, Naive Bayes, and deep learning, which gave accuracies of 86.87%, 86.87%, and 86.06%, respectively [14]. Bidabadi et al [30] showed results were very similar to the current findings, although the focus was on a different joint. This suggests that decision-tree-based ML algorithms may be the best option for classifying IMU data for joint movement. The classifier used in this study would be able to distinguish atypical and reduced movement, which can potentially be useful for people with different joint movement disorders such as arthritis and Parkinson disease.

There are some limitations to the IMU setup used in this study, such as the inherent drift of IMUs, which can be corrected by

the drift mitigation techniques described in the methods. These techniques may prove problematic for longer trials. There were other issues during the data collection sessions, such as touching the 2 (hand and forearm) sensors because of the small hands of some participants or accidental touching of the sensors by the therapist while using the goniometer, which leads to an increase in noise in the data. Bugs in the data collection interface created for technicians also resulted in some corrupted data and data loss, which added to the preprocessing time of the ML section of this study. Finally, at the initial stages of the project, the scale of the accelerometer was set at +2 g because the slower moving trials rarely reached this value. Once free play situations were introduced that would usually contain rapid movement, particularly in younger children, it was observed that the scale of g needed to be extended beyond this threshold, which resulted in reduced accuracy. This reduction caused some data loss, so the scale was switched to +16 g for faster trials.

As part of future work, real-time calculation of joint angle and orientation data can be implemented so that direct quaternions can be collected and used for this calculation. The research team involved in this paper began the preliminary work on this next step and plans to publish their results once the solution has been fully created. The sensor setup will also be updated to remove the reliance on a separate receiver dongle by switching the communication module to Bluetooth Low Energy transfer to a smartphone application. These changes to the user experience and the medium of transfer would improve the utility of the process of data collection, better continued monitoring of children with CP, and quicker trial sessions in routine appointments for children with CP.

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Authors' Contributions

Conceptualization of the study was by IM and SK. Data curation was conducted by CE, CI, AC, and CW. Formal analysis was conducted by SK. Investigation was conducted by SK and HA. Methodology was devised by SK and IM. Resources were provided by CE and CI. Software provision was by SK and HP. Supervision was conducted by IM and WL. Validation was carried out by SK. Visualization was conducted by SK and BB. Original draft was written by SK. BB, HA, CE, and CI were involved in reviewing and editing the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-eHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 1080 KB - [rehab_v8i4e29769_app1.pdf](#)]

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Abbreviations

AUC: area under the curve
CP: cerebral palsy
I2C: interintegrated circuit
IMU: inertial measurement unit
IR: infrared
iWHOT: Infant Wrist Hand Orthosis Trial

MIT: Minimising Impairment Trial

ML: machine learning

RCT: randomized controlled trial

RF: radio frequency

ROC: receiver operating characteristic

ROM: range of motion

SPI: serial peripheral interface

Weka: Waikato Environment for Knowledge Analysis

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Original Paper

Investigating the Use of Virtual Reality Headsets for Postural Control Assessment: Instrument Validation Study

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Abstract

Background: Accurately measuring postural sway is an important part of balance assessment and rehabilitation. Although force plates give accurate measurements, their costs and space requirements make their use impractical in many situations.

Objective: The work presented in this paper aimed to address this issue by validating a virtual reality (VR) headset as a relatively low-cost alternative to force plates for postural sway measurement. The HTC Vive (HTC Corporation) VR headset has built-in sensors that allow for position and orientation tracking, making it a potentially effective tool for balance assessments.

Methods: Participants in this study were asked to stand upright on a force plate (NeuroCom; Natus Medical Incorporated) while wearing the HTC Vive. Position data were collected from the headset and force plate simultaneously as participants experienced a custom-built VR environment that covered their entire field of view. The intraclass correlation coefficient (ICC) was used to examine the test-retest reliability of the postural control variables, which included the normalized path length, root mean square (RMS), and peak-to-peak (P2P) value. These were computed from the VR position output data and the center of pressure (COP) data from the force plate. Linear regression was used to investigate the correlations between the VR and force plate measurements.

Results: Our results showed that the test-retest reliability of the RMS and P2P value of VR headset outputs (ICC: range 0.285-0.636) was similar to that of the RMS and P2P value of COP outputs (ICC: range 0.228-0.759). The linear regression between VR and COP measures showed significant correlations in RMSs and P2P values.

Conclusions: Based on our results, the VR headset has the potential to be used for postural control measurements. However, the further development of software and testing protocols for balance assessments is needed.

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KEYWORDS

postural sway; virtual reality; force plate; center of pressure

Introduction

An individual's ability to maintain their balance is key for performing daily activities. One way to gauge an individual's balance is to measure how much their center of pressure (COP) varies in the anteroposterior and mediolateral planes during quiet standing. This movement, which is referred to as *sway*, can be indirectly measured by using a force plate to record changes in the COP during quiet standing [1]. Postural sway in particular is an important indicator of an individual's overall

balance stability. As such, numerous studies have investigated the relationship between postural sway and physical activity performance [2]. However, the high costs and space requirements associated with the precision force plates used to measure postural sway can limit access to the use of the equipment for researchers and clinicians. There exists a need for a less resource-intensive solution.

A virtual reality (VR) system, which is defined as an interactive system that includes computers and media peripherals, can be used to create an environment that is similar to the real world

and provide audio and video stimuli to users [3]. VR equipment used to be very expensive and used to require a lot of space. However, thanks to technological advances and flourishing innovations in the gaming industry, an affordable home-based VR headset with a built-in gyroscope and triaxis accelerometer for tracking the positions of users was developed to promote video games [4]. Research has shown that a home-based VR system can provide accurate data on motion and position changes (ie, for clinical and research purposes) that are as accurate as those provided by a significantly more expensive kinematic motion capture system [5]. Further, although Niehorster et al [6] did not suggest the use of a home-based VR system for scientific experiments due to the system's lower latency at the millisecond level, Niehorster et al [6] did report that the precision of the VR tracking measurements was high. For balance measurements in clinical and lab settings, highly precise position data is more important than low latency. A study also proposed using a VR system to improve balance function [7]. Additionally, home-based VR systems have been proven to have reasonably accurate position tracking [6] and spinal mobility measurement [8] functions.

In a lab or clinic setting, expensive force plates are used to quantify balance performance. However, their costs and space requirements prevent the use of a force platform in home settings for health care purposes. A home-based VR system has the advantage of providing balance measurements via the VR headset's outputs [9]. Studies have investigated using VR headsets to assess human balance performance based on the inverted pendulum model of balance [10]. These studies' results validated the use of VR headset outputs as a method for quantifying postural sway in balance performance assessments [9]. However, the test-retest reliability of this method has not been reported, and it is unknown if the same results can be generated by a different brand of VR headset.

The goal of this study was to investigate the use of a VR headset (HTC Vive; HTC Corporation) as a cost-effective alternative to a force plate for measuring postural sway. If a VR headset's motion tracking equipment was valid for use in measuring values such as postural sway variables, many options for researching the effects that VR environments have on an individual's postural sway and balance without the need for extra equipment would become available. VR headsets could eventually become clinical tools that clinicians can use for balance assessments in a clinic or home setting. In this study, we compared the position outputs from a VR headset to the COP readings from a force plate to determine if the headset can effectively measure balance control.

Methods

Participants

A total of 20 healthy participants (age: mean 45 years, SD 26 years) were asked to participate in this study after institutional review board approval was received. Physical health screening

was performed on all participants to exclude anyone with balance issues, dizziness, or mobility deficits. After receiving informed consent from each participant, screening was conducted to exclude individuals with neurological and orthopedic disorders and any potential balance or dizziness issues.

Procedure

The participants were asked to stand quietly, either with their eyes open or with their eyes closed, on a force plate (NeuroCom; Natus Medical Incorporated) while wearing the HTC Vive. Three 20-second trials were performed for the eyes open and eyes closed conditions. During the trials for the eyes open condition, a static virtual scene was shown to the participants to reduce visual feedback and to help them maintain their balance. Figure 1 shows the virtual scene (Unity version 2018.3.8; Unity Technologies) that was seen by the participants of this study.

The COP data were recorded by the force plate at a sampling frequency of 200 Hz. The VR position data were recorded at a sampling frequency of 10 Hz. The COP and VR position data were computed to find the normalized path length (NPL) [11], root mean square (RMS) [11], and peak-to-peak (P2P) value [11] for sway in the medial-lateral and anterior-posterior directions by using a customized MATLAB code (MathWorks). The NPL, RMS, and P2P value were calculated as follows:

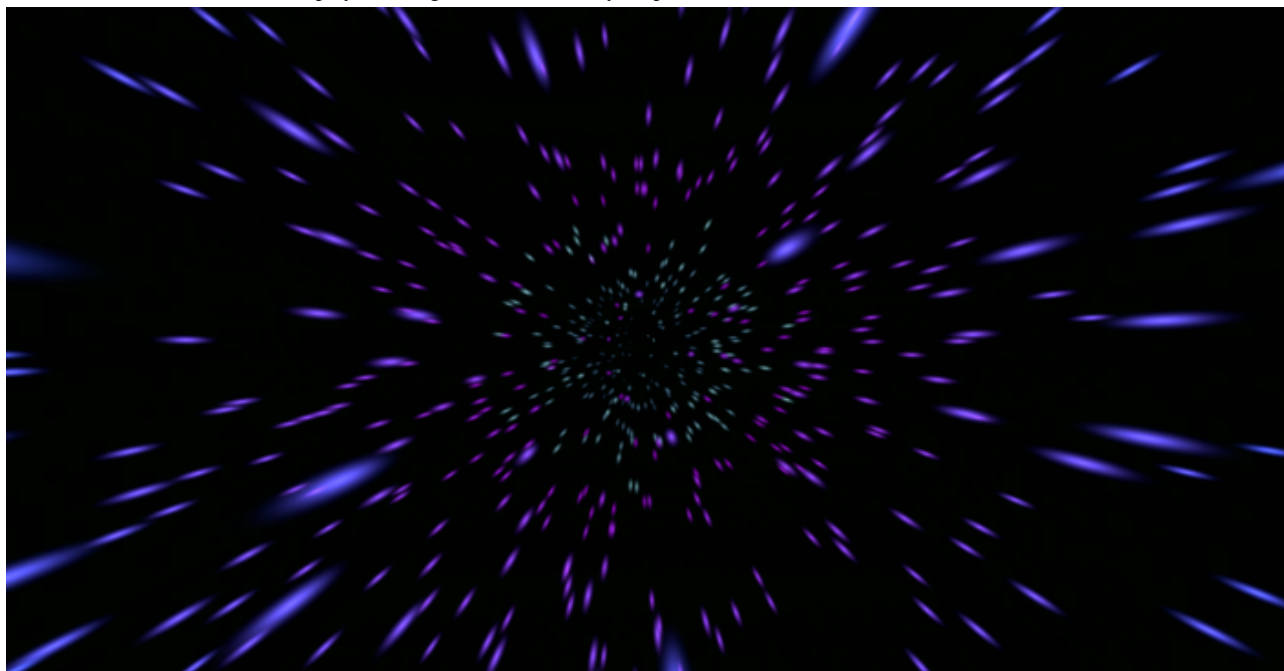


In these equations, t is the time duration, N is the number of samples, p_{avg} is the mean of the data, and p_j is either COP data or VR data at time sample j .

The test-retest reliability of the NPLs, RMSs, and P2P values in the three trials for each test condition were examined by using intraclass correlation coefficients (ICCs) and 95% CIs. A 2-way mixed-effects analysis of variance was conducted with a model comprised of the subject and trial numbers. ICCs were classified as poor (<0.5), moderate (0.5-0.75), good (0.75-0.9), or excellent (>0.90) [12].

The strength of the association between the COP and VR outputs was computed via linear regression by using the NPL, RMS, and P2P value of the COP data as the dependent variables and the VR output as the univariate predictor for each measure separately. The data from the first trial and the 3-trial averages were analyzed. Coefficients of determination (R^2) were reported as the amount of variance in COP data, which was estimated by using the VR outputs. The significance level was set to $\alpha < .05$. IBM SPSS Statistics software (version 25.0.0.1; IBM Corporation) was used to conduct the statistical analysis.

Figure 1. A virtual scene that was displayed during the trials for the eyes open condition.



Results

We first examined the COP and VR position trajectory. Examples of the raw medial-lateral and anterior-posterior

displacement data collected from the force plate and the VR headset are shown in Figure 2 and Figure 3. The COP and VR outputs showed similar patterns for sway in the medial-lateral and anterior-posterior directions during a test trial.

Figure 2. The blue line represents the VR data, and the green line represents the center of pressure data from the FP for sway in the medial-lateral direction. FP: force plate; VR: virtual reality.

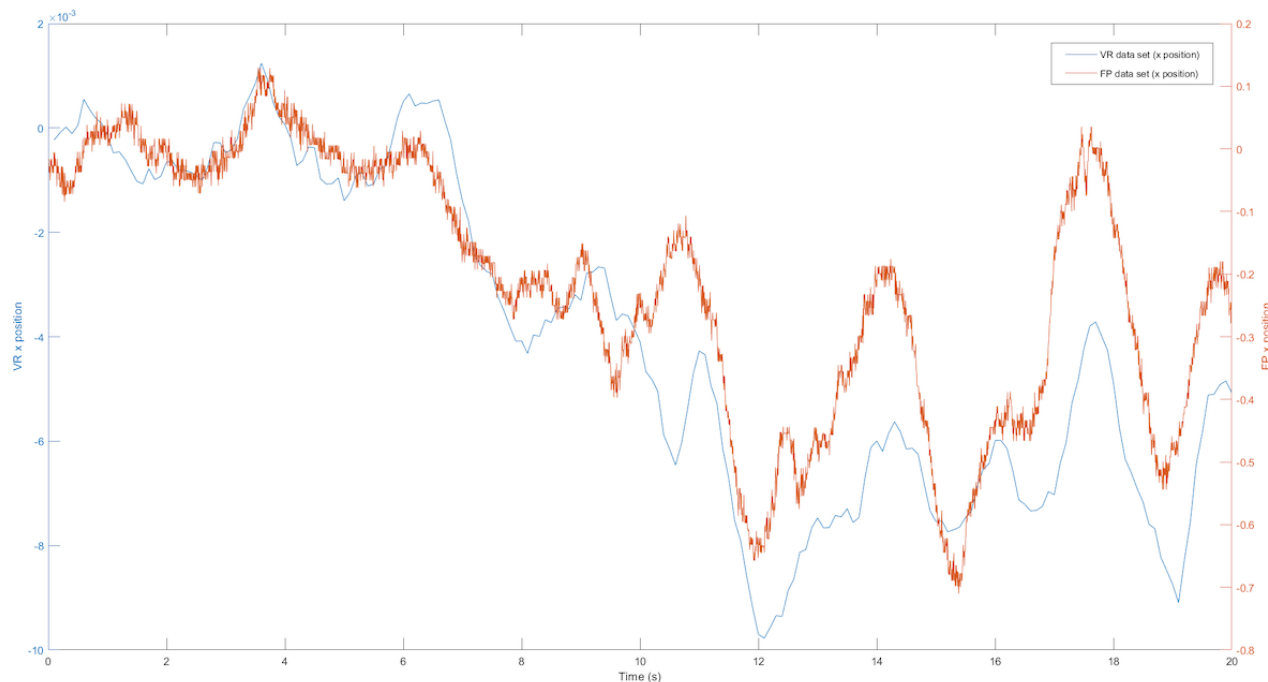
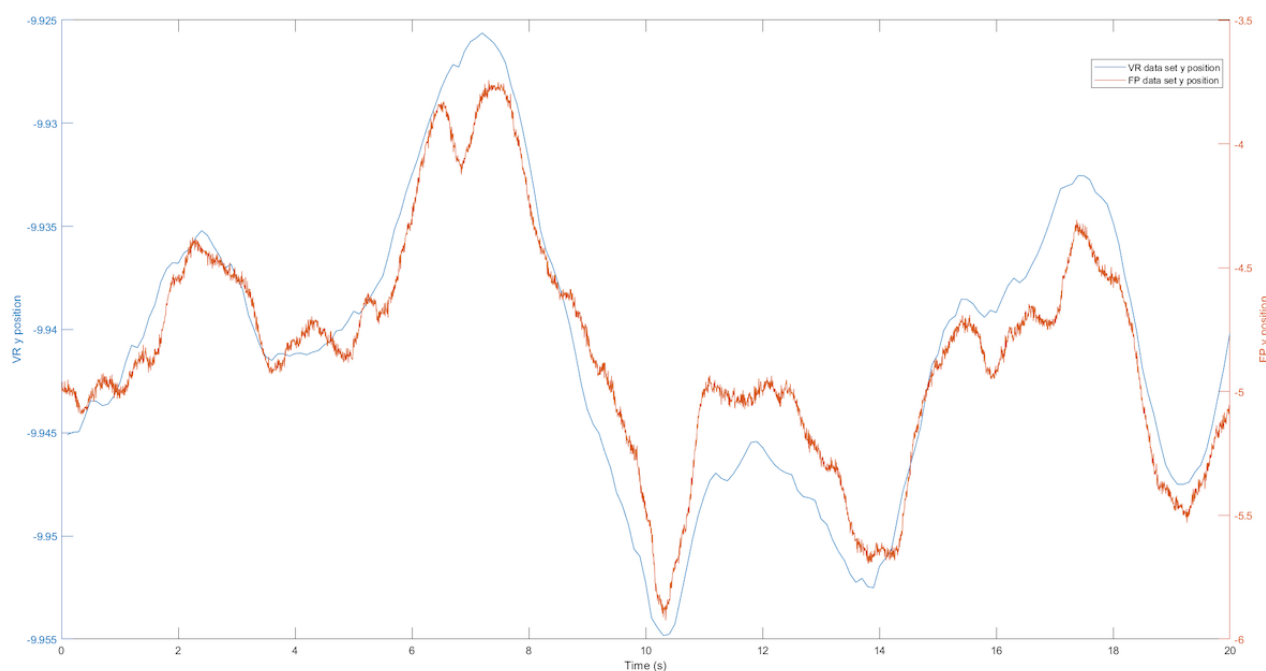


Figure 3. The blue line represents the VR data, and the green line represents the center of pressure data from the force plate for sway in the anterior-posterior direction. FP: force plate; VR: virtual reality.



Figures 4-9 summarize the results of the COP and VR measurements for the two postural sway directions, which were taken during the trials for the eyes open and eyes closed conditions for COP and VR measurements; the bars represent the 3-trial averages for sway in the medial-lateral and anterior-posterior directions and the eyes open and eyes closed conditions. The test-retest reliability of the RMS and P value of VR outputs was as good as that of the RMS and P2P value of force plate outputs. However, the test-retest reliability of the NPL of VR outputs was slightly worse than that of the NPL of force plate outputs (Table 1). Among the COP outputs, the NPL had the highest test-retest reliability (ICC: range 0.982-0.997), followed by the RMS (ICC: range 0.360-0.740) and P2P value (ICC: range 0.228-0.759). The test-retest reliability of the NPL, RMS, and P2P value of VR outputs, which ranged from 0.448

to 0.763, 0.285 to 0.574, and 0.348 to 0.636, respectively, was similar. VR data were significantly associated with the COP data for the RMS and P2P value (Table 2). In the first trial, the RMS and P2P value of VR outputs had a strong association with the RMS and P2P value of COP data. The 3-trial averages for the same VR output measures also had a strong association with the corresponding 3-trial averages for COP data. However, medial-lateral postural sway and the standing with eyes open condition were not strongly associated with the RMS and P2P value of COP data. The coefficients of determination for the NPL of VR outputs were lower than those for the RMS and P2P value of VR outputs. Swaying in the anterior-posterior direction and standing with eyes closed had a strong association with the COP data for the RMS and P2P value.

Figure 4. Center of pressure outputs (means and 1 SD) by postural sway direction for normalized path length. A-P: anterior-posterior; EC: eyes closed; EO: eyes open; M-L: medial-lateral.

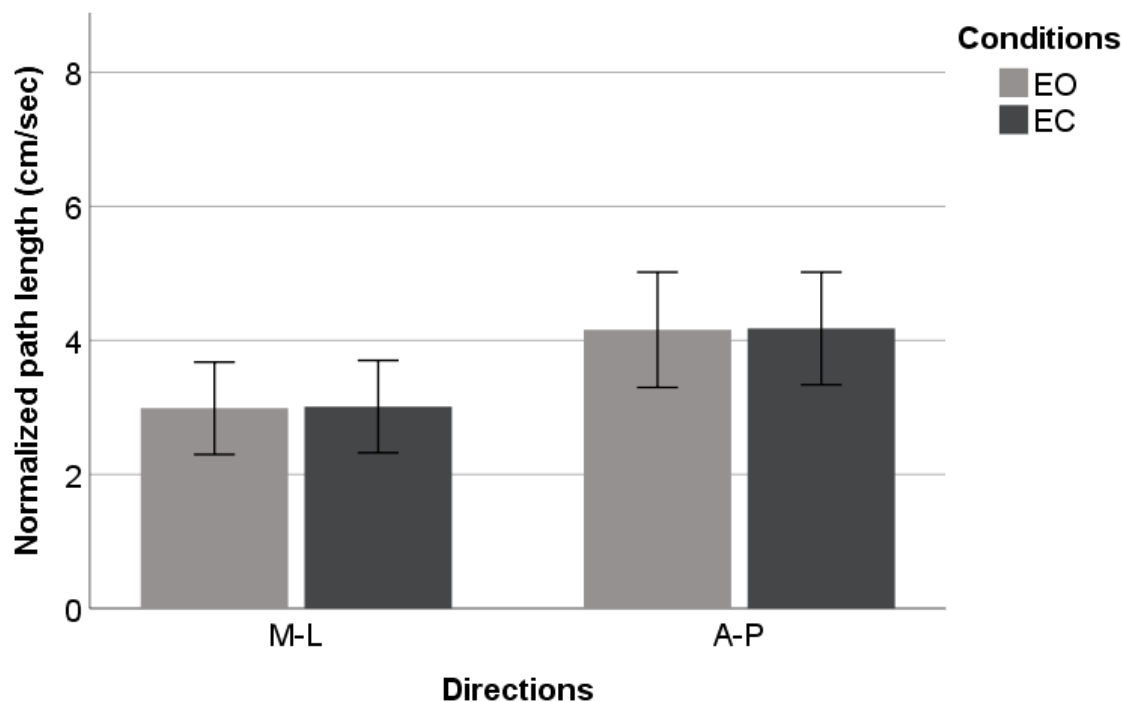


Figure 5. Virtual reality headset outputs (means and 1 SD) by postural sway direction for normalized path length. A-P: anterior-posterior; EC: eyes closed; EO: eyes open; M-L: medial-lateral.

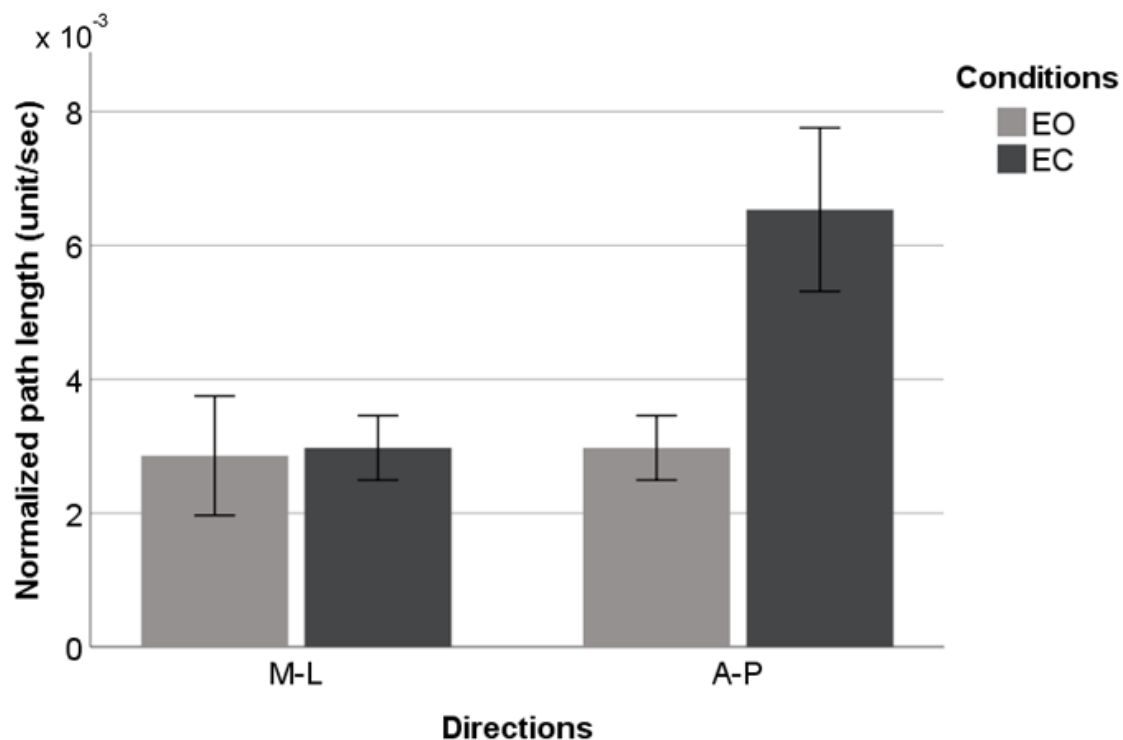


Figure 6. Center of pressure outputs (means and 1 SD) by postural sway direction for the center of pressure RMS. A-P: anterior-posterior; EC: eyes closed; EO: eyes open; M-L: medial-lateral; RMS: root mean square.

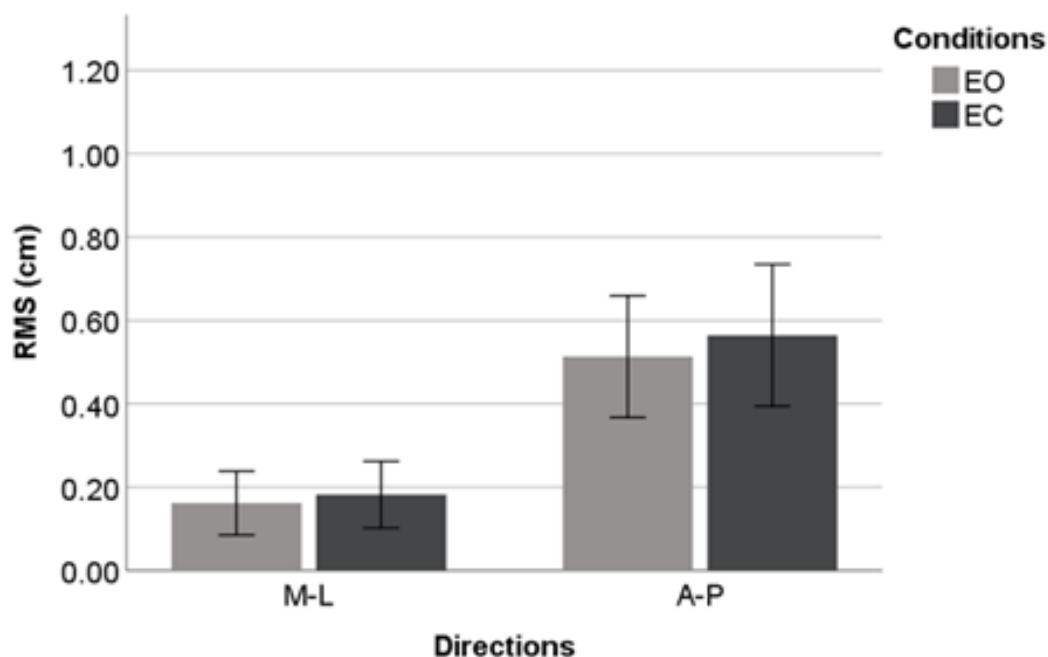


Figure 7. Virtual reality headset outputs (means and 1 SD) by postural sway direction for the virtual reality RMS. A-P: anterior-posterior; EC: eyes closed; EO: eyes open; M-L: medial-lateral; RMS: root mean square.

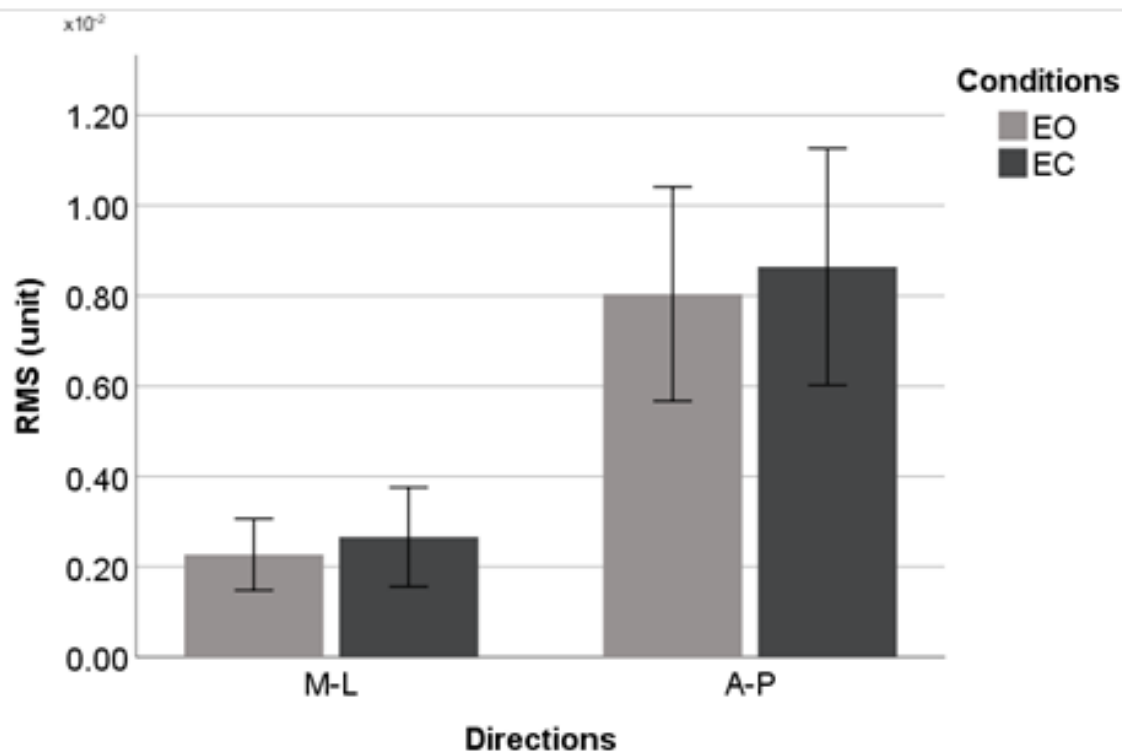


Figure 8. Center of pressure outputs (means and 1 SD) by postural sway direction for the peak-to-peak value. A-P: anterior-posterior; EC: eyes closed; EO: eyes open; M-L: medial-lateral.

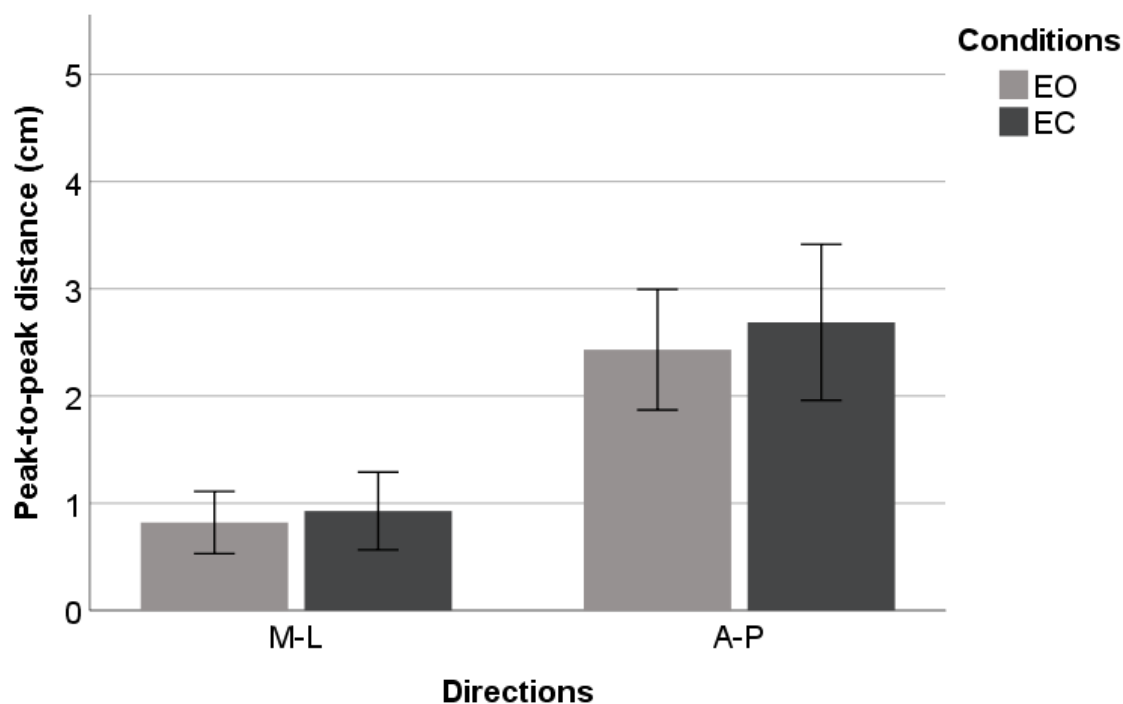


Figure 9. Virtual reality headset outputs (means and 1 SD) by postural sway direction for peak-to-peak value. A-P: anterior-posterior; EC: eyes closed; EO: eyes open; M-L: medial-lateral.

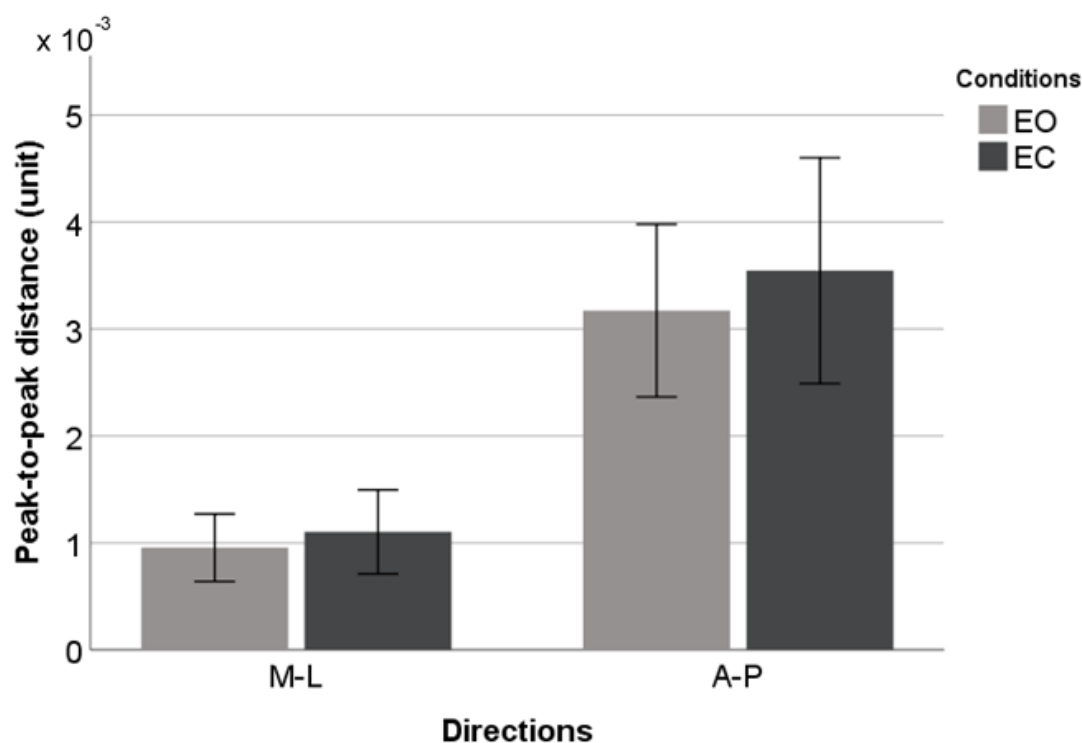


Table 1. The test-retest reliability in the three trials. The intraclass correlation coefficients and 95% CIs were calculated for the normalized path length (NPL), root mean square (RMS), and peak-to-peak (P2P) value of the force plate (FP) and virtual reality (VR) outputs for sway in the medial-lateral (M-L) and anterior-posterior (A-P) directions and the eyes open (EO) and eyes closed (EC) conditions.

Condition (sway direction)	Intraclass correlation coefficients (95% CI)					
	NPL of FP outputs	NPL of VR outputs	RMS of FP outputs	RMS of VR outputs	P2P value of FP outputs	P2P value of VR outputs
EO (M-L)	0.994 (0.987-0.997)	0.448 (0-0.771)	0.360 (0-0.726)	0.496 (0-0.786)	0.228 (0-0.673)	0.579 (0.102-0.824)
EC (M-L)	0.997 (0.994-0.999)	0.689 (0.341-0.870)	0.740 (0.462-0.888)	0.574 (0.124-0.819)	0.759 (0.503-0.896)	0.636 (0.241-0.846)
EO (A-P)	0.989 (0.977-0.995)	0.576 (0.100-0.823)	0.523 (0-0.802)	0.520 (0-0.802)	0.469 (0-0.775)	0.481 (0-0.777)
EC (A-P)	0.992 (0.984-0.997)	0.763 (0.492-0.902)	0.499 (0-0.787)	0.285 (0-0.704)	0.428 (0-0.758)	0.348 (0-0.732)

Table 2. Linear regression coefficients of determination for the center of pressure (COP) values predicted by the virtual reality (VR) headset outputs for each condition (COP and VR outcomes of the first trial and the 3-trial average of outcomes). Coefficients for the normalized path length (NPL), root mean square (RMS), and peak-to-peak (P2P) value of the force plate and VR outputs for sway in the medial-lateral (M-L) and anterior-posterior (A-P) directions and the eyes open (EO) and eyes closed (EC) conditions are shown.

COP and VR outcomes	Coefficients of determination, R^2			
	EO condition and M-L sway	EO condition and A-P sway	EC condition and M-L sway	EC condition and A-P sway
NPL				
First trial	0.005	0.024	0.004	0.001
3-trial average	0.089	0.038	0.013	0.038
RMS				
First trial	0.173	0.891 ^a	0.449 ^b	0.887 ^a
3-trial average	0.735 ^a	0.862 ^a	0.556 ^a	0.934 ^a
P2P				
First trial	0.626 ^a	0.734 ^b	0.418 ^b	0.840 ^a
3-trial average	0.718 ^a	0.769 ^b	0.608 ^a	0.890 ^a

^aSignificant the $P < .001$ level.

^bSignificant at the $P < .05$ level.

Discussion

Principal Findings

The test-retest reliability of VR position outputs was similar to that of COP data for the RMS and P2P value. Our results suggest that the position outputs from the VR headset had a strong correlation with postural sway variables, such as the RMS and P2P value computed from the COP data. However, the NPL of VR outputs had a weak correlation with the NPL of COP outputs, and this might have been due to the characteristics of VR position data and COP measurements. Force plates take COP measurements from below an individual's center of gravity, and VR headsets take position measurements from above an individual's center of gravity. Therefore, postural sway in an individual would have had a greater impact on the headset's measurements than on the force plate's measurements, resulting in weaker correlations in NPLs.

A different brand of VR headset was validated for measuring balance, and the results showed good to excellent correlations between COP and VR headset outputs [9]. Our study demonstrated similar results for a different brand of VR headset. Moreover, our data further validated the test-retest reliability of the VR headset we used. The Wii Balance Board (Nintendo) was used to take COP measurements in a study by Marchetto and Wright [9]. The Wii Balance Board was designed as a video game controller with a low sampling frequency (40 Hz) [13]. In our study, a laboratory-grade force platform was used to collect the COP data. Although the Wii Balance Board was validated for taking COP measurements, a laboratory-grade force platform may provide more accurate data, especially in studies that validate other devices for balance assessments [13,14].

The average ICC was better in the trials for the eyes closed condition. This may have been due to the lack of variability in postural sway when standing with eyes open [15]. The ICC values may improve if variables with larger variations or more

challenging balance variables, such as optic flow, are analyzed. Moreover, the sample size is another key factor that affects the ICC. Having a larger sample size may help to improve the test-retest reliability of VR position outputs.

This study presents promising results that indicate the usefulness of a VR headset as an alternative device for measuring balance control. Overall, the position data that were recorded by the VR headset correlated strongly with the COP data that were recorded by the force plate. The RMSs and P2P values of the data seem to indicate that there may be magnitude differences between the position data recorded by the headset and the COP data recorded by the force plate. Future work could be conducted to establish how much of a magnitude difference this is and if further data manipulation is necessary to obtain better correlations between the COP and position data.

Although the data show promise, there is still a need for improvement. In several trials, the correlation values were lower than 0.2. This indicated weak correlations among data sets. Since these correlation values tended to be outliers, it is likely that these lower values stemmed from calibration or procedure issues. The data analyzed in these trials also may have exhibited little variability, and this could have contributed to the low correlation values. Further software development for taking measurements by using the headset can be conducted, and improvements to the software used to analyze the data can be made. The further calibration of the headset and other data collection devices may also improve results. Adjustments can be made to the procedures used during data collection, such as

syncing the headset and force plate to start data collection at the same time by inputting the same input command on a single PC. Future work can be conducted to investigate the correlations between position data recorded by VR headsets and position data recorded by motion capture systems. Comparisons between such data can be conducted to further support the use of a VR headset as a clinical and research tool.

Conclusion

Using VR position outputs could be an alternative way of measuring postural sway. However, a standard method will need to be established before such data can be used in this manner. Overall, VR headset position outputs appear to have good potential for being used in balance control studies. The lower cost of a VR headset system is an advantage and promotes the use of this device in clinic settings. However, further validation and software development may be needed.

Key Points

An affordable home-based VR headset with a built-in gyroscope and triaxis accelerometer for tracking the position of a user was developed to promote video games. The goal of this study was to investigate the use of a VR headset as a cost-effective alternative to a force plate for measuring postural sway. The test-retest reliability of the VR headset and the postural control variables that were computed by the VR headset and a laboratory-grade force platform were compared. The lower cost of a VR headset system is an advantage and promotes the use of this device in measuring postural sway. However, further validation and software development may be needed.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

COP: center of pressure
ICC: intraclass correlation coefficient
NPL: normalized path length
P2P: peak-to-peak
RMS: root mean square
VR: virtual reality

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Original Paper

Technology-Aided Spatial Cues, Instructions, and Preferred Stimulation for Supporting People With Intellectual and Visual Disabilities in Their Occupational Engagement and Mobility: Usability Study

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Abstract

Background: Persons with severe or profound intellectual disability and visual impairment tend to be passive and sedentary, and technology-aided intervention may be required to improve their condition without excessive demands on staff time.

Objective: This study aims to extend the assessment of technology-aided interventions for supporting functional occupational engagement and mobility in 7 people with intellectual disability and visual impairment and to use a technology system that is simpler and less expensive than those previously used.

Methods: The technology system involved a Samsung Galaxy A10, 4 Philips Hue indoor motion sensors, and 4 mini speakers. Within each session, the participants were to collect 18 objects (ie, one at a time) from 3 different areas (stations) located within a large room, bring each of the objects to a central desk, and put away each of those objects there. For each object, the participants received verbal (spatial) cues for guiding them to the area where the object was to be collected, a verbal instruction (ie, request) to take an object, verbal (spatial) cues for guiding them to the central desk, a verbal instruction to put away the object collected, and praise and preferred stimulation.

Results: During baseline, the frequency of responses completed correctly (objects collected and put away independently) was 0 or near 0. During the intervention phase (ie, with the support of the technology setup), the frequency increased for all participants, reaching a mean of almost 18 (out of 18 response opportunities) for 6 participants and about 13 for the remaining participant. The mean session duration ranged from 12 to 30 minutes.

Conclusions: A program, such as the one used in this study, can be useful in promoting occupational engagement and mobility in persons with intellectual disability and visual impairment.

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KEYWORDS

technology; smartphone; motion sensors; intellectual disability; visual impairments; occupational engagement; mobility; mobile phone

Introduction

Background

People with severe to profound intellectual disability tend to be passive and sedentary when not provided with direct supervision from staff or caregivers [1-6]. Passivity and sedentariness may become even more serious when people present with a combination of intellectual disability and visual impairment [7-12]. To modify this negative situation, efforts are required to design intervention strategies suitable for promoting occupational engagement and mobility (ie, indoor walking), that is, for (1) providing people with a chance of meaningful actions and (2) increasing their opportunities for physical exercise and environmental stimulation [13-19].

To be effective, intervention strategies are expected to support people in critical areas such as (1) the appropriate use of objects (eg, taking and putting away objects at the right places), (2) spatial orientation for moving from one place to another (eg, to reach and use the objects), and (3) engagement motivation (eg, willingness to walk, orient to the cues, and use objects appropriately) [13,15,20-22]. To ensure sufficient support in the aforementioned areas and promote functional occupation and mobility independent of staff, intervention strategies need to rely on the support of technology [11,16,22-25].

One of the intervention strategies that rely on technology [11] was designed to provide the participants with (1) spatial (verbal) cues to help them reach different destinations where objects had to be collected, (2) preferred stimulation for reaching the destinations, (3) spatial (verbal) cues to transport the objects collected to a container, and (4) preferred stimulation for reaching the container and putting away the objects transported. The technology at the basis of this intervention strategy was expressly built for the study and included (1) electronic boxes with optic sensors (one box and sensor at each of the destinations) used for presenting spatial cues, detecting the participant's arrival, and delivering preferred stimulation and (2) a remote electronic control unit used to regulate the functioning of the boxes and sensors.

Another intervention strategy relying on technology [16] differs from the one described earlier in two main aspects. First, it also provides the participants with instructions for the use of objects at the destinations (ie, *take an object* or *put away the object*). Second, the technology components on which this strategy was based are all commercially available (as opposed to being specifically built) and include a number of smartphones, mini speakers, and portable light sources that are combined in clusters. A cluster (ie, a smartphone, mini speaker, and light source) was available at each destination to be reached for taking or putting away objects.

The aforementioned technology-aided intervention strategies were reported to be effective in helping participants reach independent occupation and mobility. Notwithstanding the encouraging results, additional research is warranted to (1) verify whether these results can be replicated across studies and (2) upgrade (improve on) the technology previously used. Successful replications would allow one to make more definite statements about the overall impact and generality of technology-aided intervention strategies [26,27]. Upgrading the technology may be critically important in view of the fact that (1) the technology system used by Lancioni et al [11] was specifically built for the purpose of the study and thus is not easily accessible and rather expensive and (2) the technology system used by Lancioni et al [16] involved several clusters of smartphones, mini speakers, and light sources; thus, it may be considered fairly complex and expensive.

Objectives

This study was conceived as a systematic replication effort whose main purpose was to (1) extend the assessment of technology-aided strategies to support independent functional occupation and mobility in people with intellectual disability and visual impairment, and (2) evaluate a relatively simple, commercially based technology system, which would be cheaper and more accessible than the systems used for the aforementioned strategies. The new technology system was based on the use of a single smartphone combined with motion sensors and mini speakers and was assessed with 7 participants.

Methods

Participants

Table 1 identifies the 7 participants (representing a convenience sample) by their pseudonyms and reports their chronological age, their visual and motor impairments, and the age equivalents for their daily living skills on the second edition of the Vineland Adaptive Behavior Scales [28,29]. The participants' chronological age ranged from 14 to 54 years. One of the participants (Alec) had functional residual vision, which allowed him to see immediate objects and obstacles. The remaining 6 participants were completely blind. One of these 6 (Davis) also presented with severe motor impairment and required the use of a wheelchair. The Vineland age equivalents for daily living skills (personal domain) ranged from 1 year and 7 months (Davis) to 3 years and 2 months (Maggie and Alec). All participants attended rehabilitation and care centers. Their psychological records indicated that their level of intellectual disability had been estimated to be within the severe or severe to profound range, but no specific tests were applied for their assessment.

Table 1. Participants' pseudonyms, chronological ages, visual and motor impairments, and Vineland age equivalents for Daily Living Skills, Personal Sub-domain (DLSP).

Participants' pseudonyms	Chronological age (years)	Visual and motor impairments	Vineland age equivalents ^{a,b} (DLSP)
Maggie	23	Blindness	3; 2
Lauryn	14	Blindness	3; 1
Alec	40	Severe visual impairment with functional residual vision	3; 2
Bill	35	Blindness	2; 8
Jay	22	Blindness	2; 9
Davis	44	Blindness and severe motor impairment requiring the use of a wheelchair	1; 7
Erin	54	Blindness	2; 11

^aThe age equivalents are based on the Italian standardization of the Vineland scales.

^bThe Vineland age equivalents are reported in years (number before the semicolon) and months (number after the semicolon).

The participants were included in the study based on the following criteria: First, they could follow auditory spatial cues and reach the destinations indicated by these cues. Second, they could respond to simple verbal instructions concerning taking and putting away objects. Third, they were known to enjoy (eg, to show behaviors such as alerting and smiling in relation to) forms of preferred environmental stimulation such as music, praise, and voices of favorite family or staff members. Thus, it was thought that the use of such stimuli contingent on their response performance could be a motivating (reinforcing) event for strengthening and maintaining such performance. Fourth, activities involving mobility and object use were considered important examples of functional occupation to counter the participants' sedentariness and passivity. Moreover, the participants were reported to be comfortable (eg, to show no signs of fatigue or anxiety) when engaging in such types of activities under staff supervision. Fifth, staff supported the study (whose purpose and required technology had been presented to them in advance), as they thought that an effective technology-aided intervention could have clearly positive implications for the participants' activity engagement within the daily context.

Although the availability of preferred stimuli during the study sessions gave reason to believe that the participants might enjoy their involvement in the study, there was no reliable way to determine their assent to be involved. Thus, their legal representatives were asked to sign a consent form on their behalf before the start of the study. The study complied with the 1964 Helsinki Declaration and its later amendments and was approved by an institutional ethics committee.

Setting, Activities, Sessions, and Research Assistants

Quiet rooms of the centers that the participants attended constituted the setting for the study sessions. An activity consisted of collecting 18 objects (ie, one at a time) from 3 different areas (stations) located within a large room, transporting each of the objects to a central desk, and putting away each of those objects there (ie, depositing each object into a specific container available on the desk). Activities could vary across sessions in terms of the objects to be collected, transported, and put away. The objects could involve kitchen

tools, food or drink items, and other simple materials for daily use. For each activity response (ie, object to collect, transport, and put away), the technology system provided (1) verbal cues for guiding the participant to an area with objects to be collected, (2) a verbal instruction (request) to take an object, (3) verbal cues for guiding the participant to the central desk, (4) verbal instruction to put away the object collected, and (5) praise and preferred stimulation. Sessions consisted of the time required for the participants to complete an activity (ie, collect and put away 18 objects). Sessions could also be interrupted before the activity was completed (ie, if a 30-minute time limit had elapsed or the research assistant's guidance had occurred for 4 consecutive activity responses). Research assistants, who were responsible for implementing the sessions and recording the participants' responses, had experience in using technology-aided interventions for people with intellectual disabilities and other disabilities.

Technology System

The technology system used during the intervention phase of the study involved (1) a Samsung Galaxy A10 with an Android 10.0 operating system that was equipped with Amazon Alexa, MacroDroid, and Philips Hue apps; (2) 4 Philips Hue indoor motion sensors; (3) a Philips Hue Bridge and Philips Hue smart bulb working via Bluetooth; (4) a 4G Long-Term Evolution Wi-Fi router; and (5) 4 Bluetooth mini speakers. The Philips Hue Bridge, Philips Hue smart bulb, and Philips Hue app were used to ensure the functioning of the Philips Hue sensors.

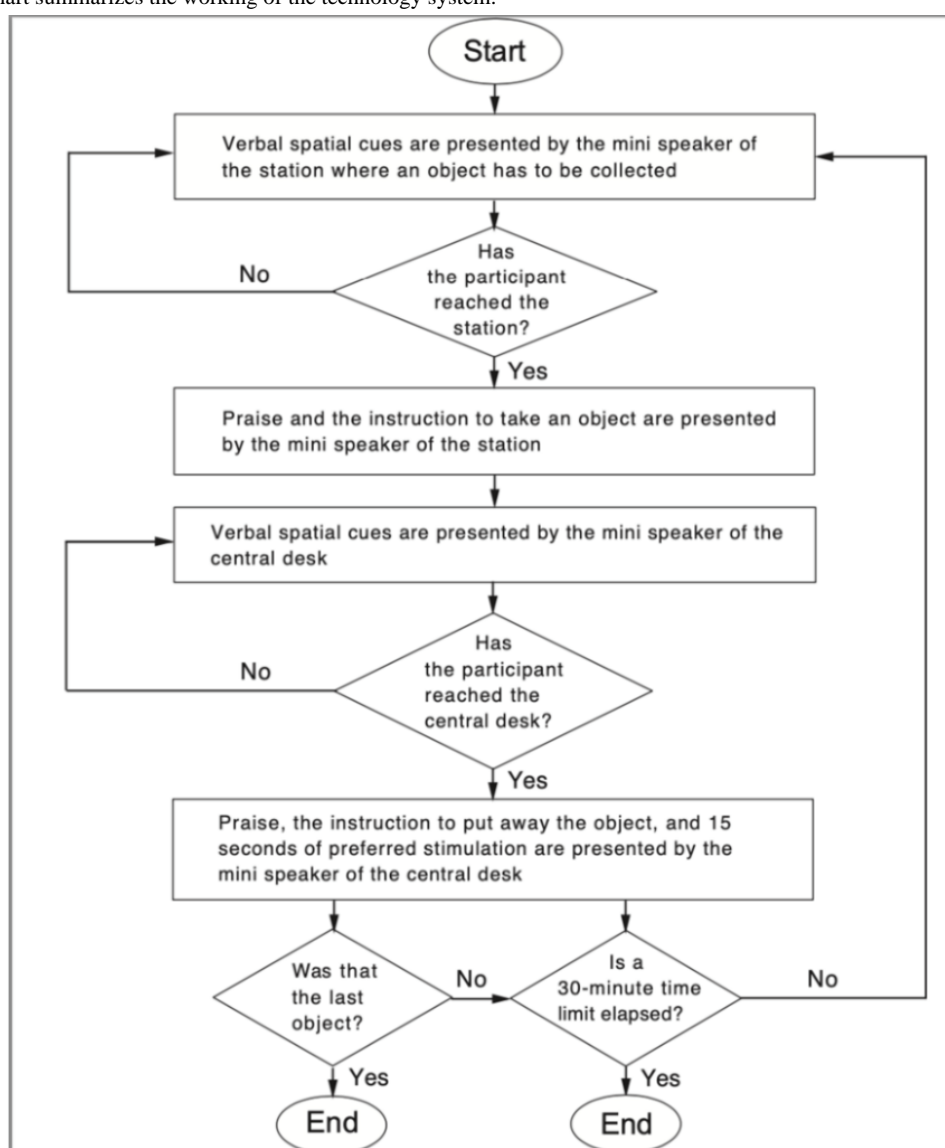
The sensors were box-like devices of 5.5 cm width and 3.5 cm height. One of the sensors was placed in front of a central desk to which the participants were to transport the objects collected from 3 different stations in the workroom (setting). The other 3 sensors were placed in front of the 3 stations (one sensor per station). The Bluetooth mini speakers were placed on the desk and at the stations. Any activation of a sensor by the arrival of a participant was detected through the Amazon Alexa app. This app transmitted the arrival message to the smartphone via MacroDroid.

Figure 1 summarizes the working of the technology system. Switching on the system (ie, starting a session) resulted in the

mini speaker of the first station to be reached being activated and starting to call the participant (ie, 1-word or 2-word calls that could involve the participant's name) at intervals of about 5 seconds. The calls served as spatial orientation cues and encouragement to help the participant reach the station. As soon as the participant reached the station (ie, was detected by the sensor before that station and in turn by the Alexa and MacroDroid apps), the mini speaker available at the station presented verbal praise and the instruction to take an object. After a 4-second interval from the instruction, the mini speaker of the central desk started calling the participant, as described above. In response to this sequence of inputs, the participant was expected to take an object and transport it to the central desk. Once the participant reached the central desk and was detected by the sensor there, the mini speaker available at the

desk presented praise, the instruction to put away the object, and 15 seconds of preferred stimulation (eg, a 15-second segment of a preferred song or music). At the end of the stimulation, the mini speaker of the next station to be reached was activated (ie, started to call the participant). When the participant arrived, the speaker presented praise and the instruction to take an object, as described above. The same conditions were in use for the other objects that the participant was to collect and transport to the central desk. The session continued until (1) the system had provided the support (ie, spatial cues, instructions, praise, and preferred stimulation) for completing 18 responses, that is, for collecting, transporting, and putting away 18 objects or (2) a 30-minute period had elapsed, whichever came first.

Figure 1. The flowchart summarizes the working of the technology system.



To prevent accidental errors, the system had only one sensor and one speaker functioning at a time during the session; that is, the sensor and speaker of the destination (station or central desk) the participant was to reach. If the participant reached the correct destination, the sensor available there was triggered and the system enacted the programmed events as described earlier.

If the participant reached a different destination, the system simply ignored that presence (ie, did not deliver praise, instruction, or preferred stimulation). Meanwhile, the mini speaker of the correct destination continued to call the participant.

Experimental Conditions

Design and General Procedures

The study was conducted according to a nonconcurrent multiple baseline design across participants [30]. In line with the design requirements, the participants were scheduled to receive different numbers of baseline sessions (ie, between 5 and 9) without the support of the technology system. These sessions were followed by intervention sessions, which were carried out with the support of the technology system. In total, 92 to 124 intervention sessions were available for the different participants, with the numbers changing across participants in relation to their availability. Video recordings of the sessions were viewed by a study co-ordinator who was in charge of supervising (providing feedback to) the research assistants to ensure procedural fidelity [31].

Baseline

Before the start of a baseline session, the research assistant guided the participant physically and verbally to the different stations where groups of about 10 objects were available. Then, the research assistant (1) accompanied the participant to the proximity of the central desk (as it would occur during the intervention sessions with the technology system) and (2) presented the participant with the instruction to *Go and take an object*. If the participant remained inactive or failed to make progress for 30 to 40 seconds, the research assistant intervened with guidance (ie, guided the participant to take an object from one of the stations, transport the object to the central desk, and put it away in a container available there). This was followed by a new instruction to *Go and take an object*. The research assistant's guidance was used as described earlier. The session continued until the participant had responded to all the 18 instructions scheduled or until 4 consecutive responses had occurred with the research assistant's guidance. Session interruption after 4 consecutive guidance instances was used to minimize frustration following repeated failures.

Intervention

The intervention phase was introduced by 2 or 3 practice sessions to familiarize the participants with the technology system's support. During these sessions, the research assistant's guidance could be used to facilitate the participants' successful use of such support, even though all participants were known to have the prerequisites for managing such support (ie, for using the cues and responding to the instructions) independently. The regular sessions that followed the practice sessions did not involve the research assistant's guidance. The research assistant would only accompany the participant to the proximity of the central desk and switch on the technology system to get the sessions started.

Once switched on, the system worked as described earlier (in Technology System; Figure 1). Specifically, the system presented spatial cues, instructions, praise, and preferred stimulation with regard to each of the 18 objects the participant was scheduled to collect and put away within a session that did not exceed a 30-minute limit. The objects were collected from 3 different stations. As in the baseline, each station typically contained 10 objects.

Measures

The measures were (1) responses completed correctly and (2) session duration. During baseline, a response was completed correctly if the participant reached a destination, took an object (or 2 objects), transported the object to the central desk, and put the object into the container independently, following the initial research assistant's instruction to *Go and take an object*. During the intervention, a response was completed correctly if the participant displayed the performance sequence mentioned earlier with the support of the technology system (in Technology System; Figure 1). The first measure (ie, responses completed correctly) was recorded by the research assistants who implemented the sessions. The second measure was recorded by (1) the smartphone during the intervention (ie, the smartphone logged the time elapsed from the delivery of the first instruction to the delivery of the last stimulation event at the central desk) and (2) the research assistants during baseline. Interrater agreement was checked in more than 20% of the sessions of each participant on the first measure and all baseline sessions on the second measure by having a reliability observer join the research assistant to record the data. The percentage of agreement on the first measure (computed for each session by dividing the number of responses for which research assistant and reliability observer reported the same *correct* or *incorrect* score by the total number of responses and multiplying by 100%) ranged from 92 to 100, with means exceeding 98 for all participants. The percentage of interrater agreement on the second measure (computed by dividing the number of sessions for which the reported durations differed by <1 minute by the total number of sessions and multiplying by 100%) was 100.

Data Analysis

The participant's data for the two measures (ie, responses completed correctly and session duration) are reported in graphic form. To simplify the graphic display, the data were summarized into blocks of sessions (ie, each data point reported in the graphs represents a mean session frequency or a mean session duration computed over a block of sessions). The Kolmogorov-Smirnov test [32] was to be used to analyze the differences between the baseline and intervention frequencies of responses completed correctly for any participant whose data in the two phases presented some level of overlap. In reality, no overlaps were observed.

Ethical Approval and Informed Consent

Approval for the study was obtained from the Ethics Committee of the Lega F. D'Oro, Osimo, Italy. All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Written informed consent for the participants' involvement in the study was obtained from their legal representatives.

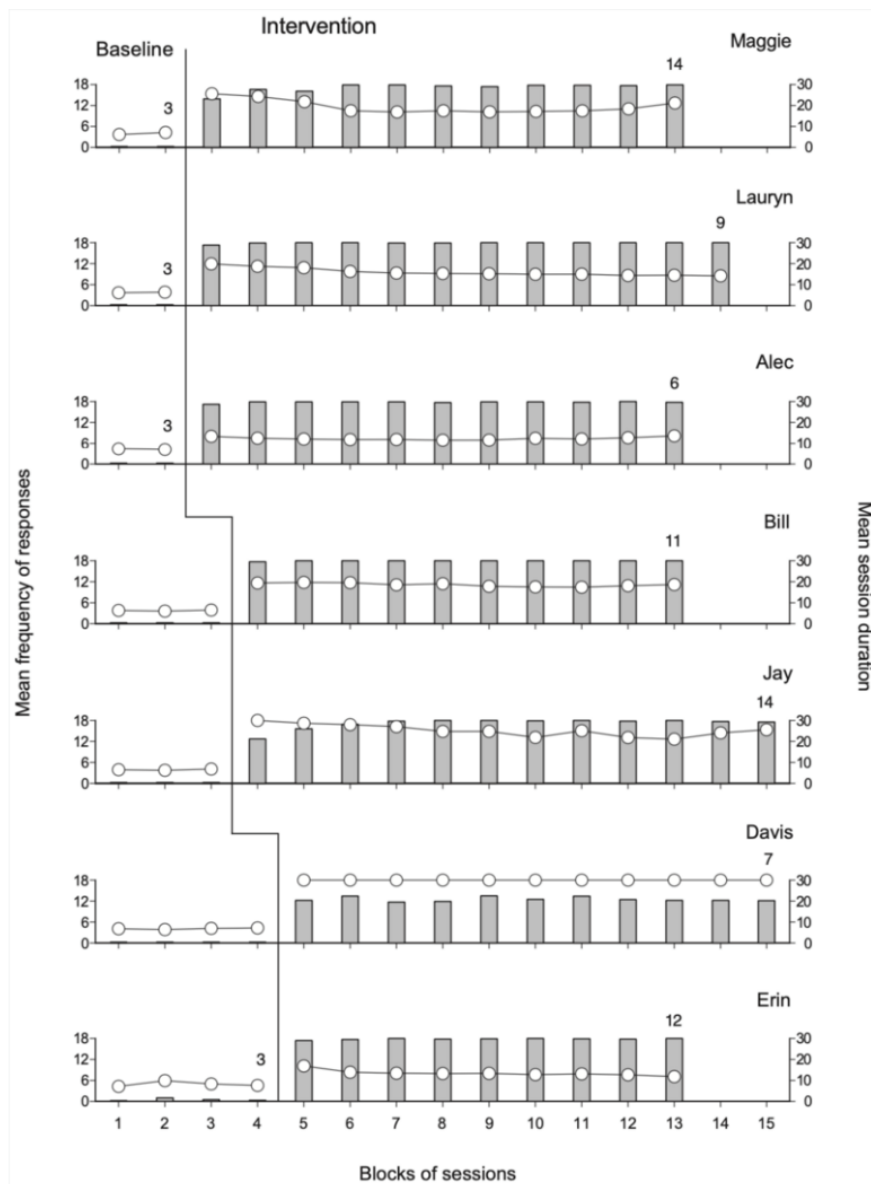
Results

The 7 panels of Figure 2 report the participants' mean frequency of responses completed correctly and mean session duration over blocks of baseline and intervention sessions. The bars

represent the mean frequency of responses completed correctly per session over blocks of 2 sessions during the baseline and 10 sessions during the intervention. The circles represent the mean session duration for the same blocks of sessions. Baseline and intervention blocks with different numbers of sessions (ie,

appearing at the end of the baseline or the intervention phase) are marked with a numeral that indicates how many sessions they include. The practice sessions occurring at the start of the intervention phase are not reported in the figure.

Figure 2. The 7 panels report the participants' mean frequency of responses completed correctly and mean session duration over blocks of baseline and intervention sessions. The bars represent the mean frequency of responses completed correctly per session over blocks of 2 sessions during the baseline and 10 sessions during the intervention. The circles represent the mean session duration for the same blocks of sessions. Baseline and intervention blocks with different numbers of sessions (ie, appearing at the end of the baseline or the intervention phase) are marked with a numeral that indicates how many sessions they include.



During baseline, the frequency of responses completed correctly was 0 for all participants except for Erin, whose level was close to 0. Indeed, all baseline sessions were interrupted after 4 consecutive responses had required guidance from the research assistant. The participants' mean session duration ranged from 6 to slightly over 8 minutes. During the intervention phase (ie, with the support of the technology system), the mean frequency of responses completed correctly increased for all participants. Six of them (Maggie, Lauryn, Alec, Bill, Jay, and Erin) showed mean frequencies ranging between approximately 13 (Jay) and close to 18 (Bill) during the first block of sessions and

approaching 18 during the following blocks of sessions. The mean session duration for these 6 participants varied between approximately 12 (Alec) and 23 minutes (Jay). Session interruptions (ie, after a 30-minute period had elapsed) occurred for Maggie and Jay almost exclusively during the first block of sessions. The intervention data of the remaining participant (Davis) showed a mean frequency of nearly 13 responses completed correctly per session and a mean session duration of 30 minutes. The differences between Davis' and the other participants' data are because Davis carried out the responses by propelling his wheelchair. This condition increased the time

he needed for each response, and consequently, he could manage only slightly more than two-thirds of the responses scheduled for the sessions before the sessions were interrupted (ie, before the 30-minute time limit was reached).

The absence of overlaps between the baseline and the intervention data in terms of responses correctly completed was seen as clear evidence of the difference between the 2 phases and consequently of the effectiveness of the technology system in promoting correct responses. In light of this evidence, the use of the Kolmogorov-Smirnov test was considered superfluous.

Discussion

Principal Findings

The data suggest that the technology system used during the study was effective in supporting the performance of all 7 participants. These results (1) confirm previous data on the feasibility of helping people with intellectual and visual disabilities to independently manage occupational engagement involving mobility and object use through the support of technology-aided programs and (2) add to those data, as a new and relatively simple (commercially based and less expensive) technology system was used to successfully support the participants' performance [11,14,16,22]. In light of the above, several considerations may be made.

First, given the participants' baseline performance, which reflected their persistent difficulties in managing occupational engagement, orientation, and mobility, the results of the intervention phase may be considered relevant [11,21,22,33,34]. During the intervention, in fact, the participants managed constructive occupation as well as orientation and mobility with no need for staff supervision. Mobility (via ambulation or self-propelled wheelchair) can be seen as an important component of the results as it represents a form of physical exercise that may have beneficial health-related effects for people like the participants of this study who tend to be largely sedentary [11,35-38].

Second, the technology-based support ensuring the aforementioned results included 3 main components (ie, the calls from the stations or central desk that were to be reached, the instruction to take or put away an object, and the praise or praise and preferred stimulation), which were known to be suitable for the participants (in Participants). The calls were instrumental in helping the participants find the right destinations and may have served as a form of prompt fostering engagement and reducing breaks in performance [11,16]. The instructions may have been critical to ensure that the participants always knew what they were to do, thus avoiding uncertainty and errors [11,14,34]. Praise and preferred stimulation may have been instrumental in motivating the participants' performance through the sessions and possibly their satisfaction with the sessions [39,40]. Anecdotal reports suggest that the participants showed behaviors such as smiles and vocalizations in connection with the preferred stimulation events.

Third, the technology system used in this study represents a relatively simple and practical tool compared with the systems

used previously (ie, systems that relied on specifically built technology devices or on clusters of smartphones, mini speakers, and light sources) [11,16,22]. The cost of the present technology system may be estimated at about US \$600 (ie, approximately US \$150 for the Samsung smartphone, US \$200 for the 4 Philips Hue sensors, US \$100 for the 4 mini speakers, and US \$150 for the Philips Hue Bridge, the Philips Hue smart bulb, and the 4G Long-Term Evolution Wi-Fi router). Although this cost is significant, one may argue that the present technology system (1) can be one of the few options available to enable people with intellectual and visual disabilities to manage independent occupation and mobility and (2) is fairly easy to operate for personnel in charge of the sessions and friendly for the participants [41-44]. The main obstacle rehabilitation professionals may encounter in accessing such a technology system is represented by the fact that it is not a ready-made (off-the-shelf) tool but needs to be set up through the aforementioned commercial components.

Fourth, research assistants were employed to conduct the study sessions. However, in view of the fact that the technology system seems rather easy to operate, one might envisage regular staff being directly responsible for managing the daily use of the technology and carrying out the sessions. Direct staff responsibility would foster their commitment to maintain the results obtained and an increased likelihood of intervention continuity over time [45,46].

Limitations

Several limitations of the study should be noted. The first limitation concerns (1) the relatively small number of participants involved in the study and (2) the fact that the participants represented a convenience sample. This limitation makes it difficult to draw conclusive statements about the overall potential and usability of the technology system being evaluated. Direct and systematic replication studies will be essential to determine the strength and reliability of such a system and investigate parallel versions and upgrades of it to improve its suitability and impact [26,27].

The second limitation concerns the lack of assessment of the participants' satisfaction with the technology system and sessions. Although their successful performance over time suggests that the praise and preferred stimulation available for responding were adequate to motivate their performance, checking their mood during the sessions may add relevant information. Checks might be conducted by recording any behavior that could be representative of happiness and satisfaction (eg, smiles and vocalizations) during the sessions [47-49].

The third limitation concerns the absence of social validation of the technology and its impact. Although staff expressed support for the technology system and its programmed use before the start of the study (Participants), it would be important to determine their opinion as to what the study managed to achieve. Such an assessment (social validation) could be carried out by (1) showing staff a few segments of the sessions carried out with the participants and (2) seeking their ratings of those segments and the technology used in terms of perceived efficacy, friendliness, and applicability [22,50,51].

The fourth limitation is the lack of generalization and maintenance assessments. On the basis of the characteristics of the system, one might reasonably expect successful generalization across settings and intervention agents to occur, as the conditions responsible for the participants' performance (ie, spatial orientation cues, instructions, and praise and preferred stimulation) would remain identical regardless of the setting and the intervention agents involved [39]. With regard to maintenance, the perspectives might be closely tied to whether preferred (motivating) stimulation continues to be available. In essence, participants are likely to maintain their positive performance if the stimulation they receive contingent on it is enjoyable for them [39,40].

Conclusions

In conclusion, one might argue that the technology system assessed in this study can be effective in helping people with intellectual and visual disabilities manage independent occupational engagement involving mobility and object use. Although the data appear quite encouraging, general statements about the system and its usability cannot be made until new research has successfully addressed the aforementioned limitations of this study. Future research may also explore the possibility of simplifying the present system through the use of new (cheaper) commercial technology components so that the new version could be more easily arranged and more readily applicable in daily contexts.

Conflicts of Interest

None declared.

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Original Paper

Effect of a Mobile Health App on Adherence to Physical Health Treatment: Retrospective Analysis

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Abstract

Background: Adherence to prescribed medical interventions can predict the efficacy of the treatment. In physical health clinics, not adhering to prescribed therapy can take the form of not attending a scheduled clinic visit (no-show appointment) or prematurely terminating treatment against the advice of the provider (self-discharge). A variety of interventions, including mobile phone apps, have been introduced for patients to increase their adherence to attending scheduled clinic visits. Limited research has examined the impact of a mobile phone app among patients attending chiropractic and rehabilitation clinic visits.

Objective: This study aims to compare adherence to prescribed physical health treatment among patients attending a chiropractic and rehabilitation clinic who did and did not choose to adopt a phone-based app to complement their treatment.

Methods: The medical records of new patients who presented for care during 2019 and 2020 at 5 community-based chiropractic and rehabilitation clinics were reviewed for the number of kept and no-show appointments and to determine whether the patient was provider-discharged or self-discharged. During this 24-month study, 36.28% (1497/4126) of patients seen in the targeted clinics had downloaded the Kanvas app on their mobile phone, whereas the remaining patients chose not to download the app (usual care group). The gamification component of the Kanvas app provided the patient with a point every time they attended their visits, which could be redeemed as an incentive.

Results: During both 2019 and 2020, the Kanvas app group was provider-discharged at a greater rate than the usual care group. The Kanvas app group kept a similar number of appointments compared with the usual care group in 2019 but kept significantly more appointments than the usual care group in 2020. During 2019, both groups exhibited a similar number of no-show appointments; however, in 2020, the Kanvas app group demonstrated more no-show appointments than the usual care group. When collapsed across years and self-discharged, the Kanvas app group had a greater number of kept appointments compared with the usual care group. When provider-discharged, both groups exhibited a similar number of kept appointments. The Kanvas app group and the usual care group were similar in the number of no-show appointments when provider-discharged, and when self-discharged, the Kanvas app group had more no-show appointments compared with the usual care group.

Conclusions: Patients who did or did not have access to the Kanvas app and were provider-discharged exhibited a similar number of kept appointments and no-show appointments. When patients were self-discharged and received the Kanvas app, they exhibited 3.2 more kept appointments and 0.94 more no-show appointments than the self-discharged usual care group.

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KEYWORDS

adherence; self-discharge; phone app; physical therapy; chiropractor; mobile phone

Introduction

Background

In health care, adherence has been defined as “the extent to which a person’s behavior corresponds with the recommendations from a healthcare provider” [1] and is the primary determinant of treatment success [1]. When the prescribed medical treatment involves physiotherapy to treat chronic musculoskeletal pain, adherence to the prescribed therapy has been reported to be critical for the successful resolution of the problem [2]. Low adherence to prescribed treatment has been identified as a challenge among many health care disciplines, including physiotherapy. Maintaining adherence to prescribed medical treatment is essential to facilitate maximum recovery following an injury and promote optimal health [3]. Sluijs et al [4] reported that between one-third and two-thirds of patients involved in treatment programs that included physiotherapy are not adherent with the prescribed treatment plan. A component of not adhering to prescribed medical treatment in primary care is not attending scheduled clinic appointments. When a patient prematurely terminates treatment against the advice of the provider, it is termed *self-discharge* as compared with the patient completing their prescribed treatment, which is termed *provider-discharged*. Not attending a single scheduled clinic appointment is termed a *no-show appointment* and is defined as an appointment in which the patient did not present for treatment or did not contact the clinic to cancel the appointment [5]. Both self-discharge and no-show appointments reduce revenue, result in suboptimal use of clinical and administrative staff, may lengthen wait times for patients, and negatively affect the continuity of care [6]. In primary care, the rate of no-show appointments ranges from 19% [7] to 42% [8] and is estimated to cost the US health care system US \$150 billion per year [9]. Moore et al [10] reported that no-show appointments negatively affected 25% of scheduled time in a family medicine clinic and resulted in a loss of 14% of the anticipated daily revenue. Patients with frequent no-show appointments experienced worse health care outcomes [3]. In a nationwide survey of physical therapists, investigators reported that 10.4% of their patients’ appointments were no-show appointments in private clinics, which was significantly lower than the percentage of patients who were no-show appointments in hospital campus clinics (14.53%) [11]. This low adherence to physiotherapy treatment has not changed over the past 27 years [11]. Other investigators have reported adherence rates with prescribed physiotherapy to be as low as 37.6% [12]. Thus, a primary explanation for the less-than-expected impact of physiotherapy in treating chronic musculoskeletal problems [13] may be a lack of adherence to the prescribed therapy by the patients and not the efficacy of the prescribed physiotherapy.

A variety of procedures have been introduced in outpatient clinics in an attempt to reduce the problem of self-discharge and no-show appointments. Providers have introduced different methods to reduce no-show appointments, including reminder procedures or penalizing the patient financially for a no-show appointment. The efficacy of these methods has not been clearly determined. Satiani et al [14] reported that automated reminder systems did not significantly reduce the rate of no-show

appointments. Other investigators found no effect [15] or only moderate effects [7] of automatic reminder systems to reduce no-show appointments. However, when appointment reminders were from actual clinic staff, the no-show rate was significantly reduced [16]. A continuous quality improvement study by Teo et al [17] indicated that reminders from an actual person resulted in lower no-show appointments (3%) when compared with message or voice mail reminders (24%). In a randomized controlled trial (RCT) where physical therapy patients received clinic appointment reminders sent to their cell phone, the no-show appointment rate was lower (11%) compared with patients who did not receive an appointment reminder (16%) [18]. A comprehensive review of the literature concluded that reminder interventions, including telephone, mail, SMS text messaging, and email reminders, all moderately reduced no-show outpatient clinic appointments [19]. This finding is consistent with a more recent meta-analysis of the literature that concluded that patients who received a text-based electronic notification of an upcoming health care appointment were 25% less likely to no-show for their appointment [20]. Penalizing or imposing a financial charge on patients for no-show appointments has been proposed as an effective approach to reducing this problem by economists [21]. However, a large empirical study did not demonstrate the efficacy of imposing a financial charge on no-show appointments to reduce future no-show appointments among outpatients [22]. Reminder procedures or penalizing the patient financially for no-show appointments have not consistently demonstrated reductions in no-show appointments.

A number of recent studies have presented evidence that supports the feasibility, acceptability, and efficacy of digital health interventions in treating different chronic medical conditions. In addition to providing text-based messaging about upcoming health care appointments, mobile phone apps have been designed to promote patient engagement in their care, including improving self-care and adherence to prescribed health care therapies. In a review of 279 commercially available mobile phone apps to manage pain that included education, self-monitoring, social support, and goal setting, the authors concluded that the efficacy of most apps was not supported by empirical research [23]. A more recent review of 15 studies evaluating the effects of phone-based apps involving pain management concluded that these apps are workable, well-liked by patients and health care professionals, and can result in reductions in pain [24]. In a more recent study, Huber et al [25] reported that a multidisciplinary phone-based app to manage pain, Kaia, including prescribed exercises, education, relaxation exercises, and coaching, resulted in statistically and clinically significant reductions in pain. MacIsaac et al [26] examined an innovative, smartphone app-based resilience intervention—the JoyPop app—introduced among first-year undergraduate students. After using the app at least twice daily for 4 weeks, 156 participants reported improved emotional regulation and depression. This positive impact of the JoyPop app was directly related to the frequency of using the app. Irvine et al [27] studied a mobile web intervention called *FitBack* that was designed to encourage users to adopt cognitive and behavioral strategies based on social cognitive theory and the theory of planned behavior to support their self-efficacy to engage in prescribed

pain management and prevention behaviors. The findings of this study demonstrated that the standalone mobile web intervention that tailored content to users' preferences and interests was an effective tool for self-management of lower back pain. The researchers concluded that there is considerable value in this type of intervention as a potentially cost-effective tool that can reach large numbers of patients to encourage adherence to prescribed medical treatment [27]. More recently, electronic medical record (EMR)-tethered patient portals have become available on phone-based apps. In a study of 957 patients who accessed an EMR-tethered portal, participants reported positive experiences and decreases in health system use and exhibited fewer no-show appointments [28]. The authors of a retrospective, observational study of 46,544 primary care patients reported that adoption, use, and benefits of using EMR-tethered portals available on a phone app were not clearly linked. However, these authors concluded that patients who used the messaging and laboratory functions of the app were less likely to exhibit no-show appointments compared with other user subgroups [29].

In addition to these individual trials, a number of review articles support the positive impact of technology-based health interventions. Ramsey et al [30], after their review of 21 peer-reviewed journal articles, reported the efficacy and increasing access to digital technologies, including eHealth and mobile health (mHealth), may improve the mental and physical health of youth undergoing cancer treatment and survivors of childhood cancer. Following a systematic review, Badawy et al [31] concluded that mobile phone app interventions could improve medication adherence among adolescents with chronic health conditions, and the current literature indicates that these mobile phone app interventions are feasible and accepted by adolescents, and there is modest evidence to support the efficacy of these interventions. These findings are consistent with those of Oikonomidi et al [32], who conducted a systematic review of mHealth behavior change interventions (SMS text messages and smartphone apps) in RCTs. After reviewing 231 RCTs, the authors concluded that mHealth behavior change interventions lack information that would be useful for providers, including the long-term impact of the interventions' health outcomes and information needed for replication of the RTC. Finally, Shah and Badawy [33] provided a systematic evaluation of the feasibility, accessibility, satisfaction, and health outcomes of telemedicine services among pediatric populations with different health conditions. After reviewing 11 articles in this area, the authors concluded that telemedicine services for the general public and pediatric care are comparable with or better than in-person services. Although promising, technology-based health interventions, including mobile phone apps designed to support adherence to prescribed medical treatment, have not been extensively studied on adherence to outpatient physical health treatment.

Purpose

This study aims to compare adherence to prescribed physical health treatment among patients attending a chiropractic and rehabilitation clinic who did and did not choose to adopt a phone-based app to complement their treatment.

Hypotheses

Hypothesis 1: Patients receiving physical health treatment who choose to receive the phone-based app compared with physical health patients who choose not to receive the phone app will exhibit greater rates of completing their prescribed therapy (fewer self-discharge and greater provider-discharge).

Hypothesis 2: Patients receiving physical health treatment who choose to receive the phone-based app compared with physical health patients who choose not to receive the phone app will exhibit fewer no-show appointments and more kept appointments.

Research Question

Research question 1: Does self-selecting to receive the phone-based app or not and being self-discharged versus provider-discharged differentially affect no-show and kept appointments among patients prescribed physical health treatment?

Methods

Design

A retrospective analysis of all new outpatient medical records from a multisite physical health practice was performed between January 2019 and December 2020. Beginning in January 2019, all new patients admitted to this practice were offered the opportunity to download a phone-based app, the Kanvas app, during their initial visit to complement their treatment. New patients who downloaded and registered on the phone-based app self-selected into the Kanvas app group. New patients admitted to this physical health practice during this same time who did not download and register on the app self-selected into the usual care group. Each patient's medical record was accessed 4 months after their initial visit to determine whether they prematurely terminated treatment against the advice of the provider (self-discharged) or if they completed their prescribed treatment (provider-discharged). The number of no-show appointments and the number of kept appointments were also extracted from each patient's medical records. This resulted in a quasi-experimental, 2-group design in which the records of all patients initially presenting for treatment between January 2019 and December 2020 were reviewed and included in the analysis.

Sample

The medical records of new patients who presented during the study period for care at 1 of 5 community-based physical health clinics in the Greater Washington DC area (n=4203) were initially screened as participants in this study. These clinics specialize in treating pain and increasing functional abilities. During the initial visit, all patients were informed that they could download a mobile app on their phone that they could use to complement the care they were receiving at the clinic. At this time, all patients were told about the components of the app and the reward structure as a result of using the app. Patients were also told that the use of the app was voluntary and would in no way affect their care or relationship with their provider or the clinical agency. Patients were excluded from the study

if, following their initial visit, they were referred to another medical clinic for care, were employed by one of the targeted clinics, or died before completing therapy (77/4203, 1.83%). This record review study was approved by the Sport and Spine Rehab Clinical Research Foundation institutional review board number SSR.2021.1.

Procedure

During the initial visit at one of the targeted clinics, each patient completed an initial assessment with a practitioner (physical therapist or chiropractor) who prescribed a plan of care that included home exercises and a series of follow-up clinic visits. This plan of care and the number and frequency of follow-up clinic visits were individualized to the type and severity of the patient's condition. Patients were scheduled for their next follow-up visit during the initial visit and were informed that their account would be charged US \$25 if they did not attend this scheduled visit or did not contact the clinic to cancel the

appointment within 24 hours of the appointment (no-show appointment). The Kanvas app is a customized private practice app designed for patient engagement with their specific health care provider. The initial screen includes various *tiles* in which the patient can engage with the office. These tiles include *contact us*, *about us*, *refer a friend*, *request an appointment*, *review us*, and *home exercise* (Figures 1 and 2). In addition, a built-in gamification system, the *rewards* tile (Figure 3), was designed to reward the patient for attending their scheduled clinic appointments. This feature is Office of Inspector General compliant, offering an item as a reward valued at <US \$15 once the patient completed 12 prescribed visits or was provider-discharged. This feature documented a running total of the number of clinic visits that the patient had attended. The feature is patient-directed, where they scan a QR code at the front desk of the clinic at every visit. When the patient reaches 12 prescribed visits or is provider-discharged, they are eligible for a reward.

Figure 1. Tiles from the Kanvas app.

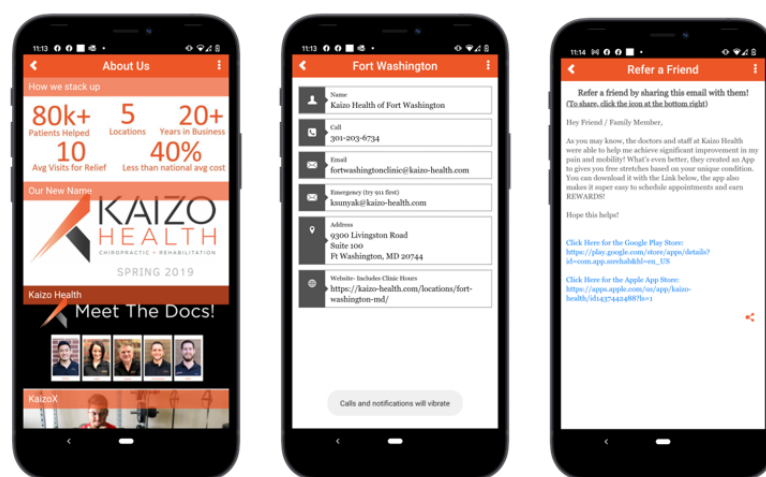


Figure 2. Additional tiles from the Kanvas app.

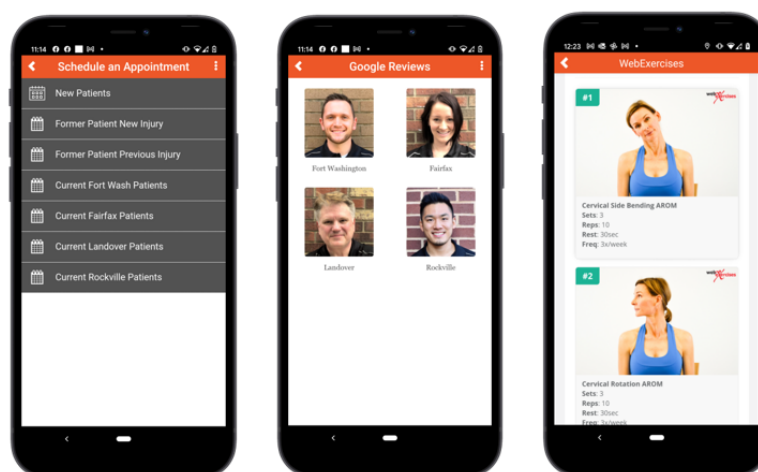
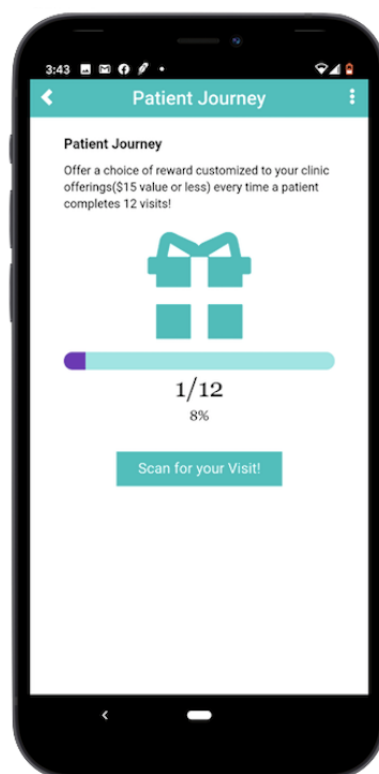


Figure 3. Kanvas app patient journey.

Outcome Variables

The medical records of all eligible patients who were initially seen in the targeted clinics over the 24-month duration of the study and were discharged from care were reviewed. On the basis of the discharge summary documentation on the patient's EMR, patients were classified as completing prescribed therapy and being discharged by their provider (provider-discharged) or not completing their prescribed therapy and self-discharging themselves (self-discharged). In addition, the number of scheduled appointments they attended (appointments kept) and the number of scheduled appointments they failed to attend (no-show appointments) were extracted from each patient's EMR.

Analysis Plan

Data were extracted from the EMRs of all patients identified as eligible for the study and transcribed into a Microsoft Excel (Microsoft Inc) spreadsheet. These data were validated to include only eligible patients, and then individuals were grouped according to the Kanvas app group or usual care group and provider-discharged or self-discharged groups. As the study took place during 2020, when the COVID-19 pandemic was occurring, the analysis to address the hypotheses was conducted separately for both study years. The first hypothesis was addressed by calculating chi-square statistics to compare the proportion of the Kanvas app group or the usual care group participants who were classified as provider-discharged or self-discharged. The remaining outcome variables were all continuous, and to address the second hypothesis, separate repeated-measures analysis of variance (ANOVA) statistics were calculated with year (2019 vs 2020), group (Kanvas app vs usual care), and the interaction of year and group as

independent factors to determine differences in no-show appointments or kept appointments. Significant main or interaction effects detected in any of these repeated-measures ANOVA statistics were further explored by calculating Bonferroni post hoc comparisons to determine differences between the means being compared. Finally, the research question was addressed by collapsing the data across both study years and then conducting a 2×2 factorial ANOVA of the outcome variables of no-show appointments and kept appointments. The independent factors in these factorial ANOVAs were the usual care group versus the Kanvas app group and self-discharged versus provider-discharged and the interaction of study group and discharge type. Significant main or interaction effects were further explored by calculating Bonferroni post hoc comparisons to determine the differences between the means being compared. The level of statistical significance for all analyses was set a priori at $P < .05$. A total of 4126 patients were included in this study, with 2629 (63.72%) choosing to receive the usual care and 1497 (36.28%) choosing to use the Kanvas app. This sample size, using the 2×2 factorial ANOVA statistic with type 1 error set at 0.05 and maintaining statistical power at 0.8 (1-β), would be able to detect a small effect size Cohen $d = 0.05$ in no-show appointments or kept appointments between the 2 study groups.

Results

Description of the Sample

A total of 4203 patient records were reviewed, and 98.17% (4126/4203) were included in the analysis, with 49.1% (2026/4126) and 50.9% (2100/4126) of patients being initially seen in the targeted clinics in 2019 and 2020, respectively. In 2019, 69.2% (1402/2026) of the patients initially seen that year

self-selected into the usual care group (mean age 40.38, SD 13.82 years), whereas this percentage significantly declined ($\chi^2_1=51.8$; $P<.001$) to 58.42% (1227/2100) of the sample who were initially seen in the targeted clinics during 2020. **Table 1** indicates that during 2019, 50.8% (317/624) of the Kanvas app group (mean age 38.31, SD 11.63 years) were provider-discharged, which was significantly greater than the

46.01% (645/1402) of the usual care group who were provider-discharged ($\chi^2_1=4.0$; $P<.046$). This pattern was repeated in 2020 during the COVID-19 pandemic, with 38.4% (335/873) of the Kanvas app group being provider-discharged, which was significantly greater than the 31.38% (385/1227) of the usual care group being provider-discharged ($\chi^2_1=11.1$; $P<.001$).

Table 1. Type of discharge by the Kanvas app group versus the usual care group.

Variables	2019			2020			Total
	Sample size	Self-discharge	Provider-discharge	Sample size	Self-discharge	Provider-discharge	
Group, n (%)							
Usual care	1402 (100)	757 (53.99)	645 (46.01)	1227 (100)	842 (68.62)	385 (31.38)	2629 (63.72)
Kanvas app	624 (100)	307 (49.2)	317 (50.8)	873 (100)	538 (61.6)	335 (38.4)	1497 (36.28)
Total	2026 (100)	1064 (52.52)	962 (47.48)	2100 (100)	1380 (65.71)	720 (34.29)	4126 (100)
Test statistic within study year							
Chi-square (<i>df</i>)	N/A ^a	4.0 (1)	4.0 (1)	N/A	11.1 (1)	11.1 (1)	N/A
<i>P</i> value	N/A	.046	.046	N/A	<.001	<.001	N/A

^aN/A: not applicable.

Results to Address Hypotheses and Research Question

Table 2 presents the means and SEs for the number of kept appointments and no-show appointments in the Kanvas app and the usual care groups in 2019 and 2020. This table indicates that the Kanvas app group kept a similar number of appointments compared with the usual care group in 2019 (10.20 vs 8.68); however, the Kanvas app group kept significantly

more appointments than the usual care group in 2020 (11.63 vs 7.67). During 2020, the Kanvas app group exhibited 2.89 (SE 0.10) no-show appointments that were significantly greater than the number of no-show appointments exhibited by this group during 2019 (mean 1.89, SE 0.08) and significantly more than the no-show appointments by the usual care group during 2020 (mean 2.14, SE 0.08).

Table 2. Comparing kept and no-show appointments of the Kanvas app versus usual care groups by year.

Outcome measure	2019, mean (SE)		2020, mean (SE)		Statistical comparison: interaction effect	
	Usual care	Kanvas app	Usual care	Kanvas app	<i>F</i> test (<i>df</i>)	<i>P</i> value
Kept appointments	8.68 (0.22)	10.20 (0.33)	7.67 (0.24)	11.63 (0.28) ^a	20.28 (1, 4122) ^b	<.001
No-show appointments	1.96 (0.11)	1.89 (0.08)	2.14 (0.08)	2.89 (0.10) ^{a,c}	13.50 (1, 4122) ^d	<.001

^aIndicates a significant difference between groups within a specific year.

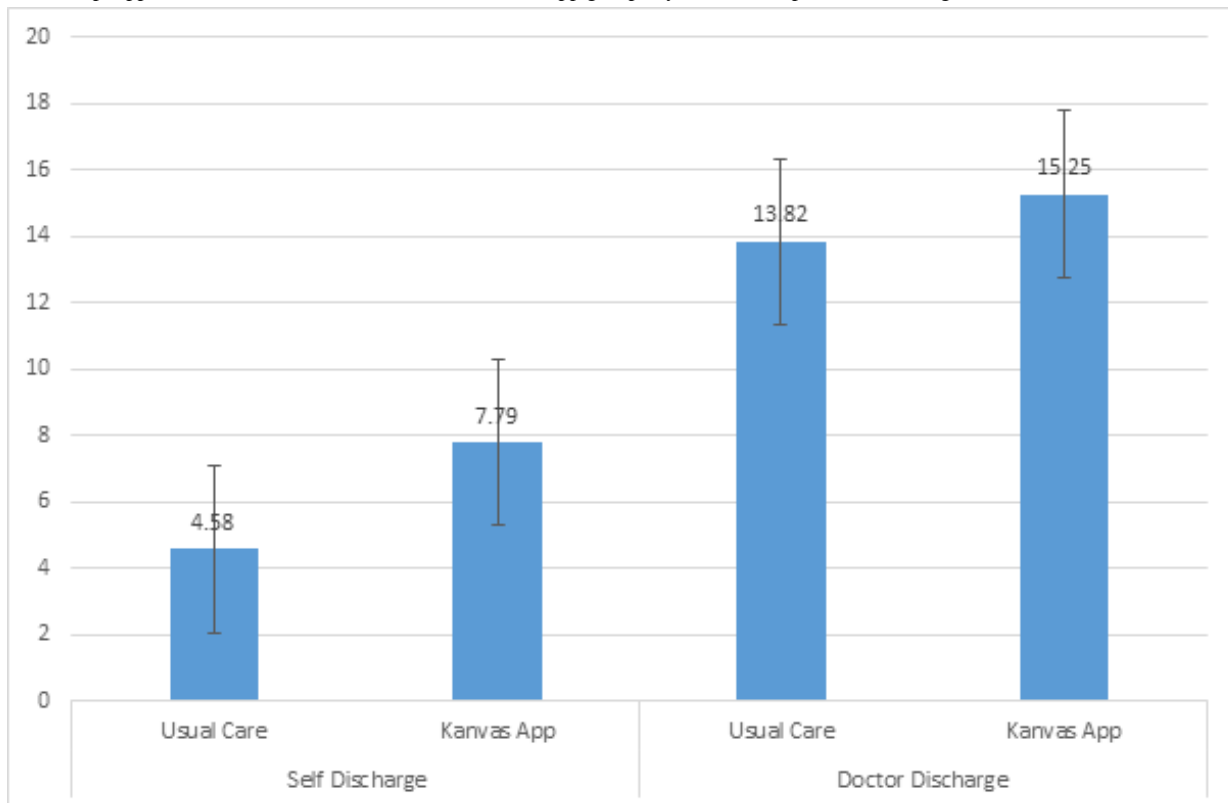
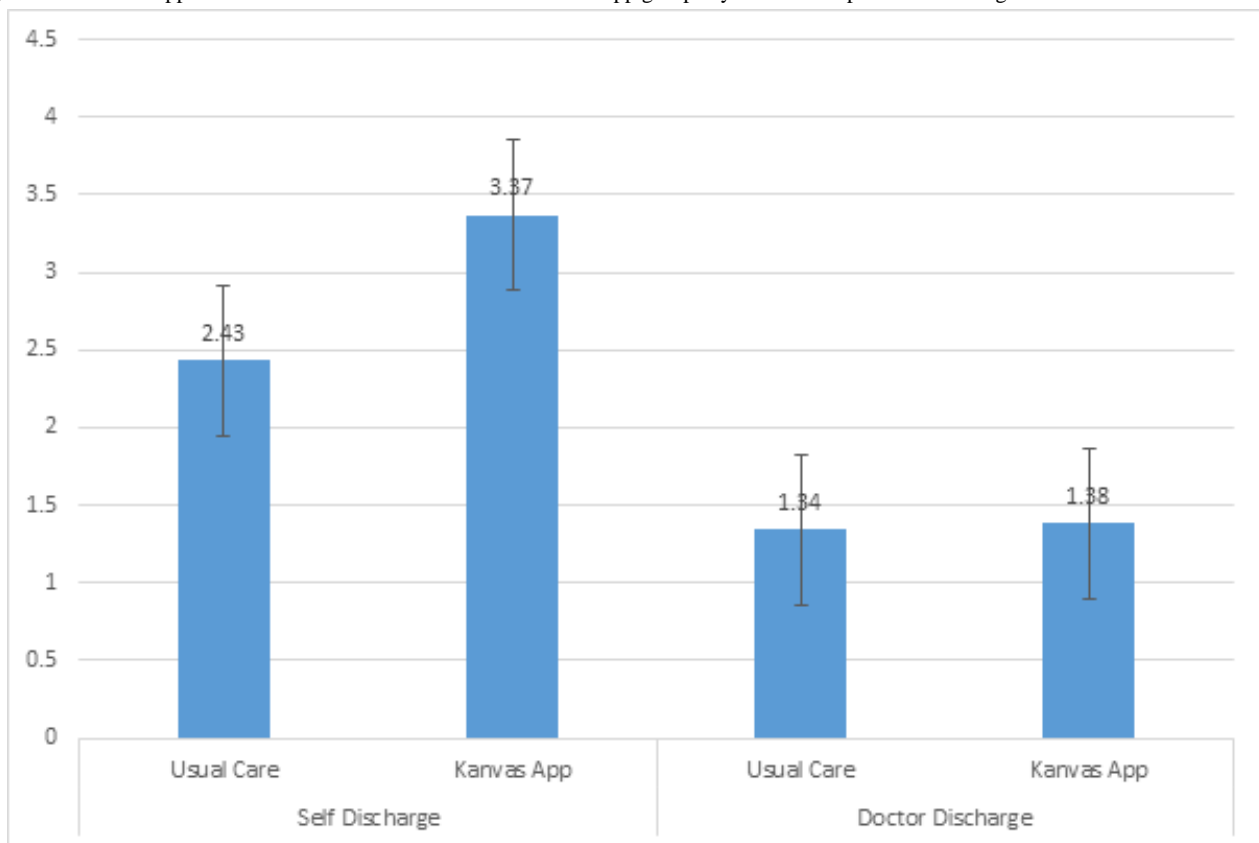
^bBonferroni minimum significant difference=2.37.

^cIndicates a significant difference within a group between study years.

^dBonferroni minimum significant difference=0.65.

Figures 4 and **5** present the kept appointments and no-show appointments within the usual care and the Kanvas app groups by self- versus provider-discharge collapsed across both study years. The 2-way ANOVA used to generate **Figure 4** indicated a significant interaction between the study group and the discharge type on kept appointments ($F_{1,4122}=14.46$; $P<.001$). Post hoc comparisons indicated that the Kanvas app group had a greater number of kept appointments (mean 7.79, SD 0.25) when compared with the usual care group (mean 4.58, SD 0.18) when both groups were self-discharged. The Kanvas app group had a similar number of kept appointments (mean 15.25, SD 0.28) compared with the usual care group (mean 13.82, SD 0.22) when both groups were provider-discharged. The usual care group had more kept appointments when they were provider-discharged compared with the usual care group who

were self-discharged, whereas the Kanvas app group had a similar number of kept appointments when self- or provider-discharged. **Figure 5** presents the means of no-show appointments by study group and self- versus provider-discharge. The 2-way ANOVA indicated a significant study group-by-discharge type interaction on no-show appointments ($F_{1,4122}=25.09$; $P<.001$). The Kanvas app group (mean 1.38, SD 1.17) and the usual care group (mean 1.34, SD 0.08) were similar in the number of no-show appointments when provider-discharged. The number of no-show appointments when provider-discharged was consistently lower than the number of no-show appointments when these 2 groups were self-discharged. When self-discharged, the Kanvas app group had more no-show appointments (mean 3.37, SD 0.09) compared with the usual care group (mean 2.44, SD 0.07).

Figure 4. Kept appointments within the usual care and Kanvas app groups by self- versus provider-discharge.**Figure 5.** No-show appointments with the usual care and the Kanvas app groups by self- versus provider-discharge.

Discussion

Principal Findings

In general, the results support the study hypothesis that physical health patients who choose to receive the phone-based app compared with physical health patients who choose not to receive the phone app exhibit greater adherence to prescribed physical health treatment. [Table 1](#) clearly indicates that during both 2019 and 2020, a greater proportion of patients who received the Kanvas app completed the prescribed therapy (were provider-discharged) when compared with the usual care group who did not receive this app. An interesting observation in [Table 1](#) is the decline between 2019 and 2020 in patients in both the Kanvas app and the usual care groups who were provider-discharged. This decline in the proportion of patients in both study groups between 2019 and 2020 who adhered to their prescribed therapy by being provider-discharged may be attributed to the COVID-19 pandemic-related social distancing and self-isolation recommendations provided by governmental health agencies during 2020. This effect of the COVID-19 pandemic recommendations may have also accounted for the increase in no-show appointments observed in both study groups between 2019 and 2020 ([Table 2](#)). Although this increase in no-show appointments between 2019 and 2020 was only statistically significant among the Kanvas app group (1.89 vs 2.89), the usual care group also exhibited a nonsignificant trend in increased no-show appointments between 2019 and 2020 (1.96 vs 2.14).

A further observation based on this table is that both study groups exhibited a similar number of kept appointments and no-show appointments in 2019. By contrast, during 2020, the Kanvas app group exhibited significantly greater kept appointments and no-show appointments when compared with the usual care group. A potential explanation for these findings may be that during the COVID-19 pandemic restrictions, the Kanvas app may have better engaged the patients in this group to schedule more clinic visits, which resulted in more kept appointments with a greater proportion of them adhering to their prescribed therapy and being provider-discharged. In addition, with additional scheduled appointments comes the potential to increase no-show appointments. In other words, patients in the Kanvas app group appear to have been scheduling more appointments and therefore had a greater potential for both kept and no-show appointments.

[Figures 4](#) and [5](#) clearly indicate that the number of kept and no-show appointments were similar among the group who received the Kanvas app and the usual care group when they completed their course of care and were provider-discharged. These similarities between the 2 groups are to be expected, as all the patients in these 2 groups completed their prescribed course of care with a similar number of prescribed clinic appointments and a similar potential for no-show appointments. The Kanvas app did not appear to influence the number of kept and no-show appointments among patients who completed their prescribed course of care and were provider-discharged. If the patient prematurely terminated their care or was self-discharged, then the patients in this group who received the Kanvas app had

significantly more kept appointments than the usual care group (7.79 vs 4.58). An explanation for this is that the Kanvas app group had more scheduled appointments, which may have contributed to the Kanvas app group exhibiting more no-show appointments than the usual care group when both groups were self-discharged (3.37 vs 2.43). The Kanvas app did not appear to affect adherence among patients who completed their prescribed therapy and were provider-discharged. Patients who were self-discharged and received the Kanvas app experienced on average 3.2 more kept appointments, a 70% increase, and 0.94 more no-show appointments than the self-discharged usual care group.

Comparison With Prior Work

The findings of this study are consistent with those of previous studies and address a number of gaps in the literature. The key finding of this study was that patients who self-discharged and accessed the Kanvas app exhibited greater adherence to their prescribed therapy in the form of keeping scheduled appointments when compared with patients who self-discharged and did not access the Kanvas app. This finding that technology-based health interventions, including phone apps, can increase adherence to prescribed therapies has been reported by previous authors [[24,25,27-29](#)]. This study is one of the first to demonstrate the efficacy of a phone app to increase adherence among patients prescribed physical health treatment by attending a chiropractic and rehabilitation clinic. This finding is particularly significant, as the literature indicates that physiotherapy patients are frequently not adherent and do not complete their prescribed therapy [[3,4,12](#)].

Strengths, Limitations, and Future Studies

This study has a number of strengths and limitations that may direct future inquiry in this area. The validity of this study is strengthened by the large sample size collected over multiple clinical sites using EMR as the source of the outcome variables, including kept and no-show appointments and physician versus self-discharge. These data are clinically valid, as billing and reimbursement are based on information stored in EMRs. Although encouraging, these findings must be interpreted cautiously because of a number of methodological limitations. First, participants in the study groups self-selected to download the Kanvas app; thus, patients who were more likely to adhere to their prescribed therapy may also have self-selected to download the Kanvas app. From the findings, it is unclear whether a patient characteristic that predisposed them to adhere to prescribed treatment may have also increased their likelihood of self-selecting to receive the Kanvas app. Data on demographic characteristics of the participants were not collected in this study and may have influenced the decision to self-select one of the study groups. Although generally desirable in clinical studies, the large sample size cultivated in this study increased the likelihood of detecting the statistical significance of small effect sizes. This limitation is tempered by the clinical significance of the Kanvas app group, exhibiting 3.2 more kept appointments and 0.94 more no-show appointments than the usual care group when both groups were self-discharged. Another limitation of this study was that the cost benefit of implementing the Kanvas app was not examined. Although numerous studies have reported

the clinical efficacy of technology-based health interventions, including phone apps, few studies have consistently found that these interventions generate revenue or are at least cost neutral while benefiting patients [34,35]. Finally, the findings may have been influenced by governmental recommendations for social distancing and self-isolation in 2020. The influence of these recommendations is evident in the decline in provider-discharge and the increase in no-show appointments observed in both the Kanvas app and usual care groups in 2020 compared with 2019. However, these declines in adherence metrics between 2019 and 2020 were less evident in the Kanvas app group compared with the usual care group. A final limitation to the validity of the findings is that individual patient use of the Kanvas app was not monitored, and if the patient self-selected to download the app, there was no way to monitor the type or duration of interaction the individual had with the app. Similarly, the development of the Kanvas app may have benefited from input from the end users or a feedback loop allowing the user to suggest improvements in the app that may foster long- and short-term engagement [34]. Involving end users in the refinement of health-promoting phone apps may foster

engagement, motivation, and autonomy with the app [35,36]. Future studies may wish to address these limitations by randomly assigning patients willing to download the app to study groups who do and do not receive the app. Future refinement of the Kanvas app may consider involving end users in changes to the app. In addition, qualitative methods may be used to determine why patients decided to decline downloading the app and what features of a future app may be appealing to them to increase their adherence to prescribed treatments.

Conclusions

The findings of this study support the efficacy of the Kanvas app in increasing adherence to prescribed physical health treatment among patients attending a chiropractic and rehabilitation clinic. These benefits of the Kanvas app appear to differentially affect patients who self-discharge, although not measurably affecting provider-discharged patients. Patients who self-discharged and received the Kanvas app exhibited significantly more kept appointments and more no-show appointments than a usual care group that did not receive the Kanvas app.

Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance

EMR: electronic medical record

mHealth: mobile health

RCT: randomized controlled trial

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Review

Adaptability of Assistive Mobility Devices and the Role of the Internet of Medical Things: Comprehensive Review

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Abstract

Background: With the projected upsurge in the percentage of people with some form of disability, there has been a significant increase in the need for assistive mobility devices. However, for mobility aids to be effective, such devices should be adapted to the user's needs. This can be achieved by improving the confidence of the acquired information (interaction between the user, the environment, and the device) following design specifications. Therefore, there is a need for literature review on the adaptability of assistive mobility devices.

Objective: In this study, we aim to review the adaptability of assistive mobility devices and the role of the internet of medical things in terms of the acquired information for assistive mobility devices. We review internet-enabled *assistive mobility* technologies and non-internet of things (IoT) assistive mobility devices. These technologies will provide awareness of the status of adaptive mobility technology and serve as a source and reference regarding information to health care professionals and researchers.

Methods: We performed a literature review search on the following databases of academic references and journals: Google Scholar, ScienceDirect, Institute of Electrical and Electronics Engineers, Springer, and websites of assistive mobility and foundations presenting studies on assistive mobility found through a generic Google search (including the World Health Organization website). The following keywords were used: *assistive mobility OR assistive robots, assistive mobility devices, internet-enabled assistive mobility technologies, IoT Framework OR IoT Architecture AND for Healthcare, assisted navigation OR autonomous navigation, mobility AND aids OR devices, adaptability of assistive technology, adaptive mobility devices, pattern recognition, autonomous navigational systems, human-robot interfaces, motor rehabilitation devices, perception, and ambient assisted living.*

Results: We identified 13,286 results (excluding titles that were not relevant to this study). Then, through a narrative review, we selected 189 potential studies (189/13,286, 1.42%) from the existing literature on the adaptability of assistive mobility devices and IoT frameworks for assistive mobility and conducted a critical analysis. Of the 189 potential studies, 82 (43.4%) were selected for analysis after meeting the inclusion criteria. On the basis of the type of technologies presented in the reviewed articles, we proposed a categorization of the adaptability of smart assistive mobility devices in terms of their interaction with the user (user system interface), perception techniques, and communication and sensing frameworks.

Conclusions: We discussed notable limitations of the reviewed literature studies. The findings revealed that an improvement in the adaptation of assistive mobility systems would require a reduction in training time and avoidance of cognitive overload. Furthermore, sensor fusion and classification accuracy are critical for achieving real-world testing requirements. Finally, the trade-off between cost and performance should be considered in the commercialization of these devices.

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KEYWORDS

internet of medical things framework; internet of things; adaptability; multisensor fusion; mobility aids; user system interface; assistive mobility devices; mobile phone

Introduction

The Internet of Things

Internet technology has experienced remarkable progress since its early stages. It has become a vital transmission framework aiming to connect anyone and anything at any time to any service [1]. The basic idea of the internet of things (IoT) is to allow an autonomous and secure connection and exchange of data between real-world devices and app [2]. IoT has become a crucial factor in next-generation technology and the whole business spectrum. It is the seamless interconnection of uniquely identifiable smart objects, sensors, and informatics systems within today's internet infrastructure with extended benefits. Typically, benefits include the advanced interconnectivity of these devices, systems, and services that go beyond machine-to-machine scenarios [3]. The impact of IoT has led to its application in several fields for enhancing network operation and the user's quality of experience [1]. These fields include transportation, health care, industrial automation, and public safety management [4].

Smart Health Care and Assistive Mobility

Health care is an attractive application area for IoT [5]. IoT has the potential to give rise to many medical apps, such as remote control and health monitoring, fitness programs, chronic diseases, and elderly care [3]. For instance, with a monitoring app, the patient can transmit daily or weekly blood pressure readings. This enables their physician to detect a problem and intervene earlier. Smart health care can be referred to as an organic whole of conventional mobile devices used with wearable medical devices, assistive mobility devices, and IoT gadgets (such as implantable or ingestible sensors). This can also be referred to as the internet of medical things (IoMT). This organic whole enables continuous patient monitoring and treatment, even when patients are at their homes. Examples of these assistive mobility devices are pressure monitors, glucometers, smartwatches, smart walkers, smart wheelchairs, smart contact lenses, and way finders [6].

With an increase in the percentage of people with some form of disability [7-10], assistive mobility has become an important aspect of research and has gained a lot of attention from researchers in recent years. Mobility has to do with an individual's ability to move his or her body within an environment and the ability to manipulate objects. This ability can be hampered by impaired body functions or structures and limit the individual's functioning, independence, and overall well-being [11]. Assistive mobility is a broad term used to refer to the use of aid (of any kind) to improve the mobility of an impaired individual.

Technology has been a tool used by researchers and companies to address the limitations in mobility caused by some form of impairment. For this reason, literature reviews and surveys have been conducted on assistive technologies for individuals with

some form of disability. Although literature reviews have been conducted on specific assistive mobility technologies (such as smart wheelchairs, scooters [12,13], and smart canes [14]), gait rehabilitation devices (such as smart walkers, lower-limb exoskeletons, and smart crutches) [15-19], and how these technologies have addressed mobility limitations of impaired individuals, the review of all elements needed in the adaptability of assistive mobility devices to the user in terms of information used requires more attention.

Related literature review papers have paid attention to specific elements needed in the adaptability of mobility devices, such as the survey of alternative input and feedback methods, including haptic [20], visual, and auditory [21,22] methods, as sensory replacement and sensory augmentation for certain sensory impairments and the survey of computer vision (CV) and machine learning techniques [23,24] for autonomous driving. More closely related surveys [25] approached the categorization of assistive technology based on users' needs but concentrated on the cross-application of CV for categorization. An older review in 2012 [11] focused on the seamless integration of the capabilities of the user and the assistive technology for mobility. These related reviews highlighted the adaptability of assistive technologies as crucial in the technological advancement of mobility devices. However, we believe that an approach to the adaptability of assistive mobility devices in terms of information used has not been considered.

The objective of this study is to primarily focus on a literature review of the adaptability of assistive mobility devices and the role of IoMT in terms of the acquired information for assistive mobility devices. Internet-enabled assistive mobility technologies and non-IoT assistive mobility devices will be reviewed. The technologies reviewed will provide insight into some important themes and serve as a source and reference for information on adaptive assistive mobility technology to health care professionals and researchers. More specifically, we aim to contribute to the following:

- Identifying the major areas crucial for the adaptability of internet-enabled assistive mobility technologies (such as smart wheelchairs, smart walkers, smart canes, and scooters) and other non-IoT assistive mobility devices (such as regular walkers, wheelchairs, canes, crutches, walkers, orthoses, and prostheses) to its intended users
- Categorization of the adaptability of assistive mobility devices in terms of the acquired information into three major areas: user system interfaces (USIs), perception and sensor fusion techniques, and IoMT frameworks
- Highlighting the role that IoMT plays in the adaptability of assistive mobility devices

Methods

We selected a list of studies and references to review the adaptability of assistive mobility devices and IoT frameworks

for assistive mobility to be included in the literature search. The data sources used to search for the items to be included in this review were the following databases of academic references: Google Scholar (including ResearchGate), ScienceDirect, Institute of Electrical and Electronics Engineers, Springer, and websites of assistive mobility and foundations presenting studies on assistive mobility found through a generic Google search (including the World Health Organization website).

The search criteria included the following keywords and combinations thereof: *assistive mobility OR assistive robots, assistive mobility devices, internet-enabled assistive mobility technologies, IoT Framework OR IoT Architecture AND for Healthcare, assisted navigation OR autonomous navigation, mobility AND aids OR devices, adaptability of assistive technology, adaptive mobility devices, pattern recognition, autonomous navigational systems, human-robot interfaces, motor rehabilitation devices, perception, and ambient assisted living*.

As these combinations of data sources and keywords returned a vast number of results, we selected the following inclusion criteria to identify the most relevant sources: (1) language should be English, (2) date range should be in the past 12 years (2008-2020)—most articles were published within the past 5 years to reflect the state-of-the-art (since 2015), and older references were made to technologies that substantially shaped the future direction of assistive mobility devices—and (3) its relevance should be in internet-enabled assistive mobility technologies or non-IoT assistive mobility devices.

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) criteria were applied [26]. The screening of titles and abstracts was performed by DAO and EDM and reviewed by DAO, EDM, and AMAM. Full texts were reviewed in a second screening.

Results

Overview

After excluding results with titles that were not relevant to this study, the literature search identified 13,286 abstracts, of which

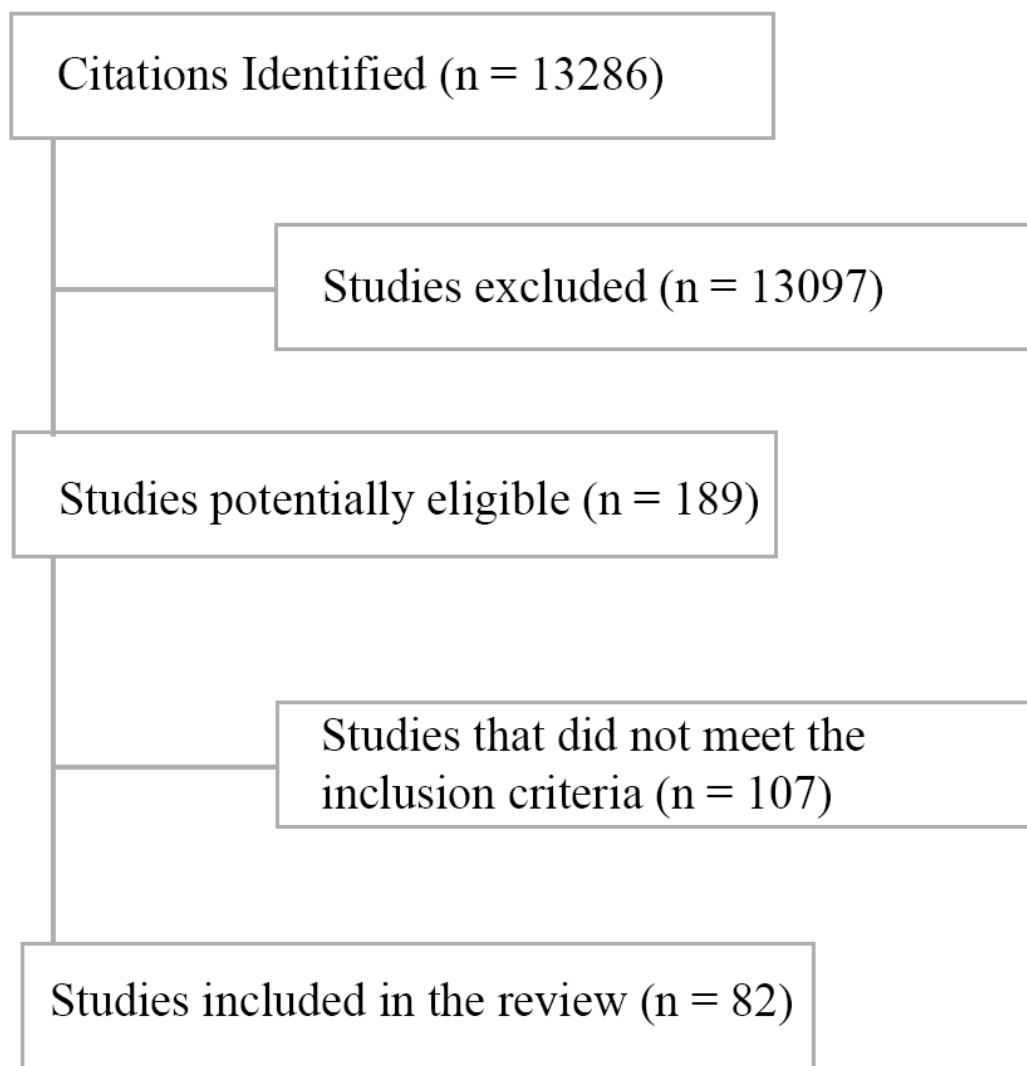
189 (1.42%) potential studies were selected for a detailed full text review.

We used the following exclusion criteria to identify the most relevant sources and reduce the number of literature search results: (1) no relevance to internet-enabled assistive mobility technologies or non-IoT assistive mobility devices in terms of the acquired information, (2) full text not available, (3) no report on promises for user adaptability as a result of simulation testing or using the technology, (4) no description of the technology, and (5) no additional contribution to the review findings compared with the previously reviewed articles.

Of the 189 potential studies, 82 (43.4%) studies remained for analysis after meeting the inclusion criteria. Some studies contributed to more than one section in this review (Figure 1).

To perform a literature review based on the type of technologies presented in the reviewed articles, we proposed a categorization of the adaptability of smart assistive mobility devices in terms of their interaction with the user (USI), perception techniques, and communication and sensing frameworks.

In recent years, advances in technology have helped to improve the quality and efficiency of assistive mobility devices. The use of traditional assistive mobility devices by users with some form of cognitive, sensory, or intellectual impairment requires the help of medical personnel or a caregiver for navigation assistance with difficult daily maneuvering tasks. To accommodate users who find operating standard mobility devices difficult or impossible, several researchers have used technologies originally developed for mobile robots to create smart mobility devices [27], such as smart wheelchairs and smart ambulatory devices. These assistive mobility devices are made smart by attaching computers, actuators, and sensor subsystems to the traditional assistive mobility device to provide easy maneuvering, system localization, object detection, and other sensory, cognitive, and health monitoring functions [12,28-30].

Figure 1. Flow diagram of search results. IoT: internet of things.

USI (Input and Output Methods)

Overview

With the advent of smart assistive mobility devices, some assistive devices have become too complex to use. In addition, improper characteristics of the target users have resulted in numerous assistive mobility projects failing to transition to real-world use [31]. For this reason, the adaptability of assistive mobility devices is very important. Some users of assistive mobility devices have comorbidities, such as sensory impairment for users with spinal cord injury (SCI) or mental health challenges because of aging or depression. This impairment needs to be taken into account in the design of efficient assistive mobility devices. Assistive mobility devices should be designed to continually evaluate and correct their actions based on their perception of the needs of the user [32]. Mobility impairment of patients can be largely classified into 2 functional groups.

The first group includes individuals with a total loss of ability to move by themselves and with a high risk of confinement in bed, and, consequently, they suffer the effects of prolonged immobility. Examples are patients with complete SCI, advanced neurodegenerative pathologies, severe lower-limb osteoarthritis, and fractures of the spine or lower-limb bones. The suitable kind of assistive mobility technology for this group is called the alternative device. Examples are wheelchairs and autonomous vehicles (AVs). The second group includes individuals with partial loss of mobility, presenting different levels of residual motor capacity that can be powered by assistive mobility devices. The suitable type of assistive device for this group of individuals is the augmentation (rehabilitation) device. Examples are wearable orthoses and prostheses or external devices (such as canes, crutches, and walkers) [28,33]. Notwithstanding the functional group of mobility-impaired patients, USIs are a crucial element in the adaptability of

assistive mobility devices. USI has to do with the acquisition of information from the user, the interpretation of this set of acquired information, and the available feedback methods that can be understood by its intended users.

USIs for assistive mobility devices are categorized based on the type of sensors and actuators used for acquisition of user's information. These include CV, brain-computer interface (BCI), and voice, touch, and haptic feedback [12]. The USI technologies presented below are categorized as follows: BCI, CV interface (CVI), and auditory and haptic interface.

BCI System

BCI generally refers to a system that measures and uses signals produced by the central nervous system. This interface enables useful functions for people with disabilities caused by neuromuscular disorders such as amyotrophic lateral sclerosis, cerebral palsy, stroke, or SCI [34]. The basic components of the BCI are signal acquisition, signal processing, and the effector or output device [35]. Signal acquisition can be invasive or noninvasive [35]. Over the past decade, many educative literature reviews and surveys have been conducted and documented by researchers on the definition, mode of operation, classifications, functionality, and applications of BCI [34-37].

The adaptability of assistive mobility devices for users with neuromuscular disorders has led to the adoption of BCI as a suitable means of user-machine communication for simple mobility tasks. BCI offers limited navigation control capabilities to assistive mobility devices. To improve the navigational abilities offered by BCI, models proposed by researchers integrate BCI with other USI and machine learning tools. For example, Rebsamen et al [38] and Long et al [39] proposed a P300-based BCI wheelchair for the execution of commands for a set of predefined locations. Some auxiliary sensors were also integrated for collision avoidance during navigation. Long et al [39] proposed a hybrid BCI system comprising a motor imagery (MI)-based mu rhythm and the P300 potential. This model was designed for the directional and speed control of a brain-actuated simulated wheelchair or a real wheelchair. Kim et al [40] proposed a prototype that addressed a user's loss of vision in their environment. The prototype uses the steady-state somatosensory evoked potential (SSSEP) paradigm to control a wheelchair by using specific frequencies and vibrations of different body parts to elicit brain responses. They also recommended the use of an auxiliary autonomous navigation system to improve performance. An asynchronous MI-based BCI protocol system control was proposed by Carlson and del R Millan [41] to improve navigational control with the help of 10 lost-range sonar sensors and 2 webcam cameras.

Furthermore, a teleoperation control for a robotic exoskeleton system based on the steady-state visual evoked potentials (SSVEPs) BCI and visual feedback was proposed by Qiu et al [42]. A camera was used to capture video for visual feedback, and a local adaptive fuzzy controller was used to drive the exoskeleton to track the intended trajectories in the human operator's mind. The controller was also used to provide, in a convenient way, dynamic compensation with minimal knowledge of the dynamic parameters of the exoskeleton robot.

Auditory and Haptic Interface

Individuals with mobility impairments having visual, hearing, or tactile disabilities require the use of an alternative sensory ability for effective communication with assistive mobility devices. Auditory interfaces are designed to take advantage of hearing ability as a substitute for visual or tactile impairment. On the other hand, haptic interfaces are designed to take advantage of the users' tactile ability as a substitute for visual, auditory, or motor impairment [43]. An extensive review has been conducted on haptic assistive technology as a means of communication for individuals with some form of sensory impairment, such as visually and auditorily impaired individuals [20,21,31,43]. Parker et al [22] also reviewed the positive effect of visual and auditory feedback on motor skills of poststroke patients during gait rehabilitation. This subtopic presents recent auditory and haptic interface technologies for individuals with mobility impairments.

Haptic technology has been a beneficial USI for certain impaired users. It has found its application in many areas for the monitoring of users' progress and for navigational assistance. It has been successfully implemented in the design of exoskeletons (such as orthoses and wearable devices for grasping and assisted movement), smart walkers, smart crutches, and smart wheelchairs. Like haptic technology, auditory technology is also used as an alternative navigational control for individuals with mobility impairment and as a navigational guide or feedback for patients with visual impairments. Many researchers have integrated haptic or auditory technology for navigational control, navigation assistance, or feedback of assistive mobility devices. Wearable devices such as the Jet Propulsion Laboratory BioSleeve [44,45], the wireless tongue drive system (TDS) to smartphone (iPhone) electric powered wheelchair (PWC; TDS to smartphone (iPhone) electric-PWC [TDS-iPhone-PWC]; [46]), and the MyoSuit [47] were designed using haptic technology for navigational control and aided mobility, respectively. The JPL BioSleeve is a wearable, hands-free gesture recognition interface that decodes as many as 20 discrete hand and finger gestures and can estimate the continuous pose of the arm. It was designed using surface electromyography (EMG) sensors, an inertial measurement unit (IMU), and embedded software. EMG and IMU acquire gesture and pose signals, whereas the embedded software classifies the signals and maps the result to commands. The wireless TDS-iPhone-PWC uses a TDS comprising a wearable TDS headset, a magnetic tongue barbell, a control unit, and magnetic sensors. The prototype wirelessly sends up to six distinct control commands to an iPhone for the navigation of a PWC after calibration training using a PC. MyoSuit is a lightweight, lower-limb, soft, wearable robot (exoskeleton) for rehabilitation training that allows active contributions from users in residual mobility. It was designed to estimate interlimb angles and trunk postures using a five-segment body model acquired from IMU. It also determines which model is suitable for the user.

Other examples of haptic-based technology for adaptive mobility include the smart cane [48], intelligent control smart walker [49], and learning shared control of an assistive robotic transport for adults wheelchair-powered platform [50]. The smart cane was designed using a force sensor for the measurement of the

exerted weight and IMU for pose estimation. The intelligent control smart walker was designed to use a force sensor to control acceleration. The learning shared control of an assistive robotic transport for adults wheelchair-powered platform was designed to regulate the level of assistance between the user and the robot by matching the location and amount of offered assistance on different trajectories.

Some recent technologies integrate multiple technologies for USI in the process of adapting mobility devices to a desired group of disabilities. An example is the electronic mobility cane (EMC) [51], which was designed using multiple sensors to contract the logical map of the surrounding environment and give feedback of the priority information to the user without causing any information overload. Another example is the EyeCane [52], which is an electronic travel aid or electronic travel support that aims to increase the perception of the environment using multiple sensors for distance estimation, navigation, obstacle detection, and feedback to the user. The last example is the multiple controlled interfaces smart wheelchair [53], which was designed to accommodate a variety of impaired individuals. It is a prototype wheelchair with multiple control options (voice, gesture, and joystick input). Another recently explored area is CV to sound technology, which is further discussed in the following section.

CVI System

As humans, we perceive 3D structures of the world around us with apparent ease [54]. The ability of computers to *see* and understand the world just like humans do gave birth to the research of CV. CV is a field of study that seeks to develop mathematical techniques that enable computers to interpret and understand the visual world (images and videos) accurately in the same way as humans do. CV starts with the acquisition of data or capturing of information, which is done with the help of vision and depth (3D ranging) sensors, such as image-based sensors (mono and stereo or depth cameras), laser-based depth sensors (light detection and ranging, laser scanner, and infrared light), sound-based depth sensors (sound navigation and ranging and ultrasonic), and radio detection and ranging sensor [55].

There are many applications of CV [56-60], and one such application is CV USI for adaptive assistive mobility devices. An example is the visual servoing-controlled wheelchair proposed by Pasteau et al [61]. The proposed smart wheelchair uses 3 cameras for autonomous corridor following and doorway passing. Another example is the autonomous scooter

navigational system proposed by Mulky et al [13] to assist people with independent transportation challenges and recognition of the fine-grained world around them. This was achieved using a long-range eye-safe laser (up to 60 m) and a stereo vision camera. Finally, the user-adaptive control intelligent walker proposed by Chalvatzaki et al [62] used CVI technology (laser range finder) to estimate the human state and classify a patient's mobility status.

CVI mostly integrates haptic or auditory technologies for user feedback and finds its applicability in user or environmental perception for assistive control, monitoring, and sensory substitution devices (SSDs). For instance, the sound of vision SSD technology [63-65] assists people with visual impairment with navigation by converting visual perception to (spatial) sound or haptic feedback. Usually, sound of vision SSDs comprise data acquisition operational modes, an image processing pipeline, and a feedback system [63-65]. An example of a multimodal USI is the iChair, a multimodal input platform that accepts commands from voice, touch, proximity switch, and head-tracking cameras and provides seamless access and control for users with severe disabilities [30].

CVI is the first phase toward autonomous navigation and is a crucial part of perception and multisensor fusion techniques [24].

Perception for Adaptability (Autonomous Navigation)

Autonomous navigation simply refers to the ability of a robot or vehicle to sense its environment and navigate accurately without human input or assistance [66]. AVs or autonomous robots (ARs) are meant to be intelligent enough to perceive, predict, decide, plan, and execute their decisions in the real world [24]. The main difference between AVs and ARs is in the fact that AVs address road networks where traffic rules have to be obeyed, whereas ARs have to cope with open environments without many specific rules to follow only to reach the final destination [67]. There are six different levels of driving autonomy (Table 1), as published by the Society of Automotive Engineers International in 2021, ranging from no automation at level 0 to full automation at level 5 [66,68]. Following the Society of Automotive Engineers International definition, existing AVs and ARs in 2021 are not fully autonomous. Mobility aids can be seen as a type of AR, and the adaptability of the mobility aid is dependent on its ability to make intelligent navigational decisions with limited to no intervention by its user.

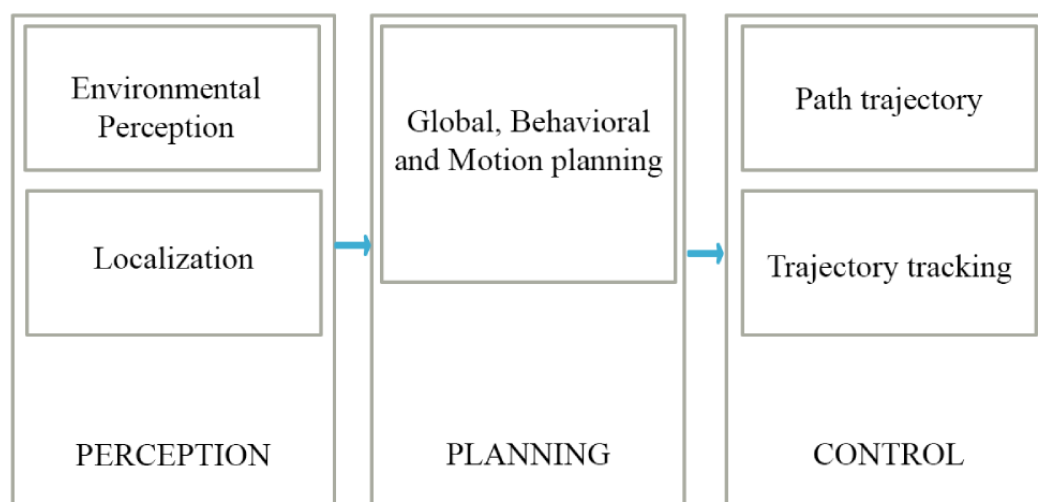
Table 1. Summary of the Society of Automotive Engineers (SAE) automation levels.

SAE [66,68] levels	DDT ^a		Driving supervision (DDT fallback)	Scenarios (ODD ^b)
	Vehicle controls	Environment monitoring (OEDR ^c)		
0: no driver automation	Driver	Driver	Driver	N/A ^d
1: driver assistant	Driver	Driver	Driver	Limited
2: partial driving automation	Driver and vehicle	Driver	Driver	Limited
3: conditional driving automation	Vehicle	Vehicle	Driver and vehicle	Limited
4: high driving automation	Vehicle	Vehicle	Vehicle	Limited
5: full driving automation	Vehicle	Vehicle	Vehicle	Unlimited

^aDDT: dynamic driving task.^bODD: operational design domain.^cOEDR: object and even detection and response.^dN/A: not applicable.

Generally, there are three main steps in the operation of an autonomous system (Figure 2): the perception stage (environmental perception and localization), the path planning stage, and the control stage. The perception stage, which is the first stage of a self-driving system, is a crucial aspect of autonomous navigation or self-driving robots. The perception stage majorly comprises environmental perception and localization [69]. The success of perception is largely dependent on the accuracy of the sensors used in the data acquisition. A combination of sensors helps improve accuracy and confidence for the best decision task in environmental perception and autonomous navigation. Although there are high-accuracy

sensors that can work alone without exhibiting some of the limitations common to regular sensors, they are often unavailable because of their operating limits and high costs. This makes them impractical for use in real-world applications [70]. This limitation, which is common to regular sensors, has led to the need for multisensor fusion to improve accuracy and confidence. Multisensor fusion has to do with the process of combining information from different sensors to provide a robust and complete description of the environment or process of interest [71]. Detailed literature about each stage has been reviewed [67,69,72,73].

Figure 2. Summary of an autonomous system.

Many recent assistive mobility technologies have made advancements in striving toward fully autonomous navigation, such as the technologies discussed in the *USI (Input and Output Methods)* section (Tables 2-4). Some examples include the P300 BCI-based controlled wheelchairs [38,74], as shown in Table 2. The authors designed the prototype to achieve a level of autonomy using cheap sensors. A bar code was used for global positioning, and a proximity sensor was used for collision avoidance. The use of multisensor fusion was not adopted in

this prototype. Feature extraction classifiers (stepwise linear discriminant analysis and support vector machine [SVM]) were used to adequately process the BCI information needed to autonomously navigate the wheelchair from the point of command to its predefined location without the help of its user.

In Table 3, the multicontrolled wheelchair [53] used an algorithm for the control and execution of commands to check for predefined commands and execute them in the navigation

and speed control of the wheelchair. An ultrasonic sensor was used for autonomous navigation.

The visual servoing-controlled wheelchair [61], as shown in Table 4, used CV with the classic Gaussian sphere projection framework and line segmentation algorithm for corridor following. A door detection and tracking framework (for indoor

navigation tasks) and a 2D edge tracker was inspired by the moving edges algorithm for autonomous doorway passing. In addition, the autonomous scooter navigation [13], as shown in Table 4, used CV and the graph-based simultaneous localization and mapping algorithm for steering control and autonomous navigation.

Table 2. Brain-computer interface (BCI) technologies for adaptive assistive mobility devices.

Brain signals and auxiliary sensors	Classifier for feature extraction	Output command	Contributions	Drawbacks
P300 (laser scanner) [74]	Stepwise linear discriminant analysis	A predefined set of locations and stops	High accuracy, no training required, and autonomous navigation after successful selection	Low information transfer rate, predefined paths, limited testing scenarios, and possible fatigue after long focus period of the eye on the target stimulus
P300 (odometer, barcode scanner, and a proximity sensor) [38]	Support vector machine	A predefined set of locations and stops	Same as Rebsamen et al [38]	Same as Rebsamen et al [38] and a modified environment requires an update of the guiding path
MI ^a -based mu rhythm and the P300 [39]	One versus the rest common spatial patterns transformation matrix	Left, right, accelerate, and decelerate	Improved performance	Limited testing scenarios and possible fatigue after long focus period of the eye on the target stimulus
MI-based BCI (10 sonar sensors and 2 webcams) [41]	Gaussian classifier	Left, right, and keep moving forward	Spontaneous and shared control	Limited testing scenarios, requires extensive training, and limited classes (typically three)
Steady-state visual evoked potentials (camera and adaptive fuzzy controller) [42]	Frequency recognition algorithm based on multivariable synchronization index	Left, right, upwards, and downwards	Teleoperation control of an exoskeleton using a brain-machine interface	Possible fatigue after a long focus period of the eye on a target stimulus and a significant reduction in recognition accuracy for inexperienced subjects
Steady-state somatosensory evoked potential [40]	Regularized linear discriminant analysis	Turn left, turn right, and move forward	Spontaneous, first of its kind, and addressed the possible fatigue after a long focus period of the eye on the target stimulus	Only healthy subjects were used, with limited testing scenarios (two)

^aMI: motor imagery.

Table 3. Brain-computer interface technologies for adaptive assistive mobility devices.

Technology name (type): additional sensors	Machine learning tools	Contributions	Drawbacks
TDS-iPhone-PWC ^a (haptic): magnetic sensors [46]	Sensor signal processing algorithm	An alternative USI ^b for people with spinal cord injury or upper limb paralysis	Tongue piercing can be a painful and uncomfortable option for some users. Extensive training is required for calibration.
Intelligent smart walker (haptic): force or torque sensor [49]	N/A ^c	An intuitive rule-based speed controller for a smart walker	Young and healthy subjects were used, so the result is not a true representation of the typical users of the walker.
EyeCane (CVI ^d , haptic, and auditory): infrared emitters, auditory frequency actuator, and tactile actuator [52]	N/A	Low cost, lightweight, small and easy to use electronic travel aid for distance estimation and navigational assistance, long battery life (one whole day), intuitive to the user, and short training time (<5 minutes)	Only an indoor experiment was conducted.
Electronic mobility cane (CVI, haptic, and auditory): liquid detection, 6 ultrasonic sensors, a metal detector, a microvibration motor, and a mono earphone [51]	A novel algorithm named <i>way-finding with reduced information overload</i> .	Offers real time multiple obstacle detection and way-finding assistance simultaneously to patients with visual impairments by an auditory (voice message) and tactile (vibration) feedback	Extensive training time (20 hours); the cognitive and perceptual load has not been ascertained
Jet Propulsion Laboratory BioSleeve (haptic): electromyography and IMU ^e sensors [44,45]	A multiclass support vector machine classifier	Intuitive control of robotic platforms by decoding as many as 20 discrete hand and finger gestures	Has not yet been integrated and tested with assistive mobility aids to determine its applicability
Smart cane (haptic): IMU and FSR ^f sensors [48]	C4.5 decision tree, artificial neural network, support vector machine, and naive bayes	To monitor and distinguish between different walk-related activities during gait rehabilitation	Fall and near-fall detection was not considered in its design and implementation.
An ARTA ^g power wheelchair platform (CVI and haptic): haptic controller, laser scanner, SICK laser measurement, and IMU sensor. [50]	Gaussian process regression model	Implementation of a learned shared control policy from human-to-human interaction	The efficiency of the learning process is dependent on the human assistant, who is prone to errors and might miss out on the certain intent of the user.
Multiple controlled interfaces smart wheelchair (haptic and auditory): microphone, joystick, leap motion, and ultrasonic sensor [53]	An algorithm for the control and execution of commands	Multiple control interfaces	Lack of details on the performance of each interface and limited testing scenarios
MyoSuit (haptic): IMU sensor and two electric motors [47]	N/A	Lightweight, soft wearable robot to aid users with a level of residual mobility during locomotion tasks	Only one incomplete spinal cord injury participant was selected for testing, so it is difficult to validate its performance.

^aTDS-iPhone-PWC: tongue drive system to iPhone electric-powered wheelchair

^bUSI: user system interface.

^cN/A: not applicable.

^dCVI: computer vision interface.

^eIMU: inertial measurement unit.

^fFSR: force sensitive resistor.

^gARTA: assistive robotic transport for adults.

Table 4. Computer vision (CV) interface technologies for adaptive assistive mobility device.

Technology name (type): additional sensors	Machine learning tools	Contributions	Drawbacks
See ColOr (CV, auditory and haptic): 3D Kinect, iPad, and Bone-Phones [63]	Multilayer artificial neural network for <i>object classification</i> , Kalman filter for <i>tracking objects</i> (finger), and randomized forest algorithm for <i>object detection</i>	A framework for the coupling of optical sensors in the context of range and color image registration and the development of a sonic code that maps colors and depth into musical instruments	Extensive training was required, and testing was limited to certain scenarios.
Wearable mobility aid for patients with visual impairments (visual, auditory, and haptic): RGBD ^a , vibro-tactile glove, and bone-conductive headsets [64]	Stereo vision algorithm and semiglobal matching algorithm; detection: random sample consensus algorithm and Kalman filter; categorization: convolution neural network	Improves on a preliminary prototype of Mattoccia [75], enabling dynamic autonomous mobility capability combining features of electronic travel support and self-localization support in a compact and lightweight setup	Patient feedback from the Mattoccia [75] study was considered, and the result that covered collision rate and cognitive and perceptual overload on tested subjects was not presented.
Visual servoing-controlled wheelchair (vision): 1 camera for corridor following and 2 cameras for ADP ^b [61]	Classic Gaussian sphere projection framework, door detection and tracking framework, and a 2D edge tracker inspired by the moving edge algorithm	Addresses, in a secure way, the autonomous stability of the wheelchair's position along corridors and also detects and passes through doorways using visual data	Human input in the control was not considered.
iChair (vision, auditory and haptic): high-definition camera, 3D scanner, 10 LEDs ^c , touch screen and voice recognition app, and head mouse [30]	Light communication algorithm, collision avoidance algorithm, and an emergency and stress detection algorithm	A multimodal input smart wheelchair to identify and classify objects, build 3D maps, and eventually facilitate autonomous navigation	A bug-free human trial has not yet been documented.
CV for patients with visual impairment (vision, auditory, and haptic): A stereo RGB ^d camera (SC), a depth-of-field camera, and an IMU ^e [65]	Detection and tracking algorithm, support vector machine classifier, and a class-specific extremal regions for text detection	Addresses the pervasiveness requirement as well as offers sensory substitution via sound feedback to patients with visual impairment	The outdoor performance noted clustering of several objects into a single one and error in identifying lower parts of the object; no outdoor and usability test was documented.
Autonomous scooter navigation (vision): MPU-9250 IMU, long-range laser, and stereo vision camera [13]	A graph-based simultaneous localization and mapping algorithm	Cost-effective and addresses the navigational and localization challenges in an unknown environment by a new hybrid far-field and near-field mapping solution	Extensive documentation of human testing has not been documented.
User-adaptive intelligent robotic walker (vision): laser range finder [62]	Interacting multiple model particle filters with probabilistic data association framework, Viterbi algorithm (human gait estimation), support vector machine classifier, and unscented Kalman filter algorithm	Human state estimation, pathological gait parametrization, and characterization for classifying users associated with risk fall	A test to evaluate the performance of the control strategy with the robotic mobility assistive device and patients was not documented.

^aRGBD: red green blue and depth.^bADP: autonomous doorway passing.^cLED: light emitting diode.^dRGB: red green blue.^eIMU: inertial measurement unit.

IoMT Frameworks: Impact of IoMT on the Adaptability of Assistive Mobility Devices

IoMT generally contributes to the adaptability of assistive mobility aids in the monitoring and control by users, caregivers, and medical personnel. The adaptability of assistive mobility devices involves the acquisition of information and the making of intelligent decisions based on the acquired information. This information is obtained from the environment and user via a means of communication (usually an interface). USIs can send and receive information from the user (individuals with some form of disability) to the mobility aid via a communication

channel that could be wired or wireless, such as the JPL BioSleeve [44,45] and the TDS-iPhone-PWC interface (Table 3) [46] that can wirelessly control a mobility aid, the P300-based BCI (Table 2) [74] that controls a wheelchair via a wired USB channel, and the autonomous scooter navigation mobility aid [13] that connects its computing module to its hard unit via a wired USB medium or a wireless Bluetooth medium. With the help of IoMT, interconnectivity between mobile devices and their environment and the storage or retrieval of relevant information for control, better autonomy, and monitoring are possible. Many recent surveys and reviews have been conducted

on IoMT's recent technologies, applications, challenges, and opportunities [3,76-78].

In recent years, many researchers have proposed IoMT frameworks for assistive devices that leverage or build on existing IoMT architectures and communication protocols and restructure them (using algorithms or management systems) to suit assistive technologies. For instance, Bae et al [79] proposed a network-based rehabilitation system, for mobility aids (knee assistive devices), as shown in Table 5. The prototype

framework distributes the control of the mobility device between the patient's side and the physiotherapist's side over a wireless network using the transmission control protocol for internet communication. A modified linear quadratic Gaussian algorithm was used to compensate for packet losses in the wireless network by modeling the losses as Bernoulli random variables. However, only simulations and experiments have been conducted. Therefore, its efficiency in tackling packet loss and robustness against modeling uncertainties, such as interactions with human emotions, has not been evaluated in real-world scenarios.

Table 5. Internet of medical things technologies for adaptive assistive mobility devices.

Name of framework	Management system or algorithms	Contributions and functions	Drawbacks
NBR ^a system framework [79]	Modified linear quadratic Gaussian algorithm	Distributes the control of a mobility device between the patient's side and the physiotherapist's side; brings convenience to patients and therapists	Only simulations and experiments have been conducted.
Global concept SEES ^b framework [64]	Intelligent transportation system	Designed to address the walking and orientation problem; functions: user tracking, sending of emergency error or alert messages to patients with visual impairment, obstacle detection, walked distance estimation, surface roughness estimation, and traffic light detection	Only one simple experiment has been conducted.
SHS ^c framework [80]	Hybrid sensing network, the IoT ^d smart gateway, and the user interfaces for data visualization and management	Monitoring and tracking of patients, personnel, and biomedical devices in real time; collecting both environmental conditions and patient's physiological parameters and delivering them to a control center	Use-case scenario testing has not been conducted except for fall detection of 1 patient.
ROS ^e framework [81]	Navigation, localization, and pick and place algorithm	For the cooperation among SWC ^f and RW ^g ; for the user to be able to interact with and control the SWC as well as any object connected to the RW	At present, the whole architecture has been tested in simulation only.

^aNBR: network-based rehabilitation system.

^bSEES: Smart Environment Explorer Stick.

^cSHS: smart health care system.

^dIoT: internet of things.

^eROS: robotic operating system.

^fSWC: smart wheelchairs.

^gRW: robotic workstations.

Yusro et al [82] proposed the global concept Smart Environment Explorer Stick framework that enhances the white cane to assist the navigation of patients with visual impairment. As shown in Table 5, it was designed to address the walking and orientation problem by assisting some of the walking and orientation functions and adopting an active multisensor (ultrasonic, camera, accelerometer, wheel encoder, compass, tactile point-wise, and audio feedback) context-awareness concept. Cellular IPv6 over low-power personal area network communication protocols and routing protocols for low-power and lossy networks were used to help patients with visual impairment to move safely and easily in any environment (indoor and outdoor). However, only one simple experiment was performed. An IoT-aware architecture for smart health care systems (SHSs), applicable to the adaptability of assistive mobility devices, was proposed by Catarinucci et al [80] (Table 5). It promised to guarantee innovative services for the automatic monitoring and tracking of patients, personnel, and biomedical devices within hospitals and nursing institutes in real time. The SHS framework [81] relies on different but complementary technologies, specifically radio frequency identification, wireless sensor networks, and smart mobile, interoperating with each other through a

constrained application protocol or IPv6 over low-power personal area network or representational state transfer network infrastructure (Table 5). However, the SHS framework was proposed to demonstrate its feasibility, and it needs to be tested in various use-case scenarios to evaluate its performance. Furthermore, Foresi et al [81] proposed a robotic operating system framework that connects robotic workstations with a smart wheelchair via a Wi-Fi protocol. It was designed to improve the intelligent navigation of the wheelchair and enable interaction between the wheelchair, its user, and any object connected to the robotic workstation. However, only a simulation has been performed on the whole architecture, and a detailed evaluation of its performance is not available.

Although IoMT assistive mobility device frameworks show promising signs to improve the adaptability of mobility aids, most proposed frameworks have not been tested. This is extremely important for evaluating their performance and applicability in adapting mobility aids to their intended users. Notable drawbacks common to IoMT frameworks, such as packet loss, user privacy and security, network robustness and scalability, and commercialization cost [1,83,84], need to be extensively evaluated.

Discussion

User System Interaction (Input and Output Methods)

BCI Systems

BCIs can generally be categorized into four types: P300, SSVEP, event-related synchronization or desynchronization, and SSSEP. P300 is an endogenous response to an oddball stimulus. A positive wave is evoked in response to an event-related potential at a latency of 300 ms (P300). SSVEP is also an endogenous response and is a resonance phenomenon visually evoked by a stimulus modulated at a specific frequency in the brain signals. It occurs in response to the observation of a persistent oscillating visual stimulus. Unlike P300 and SSVEP, event-related synchronization or desynchronization is spontaneously induced by performing mental tasks, such as MI, mental arithmetic, or mental orientation. The SSSEP paradigm is evoked, is endogenous, and spontaneous. The signal is generated in response to the feeling of touch or pressure [35,40,85].

Because of its high accuracy and the need for little to no training, P300 was used by Iturrate et al [74] and Rebsamen et al [38] for the BCI system in the design of the automated navigational wheelchair. Both prototypes still had the drawbacks common with the P300 BCI, such as low information transfer (successful orders per minute), the need for multiple trials for improved accuracy, and the *fatigue experience* that could occur as a result of the long focus period of the eye on the target stimulus. Other drawbacks included the limited testing scenarios conducted on both systems and the fact that only predefined locations could be reached. Rebsamen et al [38] used the path-following mode of operation [12] for automated navigation; therefore, a modification of the environment would require an update to the guiding path. Both prototypes had a limited number of testing scenarios and were carried out on healthy (5) subjects. Long et al [39] adopted the hybrid BCI approach for the control of wheelchair direction and speed using P300 and MI. Emphasis was given to the importance of speed and the use of hybrid BCIs to improve performance and increase command options. Although accuracy was improved (classification performance) and speed control was achieved, testing was limited to only two scenarios (5 subjects for the first and 2 for the second). In addition, the fatigue experience that could occur as a result of the long focus period of the eye on the target stimulus was not addressed.

In an attempt to address the lack of spontaneity associated with P300 and SSVEP, Carlson and del R Millan [41] adopted an MI-based BCI to control a wheelchair. The prototype focused on shared control between the user and the wheelchair, that is, the ability of the wheelchair to take actions (autonomously navigate) concerning the user's input and its perceived surroundings (using CV). Drawbacks associated with MI BCI, such as limited classes (typically 3 to avoid difficulties in discriminating MI patterns), extensive training time (a few weeks to months) and the calibration time were still evident. It took a much longer time (>160 seconds) for the 2 inexperienced MI BCI patients out of the 4 to complete the task. In addition, if shared control is not properly matched with the user, it could lead to degradation or loss of function and efficiency. Qiu et al

[42] attempted to address the complex dynamic uncertainty and input saturation (leading to tracking error), which is common to exoskeleton robots, by using vision compressive sensing, an SSVEP-based BCI (as a reference command), and an adaptive fuzzy controller for control. Limited testing was performed with 2 veterans and 1 greenhorn patient, and the results showed that training was required. Experienced subjects had a significantly better recognition accuracy (approximately 14% difference). To combat the possible fatigue problem and loss of vision to the environment because of the long focus period of the eye on a particular target stimulus, Kim et al [40] adopted the use of SSSEP BCI in the control of a wheelchair. According to Kim et al [40], this prototype is the first of its kind. Although it tested significantly better than its MI BCI-controlled equivalent, tests were limited to only healthy subjects (12) and were conducted mostly by experienced brain-machine interface subjects. In addition, only two testing scenarios were considered.

Auditory and Haptic Interface

Although many advances (in USI) have been made in an attempt to factor in individuals with varying disabilities, the extensive evaluation of the efficiency and applicability of these technologies requires more attention. Affordability, accurate detection of environmental sounds, avoidance of cognitive overload of the users, ease of use, weight of devices, and commercialization are important factors to be considered [15,20,21,31,43]. For instance, JPL BioSleeve [44,45], a very promising interface for decoding a large number of gestures (dynamic and static hand positions) at high accuracy, integrates IMU signals with EMG for gesture recognition. Its intended goal of gesture recognition with high accuracy was achieved. However, it is still unclear for which category of users and devices it would be most suitable. Therefore, proper integration and testing need to be performed with existing mobility aids to determine their applicability. TDS-iPhone-PWC [46] was designed to be an alternative USI for people with SCI or upper limb paralysis. Latched, unlatched, and semiproportion control strategies were used to send commands to the wheelchair. The commands included forward, backward, left, and right motions, as well as adjustable speed levels. The results showed that it could effectively be used to both access a computer and drive a power wheelchair in a unified, wireless, unobtrusive, and wearable form. However, tongue piercings can be a painful process, and some patients would be uncomfortable or find it difficult to use this option for control. In addition, results showed that extensive training was required for proper calibration and improved performance (task time, number of collisions, and out of tracks). MyoSuit [47] focused majorly on comfort and weight while maintaining its efficiency in aiding its users (ie, people with incomplete SCI, stroke, and multiple sclerosis or muscle dystrophy). Using elastomer springs and a *tendon driver unit*, MyoSuit was designed to act as an antigravity support during gait rehabilitation tasks. However, it was tested on only 1 patient with incomplete SCI, and so it is difficult to evaluate its efficiency and applicability for gait rehabilitation. The proposed EMC [51] focused on the simultaneous detection of multiple obstacles at different levels (in terms of height and distance) and floor status. EMC was designed using 6 ultrasonic sensors, a liquid detection sensor, a metal detection sensor, a

wireless transceiver, and microcontroller circuits. Sensors were positioned on the stick to detect floor-level to head-level obstacles, as well as for leftward and rightward detection. EMC effectively provided navigation assistance, and the categorization or prioritization of detected information was better than with the white cane. However, more training time was suggested (even after a lengthy 20-hour training time) to properly ascertain its cognitive and perceptual load in comparison with similar devices.

Promising devices, such as EyeCane [52] and intelligent smart walker [49], had drawbacks as certain testing scenarios were not considered. EyeCane was tested only indoors, and the intelligent smart walker was tested using healthy patients who do not truly represent the typical users of the walker. The smart wheelchair that was designed to accommodate multiple control interfaces lacked a detailed evaluation of the performance and intelligence of the wheelchair for each interface. An example scenario is how the wheelchair would differentiate the user's voice from an outlier when an alternative command option is in use. Therefore, there is a need for more detailed testing and evaluation before these technologies become usable and acceptable to their intended users.

CVI Systems

CVIs play an important role in the perception of mobility devices for autonomous navigation. CVI has been adopted in some technologies. For instance, See CoLoR [63] was designed as a framework for the coupling of optical sensors in the context of range and color image registration. A sonic code was developed to map colors and depth into musical instruments. However, as it was the first of its kind, extensive training was required for the participants to master it, and testing was limited to certain scenarios (outdoor scenarios were not considered). A similar drawback was observed with patients with visual impairment [65]. It was designed to address the pervasiveness requirement (by integrating both an infrared light-based depth sensor and a stereo vision system together with an IMU device) as well as offer sensory substitution via sound feedback to patients with visual impairment. It was designed to work in any environment and illumination condition using sensor fusion techniques. The results seemed promising; however, detection or 3D representation of small objects or objects close to the ground needed a lot of improvement. In addition, only testing for indoor scenarios was conducted. iChair, was designed by Leaman et al [30], to accommodate a large range of impaired users by integrating multiple interfaces for control; however, no bug-free human trial has been documented. The same drawback was noted in the autonomous scooter [13], which was designed to be a cost-effective autonomous scooter that addressed the navigation and localization challenges in an unknown environment with a new hybrid far-field and near-field mapping solution.

The work toward autonomous navigation of mobility devices is ongoing and progressive but not without its challenges. This is because many stages make up the autonomous navigation system, and therefore, the overall performance can be hampered by just a small percentage error in one of its many stages. The first stage, the perception stage, is crucial to the performance

of an autonomous navigation system as it has to do with the acquisition and processing of information. This stage, to a very large extent, determines the adaptability of the mobility device to the needs of the user. Different USIs are used to accommodate users with varying impairments; however, the ability to adequately adapt the mobility device is dependent on the quality of the information it receives. Many of the reviewed technologies applied different machine learning tools (classifiers and algorithms) to help process the acquired information. An example is the SVM classifier used by JPL BioSleeve in the studies by Assad et al [44] and Wolf et al [45] to classify gesture patterns. It was able to achieve an accuracy as high as 96%; however, as stated by Anguita et al [86], its accuracy was dependent on the chosen model, presence of noise, and data size. Drawbacks can be better tested by the comparison of similar classifiers to know which performs better for a particular technology, as was done by Wade et al [48].

In recent years, the idea of fusing data acquired from multiple sensors to improve confidence has been widely adopted because of the complementary properties exhibited by different sensors. Although this has proven to be promising, it does not come without its challenges [24,87]. This is majorly applied to CV. Examples include CV for patients with visual impairment [65] and the autonomous scooter [13], which used the fusion of 2 sensors for improved performance. To design CV for patients with visual impairment, a stereo red-green-blue camera (which is unreliable for depth estimation in the presence of poor illumination) was fused with a depth-of-field camera (which does not cope with bright light from the sun) in an attempt to improve the reconstructed 3D image output under any environmental condition. In the design of the autonomous scooter, long-range laser data were fused with that of a stereo vision camera to improve confidence under any environmental condition. Although fusion of data shows promising results, its efficiency is dependent on the accuracy of the applied fusing methods. An extensive literature review on fusion algorithms and the complementary properties of perception sensors and systems has been discussed by many researchers [24,69]. Some notable challenges in autonomous navigation and CV include improved accuracy and robustness in data fusion, trade-off between cost and performance, the self-localization problem, the detection of small or far-away objects in real time, training data set and increased testing scenarios, level of autonomy, and user training [23-25,60].

Limitations and Future Directions

Overview

This study presents a comprehensive review of the recent literature on the adaptability of assistive mobility devices in terms of the acquired information. Discussions that present interesting facts and technical details regarding recent technologies have been reported. On the basis of the literature review, the following challenges and research directions are presented:

Improved Training Time and Avoidance of Cognitive Overload

Although the exact figure for the attention span of an average human being is extremely variable, research shows that the attention span of an average human being declines as the required concentration time increases. Therefore, it is widely accepted that keeping it simple is better. This is not different from the training time for users with some form of disability [88-91]. As highlighted in the *Brain-Computer Interface* section under *Discussion*, most of the reviewed prototypes showed that training time requires more attention. In addition, in the *Computer Vision Interfaces* section, the training time needed for machine learning algorithms varied depending on the training data set, which could affect the decision made in autonomously navigating assistive mobility devices [24]. More research could be conducted to improve the accuracy of BCI options with shorter training times and hybrid BCIs. This could be achieved with the help of machine learning techniques or algorithms that study user inputs and behaviors to accurately predict commands and help reduce the number of failed commands. Finally, a widely accepted standard for validating the training time for both machine learning algorithms and BCI in a USI could be developed. This will help researchers adequately compare results and monitor improvements concerning the adaptability of assistive mobility devices.

Accuracy

The data reveal that people who are adapted to using their wheelchairs have little to no tolerance for new functional errors. This situation is similar to that of every other assistive mobility device [92]. The highlighted technologies related to autonomous navigation (perception) and CV have shown that the data fusion technique has become increasingly accepted in improving accuracy. However, this also increases the complexity and robustness of information, thereby presenting challenges such as fusion, calibration, and classification accuracy [23-25,60]. Machine learning tools or algorithms used in processing this information also have varying strengths and weaknesses. Similar to the SVM classifier highlighted earlier, these tools and algorithms show varying accuracy depending on the selected model and the level of noise. Future research could be directed toward improving the accuracy of mobile robots in unfamiliar environments as this is mostly the case for assistive mobility devices.

IoMT Latency, Security and Privacy

The integration of IoMT frameworks with the highlighted technologies shows a lot of promise in improving the adaptability of assistive mobility devices to their users. With the IoMT technology option, data stored in the cloud can be analyzed and used for further research. The user's progress (for gait rehabilitation) can also be monitored, and some level of assistive control can be done by the user's stakeholders. However, with IoMT technology come network scalability, user privacy, and security problems [1,83,84]. Most reviewed papers acknowledged the packet loss problem when remotely controlling mobility devices via an IoMT framework and proposed various management systems to combat this problem; however, only simulation tests were carried out. The scalability

of these frameworks can only be known when real-world testing is performed. Frameworks such as the robotic operating system [81] and the network-based rehabilitation system [79] may have major issues when implemented on a larger network scale. Further research could be conducted on management systems and algorithms developed to improve latency and compensate for packet loss. The developed frameworks should also indicate the number of devices that they could accommodate without any drop in performance. This could all be included in comprehensive system validation. Finally, a widely accepted standard for validating these systems or prototypes could be developed to help researchers compare results and documents on IoMT-based assistive mobility devices.

Performance Evaluation

In most of the reviewed papers, little attention was paid to real-world testing and comparing related prototypes to evaluate performance. For these technologies to be tagged fit for their intended users, their performance needs to be properly evaluated and tested under varying conditions. Proper evaluation would help examine some notable drawbacks, such as ease of use (without the need for any special training), cognitive overload (during human-machine communication), and the ease of wearing these technologies (in terms of weight while maintaining or improving their functionality) [15,20,21,31,43]. Some users of assistive mobility devices have comorbidities, such as mental health challenges because of aging or depression. If the training time or cognitive or perceptual load is high, the device will be quickly abandoned by its intended users. From the discussions, it has been shown that machine learning tools play a key role in the proper classification and processing of USI information as well as the decision-making of these mobility devices. These account for the ability of these devices to navigate autonomously with high accuracy. Future research could focus on the standardization of performance evaluation methods and the accepted testing conditions.

Another research direction is *the design of prototypes for clearly defined users*. As discussed in previous sections, specific USIs are most suitable for specific ailments. With the advent of many different USIs, there is a tendency to want to accommodate a wider range of users in a prototype design. When assistive mobility devices are tailored to specific users or ailments, there will be improved performance and accuracy in the adaptability of those devices to their specific users.

For a mobility device to be termed adaptable, it has to meet certain requirements such as the following:

1. *Intelligent perception*, that is, requires little or no effort to efficiently perceive its environment and take mobility decisions (such as obstacle avoidance and collision detection)
2. *Accurate self-localization* of user and device (user tracking).
3. *User-friendly*, that is, the movement speed and direction are controlled by the user subconsciously without the need for any special training; in addition, prompt and adequate control or feedback from and to the user are provided without cognitive overload, and communication with necessary stakeholders is easy and secure

These are needed for developed assistive mobility technologies to be easily commercialized and gain user acceptance (widespread adoption) [28,31]. These basic requirements reflect the need to evaluate the performance of mobility devices according to their major adaptability elements (ie, USIs, perception of adaptability—autonomous navigation—and IoMT framework).

Conclusions

The research community has developed many promising technologies in the past decade, taking advantage of smart sensors, machine learning tools, and IoMT frameworks to offer mobility independence to impaired individuals. For users to benefit from these technologies, adaptability must be properly evaluated and considered from design to implementation. This

study has successfully reviewed recent technologies of assistive mobility devices to identify their adaptability to users in terms of USI, autonomous navigation (perception stage), and connectivity. Tables have been presented to highlight the reviewed technology according to the major adaptability elements. Furthermore, the review presents some notable limitations, which have shown the need for improved cohesion to effectively adapt these technologies to their users. The findings discussed in the review show that for improved adaptability, more work needs to be done to reduce the training time and cognitive overload in the USIs to improve the fusion and classification accuracy; real-world scenario testing needs to be conducted and evaluated, and the trade-off between cost and performance needs to be considered in commercialization.

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Authors' Contributions

All authors were involved in the conceptualization and the methodology of the study. DAO conducted the search strategy for the study, selection process, and wrote the original draft. EDM and AMAM performed an extensive review and commented on the original manuscript. All three authors approved of the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AR: autonomous robot
AV: autonomous vehicle
BCI: brain-computer interface
CV: computer vision
CVI: computer vision interface
EMC: electronic mobility cane
EMG: electromyography
IMU: inertial measurement unit
IoMT: internet of medical things
IoT: internet of things
MI: motor imagery
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PWC: powered wheelchair
SCI: spinal cord injury
SHS: smart health care system
SSD: sensory substitution device
SSSEP: steady-state somatosensory evoked potential
SSVEP: steady-state visual evoked potential
SVM: support vector machine
TDS: tongue drive system
TDS-iPhone-PWC: tongue drive system to smartphone (iPhone) electric-powered wheelchair
USI: user system interface

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Original Paper

Use of an iPad App (Aid for Decision-making in Occupational Choice) for Collaborative Goal Setting in Interprofessional Rehabilitation: Qualitative Descriptive Study

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Abstract

Background: Goal setting is a key part of the rehabilitation process. The use of technology and electronic tools such as smartphone apps and websites has been suggested as a way of improving the engagement of users in meaningful goal setting and facilitating shared decision-making between patients and health professionals.

Objective: This study aims to describe experiences of health professionals and patients in the use of the English language version of the iPad app Aid for Decision-making in Occupational Choice (ADOC) to facilitate collaborative goal setting in rehabilitation.

Methods: We recruited participants from 3 acute and postacute care rehabilitation wards in both public and private organizations in New Zealand. Participants were registered allied health professionals, including physiotherapists, occupational therapists, and speech-language therapists, who engage in goal setting as part of their normal work, and their adult patients. We collected data via semistructured interviews to gather information about the experiences of the participants in the use of ADOC for goal setting. Data were analyzed with thematic analysis.

Results: A total of 8 health professionals and 8 patients participated in the study. Six main themes emerged from the data: changing patients' perspective on what is possible, changing health professionals' perspective on what is important, facilitating shared decision-making, lack of guides for users, logistic and organizational barriers, and app-related and technical issues.

Conclusions: Health professionals and patients found ADOC to be a valuable tool when setting shared rehabilitation goals. The use of ADOC promoted a patient-centered approach that empowered patients to engage in collaborative goal setting. The technological limitations of the app that negatively impacted experiences can be addressed in the future implementation of ADOC in rehabilitation settings.

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KEYWORDS

rehabilitation; goals; digital technology; mobile health; mobile phone

Introduction

Background

Goal setting is a key part of the rehabilitation process [1] and is ultimately geared toward helping patients make functional progress in their recovery [2]. Rehabilitation goals have been defined as “a desired future state to be achieved by a person with a disability as a result of rehabilitation activities” [1]. Rehabilitation goals are “actively selected, intentionally created, have a purpose, and are shared-where possible-by the people participating in the activities and interventions designed to address the consequence of acquired disability” [1]. Goal setting has face validity as a method to enhance communication and collaboration within rehabilitation teams and may result in improved patient-reported quality of life after rehabilitation [1]. Research from psychology suggests that the right type of goals can have a significant effect on human performance across a wide range of activities [3]. It has been suggested that patient involvement in setting rehabilitation goals may lead to measurable improvements in physical and psychosocial function [2,4-6]. It has also been proposed that involving patients in decision-making may improve the quality and person-centeredness of rehabilitation practice. Collaborative decision-making aims to ensure that patients are well informed and meaningfully involved in choices about their care and that the treatments or interventions they receive reflect their goals and concerns [7,8].

The use of technology and electronic tools such as smartphone apps and websites has been suggested as a way of improving the engagement of users in meaningful goal setting and facilitating shared decision-making between patients and health professionals [2,9,10]. The Aid for Decision-making in

Occupation Choice (ADOC) [11] is an iPad app that was developed in Japan and designed for people with any disability; it helps patients identify and express the desired activities and social roles they want to work toward during rehabilitation, and it encourages them to participate in the goal-setting process [5]. ADOC uses texts and illustrations to present goal topics based on everyday activities and social roles, drawn from the *activities and participation* domain of the International Classification of Human Functioning, Disability, and Health [12] (Figures 1 and 2). The patient satisfaction scores derived from the Japanese version of ADOC are valid and reliable [13], and patients with moderate cognitive impairment can use ADOC to communicate their preferences for meaningful areas of activity [14].

In 2018, an English language version of ADOC was developed in consultation with 14 experienced international occupational therapists (OTs) [15]. This version of ADOC changed the language used, but also revised some illustrations and the range of goals to align with westernized activities and social roles. Early testing of this content showed that most of the images in the English language version of ADOC could be identified correctly by rehabilitation or residential care service users as a fair representation of the concept they intended to represent [15]. To date, ADOC has been tested extensively in clinical rehabilitation practice in Japan and has been demonstrated to support OTs in setting person-centered goals [5]. Both Japanese and English versions of ADOC have been tested and are validated for patients with any health condition, chronic or acute, and disability who score more than 9 on the Mini Mental State Examination scale [14]. However, although the Japanese version of ADOC was designed by OTs for OTs and has only ever been tested in this context, we were also interested in the potential for ADOC to be used for goal setting by staff in a multidisciplinary rehabilitation team.

Figure 1. Example of a goal setting meeting using the iPad app Aid for Decision-making in Occupation Choice. Image source: Freepik [16]



Figure 2. Main features of Aid for Decision-making in Occupation Choice. (a) Log-in page; (b) images from which the patient chooses up to 20 meaningful activities; (c) the patient rates each selected activity by importance; (d) the health care professional chooses up to 20 of the most important activities for the patient; (e) shared-decision moment, when the patient and the health care professional choose together up to 5 of the most urgent goals; (f) matrix page to prioritize the 5 goals by importance and urgency; (g) satisfaction rate page; (h) therapy plan in PDF format.



Prior Work

In 2020, we conducted a scoping review of the use of technology for goal setting in health care and found that ADOC was 1 of just 5 mobile apps or websites that supported collaborative decision-making between health professionals and patients for goal setting. Of these 5 apps, ADOC was the only technology that focused on the shared decision moment and that could be used in an interprofessional rehabilitation context for patients with any type of health condition [17]. We were therefore interested in the potential for ADOC to facilitate shared decision-making around goal setting in an English-speaking country and a wider group of health care personnel in rehabilitation. As this app had not been previously studied in this context, we chose a qualitative, open-ended approach to explore its potential use.

Study Aim

The objective of this study is to investigate the experiences of health professionals and patients in the use of the English language version of ADOC to facilitate collaborative goal setting in English-speaking rehabilitation services. In particular, we wanted to understand what health professionals and patients liked and did not like about ADOC; how ADOC aligns with other clinical processes and practices; how ADOC can be incorporated into clinical practice; how ADOC influences clinical decision-making in an everyday rehabilitation setting; and what patient outcomes ADOC might most affect.

Methods

Study Design

We used a qualitative descriptive study design [18]. We collected and analyzed data, using semistructured interviews,

on the perspectives of participants involved in trialing ADOC in an inpatient rehabilitation setting. This allowed us to not only collect data targeting our initial research questions but also enabled patients and health professionals the flexibility to elaborate on their views on the use of ADOC during the goal-setting process [19,20]. This study received ethical approval from the Northern B Health and Disability Ethics Committee, Ministry of Health, Wellington, New Zealand (reference number: 20NTB40) before participant recruitment. This paper presents the findings following the Consolidated Criteria for Reporting Qualitative Studies guidelines (see [Multimedia Appendix 1](#)). The research team included academic researchers with extensive experience in qualitative methods and technology: a physiotherapist (WMML), a rheumatologist (RG), 2 OTs (K Tomori and K Takashi), and a PhD student with a professional background in physiotherapy (CS).

Setting

The study was undertaken in 3 inpatient rehabilitation services in the Wellington and Auckland regions of New Zealand; 2 government-funded services in public hospitals, and 1 private rehabilitation service funded mostly by the New Zealand national health insurance system for accidents (the Accident Compensation Corporation).

Participant Selection and Recruitment

We recruited both health professionals and patients. Service team leaders and health professionals were approached by the research team (CS and WMML) a few months before the study, provided with the research protocol, and asked if they were interested in participating in the study. Service team leaders then provided names of health professionals who were interested in the study.

To be included in the study, the health professionals had to be qualified and registered allied health professionals (physiotherapists, OTs, and speech-language therapists) who were involved in goal setting with patients in their rehabilitation service as part of their usual role. We used purposeful sampling [21] to ensure that the participating health professionals had diverse professional backgrounds, years of work experience, and place of employment. Health professionals were not remunerated for their contribution to the study; however, their service departments were given copies of ADOC for use on their own devices after the study at no cost.

Patients were eligible to participate if they were over 18 years of age, current recipients of hospital rehabilitation services, able to provide informed consent, and able to have a basic conversation in English about their views and experiences with at least simple phrases and words to communicate their perspectives. Patients with mild cognitive impairment were eligible to participate in the study if they had a score ≥ 3 in the Montreal Cognitive Assessment [14,22] or a score ≥ 21 in the Mini-Addenbrooke Cognitive Examination [23-25]. Type of injury or illness and time, as injury or illness onset were not reasons for exclusion. All patients participating in the study were offered a New Zealand \$20 (US \$15) retail voucher as thanks for their participation. Patients were purposively sampled to include men and women, people from a range of age groups and ethnicities, and with different levels of cognitive ability.

Materials and Training

Each rehabilitation service was provided with either an Apple iPad with ADOC already installed or the primary investigator installed ADOC on a service-owned iPad. ADOC is available only in the Apple store and only for iPads. Health professionals' participants met with the primary investigator (CS) for in-person or web-based group training in the use of ADOC. The training was conducted in person in June 2020 for both the public hospital and the private rehabilitation center in Wellington. The in-person training was held in the rehabilitation service staff room, lasted approximately 2 hours, and primarily focused on how to navigate through the app and its functions. Owing to the geographic distance, training for Auckland Hospital was conducted on the web via videoconference in August 2020. The training was conducted in each location 3 to 4 weeks before data collection began. During the training, each health professional was able to try out the app and to ask questions. As we were interested to know how intuitive ADOC was to use and how health professionals might choose to use the app when this decision was left up to them, we kept instructions on when and how to use it to a minimum. We asked the health professionals to use ADOC with patients in their service as part of their usual goal-setting process in any way they saw fit.

Data Collection

We collected data using individual semistructured, open-ended interviews with all participants between June 2020 and November 2020. Two interviews were conducted for each health professional and one interview for each patient. All interviews were scheduled and conducted by the primary investigator (CS). Interviews typically commenced with an open invitation for participants to describe their initial understanding of ADOC,

what they like or did not like about the app, and their thoughts and feelings about using the app in clinical practice. Interview schedules with broad areas for questioning were used for all interviews (see [Multimedia Appendices 2 and 3](#)). The interviews could also develop organically, according to each participant's responses. All interviews were audio-recorded using a high-quality digital recorder and transcribed verbatim.

The interviews with health professionals were performed in person at their place of work or on the web by videoconference. The first interview occurred within 7 days of the start of their use of ADOC and the second interview 4-6 weeks later. Each health professional provided information on their age, gender, professional role, and years of professional work experience.

Patients were interviewed in person or on the web by videoconference, within each rehabilitation service, in an appropriate, private, and comfortable room. The interviews were conducted within 10 days of using ADOC to set goals for their rehabilitation with their health professional. For each patient, we also gathered demographic and clinical information from the medical records including age, gender, ethnicity, current residential status, primary diagnosis, and Montreal Cognitive Assessment or mini-Addenbrooke Cognitive Examination scores. We continued recruiting participants and collecting data until we found that interviews were not identifying any new information, that is, when data saturation had been reached.

Data Analysis

Data coding, following constant comparative methods, was used to explore and better understand the meaning of the information provided by participants [26-28]. We used NVivo software (QSR International) to manage data analysis. The transcribed interviews were systematically reviewed by 2 principal researchers independently (CS and WMML) who manually coded, identified, and categorized themes to familiarize themselves with the data and to enhance the richness and trustworthiness of the analysis process and findings. The other researchers also checked some sections of the transcripts for accuracy in coding. In cases of disagreement, codes were discussed until consensus was reached. An open coding process (fracturing of the data and grouping and categorizing) was used, so codes were not preset but developed and modified during the coding process [29]. The participants' own words were used to guide the construction of codes and their definitions [30] and to enhance the credibility of the analysis. The analysis of health professionals and patient's data were kept separate during the initial stages of analysis, but as the study progressed, we looked for commonalities and differences of ideas and experiences between the groups.

The trustworthiness of this study was ensured by enhancing its credibility, transferability, and dependability [31]. Credibility was achieved via research triangulation, using multiple analysts to review data sets, generate codes, and develop themes, to ensure that the research findings were robust, rich, and comprehensive. We addressed the transferability by providing a detailed description of the setting (private and public rehabilitation services in New Zealand) and the context (this study aims to analyze the experience of health professionals and patients in the use of an iPad app for goal setting in

rehabilitation) in which this study took place. The reliability of this study was upheld by describing the research steps taken from the research protocol to the development and reporting of the findings. Anonymized extracts from the interviews are presented in the results to illustrate key findings.

Results

Overview

A total of 8 health professionals (see Table 1) and 8 patients (see Table 2) participated in this study. All participant interviews were conducted between June 2020 and November 2020 and lasted between 5 and 30 minutes (mean interview with patients 10.46 minutes, SD=5.22; mean first interview with health professionals 14:51 minutes, SD=5.23; mean second interview with health professionals 13:37 minutes, SD=7.08). All patients were inpatients in an acute rehabilitation ward, who had been hospitalized with a diagnosis of traumatic brain injury, stroke, chronic ulcer leg, or wound skin graft. None of the participants recruited dropped out from the study. Six main themes were

identified from the analysis of the interview data. Overall, ADOC was seen as a valuable addition to the rehabilitation process by patients because it helped them broaden their understanding of what rehabilitation could potentially be about and what they could discuss with their health professionals as outcomes they wanted to work toward (theme a). Health professionals valued ADOC because it had the potential to change or enrich their understanding of what type of goals might be more meaningful or important to their patients (theme b). Thus, ADOC facilitated conversations around personally meaningful goals and person-centered goal setting (theme c). However, health professionals and patients also indicated that there were limitations to ADOC. These limitations were grouped into 3 main themes: problems with the lack of guides in the form of a user manual on how to use the app in clinical practice and printed material of the illustrations goals for patients (theme d), logistical and organizational problems that limited the use of ADOC in clinical practice (theme e), and problems with aspects of the design of the app or with its interface with the localities' information technology systems (theme f). Each of these themes is discussed in more detail.

Table 1. Characteristics of health professionals interviewed (n=8).

Characteristics	Value, n (%)
Gender	
Female	7 (87)
Male	1 (13)
Age (years)	
18-34	6 (75)
≥35	2 (25)
Role	
PT ^a	3 (37)
OT ^b	3 (37)
SLT ^c	2 (25)
Work experience (years)	
<5	4 (50)
5-10	2 (25)
>10	2 (25)
Work setting	
Wellington Public Hospital	3 (37) ^d
Wellington Private Rehabilitation Service	2 (25) ^e
Auckland Public Hospital	3 (37) ^f

^aPT: physiotherapist.

^bOT: occupational therapist.

^cSLT: speech-language therapist.

^d2 physical therapists and 1 occupational therapist.

^e1 occupational therapist and 1 speech-language therapist.

^f1 physical therapist, 1 occupational therapist, and 1 speech-language therapist.

Table 2. Characteristics of patients interviewed (n=8).

Characteristics	Value, n (%)
Gender (n=8)	
Female	3 (37)
Male	5 (63)
Age (years, n=8)	
18-64	6 (75)
≥65	2 (25)
Ethnicity (ETHNIC05^a, n=8)	
Māori	1 (13)
New Zealand European	6 (75)
Pacific peoples	1 (13)
Primary diagnosis (n=8)	
Stroke	3 (37)
Traumatic brain injury	3 (37)
Wound skin graft	1 (13)
Chronic ulcers leg	1 (13)
Montreal Cognitive Assessment score (n=3)	
23/30	2 (67)
26/30	1 (33)
Mini-Addenbrooke Cognitive Examination score (n=5)	
27/30	2 (40)
28/30	1 (20)
29/30	1 (20)
30/30	1 (20)
Setting (n=8)	
Wellington Public Hospital	3 (37)
Wellington Private Rehabilitation Service	3 (37)
Auckland Public Hospital	2 (25)

^aETHNIC05: Ethnicity New Zealand Standard Classification 2005, V2.1.0.

Theme a: Changing Patients' Perspective on What Is Possible

All participating patients remembered using the app with their health professionals during the goal-setting meeting and for most of them, the initial experience with ADOC was regarded as positive. The app was described as “relatively easy to use” [P3], “worthwhile” [P4], and “straightforward” [P5]. Because of the context of the research, where the patients were in an acute ward hospitalized with a severe condition, most of them did not know what to expect from the rehabilitation process. Accordingly, they did not know what goals were potentially possible to discuss during their hospitalization period or to achieve following it. The ADOC app helped patients to have a better understanding of the treatment expectancy and gave them hope for their potential recovery:

It really did help in having those choices put in front of me and not having to think about them, it made you realize that you know you could get there eventually.
[P 8]

Theme b: Changing Health Professionals' Perspective on What Is Important

This theme relates to the health professionals' perception of what is meaningful to patients when setting rehabilitation goals. All health professionals had an overall positive first experience with using ADOC, which was described as “valuable” [HP8, first interview, “straightforward” [HP2, second interview], “easy to use” [HP4, first interview], and as “a good tool” [HP3, second interview] to support goal setting with patients. Goal setting was described as a complex conversation to have with patients, which ADOC helped them navigate:

[ADOC] it's a nice way to approach a difficult discussion. What I really like about ADOC is that allows you to explore what they [clients] feel is important to them...because sometimes the stuff that the clients feel and the stuff that the therapists want to or perceive for the client are quite different. [HP5, first interview]

In addition, most of the health professionals expressed, both during the first and second interviews, that ADOC had the potential to promote a more patient-centered approach to goal setting. They identified that the patient-centeredness model was essential and fundamental to a strong relationship with patients but was sometimes overlooked for various reasons, such as time. Health professionals stated that ADOC had the potential to reinforce engagement and provide prompts to the discussion around goal setting with their patient. Health professionals strongly expressed the view that ADOC reinforced their patient-centered approach in clinical practice while setting rehabilitation goals:

It was really good just learning more about the client and just asking them different goals. I think usually I focus on what I think they kind of need to do to get home. [HP3, second interview]

If we can find out from their viewpoint what their goals are that may help them actually feel some ownership. [HP, second interview]

I feel like it [ADOC] definitely improves the whole client-centered approach. [HP8, second interview]

Almost all health professionals were positive about using ADOC in their clinical practice in the future; however, all agreed that they would not use ADOC with every patient. Health professionals stated that ADOC was not appropriate to use with patients with severe cognitive impairment or with patients who were already clear about and able to easily express their goals for rehabilitation:

I think it has to be a certain type of client though...like it honestly doesn't work with everyone. [HP7, first interview]

I have recently had a lot of clients with cognitive impairment and a lot of them would not have been appropriate. [HP7, second interview]

So, I think it's good for people who just have no idea what sort of goals to set so they can sort of look through and brainstorm what's important to them. [HP8, second interview]

Finally, few health professionals expressed the view that they would have set the same goals with or without ADOC. They suggested that ADOC was a good device to initiate a "difficult discussion" [HP5, first interview] and to help them "identify the importance of which goals the client wanted to work on" [HP4, first interview] but that otherwise ADOC would not support identifying unique or different goals.

I don't think that the end result changes. [HP2, first interview]

I don't feel that I necessarily got any extra goals that wouldn't have come out from the standard goalsetting process. [HP8, second interview]

Theme c: Facilitating Shared Decision-Making

Overall, most of the health professionals thought that ADOC facilitated their decision-making process and the identification of meaningful goals for their patients. Some health professionals reported that goals that were important to patients were sometimes overlooked during their usual goal-setting practice without ADOC. They also said that ADOC was helpful because it allowed identifying the most significant goals for the patient in a shared environment, which facilitated a shared purpose and prioritization:

For me, I missed that goal [toileting], but it was identified with ADOC. [HP5, first interview]

It was really good because we would never have thought of that [goal], well I would have never thought about it really before. [HP7, first interview]

He picked sleeping to be his number one priority which was interesting because obviously that's not necessarily something I think of. [HP8, first interview]

Most patients reported that ADOC improved the communication with their health professional, facilitated by the accompanying images. Having the option to decide which goal to work toward from a predetermined list made patients feel more empowered and more confident. Mostly the visual aspect of ADOC, where all the goals are illustrated by a deliberately designed image, was a key advantage for the patient. The images prompted and generated conversation, favored the patients' perspective when communicating with their health professionals, and motivated patients to strive for success in their rehabilitation. ADOC was defined as a very good tool for those patients that "want to get better but don't realize the potential they have" [P8]:

You know, not just for me but for a lot of the clients in here, images tell a thousand words. [P1]

The health professionals also valued the wide range of images used to represent the goals, which were seen as "helpful" [HP8, first interview] and as "support for their [patients] comprehension" [HP6, second interview]

Especially for my clients having that visual prompt or sort of like support for them gives them a better understanding of what they're discussing when it comes to goal. [HP6, second interview]

Theme d: Lack of Guides for Users

The health professionals also identified several areas where improvements could be made to ADOC and its application to goal setting. They commented on the lack of technical guides or documentation to support the use of ADOC. Although training was provided by the primary investigator at the beginning of this study, the health professionals expressed that it would have been useful to have a user manual or prompt sheet containing all essential information and step-by-step procedures for app access and use. Some health professionals stated that although ADOC was quite intuitive, a user manual would still

have been convenient so that it could be consulted whenever doubts arose:

It would be good to have a prompt sheet for the therapist to use with like a script to avoid any confusion when you're explaining it [ADOC] to the client. [HP7, first interview]

The second problem described was the absence of a visual guide that showed all the goal illustrations for patient users in a hard copy. Some patients stated that they would have preferred to look at the images of goals using a hard copy format before using the app, to increase their confidence in app use, to have as much time as needed to analyze the most meaningful goals, and to understand the total time required to scan each goal. Some patients felt “overwhelmed” [P1] and “frustrated” [P4] by the extent of content in ADOC and found the app “too long” [P4]. These patients also highlighted their lack of confidence in using technology in general. The health professionals also agreed some patients would benefit from reviewing all the goal images in hard copy before using the ADOC app:

I didn't really know the size of it [ADOC] because it wasn't in hard copy so I didn't really know what was coming, if there was a [hard] copy I would be able to just flick through and go okay I can get an idea of what this is about. [P4]

A hard copy might be quite nice that they [patients] could look through first and then when you came to do the goal-setting process, they were more familiar with all the symbols and everything. [HP8, second interview]

Theme e: Logistic and Organizational Barriers

This theme relates to all organizational and logistical issues that limited the use of ADOC in clinical practice. For instance, the health professional identified that while they had been invited to use ADOC with as many patients as possible, use of ADOC was limited by simple matters such as knowing where the organization's iPads were stored and being able to access them easily when they wanted one:

It's just actually the accessibility of the iPad and where it is and so if it's like in your visual field day-to-day, you're more likely to use it. So, I think having one iPad that's shared between both wards with multiple people on it is a little bit of a barrier with it. [HP2, second interview]

However, the key reason limiting the use of ADOC was the degree to which health professionals could prioritize the time required to use the app effectively set rehabilitation goals in practice. ADOC was considered by most of the health professionals as “time consuming” [HP4, second interview] and “not feasible” [HP5, second interview] to use regularly in a hectic work environment:

It took a long time with that client. It took a whole 60-minute session. It takes longer than I anticipate it will take. [HP7, second interview]

It just adds time just been really stressed and I've been really stressed for time this last couple of weeks. [HP8, second interview]

Therefore, the health professionals suggested that ADOC might have better utility in a community-based rehabilitation service, where patients receive rehabilitation over a longer period than in an acute setting and where, they believed, health professionals have more time to spend with their patients during goal-setting meetings:

It definitely works [better] closer to discharge, and it would work really nicely in the community. [HP2, second interview]

Moreover, some health professionals stated that the number of long-term goals illustrated in the app was higher than the number of short-term goals and that therefore community-based rehabilitation services would probably benefit more from the app:

A lot of the goals are really nice but they're very much community more goals, like longer-term. [HP7, second interview]

Theme f: App-Related Problems and Technical Issues

The health professionals noted that some goals they wanted to set were not available in the app, such as goals related to “mental health” [HP5, first interview], “memory” [HP4, first interview], and “managing pain” [HP4, second interview]. Of note, ADOC was specifically designed to focus goal setting toward functioning at the level of activities and participation and intentionally omits goals at the level of impairments of body structure and function; however, some health professionals nevertheless wanted to set impairment-oriented goals. Patients also noted these and other types of goals as being absent and included the ability to “multitask” [P8], or “manage grief and depression” [P3]. Both health professionals and patients suggested ADOC be improved by the option to add personalized goals, especially useful for those people who have “unusual jobs or hobbies” [P8]:

We [health professionals] just wondered whether there were some options, which might be really useful for people especially people who have traumatic brain injuries around managing frustration or managing behavior. The other ones that come up for us a lot is memory and concentration, those are quite big goals for a lot of people after they've had a brain injury. And we also talked about one having an option for something around kind of dealing with grief or something around feelings. [HP4, first interview]

Moreover, some health professionals highlighted that the images in the app (which had been drawn in Japan) were not representative of the multicultural make-up of New Zealand. There was a desire among the health professionals to have images to show patients to more accurately reflected the ethnicities of the people they worked with:

The images aren't multicultural. They are all sort of Asian based pictures which is fine, but you may have

some people that would like to see their ethnicity represented. [HP2, first interview]

I think the pictures are helpful, but I think when you get ones that are maybe more culturally appropriate for New Zealand, I think that that would be really helpful. [HP8, first interview]

Furthermore, the health professionals identified a few technical issues, which seemed to have hindered the use of ADOC in everyday practice. These technical issues included the lack of an interface between the app and their organization's hardware and systems. Examples included not being able to access the PDF treatment plan and not being able to email it to their work email or print it from their organizational printer:

I think one of the things that we had difficulty with is getting access to just printing the list of goals off. It's just a bit trickier process when it's the company's device we have to go through IT to organize it. [PH4, second interview]

Discussion

Principal Findings

This study found that overall ADOC was accepted and liked by both health professionals and patients as a tool for supporting shared decision-making for goal setting in rehabilitation, although some barriers to its implementation in clinical practice were identified. The aspects of the app that were most valued were its practical utility, that it promoted a patient-centered approach to goal setting, and that it facilitated communication between health professionals and participants about the objectives and direction of rehabilitation. This is the first study to show the utility and potential value of ADOC when used in an interprofessional context rather than solely in an occupational therapy context. These findings suggest that ADOC has the potential to be incorporated into clinical practice and be used by multidisciplinary teams. In this study, ADOC was valued by most of the patient participants because it enabled them to have a better understanding of what to expect from rehabilitation and therefore it empowered them to be more involved in meaningful decisions about their care. This aligns with the known benefits of patient participation in health care decision-making, which include increased patient satisfaction and trust, a better understanding of personal requirements, more positive communication with health professionals, increased sense of self-responsibility, and has implications for ongoing motivation, autonomy, and adherence to behaviors [32-34].

Our findings also emphasized the importance of a patient-centered approach in rehabilitation. Health professionals stated that ADOC promoted a more patient-centered approach when compared with their usual goal-setting practice; the app highlighted the value of building a better understanding of their patients' preferences and priorities. As patient-centeredness seems to be positively associated with higher levels of patient satisfaction and may improve treatment outcomes, health, and psychological well-being [35], this is a desirable benefit as a result of using ADOC. The health professionals in this study also identified several shortcomings of ADOC or challenges in its application to clinical practice. These included the increased

time needed to engage in goal setting, the lack of representativeness of illustrations to reflect a New Zealand population, and the lack of a written guide for users, which was perceived to be necessary.

We are currently working on a version of ADOC that includes images and content that reflects a more ethnically diverse population, with specific attention to the representation of Māori and Pacific people who collectively make up almost 25% of the New Zealand population [36]. We have also developed more detailed guidebooks on the use of ADOC in clinical practice, which will be tested in future studies. Issues around the time taken to undertake goal setting are more challenging to address as this relates to prioritizations of activities to support person-centeredness in the clinical setting. It is widely acknowledged that the adoption of new technologies can be hindered by insufficient training and education support for health care professionals [37,38]. Zheng et al [39], argued that health care professionals may find mobile health technologies disruptive to workflow when they do not complement work habits, when they create additional work, or when they present changes to familiar routines. The participants in this study reported that having easy and immediate access to iPad devices in their workplace and more time to dedicate to the goal-setting session with the patient would have facilitated the use of ADOC. They also speculated that ADOC may be more suited to use in community rehabilitation settings.

To date, there has been limited research comparing the use of technology in acute rehabilitation settings versus community rehabilitation settings. Therefore, future research regarding technology to support goal setting in a community-based rehabilitation setting is needed. Future implementation of such software should proactively address the barriers to the update of new technology identified in this study, particularly the need to integrate new technology with existing organizational processes. Finally, some of the health professionals in this study viewed the change of goal setting from an interview process to an interactive process as unhelpful. It has previously been recognized that individuals unwilling to change behavior practices and adopt new solutions into their workflow can obstruct the uptake of innovative technologies [40]. Therefore, identification of these people and strategies to address their concerns are needed if new technology is to be successfully implemented in practice.

Strengths and Limitations

A strength of this study is that it included a variety of health care professionals who specialize in rehabilitative care in testing ADOC in clinical practice. Previously, ADOC has only been tested and used by OTs in Japan. The qualitative approach also allowed a detailed exploration of users' experiences of ADOC in rehabilitation settings, producing information that can guide future research and implementation of this technology in clinical rehabilitation. Conversely, this study only involved a small number of health professionals and patients, so the transferability of these findings still needs testing. We also did not design this study to explore whether there was any clinical benefit for use of ADOC for goal setting in rehabilitation. A clinical trial design would be necessary to draw provisional conclusions about the

comparative treatment effect of a different approach to goal setting.

We also did not ask health professionals about their familiarity with technology before the study or their general views on technology adoption. As the interviews with health professionals did not highlight any views about difficulties in engaging with ADOC, we assumed that the health professional participants in this study were those with a generally positive attitude toward the use of technology in their practice. Therefore, we acknowledge that selection bias may have influenced our findings, which should be interpreted with this caveat. Future research should aim to recruit health professionals less keen and skilled in the use of technology in clinical practice. We also reported that access to iPads was a concern for health professionals, limiting the use of the app in goal setting. We ensured each locality was loaned two iPads if none were available onsite or we installed ADOC onto service-owned iPads, assuming that a few iPads could be easily shared within an interprofessional team. However, it would be desirable in future research to ensure that all health professionals always

have access to an iPad each when working clinically if testing the utility or benefits of ADOC. It has been widely stated that research should focus on producing and developing innovative technologies for integration into the health care system [5,15,41,42]. Our study suggests incorporating technology use into clinical practice remains challenging and attention to nontechnology-related barriers will be necessary to maximize the potential for digital health technology to improve quality of service delivery, patient satisfaction, and health outcomes.

Conclusions

On the basis of the results of this study, the iPad app ADOC has been shown to be a valuable tool for health professionals and patients while setting shared rehabilitation goals. As the study was exploratory and conducted with a small sample size, we believe that future research is needed to further understand the potential for ADOC to be a suitable app for supporting goal setting in the context of interdisciplinary rehabilitation. It is also crucial that future research further explores organizational, logistic, and technical barriers and addresses these to improve the potential benefit of ADOC.

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Conflicts of Interest

The authors of this paper receive no pecuniary benefit from the sale of ADOC products. K Tomori is the director of ADOC Project, which is the group that manages the ADOC app used in this study. All income from the sale of ADOC products is used in the maintenance of the software (ie, paying for programming, when Apple updates its operating system) and for further development of the application (ie, paying for illustrations and coding).

Multimedia Appendix 1

Consolidated Criteria for Reporting Qualitative Studies.

[PDF File (Adobe PDF File), 496 KB - [rehab_v8i4e33027_app1.pdf](#)]

Multimedia Appendix 2

Interview schedule with health professionals.

[DOCX File , 22 KB - [rehab_v8i4e33027_app2.docx](#)]

Multimedia Appendix 3

Interview schedule with patients.

[DOCX File , 20 KB - [rehab_v8i4e33027_app3.docx](#)]

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Abbreviations

ADOC: Aid for Decision-making in Occupational Choice

OT: occupational therapist

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Original Paper

Acceptance of Enhanced Robotic Assistance Systems in People With Amyotrophic Lateral Sclerosis—Associated Motor Impairment: Observational Online Study

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Abstract

Background: Amyotrophic lateral sclerosis (ALS) is a fatal neurodegenerative disease characterized by a progressive paresis of the extremities and the loss of manual functioning. Due to the severe functional impairment that the disease entails, ALS requires the provision of comprehensive nursing care and a complex set of assistive technology devices. To relieve caregivers and promote autonomy of people with ALS, robotic assistance systems are being developed. This trial aims to evaluate the acceptance of technology, in general, and of robotic arm assistance among people with ALS in order to lay the groundwork for the development of a semiautomatic robotic arm that can be controlled by humans via a multimodal user interface and that will allow users to handle objects and attend to their own bodies.

Objective: The aim of this study was to perform a systematic analysis of technology commitment and acceptance of robotic assistance systems from the perspective of physically limited people living with ALS.

Methods: The investigation was conducted as a study of a prospective cohort. Participants were only included if they had received a medical diagnosis of ALS. Data collection took place via an online questionnaire on the Ambulanzpartner Soziotechnologie internet platform. Technological commitment was measured using the Neyer short scale. Furthermore, a multidimensional questionnaire was specially developed to analyze participant acceptance of robotic arm assistance: the Acceptance Measure of Robotic Arm Assistance (AMRAA). This questionnaire was accompanied by a video introducing the robot arm. ALS severity was ascertained using the ALS Functional Rating Scale–Extended (ALSFERS-EX).

Results: A total of 268 people with ALS participated in the survey. Two-thirds of the participants were male. The overall mean ALS severity score was 42.9 (SD 11.7) points out of 60 on the ALSFERS-EX, with the most relevant restrictions on arms and legs (<60% of normal functioning). Technological commitment ranked high, with the top third scoring 47.2 points out of 60. Younger participants and males showed significantly higher values. The AMRAA score was, again, significantly higher among younger participants. However, the gender difference within the overall cohort was not significant. The more limited the arm functioning

of participants according to the ALSFRS-EX subscale, the higher the acceptance rate of robotic assistance. This relationship proved significant.

Conclusions: People with ALS display high technological commitment and feel positive about using technological assistance systems. In our study, younger participants were more open to technology use, in general, and robotic assistance, in particular. Self-appraisal of technology acceptance, competence, and control conviction were generally higher among men. However, any presumed gender difference vanished when users were asked to rate the anticipated usefulness of the technology, in particular the robotic arm. The acceptance was also reflected in users' increased willingness to use a robotic arm as the functionality of their own arms decreased. From the perspective of people with ALS, robotic assistance systems are critical to promoting individual autonomy. Another key consideration in the development of future assistive technologies should be the reduction of caregiver burden.

Trial Registration: German Clinical Trials Register DRKS00012803; <https://tinyurl.com/w9yzduhd>

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KEYWORDS

amyotrophic lateral sclerosis; assistive robotics; technology commitment; robotic arm assistance

Introduction

Amyotrophic lateral sclerosis (ALS) is a fatal neurodegenerative disease characterized by a progressive paresis of the extremities, loss of manual functioning, and a high degree of need for long-term care within 2 to 4 years. Cognitive functions are mostly unaffected, but people with ALS typically develop dysphagia and dysarthria as tongue and pharyngeal muscles weaken. Prevalence peaks in the seventh decade of life [1]. Because of the severe functional impairment it causes, ALS treatment requires the provision of comprehensive nursing care and a complex set of assistive technology devices (ATDs) [2]. The most common ATDs are home modifications, daily living devices, orthoses, transfer devices, augmentative and alternative communication devices, and mobility devices, such as electric and manual wheelchairs [2-4].

Robotic assistance systems for physically impaired people, like robotic arms, have recently been introduced into the field of medical devices [5]. These systems are designed to compensate for motor limitations of the hands and arms, particularly with regard to fine motor skills and grabbing. Advanced robotic assistance systems enable users to handle objects and attend to their own bodies. There are manifold ways to control robotic devices. If it is no longer feasible for a person to use a joystick or a point-and-click cursor, eye control and speech amplification are other options. Even brain-computer interfaces have been successfully evaluated in research environments, but they can only be implemented under certain conditions [6]. For applications such as drinking and feeding, autonomous [7] or semiautonomous [8,9] approaches are currently under evaluation.

Automatized and intelligent robotic assistance systems are designed not only to promote individual autonomy but also to relieve caregiver burden. The burden on caregivers is likely to increase in parallel to the severity of the disease, and is exacerbated by the general diminishment of physical functioning of the person concerned, which, in turn, can elevate caregiver stress levels [10]. In the later stages of ALS, the demands for assistance and treatment measures increase and become of greater importance. In particular, the repeated performance of

small and comforting actions (eg, minimal repositioning of extremities, scratching, itching, wiping off saliva in cases of sialorrhea, and correcting head positioning during the use of eye-controlled communication devices) can lead to stress and demoralization among caregivers and nursing professionals.

Since assistive robotic technology has become a subject of academic research, there has been a debate about its acceptance, especially among older adults [11]. This discussion often assumes that there are basically two realms in which assistive robots can be useful: the physical and the social. However, robotic applications do not have to be limited to these categories and can intervene in both. While even skeptics concede that robots are better able to perform certain standardized tasks than human caretakers, introducing robot-human interaction in a caregiving context may still be considered controversial. Physically assistive robots, on the other hand, are complex tools that can be widely implemented, and as with other technologies that are developed incrementally, it is more likely that they will be accepted.

The aim of this study was to investigate the acceptance of robotic assistance systems among people with ALS with regard to their physical impairment and willingness to accept technology-based care. As of today, no such structured data are available on these forms of ALS treatment.

Methods

Study Design

This observational study employed a cross-sectional descriptive design to perform a quantitative requirements analysis for the research and development project ROBINA (robot-supported services for individual and resource-oriented care of patients with ALS) [4,12]. It complies with the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) guidelines [13]. The data were compiled through a closed online survey comprised of four different parts that addressed the research question and was tailored to the target group. Two validated and standardized questionnaires pertaining to motor functioning and technology commitment were followed by a video of the research robot ([Multimedia Appendix 1](#)) and the newly developed Acceptance Measure of Robotic Arm Assistance

(AMRAA) with reference to that video ([Multimedia Appendix 2](#)).

Setting and Recruitment

To reach a broad convenience sample of participants with ALS, we created an online survey using an open-source web application designed by LimeSurvey [14]. The application was embedded into the protected internet platform of Ambulanzpartner Soziotechnologie (APST) [15]. The APST platform provides users with access to specialized therapists and coordinators that focus on case management, and has a tailored digital management platform with tools for self-assessment, medical services, therapy, and assistive devices [3]. This digital and internet-supported case management network has existed since 2011 and, at the time of our survey, it coordinated the care requirements of more than 3700 people who had been diagnosed with ALS according to the revised El Escorial World Federation of Neurology criteria [16]. Those people and their caregivers were granted access to the APST platform through private individual accounts. In joining the network, participants consented to possible future contact from scientific institutions as approved by the Berlin Institutional Review Board and Data Security.

Participants

Requests to participate in the survey were submitted via email to approximately 2600 registered members of the APST platform. To qualify for our survey, participants needed to have a confirmed medical diagnosis of ALS following the revised El Escorial World Federation of Neurology criteria [16]. After registering with APST, participants provided medical documentation containing their diagnosis, including a physician's letter, which was subsequently entered into the database by an experienced case and data manager.

Variables and Data Sources

Brief Measure of Technology Commitment

Technology commitment gauges individual willingness to use technology via three distinct domains: technology acceptance, technology competence conviction, and technology control conviction [17]. Neyer et al developed a model for measuring and scaling technology commitment via these three domains. The model is premised on 12 statements upon which respondents agree or disagree on a scale from 1 (fully agree) to 5 (fully disagree). Each domain correlates to four statements, and the results can be analyzed individually or as a whole; the total score ranges from 12 to 60, with a high value corresponding to a higher general commitment to technology. The technological competence conviction numbers must be re-encoded when calculating the final score, as its statements are phrased in negative terms.

ALS Functional Rating Scale–Extended

We evaluated the functional impairment of participants using the ALS Functional Rating Scale–Extended (ALSFRS-EX), which was developed in an online community [18] and subsequently validated in German [19]. We found that the long-standing predecessor of this instrument, the ALS Functional Rating Scale–Revised (ALSFRS-R), produced

comparable results to in-clinic evaluation, even though our testing was performed online [20]. The extended version includes three additional questions, which enhances the sensitivity of the score by better reflecting the deterioration of physical functioning that occurs in advanced stages of ALS. In particular, by inquiring about the operability of buttons, the ALSFRS-EX prioritizes manual functioning and focuses on the motor restrictions that are relevant to this project. In addition to assessing fine motor functions, each individual score assesses gross motor functions of the upper and lower extremities, bulbar functions, and breathing abilities. The survey is comprised of 15 short, clear questions with responses given on a 5-point scale ranging from 0 (total loss) to 4 (fully preserved). Hence, the total score for the scale ranges from 0 to 60 points, with fewer points representing more severe symptoms. The loss of ALSFRS points per month, or delta ALSFRS, indicates the rate of deterioration and predicts survival [14].

Video of the Enhanced Research Robot

Our research program aims to develop robotic assistance and resource-oriented care for individual people with ALS. Assistive robots should not only be controllable by the patient through an interface, but they should also be able to perform minimal comforting actions with partial autonomy. The most advanced robotic arm in Germany—and perhaps anywhere in the world—is our technological starting point. The Franka Emika Panda is an industrial robot designed with a sense of touch and equipped with sensors [21]. The robot is intended to work with humans, and, in the future, it should be able to autonomously perform simple tasks, likely by integrating object recognition. To illustrate a robotic arm and the robot's potential, participants were shown a short video highlighting several features of the arm (see [Multimedia Appendix 1](#) for the video). At the time of our survey, the most recent state of development was not available, but developers were training the robot to scratch participants' skin with a small brush and have it detect and reach for objects.

Acceptance Measure of Robotic Arm Assistance

We developed a new measurement tool, the AMRAA, to evaluate how willing participants would be to accept the assistance of a robotic arm. The items and domains of this tool were developed by a group of experts from the fields of ALS research, ALS care, and aging and technology. This instrument consists of 10 statements upon which respondents agree or disagree on a 6-point Likert scale ranging from 0 (fully disagree) to 5 (fully agree). The items are merged into three domains: experience with robotic assistance (2 items), current need of robotic arm assistance (4 items), and future usage of robotic arm assistance (4 items). A maximum total score of 50 points can be achieved if the individual agrees to each statement to the greatest possible extent. A version of this scale translated into English is in [Multimedia Appendix 2](#).

The instrument went through a pretest process with people with ALS, after which the statements were strengthened. No complete validation process was carried out in advance of its use; however, rotated component analysis confirmed a strong loading ($\lambda > 0.6$) of the items in the three domains of the questionnaire,

with a balanced cross-loading of two items between current need and future usage domains ([Multimedia Appendix 3](#)).

Data Analysis

Data were analyzed with SPSS Statistics for Windows (version 25; IBM Corp). Results were expressed as means and SDs if normally distributed, and medians and IQRs if numerical data were visualized or if distribution was non-Gaussian. Correlational analysis was performed with Spearman ρ because of the ordinal nature of the scales. For group differences of nonparametric data, the Mann-Whitney U test was performed for two independent samples, and the Kruskal-Wallis one-way analysis of variance was performed for three independent samples. Factor analysis was conducted using the iterated principal factor method with varimax rotation. A P value of $<.05$ (two-tailed) was considered significant.

Protocol Approvals and Registrations

People who participate in the APST network agree to take part in scientific surveys and trials. Informed consent forms were obtained from all participants. Furthermore, the online survey and study protocol have been approved by the Medical Ethics Committee of the Charité – University Hospital Berlin, Germany, as a part of the requirements analysis for the ROBINA

project with a mixed methods approach (approval No. EA1/121/17). The trial has been registered at the German Clinical Trials Register (DRKS00012803) and with the World Health Organization International Clinical Trials Registry Platform.

Results

Overview

A total of 268 participants, 10.1% of all persons queried across 16 ALS centers in Germany, took part in the online survey. Of the total number of participants, 53.4% ($n=143$) were patients of the ALS outpatient department at Charité – University Hospital Berlin.

The mean age of all participants at the time of response was 60 (SD 10.6) years (range 33–87); participants had a median disease duration of 27 (IQR 41) months (range 2–227). There was a comparatively high percentage of long-term survivors in our trial. Out of all participants, 22.0% ($n=59$) had a disease duration of 5 years or more, which is why the cohort showed a relatively slow median course of the disease on average. [Table 1](#) summarizes the baseline population characteristics of all participants.

Table 1. Participant demographics and baseline disease characteristics.

Characteristic	Value (N=268)
Age (years), mean (SD)	60 (10.6)
Gender, n (%)	
Female	88 (32.8)
Male	180 (67.2)
ALSFRS-EX ^a baseline score, mean (SD)	42.9 (11.7)
Delta ALSFRS-EX ^b , median (IQR, range)	0.56 (0.81, 0.01–4.5)
Duration of disease (months), median (IQR, range)	27.0 (41, 2–213)

^aALSFRS-EX: Amyotrophic Lateral Sclerosis Functional Rating Scale–Extended.

^bLoss of ALSFRS-EX points per month.

Main Results

Brief Measure of Technology Commitment

The general commitment to technology use was high across all age groups (mean 47.2, SD 8.2, out of 60 points), but was significantly higher among participants under 60 years of age ([Figure 1](#)). Males showed a significantly higher technology commitment when compared to females (median 49.5 vs 44 points, respectively; $P<.001$; [Figure 1](#)).

A gender difference was also evident in the three domains of technology commitment ([Figure 2](#)). The self-assessment showed a significantly higher technology competence conviction among younger participants (age ≤ 60 years; $P<.001$; [Figure 2](#)).

There was no difference between age groups in terms of technology acceptance and technology control conviction. Within our cohort, the increasingly restricted arm functioning, as measured by the ALSFRS-EX subscale, had no measurable effect on general technology use commitment or its domains.

Figure 1. General technology commitment as a function of age and gender. The horizontal lines in the blue boxes represent the medians. Whiskers indicate minimum and maximum. *P* values were based on the Mann-Whitney *U* test.

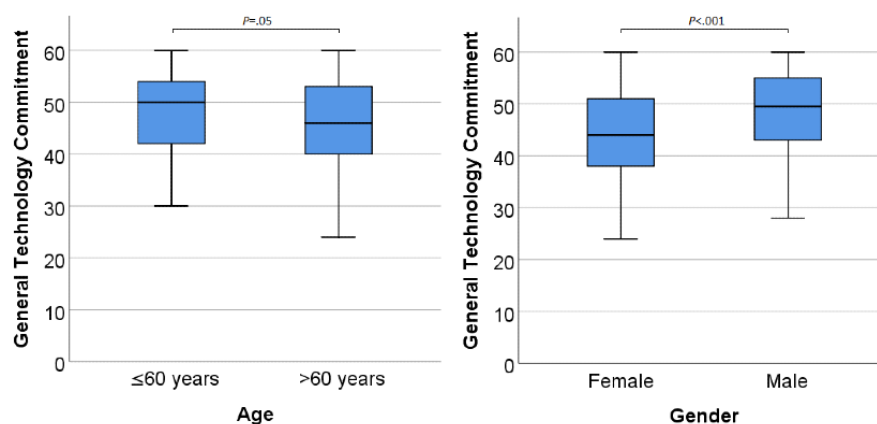
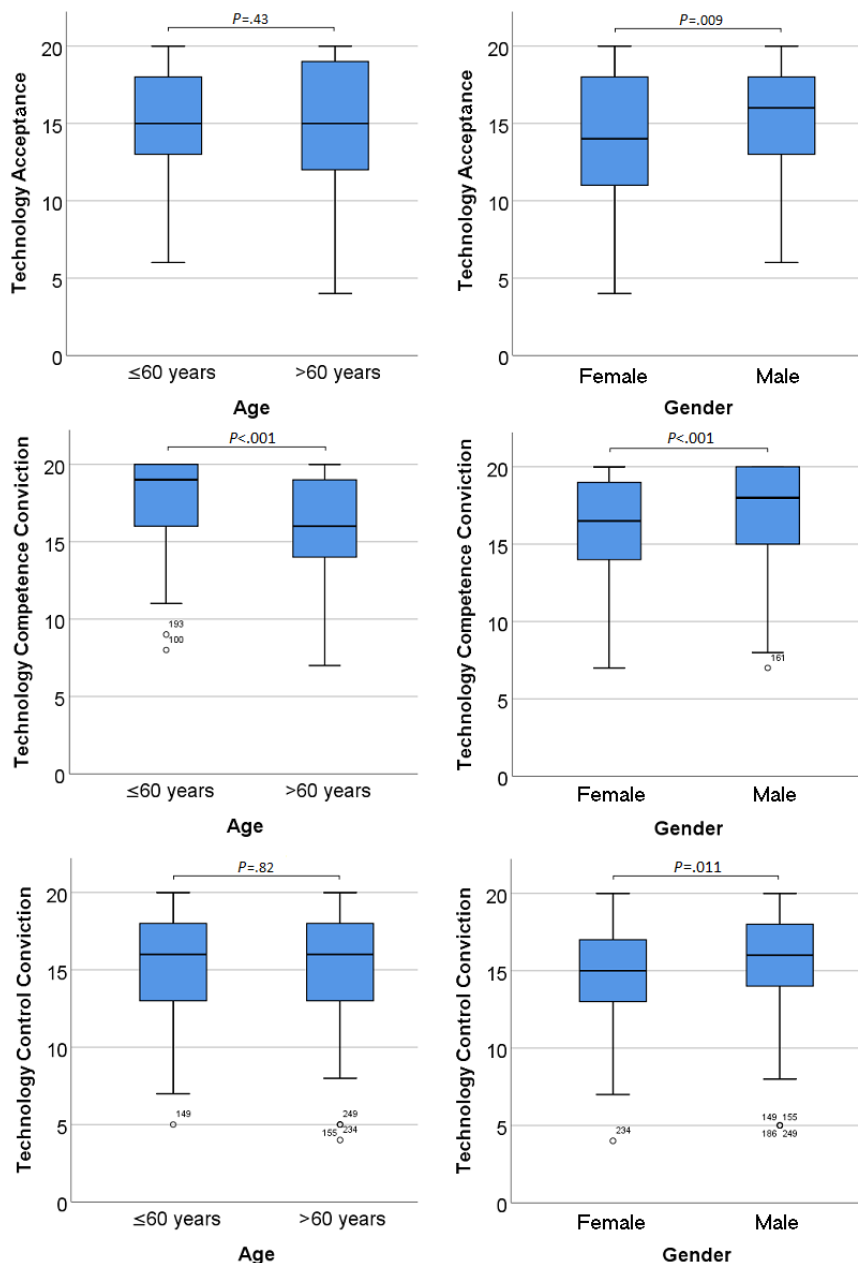


Figure 2. Single domains of technology commitment as a function of age and gender. The horizontal lines in the blue boxes represent the medians. Whiskers indicate minimum and maximum. Circles on plots represent outliers outside the 1st or 3rd quartiles $\pm 1.5 \times \text{IQR}$. *P* values were based on the Mann-Whitney *U* test.



ALS Functional Rating Scale–Extended

Respondents had a mean ALSFRS-EX score of 42.9 (SD 11.7) at the time of the survey, with a median loss since disease onset of 0.56 (IQR 0.81) points per month on average. Within our population, people were most severely impaired in arm and leg functioning. As depicted in [Table 2](#), upper and lower limbs were

functioning, on average, at less than 60% of normal rates. Bulbar and respiratory functions were less affected. This distribution can be explained if we assume that the majority of affected participants initially had symptoms in their extremities, which is referred to as spinal onset, and which occurs in about 80% of German cohorts [22].

Table 2. Functional impairment of participants according to the ALSFRS-EX and its domains.

ALSFRS-EX ^a domain	Maximum reachable points, n	Achieved points, mean (SD)	Relative function, %
Swallowing, speech, and facial expression	16	12.3 (4.0)	76.9
Upper limbs: finger and arm function	16	9.6 (5.0)	58.7
Lower limbs: walking and leg function	16	9.5 (4.9)	59.4
Dyspnea and breathing: respiratory function	12	10.5 (2.2)	83.7
All domains	60	42.9 (11.7)	71.4

^aALSFRS-EX: Amyotrophic Lateral Sclerosis Functional Rating Scale–Extended.

Acceptance Measure of Robotic Arm Assistance

Before participants were asked to rate statements about robotics and robotic arm assistance on the newly developed AMRAA, a video about a robotic arm was presented. Of the participants who evaluated the particular statements, 30.6% (79/258) reported they had already gathered information on robotic assistance systems. Additionally, 12.4% (32/258) were already using robotic assistance systems in their daily lives (eg, robotic lawn mower and robotic vacuum cleaner). A total of 19.9% (51/256) of respondents stated that they wanted robotic assistance for their daily care. With regard to the statement that a robot arm would support their independence, 28.2% (70/248) agreed. Moreover, 40.6% (99/244) of participants could imagine using robotic assistance systems for actions performed far from their bodies (ie, outbound activities, such as passing objects), and 35.0% (86/246) could imagine using a robotic device to

attend to their own body (ie, inbound activities, such as wiping off saliva and scratching). The vast majority of participants (175/241, 72.6%) felt that robotic assistance systems should be established as prescribed medical devices, as shown in [Figure 3](#).

Younger participants showed a significantly higher willingness to use robotic arm assistance compared to older participants (median 25.5, IQR 17.25, vs median 16, IQR 18.5, respectively; $P<.001$; [Figure 4](#)). Higher acceptance among younger participants was also present across all domains of the questionnaire ([Table 3](#); [Multimedia Appendix 4](#)).

There was no significant gender difference in the general acceptance of a robotic arm, although men tended to be more receptive. Interestingly, in the domain “experience with robotic assistance,” the gender difference proved significant ($P=.03$; [Table 3](#); [Multimedia Appendix 4](#)).

Figure 3. Acceptance Measure of Robotic Arm Assistance (AMRAA) ratings of statements about robotics and robotic arm assistance. Percentages of the ratings at each level (disagree = 0-1, neutral = 2-3, and agree = 4-5) for each statement are shown on the bars.

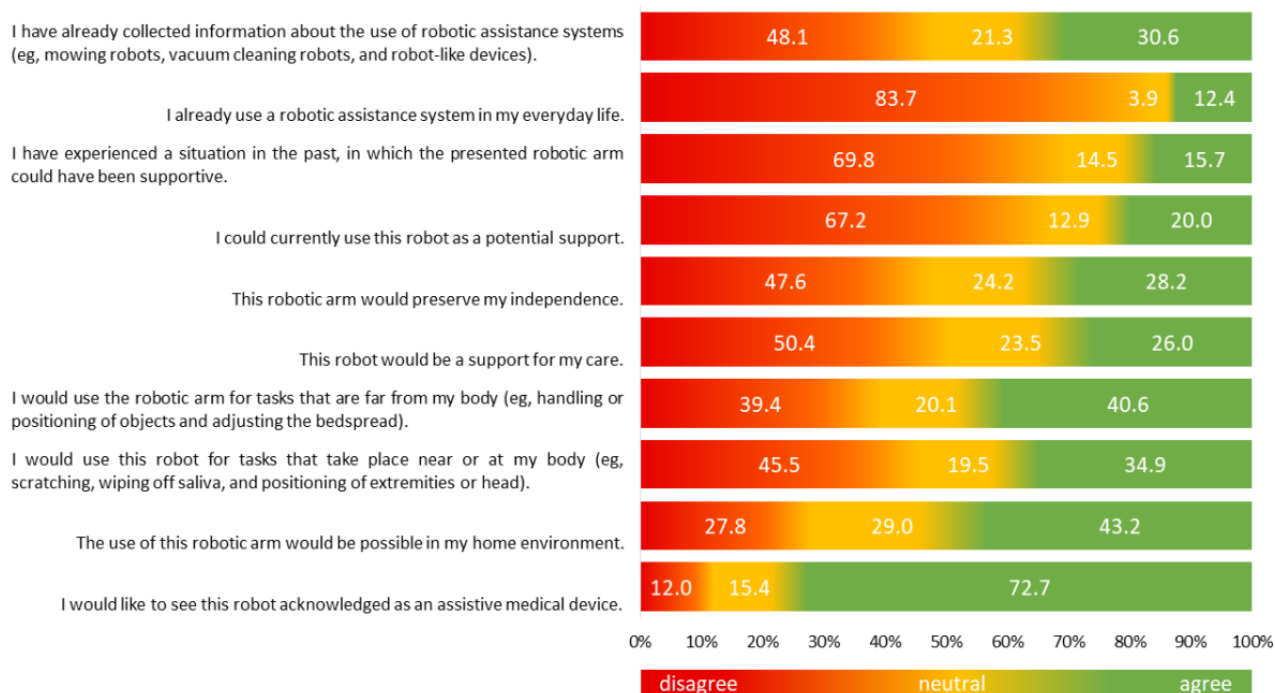


Figure 4. Acceptance Measure of Robotic Arm Assistance (AMRAA) scores as a function of age and gender. The horizontal lines in the blue boxes represent the medians. Whiskers indicate minimum and maximum. *P* values were based on the Mann-Whitney *U* test.

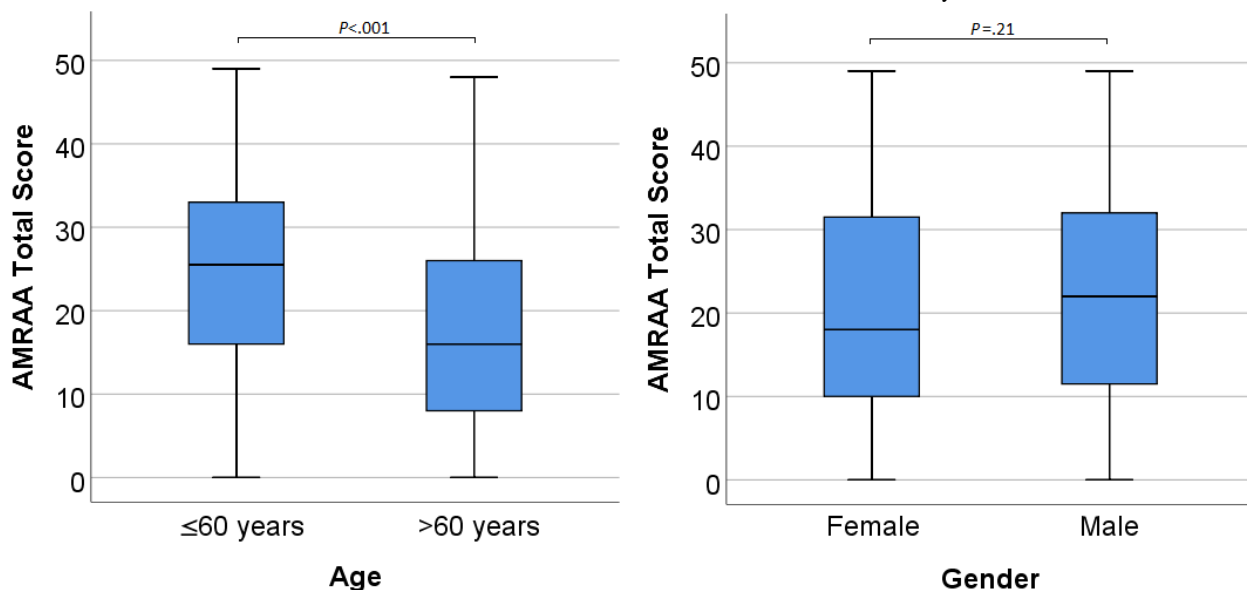


Table 3. AMRAA scores by domain for age and gender groups.

AMRAA ^a domain	Age (years), median (IQR)		<i>P</i> value ^b	Gender, median (IQR)		<i>P</i> value ^b
	≤60	>60		Female	Male	
Current need of robotic assistance (4 items)	8 (10)	3 (9)	<.001	4 (10)	6 (10)	.27
Future usage of robotic assistance (4 items)	15 (9.5)	10 (10.5)	<.001	11 (12)	13 (10)	.24
Experience with robotic assistance (2 items)	3 (5)	2 (4)	.003	1 (4)	2 (5)	.03
All domains	25.5 (17.25)	16 (18.5)	<.001	18 (21.75)	22 (21)	.21

^aAMRAA: Acceptance Measure of Robotic Arm Assistance.

^b*P* values were based on the Mann-Whitney *U* test.

Based on the ALSFRS-EX subscale for arm functioning, we categorized participants into three groups: “slightly to not restricted” (8-12 out of 12 points), “moderately restricted” (4-7 out of 12 points), and “highly restricted” (0-3 out of 12 points). Within the respective groups, we found that the more limited the arm functioning, the higher the acceptance of robotic

assistance. This relationship proved significant (Table 4 and Multimedia Appendix 5). This relationship was most evident in the domains of “current need of robotic assistance” and “future usage of robotic assistance.” A decrease in arm functioning was also moderately correlated [23] with the AMRAA score ($r=0.32$, $P=.01$; Table 4).

Table 4. Group differences between AMRAA total and domain scores for the three ALSFRS-EX arm functioning subscale groups, and correlations between AMRAA scores and arm functioning.

AMRAA ^a domain	AMRAA scores for ALSFRS-EX ^b arm functioning subscale groups, median (IQR)			<i>P</i> value ^c	Correlation between AMRAA score and arm function, <i>r</i>	<i>P</i> value ^d
	Slightly to not restricted	Moderately restricted	Highly restricted			
Current need of robotic assistance	4 (8)	7 (11.25)	10 (11)	<.001	0.38	.01
Future usage of robotic assistance	10 (10.25)	14 (10.25)	15 (9)	.03	0.22	.01
Experience with robotic assistance	2 (4)	2 (5)	3 (7)	.23	0.08	.23
All domains	17 (17.25)	22 (22.25)	32 (20)	<.001	0.32	.01

^aAMRAA: Acceptance Measure of Robotic Arm Assistance.

^bALSFRS-EX: Amyotrophic Lateral Sclerosis Functional Rating Scale–Extended.

^c*P* values for group differences were based on the Kruskal-Wallis test.

^d*P* values for correlation analysis were based on Spearman ρ .

Discussion

Principal Findings

The aim of this study was to evaluate the principal needs and conditions for the care and maintenance of people with ALS through robotic arm assistance. By using the APST network, we were able to recruit a high number of participants from ALS centers all over Germany to take part in this online survey. The study was part of the requirements analysis for the development of a semiautonomous robotic arm for people with ALS.

Participants self-assessed a high degree of technology commitment, regardless of motor restriction. Males, as compared to females, achieved significantly higher values in all three domains and higher composite scores. Age was a factor in how participants judged their own technological competence. Younger participants credited themselves with greater competence in dealing with new technologies. Interestingly, self-assessment rates via technological acceptance and the belief in being able to control technology were not significantly lower among older participants compared to younger participants.

After presenting a video of an assistive robotic arm prototype, we gave participants a newly developed questionnaire on this particular robotic arm. The results were comparable to the general outcome of technology commitment, but a gender-specific difference was much less obvious. There was clear evidence that younger participants, as compared to older participants, would prefer to use a robotic arm. This result is consistent with other studies on technology acceptance and is attributed to the fact that younger people are more familiar and experienced with new technologies [24].

In the context of moderating variables, the degree of physical limitation was a key factor in technology acceptance and intention to use technology. We also observed that the degree to which manual and arm functioning were impaired had a considerable effect on the fundamental attitudes toward the robotic arm. The more advanced the functional limitation of their arms, the more the participants could imagine using robotic assistance.

Interactions with the robotic arm, which attends to one's own body compared to the application leading away from the body, were positively evaluated by slightly fewer participants, but this difference was negligible.

Interestingly, gender played no relevant role in the demand for, or acceptance of, a robotic arm. This is of interest because technological self-efficacy is lower among women, which may have an impact on perceived usefulness. In addition, the literature suggests that women's acceptance of technology is often related to ease of use rather than the usefulness of a particular technology for a particular purpose [25]. Although in our study the use of a robotic assistive device was only shown on video, it can be assumed that this demonstration made the perceived utility more understandable. In this context, Flandorfer refers to how moderating factors, such as previous experience with the technology, can have a mediating effect, especially in counteracting age and gender differences [24]. With regard to acceptance and use patterns, studies also show the importance of positive experiences in dealing with innovative technologies, especially for user groups that are characterized by low self-efficacy and greater reluctance to use technology [24]. In addition to physical limitations, however, some people with ALS show cognitive deficits and affective disorders [26]. Since such mental illnesses can reduce the acceptance of assistive robotics, their use should be adapted to meet individual needs [27,28]. Participants also recognized the fact that the robotic arm would support caregivers and assessed the benefit to them as comparable to their own benefit.

Given the socioeconomic and psychosocial focus of ALS treatment and care, assistive technologies represent a win-win-win solution: they not only ease difficulties for functionally impaired people, but their production also propels the economy and their use addresses challenges presented by the shortage of working nurses in aging populations. Optimal and targeted handling of assistive robotic arms should minimize obstacles to implementation, and the use of such systems will improve the care and autonomy of people with ALS. This is underlined by the fact that the possibility of using robotic arms as assistive devices was supported by an overwhelming majority of respondents.

Limitations

The crucial limitation of questionnaire-based surveys is that these instruments restrict conclusions to certain concepts framed

by terminology. The newly developed AMRAA has not yet been validated and may still be further refined. A certain acquiescence tendency caused by the statements and even the aforementioned video, despite the ambition of maintaining neutrality, may lead to response bias. However, the insights that this instrument allows for are valuable for the establishment of robotics as an assistive framework and it has the potential to be used in further studies on the acceptance of ATDs.

Further limitations to our study were that we reached out to participants via email, and we conducted our survey online. It must, therefore, be assumed that those who participated had a higher technological affinity or at least good access to technology. Members of our population were treated at specialized centers in a technologically advanced country; therefore, our findings may not be applicable to other populations.

People with impaired arms, such as people with ALS, may not only acknowledge the benefits of a robotic arm, but they may also have more experience with assistive technologies and, therefore, be more motivated to use them [29]. Lastly, our trial did not focus on key sociodemographic factors, such as socioeconomic status, family and care situation, or cultural background.

Conclusions

The robotic arm supports people with limited functioning in performing elementary manual actions autonomously, such as gripping and handling, with the aid of a device. The use of assistive robotics can increase individual independence with regard to daily activities and motor self-determination. This study identifies the existing demand for assistive robotics and the relationship between this demand and functional limitations. Establishing the general and specific technological commitments of people with ALS is an important precondition for integrating the provision of a robotic arm into an individual, participatory, and autonomy-oriented understanding of medical aid in ALS treatment. Future studies should investigate how these assistive technologies improve the everyday function of grasping and, thus, the quality of life of people with ALS.

Acknowledgments

This work was part of the ROBINA (robot-supported services for individual and resource-oriented care of patients with amyotrophic lateral sclerosis) project and was supported by the German Federal Ministry of Education and Research (grant 16SV7712). The authors wish to thank the Boris Canessa ALS Stiftung (Düsseldorf), "Initiative für Menschen mit ALS" (Berlin), and Bremer ALS Stiftung (Bremen) for continuous support. We acknowledge support from the German Research Foundation (DFG) and the Open Access Publication Fund of Charité – University Hospital Berlin. The authors would like to thank editor Jessica Loudis for her editorial support.

Conflicts of Interest

AM received presentation fees from Merz Pharma GmbH & Co KGaA. TM received consulting fees from Cytokinetics, GSK, and Desitin Arzneimittel GmbH; TM served on scientific advisory boards for Cytokinetics, GSK, and TEVA. TM and CM are founders of the internet platform Ambulanzpartner and hold shares of APST GmbH. All other authors declare that they have no conflicts of interest.

Multimedia Appendix 1

Video of the robotic arm.

[MP4 File (MP4 Video), 10617 KB - [rehab_v8i4e18972_app1.mp4](#)]

Multimedia Appendix 2

Acceptance Measure of Robotic Arm Assistance (AMRAA).

[PDF File (Adobe PDF File), 572 KB - [rehab_v8i4e18972_app2.pdf](#)]

Multimedia Appendix 3

Rotated component matrix of the Acceptance Measure of Robotic Arm Assistance (AMRAA).

[PDF File (Adobe PDF File), 12 KB - [rehab_v8i4e18972_app3.pdf](#)]

Multimedia Appendix 4

Acceptance Measure of Robotic Arm Assistance (AMRAA) scores for various domains as a function of age and gender. The horizontal lines in the blue boxes represent the medians. Whiskers indicate minimum and maximum. *P* values were based on the Mann-Whitney *U* test.

[PNG File , 76 KB - [rehab_v8i4e18972_app4.png](#)]

Multimedia Appendix 5

Group differences between the total AMRAA score and three AMRAA domain scores for the three ALSFRS-EX arm functioning subscale groups: "slightly to not restricted," "moderately restricted," and "highly restricted." *P* values for group differences were based on the Kruskal-Wallis test. ALSFRS-EX: Amyotrophic Lateral Sclerosis Functional Rating Scale–Extended; AMRAA: Acceptance Measure of Robotic Arm Assistance.

[PNG File , 75 KB - [rehab_v8i4e18972_app5.png](#)]

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Abbreviations

ALS: amyotrophic lateral sclerosis

ALSFRS: Amyotrophic Lateral Sclerosis Functional Rating Scale

ALSFRS-EX: Amyotrophic Lateral Sclerosis Functional Rating Scale-Extended

ALSFRS-R: Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised

AMRAA: Acceptance Measure of Robotic Arm Assistance

APST: Ambulanzpartner Soziotechnologie

ATD: assistive technology device

CHERRIES: Checklist for Reporting Results of Internet E-Surveys

ROBINA: robot-supported services for individual and resource-oriented care of patients with amyotrophic lateral sclerosis

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Original Paper

User-Centered Design of Companion Robot Pets Involving Care Home Resident-Robot Interactions and Focus Groups With Residents, Staff, and Family: Qualitative Study

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Abstract

Background: Globally, pressure is increasing on health and social care resources due to the aging population and growing prevalence of dementia. Companion robots, such as Paro, demonstrate strong potential for helping reduce this pressure through reported benefits including reduced agitation, depression, loneliness, care provider burden, and medication use. However, we previously identified that user-centered design of robot pets is both essential and understudied. We observed that commonly used robot pets are poorly matched to end-user requirements, and that end users and developers of robot pets differ significantly in their perception of appropriate design. This may explain some of the contradictory outcome research and variance in results for robot pets, such as Paro.

Objective: In response to the literature gap, we aimed to provide user-centered insights into the design of robot pets from key stakeholders to inform future robot development and the choice of robots for real-world implementation and research. We focused on understanding user requirements.

Methods: We conducted a qualitative study with 65 participants from 5 care homes (26 care home residents, 29 staff members, and 10 family members). Care home residents formed groups of between 3 and 4 individuals and experienced free interactions with a range of 8 companion robots and toys, including Paro and more affordable alternatives. The robots provided had a range of aesthetics, shell types, interactivity levels, and designs for comparison. Care staff and family members observed the interactions. All participants then engaged in focus groups within their stakeholder category to discuss preferences and user requirements in companion robot design. Both free interactions and focus groups were video and audio recorded, transcribed, and subjected to thematic analysis.

Results: Care home residents, family members, and staff were open and accepting of the use of companion robot pets, with the majority suggesting that they would keep a device for themselves or the residents. The most preferred device was the Joy for All cat, followed by the Joy for All dog. In discussions, the preferred design features included familiar animal embodiment (domestic pet), soft fur, interactivity, big appealing eyes, simulated breathing, and movements. Unfamiliar devices were more often seen as toy-like and suitable for children, producing some negative responses.

Conclusions: This work provides important and user-centered insights into future robot designs for care home residents by means of a comprehensive comparison with key stakeholders. This work strongly supports the use of familiar embodiment in future robot pet designs, with domestic cat and dog morphologies appearing most acceptable. The results have implications for future robot designs and the selection of robot pets for both research and real-world implementations.

KEYWORDS

companion robots; social robots; Paro; older adults; dementia; care homes; engagement; acceptability; gerontology; Joy for All; social care; user-centered design

Introduction

Background

The population worldwide is undergoing a demographic shift, and with life expectancy increasing, a greater proportion of the population is of retirement age or above [1]. This puts pressure on health and social care resources [2], because human function generally deteriorates with age [3]. Due to a lack of resources, there is increasing reliance on pharmacology in care homes [4], which can be problematic due to serious side effects, increased risk of cardiovascular events [5], and mortality [6]. Steptoe et al [7] suggested that these challenges indicate an increased need for research on maintaining well-being. One psychosocial method of improving well-being is the use of companion robots [8]. The most researched companion robot is Paro the seal [9-11], with reported benefits including reduced agitation and depression in dementia [12,13], more adaptive stress response, reduced care provider burden [14], and significantly improved affect (feelings/emotions) and communication between dementia patients and day care staff [15]. Further research has suggested that Paro may reduce psychoactive and analgesic medication use [16], and even decrease blood pressure [17]. However, a particular challenge with wider implementation of Paro is its price of approximately £5000 (approximately US \$6900), which limits the number of people able to benefit [18]. Care staff in previous work suggested that this price is too high for care homes [18], demonstrating that the device is poorly matched to the context of use.

Furthermore, the positive results have been questioned as being overly optimistic [19]. A comparison between an active Paro robot and a plush toy found that the benefits of the Paro robot were limited to only engagement [8]. Robinson et al [20] found no main effect for depression (seeing a significant decrease for only loneliness). Thodberg et al [21] compared live dog visits to Paro sessions over 6 weeks and found no improvement in depression with either approach. Moyle et al [22] also found considerable variation in responses to Paro in a large randomized controlled trial. The variation may have resulted from many factors, such as participant loneliness and therefore the need for such devices, and participant like/dislike of animals. However, it is possible that design flaws limit more wide-spread acceptance. For example, research assessing the suitability of Paro for a dementia unit suggested that it may need adapting for such settings as, for instance, its vocalizations can be distressing [23]. Furthermore, while robot pet comparisons have been lacking [9], older adults expressed a significant design preference for pets with familiar embodiments (cats and dogs) when alternatives were provided for comparison with Paro, which demonstrated poor acceptability among older people when preferred devices were available [24]. It is therefore possible that the design of Paro does not match user requirements, in addition to the poor matching of the user

context in terms of affordability for real-world adoption. Robot pet implementation and impact may be more consistent with a user-centered design approach to ensure devices match user requirements and the context of use.

User-centered design is the process of involving stakeholders in all stages of product development to create products that are effective, efficient, and satisfactory for the goals of the specific user [25]. Moyle et al [2] suggested involving consumers in conceptualization, development, and testing of companion robots as this may improve appropriateness and practicality to promote acceptability and thus ultimately usage [26]. Daly-Jones et al [25] proposed a cycle of the following 4 key activities: specify user/organizational requirements, understand and specify the context of use for the device, produce prototypes, and conduct user-based assessment. This study therefore aimed to address the first of these activities and provide the understanding and specification of user requirements by engaging key stakeholders in robot evaluations and design discussions.

The design and cost challenges of Paro are problematic considering the large selection bias toward Paro in companion robot research [9-11], thus limiting formation of an evidence base for alternative devices and restricting the understanding of end-user perceptions. Our previous work [24] identified the importance of user-centered design within this field by comparing perceptions of older adults (as end-users) and roboticists (as developers) toward suitable design for a robot pet for older adults. Our results demonstrated significant mismatch in perceptions, with older adults preferring familiar and less sophisticated devices, such as the Joy for All (JfA) cat and dog, and roboticists favoring the potential of Paro. However, we had a relatively small sample of older participants who were more independent than care home residents and were living instead in supported living settings. Therefore, this study aimed to provide insights on user requirements for care home residents to inform user-centered design of companion robots, with implications for future robot design.

Previous Research

Kachouie et al [9] conducted a review and noted the lack of available companion robot comparison studies, which limits the ability to compare Paro with alternatives and understand user-centered design requirements. The few available comparison studies include the work of Heerink et al [27] who compared 4 robots and asked care providers which features were most important. Additionally, 15 people with dementia interacted with each robot for 1 minute, with researchers observing and counting reactions, such as hugs, kisses, and smiles. The results from care providers suggested that the most important features were having soft fur, looking like a real-life pet, and having appropriate sounds, among others. An issue with this research, however, is the primary focus on care provider perceptions, rather than the opinions of older adults

themselves as end-users of the devices. Research has suggested that a person's stakeholder category can influence technology acceptance [28,29]. Perceived requirements for support in health care can vary among various stakeholder groups, from patients to informal caregivers to professionals [30], and therefore preferred features may differ between the categories of end-users and care providers. The research also failed to include Paro for comparison. As Paro is the most well-researched companion robot available [10], it appears essential for any comparison of companion robots to include Paro. In response, we compared alternatives to Paro directly. A further possible limitation of the study by Heerink et al [27] is the apparent lack of randomization of robot presentation order, which may have introduced bias, as well as reliance on observation. Weaknesses of observational approaches include the Hawthorne effect, observer bias, missed information during live observation, and limited means of validating observed events after observation [31]. In response, we used recording equipment to allow multiple researchers to review and analyze the results, as done in previous research with Paro and older adults [8], resulting in improved validity.

Lazar et al [32] likewise aimed to "rethink" the design of robot pets for older adults and conducted focus groups with 41 independently living older adults, with discussions on issues around companion robots, such as the fiction of a robotic animal, the social role of the robot, and reciprocity. Participants were introduced to 6 devices. The results suggested that some tension existed toward robots as companions, particularly with reference to fiction and lack of human contact. Participants preferred soft, cuddly, and entertaining devices. An issue with this research however was that none of the 6 devices included were designed for older adults specifically, and they were primarily brightly colored children's toys. Using robots in contexts for which they are not designed can perpetrate negative stereotypes [2], potentially explaining the frictions noted from older adults toward the use of such devices.

Previous research has similarly investigated the use of different esthetics and behaviors of robots. Jones et al [33] provided robots with varying degrees of zoomorphic dog-like behaviors to general population participants and explored, using Likert scales, satisfaction and the willingness to persevere in the interaction. They found that neither look nor behavior impacted

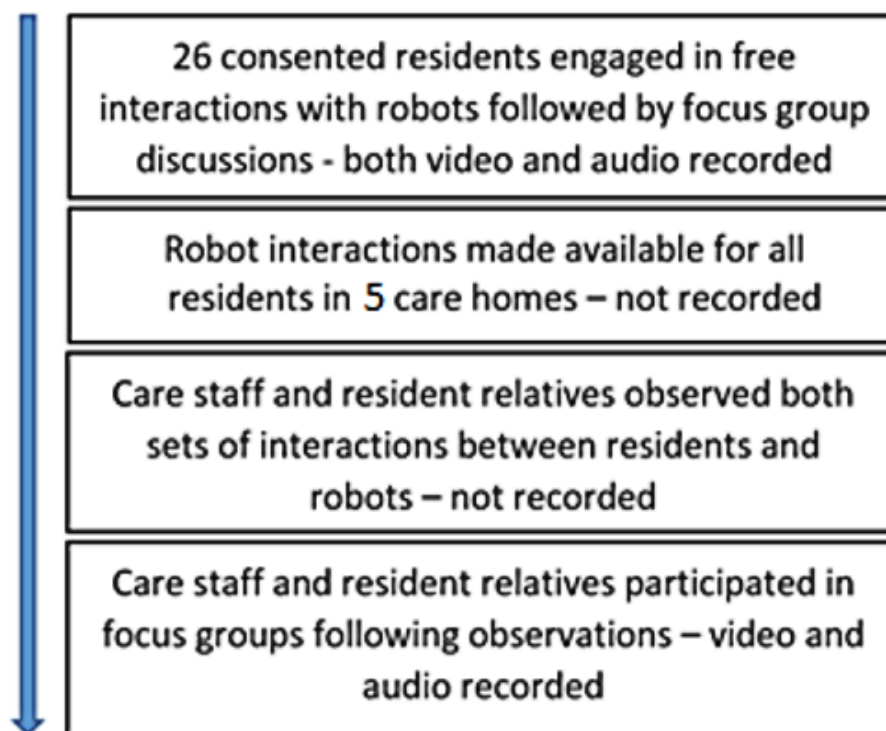
participant ratings of performance, and that there was no significant difference in self-reported frustration, excitement, or persistence with the interaction. This could suggest that zoomorphic design is unnecessary. However, it is possible that since the 2008 study, advances in robotics have improved the mimicking of animal behavior. Furthermore, a potential issue with the research is the use of the Roomba robotic vacuum cleaner. Despite being decorated with eyes, ears, a tail, and spotty fur, this robot was not specifically designed as a companion, which perhaps limited participant ability to relate and respond to the robot in either a zoomorphic or nonzoomorphic condition. In response, we compared a range of robot esthetics and behaviors, including animal robots and toys designed as companions, with some specifically for older adults.

The available literature demonstrates limitations in prior work, including a lack of appropriate devices for comparison [27,32,33] and focus only on a single device, limiting informed opinions on features and design [8,34,35]. Previous work has also noted that much robot design research has focused on only 1 stakeholder group [28], such as care staff [27] or independent older adults [32], and that users' needs and experiences in relation to robot pets remain unexplored [36]. Here, we aimed to help address this situation.

Methods

Design

This was a qualitative user-centered design study in 5 care homes involving free interactions and focus groups. Care home residents consented to participate and engaged in free interactions with devices, followed by focus groups, both of which were recorded. Interactions with the devices were then allowed for all other residents in the home wishing to experience the pets, for equity and practicality, although these interactions were not recorded. Staff and residents' relatives observed both sets of resident-robot interactions before completing separate focus groups (Figure 1). Ethical approval was given by the University of Plymouth Faculty of Health ethics committee. All participants taking part in the focus groups had the mental capacity to give consent to take part in the research.

Figure 1. Data collection flowchart.

Materials

General materials included 2 video cameras and note pads. The video cameras were used to capture audio recordings for transcription and analysis, and the video also ensured that researchers analyzing transcripts could check which robot residents were referring to, but the footage was not otherwise used for analysis. The use of recording equipment allowed greater validity than observational methods used previously [27]. Video and audio recordings are suggested to provide greater ecological validity, and the data more accurately reflect the experience and environment under analysis than traditional observational notes [37]. Furthermore, with this approach, recordings can be reviewed after the event to validate observations, missed information can be reduced, and analysis can be conducted by multiple researchers, limiting observer bias and improving the overall quality of the analysis [31].

Robots

This research used 8 robots and toys for comparison as displayed in Figure 2. The robots selected provided a range of familiar or unfamiliar/mythical embodiments, a variety of soft furry or plastic shells, and varied interactivity types and technological sophistication. Familiar robots were represented by domestic pets (cats or dogs), being animals the general population is more familiar with, whereas animals not commonly found as domestic pets were considered unfamiliar.

The devices included provide a range of esthetic, technological, and behavioral features for comparison. Some (Paro, Miro, and Pleo) are undisputed robots, with technological sophistication allowing for intelligent responses. Most provide vocalizations, interactivity, and movements (Paro, Miro, Pleo, JfA cat and dog, and Furby), while some are passive or inert (Perfect Petzzz [PP] dog and Hedgehog).

Figure 2. Robots used in the study. From left to right: Paro, Miro, Pleo rb, Joy for All dog, Joy for All cat, Furby, Perfect Petzzz dog, and Hedgehog.

Procedure

Researchers (HB, KE, and DS) visited 5 care homes and set up robot interaction stations in spare rooms, with a table and chairs for participants to be seated. Residents, staff, and family members were informed about the study ahead of the visit, and were invited to attend and participate. All residents with the

ability to consent were invited to take part if they desired. Residents, staff, and family members provided written informed consent for both recorded robot interactions and focus groups. Residents were invited into the room in groups of 2 to 4, with staff and family members invited to observe resident interactions without interference in the session. During a session, robots were presented in sets, with Pleo, Miro, and PP dog in one set;

Paro, JfA dog, and JfA cat in another set; and Furby and Hedgehog in the last set [24]. The order of set presentation was randomized with a random number generator for each group of participants to avoid presentation bias.

Residents engaged in interactions with the devices during the initial demonstrations, with each set of devices presented for around 10 to 15 minutes. After approximately 30 to 45 minutes of interactions with the 3 sets, researchers brought all devices back onto the table and commenced the focus group discussions. Nygård [38] mentioned that the use of reminders can aid in data collection for those with declining memories; thus, visibility of all devices was important during discussions. We adopted a structured interview schedule (Textbox 1), which was used for all stakeholder categories, with family members and staff being asked to consider care residents in their responses. The staff

and family members were asked additional questions around practicalities of implementation, which are not reported here. The care staff and residents' relatives combined took part in separate focus groups following observation of resident interactions, in order to allow for informed opinions. The staff and family members observed not only the interaction sessions of the consenting residents, but also the free interactions among all care home residents facilitated following completion of the consenting resident focus groups (these whole-home free interaction sessions were not recorded). This ensured that all residents were provided with the opportunity to experience the robots, and allowed the staff and family members to provide informed opinions even when a small number of residents had consented to the focus groups. The duration of the focus groups was 30 to 60 minutes.

Textbox 1. Focus group questions.

1. Preference?
2. Reason for preference?
3. Thoughts on a new robot design?
4. What should a robot pet be able to do?
5. How should it feel?
6. What expressions and behaviors should it demonstrate?
7. What features or designs should we avoid?
8. Should it be capable of talking and human speech?
9. Should robot pets be personalizable? Should residents be able to pick their design or even be involved in creating their robot, such as knitting, crocheting, or selecting animal/color/fabric?
10. Would a realistic or unrealistic design be the best?
11. If we could leave one of the devices here today, would you want one kept? If so, which one?

Data Analysis

Audio recordings of the resident-robot free interactions and focus groups were transcribed verbatim and analyzed using NVivo software (QSR International) and deductive thematic analysis. Thematic analysis is a useful and flexible method to generate a rich yet detailed and complex account of qualitative data [39]. Deductive analysis was selected as the research explored perceptions in relation to specific questions. Common threads were identified across all available data, through familiarization, initial code forming, and collating codes into themes before checking the themes, defining them, and reporting them here. Analysis was conducted by 2 researchers (HB and KE), with initial codes compared and subsequent themes coproduced. Coding was reflexive and evolved throughout the analysis, with initial codes being split, combined, or renamed as researchers developed conceptualization of the data [39]. The agreement of 2 researchers aids in the validity of a compelling interpretation. Free interactions of the residents have been reported entirely thematically, while focus group results have been displayed somewhat numerically alongside qualitative quotes, due to answers pertaining to specific questions (structured interview schedule) suitable for numerical comparison, based on the codes and counts of evidence.

Results

Participants

Five care homes participated, and from these, we recruited 65 participants (Table 1) comprising 3 sets of stakeholders perceived as influential in companion robot implementation, including residents, staff, and family members. The 5 care homes comprised a purposive sample where the manager was willing to participate, but included a range of residents from those more able to those requiring significant levels of support. Home 1 cared for people with physical disabilities and frailties, and those requiring personal care and support with activities of daily living (ADLs). Most residents in home 2 were quite able and could perform their own ADLs. Home 3 included many residents who had dementia of varying stages and required support with ADLs. Home 4 was a nursing home with residents who were more dependent, and many had dementia, mental health conditions, hearing impairments, stroke, and physical disabilities, and were quite immobile and reliant on support for ADLs. Finally, home 5 had residents who were generally quite able, with few having dementia (although some had signs of confusion); thus, they did not require much care. Four of the homes were residential care homes, while one was a nursing home, differing in the provision of care by a registered nurse.

The majority of participants were women (Table 2). While all residents were invited to interact with the robots and devices, the inclusion criteria for video-recorded interactions and focus groups were as follows: capacity to provide informed consent and willingness to participate. Any resident without the capacity to consent was excluded from direct data collection.

The following results are presented in 2 parts: (1) themes generated during thematic analysis of care home residents' free interactions with the devices, providing insights into the design and feature perceptions of currently available devices, and (2) focus group results with residents, staff, and family members discussing the design of a new companion robot.

Table 1. Participants and care homes.

Care home number	Care home description			Participants			Focus groups	
	Beds	Type	Age range of residents (years)	Residents (N=26)	Staff (N=29)	Family members (N=10)	Residents	Staff and family members
1	20	Residential	80-100	8	2	3	2	2
2	14	Residential	75-103	2	3	2	1	1
3	46	Residential	80-100	6	2	0	2	1
4	37	Nursing	70-98	2	12	4	1	5
5	26	Residential	62-107	8	10	1	2	2

Table 2. Distribution of participants by gender and stakeholder group.

Gender	Residents (N=26)	Staff (N=29)	Family members (N=10)	Total (N=65)
Male	6	1	2	9
Female	20	28	8	56

Section 1: Thematic Analysis of Free Interactions

Themes During Free Interactions

During the free interactions residents engaged in prior to the focus group discussions, analysis identified 5 key themes, namely, familiarity of design, robot actions, embodiment, acceptability, and robots as a focal point. While some evidence is presented in the narrative below, further example evidence is available in [Multimedia Appendix 1](#). Each quote is provided with a unique identifier, with P representing participating resident, followed by the care home number.

Familiarity

Evidence during the free interactions strongly supported a preference for familiar embodiment through codes involving (1) preference for a familiar animal, (2) plastic and unfamiliar devices as infantilizing, (3) unfamiliar devices as unrecognizable, and (4) robot rejection. Residents repeatedly expressed a preference for "something that looks like an animal" [P5_Home_5], stating

I prefer more natural things, the best one is that cat
[P1_Home_4]

This would suggest a preference for animal embodiment based on domestic pets that older people are likely to have experience with and be familiar with. The unfamiliar devices were described as "not the sort of creature you'd find in a home [Paro]," although despite the incongruent embodiment, Paro was "still my favorite because it's so soft" [P3_Home_5]. In contrast, another resident felt unable to enjoy Paro and stated

You live in the water and I hate the sea [Paro]
[P4_Home_5]

Another resident stated they disliked Paro "because it's not natural" [P7_Home_3], perhaps referring to having a seal in the home or to petting a seal on their lap. Unfamiliar Pleo was even told

Well, nobody could love you like your mother could they, no no no, I'm sorry [P1_Home_5]

Further to generally being less preferred, unfamiliar devices were seen as more suited to "children" [P1_Home_5]. Other comments were as follows:

Popular with young children [Miro] [P2_Home_4]

Younger child would like to play with these [Miro]
[P2_Home_4]

That's alright for children [Pleo] [P5_Home_1]

My great granddaughter would love that [Pleo]
[P11_Home_1]

A tiny little boy might like [Miro] [P11_Home_1]

I should give a child something like this [Furby]
[P6_Home_1]

More appropriate for young children, they'd love this
[Paro] [P2_Home_5]

It is possible therefore that the toy likeness of devices could create feelings of infantilization. Such comments were almost entirely made toward either Paro, Pleo, Furby, or Miro. Some residents even stated "we must be crazy" [P7_Home_5] and "we're nuts, we're nuts" [P5_Home_3], when interacting with Pleo and Paro, although 1 resident interacting with Paro and JfA dog also felt "people will think I'm stupid if they see me now" [P1_Home_2]. While participants were happy and jovial, some clearly felt that some robot designs were unsuitable.

You're making fools out of us, do you know that?
[Paro] [P4_Home_5]

They stated that it appeared toy-like, and unfamiliar designs created the least positive responses. Participants sometimes reported unfamiliar devices as unrecognizable, suggesting that the hedgehog “could be a duck” [P1_Home_3] or “a baaa lamb” [P1_Home_3], and that Furby may be “a bat” [P1_Home_4]. There were however several accounts of robot rejection.

[Shown pleo] [bats it away] not for me [P4_Home_3]
I don't want it [Furby] [P4_Home_3]

These were all related to Pleo, Furby, Miro, the hedgehog, or Paro.

The white one I wouldn't go for. I don't know. She's a bit, no, there's nothing to encourage me to touch it. No I couldn't do it. No I would go away from it
[Paro] [P5_Home_3]

The unfamiliar Paro also triggered surprising schemas, with 1 resident suggesting they would eat the seal “for tea tomorrow night” [P1_Home_1], and another 2 residents commenting on how people “skin you to make a coat” [P4_Home_5] or how they are “skinned alive when they are born” [P5_Home_1]. Use of familiar embodiment thus seems important for older adults to enhance positive response and recognizability, and to reduce infantilization and chances of rejection.

Robot Actions

Residents certainly supported the importance of movement and interactivity in devices, through the code *Important Expressions and Behavior*. On interacting with the JfA cat, 1 resident commented “I like him [...] because of his activity and response” [P5_Home_5], and another commented “the cat is very good isn't it, active” [P3_Home_5]. The residents seemed to understand that most robots were interacting with them.

When you talk, it will answer. When you talk it will answer, because it can hear the vibrations from your voice. That's why she answers [P5_Home_1]

Participants particularly praised the dog “moving his face” [P3_Home_3] and the cat “purring” [P5_Home_1]. They also praised devices blinking their eyes.

Oh look at the eyes closing [Paro] [P1_Home_4]
The eye blinking is lovely [Cat] [P2_Home_4]

The eyes of the devices appeared important, with Furby's eyes described as “nice animated eyes, that's really special” [P3_Home_5]. Noninteractive devices were viewed as “just an ornament really, I like the movement ones” [P2_Home_1]. For example, the PP dog, although praised for being “something that looks like an animal” [P5_Home_5], was perceived as “dead [...] poor old sod” [P5_Home_1]. The activity and movements of Pleo even seemed to reduce some of the dislike associated with its unfamiliar and rubber embodiment for some participants.

He's the liveliest, fantastic [Pleo] [P7_Home_3]
He's more active [Pleo] [P7_Home_3]

Despite the apparent acceptability of JfA cat's vocalizations and purring, some evidence arose against JfA dog's

vocalizations, through the code *Less Vocalization*. Participants made the following comments about the JfA dog:

Barking aren't you, you don't have to bark
[P1_Home_3]
No barking [[P2_Home_4]]
He's a good animal but he's not supposed to bark
[P2_Home_4]
Can't you shut up? [P2_Home_1]

These suggested that the devices makes “a lot of noise” [P4_Home_5], which “would irritate other residents” [P2_Home_4]. While movements and interactivity appeared important, and cat purring was enjoyed, the vocalizations of the JfA dog appeared somewhat undesirable.

Embodiment

While familiar animal embodiment was addressed in an earlier theme, here residents provided further insights under the codes *Desirable Esthetics*, *Not too Big or Heavy-Lap Size*, *Soft Feel*, and *Treating as Living Being*. Desirable esthetics were particularly focused on the robots' eyes and face.

You've got a beautiful face you do [JfA cat]
[P6_Home_5]

Of all devices, Furby had particularly expressive animated eyes.

I like the eyes [Furby] [P6_Home_5]

Paro also had large eyes, which appeared appealing.

Those great big eyes, yes those great big eyes [Paro]
[P2_Home_2]

His eyelashes too! [Paro] [P2_Home_4]

Residents also commented on the size and weight of the robots. They generally felt that Paro was “a bit big” [P4_Home_5] and “quite heavy” [P1_Home_4], with a resident saying “[didn't] like the weight of him [...] not for me” [P2_Home_1]. On 1 occasion, Miro and the JfA dog were both described as “too big” [P6_Home_3] and “big” [P3_Home_3], respectively. Further to needing familiar embodiment, appealing face and eyes, and appropriate size and weight, residents very strongly preferred soft furry devices.

I like the fact they're soft, it's really nice [Paro]
[P3_Home_5]

Participants “don't like [...] rubber” [P6_Home_5] or plastic for robot shells, as “you can't cuddle it” [P11_Home_1]. Interestingly, residents also commented on the feeling of robot insides and stated that they were “really solid [JfA cat]” [P7_Home_3], with the rigidity making the device “look as if he's dead” [P6_Home_3]. Another resident felt Pleo was “tough as cement inside” [P2_Home_4]. Despite the limitations of available devices, residents very often engaged with the robots as biological beings, and treated the animals as living beings.

Do you like your belly scratched? [P6_Home_5]

Residents asked if robots would “bite” [P1_Home_3], and commented they may be “sick” [P1_Home_3], such as when Miro was turned off. A participant even told a device gently “I won't hurt you darling [JfA dog]” [P1_Home_3], suggesting some attribution of social qualities to the devices.

Acceptability

Importantly, the robots seemed to have mainly good acceptability among care home residents, seen through the themes of *Likeability*, *Ownership*, and *Interest in Technology*. Residents demonstrated likability through general positive comments, such as “handsome isn’t he [Paro]” [P3_Home_3] and “he is beautiful [PP Dog]” [P3_Home_3]. Participants generally spent the sessions petting, cuddling, squeezing, and kissing the devices.

I love it, I love the wool [kisses hedgehog 5 times and cuddles tightly] [P8_Home_5]

Participants enjoyed the robots very much, and many reported interest in owning or keeping an animal.

He’s mine [PP Dog] [P1_Home_3]

Sold, I would like that hedgehog [P11_Home_1]

I’d like you in my bed! [Paro] [P8_Home_5]

Many residents also spontaneously provided names for the devices, such as “Chatterbox [JfA cat]” [P1_Home_2], “Snowy [Paro]” [P1_Home_2], “Ginge [JfA cat]” [P5_Home_5], and “Lassie [JfA dog]” [P1_Home_3]. The interest of residents in the technology involved in the robots showed some level of understanding of the devices, with participants aware that these are robots or toys, rather than live animals, and yet happy to interact anyway. Participants asked “how does it work?” [P2_Home_2] or “what is the energy source?” [P2_Home_4]. Residents often asked “who made these?” [P1_Home_5] and commented “I’d like to see what’s on the inside of them” [P5_Home_5].

Focal Point

The final theme resulting from the analysis was focal point, from the code *Conversations*. This theme represented the time participants spent talking to each other during the free interactions (about the robots), demonstrating that devices can

provide a topic to promote conversation between residents. Some examples are included below, but generally, the resulting conversation was humorous and jovial, with 1 focus group erupting into a chorus of “how much is that doggy in the window?”

One conversation was as follows:

P1_Home_5: Mind my cat!

P2_Home_5: It’s a dog darling [laughs]

P1_Home_5: [laughs] I do need to see the optician don’t I!

Another conversation was as follows:

P6_Home_5: He’s laughing at you [Furby]

P8_Home_5: He’s laughing because I’m tickling his belly

P6_Home_5: Oh I thought he was laughing at your face! [laughs]

P8_Home_5: [Laughs] he might be!

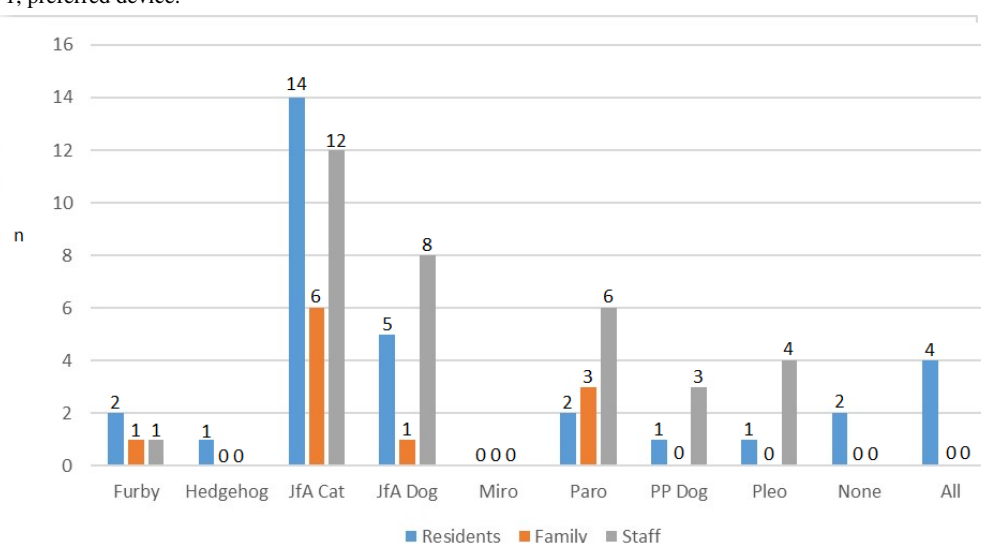
Section 2: Focus Group Results

The results of the focus groups involving residents, family members, and staff are summarized below, although further example evidence is available in [Multimedia Appendix 2](#). Each quote has been assigned a unique identifier, with P representing participating residents, F representing family members, and S representing staff. The graphical representations result from common codes in the data.

Preferred Animal

Some participants picked more than one device as their preferred device. Residents, family members, and staff all preferred the JfA cat ([Figure 3](#)). The JfA dog was the second most preferred device for residents and staff, while Paro was the second most preferred device for family members, also being the third most preferred device for staff.

Figure 3. Question 1, preferred device.



Reason for Preference

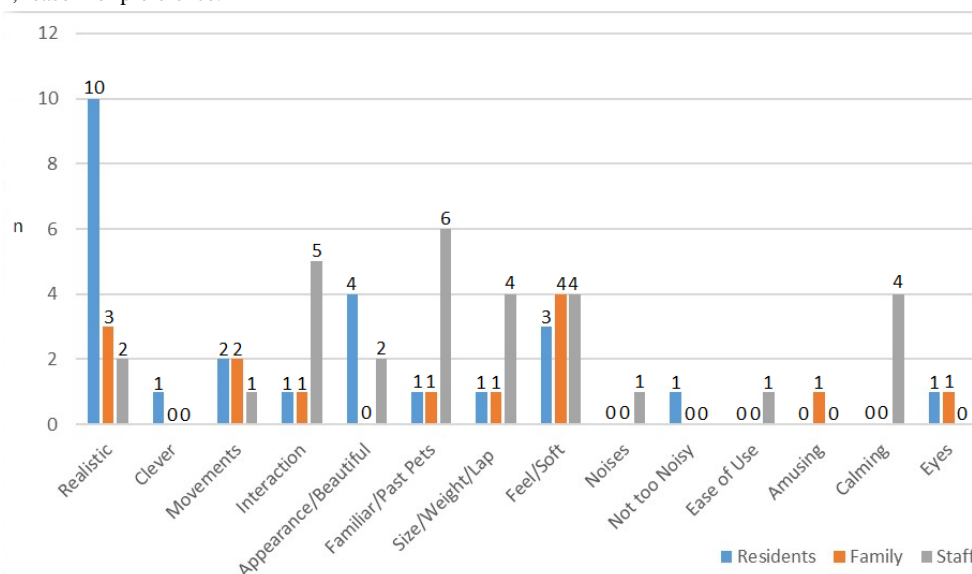
The most common reason for residents selecting their preferred device was it “seem[ed] so real” [P1_Home_2] ([Figure 4](#)).

Residents may have also been referring to familiar devices as most realistic, suggesting the cat was “very realistic [...] not like that seal” [P2_Home_1]. The most common reason for staff

preference was that the device represented a familiar animal, such as a cat or dog, as “everybody will stroke a cat or a dog, who strokes a seal?” [S2_Home_1]. For family members, the most common reason for preference was the soft furry feeling,

making them “very tactile” [F1_Home_1]. Residents also displayed interest in devices being beautiful and feeling soft, while staff displayed interest in devices being interactive and calming.

Figure 4. Question 2, reason for preference.



Design of a New Robot

Participants repeated the importance of a realistic and familiar design, and some design improvements were mentioned alongside measures to enhance practicality. One resident expressed a desire for removing sounds.

No sounds, wakes somebody up. [P1_Home_3]

This was supported by a family member who felt robots could sense when to be quiet.

When they have their snooze and they drop off, it drops off and doesn't disturb them. [F3_Home_1]

Desirable features also included being “something warm, purring on her lap” [F1_Home_5]. A staff member felt “breathing is good” [S1_Home_2]. Participants also valued the device turning “its head towards you” [F1_Home_5] and appearing to provide attention. Some family members and residents desired command responses, such as “the dog should sit up and beg” [P3_Home_3] or “wanting to play like a dog” [F1_Home_2].

For the physical body, participants discussed “the weight” [S8_Home_4], as “it could be a bit lighter” [F1_Home_4]. This links with being “the right shape to go on their lap, the cat is perfect to go on a lap” [S1_Home_3]. Devices that are “too heavy,” such as “Paro,” may be less “accessible” for “older people [who] are quite frail” [S1_Home_3]. Participants felt future devices should certainly “look like something [residents] had in the past or it will be alien to them” [S10_Home_5]. One staff member also felt they could be “softer [...] in the body” rather than feeling “robotic” under the soft surface [S2_Home_2].

For practicality, it was noted the devices should be “robust” [S1_Home_1]. A number of participants also requested robot “covers come off” [S2_Home_1], as “it needs to be washable”

[S6_Home_4 and S5_Home_4]. Family members also commented “the fabric [...] can you take it off and wash it? Because [...] they're old and it gets greasy and mucky” [F3_Home_1], which “could see it getting quite dirty after a while” [F2_Home_1].

Abilities for a New Robot

Residents agreed that the abilities of a new robot should include being “interactive” as “that's the idea of a robot” [P2_Home_1] and valued when it “talks at me and he looks at me” [P5_Home_1]. The importance of interactivity was supported in criticism of the PP Dog, as “you want it to play, a bit more action” [P11_Home_1]. Staff and family members agreed it should “respond to her” [F1_Home_5] and “it's got to be interactive [...] so residents have something to have their minds think about” [S2_Home_2].

Command responses were mentioned again.

It would be nice if it could say [...] roll over or beg [S1_Home_1]

If you tell it to stop moving or sit or something it gives them vocabulary they might have forgotten. [F2_Home_1]

The use of warmth was mentioned again with the comment “kind of like temperature, like warmth” [F1_Home_2]. Eye contact or perceived attention was certainly praised with the comment “looking for them [...] the heads moving, eyes opening and closing” [S1_Home_3]. Such movements involve fairly simple technology, and staff felt “[Paro is] probably too complex really for [residents] needs” [S1_Home_1].

The possibility for command responses for some residents could be solved through the suggestion of making a device “adaptable to the person” where the pet could be “peaceful and relaxing [...] but do other things when needed” as “if you're gonna make

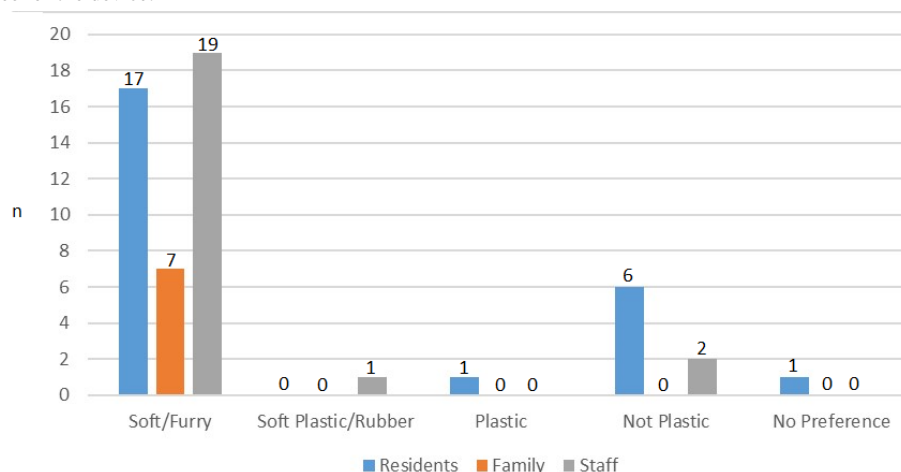
something make it wide ranging, make it as adaptable as possible” [S10_Home_5].

Feel

All categories of participants supported soft furry embodiment for future robot designs (Figure 5), which were considered “pleasant to touch” [S2_Home_1], and “they could stroke it”

[S2_Home_1], which was “more therapeutic” [S1_Home_5]. Plastic or rubber was not generally desired as “you don’t get rubber animals” [P6_Home_5] and it could “be too cold” [P2_Home_5]. One resident liked all the robots and felt “the rubber one interacted anyway so I’ve got no preference” [P7_Home_5].

Figure 5. Question 4, feel of the device.



Expressions and Behaviors

Participants talked of the importance of “facial” [F1_Home_2] expressions being the “first thing” [F2_Home_2] that “people look at” [P2_Home_4]. Staff also felt it “would be quite good” if “eyebrows move and eyelids move” [S1_Home_2]. Linked with facial expressions was the appearance that the device is looking at the user.

It’s got an expression and it looks at you. [P2_Home_1]

The looking, that sort of interaction. [S5_Home_4]

To look towards you. [S12_Home_4]

This is also related to the importance of eye design.

The eyes, the eyes. [P1_Home_4]

See the eyes moving. [P2_Home_4]

Moreover, breathing and “purring” [P6_Home_5] were praised.

Once she realized it was breathing, she was like aw, she wanted to listen. [S1_Home_3]

The breathing is relaxing. [S5_Home_5]

I love to hear them purr. [P8_Home_5]

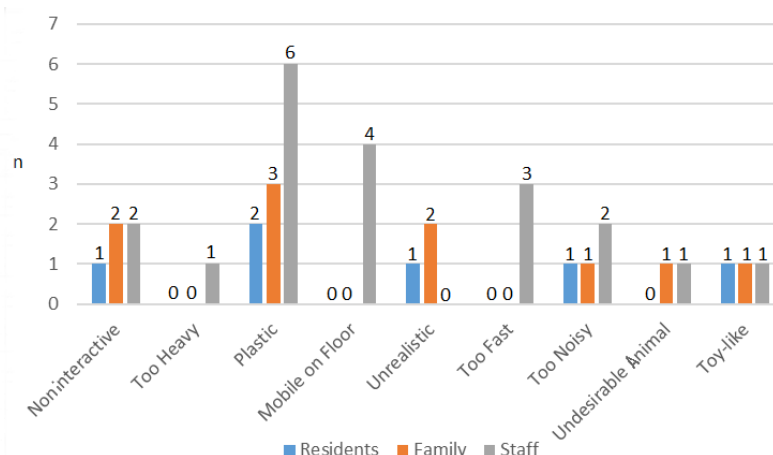
Purring was considered useful for those with hearing impairments, as “you can feel the cats purring even if they can’t hear it” [S8_Home_5]. Further behaviors enjoyed included the cat “rolling over” [S10_Home_5], as “their movement is what makes them look real” [P7_Home_5] and “more interesting”

[P2_Home_5]. Command responses were mentioned again, such as “give me a paw” [F1_Home_1].

The animal demonstrating its mood was considered important, possibly through known behaviors, such as “wagging the tail for the dog [...] cat purring” [F1_Home_1], or possibly through lights, where a device may “light up to show their mood” [S2_Home_2]. Generally, participants felt the device should appear “happy” [F1_Home_2], but could indeed be adaptable depending on the resident’s needs, so robots could be set on a “chilled, or happy, placid” [S2_Home_2] mood, depending on the need of each resident.

Design Features to Avoid

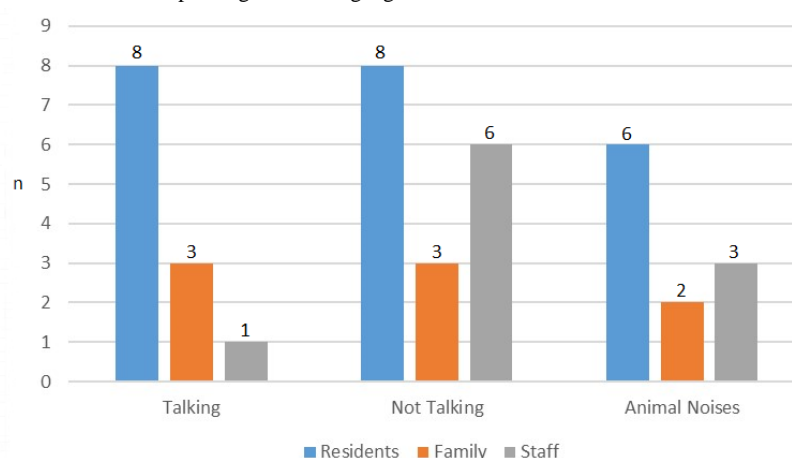
Design features to avoid received fewer responses (Figure 6), likely due to discussion elsewhere, but the feature most commonly mentioned by residents, family members, and staff to avoid was plastic embodiment. Staff also felt it was important robots were not autonomous and mobile on the floor, which could cause “hazards” [S6_Home_4]. It was also felt that the devices should not move “too quick” [S5_Home_4], or be vocalizing “too loud” [F1_Home_4] or “all the time,” as it could “irritate the other residents” [P2_Home_4]. Participants felt the design should avoid being toy-like, with Miro, Pleo, and Furby described as “childlike” [P5_Home_5]. Family members felt residents may “take offence” [F1_Home_4] at being given robots that resemble toys too much, comparing toy-like robots to “children’s puzzles” [F1_Home_4].

Figure 6. Question 6, features to avoid for a new robot.

Talking

There was no definitive answer on a device speaking human language (Figure 7), although combining *not talking* responses with *animal noise* responses would suggest talking was far less desirable, but still of interest to a number of participants. Reasons for desiring speech included the potential for “speech therapy” [F1_Home_1] to “encourage [residents] to speak” [F2_Home_1]. Some staff felt residents “might be able to express their feelings more than what they can do to a carer or

doctor” if the robot spoke [S2_Home_2]. Some residents felt it would be “wonderful” [P6_Home_1] and would “like it if he spoke back” [P1_Home_3], as it “would be very interesting” [P2_Home_5]. However, other residents responded “I’d say you were nuts and I was nuts, round the bend good and proper” [P5_Home_1]. Family members and staff also worried it was “just too weird” [F1_Home_2], or could cause “sensory overload, like processing why is a cat talking to me” [S1_Home_3] and even be “disturbing” [S6_Home_4].

Figure 7. Question 7, opinions on a new device speaking human language.

Personalization

Most participants were generally positive about personalizing devices, and being able to choose “your own color” [P2_Home_1], “which animal I’d like” [P6_Home_1], or even “a pet they’ve had in the past” [S1_Home_2], which may “spark something off” in their memory [F4_Home_4]. Some participants felt the available devices needed no improvement however, as “they’re done well enough aren’t they” [P11_Home_1]. Staff worried about personalizing robots not being “cost effective” [S1_Home_2]. They commented “that robot is going to be personable to them [...] everyone’s going to have different opinions” [S1_Home_1] and “when that person’s gone, that animal is not going to be significant for anyone else,” but then stumbled across the idea to “change the outer” [S1_Home_2], therefore allowing customizability with “a robotic framework that goes into every animal, and then a

shell you could change” [S1_Home_3]. Having individual covers would also mean covers would be “washable” [S1_Home_5]. Having residents involved in creating the shell was also interesting, with staff suggesting residents could “knit and crochet” [S2_Home_2] to create something like the handmade hedgehog. Being involved and either creating or personalizing the device “would feel like they’re part of something” [S2_Home_2] and would help them “get more attached” to the device [S3_Home_2].

Realistic and Familiar

Participants discussed both the concept of it looking “realistic” [P8_Home_5] and “life-like” [P4_Home_5], further to being a familiar animal “they can relate to” [S1_Home_3], particularly a “domestic animal [...] I don’t know whether the seal would go down as well” [F2_Home_2]. All groups generally supported more realistic and familiar embodiments, with Miro described

as “too futuristic” [S1_Home_2], and Paro felt incongruent in the setting.

Why have you got a seal in a home, you wouldn't.
[F1_Home_1]

In contrast, familiar animals received the following comments:

It's easy to identify with the cat. [F1_Home_1]

It's more therapeutic if they recognize it.
[F3_Home_4]

Everybody [...] will stroke a cat or a dog.
[S2_Home_1]

The benefits of a familiar animal included that it “stimulated their memories” [S2_Home_1], as it represented “something I recognize” [P2_Home_5]. Unfamiliar and unrealistic forms were considered “better for people with learning disabilities”

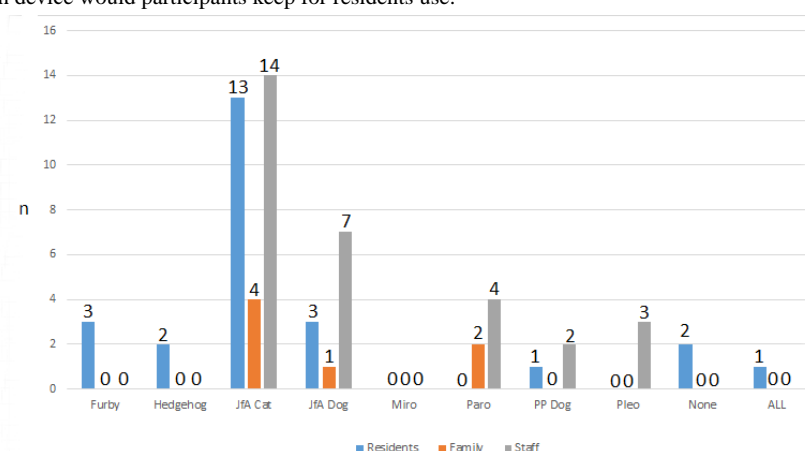
[S6_Home_5] or “children” [F4_Home_4]. A very small number of residents displayed interest in unrealistic embodiment as “it would hold your gaze because it's different” [P2_Home_5].

Keeping a Robot

For Question 10, participants were asked if we could leave a device behind for the benefit of residents, which one (if any) would they want left.

Similar to Question 1 where preference was shown for the JfA cat and dog, the combined choices of participants favored keeping the JfA cat, followed by the JfA dog (Figure 8). In total, 47 participants responded to this question, and 45 of them agreed to keep a device, with only 2 participants responding “no” [P7_Home_5]. Some family members and staff chose to keep Paro, but this device was not selected by residents.

Figure 8. Question 10, which device would participants keep for residents use.



Summary

The most preferred and most likely to be adopted devices were the JfA cat and JfA dog. Based on the focus groups and free interactions, the combined evidence has produced a *recipe* for future robot pets aimed at care home residents, based on the user-centered inputs of residents themselves, as well as their family members and care team. The requirements are as follows: (1) appear familiar and realistic (dog or cat) to avoid infantilization, (2) be soft and furry, (3) look at the user, blink, show expressions, and have engaging eyes, (4) breath, purr, and be warm (tactile responses for those with hearing impairments), (5) be of suitable size and weight for laps, (6) have adjustable volume and frequency of noise and vocalizations, (7) have removable skin for cleaning, (8) have a customizable appearance, (9) possibly respond to commands, (10) possibly have more realistic robot *insides*, (11) possibly sense when to shut down, (12) possibly adapt to the need of each user (eg, displaying certain moods dependent on the requirement to calm, sooth, or entertain), and (13) have the ability to talk (further research).

Discussion

Overview

This work has provided important insights into the views of care home residents, family members, and care staff regarding

the design and use of companion robot pets. This work demonstrates an overall good acceptability of robot pets, with the majority of residents, family members, and staff selecting a preferred device and suggesting they would keep a robot if they had the opportunity to do so. This work also highlights some interesting design considerations.

Principal Results

Evidence suggests the most important design requirements to be familiar animal embodiment and a soft furry shell, congruent with previous work [27,32]. However, some participants, including residents, reported that feel was less important than interactivity, with the lively interaction of Pleo creating positive appeal despite an undesirable rubber shell. Interestingly, further to a soft shell, participants expressed an interest in warmth. Desire for such tactile features may relate to the human use of touch as a primary nonverbal communication channel [40]. Social touch has an important role in prosocial and bonding behaviors, even between humans and robots [40]. Human skin has specific receptors to process affective touch [41], and therefore, tactile feedback provided by robots is a key consideration for future developments. An additional feature discussed in this work, which was unexplored previously, is the feeling of robot *insides*. Participants felt the JfA cat was somewhat rigid, and other residents commented on the hard-feeling robotics under the soft exterior of devices. Thus, there may be value in improving the *feel* of the insides of robots,

further to the shell, by perhaps providing extra padding for softness or replicating a realistic body frame.

Regarding familiarity, we know Paro was designed with unfamiliar seal embodiment to avoid expectations [42]. Paro is the most well researched companion robot [10]; however, Moyle et al [8] previously saw considerable variation in older adults' responses to Paro during a randomized controlled trial, with some residents rejecting the seal. Our work suggests that this may result from the unfamiliar embodiment of Paro, as residents in our study sometimes rejected Paro, alongside other unfamiliar devices (Pleo and Miro), whereas the best acceptability and preference were shown for familiar devices that represented domestic pets (JfA cat and dog). Some devices were perceived as more suitable to children, perhaps because they were more toy-like (bright colored Furby or rubber Pleo), or because they were unfamiliar embodiments that would not usually be found in a care home, thus being obviously a toy. This should be investigated further to consider any impact of unfamiliarity or toy-likeness on perceived infantilizing. Any evidence of infantilization would support the ethical concerns raised by Sparrow and Sparrow [43] on the inappropriateness of robot pets for older adults. Several residents in this study reported feeling "nuts" or "like fools" for interacting with such devices, although this is not necessarily a negative response and would need further exploration. Family members showed some disagreement with unfamiliar devices, and felt residents may take offence, with 1 comparing toy-like robots for older people to children's puzzles. Use of familiar and recognizable embodiment thus seems important for older adults to enhance positive response and recognizability, and reduce risks related to possible infantilization and rejection. Further to being familiar, participants also desired robots to appear as realistic and life-like as possible, as realistic embodiment appeared to reduce perceptions of devices as toys.

The use of familiar and realistic animal embodiment may conjure ethical concerns on deception, if a robot appears too similar to a living creature. Previously, Sparrow and Sparrow [43] suggested enjoying robot pets required people to deceive themselves as to the realness of the interaction; however, care home residents in this study showed good acceptability of robots despite awareness and interest in the devices' technology, thus being aware of their nonliving nature. Conversely, residents did treat robots as living beings, and our sample consisted only of residents with the capacity to consent. It is possible residents with dementia (without capacity) may indeed be deceived as to the real nature of such devices [44]. A few family members raised ethical concerns toward their relatives interacting with robots, particularly unfamiliar ones (eg, comparing robots to children's puzzles), and a resident's relative did present some opposition in previous work [23]. While residents did not directly report offense, they did suggest that unfamiliar devices were more "childlike." The ethical considerations of companion robot use thus requires further enquiry, particularly considering familiar and realistic devices, which may be even more deceptive than devices such as Paro. We have discussed the ethical considerations of robot pets elsewhere [45].

With regard to robot appearance, eye and face design seemed particularly important, as did the device appearing to look at

the user. As mentioned by participants, residents naturally look at the face and eyes the most, and participants appeared to prefer "animated" and "big" eyes. Regarding robot body size, this research confirmed that Paro is indeed too big for older people, as noted previously [10]. Participants reported that residents are often slight and frail, and commonly engage with robots on their laps, with Paro being too heavy for comfortable use. Likewise, the upright position of the JfA dog was not considered the best suited to the lap. The negative response to Paro's size and weight seen here may help further explain some negative reactions to Paro in previous work [23], combined with evidence against the use of unfamiliar devices, which can shed doubt on the continued selection bias for Paro in companion robot research [9,10].

Regarding interactivity and displayed behavior, Moyle et al [8] suggested previously that Paro was more engaging than a plush toy. Here, stakeholders confirmed the requirement for movement and interactivity from a companion robot, viewing inanimate options as ornaments and pretty things rather than companions, thus implying that movement/interactivity produced the perception of a social entity. However, the level of interactivity required remains uncertain. Participants in this study reported preference for the JfA cat and dog, as in our prior work with a smaller more independent sample of older adults [24], suggesting that devices less sophisticated than Paro may prove to be adequate companions. The JfA devices respond only to touch and sound, with a limited range of set movements, in comparison to Paro's artificial intelligence, range of sensors (including touch, sound, light, and position), and bespoke responses. Indeed, 1 member of the staff reported that Paro's technology was too complex for this client base. Generally, desired movements included looking toward the user, rolling over, wagging the tail, being expressive, breathing, and possibly feeling warm. There was some interest in command responses, and there were indefinite opinions on robots talking, as seen in our prior work [24]. However, a limitation of exploring the interactivity requirement in this study is the short interaction time. It is possible that more sophisticated technology and interactions would hold engagement better over longer-term use. Some research exists on the longitudinal use of Paro [13], but literature is generally limited for more affordable devices, reducing our understanding of the interactivity required for long-term engagement. Although one of our other studies indicated no novelty effect of affordable pets over 6 months, the research included only 2 implementation sites [46], leaving scope for further exploration of longitudinal studies on affordable robots. A further limitation of exploring interactivity in this study is that our sample included only residents with the capacity to consent, who are less likely to have a diagnosis of moderate or severe dementia. A sample of residents with moderate to severe dementia may respond differently to interactive robots.

Another aspect related to robot behavior is vocalization. Previously, Robinson et al [23] suggested that Paro's vocalizations may be distressing for residents of a dementia unit. In this work, we also found that residents did not like loud or frequent vocalizations, particularly the barks and yaps of the JfA dog. In contrast, during focus groups, many residents

commented on the value of the purring and vocalizations of the cat, and participants in all stakeholder groups commented positively on devices making animal noises. Some residents even discussed the value of auditory responses for older adults with sight impairments. This factor clearly requires further specific enquiry on the acceptable type, frequency, and volume of vocalization.

This study has thus contributed toward user-centered discussions on embodiment, behavior, interactivity, and vocalizations, although further enquiry is needed. Some additional interesting features also arose. Particularly, the interest in breathing and warmth meant life-simulation features should be considered for inclusion in future work. Further interesting discussions arose on removable fur for hygiene purposes due to concerns on shared objects becoming unclean. Although this study was conducted prior to the COVID-19 pandemic, infection control considerations for shared robots in care homes are particularly relevant in the current context [47,48].

The study also hinted at some potential benefits of robots, despite the short interaction time, on communication, in particular through the theme of *robots as a focal point*. This is congruent with the conclusions of a recent scoping review on the impacts of affordable robot pets [49]. In our study, it is quite possible that residents engaged in additional conversations around robots as they were new and exciting, again demonstrating the requirement to assess any novelty affect [50], furthering our exploratory prior work with affordable pets [46], and the limited number of available impact studies with such devices [49,51].

Strengths and Limitations

The strengths of this work include the participation of 3 stakeholder categories (residents, family members, and care home staff) and the consideration of responses based on first-hand observations, thus ensuring informed opinions. While views between stakeholder categories can vary [28], our work found that residents, staff, and family members had good congruence in responses for many features. The most variation was seen for robots talking, with residents and family members less decisive, while staff responded more negatively to robots speaking. Perhaps this represents an area of unmet need underestimated by care staff. Future work could explore this further, but it is likely that the most weight should be applied to the end-user perspective. While acceptability among wider stakeholders is essential for devices to be procured, facilitated, and maintained, the perception of the end-user on functions is likely of most importance. Future work may also seek to expand the stakeholder categories even further to include independently living older adults and compare perceptions on robot preferences

for more able older adults. This work also responded to an identified literature gap regarding the lack of companion robot comparison studies [9]. Previously available comparison studies focused mainly on the input of care providers, and lacked Paro as a comparator [27] or the use of companion robots designed for older adults [32]. These limitations were responded to in this work. A further strength of this work in comparison to previous studies is the randomization of robot presentation order. The serial position effect theory suggests that the first and last presented items may be better remembered than those within the sequence (primacy and recency effect) [52], and particularly when working with older adults who may experience some cognitive impairments, the method of presentation requires additional consideration. For this reason, we randomized the order of robot presentation and represented all robots together during the focus groups to ensure that all devices were recorded in the short-term memory for discussion and comparison. As already discussed, the limitations of this work include the short interaction time and the inclusion of only residents with the capacity to consent. The short interaction time may have resulted in a novelty effect, meaning longer-term studies with more affordable devices are required to explore longitudinal engagement. Future research may also consider other devices that fit the design requirements stated here, but with additional functions to explore, such as the JustoCat. Another possible limitation is that we focused on explicit design preferences, rather than long-term engagement or well-being outcomes. However, in line with the user-centered approach [25], an understanding of user requirements is the essential first step in user-centered design. Based on the results of this study, future robot developments may more accurately match user requirements and provide more consistent results. Additionally, the acceptability and preference of affordable JfA devices provide scope for future research considering these pets in long-term trials for assessing their impact on well-being.

Conclusion

Care home residents, family members, and staff were all generally open and accepting of the use of companion robot pets, although a very strong preference was shown toward the JfA cat and dog, due to the familiar embodiment. Participants discussed many design features, with soft fur, interactivity, nice eyes, and movements appearing important. Unfamiliar embodiment and appearing toy-like produced fewer positive responses. Further work is required for feature prioritization, and to achieve a greater understanding of suitable sizes and weights for such devices. As this work suggests strong acceptability of affordable JfA devices by residents in care homes, further work is required to explore the use and impact of devices, such as these familiar robot pets, in this setting.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Further evidence from free interactions.

[\[DOCX File, 42 KB - rehab_v8i4e30337_app1.docx\]](#)

Multimedia Appendix 2

Further evidence from focus groups.

[\[DOCX File, 39 KB - rehab_v8i4e30337_app2.docx\]](#)

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Abbreviations

ADLs: activities of daily living

JfA: Joy for All

PP: Perfect Petzzz

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Original Paper

An Immersive and Interactive Platform for Cognitive Assessment and Rehabilitation (bWell): Design and Iterative Development Process

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Abstract

Background: Immersive technologies like virtual reality can enable clinical care that meaningfully aligns with real-world deficits in cognitive functioning. However, options in immersive 3D environments are limited, partly because of the unique challenges presented by the development of a clinical care platform. These challenges include selecting clinically relevant features, enabling tasks that capture the full breadth of deficits, ensuring longevity in a rapidly changing technology landscape, and performing the extensive technical and clinical validation required for digital interventions. Complicating development, is the need to integrate recommendations from domain experts at all stages.

Objective: The Cognitive Health Technologies team at the National Research Council Canada aims to overcome these challenges with an iterative process for the development of bWell, a cognitive care platform providing multisensory cognitive tasks for adoption by treatment providers.

Methods: The team harnessed the affordances of immersive technologies while taking an interdisciplinary research and developmental approach, obtaining active input from domain experts with iterative deliveries of the platform. The process made use of technology readiness levels, agile software development, and human-centered design to advance four main activities: identification of basic requirements and key differentiators, prototype design and foundational research to implement components, testing and validation in lab settings, and recruitment of external clinical partners.

Results: bWell was implemented according to the findings from the design process. The main features of bWell include multimodal (fully, semi, or nonimmersive) and multiplatform (extended reality, mobile, and PC) implementation, configurable exercises that pair standardized assessment with adaptive and gamified variants for therapy, a therapist-facing user interface for task administration and dosing, and automated activity data logging. bWell has been designed to serve as a broadly applicable toolkit, targeting general aspects of cognition that are commonly impacted across many disorders, rather than focusing on 1 disorder or a specific cognitive domain. It comprises 8 exercises targeting different domains: states of attention (Egg), visual working memory (Theater), relaxation (Tent), inhibition and cognitive control (Mole), multitasking (Lab), self-regulation (Butterfly), sustained attention (Stroll), and visual search (Cloud). The prototype was tested and validated with healthy adults in a laboratory environment. In addition, a cognitive care network (5 sites across Canada and 1 in Japan) was established, enabling access to domain expertise and providing iterative input throughout the development process.

Conclusions: Implementing an interdisciplinary and iterative approach considering technology maturity brought important considerations for the development of bWell. Altogether, this harnesses the affordances of immersive technology and design for

a broad range of applications, and for use in both cognitive assessment and rehabilitation. The technology has attained a maturity level of prototype implementation with preliminary validation carried out in laboratory settings, with next steps to perform the validation required for its eventual adoption as a clinical tool.

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KEYWORDS

virtual reality; clinical psychology; cognitive assessment; neuropsychology; mental health; cognitive rehabilitation; digital therapeutics; mobile phone; cognitive training

Introduction

Background

Mental health issues are increasing worldwide [1]. In middle- and high-income countries, 50% of the general population will experience at least one mental health disorder during their lives [2]. Mental illness impacts national productivity, estimated to be up to a 4% loss as measured by gross domestic product [3]. The cumulative economic output loss associated with mental disorders between 2011 and 2030 is projected to be US \$16.3 trillion worldwide, putting it in close contest with cardiovascular disease, which is the leading health care burden [2]. Mental health disorders encompass many conditions, challenging people throughout their lives by impacting their ability to learn, build flourishing lives, and age gracefully into their senior years [4]. Although mental health issues are prevalent, they remain difficult to assess and treat.

To best manage a mental health condition, it is important to understand the different ways in which functioning is impacted in an individual. A core feature of psychopathology is cognitive dysfunction, in which impairments can occur broadly and nonspecifically among domains such as attention, response inhibition, and visual memory, cutting across disorder boundaries [5]. Current assessments of cognitive functions, traditionally including in-person clinical evaluations consisting of a battery of pen-and-paper and 2D computerized cognitive tasks [6,7], may not be able to capture the complex processes underlying behavior because they are based on a common set of neuropsychological tools evaluating unitary cognitive constructs [8]. On the other hand, looking at treatment, it becomes evident that cognitive rehabilitation has emerged as a promising strategy. It is based on the premise that repeated practice of tasks targeting deficits can lead to improvements in specific cognitive domains [9]. However, it remains unclear whether these improvements translate into real-world functioning.

Neuropsychological assessments are currently experiencing a shift, moving away from traditional *construct-driven* pen-and-paper paradigms toward tests that are representative of everyday life, attracting the use of immersive, otherwise known as extended reality (XR) technologies [10-12]. In particular, virtual reality (VR) allows for almost complete sensory immersion with vast design possibilities and tight experimental control, making it ideal for assessing cognitive functioning in the performance of simulated real-life tasks. The ability of VR to deliver and control stimuli while capturing responses with high fidelity during an exercise, provides a controlled and repeatable tool that is unavailable in traditional

testing methods. The opportunities VR provides for both assessment and rehabilitation have led to growing interest from the research and clinical neuropsychology communities in recent years [13]. The feasibility of using VR for cognitive assessment and care has been demonstrated across various cognitive domains, such as attention [6,14,15], executive functions [16], memory [11,17,18], and spatial abilities [19]. Moreover, in an extensive review describing the status of clinical VR, Rizzo et al indicate that studies on the use of VR for cognitive assessment have demonstrated construct validity and discrimination of clinical groups from healthy controls, while VR cognitive rehabilitation studies, though promising, have produced mixed results [20]. In a systematic review of VR cognitive rehabilitation, Larson et al [21] identify a few randomized controlled trials demonstrating effective training for memory [22-24], executive functioning [25], and visual attention [26] and conclude that further studies in the field are needed.

Although existing solutions have shown great promise for the use of digital cognitive health interventions in general, and even VR interventions specifically, these interventions have not yet been widely adopted. The majority of the VR platforms mentioned above comprise a single exercise tailored to a specific disorder, require manual exercise reconfiguration to support repeated measures, and support limited and often specific user display and interaction hardware [6,21,27,28]. Here, we outline a co-design development framework for a cognitive care platform and the platform developed using this process that addresses these limitations. The development framework includes an interdisciplinary team to match clinical intentions with exercise software design for stimuli and measurements, and a set of clinical partners to configure and validate multipurpose exercises for specific use cases.

Objective

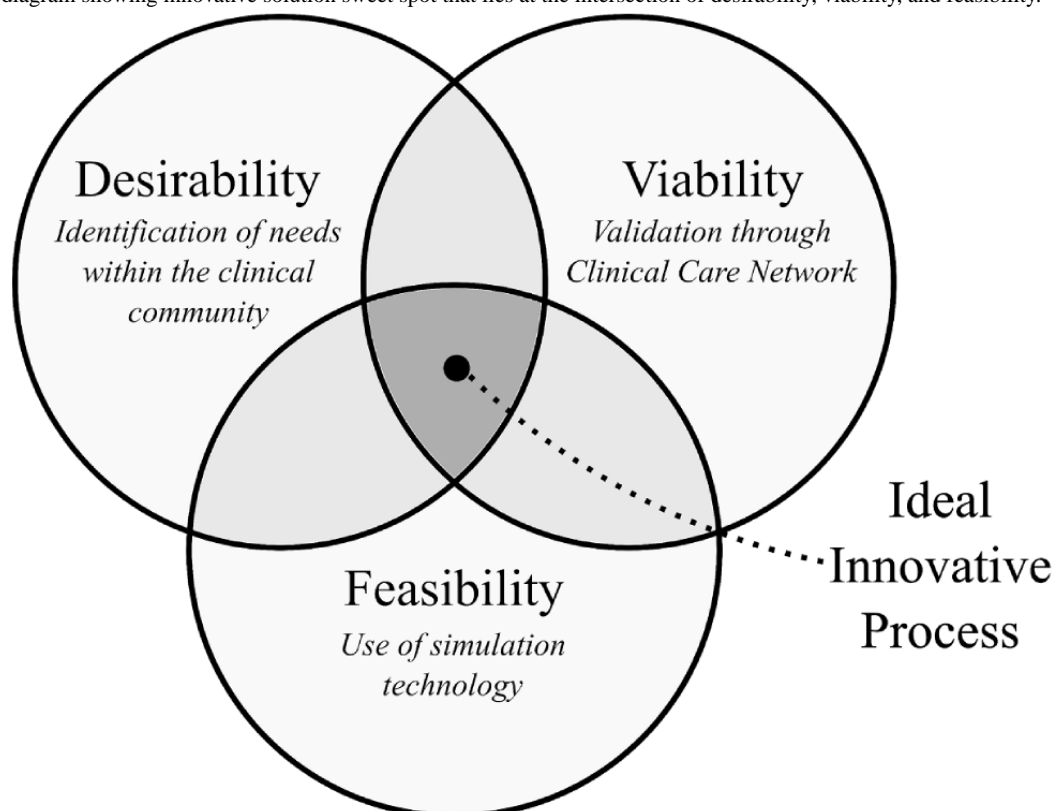
The aim of this work is to create a toolkit for clinicians to perform assessment and rehabilitation on a platform enabled with immersive technologies. Because of the novel, interdisciplinary nature of developing software for immersive cognitive care, a secondary goal is to outline a process for the iterative development of cognitive care software in collaboration with domain experts.

Methods

A human-centered approach and design thinking were used to identify key requirements for the proposed platform such that it would satisfy the criteria of being desirable, viable, and feasible (Figure 1). When these components are balanced, one can arrive at an innovation process that integrates the needs of

the end users as well as the potential of technology in a sustainable fashion [29].

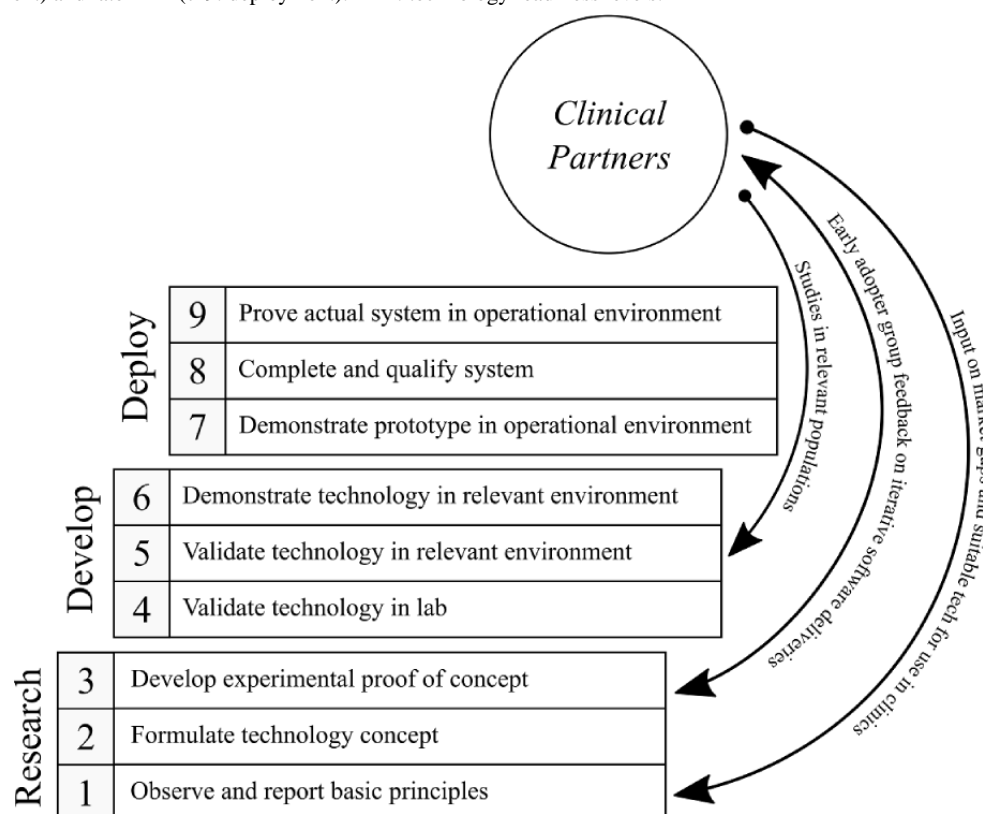
Figure 1. Venn diagram showing innovative solution sweet spot that lies at the intersection of desirability, viability, and feasibility.



Specifically, an interdisciplinary approach [30,31] previously employed by the National Research Council Canada (NRC) was leveraged to develop the bWell cognitive care platform. This approach has been successfully applied by the NRC to create surgical simulation platforms [30-35], most notably for neurosurgery, NeuroTouch (now distributed worldwide as NeuroVR by CAE Healthcare). For a feasible solution, the technology was built on the team's strengths in simulation. Over the years, the team has developed skills and expertise in assembling the pieces required for user interactivity in realistic real-time simulation, engaging users through multiple senses (visual, audio, and touch). Desirability, or the need for the platform within the clinical community, was determined through active discussion with clinical care providers and by identifying

gaps in existing solutions in the market. In the interest of viability, early on, the team established long-term collaborative research agreements with 5 world-renowned clinical sites across Canada and 1 in Japan—a cognitive care network (CCN). The CCN consists of an early adopter group that has provided domain-specific perspectives as well as feedback on iterative deliveries of the platform as bWell development progressed. The CCN is currently launching several studies investigating the content of bWell exercises, as well as its use, specific to target populations. In addition, the technology readiness level (TRL) framework [36] has been used to integrate and structure the stages of clinical collaboration within the technology development phases according to the level of maturity (Figure 2).

Figure 2. Schematic demonstrating the stages of clinical collaboration at the different TRL: early TRL (1-3: Foundational research), mid TRL (4-6: Technology development) and late TRL (7-9: deployment). TLR: technology readiness levels.



Results

Technology Readiness

The development of the bWell platform began in 2017, and activities to date have focused on research to demonstrate technical feasibility as defined in the early TRLs. During this phase of technology development, 4 main activities were advanced: (1) identification of basic requirements and key differentiating criteria (TRL-1), (2) prototype design and foundational research to implement key components (TRL 2-3), (3) testing and validation in laboratory settings (TRL 3-4), and (4) the establishment of the CCN early adopter group. The CCN was formed in 2019 to prepare for the time when the platform would reach an intermediate TRL (TRL 4-6), ready to be shifted from validation in the laboratory to validation in clinical settings.

Identification of Requirements and Differentiators

The fundamental objective of this work is to harness the affordances of immersive technologies to enable assessment and therapy that can meaningfully align with real-world problems in cognitive functioning. By creating simulations that engage users through multiple senses (visual, audio, and touch) while permitting natural movement, immersive VR creates a sense of presence (*being there*) that elicits a genuine response in an individual [37]. The use of VR environments also permits tight experimental control, which makes it feasible to measure and study everyday functioning that can otherwise be prohibitively difficult in real-world settings.

Taking into consideration the needs for cognitive care, technology affordances and innovation potential, four main requirements were identified for the bWell platform:

Requirement 1: Support for Multiple Hardware Platforms and Different Modes of Immersion (Fully, Semi-, or Nonimmersive)

Support for third-party hardware with varying levels of technical maturity facilitates the planning of clinical interventions and research in the ever-changing technical landscape of VR hardware. In addition, different modes of immersion allow for flexible content delivery in cases where immersive technology is not available or where a fully immersive environment is not well tolerated by a patient. Integrating this support also enabled the use of a range of low-cost to high-end consumer devices for clinical and home settings.

Requirement 2: A Suite of Customizable Tasks

This approach allows clinical partners to choose from the available tasks and options based on the needs of a specific patient or target clinical population (eg, pediatric and older adult patients). Common core features required by all tasks were standardized to enable a faster, more agile software development process and to open up possibilities for adding customized features. Tasks were selected to address aspects of cognition common to a variety of mental health disorders rather than a specific disorder. Additionally, configurable exercises permit pairing standardized assessment with corresponding adaptive and gamified variants for therapy, providing therapeutics that do not stand in isolation from assessment.

Requirement 3: A Clinician-Facing UI to Control the Task Parameters

This interface had to contain a wide range of adjustable parameters, exposing the extensive design options afforded by the platform. Exposed parameters would permit the clinician to administer and prescribe interventions (dosing, duration, and frequency) as well as facilitate their surveillance and control for a trial.

Requirement 4: Data Logging Mechanism

Behavioral and experimental data recorded with precise timing are required for the study of cognitive processes. To enable intra and intersubject analysis of user response and physical interaction, recording of movement data, user performance, and simulation cues and events were also required.

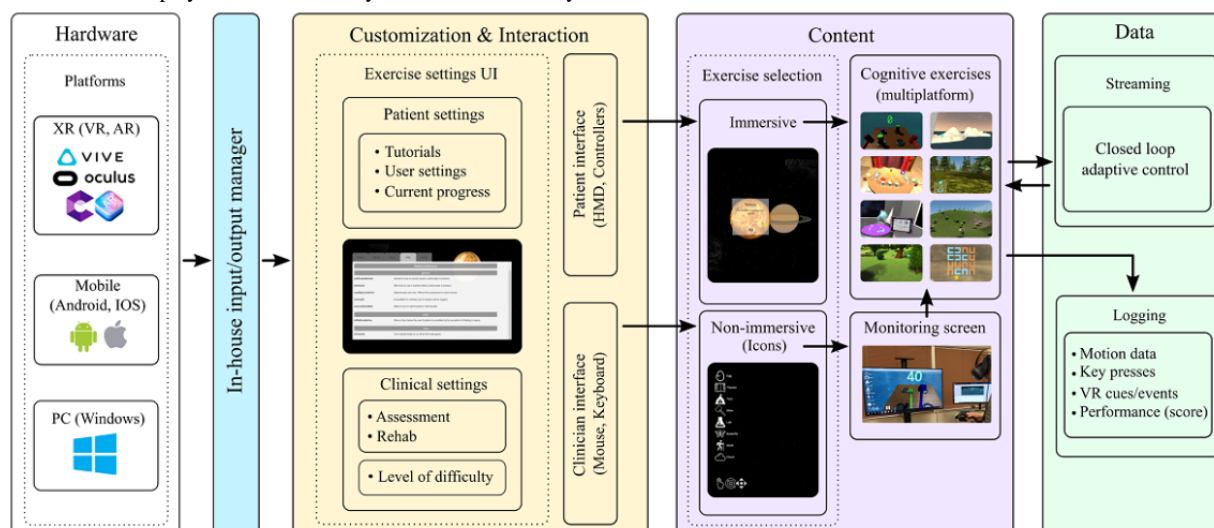
Implementation

The implementation consisted of developing a platform enabled by immersive technologies and translating the requirements identified through the active co-design process (outlined above) into hardware and software components, including the design of the content.

bWell was developed using the Unity 3D game engine and was implemented with multiple components (Figure 3). Tasks were developed around a generic core that defines the flow and

interactions between different software and hardware components. To support a variety of hardware (XR headset, mobile device, PC), an in-house input manager was developed. This component is an abstract layer that maps device inputs and outputs to a functionality in the software. The clinician and the patient interact with the platform through different interfaces to facilitate patient-clinician interactions. When the platform is launched, the clinician can access a nonimmersive user interface (UI) to configure the trial settings required to customize the intervention for the patient. The patient can interact within the virtual environment for the selection of exercises using immersive hardware. The content component contains the exercises and the monitoring system. The exercises include the virtual environment, task logic (rules and goals), instructions, and exercise-specific interactions. When using an immersive headset, the patient's point of view in their head-mounted display (HMD) is also displayed on a second screen to enable monitoring. This is the same screen through which the clinician can access the exercise settings. In addition, the clinician can launch a task by clicking on the representative 2D icon in the overlay. The final component concerns the data. Streaming data are used in a closed loop to control the evolution of the exercises based on user performance. Detailed data including motion, key presses, cues, events, and patient performance are also logged into files for post analysis.

Figure 3. bWell architecture components (Unity 3D engine): (1) in-house input or output manager for hardware, (2) comprehensive user interface for customization of patient and clinical settings, (3) content displayed immersively to the patient or nonimmersively for clinician administration, control and monitoring, and (4) resulting data are streamed for real-time adaptive control and automatically logged for offline analysis. AR: augmented reality; HMD head-mounted display; VR: virtual reality; XR: extended reality.



Development Process

The research team made use of agile software development, including feature-oriented code implementation, common code repository, software testing, user tests, bug tracking, and frequent software releases. Standardized user testing was developed to solidify the integration of hardware and software features. Individuals new to the platform were included as testers to reinforce usability and to reveal issues that those familiar with the system could no longer identify. Furthermore, to help maintain the major features of each of the exercises and the core features, unit tests developed with the integrated Unity 3D tools

were put in place to automate the process. To obtain active input from domain experts, the agile methodology included regular delivery of technology to early adopters to obtain iterative feedback. This feedback informed the successive phases of software development.

Prototype Development

The technical feasibility activities for bWell led to the development of a prototype at a TRL-4 maturity level that has been tested and validated in a laboratory environment (Figure 4).

Figure 4. bWell laboratory set-up with a user immersed in a virtual reality environment and the point of view displayed on an auxiliary monitoring screen.



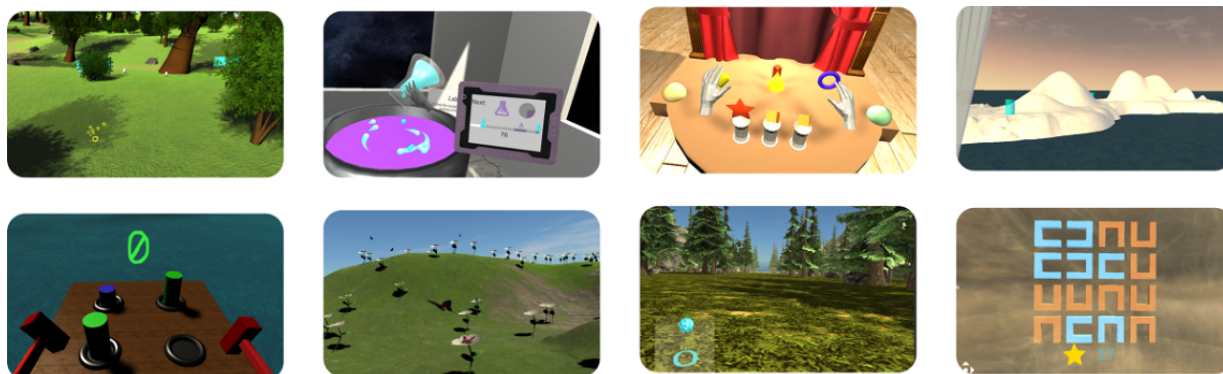
The prototype was designed to be administered by clinicians in various clinical environments. Its architecture was kept flexible, accommodating various input modalities and administration hardware, because it was identified that each clinic had different hardware needs depending on their patient constraints or limitations, price, availability, and the hardware that they already owned. Thus, the prototype was implemented as multimodal (fully, semi-, or nonimmersive) and multiplatform (Oculus, HTC Vive, Hololens, tablet [iOS and Android], and desktop). Automatic detection of the connected devices is executed when the platform is launched, making it a seamless feature for the

user, thereby facilitating the long-term goal of functioning in a home environment with remote monitoring by a clinician.

Exercises

The exercises provided in the prototype were developed to target cognitive domains common to multiple mental health disorders, including attention, memory, and executive control. To promote presence and immersion in the simulation, all exercises make use of multisensory feedback (visual, audio, and touch). Some exercises were designed to target a specific domain of interest, whereas others simultaneously engage multiple cognitive domains to be representative of everyday tasks. A total of 8 exercises were implemented (Figure 5).

Figure 5. Cognitive exercises: (Top row) states of attention (Egg), multitasking (Lab), visual working memory (Theater), relaxation (Tent); (Bottom row) response inhibition and cognitive control (Mole), self-regulation (Butterfly), sustained attention (Stroll), visual search (Cloud).



States of Attention (Egg)

The user must first scan the environment for eggs. They are then required to direct and hold their gaze on a located egg long enough to make it hatch (attentional focus). Audio and visual

distractors in the environment challenge the user, and bonus points are awarded if the user reacts to a cue while fixating (covert attention).

Multitasking (Lab)

The user must complete 2 recipes simultaneously to investigate their ability to accomplish a range of tasks by swapping between them strategically or by planning the order in which they can be performed most efficiently. This requires the user to closely follow the recipe steps (ability to monitor) displayed on the virtual tablet screens in front of them.

Visual Working Memory (Theater)

Inspired by matching tasks for visual and short-term memory, the user is presented with target shapes ordered from left to right. After a set viewing time, the targets are hidden. After a specific time (delay recall), objects fall into view of the user, some of which are the target and others are not (comparison objects). The user is required to select the targets from all the objects and place them in the order presented within a limited time.

Response Inhibition & Cognitive Control (Mole)

A Whack-A-Mole variation is used where the user has a hammer in each hand and has to hit cylinders that pop up in front of them. The colors of the hammers change over time, and the cylinders also have different colors. The user should only hit cylinders with a hammer of the same color (go signal).

Self-regulation (Butterfly)

The user engages in motor self-regulation through an activity that rewards self-restraint. The user is instructed to catch butterflies with a net but must do so in a gentle fashion because brisk movements scare them away. A motion speed indicator is visible on the net to promote self-awareness. The user can monitor, control, and inhibit unproductive motor responses that may be triggered when the butterflies are near.

Sustained Attention (Stroll)

This is an immersive version of a sustained attention to response task, a go or no-go task with infrequent no-go events to measure user attention. The user is provided a self-avatar, taking a stroll in a natural scene. Shapes continuously appear in front of the user, and a button must be pressed when each new shape appears, except when it is a green diamond.

Visual Search & Attention (Cloud)

This is an immersive version of a visual search and attention test, in which a grid of orange and blue *U* shapes is displayed in front of the user. The user must find the only blue *U* shape that points upward or downward and respond with the corresponding up or down response on their controller. Orange shapes and blue shapes pointing left or right are distractors that must be ignored.

Relaxation (Tent)

In relaxation and sensory exploration, the user is immersed in scenic views and asked to look around while focusing on their breathing. A rhythmic object is present to guide their breathing pace. Close adherence to the rhythmic object should have a calming effect. The user is free to explore the scene in which they are or to select a different scene from a set of options presented to them as pages in a book. This exercise was also designed for eventual self-guided stress management, where future efforts will include the integration of heart rate variability biofeedback based on slow-paced breathing within virtual nature scenes.

Clinician Customization and Monitoring Interfaces

The clinician-facing UI was developed to allow the exercise parameters to be customized and for functionalities to be turned on or off during the exercises. A scrolling menu (Figure 6) provides access to the settings to design the variants of a given exercise, or establish the dosing of an intervention, pairing standardized assessment with corresponding adaptive and gamified variants for personalized rehabilitation training. The settings can be saved and shared, allowing multiple clinical sites to conduct studies with standardized configurations. While a patient participates in a bWell trial with an HMD, a white overlay of clickable icons are available to the clinician to assist with operating and controlling the VR experience received (Figure 7). The icons allow the clinician to launch a specific exercise (left panel) and to intervene if needed, such as start or end the exercise, recenter the user in the immersive environment, or pause the session (bottom panel).

Figure 6. Clinician-facing user interface with clinical exercise settings interface under Clinical tab.

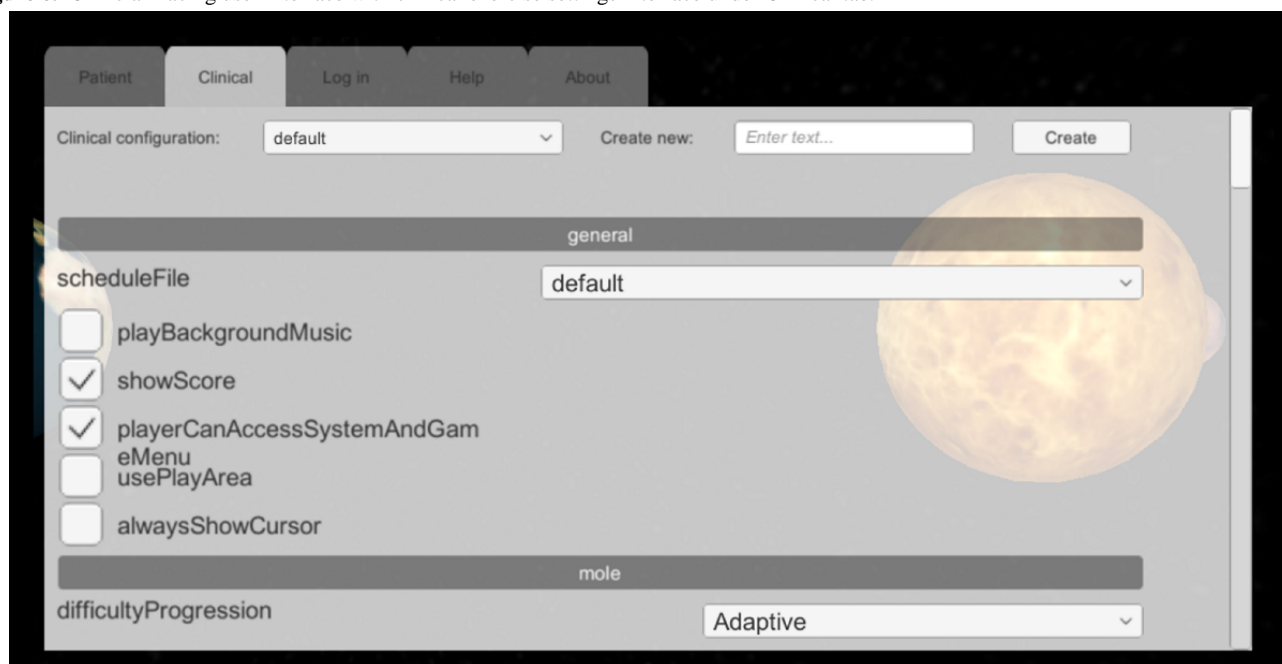
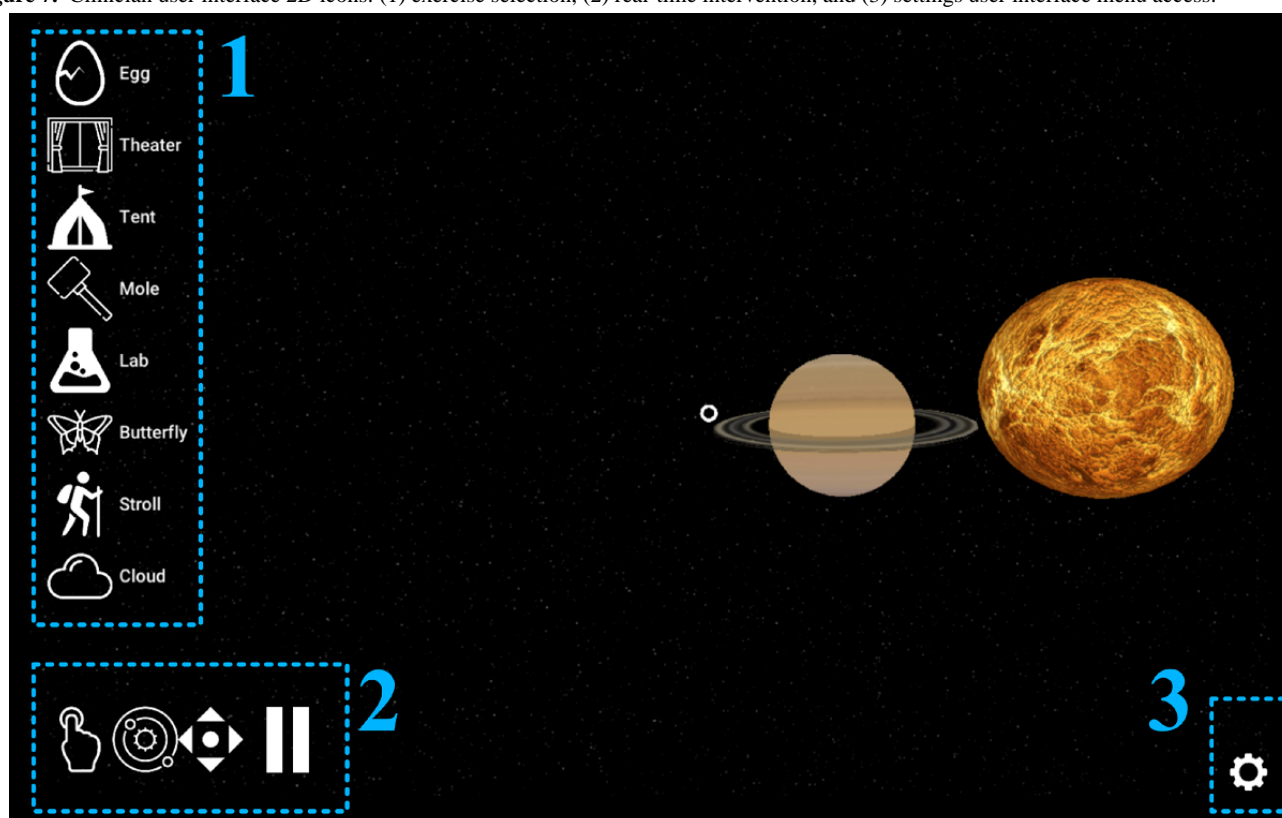


Figure 7. Clinician user interface 2D icons: (1) exercise selection, (2) real-time intervention, and (3) settings user interface menu access.



Task Parameters

bWell was designed to serve as a toolkit; so, task parameters were designed to be highly configurable. Several personalization elements were included to promote a sense of embodiment. The self-avatar can be personalized with elements such as gender, skin color, height, and dominant hand that can be modified in a patient settings tab added to the clinician-facing UI. bWell's design also considers potential physical limitations of users,

giving them the option to play while standing or sitting. The patient settings can also be used to adjust the height of certain elements inside an exercise if the auto-adjusting features are insufficient. In addition, the patient VR interactions in bWell use multiple input types, such as gaze direction, teleportation, and grabbing or hitting objects, to accommodate participants with conditions that limit dexterous hand movements.

Task difficulty parameters were configured to allow for personalized assessments and rehabilitation plans. Difficulty

levels can be set at fixed levels by the clinician, ensuring trial reproducibility for comparison with past performance or across participants, or set to use an adaptive algorithm configured to achieve an 80% success rate. Intra and intersession difficulty progression settings are also available.

All task parameters are logged using a completely automated logging system to facilitate offline analysis. In addition to logging exercise settings, event orders, and difficulty levels, the system records an array of timestamped, synchronized data, including motion tracking, exercise events, cues presented to the user, and performance measures. The logs, anonymized for confidentiality, are output as JSON and CSV files, which are compatible with standard data analysis software.

Other features were included to add variety to gameplay and to promote the repetition of tasks typically required in cognitive rehabilitation protocols. Gamification elements, such as rewards and animations, were integrated to promote adherence and engagement and to provide feedback on performance. Visual cues, audio cues, and sometimes distracting elements were also incorporated. In certain exercises, the displayed virtual environment can be explored with a teleportation feature, or the user can select between different virtual environments.

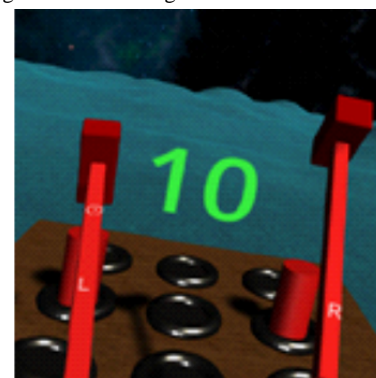
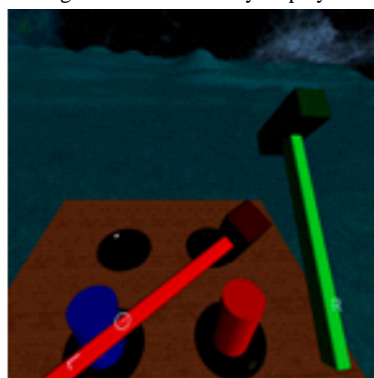
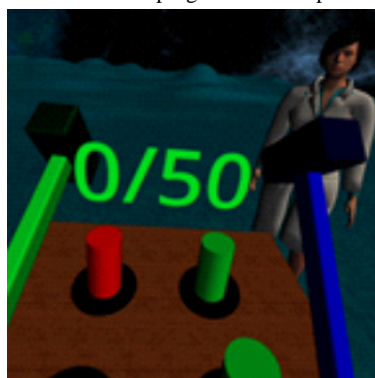
Intervention Modes

bWell is designed to operate in three modes: (1) tutorial, (2) assessment, and (3) rehabilitation. Each mode is designed to address a specific set of clinical requirements determined through early adopter feedback.

Tutorial Mode

In the tutorial mode, participants engaged in structured learning of the required actions for each task. This was implemented to ensure that participants began assessment and rehabilitation exercises with comparable levels of familiarity with the actions required to complete the exercises, even if they had different baseline levels of familiarity with XR. During the tutorial for each exercise, a standardized set of instructions is presented in writing and verbally by a humanoid avatar. If an action was not executed after a specified time interval, a revised version of the instructions was presented to increase the likelihood that participants properly understood what was required. The humanoid avatar also provided verbal feedback about successes and failures throughout the tutorial (Figure 8, left). The only way to progress through the tutorial is by successfully executing the specific required actions, at which point the participant can continue engaging in free practice without any specified goal. The clinician can then transition from the tutorial mode to the assessment or rehabilitation mode through the clinician-facing UI.

Figure 8. bWell Mole exercise as an example of modes and configurable parameters. The left image shows the tutorial mode with the score that must be achieved before the exercise can begin. The humanoid avatar provides instructions and verbal feedback on successes and failures. The center image shows the mole exercise in progress at a fixed, low difficulty level (4 cylinders) without any feedback on successes and failures. The right image shows the mole exercise in progress with adaptive difficulty leveling and a score visually displayed. This configuration aims for gamified rehabilitation.



Assessment Mode

In the assessment mode, participants completed the exercise with events always occurring in the same order and with the same timing (ie, based on a fixed randomization seed) and with fixed difficulty levels [38] (Figure 8, center). The seed number that determines the order and timing of events can be modified by the clinician such that assessments can be pseudorandomized across sessions or participants. The clinician configures the settings for each difficulty level to best meet their assessment needs. Because the presentation to each user is consistent, it is possible to assess user performance against established results or in comparison to others in the same study. For example, commission errors (incorrect hits) are of particular interest when investigating cognitive control.

Rehabilitation Mode

In the rehabilitation mode, the emphasis is on parameters that promote patient adherence by increasing engagement and providing feedback on performance. Adaptive algorithms adjust current level of difficulty based on performance to ensure that it is never too easy (boring) or too hard (demoralizing) for the user [39]. For enhanced motivation, real-time feedback is provided with level or score changes as well as success and error indications (Figure 8, right). Finally, in the rehabilitation mode, the series of events in each session is randomized to avoid redundancy. Therefore, even if the progress is reset between sessions, a patient should never see the exact same series of events twice.

Acceptability Study Results

The authors conducted 2 preliminary acceptability studies with healthy participants and have described them in previous reports [40,41]. These studies showed that using immersive VR for clinical applications is not only technically feasible but also well tolerated and has advantages over traditional 2D equivalents. The first study showed that subjective reports of engagement when performing a task in bWell (an immersive environment) were greater than those when performing the same task on a tablet (a nonimmersive environment) [40]. The second study showed that two types of passive displacement, linear and sinusoidal walking vection, did not increase subjective reports of cybersickness during a visual attention task [41].

The results of these preliminary studies demonstrate the acceptability of the bWell platform. The careful attention taken during the design regarding cybersickness has shown successful administration even in participants who reported being highly susceptible to motion sickness. bWell tasks in immersive VR, both in static scenes and those involving more complex user motion, were well tolerated and engaging for healthy participants and provided the required support for testing in clinical populations as the next steps. In addition, as it was determined that engagement is not the same for immersive versus nonimmersive delivery of the exercises, the fully semi-, or

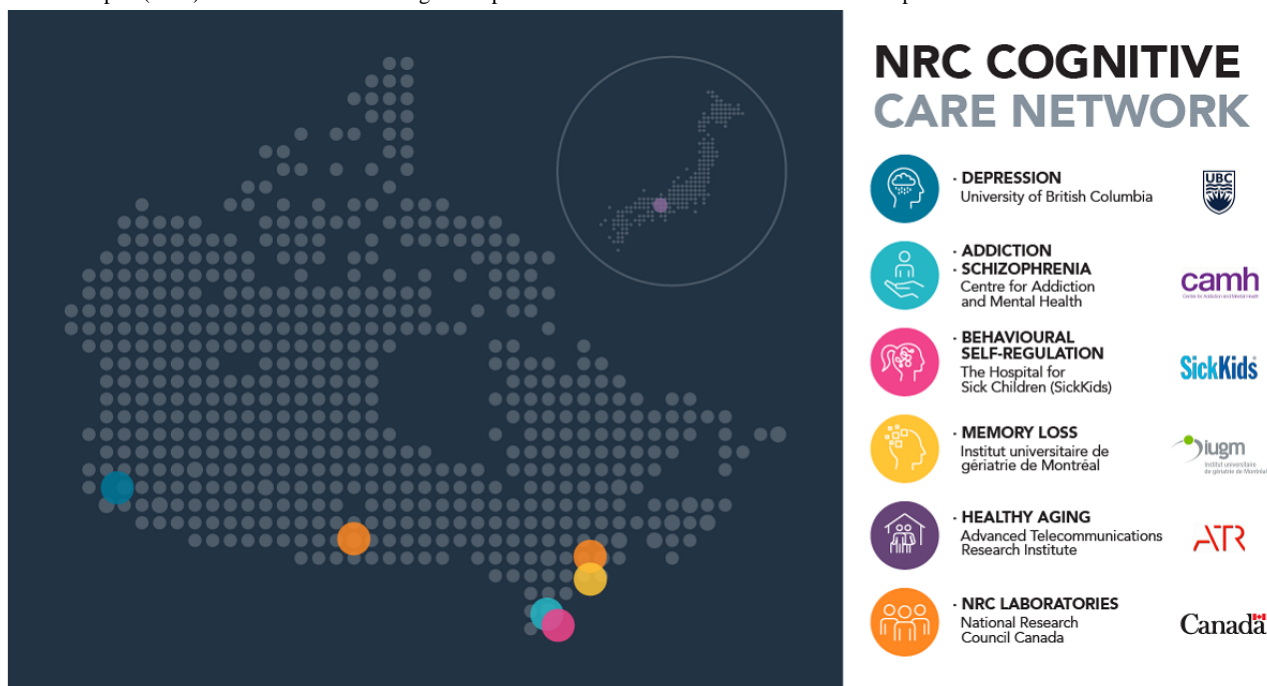
nonimmersive modes may result in different user performances. As such, and in particular for cognitive assessment, comparisons of task results should be performed within a given mode of immersion.

Although bWell has shown general acceptability and tolerability, a small number of users experienced mild cybersickness. The Biomedical Data Intelligence team at the NRC investigated the use of an avatar within the bWell environment to monitor user discomfort. The dialog agent provides instantaneous and interactive assistance to users in the form of personalized advice on symptom relief [42]. The results show promise for the development of virtual agents for cognitive self-care and will be further explored for use within bWell.

Cognitive Care Network

The prototype is currently being taken beyond the laboratory and into clinical settings. To provide domain-specific expertise and clinical validation, a CCN was assembled consisting of 4 institutions across Canada and 1 in Japan (Figure 9). They have expertise in addiction, schizophrenia, memory and mild cognitive impairment in older adults, executive functioning in pediatric populations and major depressive disorders with backgrounds in neuropsychology, psychiatry, and clinical psychology.

Figure 9. Cognitive Care Network (CCN) sites. The CCN includes 5 clinical partners at 4 sites across Canada (CAMH, IUGM, SickKids, and UBC) and 1 site in Japan (ATR). Sites cover a broad range of expertise and are critical for the iterative development of bWell.



Evaluation of bWell by clinicians began in 2019 to provide domain-specific input throughout the bWell development process. bWell has thus far been installed at 4 locations, and ongoing feedback from early testing at these installations has been incorporated in iterative improvements. Adaptations of bWell exercises to target clinical populations have begun. These activities are structured according to the Birkhead et al VR trial methodology [43], including co-design of content with patients and early studies (feasibility, acceptability, tolerability, and initial clinical efficacy), as well as randomized controlled

trials investigating the outcomes of the use of bWell. As these activities are currently underway, they are beyond the scope of this paper.

Discussion

Principal Findings

The use of digital solutions has the potential to address the current gap in mental health care resources. To this end, digital therapeutics have entered the pharmaceutical landscape [44].

Web-based and mobile apps can improve the accessibility and affordability of care and can help keep patients motivated and engaged during interventions. To maximize the latter value, digital solutions have taken creative approaches, using game-based therapy or leveraging technology to create more immersive experiences [45]. XR platforms on the market currently include mental health care for behavioral health (BehaVR), autism and developmental delay screening (Cognoa), and stress management (Healium). Although XR solutions are currently in the stages of demonstrating evidence on the benefits of use, some mobile-based digital therapeutics have reached regulatory approval [46]. For example, Pear Therapeutics has received authorization from the US Food and Drug Administration (FDA) for prescription-based digital therapeutics for substance abuse disorders and chronic insomnia. Moreover, in 2020 the FDA permitted the marketing of the first game-based digital therapeutic by Akili Interactive to improve attention function in children with attention-deficit/hyperactivity disorder [47,48].

A primary driver for the use of VR technology is its capacity for sensory immersion with tight experimental control, making it feasible to test or study cognitive and sensory-motor functioning that is typically prohibitive in real world settings because of the unpredictable and uncontrolled events that occur in everyday life. Immersive and engaging tasks were selected in bWell to encourage meaningful user interactions. The simulated scenes were also designed to be multisensorial and interactive to permit naturalistic movement, increasing the likelihood that skills learned within VR would be transferable to real life.

Another driver for the use of simulation technologies is the ability to capture rich behavioral data simultaneously. As users interact in virtual environments, all activities can be recorded for analysis. bWell was implemented with two data workflows—one with data streaming for real-time adaptive exercises and the other with data logging for offline analysis. In bWell, streaming data are used in a closed loop to adapt the exercises in real time, targeting patient-specific rehabilitation. Currently, data on user performance are used as input for adaptive algorithms that adjust the difficulty levels of the exercise accordingly. The integration of wearable, physiological sensors in XR scenes is also currently in progress to enable biofeedback. In this case, features derived in real time from sensor data are used as input to adapt the exercises. As part of the collaboration with the Advanced Telecommunications Research Institute from the CCN, new exercises are being developed for cognitive training using an electroencephalography-based brain-machine interface to control a virtual third arm [49]. This work has broad applicability as it provides a novel form of multitasking training for elderly users to cognitive load training in operational environments.

In bWell, data are also currently being logged for offline analysis, with information including motion, key presses, VR cues, events, and patient performance. In this workflow, the goal is to derive features from sensor data that cannot be obtained from real-time processing. For example, classification of user states can be obtained with predictive models built using techniques performed offline, such as cognitive modeling and

machine learning. With user state obtained from quantitative measures, such as user reaction to an increase in exercise difficulty or adverse response, VR assessments coupled with physiological sensors can provide more objective measures of individual function than a traditional self-report, which is known to be an unreliable index of functional outcomes [50]. By collecting behavioral and physiological responses during carefully designed VR interventions, the long-term vision is to create closed-loop adaptive digital interventions for characterizing and treating cognitive deficits, as well as enabling treatment providers to predict real-world clinical outcomes.

During the development of the platform, two lessons were learned. First, design with a generic core and providing users with customizable options is a valuable approach for developing applications for a variety of treatment providers. To accomplish this, the bWell platform was designed to target specific cognitive domains rather than specific pathologies. Clinicians select exercises from the available ones to address the needs of a particular patient. This choice provides an opportunity to address symptoms rather than disorders. The treatment provider can further customize individual exercises by choosing from the configurable settings, such as enabling 1 of the 3 basic modes (tutorial, assessment, and rehabilitation) or turning specific functionalities on or off. In the study of cognitive functioning, this means that one is able to design a paradigm specific to a research question by choosing the virtual environment (eg, game-based or real-world setting), the type of experimental stimuli (eg, target, distractors, cueing, and feedback), the time and type of presentation (multisensorial or not), and the type of user response (eg, aim to minimize errors or perform as quickly as possible).

Second, avoiding dependence on specific hardware is advantageous when developing with XR. The implementation in bWell was hardware agnostic, multimodal, and multiplatform, accommodating the range of specifications coming from different potential clinical applications and increasing its staying power in the rapidly changing technological landscape. The work done on bWell focused on the use case where clinicians administer the intervention. However, the hardware agnostic core of the platform considers its eventual use at home with remote monitoring by clinicians. bWell's core was also designed to accommodate the evolution of commercially available HMDs. HMDs have come a long way, from unwieldy, tethered devices to performant and comfortable standalone units aimed at the mass market. bWell's core also allows for other modes of content delivery, such as AR or mobile, when immersive VR is not suitable. For instance, Google AR glasses have shown to be promising for teaching children on the autism spectrum to recognize emotions in real time [51]. Given that a headset obscures facial expressions, the use of VR is not suitable in this context. The use of bWell as a mobile app might also facilitate pervasive use at home, given the ubiquity of smartphones. Nonimmersive XR may also provide an option for those susceptible to cybersickness in immersive environments. Thus, further advancement of bWell is planned in these directions.

Conclusions

bWell, developed by the NRC, is an immersive and interactive cognitive care platform that delivers assessment and therapeutic tasks as a multisensorial experience (visual, auditory, and touch). The technology has attained the maturity level of prototype implementation with preliminary validation carried out in

laboratory settings. A CCN of early adopters was formed to evaluate the system and access domain-specific perspectives. Within this network, 4 installations of bWell prototypes have been completed, and the next steps have begun to adapt the system and to co-design content targeting specific clinical populations. In addition, we plan to perform the validation required for the eventual adoption of bWell as a clinical tool.

Conflicts of Interest

None declared.

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Abbreviations

AR: augmented reality
CCN: cognitive care network
FDA: US Food and Drug Administration
HMD: head-mounted display
NRC: National Research Council Canada
TRL: technology readiness level
UI: user interface
VR: virtual reality
XR: extended reality

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Original Paper

A Virtual Smash Room for Venting Frustration or Just Having Fun: Participatory Design of Virtual Environments in Digitally Reinforced Cancer Rehabilitation

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Abstract

Background: Cancer rehabilitation is central for helping patients and relatives create a functional everyday life based on the changes in life conditions. The needs are highly individual and include physical, mental, and social challenges. Cancer rehabilitation programs offer coping strategies, including guidelines on how to handle emotions.

Objective: This paper presents a participatory design activity where patients in cancer rehabilitation use a virtual smash room, which is a virtual environment where the user can break things, mainly porcelain or glass items such as vases or plates. The objective is to understand attitudes to, and some effects of, using this application, as well as eliciting ideas of other virtual environments that would be desired.

Methods: The virtual environment presented here, the virtual smash room, was designed at the request of a patient with cancer who wanted a tool for venting frustration. In this virtual environment, the user can break porcelain, vases, and plates. Patients participating in a week-long cancer rehabilitation program tested the virtual smash room and reported their experiences through a questionnaire. The questionnaire comprised three sections: (1) a subset of the Intrinsic Motivation Inventory (IMI), (2) a subset of the Virtual Reality Symptoms Questionnaire (VRSQ), and (3) a free-text response section.

Results: A total of 101 responses were gathered. The results from the IMI questions showed that the participants found the virtual experience enjoyable (mean 4.52, maximum 5, SD 0.73), and it helped them retain their focus (mean 4.44, maximum 5, SD 0.74). The VRSQ revealed that there were only minor symptoms related to general discomfort (5.9%, n=6), fatigue (5.9%, n=6), nausea (3.0%, n=3), and tired eyes (8.9%, n=9), while several participants experienced dizziness (22.8%, n=23). Since only postmeasurements were gathered, nothing could be concluded about the prevalence of these symptoms before testing. The free-text responses indicated that the user group had many ideas for other virtual environments to use in cancer rehabilitation.

Conclusions: This study presents a concept of using virtual reality in the cancer rehabilitation process and exemplifies activities of patient participation in the design process. Virtual reality has potential in being both distracting and enjoyable, while certain aspects of cybersickness might be especially important to consider for a user group already experiencing physical and mental issues. The results will act as input in the process of further designing virtual applications in digitally reinforced cancer rehabilitation.

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KEYWORDS

virtual reality; virtual environment; cancer rehabilitation; emotions; participatory design; virtual smash room; human factors

Introduction

The global cancer burden is continuously rising, with more people living with the effects of cancer illness and treatments [1-3]. Both patients and their relatives find it difficult to find a satisfactory and productive life after cancer treatment [4-6]. This is where cancer rehabilitation plays an important role, as patients are helped to return to activities of daily living by overcoming physical, emotional, or social issues affecting their quality of life [7]. The demand for cancer rehabilitation is growing. It is difficult, however, to meet these demands in an already pressured health care system, especially since the effects of both cancer and cancer treatments are highly individualized and can be very complex. They may include physical aspects, such as pain, physical fatigue, and balance issues; mental aspects, such as mental fatigue, distress, and anxiety; social aspects, such as managing relations and adjusting the work situation; and economical aspects owing to a low working capacity. Alternative ways of organizing cancer rehabilitation that take into account this complexity along with the individual needs of each patient need to be addressed [4-6,8]. Digital solutions, including websites, mobile technology, wearables, and virtual reality (VR), are being explored in cancer rehabilitation as a way to empower patients and ease the burden on the health care system [9-11].

In a Swedish research program, the opportunities for digital support in cancer rehabilitation have been explored in a participatory process, in which researchers, patients, patient organizations, health care staff, and their organizations have cocreated ideas and concepts for this purpose. One patient with cancer, and similarly a researcher and coauthor of this paper, expressed a desire for a tool that would distract and enable venting one's frustration when dealing with specific situations in the cancer rehabilitation process. The use of VR for such a tool was proposed as a potential method, and the idea of a virtual environment where objects could be smashed was devised. This was the background for creating the specific application of a virtual smash room, corresponding to the real-world analogy referred to as "smash rooms," "rage rooms," or "anger rooms" [12].

VR enables users to immerse themselves in an alternative reality where they experience presence; that is, the sense of being present in the environment depicted by the VR system [13]. Here, they can interact by reacting to the actions and objects

the virtual environment encompasses. Research shows that people react in VR in ways that are similar to how they react to corresponding real-world environments [14,15]. There are also indications that virtual nature experiences can promote recovery from stress [16], and that interacting with virtual scenarios can elicit or strengthen different emotions in a user [17]. A cancer diagnosis inevitably evokes a lot of emotions [4,18-20], including fear, anxiety, frustration, hope, and guilt. Many patients also struggle with existential issues [21]. Life changes in different ways and coping strategies on how to handle this are being explored [22-24]. It is thus worth exploring if VR can be a complement to today's methods for coping in cancer rehabilitation.

Working participatory in health care, and making the patient an active part of health care interventions, is an approach to let patient's needs and perspectives guide the design of solutions and the changes to clinical practice [25]. Furthermore, this does not simply involve asking patients what their problems are and then create solutions based on them, but rather this involves continuous activities in which patients and designers define and redefine the problems and iteratively create potential solutions [26].

This study reports on such a participatory design activity where patients in cancer rehabilitation use the virtual smash room, with the objective to understand attitudes to, and some effects of, using this application. Our results would provide further input to the concept of using virtual applications for coping in cancer rehabilitation.

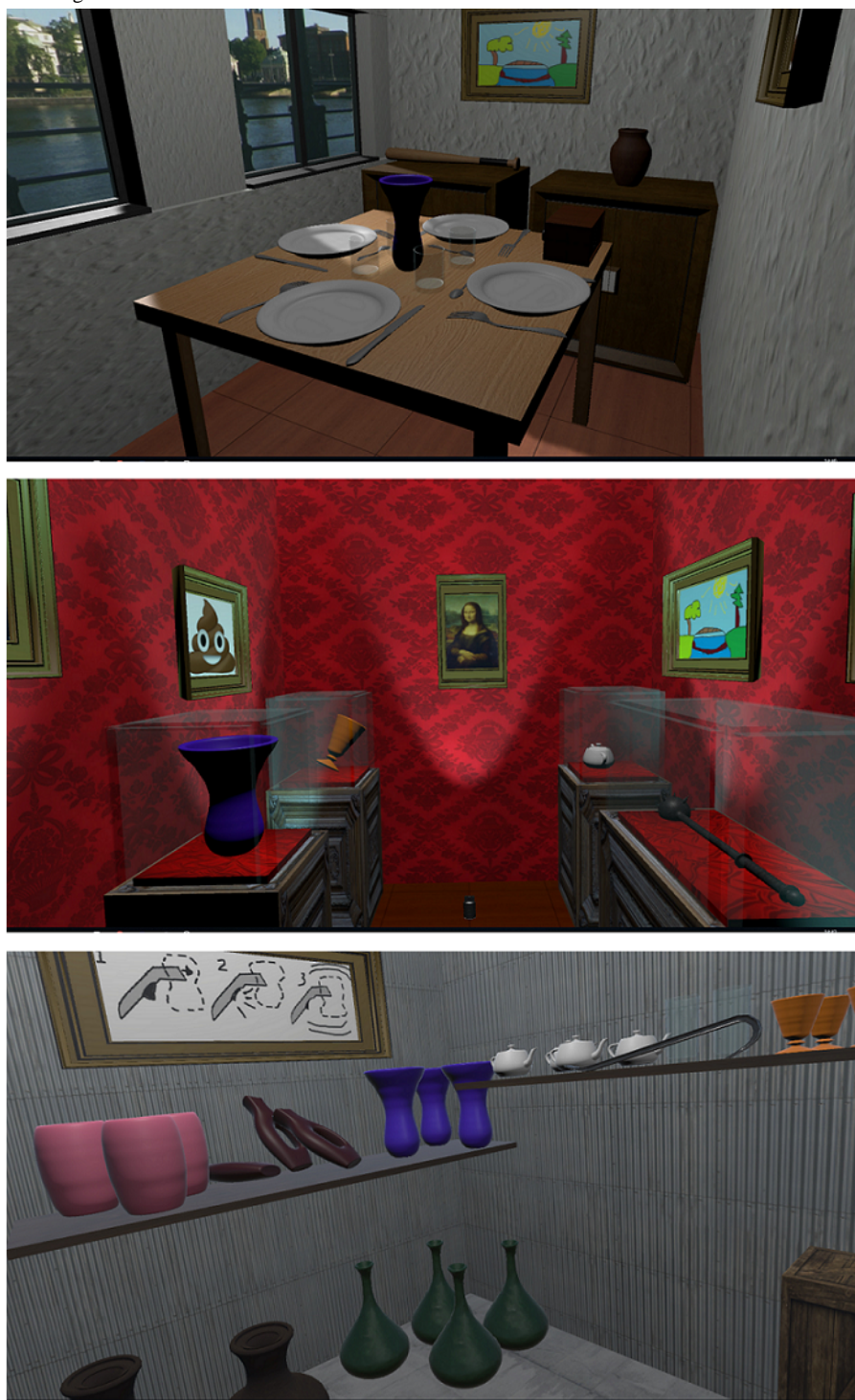
Methods

The Virtual Smash Room

The virtual smash room is a virtual environment where the user can break things, mainly porcelain or glass items such as vases or plates. The application was developed in a participatory process in which a key user—the patient, researcher, or coauthor—continuously tested and provided feedback until a VR application was ready to be evaluated by a wider user group [27].

The virtual smash room consists of 3 different settings, each with its own theme: a dining room with a table and 2 cupboards filled with glass and porcelain, a museum with glass showcases containing fragile objects, and a factory containing large vases and boxes that require a little more force to break (Figure 1).

Figure 1. Screenshots from the 3 settings in the virtual smash room (from top to bottom): a dining room with glass and porcelain, a museum with glass showcases, and a factory with large vases and boxes.



The virtual smash room was developed using Unity for usage with an HTC Vive VR system. The latter is a head-mounted display (HMD) accompanied by 2 hand controllers for manual interaction with the displayed environment. The movements of the HMD and the hand controllers are registered by an optical tracking system capable of tracking an area of approximately 3.5×3.5 meters. Consequently, the user can move around within a limited area and interact with objects in the virtual environment by using the hand controllers. The user can pick up breakable objects and throw them or smash them against

surfaces in the room. There are also virtual tools the user can pick up and use to smash the breakable objects, such as a wooden paddle, a morning star, a hammer, or a crowbar.

When used as envisioned, the virtual smash room requires the user to be physically active by moving around and waving his or her arms. The user can interact either by standing up or sitting down if so desired, or required owing to physical limitations. [Figure 2](#) illustrates one of the authors using the virtual smash room.

Figure 2. One of the authors using the VR application, wearing the HTC vive with the head-mounted display and the handheld controls. The computer screen in the background shows what the user is seeing.



Setting

The location of the study was a cancer rehabilitation venue in Sweden. A room was made available to house the virtual reality equipment for patient usage. The venue hosts a week-long cancer rehabilitation program for patients. Each week, up to 16 people participate in activities including the following:

1. Lectures and practical exercises related to physical and psychological side effects, fatigue, emotional effects, etc.
2. Physical exercise and body literacy with a physiotherapist.
3. Mindfulness, yoga, and qigong both indoors and outdoors.
4. Group and individual therapeutic conversations.

The VR experience was scheduled in the middle of the week on the day focused on patient's emotions during their cancer trajectory.

Study Design

In the early phase of the participatory design process, ideas and concepts are explored together with user groups to collect input and find ways for further development. Before entering the stage

of validating an application for certain effects, it is central to ensure that it is the right application that is being developed. The purpose of testing the virtual smash room in the cancer rehabilitation venue indicated above was to gain input regarding the use of a VR application for ventilating emotions by the actual user group as a formative step in the development process. The focus in the test situation was to capture reactions to the VR application itself, to determine whether it was engaging to use, and to allow for for alternative applications. Accordingly, the virtual smash room served as an artefact for inspiration.

All participants in the rehabilitation week were offered to test the virtual smash room, except for certain weeks when, for example, the group of patients were considered too fragile, or part of the patients needed to spend time on other activities. The staff of the cancer rehabilitation venue determined this from week to week.

A member from the staff was present throughout the whole session. That person introduced the technology and potential side effects, and assisted participants in using the system. The HTC Vive over-ear headphones were used to provide sound

feedback but never completely obscured the sound from other people in the room; thus, communication between the participant wearing the HMD and others was possible when using the VR system. Since this is a sensitive user group that might experience physical issues, mental fatigue, and emotional distress, the test was designed to minimize the effort from the participants. Hence, there were no strict instructions, and the participants were free to test a longer or shorter time, and test one or several of the “rooms” in the application. The participants could furthermore choose to either stand or sit down while using the VR system.

The study was performed in line with ethical standards and was approved by the Swedish Ethical Review Authority (2019-01542). Each person who accepted to participate received information about the study and his/her right to end the participation at any time.

Data Collection

After testing the VR system, each participant was asked to fill in a paper questionnaire to provide data about their experience. The questionnaire comprised three sections based on content from: (1) the Intrinsic Motivation Inventory (IMI) [28,29], (2) the Virtual Reality Symptoms Questionnaire (VRSQ) [30], and (3) a free-text response section.

Since just being in the virtual environment can be a tiring experience in and of itself for this user group (many already experienced mental and physical fatigue), a limited selection of questions to answer was chosen. No personal data, regarding age, gender, or health information, was collected since it was not considered relevant at this stage of the design process. The questionnaire included nine items: 4 from the IMI and 5 from the VRSQ, and 1 section for free-text answers. The process of designing the questionnaire was carried out together with the patient with cancer/researcher/coauthor, and the questions were carefully selected to provide a relevant representation of the content of each questionnaire, without risking that the users did not have energy to answer any questions at all.

The IMI instrument assesses multiple dimensions of a person's experience of a specified activity, in this case the VR system. The original instrument measures the following: interest/enjoyment, perceived competence, effort, value/usefulness, felt pressure and tension, and perceived choice.

The IMI statements can be adjusted so that only certain dimensions are in focus, or can be rephrased to match the specific activity [31]. The 2 dimensions—interest/enjoyment and felt pressure and tension—were considered most important for evaluating the virtual environment for this user group. Only a selection of the questions from these subscales (4 in total) were used at this point to minimize the size of the questionnaire. A 5-point Likert scale was used, ranging from 1=not at all true to 5=very true.

The VRSQ consists of 13 questions that measure physical symptoms, such as headache or nausea that may be experienced when using a VR system [30]. Potential symptoms are important to detect since the user group can be extra sensitive to these effects owing to their disease profile. Again, a subset of questions was selected, to make sure that the questionnaire was not too extensive. Five of the original questions were included to capture any symptoms of general discomfort, fatigue, headache/dizziness, nausea, or tired eyes. The response alternatives were limited to yes/no.

In the free-text section, participants could comment on their experience in their own words. They were also asked to write down ideas they had for other environments they would like to experience in VR.

Results

Results Overview

In total, 101 questionnaires were collected from unique participants who tested the virtual smash room at the cancer rehabilitation venue, from October 2019 to March 2020.

Tables 1 and 2 present the results from the IMI and VRSQ parts of the questionnaire. Table 1 lists the 4 IMI statements relating to “interest/enjoyment” and “felt pressure and tension.” The results show that the participants agreed that the VR experience was enjoyable and that it held their attention and were not distracted by other things around them. The results indicate that the majority did not feel tense and were fairly relaxed. Several participants did, however, indicate that they felt tense or did not feel completely relaxed in the virtual environment. Nonetheless, one participant explicitly stated in the free text that it was a positive tension—something exciting—rather than a negative tension.

Table 1. Responses to the 4 statements from the Intrinsic Motivation Inventory. The scale ranged from 1=not at all true to 5=very true.

Statements	Intrinsic Motivation Inventory score, mean (SD)
The virtual experience was enjoyable.	4.52 (0.73)
I was able to maintain my attention while doing this activity.	4.44 (0.74)
I felt tense while doing this activity.	2.27 (1.14)
I felt relaxed while doing this activity.	3.67 (1.11)

Table 2 summarizes the occurrence of various physical symptoms. It shows the percentage and number of people who answered “yes” to the respective questions about sensing the symptom. “Headache or dizziness” is the most prominent problem, with 23 of 101 (22.8%) participants stating that they

experienced it. It is worth emphasizing that these symptoms were only measured postquestionnaire, and the extent to which the participants felt headache or dizziness before testing VR or how susceptible they are to these symptoms in general are not known.

Table 2. Responses to the 5 questions from the Virtual Reality Symptoms Questionnaire. The table shows the number of participants answering “yes” when asked if they experienced the symptoms.

Symptoms	Participants, n (%)
General discomfort	6 (5.9)
Fatigue	6 (5.9)
Headache or dizziness	23 (22.8)
Nausea	3 (3.0)
Tired eyes	9 (8.9)

Free-Text Responses

Almost half of the participants (n=49/101) wrote a free-text response. These responses were grouped into six different categories: positive/enjoyable experience (20 entities), physical symptoms (3 entities), difficulties in gripping the virtual tools (7 entities), problems with the hardware (4 entities), using the application together with others (3 entities), and additional suggestions on how to use VR in the cancer process (23 entities). Some of the responses contained information such that they were sorted into several categories, explaining that there are more entities in the 6 categories than the 49 responses.

In total, 20 responses contained comments about the virtual smash room being an enjoyable experience, through statements such as the following: “A lot of fun,” “I would like to do this again,” and “Nice sound when breaking things.” Three participants additionally emphasized their physical symptoms in the free-text section although they had already answered questions about them in the questionnaire. Two participants experienced dizziness and the third one experienced arm fatigue. Seven participants experienced difficulty in gripping the virtual tools used to break things in the virtual smash room. These tools were sometimes referred to as “weapons” as in the following statement: “It was difficult to hold on to the ‘weapons’.” Four users expressed problems with the hardware. One of them wore glasses while wearing the HMD and expressed that this resulted in a blurred view. Two users complained about the handheld controllers temporarily failing and consequently there was a mismatch between the real-world and virtual actions. The fourth user was worried about tripping on the wires.

Three participants commented on using the virtual smash room together with the other participants. Two participants expressed this as a positive experience, while another participant found it to be a negative experience since this activity is about expressing emotions, which can be a very private experience. Finally, 23 additional suggestions on how to use VR in cancer rehabilitation were received; a few were directly related to the virtual smash room, with some participants stating that they wanted to be able to switch to some other room, and other suggestions were of a more general character where a desire to test other environments arose, without specifying exactly which ones. Several participants wanted something calmer, preferably an outdoor nature environment. One participant wanted to organize rather than disorganize: “Instead of smashing things, for example, set the table, arrange flowers, furnish a room, look for things.” Other suggestions were related to sports and hobbies (“Bowling, Darts” and “Go skiing, fishing, hunting”).

Discussion

Overview

This study explored the use of VR in cancer rehabilitation. A virtual smash room was developed on request from a patient with cancer or researcher, as a tool for venting frustration, and then evaluated by 101 patients in a cancer rehabilitation program, as part of a participatory design process of digitally reinforced cancer rehabilitation.

Principal Findings

The majority of the patients who tested the virtual smash room thought it was a positive and enjoyable experience. Nonetheless, several participants felt tense or not completely relaxed, and the prevalence of headache and dizziness indicates that the virtual experience is not comfortable for everyone. However, using only a postmeasure of these symptoms is not enough to state that it is a direct effect of the VR experience. For future testing, a premeasure of the participants’ susceptibility to the measured symptoms is required. Since fatigue or general discomfort might be further prevalent in this user group, it is necessary to thoroughly investigate these effects.

The virtual smash room is an environment in which the user remains almost stationary. He/she can take a few steps in either direction and move the head in any direction, but no more locomotion than that is possible. This implies that all movements in the virtual environment correspond well with those in the real world, which decreases the risk of feeling discomfort, dizziness, or nausea [32]. Even so, despite accurate room-scale tracking, Yildirim [33] reported that cybersickness is still a prevalent human factor issue in modern VR headsets such as HTC Vive and Oculus Rift CV1. Little is known about the underlying reasons, but anecdotal evidence from the VR gaming community suggests the involvement of the so-called screen door effect (SDE). Since the user’s eyes are very close to the display, the area of unlit space between pixels creates a sensation of having your vision disrupted by a black grid or a screen door. The SDE is a common problem in many modern VR headsets, especially those equipped with organic light-emitting diode displays such as HTC Vive. It is, however, important to point out that HTC Vive belongs to the first generation of modern consumer VR headsets, and that the fast-paced technological development will result in increasingly advanced and comfortable VR headsets. For example, the HP Reverb G2 VR headset has a resolution of 2160 × 2160 pixels per eye (as opposed to 1080 × 1200 pixels per eye for HTC Vive), which renders the SDE almost unnoticeable. Another plausible cause

of the reported headache/dizziness is related to the fact that the user group likely has a greater tendency to experience these symptoms. Many factors affect one's susceptibility to cybersickness [34], and this is definitely something to consider and investigate further when developing VR for this user group.

The two dominant free-text answer categories contained (1) comments about the virtual smash room being an enjoyable experience and (2) suggestions for additional virtual environments to use in cancer rehabilitation. These support further exploration of VR in cancer rehabilitation. The fact that several participants complained about difficulties holding on to, or gripping, the virtual objects indicates that the user interface needs redesigning, and possibly also that the hand controllers should be replaced. Tracking of hand gestures or eye gaze, or a combination of these, as proposed by Pfeuffer et al [35], might be interesting alternatives. Even though only 7 of our 101 participants complained about this, it is enough to call for an improvement. This shows that including the primary users in the design process is a central source of information about which applications to develop and which user interface mechanisms to improve.

The participatory approach is worth highlighting in a domain that traditionally has been technology-centered rather than human-centered with regard to the development of new applications [36,37]. This is also relevant from a cancer rehabilitation perspective, since many studies show that being able to influence and participate in one's own care process is beneficial [38-41]. By participating in the development and implementation of VR in cancer rehabilitation, patients are able to try new ways of experiencing different realities. Through this, we hope that they will be inspired to think about how their own rehabilitation, as well as that for future patients, can benefit from using VR technology.

In the free-text responses of the evaluation, there was an explicit request for nature and relaxing environments, and this is an area where VR can be a complement to real outdoor, natural environments [16,42]. The effect of VR on emotions and the mental state is simultaneously being studied in dementia and geriatric care where applications for reducing anxiety and apathy are explored [43-45]. Learnings from these studies will also be applicable to cancer rehabilitation to some extent.

Other environments and activities that can be explored in VR are desired, whether they are more peaceful or more active. In particular, aspects related to human factors must be considered when implementing VR. This implies that the technical solution is part of a comprehensive system consisting of people, a physical environment, technical artefacts, and a work organization, all of which must function together [46]. In this case, the technical solution includes the virtual environment and the user interface as well as the hardware, the physical surrounding, the conditions of the users, and the organization of the cancer rehabilitation venue. The HMD is still a cumbersome device to handle and wear. The user group also has a higher risk for infection; hence, the hardware needs to be sterilized between use. The environment must accommodate users with physical disabilities; some may need to sit down, and certain virtual environments may be more prone than others

to cause dizziness or nausea. If the aim is to manage difficult emotions, simply being in the virtual environment might be so exhaustive that resources, such as a psychologist, should be available for consultation at some stage in the experience.

Limitations

The original idea came from experiencing frustration with certain issues in the cancer rehabilitation process, and the ideal solution would be to offer the virtual smash room in relation to such a situation, when a person feels frustrated. In this study, the application was presented as a test activity at 1 specific moment during the rehabilitation week, and not at a moment when the participants necessarily felt frustrated, which makes it difficult to draw conclusions about the VR application's ability to be a tool for venting frustration or for coping in general. It did, however, evoke feelings of having fun, which is an important aspect in the process of handling frustration and stress [47]. If the participants had had on-demand access to VR equipment and could use it whenever they wanted, in private or in pairs, and could choose a VR application that matched their current state of emotion, perhaps other behaviors would have been observed.

This study is a step in an exploratory phase of the design process; hence, the generalizability of our results is limited. The value of the study is to explore the use of VR as a supplement in cancer rehabilitation together with the specific user group and elicit users' voices in the development of digitally reinforced cancer rehabilitation. In this analysis, no specific instructions were provided to the user when testing the application. Users were free to test the application for a long or short period in one or several of the "rooms" in the application. It would have been valuable to observe this more thoroughly; for example, to observe what the users did and measure the time during which they interacted with the VR application, but this could not be done owing to practical reasons. The researchers were not allowed at the venue when the patients were there owing to infection risks, and there were no additional staff members who would spend time in performing this activity. This is, of course, challenging for future studies but could be assessed in another setting or with observations using digital tools or video recordings.

Conclusions and Future Prospects

This study explores the use of VR in cancer rehabilitation, with a virtual smash room designed to evoke feelings, and demonstrates how the patients can be the innovators and participates in the development. The results show that the participants found the VR experience enjoyable and that it distracted them from their surroundings. Some participants experienced dizziness and had problems with the user interface. The user group expressed many ideas for other virtual environments to use in cancer rehabilitation. Our results would serve as input in the process of designing other VR applications for cancer rehabilitation, in participation with the patients, their families, and the staff.

The next step in this process involves broadening the sources of VR experiences to test—either in virtual worlds, augmented worlds, or interactive 360 videos—and explore the surrounding

practical aspects of employing this technology with lessons from this feasibility study in mind. Future studies also involve more controlled test setups, including, for example, pre- and

postmeasures of symptoms, observations of the time spent in the virtual environment, and individual behavior and attitudes.

Acknowledgments

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Authors' Contributions

All authors contributed to the study conception and design, based on an idea from US (who is both a researcher and patient with cancer). DC developed the VR application under the supervision of MW and in close collaboration with US. JP coordinated the testing and designed the data collection together with DC and MW. JP performed the analysis and wrote the first draft of the manuscript. All authors contributed to the text and read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

HMD: head-mounted display

IMI: Intrinsic Motivation Inventory

SDE: screen door effect

VR: virtual reality

VRSQ: Virtual Reality Symptoms Questionnaire

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Original Paper

Biopsychosocial Profiles of Patients With Cardiac Disease in Remote Rehabilitation Processes: Mixed Methods Grounded Theory Approach

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Abstract

Background: Digital development has caused rehabilitation services and rehabilitees to become increasingly interested in using technology as a part of rehabilitation. This study was based on a previously published study that categorized 4 groups of patients with cardiac disease based on different experiences and attitudes toward technology (e-usage groups): *feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using*.

Objective: This study identifies differences in the biopsychosocial profiles of patients with cardiac disease in e-usage groups and deepen the understanding of these profiles in cardiac rehabilitation.

Methods: Focus group interviews and measurements were conducted with 39 patients with coronary heart disease, and the mean age was 54.8 (SD 9.4, range 34-77) years. Quantitative data were gathered during a 12-month rehabilitation period. First, we used analysis of variance and Tukey honestly significant difference test, a *t* test, or nonparametric tests—Mann–Whitney and Kruskal–Wallis tests—to compare the 4 e-usage groups—*feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using*—in biopsychosocial variables. Second, we compared the results of the 4 e-groups in terms of recommended and reference values. This analysis contained 13 variables related to biomedical, psychological, and social functioning. Finally, we formed biopsychosocial profiles based on the integration of the findings by constant comparative analysis phases through classic grounded theory.

Results: The biomedical variables were larger for waistline (mean difference [MD] 14.2; 95% CI 1.0-27.5; *P*=.03) and lower for physical fitness (MD -0.72; 95% CI -1.4 to -0.06; *P*=.03) in the *being uninterested* group than in the *enthusiastic using* group. The *feeling outsider* group had lower physical fitness (MD -55.8; 95% CI -110.7 to -0.92; *P*=.047) than the *enthusiastic using* group. For psychosocial variables, such as the degree of self-determination in exercise (MD -7.3; 95% CI -13.5 to -1.1; *P*=.02), the *being uninterested* group had lower values than the *enthusiastic using* group. Social variables such as performing guided tasks in the program (*P*=.03) and communicating via messages (*P*=.03) were lower in the *feeling outsider* group than in the *enthusiastic using* group. The *feeling outsider* and *being uninterested* groups had high-risk lifestyle behaviors, and adherence to the web-based program was low. In contrast, members of the *being uninterested* group were interested in tracking their physical activity. The *reflecting benefit* and *enthusiastic using* groups had low-risk lifestyle behavior and good adherence to web-based interventions; however, the *enthusiastic using* group had low self-efficacy in exercise. These profiles showed how individuals reflected their lifestyle risk factors differently. We renamed the 4 groups as *building self-awareness*, *increasing engagement*, *maintaining a healthy lifestyle balance*, and *strengthening self-confidence*.

Conclusions: The results facilitate more effective and meaningful personalization guidance and inform the remote rehabilitation. Professionals can tailor individual web-based lifestyle risk interventions using these biopsychosocial profiles.

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KEYWORDS

coronary disease; experience; biopsychosocial model; digital cardiac rehabilitation; mixed methods grounded theory; web-based program; physical activity; self-efficacy; quality of life

Introduction

Background

Coronary heart disease (CHD) affects working-age populations and is the most common cause of death globally [1,2]. The main risk factors for CHD include age-related, gender-related, lifestyle-related, and socially-related risk factors [3-6]. Biomedical risk factors include smoking, high blood pressure and high cholesterol, obesity, type 2 diabetes, inappropriate diet, and sedentary behaviors [3-5]. Psychosocial factors, such as depression, lack of social support, stress, and personality type, have also been shown to affect the management of cardiovascular risks [7,8]. Cardiac rehabilitation focuses on decreasing patients' biomedical and lifestyle risk factors and increasing psychosocial management, physical activity counseling, and exercise training [3,4,9-11]. Currently, technology can provide an opportunity for individually tailored rehabilitation, irrespective of time and place [12]. Digital development has led patients with cardiac disease to become increasingly interested in using technology [13]. Therefore, theory- and evidence-based behavior change methods [13,14] and approaches have been gradually developed in web-based programs for cardiac rehabilitation [15-19].

It is a widely held view that most people find it difficult to change their health behaviors [20]. Therefore, it is important to understand how physical, psychological, and social factors contribute to behavioral change [21]. This study is based on behavioral medicine from a biopsychosocial model perspective [21-24] to understand the lifestyle risk management of patients with cardiac disease. Behavioral medicine integrates behavioral and biomedical knowledge on health and illness and applies this information, for example, to the counseling process of remote rehabilitation [24-26]. This study is also founded on behavior theories in behavioral medicine, that is, theories of learning (social cognitive theory [SCT] and self-efficacy) and motivation in exercise contexts (self-determination and self-regulation).

SCT focuses on the dynamic interaction of personal, environmental, and health behavior factors [27,28]. Part of the theory relates to health behavior self-efficacy, which refers to personal efficacy and guides how well people motivate themselves and their thoughts and actions [28]. Several studies have shown that low self-efficacy in health behaviors is associated with increased cardiovascular risk behavior [29,30]. On the other hand, individuals with higher self-efficacy are more effective in managing their cardiovascular risk behavior [31,32]. Moreover, high self-efficacy in using technology may increase the participation of individuals in web-based rehabilitation settings [32,33].

Self-determination theory focuses on the degree to which human motivation, development, and personality functioning occur within social contexts [34]. This theory has been used to examine behavior self-regulation [35] in cardiac rehabilitation [36,37]. Research has shown that decreases in external regulation and increases in intrinsic motivation may positively affect the physical behavior of patients with cardiac disease [36]. Self-determination theory represents a framework for understanding the exercise motivation of patients with cardiac disease.

Biopsychosocial profiles have been studied in the context of disease [38-42]; however, research has rarely looked at the biopsychosocial profiles of patients with cardiac disease in web-based rehabilitation settings. It is important to identify the biopsychosocial profiles of patients with cardiac disease to which web-based interventions can be tailored individually. The digital context offers an expanded means of understanding individual experiences with digital health solutions [22].

Objective

The purpose of this study is to enhance the understanding of biopsychosocial behaviors for the 4 previously defined different e-usage groups [43]. In our previous qualitative study, we identified 4 different e-usage groups using the Glaser mode of the grounded theory approach. These groups were *feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using* [43]. The qualitative study shows that patients with cardiac disease were different as technology users in technology experiences and attitudes toward technology and web-based guidance. Patients who felt outsiders and were not interested in technology needed more face-to-face guidance for rehabilitation, whereas patients who reflected the benefits and were enthusiastic about using technology felt that web-based coaching is sufficient support in rehabilitation [43].

In this study, we identify biopsychosocial variables related to CHD risk factors. The main biomedical and physical risk factors for CHD include physical inactivity and obesity. Psychological risk factors, such as depression, low psychological quality of life, and poor self-efficacy and behavioral control, are associated with increased CHD and risk behavior. Social determinants such as social isolation and low participation are also well-known risk factors for CHD.

In light of the previous study [43], we hypothesize that there would be differences among the 4 e-usage groups—*feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using* [43]—in each of the biomedical, psychological, and social areas. Propositions for differences among the 4 groups are as follows:

Proposition 1: The *feeling outsider* group might benefit from developing self-efficacy in physical activity and adequate positive support, as individuals in this group consider themselves as outsiders and find technology fearsome.

Proposition 2: The *being uninterested* group might benefit from weight management and physical activity self-monitoring with reminders and prompts, as they feel externally motivated.

Proposition 3: The *reflective benefit* groups might benefit from easy-to-use and interactive technology, as their interest is maintained by technology with personalized information and interactive tracking tools.

Proposition 4: The *enthusiastic users* group might benefit from empowering their self-efficacy and personalized lifestyle feedback, as they have a positive technology mastery experience.

Methods

Study Approach

We used a mixed methods grounded theory (GT) approach in this study. During the previous study in our research project, we used the Glaser inductive GT approach and open coding strategies [44]. We derived the contents of patients' experiences with modern technology from survey responses and focus group interviews [43]. Methodologically, this study aims to further understand our previous qualitative results on the 4 e-usage groups [43] and to deepen the analysis to the core category level. Therefore, we decided to apply a qualitative and quantitative combination of the GT approach [45]. The GT methodology with quantitative data has been used across disciplines [46–49] and in health sciences because of the diversity of study questions [50]. However, it has not been used in rehabilitation settings

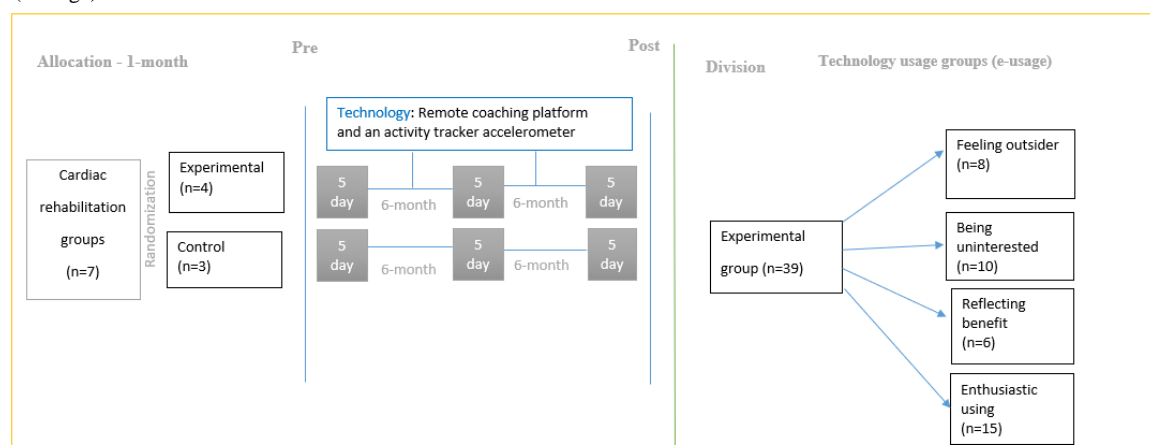
for patients with CHD. Mixed data, methods, and techniques facilitated a balanced theory generation [49]. This helped us identify a biopsychosocial profile within 4 e-usage groups—*feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using*—and generate substantive theory.

Study Design

This study is part of a larger project, with a cluster randomized controlled trial of a rehabilitation intervention registered in the ISRCTN registry (ISRCTN61225589). The ethics committee of the Central Finland Health Care District approved the study. The intervention assessing the effect of additional remote technology rehabilitation on patients with CHD was conducted from 2015 to 2017 in a rehabilitation center in the middle of Finland, where the Social Insurance Institution of Finland arranges regular cardiac rehabilitation courses. Before 12 months of rehabilitation, the participants were randomly allocated into intervention groups (n=10 in each group) with scheduled rehabilitation sessions for each group. Groups were randomized in pairs into the experimental groups (n=4 groups, which included 1 pilot group of experiments) and control groups (n=3 groups).

In this study, participants were from the 4 experimental groups that used digital health tools in addition to the traditional 12-month cardiac rehabilitation (15 days in total). We derived the contents of patients' experiences with modern technology from focus group interviews, the details of which have been presented in our previous study [43]. Half a year after the intervention, participants were divided into 4 categorized e-usage groups—*feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using*—which were based on the results of the qualitative data (Figure 1) [43].

Figure 1. The study design of the 12-month cardiac rehabilitation (15-day) intervention within used digital health tools and division into 4 technology use groups (e-usage).



Participants

Qualitative and quantitative data were collected from participants at the rehabilitation center (10/39, 26% female; 29/39, 74% male). The participants' mean age was 54.8 (SD 9.4, range 34–77) years; 71% (27/38) participants had completed lower professional education. Of the 39 participants, 32 (82%) had undergone coronary angioplasty, and 4 (10%) had undergone coronary artery bypass surgery in the past 12 months

before rehabilitation. Approximately 92% (25/27) of participants used the internet, and 37% (10/27) of participants used wrist activity trackers (Table 1 presents a description of participants at baseline by e-usage groups).

The e-usage groups of patients with cardiac disease—*feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using* [43]—were discovered in the same study population as in our previous study by using GT [43]. When we compared the groups' background characteristics, only one statistically

significant difference emerged. Mean age was significantly different among the groups ($P=.003$; analysis of variance [ANOVA] test). The *being uninterested* group participants were younger than participants in the other groups. The mean age of the *being uninterested* group was significantly lower than the mean age of the *feeling outsider* (mean difference [MD] -12.9 ;

95% CI -23.2 to -2.6 ; $P=.009$; Tukey honestly significant difference [HSD] test), *reflecting benefit* (MD -14.1 ; SD 4.15; 95% CI -25.3 to -2.9 ; $P=.009$; Tukey HSD test) and *enthusiastic using* groups (MD -6.4 ; 95% CI -12.6 to -0.2 ; $P=.04$; pairwise with 2-tailed t test).

Table 1. Description of participants at baseline by e-usage groups (N=39).

Description of participants	Feeling outsider (n=8)	Being uninterested (n=10)	Reflecting benefit (n=6)	Enthusiastic using (n=15)	Total
Age (years), mean (SD)	60.5 (7.6)	47.6 (5.6)	61.7 (11.2)	54 (8.2)	54.8 (9.4)
Gender, n (%)					
Female	2 (25)	4 (40)	0	4 (27)	10 (26)
Male	6 (75)	6 (60)	6 (100)	11 (73)	29 (74)
Professional education, n (%)					
Lower education level	5 (63)	5 (56)	5 (83)	12 (80)	27 (71)
Higher education level	3 (38)	4 (44)	1 (17)	3 (20)	11 (29)
Time of heart operation, n (%)					
0-12 months before rehabilitation	5 (63)	6 (60)	4 (67)	10 (67)	25 (64)
Over 12 months before rehabilitation	2 (25)	2 (20)	1 (17)	5 (33)	10 (26)
No operations	1 (13)	2 (20)	1 (17)	0	4 (10)
Technology, n (%)					
Use internet	4 (80)	7 (100)	6 (100)	8 (89)	25 (93)
Use physical activity tracker	2 (40)	4 (57)	1 (17)	3 (33)	10 (37)

Intervention

The rehabilitation of patients with CHD occurred in three 5-day periods during the year. The aim of rehabilitation was to promote a patient's adaptation to CHD and improve his or her functional capacity and ability to work [51]. A team of professionals included a physician, physical therapist, and nurse and optionally, a social worker, psychologist, or dietitian. For the remote component of the rehabilitation program, we used a secured remote coaching platform (m-coach Movendos) and an activity tracker accelerometer (Fitbit Charge HR). The 12-month web-based program involved feedback from each participant's own physiotherapist. The program sent automatic motivational messages every month, and peer support was available in group discussions. Research participants set and monitored their health-related behavior goals by keeping a lifestyle and exercise diary and completing assignments.

Data Collection

Data collection was guided by a purposeful sampling strategy called theoretical sampling in the GT method. This includes the purposeful selection of data samples to allow us to determine the variables that we would need to select to meet theoretical needs [44,45]. Table 2 presents the study's biopsychosocial variable time points for collection.

Biomedical variables comprised measures such as waistline [52] and physical fitness (the 6-minute walk test [6MWT]) [53]. Physical activity was measured with a physical activity monitor of light-intensity physical activity using a Fitbit (Fitbit Inc) tracker [54] and the self-report International Physical Activity Questionnaire (IPAQ; 9 items) [55]. The World Health Organization Quality of Life-BREF (WHOQOL-BREF) questionnaire was used to assess individuals' quality of physical health (domain 1). Other quality of life BREF domains are psychological health (domain 2), social relationships (domain 3), and the environment (domain 4) [56].

Table 2. Biopsychosocial variable time points for collection.

Biopsychosocial variables	Time point	
	0-month	12-month
Biomedical		
Waistline [52]	✓	N/A ^a
Physical fitness (6-minute walk test [6MWT]) [53]	✓	N/A
Light-intensity physical activity accelerometer (LPA) [54]	✓	N/A
International physical activity questionnaires (IPAQ) [55]	✓	N/A
The World Health Organization Quality of Life-BREF (physical health, domain 1) [56]	✓	N/A
Psychological		
Self-Efficacy to Regulate Exercise Scale (SERES) [57]	— ^b	✓
The Behavioral Regulation in Exercise (BREQ-3) [58,59]	—	✓
Questionnaire Depression Scale (DEPS) [60]	✓	N/A
Quality of Life-BREF (psychological health, domain 2) [56]	✓	N/A
Social		
Web-based participation (the number of task and message marks)	— ^b	✓
Quality of Life-BREF (social relationships, domain 3, and environment, domain 4) [56]	✓	N/A

^aN/A: not applicable.^bData not available.

Psychological variables were measured using 3 questionnaires: quality of psychological health (WHOQOL-BREF, domain 2) [56,61], Self-Efficacy to Regulate Exercise Scale (SERES) based on SCT [57], and the Behavioral Regulation in Exercise Questionnaire (BREQ-3). BREQ-3 is a 24-question instrument and is based on self-determination theory [58,59]. The Depression Scale (a 10-item DEPS) [60] was also included to measure psychological variables.

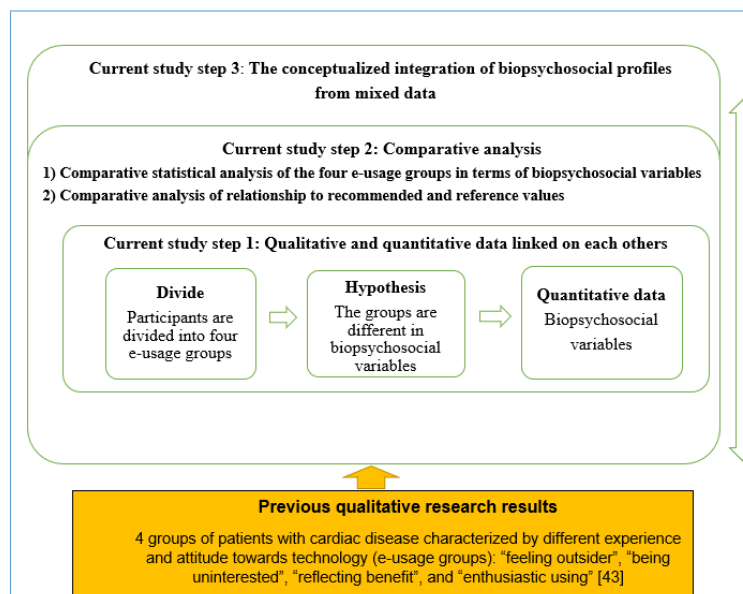
Social variables comprised participation in the web-based program and the quality of life questionnaire. Participation in the program was measured by individuals' visits to the site, including the number of pages they visited, the number of tasks they had completed (the number of completed task marks), and the number of conversations they had participated in (the number of message marks) during the 12 months of intervention. Social preintervention variables were also included in the questionnaire responses regarding the quality of social relationships and the environment (WHOQOL-BREF; domain 3 and domain 4) [56].

Data Analysis

The constant comparative method of the classic GT [44,45] guided the data analysis. That is, we analyzed data for similarities and differences at a more abstract level to move toward substantive theory building [44,46,47]. We recorded our research group's reflective discussions and wrote both theoretical and analytical memos. Memos were seen as a link

between the research group's notions and theoretical ideas, and they helped us in data analysis and meaning interpretation. In the following paragraphs, we describe our quantitative analysis and use of a mixed methods GT approach.

In our previous study, we analyzed interview data using GT. The result of the qualitative study was 4 e-usage groups—*feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using* [43]. In the first step, we divided participants into these 4 e-usage groups. A total of 2 researchers (MRA, HK) in our study independently read the interview responses of the participants. These researchers independently divided participants into 4 e-usage groups, taking into account the qualitative descriptions of the different e-usage groups: (1) technology experience, (2) attitude, and (3) expectations of remote counseling. There was moderate agreement between the 2 researchers in the coding of responses into the groups, $\kappa=0.521$ [62]. The 2 researchers compared their divided results, discussed disagreements, and reanalyzed the disagreed-upon results together. The results were also discussed with a third researcher (TS) to finalize the coding results. On the basis of our previous qualitative results [43], we presented a hypothesis, selected available biopsychosocial variables, and used quantitative methods and techniques to promote the generation of a substantive theory [43,44]. Figure 2 describes the entire three-step analysis.

Figure 2. Three-step analyses process.

In the second step, statistical analyses were used to examine the differences in biopsychosocial variables among the 4 groups. All quantitative data analyses were performed using the SPSS (version 24, SPSS Inc). We report descriptive statistics for the variables being compared. We examined the differences in biopsychosocial variables among the groups with probability statistics ($P < .05$) to determine whether the proposed differences within the group could be confirmed. As a measure of precision for the estimate, a 95% CI was reported.

ANOVA, t test, or nonparametric test (Mann–Whitney and Kruskal–Wallis tests) was used when appropriate. Thereafter, pairwise comparisons between the groups were analyzed with ANOVA (the Tukey HSD test, the Kruskal–Wallis or Mann–Whitney test (with Bonferroni correction). For comparisons of three or more group means, we performed the (one-way) ANOVA or nonparametric Kruskal–Wallis test. ANOVA was only used if the data in each group were normally distributed and the variances were homogeneous. Normality of the groups was assessed by the Shapiro–Wilk test, as all group sizes were < 50 . Homogeneity of variances was evaluated by the Levene test. When we had a significant result for differences between group means in the main test, we performed post hoc comparisons. For ANOVA, we applied the Tukey test, and for the Kruskal–Wallis test, we used the Mann–Whitney pairwise comparisons while adjusting the significance values by the Bonferroni correction for multiple tests.

After completing the series of quantitative analyses, we compared the results of the 4 groups in terms of recommended and reference values. We compared physical activity level (accelerometer and questionnaire) with World Health Organization's global recommendations for physical activity for health, that is, 150 minutes each week [54] and the quality

of life questionnaire results with averages for the Finnish population (aged 18–98 years) [61]. In the DEPS (0–30), the cutoff point for depression is ≥ 8 points, which indicates sensitivity to depression [60]. The questionnaire (SERES and BREQ-3) results were compared with the mean value of the scale. The mean value of SERES is 50 (0–100) [57] and that of BREQ-3 is 0 (–24 to 24) [58,59]. We compared the number of completed remote tasks and messaging markings with the total sample mean values of participation in the web-based program (the number of completed tasks was 87 for remote tasks and 6.6 for messaging).

In the final step of the analysis, a constant comparison was performed conceptually by analyzing the meanings behind the numbers for discovering and generating substantive theory based on GT [44,45]. Quantitative data were compared systematically by theoretical coding variables within groups. We grounded profile conceptualization by critically examining and questioning the data, which was theoretically sensitive. Finally, we formed biopsychosocial profiles based on the integrated findings of the constant comparative analysis phases. On the basis of these conceptualization processes, we renamed the profile of each group and formed the main category (Table 3 shows an example of a constant comparative analysis process in the *feeling outsider* group).

The results of this study's quantitative phase align with our qualitative findings. Our analyses moved toward substantive theory when we performed a constant comparative analysis of the qualitative and quantitative data [45,46]. As Glaser stated, "it is important to fully understand the meaning behind the numbers and techniques when using quantitative data [45]." The following paragraphs describe the results of the intermediate stages of comparative analyses in more detail.

Table 3. The feeling outsider group constant comparative analysis (n=8)^a.

Variables	Feeling outsider, mean (SD)	Result in significant differences between groups	RV ^b	Values, mean/RV (%)	Profile descriptions ^c
Waistline (centimeters)	107.1 (11.1)	— ^d	<94	+13.9	The <i>feeling outsider</i> group had high-risk behavior related to overweight
6-minute walk test (meters)	575.5 (73.3)	The <i>feeling outsider</i> group had lower physical fitness ($P=.047$) than the <i>enthusiastic using</i> group.	>623	−7.6	The <i>feeling outsider</i> group had high-risk behavior related to being inactive
Light-intensity physical activity, accelerometer (n=6)	134.9 (58.6)	—	>150	−10	Self-reported weekly physical activity differed from accelerometer-measured physical activity
IPAQ ^e (n=7)	421.4 (468.4)	—	>150	+280.9	Self-reported weekly physical activity differed from accelerometer-measured physical activity
WHOQOL-BREF ^f physical health	13.6 (2.9)	—	>16.5	−17.6	Physical quality of life was low at the beginning of rehabilitation
Self-Efficacy to Regulate Exercise Scale (0-100; n=7)	67.0 (19.2)	—	>50	+34	They had a high self-efficacy to regulate exercise at the end of the rehabilitation according to their own estimate
The number of completed task mark ^g	45 (126.1)	Performing guided tasks in the program ($P=.03$) were lower in the <i>feeling outsider</i> group than in the <i>enthusiastic using</i> group	>87	−48.3	Their engagement in technological solution was low
The number of discussions mark ^g	4.3 (7.6)	Communicating via messages ($P=.03$) were lower in the <i>feeling outsider</i> group than in the <i>enthusiastic using</i> group	>6.6	34.8	Their engagement in technological solution was low

^aHypothesis: There would be differences between the 4 e-usage groups *feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using* [43]. Proposition: The *feeling outsider* group might benefit from developing self-efficacy in physical activity and adequate positive support, as individuals in this group consider themselves as outsiders and find technology fearsome.

^bRV: recommended value.

^cOn the basis of these results, a profile for the group *feeling outsider* was renamed *building self-awareness*.

^dNo significant differences between the *feeling outsider* and others e-usage groups.

^eIPAQ: International Physical Activity Questionnaire.

^fWHOQOL-BREF: The World Health Organization Quality of Life Questionnaire, Short Form.

^gPostintervention variables.

Results

Comparative Statistical Analysis of the 4 e-Usage Groups in Terms of Biopsychosocial Variables

The results of the comparative analysis provide an understanding of the biopsychosocial profiles of e-usage groups.

Statistically significant differences ($P<.05$) between groups were found for the biomedical variable waistline, which significantly differed between the *being uninterested* and *enthusiastic using* groups (MD 14.2; 95% CI 1.0 to 27.5; $P=.03$; Tukey HSD test). The *being uninterested* group had a larger waistline than the *enthusiastic using* group. The 6MWT also showed significant differences between *being uninterested* and *enthusiastic using* groups (MD −0.72; 95% CI −1.4 to −0.06; $P=.03$; Tukey HSD test) and between the *feeling outsider* and *enthusiastic using* groups (MD 55.8; 95% CI −110.7 to −0.92; $P=.047$; 2-tailed t test). The *feeling outsider* group had lower physical fitness than the *enthusiastic using* group. For the

biomedical variables, light-intensity physical activity and IPAQ, there were no significant differences among the 4 groups, and the psychological and social variables, DEPS and quality of social life, were also nonsignificant (Table 4).

The results for the postintervention variables are presented next. The BREQ-3 scores were significantly different between the *being uninterested* and *enthusiastic using* groups in a t test (MD −7.3; 95% CI −13.5 to −1.1; $P=.02$); the degree of self-determination in exercise was lower for the former than for the latter. The results for SERES were nonsignificant. Participation in the web-based program (0-12 months) was the only statistically significant difference in group comparisons, with task marking differing significantly. Pairwise comparison revealed significant differences. Performing guided tasks in the program in the Kruskal–Wallis test ($P=.04$) and communicating via messages were lower in the *feeling outsider* group than in the *enthusiastic using* group ($P=.03$) in the Mann–Whitney test (Table 5).

Table 4. Comparative quantitative analysis among the 4 groups in terms of biopsychosocial preintervention variables.

Biopsychosocial variables preintervention	Group 1, <i>feeling outsider</i> (n=8)		Group 2, <i>being uninterested</i> (n=10)		Group 3, <i>reflecting Benefit</i> (n=6)		Group 4, <i>enthusiastic using</i> (n=15)	
	Value, mean (SD)	n (%)	Value, mean (SD)	n (%)	Value, mean (SD)	n (%)	Value, mean (SD)	n (%)
Biomedical variables								
Waistline (centimeters) [52]	107.1 (11.1)	— ^a	112.7 ^b (13.6)	—	102.3 (12.3)	—	98.4 ^b (11.3)	—
6-minute walk test (meters) [53]	575.5 ^b (73.3)	—	558.9 ^c (61.1)	9 (90)	624.3 (28.8)	4 (67)	631.3 ^{b,c} (52.7)	—
Light-intensity physical activity, accelerometer (minutes/week) [54]	134.9 (58.6)	6 (75)	174.6 (48.8)	6 (60)	137.2 (49.1)	4 (67)	148.3 (59.8)	13 (87)
The International Physical Activity Questionnaire (min/week) [55]	421.4 (468.4)	7 (88)	461.3 (445.5)	8 (80)	320.8 (411.4)	—	291.0 (307.4)	—
WHOQOL-BREF ^d physical health (4-20) [56]	13.6 (2.9)	—	13.7 (2.2)	—	14.4 (2.3)	—	14.2 (2.2)	—
Psychological variables								
WHOQOL-BREF psychological health (4-20) [56]	14.3 (2.7)	—	14.2 (2.2)	—	14.4 (3.0)	—	15.5 (1.9)	—
The Depression Scale (0-30) [60]	6.8 (5.9)	6 (75)	6.7 (5.3)	—	2.0 (1.9)	5 (83)	4.2 (3.9)	—
Social variables								
WHOQOL-BREF social relationship (4-20) [56]	14.3 (2.5)	—	15.9 (2.5)	—	15.7 (1.9)	—	16.3 (2.9)	—
WHOQOL-BREF environment (4-20) [56]	14.9 (2.6)	—	14.3 (2.3)	—	15.3 (1.7)	—	15.0 (2.2)	—

^aNo missing data.^bSignificant difference ($P<.05$) among groups.^cSignificant difference ($P<.05$) among groups.^dWHOQOL-BREF: The World Health Organization Quality of Life Questionnaire, Short Form.**Table 5.** Comparative quantitative analysis among the 4 groups in terms of biopsychosocial postintervention variables.

Biopsychosocial variables postintervention	Group 1, <i>feeling outsider</i> (n=8)		Group 2, <i>being uninterested</i> (n=10)		Group 3, <i>reflecting benefit</i> (n=6)		Group 4, <i>enthusiastic using</i> (n=15)	
	Value, mean (SD)	n (%)	Value, mean (SD)	n (%)	Value, mean (SD)	n (%)	Value, mean (SD)	n (%)
Biomedical variables								
The number of completed tasks mark	45 ^a (126.1)	— ^b	31.4 (48.4)	—	116.8 (142.8)	—	156.0 ^a (204.7)	—
The number of discussions mark	4.3 ^a (7.6)	—	6.1 (4.2)	—	7.8 (8.0)	—	8.1 ^a (6.9)	—
Self-Efficacy to Regulate Exercise Scale (0-100) [57]	67.0 (19.2)	7 (88)	56.6 (18.3)	7 (70)	62.0 (9.2)	—	54.2 (17.4)	14 (93)
The Behavioral Regulation in Exercise Questionnaire 3 (–24 to 24) [58,59]	12.0 (8.3)	6 (75)	5.7 ^a (8.0)	7 (70)	11.8 (2.1)	—	13.1 ^a (5.5)	14 (93)

^aIndicates significant difference ($P<.05$) among the groups.^bNo missing data.

Comparative Analysis of Relationship to Recommended and Reference Values

We compared the results of the 4 groups in terms of recommended and reference values. All e-usage groups had larger waistline and lower 6MWT values compared with the risk of disease cutoff values (waistline <94/6MWT >623); *feeling outsider* (mean 107.1/mean 575.5), *being uninterested* (mean 112.7/mean 558.9), *reflecting benefit* (mean 102.3/mean 624.3), and *enthusiastic using* (mean 98.4/mean 631.3). Regarding the quality of social relationships (>16.5), the *feeling outsider* (mean 14.3) and *being uninterested* (mean 15.9) groups reported lower quality of social relationships than that of the

reflecting benefit (mean 15.7) and *enthusiastic using* (mean 16.3) groups. Except for the *enthusiastic using* group, which had near-average values, the quality of life results for all groups were lower than the average values for the Finnish population (Table 6).

The self-efficacy values of all groups were better than the mean value of the scale (>50). On the other hand, the opposite results were observed for variables of exercise self-efficacy, in which the *enthusiastic using* group had lower self-efficacy (mean 54.2) than the *feeling outsider* (mean 67), *being uninterested* (mean 56.6) and *reflecting benefit* (mean 62; Table 7) groups.

Table 6. Comparative analysis of relationship to recommended and reference values (preintervention).

Biopsychosocial preintervention variables	RV ^a	<i>Feeling outsider</i> (n=8)		<i>Being uninterested</i> , mean (n=10)		<i>Reflecting benefit</i> (n=6)		<i>Enthusiastic using</i> (n=15)	
		Values, mean (SD)	Level of factor, mean/RV (%)	Values, mean (SD)	Level of factor, mean/RV (%)	Values, mean (SD)	Level of factor, mean/RV (%)	Values, mean (SD)	Level of factor, mean/RV (%)
Biomedical variables									
Waistline (centimeter) [52]	<94	107.1 (11.1)	+13.9	112.7 (13.6)	+19.9	102.3 (12.3)	+8.8	98.4 (11.3)	+4.7
Physical fitness (meter) [53] (6-minute walk test)	>623	575.5 (73.3)	−7.6	558.9 (61.1)	−10.3	624.3 (28.8)	+0.2	631.3 (52.7)	+1.3
Light Physical activity, accelerometer (minutes/week) [54]	>150	134.9 (58.6)	−10	174.6 (48.8)	+16.4	137.2 (49.1)	−8.5	148.3 (59.8)	−1.1
The International Physical Activity Questionnaires (minutes/week) [55]	>150	421.4 (468.4)	+280.9	461.3 (445.5)	+307.5	320.8 (411.4)	+213.9	291 (307.4)	94
WHOQOL-BREF ^b Physical health [56]	>16.5	13.6 (2.9)	−17.6	13.7 (2.2)	−17.0	14.4 (2.3)	−12.7	14.2 (2.2)	−13.9
Psychological variables									
WHOQOL-BREF psychological health [56]	>15.5	14.3 (2.7)	−7.7	14.2 (2.2)	−8.4	14.4 (3.0)	−7.1	15.5 (1.9)	0
The Depression Scale (0-30) [60]	<8	6.8 (5.9)	−15	6.7 (5.3)	−16.3	2.0 (1.9)	−75	4.2 (3.9)	−47.5
Social variables									
WHOQOL-BREF social relationship [56]	>16.5	14.3 (2.5)	−13.3	15.9 (2.5)	−3.6	15.7 (1.9)	−4.8	16.3 (2.9)	−1.2
WHOQOL-BREF environment [56]	>16.5	14.9 (2.6)	−9.7	14.3 (2.3)	−13.3	15.3 (1.7)	−7.3	15.0 (2.2)	−9.09

^aRV: recommended value.

^bWHOQOL-BREF: The World Health Organization Quality of Life Questionnaire, Short Form.

Table 7. Comparative analysis of relationship to recommended and reference values (postintervention).

Biopsychosocial postintervention variables	RV ^a	<i>Feeling outsider</i> (n=8)		<i>Being uninterested</i> (n=10)		<i>Reflecting benefit</i> (n=6)		<i>Enthusiastic using</i> (n=15)	
		Values, mean (SD)	Level of factor, mean/RV (%)	Values, mean (SD)	Level of factor, mean/RV (%)	Values, mean (SD)	Level of factor, mean/RV (%)	Values, mean (SD)	Level of factor, mean/RV (%)
Postintervention variables									
Task marks	>87	45 (126.1)	−48.3	31.4 (48.4)	−63.9	116.8 (142.8)	+34.3	156.0 (204.7)	+79.3
Discussion marks	>6.6	4.3 (7.6)	−34.8	6.1 (4.2)	−7.6	7.8 (8.0)	+18.2	8.1 (6.9)	+22.7
Self-Efficacy to Regulate Exercise Scale [57]	>50	67.0 (19.2)	+34	56.6 (18.3)	+13.2	62.0 (9.2)	+24	54.2 (17.4)	+8.4
The Behavioral Regulation in Exercise Questionnaire [58,59]	>0	12.0 (8.3)	+12	5.7 (8.0)	+5.7	11.8 (2.1)	+11.8	13.1 (5.5)	+13.1

^aRV: recommended value.

Conceptualized Integration of Biopsychosocial Profiles From Mixed Data

The results were synthesized to build the biopsychosocial profiles for the 4 groups—*feeling outsider*, *being uninterested*, *reflecting benefit*, and *enthusiastic using*—as part of the rehabilitation process. We formed biopsychosocial profiles based on constant comparative analysis through narrative description.

Proposition 1: The *feeling outsider* group might benefit from developing self-efficacy in physical activity and adequate positive support, as individuals in this group consider themselves as outsiders and find technology fearsome:

That technology hasn't really come [...] My wife taught the computer [...] supported, well, taught—so I went to the courses. And the kids did. I thought that if I'm still starting to tinker, there won't be enough hours in the day to learn [43]. [participant 25, 60-year-old man, focus group 1]

The *feeling outsider* group had high-risk behavior related to being inactive and overweight. Self-reported weekly physical activity differed from accelerometer-measured physical activity. In addition, physical quality of life was low at the beginning of rehabilitation. Members of this group had a high self-efficacy to regulate exercise at the end of the rehabilitation according to their own estimate; however, their engagement in technological solutions was low. Their biomedical results were inconsistent between their self-reported physical activity and objectively measured data, which may have been because of a lack of lifestyle self-awareness. On the basis of these results, the profile for the *feeling outsider* group was renamed *building self-awareness*.

Proposition 2: The *being uninterested* group might benefit from weight management and physical activity self-monitoring with reminders and prompts, as they feel externally motivated:

I'm waiting for it and I'm truly interested, as if I were waiting for something like a spark. That it is

something, something like, motivating, and...well...I can't say, but it like maybe not now for sure every week. If once a month, certainly something could come...a reminder [43]. [participant 56, 45-year-old man, focus group 3]

When I could enter inputs in there, and if my own activities could be there, then I would be like a response: Is this the right or wrong direction, and...And that's when it's really somebody, something and someone monitoring what you're doing [43]. [participant 41, 49-year-old woman, focus group 2]

The *being uninterested* group had low levels of physical fitness, poor self-assessed physiological quality of life, and a high waist circumference. Their exercise behavior can be described as externally regulated, with low scores in self-determination. In addition, they were interested in self-monitoring their physical activity but were uninterested in participating in web-based coaching. Their self-monitoring technology may have motivated them to improve their physical activity levels and engagement in lifestyle changes. The profile for the *being uninterested* group was renamed *increasing engagement*.

Proposition 3: The *reflective benefit* groups might benefit from easy-to-use and interactive technology, as their interest is maintained by technology with personalized information and interactive tracking tools:

Let's put it in this way: I'm not actually now that way from being pushed, yeah. Yes it comes from my own desire. The main purpose is monitoring: it's for that. It's interesting to follow what happens if you change some exercise habits, and you can see from this, what changes have happened in the background. Very okay [43]. [participant 17, 57-year-old man, focus group 2]

The *reflecting benefit* group showed healthy lifestyle choices related to eating behavior and exercise. They may have had intrinsic motivation for exercise and high self-determination, including a positive balance in life. Higher scores indicated

higher self-efficacy for exercise and health technology interest. Their biopsychosocial outcomes were balanced and maintaining these outcomes could be the most important goal for them. The *reflecting benefit* group was renamed *maintaining a healthy lifestyle balance*.

Proposition 4: The *enthusiastic users* group might benefit from empowering their self-efficacy and personalized lifestyle feedback, as they have a positive technology mastery experience:

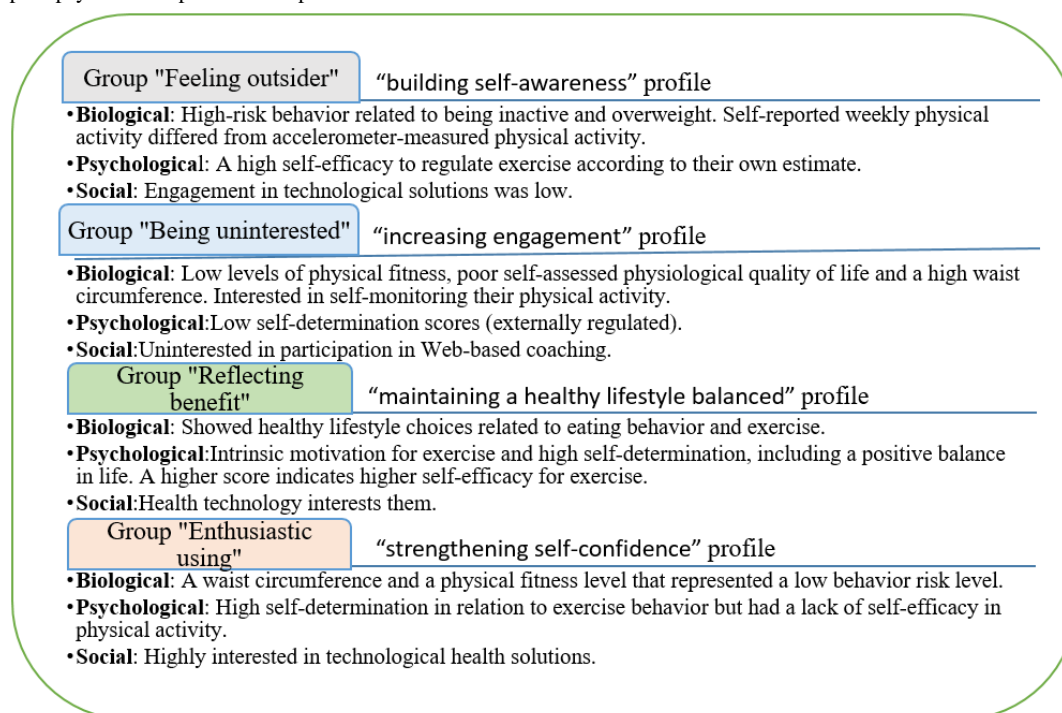
I'm waiting and I'm interested. Yes, of course, this here now gives little push in the pants. I'm already moving pretty well, that's what this thing around my arm tells me...Yeah...and then yes, I have the Sport Tracker on my phone, also. When I go somewhere, I tell it to draw a map, and I see the time and all that [43]." [participant 66, 34-year-old man, focus group 3]

Modern opportunities. And if now, of course...from where soon could come a little spark, and that spark

continues than exercise could begin. And it's really the same benefit. And then, of course, if nothing's heard from there. It sounds real good, and then reminders. Something like you can write comments, and [...] [43] [participant 26, 61-year-old woman, focus group 2]

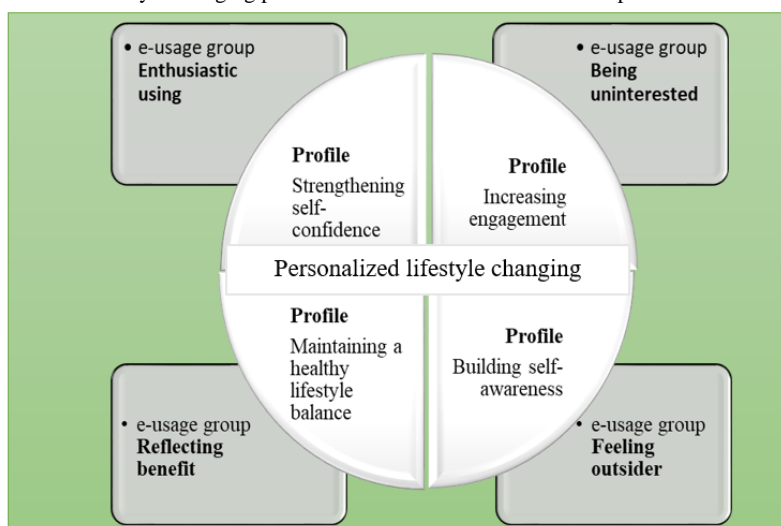
The *enthusiastic using* group had a waist circumference and a physical fitness level that represented a low behavior risk level. They had high self-determination in relation to exercise behavior but lacked self-efficacy in physical activity. They were highly interested in technological health solutions. This group had a healthy lifestyle; however, their physical self-efficacy related to exercise was low. A heart event may have lowered their self-confidence in health behaviors. The profile for the *enthusiastic using* group was renamed *strengthening self-confidence*. Figure 3 shows a summary of the groups' similarities and differences in the comparative analysis results.

Figure 3. Group biopsychosocial profile descriptions.



On the basis of these results, we were able to synthesize all groups' biopsychosocial profile descriptions to a thematic meaning, that is, *personalized lifestyle changing as part of the rehabilitation process*, which can be the start of substantive theory development integrated into all 4 groups' profile descriptions. On the basis of the analysis, we identified and

renamed the 4 groups to *building self-awareness*, *increasing engagement*, *maintaining a healthy lifestyle balance*, and *strengthening self-confidence*. These profiles showed how individuals in the 4 groups identified their different lifestyle management reflections in rehabilitation progress. The main results of the analysis are shown in Figure 4.

Figure 4. Biopsychosocial personalized lifestyle changing profiles in relation to the rehabilitation process.

Discussion

Principal Findings

The main result of the study was *personalized lifestyle changing as part of the rehabilitation process*, which refers to the 4 groups' profiles related to rehabilitation progress. On the basis of the qualitative and quantitative GT analysis, we identified 4 profiles: *building self-awareness*, *increasing engagement*, *maintaining a healthy lifestyle balance*, and *strengthening self-confidence*. The main message of this study is that it is important to identify different biopsychosocial profiles with respect to the reflections of patients with cardiac disease on their lifestyle risk factor management in the counseling process of remote rehabilitation. This knowledge can give cardiac rehabilitation professionals evidence and enable them to tailor theory-based web-based behavior change interventions.

Patients in the *feeling outsider* group were afraid to use technology, and they expected supportive behavior change counseling [43]. This group, with the *building self-awareness* profile, had low daily physical activity and was overweight. In their self-reports, members of this group overestimated the amount of physical activity relative to their objectively measured data. A possible explanation for these results may be their lack of self-awareness concerning self-management of lifestyle risk factors. However, studies have shown a higher estimate of physical activity using the IPAQ than the accelerometer data [63]. Self-management skills and attitudes included in lifestyle change are based on motivational, goal-setting, controlling, and self-regulatory skills, which require self-awareness [64]. Although promoting the ability to recognize how self-efficacy, thoughts, feelings, and actions are interconnected, rehabilitation also improves self-awareness for self-management of lifestyle change processes [30,31,33,64,65]. The group with this profile needs guidance and positive support in using technology [43] and in increasing their self-awareness. Patients in this group may benefit from web-based goal-setting tools for self-awareness. Goal setting could help these patients identify their own risk factors and set realistic and meaningful goals. Health professionals should take into account patients' aims,

needs, and self-efficacy, as well as health outcome information in individual goal-setting.

The *being uninterested* group expected problem-free technology with activity-empowering web-based counseling [43]. This group, with the *increasing engagement* profile, had lower self-efficacy, and they might have quickly given up when they ran into difficulties [43]. In addition, we found that the group was uninterested in participating in web-based coaching. However, members showed interest in tracking their physical activity with a wearable accelerometer. Patients in this group showed low scores in self-determination, and thus, their motivation can be described as externally regulated. Previous studies have reported that regular physical activity can reduce cardiovascular risk factors [1-4]. Activity tracking accelerometers with feedback may boost self-efficacy, which has been shown to promote cardiovascular risk self-management [29-31]. Wearing an accelerometer itself may promote and motivate physical activity [66]. Patients in this group had low levels of physical fitness, poor self-assessed physiological quality of life, and high waist circumferences. Previous research has shown that biopsychosocial characteristics are related to lower scores in risk factor self-management, especially in women [6,37,41]. Additional support can be provided using evidence-based health behavior change techniques with the help of technology in rehabilitation [15,30,32,65]. Patients in this group may benefit from support and guidance to increase their engagement in lifestyle-changing processes. Health professionals should take into account such patients' motivations to use self-monitoring technology and their interests in personalized and regular feedback, reminders, and prompts.

Patients in the *reflecting the benefit* group expected easy-to-use and useful technology with interactive tools [43]. The group showed healthy lifestyle choices, such as healthy eating and exercising. These patients had high self-efficacy in achieving physical activity goals, and they were interested in health technology. This group, with a *maintaining a healthy lifestyle balance* profile, had a fair amount of intrinsic motivation for exercise and high self-determination for exercise behavior, which is needed to increase self-management skills and facilitate lifestyle change [64,67]. Self-monitoring and realistic

goal setting are important factors in the process of self-regulation [10,16]. Our findings indicate that increases in regular exercise competence could improve intrinsic motivation, as shown in previous studies [35,36]. Patients with this profile may benefit from interactive and easy-to-use tracking tools through which self-monitoring allows them to manage their health. Health professionals should monitor the goal progress to meet their desired functional goals.

The *enthusiastic using* group expected smoothly functioning technology that offered empowering self-tracking with feedback [43]. This group had minor risk behavior but the lowest self-efficacy in physical activity compared with the other group profiles. The results of Kärner Köhler et al [68] indicate that self-efficacy is not related to chronic conditions. However, a cardiac event may have reduced these patients' self-confidence in their own lifestyle management. They may not have believed in their own behavior choices for reaching the desired goal. A possible explanation might be that patients conscientiously followed a healthy lifestyle. A previous study showed that people with higher conscientiousness were more intrinsically motivated [35]. Early self-efficacy support may improve individuals' participation in web-based programs [31,33]. Patients with the *strengthening self-confidence* profile may benefit from early self-management support for self-confidence. Health professionals should provide support, especially in the early stages after heart events, by focusing on positive achievements.

The profiles showed how patients in the 4 groups adjusted their lifestyles differently on the part of rehabilitation progress. Patients in the *feeling outsider* and *being uninterested* groups had high-risk behavior and low engagement in technological solutions. In contrast, patients in the *reflecting benefit* and *enthusiastic using* group profiles had low-risk behavior and good adherence to web-based interventions. Biopsychosocial profiles have been used to tailor interventions for patients with chronic pain [38,39], diabetes [40], overweight and obesity [41], and hypertension [42]. It is also important to identify the biopsychosocial profiles of patients with cardiac disease, as it allows for evidence- and theory-based and individually tailored lifestyle counseling programs in multidisciplinary fields.

Limitations and Strengths

This study has some limitations related to the sample size, which was unevenly distributed among the groups. The purpose of the study was theoretical verification using GT, and for this purpose, there was an inductive generalization regarding the phenomenon under study and no statistical generalization. We have provided

detailed descriptions that were not intended for extrapolation of the findings to other settings but to provide information about the phenomenon and build substantive theory. The possible sampling bias, small sample size, and sampling strategy certainly limited our quantitative analyses; however, we used GT and mixing methods of constant comparative analysis, which was beneficial to our study when we grounded several variables. This study was based on GT, and the results can be said to be reliable based on thick descriptions, taking into account thorough descriptive information about the study setting, study participants, and processes. There are weaknesses in this study; for example, we collected data from the BREQ-3 and SERES questionnaires only at the end of the intervention. It would have been better if all questionnaire data had also been collected preintervention. However, despite this shortcoming, the BREQ-3 and SERES questionnaires provided valuable information. The mixing of methods was an innovative challenge. The credibility of the results was based on conceptualization to enable a greater understanding of patient experiences with technology in the context of digital cardiac rehabilitation. There is also a need for information on whether there might be a change in patients' experiences and attitudes toward technology during rehabilitation. The implementation of these results might be useful, especially in the planning of rehabilitation counseling and teaching.

Conclusions

The study showed that *personalized lifestyle changing as part of the rehabilitation process* relates to the profile descriptions of the 4 groups. On the basis of the profiles, we identified 4 profiles related to the rehabilitation process: *building self-awareness, increasing engagement, maintaining a healthy lifestyle balance, and strengthening self-confidence*. The results might help to understand what is meaningful for Finnish patients with cardiovascular disease who participate in a rehabilitation program with face-to-face and remote web components. The personalized behavior change components can be embedded in the technology part of cardiac rehabilitation, for example, individual goal setting, self-monitoring, reminders and prompts, positive social and peer group support, personalized information, and feedback. These components increase the *spark* for motivation to a lifestyle change by taking into account the different life situations, needs, and concerns of individuals and their experiences and attitudes toward the use of technology. However, future studies are needed that back up our current results with larger sample sizes and a sociodemographic structure that mirrors the study population.

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Conflicts of Interest

None declared.

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Abbreviations

6MWT: 6-minute walk test

ANOVA: analysis of variance

BREQ-3: The Behavioral Regulation in Exercise-3

CHD: coronary heart disease

DEPS: the Depression Scale

GT: grounded theory

HSD: honestly significant difference

IPAQ: The International Physical Activity Questionnaire

MD: mean difference

SCT: social cognitive theory

SERES: Self-Efficacy to Regulate Exercise Scale

WHOQOL-BREF: The World Health Organization Quality of Life-BREF

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Review

Effects of Telerehabilitation Interventions on Heart Failure Management (2015-2020): Scoping Review

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Abstract

Background: Heart failure is one of the world's most frequently diagnosed cardiovascular diseases. An important element of heart failure management is cardiac rehabilitation, the goal of which is to improve patients' recovery, functional capacity, psychosocial well-being, and health-related quality of life. Patients in cardiac rehabilitation may lack sufficient motivation or may feel that the rehabilitation process does not meet their individual needs. One solution to these challenges is the use of telerehabilitation. Although telerehabilitation has been available for several years, it has only recently begun to be utilized in heart failure studies. Especially within the past 5 years, we now have several studies focusing on the effectiveness of telerehabilitation for heart failure management, all with varying results. Based on a review of these studies, this paper offers an assessment of the effectiveness of telerehabilitation as applied to heart failure management.

Objective: The aim of this scoping review was to assess the effects of telerehabilitation in the management of heart failure by systematically reviewing the available scientific literature within the period from January 1, 2015, to December 31, 2020.

Methods: The literature search was carried out using PubMed and EMBASE. After duplicates were removed, 77 articles were screened and 12 articles were subsequently reviewed. The review followed the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses for scoping reviews) guidelines. As measures of the effectiveness of telerehabilitation, the following outcomes were used: patients' quality of life, physical capacity, depression or anxiety, and adherence to the intervention.

Results: A total of 12 articles were included in this review. In reviewing the effects of telerehabilitation for patients with heart failure, it was found that 4 out of 6 randomized controlled trials (RCTs), a single prospective study, and 4 out of 5 reviews reported increased quality of life for patients. For physical capacity, 4 RCTs and 3 systematic reviews revealed increased physical capacity. Depression or depressive symptoms were reported as being reduced in 1 of the 6 RCTs and in 2 of the 5 reviews. Anxiety or anxiety-related symptoms were reported as reduced in only 1 review. High adherence to the telerehabilitation program was

reported in 4 RCTs and 4 reviews. It should be mentioned that some of the reviewed articles described the same studies although they employed different outcome measures.

Conclusions: It was found that there is a tendency toward improvement in patients' quality of life and physical capacity when telerehabilitation was used in heart failure management. The outcome measures of depression, anxiety, and adherence to the intervention were found to be positive. Additional research is needed to determine more precise and robust effects of telerehabilitation.

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KEYWORDS

heart failure; telerehabilitation; quality of life; physical capacity; depression; anxiety; telehealth; rehabilitation; cardiac rehabilitation; cardiovascular disease; CVD; mental health; adherence; quality of life; physical capacity

Introduction

Heart failure (HF) is one of the world's most frequently diagnosed cardiovascular diseases [1]. It is estimated that throughout the world, more than 37 million people have been diagnosed with HF [1]. HF is highly prevalent, and it is predicted that the prevalence will increase in the future and will therefore be a growing burden on the health sector [2]. Cardiac rehabilitation is an important part of HF management, as it aims to improve patients' recovery and enhance their functional capacity, psychosocial well-being, and health-related quality of life (QoL). Cardiac rehabilitation focuses on weight control, psychosocial coping, disease management, and improving both physical activity and diet management [3]. Cardiac rehabilitation has often been conducted in a rehabilitation facility, which can be a challenge when patients have limited means of transportation. Patients in cardiac rehabilitation may also lack motivation, especially if they feel that the rehabilitation process is not adequately tailored to their needs [3,4]. A strategy for managing these challenges is the use of telerehabilitation. Telerehabilitation is defined as the delivery of rehabilitation services via information and communication technologies and generally takes place in the patient's home [4-6].

A review from 2015 assessed whether telerehabilitation was effective for improving physical or functional outcomes in patients with cardiopulmonary diseases [7]. This review found only 4 studies carried out between 2000 and 2012 that had utilized telerehabilitation to manage HF [8-11]. The use of telerehabilitation for assisting patients with HF has thus been available for several years. However, it was not used as a part of rehabilitation for HF management among patients in many

studies until a few years ago. In recent years, evidence assessing the effectiveness of telerehabilitation and HF management has grown, showing varying results. Nevertheless, there remains a lack of reviews on the general effectiveness of telerehabilitation for HF management. The aim of this review was to investigate the effects of telerehabilitation in the management of HF by systematically reviewing the most recent, available scientific literature from the 6-year period from January 1, 2015, to December 31, 2020.

Methods

Search Strategy

A research protocol for reviewing the available literature was designed. The protocol included inclusion and exclusion criteria, type of studies, identification of telerehabilitation technologies, intervention duration, and outcome measurements. We conducted a literature search of randomized controlled trials (RCTs), prospective intervention studies, reviews, and meta-analyses, all of which aimed to examine the effectiveness of telerehabilitation on patients with HF. Inclusion and exclusion criteria are summarized in [Textbox 1](#). The literature search was performed using the PubMed and Excerpta Medica (EMBASE) databases, as these two databases were thought to contain many telerehabilitation studies. In searching through the two databases, the following search words were used in combinations: "heart failure," "HF," "telecardiology," and "telerehabilitation." MeSH (Medical Subject Headings) terms were used, where possible, on PubMed, and Emtree terms were used, where possible, on EMBASE. The literature search was limited to the time frame January 1, 2015, to December 31, 2020. [Multimedia Appendix 1](#) provides the protocol with the full search strategy.

Textbox 1. Inclusion and exclusion criteria for the search.**Inclusion criteria**

- A home telerehabilitation program for patients with heart failure (HF)
- A comparative study with telerehabilitation and traditional home care or other approaches
- Participants who are older than 18 years
- At least one of the following outcome measures were reported to have been used: quality of life, physical capacity, depression or anxiety, or adherence to the intervention
- Randomized controlled trials, prospective intervention studies, reviews, and meta-analyses published in the preceding 6 years (January 1, 2015, to December 31, 2020)

Exclusion criteria

- Languages other than English
- Studies where results from patients with chronic diseases other than HF are not reported separately from the results pertaining to patients with HF
- Protocols
- Only abstracts

Outcome Measures

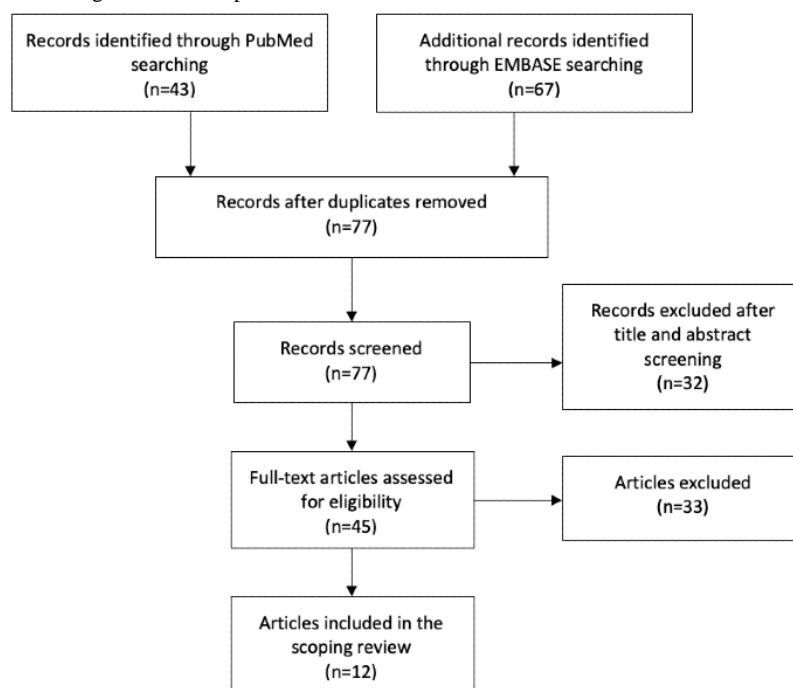
In assessing the effectiveness of telerehabilitation, the various studies used a range of outcome measures. The most common effect measures in HF and telerehabilitation are QoL, physical capacity, depression or anxiety, and adherence to the intervention [2]. Therefore, our review used these four outcomes as well.

Screening

The review has followed the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses for scoping reviews) guidelines [12]. First, 2 authors (CSS and NCH)

independently performed the literature retrieval. Then, 2 authors (CSS and NCH) independently screened the abstracts identified during the search. Based on the screening of the titles and content of the abstract, each article was assessed as to whether it fulfilled the inclusion or exclusion criteria. Articles that were deemed relevant and met the inclusion criteria were selected for inclusion in our study. Disagreements between the 2 reviewers were resolved by discussion until consensus was reached. The initial systematic literature search resulted in 110 articles on HF. The final selection of relevant articles comprised 12 articles on HF and telerehabilitation [7,13-23]. Figure 1 outlines the screening process.

Figure 1. Flow diagram of the screening and selection process of articles.



Data Extraction

The following information was collected from all included studies: references, design of the study, sample size, severity of HF (reported per the New York Heart Association Functional Classification), intervention type, technology, duration of intervention and follow-up, health care utilization, outcomes (QoL, physical capacity, depression or anxiety, adherence to the intervention), and questionnaires or tests used to measure QoL, physical capacity, and depression or anxiety.

Synthesis of Results

The synthesis of the review was performed in 3 steps:

1. For HF and telerehabilitation, an overview of the main results of the studies that are relevant to this review were presented in a tabular format.
2. Only significant results were reported in the overviews. Hence, we did not report tendencies.
3. A summary of HF and telerehabilitation within the time frame 2015-2020 was presented in a tabular format.

Results

HF and Telerehabilitation

For HF, a total of 6 RCTs [13,15,17,20,22,23], 1 prospective study [16], and 5 reviews [7,14,18,19,21] were included. The sample size in the RCTs varied from 17 to 850 patients with HF. The telerehabilitation interventions described in the studies varied from 8 weeks to 5 months, and follow-up periods varied from 12 weeks to 16 months. The technologies discussed in the studies were educational interventions, telephone monitoring,

exercise programs, teleconsultations, video-based consultations, mobile phones, and forwarding technologies.

Study Selection, Characteristics, and Outcomes

Table 1 provides an overview of the studies on telerehabilitation and HF published in the 2015-2020 period. The outcome measures were QoL, physical capacity, depression or anxiety, and adherence to the intervention, and these are presented in Table 2. The boxes containing the abbreviation “N/A” (not applicable) indicate that the parameter was evaluated in the specific study but that the result of the evaluated parameter was not significant. An arrow indicates that the result of the specific outcome measure was significantly different, which could either be upward, meaning that the outcome measure was increased during the intervention, or downward, meaning that the outcome measure was decreased. The arrow is followed by either “the intervention group” or “in both groups,” which indicates the group(s) to which the study results relates. Furthermore, if the questionnaires or tests used to measure the outcome measures were reported in the study, the results of the outcomes are followed by the name of the questionnaires or tests in brackets. For the review articles, the number of studies showing significant results of the specific outcome are listed in brackets. The control group category refers to patients with HF receiving conventional rehabilitation care, where some received education with no exercise and others received center-based rehabilitation with exercise. The outcome adherence is reported in Table 2 as reported in the studies. “Adherence” refers to the degree to which participants in the study follow the intervention assigned to them; thus, high adherence or a high percentage of adherents refers to those participants showing behavior that corresponds with the intervention.

Table 1. Overview and characteristics of studies on telerehabilitation and heart failure (HF).

Reference	Country	Type of study and sample size	Severity of HF (NYHA ^a Functional Classification)	Intervention	Technology	Duration of intervention and follow-up
Brunetti et al [18] ^b	Italy	Expert review	— ^c	Home-based telerehabilitation; telemanagement and home-based telesurveillance, remote patient monitoring; home-based nurse telemanagement by telephone and interactive teleconsultation; interactive telecommunication; cooperation between general practitioners and a tele-monitoring HF clinic	Phone calls, videoconferencing, ECG ^d recorder with transmission	—
Hamilton et al [14]	Australia	Systematic review (4 HF studies)	II, III, and IV	Mobile health home-based telerehabilitation	Smartphone with apps, digital weight scale, automatic blood pressure monitor, and ECG recorder; all transmitted via Bluetooth	—
Hwang et al [7]	Australia	Systematic review (4 HF RCTs ^e)	—	Home-based telerehabilitation	Telephone communication, ECG recorder	8-36 weeks of intervention and follow-up from none to 1 year
Hwang et al [23]	Australia	RCT (N=53; intervention group, n=24; control group, n=29)	I, II, and III	Group home-based telerehabilitation with real-time online video conferencing exercise and education	Computer, video conferencing program, electronic slide presentations with educational topics, telephone contact, automatic sphygmomanometer, finger pulse oximeter	12 weeks and follow-up after 12 weeks
Nakayama et al [16]	Japan	Prospective intervention study (N=236; home-based intervention group, n=30; outpatient-based intervention group, n=69; control group, n=137)	IV	Home-based telerehabilitation, and outpatient-based telerehabilitation with telephone consultations	Telephone communication and consultations, pedometer, educational rehabilitation DVD with exercises, blood pressure, weight scale	30 days
Peng et al [15]	China	RCT (N=98; intervention group, n=49; control group, n=49)	I, II, and III	Home-based telerehabilitation with a telehealth exercise training program	Text-based, audio, or video conversations regarding follow-up; computer; and a home-based platform (WeChat) for communicating with nurses	8 weeks and follow-up after 4 months
Piotrowicz et al [13]	Poland	RCT (N=111; intervention group, n=77; control group, n=34)	II and III	Home-based telemonitored walking training	ECG recorder (EHO-MINI device), blood pressure monitor, weight scale; all data were transmitted via a mobile phone to the monitoring center	8 weeks
Piotrowicz et al [20]	Poland	RCT (N=131; intervention group, n=77; control group, n=75)	II and III	Home-based telemonitored walking training	ECG recorder (EHO-MINI device); transmitted via a mobile phone to the monitoring center	8 weeks

Reference	Country	Type of study and sample size	Severity of HF (NYHA ^a Functional Classification)	Intervention	Technology	Duration of intervention and follow-up
Piotrowicz et al [21] ^b	Poland	Review (6 HF studies)	—	Home-based telerehabilitation	Telephone communication or transmission of data via telephone, ECG recorder, blood pressure monitor, weight scale, saturation, respiration, cardiovascular implantable electronic device, hemodynamic implantable electronic devices	—
Piotrowicz et al [17]	Poland	RCT (N=111; intervention group, n=77; control group, n=34)	II and III	Home-based telemonitored walking training	ECG recorder (EHO-MINI device), blood pressure monitor, weight scale; all data were transmitted via a mobile phone to the monitoring center	8 weeks
Piotrowicz [19]	Poland	Expert review (5 studies)	II and III	Home-based telerehabilitation	Telesupervised exercise training	—
Piotrowicz et al [22]	Poland	RCT (N=850; intervention group, n=425; control group, n=425)	I, II, and III	Hybrid home-based telerehabilitation with remote monitoring of training at patients' homes	ECG recorder (EHO-MINI device), blood pressure monitor, weight scale; all data were transmitted via a mobile phone to the monitoring center	9 weeks and follow-up over a period of 14-16 months

^aNYHA: New York Heart Association.

^bResults pertaining to patients with heart failure were difficult to distinguish from those of patients with other cardiac diseases.

^cParameter not evaluated.

^dECG: echocardiogram.

^eRCT: randomized controlled trial.

Table 2. Overview of outcomes of studies on telerehabilitation and heart failure.

Reference	Quality of life	Physical capacity	Depression or anxiety	Adherence to the intervention
Brunetti et al [18] ^a	↑ (1 study)	↑ (1 study)	— ^b	—
Hamilton et al [14]	↑ (SF-36 ^c , 1 study)	—	—	High adherence in all studies included; reported as 94% and 95% in 2 of the studies
Hwang et al [7]	↑ (3 studies)	↑ (6MWT ^d , 1 study) in the intervention group	—	Higher adherence in telerehabilitation than center-based exercise (2 studies)
Hwang et al [23]	↑ (EQ-5D ^e) in both groups	N/A ^f (6MWT, 10MWT ^g)	—	71% adherence in the intervention group
Nakayama et al [16]	↑ (EQ-5D) in the intervention group	—	—	—
Peng et al [15]	↑ (MLHFQ ^h) in the intervention group	↑ (6MWT) in the intervention group	N/A (HADS ⁱ) for both depression and anxiety	—
Piotrowicz et al [13]	↑ (SF-36) in the intervention group	↑ (peak oxygen consumption [VO ₂], 6MWT) in the intervention group	—	94.7% adherence in the intervention group
Piotrowicz et al [20]	↑ (SF-36) in both groups	↑ (physical capacity subscale in SF-36) in both groups	—	—
Piotrowicz et al [21] ^a	↑ (2 studies)	↑ (2 studies)	↓ depression (1 study) and ↓ anxiety (1 study)	Higher adherence to telerehabilitation than usual care
Piotrowicz et al [17]	—	↑ (cardiopulmonary exercise test peak VO ₂) in the intervention group	↓ (BDI ^j) depression in both groups	—
Piotrowicz [19]	↑ in both groups	↑ (3 studies)	↓ depression (1 study)	High adherence in the intervention group (2 RCTs ^k)
Piotrowicz et al [22]	N/A (SF-36); significant differences were reported only between groups and not internally within groups	N/A (6MWT, cardiopulmonary exercise test, peak oxygen consumption peak VO ₂); significant differences were reported only between groups and not internally within groups	—	88.4% adherence in the intervention group

^aResults pertaining to patients with heart failure patients were difficult to distinguish from those of patients with other cardiac diseases.

^bParameter not evaluated.

^cSF-36: 36-Item Short Form Survey.

^d6MWT: 6-minute walk test.

^eEQ-5D: European Quality of Life–5 Dimensions.

^fN/A: not applicable.

^g10MWT: 10-minute walk test.

^hMLHFQ: Minnesota “Living with Heart Failure” Questionnaire.

ⁱHADS: Hospital Anxiety and Depression Scale.

^jBDI: Beck Depression Inventory.

^kRCT: randomized controlled trial.

Synthesis of Studies on HF and Telerehabilitation

The studies on the use of telerehabilitation for patients with HF indicated that 4 out of 6 RCTs, 1 prospective study, and 4 out of 5 reviews reported an increase in QoL (Table 3). In terms of physical capacity, 4 RCTs and 3 systematic reviews reported increased physical capacity. Depression or depressive symptoms

were reported as reduced in 1 RCT and 2 reviews. Anxiety or anxiety-related symptoms were reported as reduced in 1 of 6 reviews. High adherence to the telerehabilitation program was reported in 4 RCTs and 4 reviews. It should be noted that some of the reported articles described the same studies but presented different outcome measures.

Table 3. Synthesis of studies on heart failure and telerehabilitation, 2015-2020.

Study type	Quality of life	Physical capacity	Depression or anxiety	Adherence to the intervention
Randomized controlled trial (n=6)	↑ (4 studies)	↑ (4 studies)	↓ depression (1 study)	High (4 studies)
Prospective study (n=1)	↑ (1 study)	— ^a	—	—
Review (n=5)	↑ (4 studies)	↑ (3 studies)	↓ depression (2 studies) and ↓ anxiety (1 study)	High (4 studies)

^aParameter not evaluated.

Discussion

Principal Findings

The aim of this study was to investigate the effects of telerehabilitation on the management of HF by reviewing the available scientific literature within the period from January 1, 2015, to December 31, 2020. This review was based on the following outcomes: QoL, physical capacity, depression or anxiety, and adherence to the telerehabilitation intervention. Overall, it was found that telerehabilitation had a positive influence on the outcome measures. The 12 articles reviewed here showed wide variation in terms of the numbers of patients included, the duration of the intervention, the duration and absence of a follow-up period, the outcome measurements, and the technologies used.

Telerehabilitation interventions for patients with HF showed that patients who participated in telerehabilitation programs improved their QoL compared to those in conventional rehabilitation programs [7,13-18,20,21,23]. However, 2 RCTs showed a significant improvement in QoL both in the telerehabilitation and the control groups [20,23]. Furthermore, 1 study did not show an improvement in QoL internally in the groups; however, a significant difference in QoL between the groups was seen, with QoL being highest in the telerehabilitation group compared to the control group [22]. These results indicate that in most cases, telerehabilitation helped increase QoL in patients with HF compared to conventional care.

Increased physical capacity was seen in 7 out of the 10 studies that reported this outcome [13,15,17-21]. Physical capacity was measured by using a variety of outcomes in the identified studies, but most studies employed the 6-minute walking test for assessing the effectiveness of telerehabilitation. However, physical capacity or physical activity can be measured by other methods. In a RCT with patients with HF enrolled in a telerehabilitation program, Gade et al [24], whose study was not included in this review, measured physical activity using a Fitbit step counter for 1 year. The study found no increase in the number of steps. However, a significant correlation was found between the increased number of steps and the reduction in the ejection fraction. Furthermore, it was found that a step counter can be a useful tool to help patients monitor their own physical activity [24]. These findings suggest that measurement of patients' physical activity can be carried out using technologies such as a step counter instead of tests.

All the included studies in our review used home-based telerehabilitation as their intervention. However, there were variations in the way the patients were approached, where some

were group-based and others were individually based. Only 1 out of 12 studies were group-based [23], thereby indicating that the home-based intervention is most commonly used as a single-based intervention. Many of these studies used the same types of technologies, such as cell phones, which was seen in 8 of the included studies [7,14,16-18,20-22]. Other types of technologies used were different types of ECG recorders, blood pressure meter, weight scale, saturation device, respirometer video, oximeter sphygmomanometer, computer, and others (Table 1) [7,13-23]. However, other studies on telerehabilitation use among patients with HF and patients with other cardiac disorders utilized technologies such as pedometers, sleep sensors, tablets, online portals, and apps [24-26]. This suggests that other studies will employ additional, more advanced, and newer technologies than the ones mentioned in this review, such as wearables. The implication is that future research will need to focus on the potential of these technologies as part of a telerehabilitation regime for patients with HF.

Depression was used as an outcome measure in only 4 of the 12 studies [15,17,19,21]. Three of these 4 studies showed a significant decrease in depression with telerehabilitation use among patients with HF [17,19,21]. Only 2 of the 4 studies had anxiety as an outcome measure [15,21]. Piotrowicz et al [21] found a decrease in both anxiety and depression when using telerehabilitation. Peng et al [15] investigated the effects of home-based telehealth exercise training on both depression and anxiety. However, the results proved to be not significant, thereby indicating that the home-based telehealth exercise program in this study did not produce any significant improvement in either of the two outcome measures [15]. Other studies reported similar results in patients with cardiac disorders, thus showing that telerehabilitation can have positive effects on depression and anxiety outcome measures [26-28].

Patients' adherence to the interventions was measured in 7 of the studies included, and all 7 reported high adherence to the telerehabilitation intervention [7,13,14,19,21-23]. Furthermore, in most of the studies, adherence was reported to be higher in the telerehabilitation group compared to the standard care group. Studies reported adherence using different measures like self-reported activity, daily phone contacts, number of exercises per week, or number of rehabilitation sessions attended. As telerehabilitation is often home-based, there may be uncertainty regarding the degree to which patients actually adhere to the program. Daily phone contacts with patients, which was the measure used in 2 studies [13,22], ensured a more stable monitoring of adherence; however, phoning patients every day requires considerable resources. Another, less labor-intensive method of monitoring adherence to a program could be the use

of a pedometer, as the patient would be able to monitor their physical activity without any subjective reporting, assuming that the results are then accurately transmitted.

Telerehabilitation is still a developing feature in the management of HF. There is a growing body of literature on the effect of telerehabilitation compared to conventional care in both patients with HF as well as other diseases [6]. This is especially relevant now since the COVID-19 pandemic has drawn attention to and accelerated the use of telerehabilitation, due to restrictions on the use of physical therapy sessions in many countries. Therefore, it is likely that the use of telerehabilitation will become more integrated into clinical practice in the future, as the pandemic has stimulated the use of new approaches for rehabilitation for patients with chronic diseases [29]. This scoping review has been conducted in order to examine to what extent telerehabilitation has been implemented for patients with HF and to document the impact of telerehabilitation for patients with HF in terms of QoL, physical capacity, depression, anxiety, and intervention adherence. The evidence from our review indicates that future research within telerehabilitation for patients with HF should focus on larger-scale clinical trials, longer duration of interventions and follow-up periods, and patients' adherence to telerehabilitation interventions.

Limitations

As telerehabilitation is still a relatively new approach to cardiac rehabilitation, studies of the use of telerehabilitation for patients with HF are often not comparable. There is still no consensus on optimal outcomes, which makes it a challenge to compare studies since outcomes are measured differently. Furthermore, reviews often focus on cardiac telerehabilitation concerned with various cardiac diseases, which again makes it a challenge in distinguishing HF results from other cardiac diseases in reviews.

The studies reviewed here did not focus extensively on patient education. Instead, their focus was on physical tests. However, we are aware of telerehabilitation programs where patient education is part of the program [25].

Conclusion

The review has shown that the effect of telerehabilitation in patients with HF is still relatively new. Our review indicates a relative consensus that use of telerehabilitation for patients with HF helps improve patients' QoL and their physical capacity. The outcome measures of depression and anxiety were found to be reduced as well. Moreover, high adherence to telerehabilitation interventions was found in most of the studies. However, there is still no consensus on how and which outcomes should be measured within telerehabilitation. Therefore, additional research is needed to determine more precise and robust effects of using telerehabilitation for patients with HF.

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Authors' Contributions

This scoping review was designed by BD, CSS, and NCH. BD, CSS, and NCH conducted the scoping review and drafted the manuscript. Feedback for the manuscript was provided by all authors. All authors approved the final manuscript before submission.

Conflicts of Interest

TK, TT, NK, and HD are affiliated with an endowed department sponsored by Philips, Asahi Kasei, Toho Holdings, and InterReha. The remaining authors declare no conflicts of interest.

Multimedia Appendix 1

Scoping review protocol.

[DOCX File, 23 KB - [rehab_v8i4e29714_app1.docx](#)]

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Abbreviations

HF: heart failure

MeSH: Medical Subject Headings

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses for scoping reviews

QoL: quality of life

RCT: randomized controlled trial

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Review

Digital Therapeutic Care and Decision Support Interventions for People With Low Back Pain: Systematic Review

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Abstract

Background: Low back pain (LBP) is the leading cause of worldwide years lost because of disability, with a tremendous economic burden for health care systems. Digital therapeutic care (DTC) programs provide a scalable, universally accessible, and low-cost approach to the multidisciplinary treatment of LBP. Moreover, novel decision support interventions such as personalized feedback messages, push notifications, and data-driven activity recommendations amplify DTC by guiding the user through the program while aiming to increase overall engagement and sustainable behavior change.

Objective: This systematic review aims to synthesize recent scientific literature on the impact of DTC apps for people with LBP and outline the implementation of add-on decision support interventions, including their effect on user retention and attrition rates.

Methods: We searched bibliographic databases, including MEDLINE, Cochrane Library, Web of Science, and the Physiotherapy Evidence Database, from March 1, 2016, to October 15, 2020, in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and conducted this review based on related previously published systematic reviews. Besides randomized controlled trials (RCTs), we also included study designs with the evidence level of at least a retrospective comparative study. This enables the consideration of real-world user-generated data and provides information regarding the adoption and effectiveness of DTC apps in a real-life setting. For the appraisal of the risk of bias, we used the Risk of Bias 2 Tool and the Risk of Bias in Non-Randomized Studies of Interventions Tool for the RCTs and nonrandomized trials, respectively. The included studies were narratively synthesized regarding primary and secondary outcome measures, DTC components, applied decision support interventions, user retention, and attrition rates.

Results: We retrieved 1388 citations, of which 12 studies are included in this review. Of the 12 studies, 6 (50%) were RCTs and 6 (50%) were nonrandomized trials. In all included studies, lower pain levels and increased functionality compared with baseline values were observed in the DTC intervention group. A between-group comparison revealed significant improvements in pain and functionality levels in 67% (4/6) of the RCTs. The study population was mostly homogeneous, with predominantly female, young to middle-aged participants of normal to moderate weight. The methodological quality assessment revealed moderate to high risks of biases, especially in the nonrandomized trials.

Conclusions: This systematic review demonstrates the benefits of DTC for people with LBP. There is also evidence that decision support interventions benefit overall engagement with the app and increase participants' ability to self-manage their recovery process. Finally, including retrospective evaluation studies of real-world user-generated data in future systematic reviews of digital health intervention trials can reveal new insights into the benefits, challenges, and real-life adoption of DTC programs.

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KEYWORDS

digital therapeutic care; decision support interventions; low back pain; behavior change techniques; back; orthopedic; systematic review; digital therapy; decision support; mobile phone

Introduction

Background

Low back pain (LBP) is the leading cause of worldwide years lost because of disability, with a global point prevalence of 9.4% and a reported lifetime prevalence of up to 84% [1,2]. Moreover, LBP is responsible for most absences from work as well as productivity losses, which ultimately results in a tremendous societal and economic burden [3]. Current clinical guidelines recommend a multimodal treatment approach for people with nonspecific, nonacute LBP, including remaining physically active, exercising and receiving educational therapy, and using psychosocial interventions [4,5].

Digital therapeutic care (DTC) programs provide a scalable, universally accessible, and low-cost approach to deliver these key components of a multimodal treatment. Using smartphone or browser-based apps, people with LBP can proactively self-manage their recovery process through remote physical and mindfulness exercises and in-depth explanatory educational material. Initial research investigating a DTC app to self-manage LBP has shown an overall positive effect on pain levels and functional disability [6]. In this virtually unsupervised approach, motivational factors, coping behavior, and self-management abilities play a critical role in patient literacy and empowerment with regard to adherence to the treatment program [7]. Thus, novel add-on personalized decision support interventions provide the possibility of guiding the user through the program and achieving sustainable behavior change through, for instance, tailored feedback messages, push notifications, and data-driven activity recommendations [8]. However, the benefits of a DTC program with add-on decision support interventions remain unclear and require further investigation [9].

Moreover, low user retention and high attrition rates are unresolved challenges, with reported nonengagement levels of up to 70% [10,11]. In this regard, user retention describes the adherence to, and overall response rate of, the DTC program [12]. This involves the sustained use of individual treatment modules. Engagement in the program can be measured, for instance, by the number of completed exercises or the time spent on the educational material [11]. Alternatively, the attrition rate focuses on the dropout of participants and, thus, their discontinuation of the DTC program [13]. In the treatment of people with LBP, both user retention and attrition rate play a critical role in understanding the causal dependencies with regard to the long-term impact of digital therapeutic interventions.

Previous systematic reviews focused on investigating the impact of DTC apps or decision support interventions in a controlled clinical trial-based environment, which determines the efficacy of the intervention under considerably ideal conditions [14]. In contrast, the intervention's effectiveness provides information on health-related outcomes in a real-world setting from people using the app either on their own initiative or after receiving a

physician's prescription. Evidence regarding the difference in outcomes between a controlled trial setting and real-world use is lacking because previous systematic reviews only included randomized controlled trials (RCTs) because they represent the gold standard [9,14,15]. However, in future data-driven research on digital health interventions, retrospective evaluations could generate new insights into the effectiveness and engagement of DTC programs. In fact, the quickly evolving regulatory environment in favor of digital ecosystems advocates research platforms and databases to facilitate the evaluation of real-life user data. Finally, Germany's newly introduced Digital Healthcare Act allows the reimbursement of the cost of digital health apps by the statutory health insurance providers once the app is listed in the Digital Health Applications directory [16,17]. For this purpose, manufacturers are obliged to provide scientific evidence in the form of at least retrospective comparative studies proving that their digital health app yields positive health care effects [16]. This approach directly enables the consideration of real-life user-generated data and provides information regarding the adoption and effectiveness of the digital health app in a real-world setting.

Related Work

Various systematic reviews have elaborated on the impact of digital therapeutic interventions for people with LBP [9,15]. Nicholl et al [9] performed a comprehensive review with the most substantial overlap to our research question investigating digital support interventions for the self-management of LBP. Their work is part of the European Union (EU)-funded selfBACK project, which aims to develop an app that provides tailored, algorithm-based digital decision support interventions for the self-management of LBP [18]. The authors identified 6 completed RCTs but could not conclude under what circumstances which type of digital support intervention was effective for people with LBP. Because of the variability of study interventions and the homogeneous participant cohorts, which consisted predominantly of White, well-educated, and middle-aged women, it became clear that further studies are necessary to evaluate the benefits of digital support interventions for broader populations.

In a more recent review, Hewitt et al [15] investigated the impact of digital health interventions in a broader context of musculoskeletal conditions. In their review, the authors included 19 studies, of which 9 reported statistically significant reductions in musculoskeletal pain and 10 reported statistically significant improvements in functional disability. However, because of the consideration of predominantly stand-alone interventions and missing relatedness to LBP specifically, a recent systematic literature review dedicated to a holistic DTC program is, to the best of our knowledge, currently lacking.

It is worth mentioning that 2 systematic reviews have investigated apps that aim to support people with LBP with self-management, monitoring, or decision support interventions and are available on the iTunes and Google Play stores [19,20].

The first review, from 2017, found 61 smartphone apps, whereas the more recent one, from 2020, identified 74 apps available to download for smartphone users. The high and still increasing number of smartphone apps also underlines the need for an updated review from a scientific, clinical trial-based perspective.

Objective

The aim of this review is to evaluate recently published clinical evidence regarding the efficacy and effectiveness of digital therapeutic interventions for people with LBP. Moreover, we seek to synthesize the characteristics and components of the respective digital therapeutic programs, the type of delivery and interactivity with the user, and the extent of the deployed decision support interventions. Thereby, we aim to extract overall retention and attrition rates of the therapeutic care apps and summarize how current decision support interventions contribute to overall engagement levels and possibly influence health-related outcome measures.

Methods

Study Design

Following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement, we performed a systematic literature review to identify and analyze recent scientific evidence regarding digital therapeutic and decision support interventions for people with LBP [21]. Notably, this systematic review was not preregistered in an international prospective registry such as PROSPERO. The new field of DTC apps and decision support interventions for LBP has rapidly emerged in scientific research over the past years. New nomenclature has arisen from ongoing software implementations and the increase in the number of innovational digital therapy features. These developments required an explorative approach to defining the inclusion and exclusion criteria for a profound systematic review to ensure that all relevant studies could be included. Therefore, we chose a snowballing search method and, subsequently, extended our ongoing search to a systematic review. Nonetheless, being aware of potential biases that may result from the lack of a prospective preregistration, we have presented our findings using a narrative approach, with the primary goal of summarizing recent technological improvements and implications in the field of digital therapy for LBP.

Search Strategy

We searched the bibliographic databases (1) MEDLINE through PubMed, (2) Cochrane Central Register of Controlled Trials in

the Cochrane Library, (3) Web of Science Core Collection, and (4) the Physiotherapy Evidence Database and included English- and German-language literature published in peer-reviewed journals. In addition, we screened the reference lists and tracked the citations of all included studies for eligibility.

This review's search concept is based on 2 main pillars: (1) LBP and (2) digital therapeutic and decision support interventions. These search terms were extended with specific terminology and synonyms using Boolean operators and the respective Medical Subject Headings and are aligned with the updated method guideline for systematic reviews provided by the Cochrane Back and Neck group [22]. The detailed search queries for the corresponding databases are presented in [Multimedia Appendix 1](#).

The final search was conducted on October 15, 2020. All collected studies were saved in a reference management software program, and duplicates were removed. In the first iteration, the titles and abstracts of the remaining studies were screened by 2 reviewers (DL and AMW) independently. Any disagreements would lead to the inclusion of a study for full-text screening. Subsequently, full-text screening was also conducted by 2 independent reviewers (DL and AMW). This time, the studies on which the reviewers disagreed were assessed for eligibility by a third reviewer (SW) and resolved through discussion.

Inclusion Criteria

We have summarized our inclusion and exclusion criteria in [Textbox 1](#). In brief, we included all publications, with the primary aim of investigating the efficacy or effectiveness of a multidisciplinary DTC program with respect to health-related outcomes for people with LBP. Furthermore, our presearch and small pilot review of related work showed that prior systematic reviews had evaluated our research questions or comparable ones before 2016. Therefore, our systematic review complements the benchmark work of Nicholl et al [10], who have adequately elaborated the time frame until March 2016; therefore, we have included published studies from March 1, 2016, to October 15, 2020. Our approach is underpinned by our focus on the significant technological improvements in the field of decision support interventions as a new feature in DTC apps that have become available in recent years. Because of these emergent advancements and the changing terminology, the continuation of, and comparison with, the work of Nicholl et al [10] are not within the scope of this review.

Textbox 1. Inclusion and exclusion criteria according to the population or patient problem, intervention, control, and outcomes (PICO) concept.

Inclusion criteria

- Population: People aged >16 years with low back pain.
- Intervention: Any interactive digital and internet-based (health) app that provides digital treatment therapy through an electronic device, that is, computer, tablet, or smartphone. Digital treatment includes access to a digital exercise program, including exercise instructions (eg, video-guided). Moreover, the app contains at least one intervention that addresses the biopsychosocial factors of low back pain, for example, through digital educational material or a digital psychological intervention in the form of cognitive behavioral therapy, or enables self-management, for example, through digital decision support interventions.
- Control: Treatment as usual or any other nondigital form of therapy regarding exercises and educational material for people with low back pain or older versions of the investigated digital therapeutic app or baseline measures.
- Outcomes: Any health-related primary outcome measure that is related to pain or functional disability. Secondary outcomes might include psychological factors (eg, depression), physical activity, medication use, health care resource use, health care costs, or digital therapy program adherence and retention rates.
- Study design: Randomized and nonrandomized controlled trials (including pilot randomized controlled trials); observational analytical studies, either prospective or retrospective; or intraindividual single-arm comparison studies.

Exclusion criteria

- Patient problem: Unspecified chronic pain or other musculoskeletal disorder conditions, for example, neck or knee pain.
- Intervention: Digital health apps using a fully automated text-based health care chatbot; smartphone-based standing posture, sitting posture, or range-of-motion recording or human activity recognition; self-referral decision support interventions; smartphone use only for a 6-minute walking test; internet interventions that include only a reminder or pain monitoring or reporting systems; stand-alone digital cognitive functional therapy; exercise therapy through DVD, CD, or a console, for example, Nintendo Wii; or other website-based interventions.
- Study design: Observational, purely descriptive studies, for example, cross-sectional, qualitative, mixed methods, acceptability, or development studies.

In our review, we also included study designs with an overall lower scientific evidence level than RCTs of at least retrospective comparative studies for the following reasons: first, because of Germany's newly introduced Digital Healthcare Act, German manufacturers of digital health apps are obliged to provide scientific evidence in the form of at least retrospective comparative studies proving that their app yields positive health care effects [16,17]. Therefore, we adopted this selection criterion of scientific evidence for this review to elaborate on the feasibility of a framework that considers real-world evidence for regulatory decisions.

Second, although RCTs remain the gold standard for providing the highest clinical evidence, the optimal control conditions in digital health intervention trials require further investigation [23]. Choosing treatment as usual as the control group in prospective RCTs might lead to a so-called "app-physician competition bias" [23]. The physicians' awareness of the controlled study design, for example, when competing against a digital therapeutic app for LBP, may cause them to update their knowledge regarding the newest guidelines and treatment recommendations. Thus, the consideration of divergent control groups and retrospective, cohort study designs might be useful for digital therapeutic apps, which will be evaluated with regard especially to the number of associated biases and confounders.

Data Synthesis

Data of all included studies were extracted by 2 independent reviewers who were randomly selected from a pool of 5 reviewers (DL, AW, TS, SW, and AMW) for each included study regarding the following outcomes: characteristics of included studies, characteristics of the participants, characteristics and components of the digital therapeutic

interventions as well as retention rates, and data related to primary and secondary outcome measures. Because of the heterogeneity of the included studies, it was not feasible to conduct a meta-analysis. Despite making assumptions of the apparent similarity of most of the included studies in this review, we decided not to conduct a statistical meta-analysis because it could further compound possible biases regarding meaningful clinical recommendations and is therefore not justified. We have included a broad range of different DTC apps to narratively describe the progress made in this enormously increasing field of digital health. Our primary goal of following a narrative approach in the data synthesis is to provide information to researchers, manufacturers, and decision-makers on the status of scientific research in DTC. Thus, we focused on creating an overview of recent technological improvements, for example, decision support interventions that accompany digital therapy for people with LBP. Because of this focus, we did not extensively narrow the inclusion and exclusion criteria concerning the study design, that is, the time frame of follow-up measures, the comparator group, or the outcome measurements, including different tools and scales. Moreover, combining only a subgroup of our review's included studies into a meta-analysis would potentially have led to misleading conclusions, especially because we have only included studies published from March 1, 2016, to October 15, 2020.

Quality Appraisal

For the assessment of the methodological quality of the included studies, we used 2 separate tools to adequately elaborate on the RCTs as well as the observational studies [24]. We chose the Risk of Bias 2 (RoB 2) Tool for assessing "risk of bias in randomized trials" [25], which is based on an earlier version of

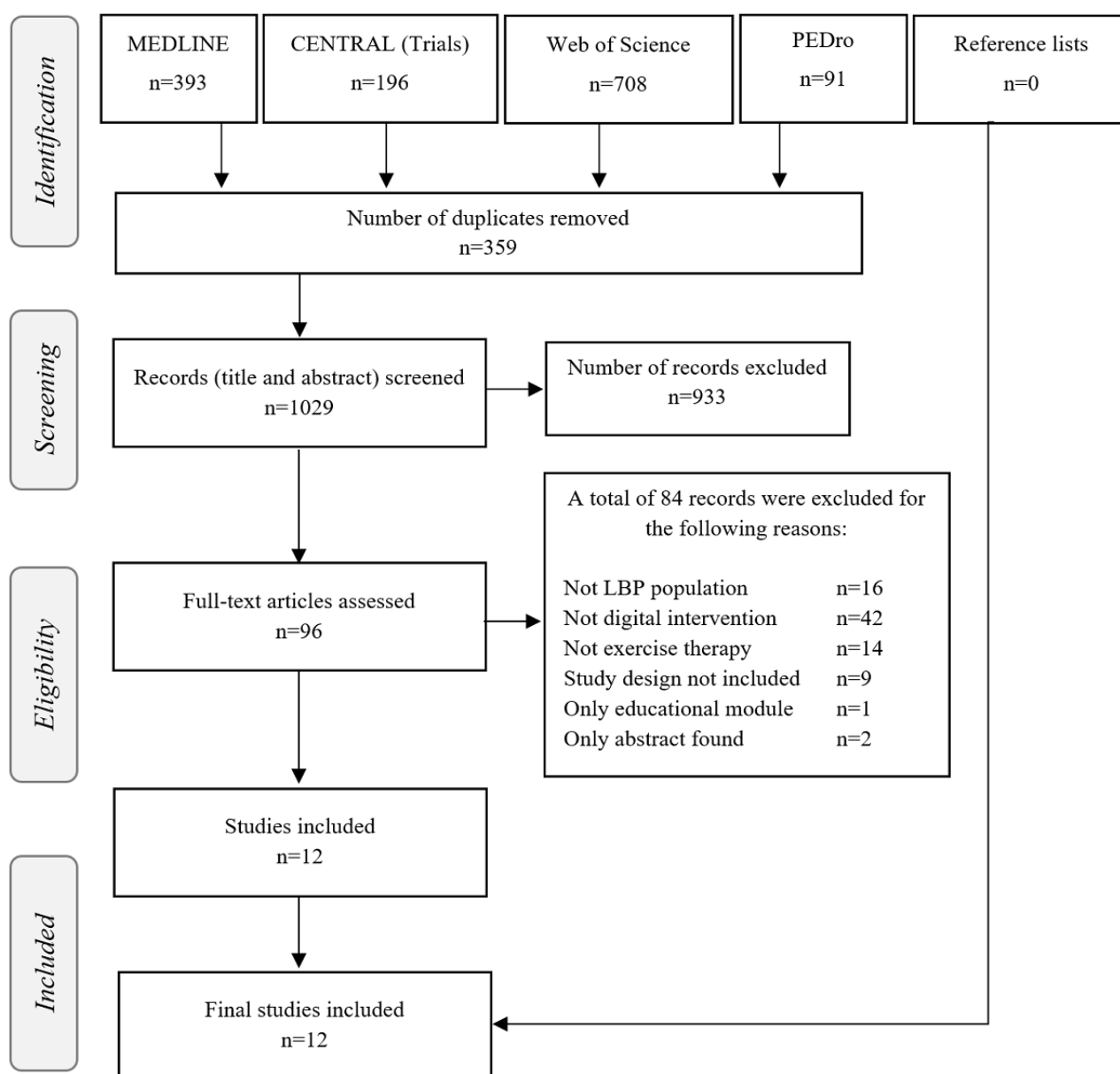
the Cochrane Collaboration tool for assessing the risk of bias in randomized trials [26], and the Risk of Bias in Non-Randomized Studies of Interventions (ROBINS-I) Tool for assessing the risk of bias in observational studies [27]. Quality assessment was performed independently for each included study by 2 reviewers who were randomly selected from a pool of 5 reviewers (DL, AW, TS, SW, and AMW) for each included study. Studies on which the reviewers disagreed were assessed by a third reviewer (TS or SW) independently and resolved through discussion.

Results

Search Results

We retrieved 1388 citations in total, and after removing 359 duplicates, we screened 1029 publications that were potentially eligible for inclusion in this review. Of the 1029 studies, 96 remained after title and abstract screening for full-text assessment. In the end, of these 96 studies, we included 12 in this systematic review. No additional publications were identified by screening the reference list or Google Scholar's *Cited by* option of included studies. The iterative steps of our literature search and the reasons for excluding several studies are shown in a PRISMA flow diagram (Figure 1).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of the search process (N=1388). CENTRAL: Cochrane Central Register of Controlled Trials; LBP: low back pain; PEDro: Physiotherapy Evidence Database.



Description of Included Studies

Of the 12 studies, 6 (50%) [28-33] were RCTs and 4 (33%) [34-37] had a retrospective cohort design, whereas the remaining

2 (17%) were a retrospective evaluation [38] and a prospective single-arm trial [39], respectively. Of the 12 studies, 5 (42%) were published in 2020 [28,33,34,37,39], 3 (25%) in 2019 [29-31], 3 (25%) in 2018 [32,36,38], and 1 (8%) in 2017 [35];

moreover, 2 (17%) each were conducted in the United States [30,34], Germany [28,31], and China [29,38], 1 (8%) in India [32], and 1 (8%) in Jordan [33], whereas the remaining 3 (25%) were conducted in multiple countries. Of these 3 studies, 1 was conducted in Denmark and Norway [39] and 1 included participants from Germany, Austria, and Switzerland [35]. In addition, a follow-up study that used the same DTC app was conducted in the United States and the United Kingdom [36]. Of the 12 studies, in 1 (8%), it was not clearly stated from which country the users signed up for the program [37]. Regarding the names of the projects or apps, in 42% (5/12) [28,31,35-37] of the studies, the *Kaia* app was investigated; in 17% (2/12) [30,34], the *Hinge Health* app was investigated; whereas the *selfBACK* app [39], *Snapcare* app [32], *Relieve my back* app [33], *Well Health* app [38], and *eHealth program* [29] were investigated in 8% (1/12) each. The study durations with regard

to the digital therapeutic intervention did not vary significantly. In 58% (7/12) [28,30-32,34,35,37] of the studies, the intervention was investigated for 12 weeks or 3 months, 17% (2/12) [33,39] had an intervention duration of 6 weeks, 17% (2/12) had an intervention duration of 24 weeks [36] and 24 months [29], whereas in 8% (1/12) [38], the duration was inconsistent and not clearly reported.

Study Population

The detailed characteristics of the study participants are listed in Table 1. Overall, the reviewed studies included 10,275 participants. The variation in the total number of study participants was significant, ranging from 41 participants in an RCT [33] to 6468 in a retrospective cohort study [34]. In most of the studies, the number of participants ranged from 93 to 180 [29-33,35,38].

Table 1. Characteristics of the participants in the included studies (N=12).

Reference	LBP ^a duration of included participants	LBP diagnosis ^b	Total number of participants	Age (years), mean (SD)	Female (%)	BMI, mean (SD)
Bailey et al [34]	>12 weeks	Self-reported	6468	42.58 (10.91)	48.53	29.76 (7.11)
Priebe et al [28]	<12 weeks	General practitioner	1245; I ^c : 933; C ^d : 312	I: 42.0 (12.4); C: 37.0 (12.6)	I: 65; C: 64	I: 26.5 ^e ; C: 26.3
Hou et al [29]	Underwent surgery	General practitioner	168; I: 84; C: 84	I: 51.11 (9.54); C: 49.36 (9.52)	I: 57; C: 50	NR ^f
Shebib et al [30]	>6 weeks in the past 12 months	Self-reported	177; I: 13; C: 64	I: 43 (11); C: 43 (12)	I: 37; C: 48	I: 26 (5); C: 26 (4)
Toelle et al [31]	From 6 weeks to 1 year	General practitioner	101; I: 53; C: 48	I: 41 (10.6); C: 43 (11.0)	I: 72.9; C: 67.4	I: 24.4 (3.31); C: 25.4 (4.6)
Chhabra et al [32]	>12 weeks	General practitioner	93; I: 45; C: 48	I: 41.4 (14.2); C: 41.0 (14.2)	NR	I: 23.15 (4.2); C: 23.54 (3.8)
Almhdawi et al [33]	>3 months	Self-reported	41; I: 21; C: 20	I: 40.48 (7.22); C: 41.70 (6.35)	I: 67; C: 60	I: 27 (3.00); C: 35 (3.00)
Lo et al [38]	<3 months	Self-reported	161	— ^g	24.68	NR
Huber et al [35]	<6 weeks: 13.9%; <12 weeks: 12.8%; >12 weeks: 73.3%	Self-reported	180	33.9 (10.9)	58.3	NR
Clement et al [36]	NR	Self-reported	1251; V1 ^h : 196; V2 ^h : 1055	V1: 34.8 (11.0); V2: 45.6 (11.6)	V1: 58.2; V2: 49.3	NR
Priebe et al [37]	NR	Self-reported	339; V1: 180; V2: 159	V1: 33.9 (10.86); V2: 46.9 (13.10)	V1: 58.33; V2: 43.79	NR
Sandal et al [39]	Any duration	Physiotherapist or general practitioner	51	45.5 (15.0)	58	27.2 (5.5)

^aLBP: low back pain.

^bDefines who referred the participant to the study or who diagnosed low back pain.

^cI: intervention group.

^dC: control group.

^eCalculated based on in-study reported height and weight values.

^fNR: not reported.

^gOnly categorized values were reported: age 18-25 years: 30 users; age 26-30 years: 31 users; age 31-40 years: 56 users; age 41-50 years: 19 users; age 51-60 years: 20 users; age >60 years: 1 user.

^hComparison between 2 subsequent app versions: version 0.x (V1) and version 1.x (V2). V1 includes users who signed in before May 1, 2017, and V2 includes users who signed in after that date.

Of the 12 studies, 1 (8%) [33] included only people who were aged between 30 and 55 years by addressing only office workers, whereas the other 11 (92%) included participants aged ≥ 18 years up to the age of 65 years, 80 years, or without an upper-bound specification. In 50% (6/12) of the studies [28,30–34], the mean age in the intervention group was between 40 and 43 years. The highest reported mean age was 51.11 years [29], and the lowest was 33.9 years [35]. Regarding the sex of the participants, women were overrepresented in 67% (8/12) of the studies, peaking at 72.9%, 67%, and 65% in 38% (3/8) [28,31,33] of these studies. Of the 12 studies, 1 (8%) [34] reported no significant difference in the female-to-male ratio, 1 (8%) [32] did not report any information, and 1 (8%) [38] reported a female rate of only 24.68%. Of the 12 studies, only 7 (58%) [28,30–34,39] reported on the BMI of the included participants. The average BMI values ranged between 23.15 kg/m² [32] and

29.76 kg/m² [28] in the intervention group, including 17% (2/12) [31,32] of the studies with participants with BMI < 25 kg/m² (people of normal weight). The ethnicity and comorbidities of participants were not reported in any of the included studies.

Risk-of-Bias Assessment

The results of the risk-of-bias assessment of the included studies are presented in Tables 2 and 3. We used the RoB 2 Tool for the included RCTs (6/12, 50%; Table 2) and the ROBINS-I Tool for the nonrandomized studies (6/12, 50%; Table 3). In the RoB 2 analysis, the studies were assessed using predefined signaling questions and were accordingly categorized using standardized wording, that is, *low risk*, *some concerns*, or *high risk* of bias. Similarly, in the nonrandomized trials, the risk of bias was judged to be *low*, *moderate*, *serious*, or *critical*.

Table 2. Risk-of-bias assessment of included randomized controlled trials (N=6).

Risk of Bias 2 Tool	Bias arising from the randomization process	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
Priebe et al [28]	Some concerns	Some concerns	Low	Some concerns	Low
Hou et al [29]	Low	Some concerns	Low	Some concerns	Low
Shebib et al [30]	Low	Some concerns	Low	Some concerns	Low
Toelle et al [31]	Some concerns	Low	Low	Some concerns	Low
Chhabra et al [32]	Low	Low	Low	Some concerns	Low
Almhdawi et al [33]	Low	Some concerns	Low	Low	Low

Table 3. Risk-of-bias assessment of included nonrandomized studies (N=6).

Risk of Bias in Non-Randomized Studies of Interventions Tool	Bias due to confounding	Bias in selection of participants	Bias in classification of intervention	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
Bailey et al [34]	Low	Serious	Low	Moderate	Low	Moderate	Moderate
Lo et al [38]	Moderate	Serious	Moderate	Moderate	Unclear	Serious	Moderate
Huber et al [35]	Serious	Serious	Moderate	Moderate	Serious	Moderate	Moderate
Clement et al [36]	Serious	Serious	Moderate	Serious	Moderate	Moderate	Moderate
Priebe et al [37]	Serious	Serious	Moderate	Moderate	Serious	Moderate	Moderate
Sandal et al [39]	Moderate	Moderate	Low	Low	Low	Moderate	Low

The overall risk of bias in a study was determined based on the highest level of risk in at least one domain, that is, the study was judged to be at high risk of bias when at least one domain was considered *high*. The RoB 2 Tool encompasses 5 domains, whereas the ROBINS-I tool encompasses 7. Of the 6 RCTs, 6 (100%) were appraised as having low risk or some concerns regarding potential biases, predominantly regarding bias due to deviations from intended intervention and outcome measurement. Notably, of the 6 RCTs, 1 (17%) achieved double-blinding of participants and assessors by providing a *placebo* version of the same app, which included only advice about general nutrition as a control. In the 6 nonrandomized trials, the overall methodological quality was low and associated with a greater risk of bias: 1 (17%) provided sound to moderate evidence for a nonrandomized trial, whereas 5 (83%) exhibited a serious risk of bias and thus have some important problems

across domains. The major biases occur because of confounding in the selection of participants and because of missing outcome data. In detail, these include different durations of the observational period between groups; missing or significantly different demographic compositions between groups; a retrospective recall of preintervention outcome measures, for example, pain level; predefined inclusion criteria that consider only users who have already completed a certain number of exercises in the first 2 weeks after registration; or the inclusion of only users of the pro version of an app that costs €9.99 (US \$11.56) per month. Bias due to missing data arose when incomplete data were provided, either because of a high attrition rate or because of a fragmentary analysis of an app's user database.

Digital Therapeutic Key Components

We have summarized all investigated DTC apps, including their key components, recommended timing and use frequency, and implemented decision support interventions, in [Table 4](#). The DTC apps involved multiple key components that address the clinical guideline-based recommended multimodal treatment for people with LBP. In all included studies, participants had access to in-app exercise therapy either in the form of videos [[28-32,34-39](#)] or picture-based instructions [[33](#)]. As another key component, educational material was provided in 92%

(11/12) of the apps and involved back pain-specific reading material and papers or rehabilitation plans. The third key component comprised psychosocial interventions that address stress and individual behavioral traits that could influence LBP, that is, in the form of cognitive behavioral therapy, personal health and behavioral coaching, or mindfulness and relaxation techniques in 58% (7/12) of the studies [[28,30,31,34-37](#)]. The timing and frequency at which the user was required to engage with the app varied between studies, described in detail in [Table 4](#). All DTC programs were fully digital, that is, they were either smartphone-based or browser-based.

Table 4. Digital therapeutic components, decision support interventions, user retention and engagement, and attrition rates in the included studies (N=12).

Study, duration	Digital therapeutic components	Recommended timing and frequency	Decision support interventions	Underlying BCTs ^a	User retention and engagement	Attrition rate, ^b %
Bailey et al [34], 12 weeks	1. Sensor-guided exercise therapy: instructional videos and real-time graphics; 2. Remote personal health coaching and educational papers	Weekly 3 sessions of sensor-guided exercise therapy, 2 educational papers, 3 aerobic exercise activities, and 4 modules based on cognitive behavioral therapy	Peer-group interaction and support through in-app discussion feed; 20-30 participants who each used a discussion forum	Catastrophizing, active coping methods, fear avoidance, goal setting, and health tracking	Per week: Exercise therapy sessions: mean 2.9 (SD 1.46); education sessions: mean 2.2 (SD 1.55); interactions with coach: mean 7.0 (SD 3.09)	27.71 ^c
Priebe et al [28], 12 weeks	RE ^{d,e}	RE	RE	RE	Physical exercise: mean 23 days ^f ; mindfulness: mean 15 days; education: mean 16 days	27.20
Hou et al [29], 24 months	1. Rehabilitation video instructions; 2. Rehabilitation plans; 3. Communication with physicians through the app	Rehabilitation exercise: twice daily, with each session lasting 20 minutes	Daily rehabilitation exercise reports and alerts (prompting the user to return to the system)	Reminder	High ^g : 62.29%; medium: 26.23%; low: 11.48%	28.57
Shebib et al [30], 12 weeks	1. Sensor-guided exercise therapy; 2. Education, cognitive behavioral therapy, and behavioral coaching; 3. Activity and symptom tracking	Weekly 3 sessions of exercise therapy, 3 aerobic activities, 1-2 educational articles, and cognitive behavioral therapy on a subset of weeks	Peer-group interaction and coach support through in-app discussion feed, checklists, and point goals; weekly	Reminder, peer support, and gamification	Users engaging with the program per week: 75%; total number of workouts: mean 35.7 (SD 28.9); educational articles: mean 7.4 (SD 4.4); cognitive behavioral therapy session: mean 1.4 (SD 1.2)	24.2
Toelle et al [31], 12 weeks	1. Physiotherapy and physical exercise; 2. Back pain-specific education; 3. Mindfulness and relaxation	Daily content consists of components 1-3; recommended use 4 times per week; up to 5 exercises per day	Customizable reminders, push notifications, health coach (chat function)	Reminder and motivation	Kaia app was used on mean 35 days ^f (SD 22)	20.07
Chhabra et al [32], 12 weeks	1. Tailored home exercise program, including back and aerobic exercises; 2. Activity and health plan	Daily: 4-km walk at a single stretch and 2 sets of 7 back exercises	Daily notifications and reminders; rewards system: points for each milestone achieved and access to the next level once enough points were collected	Gamification and reminder	NR ^h	2.15
Almhdawi et al [33], 6 weeks	1. Set of stretching and evidence-based strengthening exercises; 2. Educational short posts modified from the Back Book	Weekly 3-4 sessions, each session lasting 20 minutes	Daily notifications (sound, vibration, and pop-up screen): 1. Reminder to take a walk break; 2. Reminder of the right posture; 3. Reminder of the stretching exercises; 4. Reminder of the home-based exercises	Reminder	NR	4.88
Lo et al [38], inconsistent	1. Physical exercise program; 2. Educational material <i>pushed</i> to users through a social media platform	Recommended exercise duration: 20-30 minutes per day	Points-based rewards system to promote engagement with the app; reminder functions (daily)	Gamification and reminder	Time spent on exercises: mean 25 (SD 4) minutes per day; time spent on reading educational materials: mean 15 minutes per day (SD 14)	NR

Study, duration	Digital therapeutic components	Recommended timing and frequency	Decision support interventions	Underlying BCTs ^a	User retention and engagement	Attrition rate, ^b %
Huber et al [35], 12 weeks	1. Physiotherapy and physical exercise; 2. Back pain-specific education; 3. Mindfulness and relaxation techniques	Daily content consists of components 1-3, up to 5 exercises per day	Chat function connects user with a coach to receive motivation and help	Motivation	NR	82.2
Clement et al [36], 24 weeks	RE ^c ; additional component (4): Increased pool of each of the different exercise types (subdivided into 19 different difficulty levels in version 1.4 instead of 3 levels)	RE	RE	RE	Physical exercises: V1 ⁱ : mean 1.99 (SD 1.61); V2 ⁱ : mean 3.15 (SD 1.72); mindfulness exercises: V1: mean 1.36 (SD 1.43); V2: mean 2.42 (SD 1.82); educational content: V1: mean 1.51 (SD 1.42); V2: mean 2.71 (SD 1.89)	64.9
Priebe et al [37], 12 weeks	1. Physiotherapy and physical exercise; 2. Back pain-specific education; 3. Mindfulness and relaxation techniques	Daily content consists of components 1-3, up to 5 exercises per day	Feedback (smileys and congratulatory messages) for achieving improvements, health coach (chat function), and push-up reminders ^e	Motivation and reminders	Mean number of days the app was used: V1: mean 22.11 days ^{f,j} (SD 10.56); V2: mean 30.92 days (SD 32.27)	V1: 82; V2: 62
Sandal et al [39], 6 weeks	1. General physical activity; 2. Strength and flexibility exercises; 3. Patient education (access to variety of tools and information for low back pain)	Daily goal: 10,000 steps; 4 weekly exercise sessions; 1 reading task on education	Weekly tailored self-management plans: 1. Suggest activity goals; 2. Suggest a new exercise program; 3. Suggest new education sessions	Multiple BCTs	After 6 weeks; mean values 65 app visits (range 1-188); 134 minutes spent on the app (range 0-889); visited the app on 22 of the 42 possible days (range 1-42)	13.72

^aBCT: behavior change technique.

^bAt final follow-up measurement of the intervention group.

^cDefined as completing at least one exercise session or reading 1 educational paper in weeks 9-12.

^dRE: reported elsewhere; see Toelle et al [31] and Huber et al [35].

^eInvolves studies including the Kaia app; all information on the type of therapeutic components and applied interventions was extracted as described within the respective publication.

^fNumber of days within the whole intervention length.

^gThose who completed ≥5 training sessions each week were considered high adherence, 3-5 training sessions medium adherence, and ≤2 training sessions low adherence.

^hNR: Not reported.

ⁱComparison between 2 subsequent app versions: version 0.x (V1) and version 1.x (V2). V1 includes users who signed in before May 1, 2017, and V2 includes users who signed in after that date.

^jA day was classified as an active day when the user logged into the app and completed at least one module.

Personalized Decision Support Interventions

In all included studies, different kinds of decision support interventions were deployed to guide and accompany the user through the DTC program and to increase engagement with the app. Basic reminders in the form of push notifications were implemented most often [29-33,37,38], followed by a health coach chat function for motivational and reinforcing purposes [28,31,34-37], peer-group support through interactive discussion feeds or forums [28,30,34], a points-based rewards system [30,38], feedback messages after achieving improvements [37], and a tailored self-management plan that prompted suggestions

on personalized activity goals and education sessions [39]. The applied decision support interventions encompassed a broad spectrum of behavior change techniques, including reminders, peer support, motivational messages, goal setting, coping methods, and gamification.

User Retention and Attrition Rates

Overall, user retention with regard to the DTC app was mentioned in 75% (9/12) of the studies [25-39]. Of these 9 studies, 7 (78%) reported predominantly high engagement levels [28-31,34,36,38]. However, the reporting metrics were highly heterogeneous, with unclear relation to, and association with,

the prerecommended time and app use frequency. Of these 9 studies, 2 (22%) [34,36] calculated the mean number of completed units per week, 2 (22%) [31,37] reported the mean number of days the app was used over the whole study duration, 1 (11%) [28] reported the mean number of days the respective therapeutic component was used, 1 (11%) [30] reported the mean number of completed therapeutic modules over the whole study duration, 1 (11%) [38] reported the mean number of minutes per day spent on the respective therapeutic modules, and 1 (11%) [39] reported the total number of app visits and the number of minutes spent in the app. The remaining study categorized engagement in high- to low-adherence groups based on the number of weekly training sessions [29]. The exact numbers with regard to user retention and engagement are presented in Table 4. Attrition rates ranging from 2.15% to 82.2% were reported in 92% (11/12) of the studies. In most studies [28-31,34], the attrition rates varied between 20% and 28%. Remarkably, in the studies with the lowest attrition rates [32,33,39], an RCT or prospective trial was conducted. In contrast, the studies with the highest attrition rates [35-37] were based on real-world evidence and retrospective app user-generated data analysis.

Impact of DTC Apps

The impact of DTC apps and add-on decision support interventions was evaluated by considering the primary outcomes of pain and functional disability. In the included studies, the level of pain was measured using the Visual Analog Scale, the Numeric Rating Scale, and the Modified von Korff Pain Scale. The level of functional disability was measured using the Modified von Korff Disability Scale, the Roland Morris Disability Questionnaire, the Oswestry Disability Index, and the Modified Oswestry Disability Index. In 33% (4/12) [29,30,32,33] of the studies, both pain and functional disability were measured. In 67% (8/12) [28,31,34-38] of the studies, only pain levels were reported using the Numeric Rating Scale or Visual Analog Scale, and in 8% (1/12) [39] of the studies, only the functional outcome was measured using the Roland Morris Disability Questionnaire. Overall, in all included studies, there was a positive care effect in the DTC intervention group compared with baseline values, that is, in lower pain levels and increased functionality. A between-group comparison within 67% (8/12) of the studies revealed no significant difference in pain levels in 2 RCTs [31,32]. It should be noted that in some studies [21,24,34,39], participants had ongoing access to treatment as usual in addition to the DTC app, which was not described in detail. The results of the primary outcome measures and the respective treatment groups are presented in Table 5.

Table 5. Treatment groups and primary outcome results of the included studies (N=12).

Study	Intervention group	Control group	Primary outcome results ^a
Bailey et al [34]	Hinge Health Digital Care Program, including a new tablet, 2 Bluetooth wearable motion sensors, and one-on-one remote health coaching; treatment as usual	No control group	VAS ^b ↑ ^c
Priebe et al [28]	GP ^d -centered LBP ^e treatment: 1. Electronic case report form; 2. Treatment algorithm for guideline-based clinical decision-making of GPs; 3. Teleconsultation between GPs and pain specialists for patients at risk for chronic back pain; 4. <i>Kaia</i> app	Treatment as usual with consideration of the <i>National guideline for the treatment of non-specific back pain</i>	NRS ^f ↑ (↑) ^g
Hou et al [29]	Patients with LBP who underwent lumbar spinal surgery were provided with a mobile phone-based eHealth program app as part of their rehabilitation program	Nonspecific usual care rehabilitation treatment	VAS ↑ (↑); ODI ^h ↑ (↑)
Shebib et al [30]	Hinge Health Digital Care Program, including a new tablet, 2 Bluetooth wearable motion sensors, and one-on-one remote health coaching; treatment as usual	A total of 3 digital education articles from the digital care program; treatment as usual	MvK ⁱ (pain) ↑ (↑); MvK (disability) ↑ (↑); ODI ↑ (↑)
Toelle et al [31]	Provided with the <i>Kaia</i> app	A total of 6 individual physiotherapy sessions over 6 weeks and high-quality web-based education, including motivating messages	NRS ↑ (↔) ^j ^g
Chhabra et al [32]	Provided with the <i>Snapcare</i> app; written prescription from the physician (see <i>Control group</i>)	Participants received a written prescription from the physician listing the prescribed medicines and dosage and stating the recommended level of physical activity	NRS ↑ (↔); MODI ^k ↑ (↑)
Almhdawi et al [33]	Provided with the <i>Relieve my back</i> app; treatment as usual	Control group received a <i>placebo</i> version of the same app that included only advice about general nutrition and daily notifications with nutritional facts; treatment as usual	VAS ↑ (↑); ODI ↑ (↑)
Lo et al [38]	Retrospective evaluation study of the artificial intelligence-embedded <i>Well Health</i> app	No control group	NRS ↑
Huber et al [35]	Retrospective analysis of user data: <i>Kaia</i> app users who signed up before March 2017	No control group	NRS ↑
Clement et al [36]	Retrospective analysis of user data: <i>Kaia</i> app users who signed up on or after May 1, 2017	<i>Kaia</i> app users who signed up before May 1, 2017	NRS ↑ (↑)
Priebe et al [37]	Retrospective analysis of user data	<i>Kaia</i> app users who signed up before March 2017	NRS ↑ (↑)
Sandal et al [39]	Provided with the <i>selfBACK</i> app; treatment as usual	No control group	RMDQ ^l ↑

^aMain result of the intervention group after the last measurement in the study.^bVAS: Visual Analog Scale.^cIntervention had positive effect compared with baseline measurement.^dGP: general practitioner.^eLBP: low back pain.^fNRS: Numeric Rating Scale.^gBetween-group differences are reported in parentheses.^hODI: Oswestry Disability Index.ⁱMvK: Modified von Korf Scale.^jNo difference in outcome.^kMODI: Modified Oswestry Disability Index.^lRMDQ: Roland Morris Disability Questionnaire.

Regarding adverse health events, in 75% (9/12) of the studies, no evidence of harm was reported after the implementation of DTC. Participants in a study [33] reported temporary discomfort; in another study [31], a patient was diagnosed with a lumbar

disk herniation, which was declared an incidental finding. In the remaining study [29], 9 patients reported mostly mild, self-limited joint and back pain; of note, the patients underwent spinal surgery before starting the DTC. We have presented the

results of additional secondary outcome measures, the time and frequency of measurements, and the mode of administration of surveys in [Multimedia Appendix 2](#) [28-39].

Discussion

Principal Findings

This systematic review investigated the efficacy and effectiveness of DTC and add-on decision support interventions for people with LBP. Our analysis shows that all included studies observed positive health effects in the intervention group compared with baseline measures. In 67% (4/6) of the RCTs, between-group analysis indicated superior primary outcomes of the DTC program. Moreover, different DTC apps proved to have potentially significant benefits for particular cohorts. In a study [29], patients who had undergone spinal surgery shortly before starting the DTC and did not live close to the clinic received the DTC app as part of a remote rehabilitation program. Another study [33] explicitly targeted office workers aged 30-55 years to investigate the benefits of a digital care app on quality of life and functionality at work. In another study [28], the researchers aimed to prevent the development of chronic LBP by stratifying patients classified as high risk based on the STarT Back questionnaire through a general practitioner and, thus, providing them with a DTC app as early as possible to prevent a worsening condition [37,40]. Overall, no evidence of harm was reported, except for mild pain and a presumably incidental finding.

Notably, these results must be interpreted with caution when considering that 33% (4/12) of the studies did not include a control group, and in 63% (5/8) of the studies that included a control group, it did not have recommended treatment according to current clinical guidelines. Most trials included small to medium sample sizes, which applies to 67% (8/12) [29-33,35,38,39] of the studies with <200 participants and 42% (5/12) [29,31-33,39] of the studies with <85 participants in the intervention group. Overall, the study population was mostly homogeneous, with predominantly female, young to middle-aged participants of normal to moderate weight, limiting the transferability of the studies' outcomes to other patient cohorts. The lack of long-term follow-up is another limitation in 83% (10/12) [28,30-35,37-39] of the studies. Moreover, overall user engagement and retention rates were reported to be medium to high, which we cannot ascertain in some cases because of unclear reporting. For instance, some studies reported their overall retention rates based on the mean days on which the participant completed at least one module or based on completing at least one therapy module in the last 3 weeks of the study, both of which are not attributable either to perpetual engagement or the use of differentiated key therapeutic components [34,37]. This adds to the difficulty of objectively measuring the actual number of completed therapeutic modules. To circumvent these challenges as well as the self-reporting biases, some DTC apps take advantage of wearable motion sensors or use an analytics platform to track interaction with the app [34,39].

Add-on decision support interventions accompanied DTC to enhance digital treatment by increasing user engagement and

self-management capabilities in all investigated apps. Nonetheless, in most of the studies, rather basic rule-based decision support interventions were implemented, such as alert reminders or similar motivational push notifications. A more advanced data-driven recommendation system based on machine-learning was reported in a single study [38]. Research on data-driven support interventions has already demonstrated higher retention rates and increased user satisfaction in the self-management of LBP [41,42]. Therefore, implementing more complex decision support interventions is essential for achieving sustainable behavior change and high user engagement over a longer period, especially in a noncontrolled real-life environment.

In this review, it was not feasible to appraise the direct impact of either the single DTC key components, for example, exercise, educational material, or psychosocial content, or the decision support interventions, for example, peer support, on the primary health outcomes. Subsequently, it remains unclear to what extent DTC needs to be prescribed to achieve a marginal positive health effect for individual patient cohorts in terms of duration and number of exercise or education modules. In this regard, the effectiveness of DTC apps on the distinct subgroups of patients with LBP stratified according to acute, subacute, or chronic pain levels remains unclear and requires further subgroup-specific research. Despite overall positive findings, our assessment of the methodological quality revealed that the risk of bias in the included studies was moderate to high, especially in the nonrandomized trials.

Correlation Among Retention, Attrition, and Health Outcome

A major unresolved research endeavor deals with the correlation between engagement levels in a DTC program and improvements in health-related outcomes. The studies in which this effect was examined more closely reported positive as well as negative findings. A positive correlation between higher user retention and a significantly better health outcome was found in 25% (3/12) [29,34,35] of the studies. In contrast, another 25% (3/12) [28,31,36] of the studies also concluded that there was no correlation between app use frequency and improved pain level or functional disability. The underlying rationale for participants to stay with the program or choose to discontinue is yet unknown and could be multidimensional. For instance, depending on whether a participant experiences sudden or early improvement in pain levels can be a driving factor for the decision to either quit or continue to reinforce the positive outcome [28]. Nonetheless, these contrary and contrainuitive findings should be analyzed in future trials by monitoring primary outcome levels more frequently and collecting valuable feedback from participants. This demand is also associated with the ongoing need for consistent reporting of user retention and attrition rates. The use of standardized metrics for subjective and objective use of DTC apps is necessary to gain more insights and enhance the comparability of studies [11].

Another interesting observation in this review is the divergence of attrition rates when comparing RCTs and retrospective evaluation studies, which specifically consider people who have downloaded the DTC app on their own initiative. The lowest

attrition rates were observed in 2 RCTs [32,33] and a prospective trial [39]. In contrast, the studies [35-37] with the highest attrition rates were based on real-world evidence and retrospective user-generated data analysis. One apparent reason for low attrition might have been the user's awareness of being part of a trial or the participant's compensation for the RCT, which involved vouchers, money, or free access to the app after the conclusion of the study. In contrast, participants who self-reportedly downloaded the app and eventually also paid for it on a monthly basis tended to quit the program earlier. Despite the fact that this observation was not adjusted based on the varying number of participants or the duration of the intervention, it shows that retrospective studies based on real-world evidence possibly provide insights into the real-life adoption and use of DTC apps [12]. In fact, in future data-driven research on digital health interventions, the analysis of homogeneous and structured data related to engagement and self-reported outcome measures could further advocate retrospective cohort evaluation studies. Data obtained from users who have downloaded a DTC app either on their own initiative or after receiving a physician's prescription could be provided to research platforms and databases and, thus, facilitate the evaluation of real-life adoption and effectiveness. These benefits and the quickly evolving regulatory environment in favor of digital ecosystems in the EU, such as the EU-funded Smart4Health project, underline the relevance and timeliness of this review's approach [43].

Rising Uptrend of DTC App-Based Clinical Trials

We found additional studies investigating the benefits of divergent internet interventions or apps to support digital treatment of LBP during our search process. For instance, we identified a study involving an app that enables continuous pain monitoring for people with LBP [44], a study investigating the use of a website to support people in their self-management of LBP [45], a study that aimed to examine the benefits of a DTC app on the depressive disorder in patients with LBP [46], and a publication that describes 2 case studies in which a virtual reality system delivers functional rehabilitation exercises to people with LBP [47]. Moreover, we found several other research projects investigating their app-based therapeutic programs at an early stage of their development in the form of proof-of-concept, qualitative acceptability studies or research protocols [18,48-52]. This underlines our observation with regard to the exponential rise of clinical trials concerning DTC and decision support apps in the past 5 years.

Limitations

This systematic review includes some limitations. First, we only considered English- and German-language literature, which might have led to excluding other potential eligible studies. Moreover, we only included LBP-related studies and excluded

those investigating DTC apps for other similar health conditions, for instance, neck pain, shoulder pain, or musculoskeletal pain in general. Another limitation is the validity of this review with regard to the level of evidence. We are aware that systematic reviews that include only RCTs provide the highest level of evidence; however, considering studies based on real-world user data as well turned out to be a feasible approach, which we consider inevitable for future systematic reviews of digital health app trials.

Furthermore, although most of the included studies in this review reported overall positive health effects, we are cautious about deriving any clinical implications based on our findings. Because of the explorative approach that involved waiving study preregistration, not including traditional search terms such as *eHealth* and *mHealth*, and the fact that we focused on studies published from March 1, 2016, to October 15, 2020, we cannot exclude a variety of biases that may have occurred. Therefore, we have refrained from providing essential clinical recommendations for regulatory decisions and do not recommend copying this search strategy, which supported the specific objective of this review exclusively. The aim of this paper is to evaluate recently published clinical evidence regarding the efficacy and effectiveness of digital therapeutic interventions for people with LBP. However, DTC apps, including the broad range of implemented decision support interventions, experience continual improvements with new features and amendments concerning both front-end and back-end of an app. These advancements require ongoing clinical trial-based evaluations regarding their impact on health outcomes, user retention, and attrition rates, especially in this new field of digital therapy. Further research is needed to clarify whether DTC apps are so unique that they need to be evaluated individually or clinical implications can be made based on an overarching systematic review.

Conclusions

This systematic review demonstrates the benefits of DTC for people with LBP with regard to both primary outcomes of pain and functional disability. There is also evidence that decision support interventions benefit overall engagement with the app and increase participants' ability to self-manage their recovery process. However, because of mostly homogeneous study populations and the unclear correlation between user retention and improvements in primary outcomes, no general conclusion can be drawn either on the optimal intervention duration or the required number of exercise modules for individual cohorts. Finally, including retrospective evaluation studies of real-world user-generated data in future systematic reviews of digital health app trials can reveal new insights into the benefits, challenges, and real-life adoption of DTC programs.

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Authors' Contributions

DL conceptualized the study. DL and AMW conducted the literature searches and literature screening. DL, AMW, AW, TS, and SW were involved in one or more of the following stages of the review: study analysis, data collection, and risk-of-bias appraisal. DL completed the data synthesis with input from the contributors and drafted the manuscript. DL, AMW, AW, TS, SW, and EB contributed to refining all sections and critically editing the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Search queries.

[DOCX File, 15 KB - [rehab_v8i4e26612_app1.docx](#)]

Multimedia Appendix 2

Results of all reported primary and secondary outcome measures.

[DOCX File, 64 KB - [rehab_v8i4e26612_app2.docx](#)]

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Abbreviations

DTC: digital therapeutic care

EU: European Union

LBP: low back pain

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RCT: randomized controlled trial

ROB 2: Risk of Bias 2

ROBINS-I: Risk of Bias in Non-Randomized Studies of Interventions

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