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Original Papers

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Original Paper

Counting Grasping Action Using Force Myography: An Exploratory Study With Healthy Individuals

Zhen Gang Xiao[1], BAppSc; Carlo Menon[2], PhD

[1]Simon Fraser University, Burnaby, BC, Canada

[2]Schools of Mechatronics Systems Engineering and Engineering Science, Simon Fraser University, Surrey, BC, Canada

Corresponding Author:
Carlo Menon, PhD
Schools of Mechatronics Systems Engineering and Engineering Science
Simon Fraser University
SFU Surrey, 4374 Galleria
250-13450 102 Avenue
Surrey, BC, V3T 0A3
Canada
Phone: 1 778 782 9338
Fax: 1 778 782 7514
Email: cmenon@sfu.ca

Abstract

Background: Functional arm movements generally require grasping an object. The possibility of detecting and counting the action of grasping is believed to be of importance for individual with motor function deficits of the arm, as it could be an indication of the number of the functional arm movements performed by the individuals during rehabilitation. In this exploratory work, the feasibility of using armbands recording radial displacements of forearm muscles and tendons (ie, force myography, FMG) to estimate hand grasping with healthy individuals was investigated. In contrast to previous studies, this exploratory study investigates the feasibility of (1) detecting grasping when the participants move their arms, which could introduce large artifacts to the point of potentially preventing the practical use of the proposed technology, and (2) counting grasping during arm-reaching tasks.

Objective: The aim of this study was to determine the usefulness of FMG in the detection of functional arm movements. The use of FMG straps placed on the forearm is proposed for counting the number of grasping actions in the presence of arm movements.

Methods: Ten healthy volunteers participated in this study to perform a pick-and-place exercise after providing informed consent. FMG signals were simultaneously collected using 2 FMG straps worn on their wrist and at the midposition of their forearm, respectively. Raw FMG signals and 3 additional FMG features (ie, root mean square, wavelength, and window symmetry) were extracted and fed into a linear discriminant analysis classifier to predict grasping states. The transition from nongrasping to grasping states was detected during the process of counting the number of grasping actions.

Results: The median accuracy for detecting grasping events using FMG recorded from the wrist was 95%, and the corresponding interquartile range (IQR) was 5%. For forearm FMG classification, the median accuracy was 92%, and the corresponding IQR was 3%. The difference between the 2 median accuracies was statistically significant (P<.001) when using a paired 2-tailed sign test. The median percentage error for counting grasping events when FMG was recorded from the wrist was 1%, and the corresponding IQR was 2%. The median percentage error for FMG recorded from the forearm was 2%, and the corresponding IQR was also 2%. While the median percentage error for the wrist was lower than that of the forearm, the difference between the 2 was not statistically significant based on a paired 2-tailed sign test (P=.29).

Conclusions: This study reports that grasping can reliably be counted using an unobtrusive and simple FMG strap even in the presence of arm movements. Such a result supports the foundation for future research evaluating the feasibility of monitoring hand grasping during unsupervised ADL, leading to further investigations with individuals with motor function deficits of the arm.

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KEYWORDS

myography; classification; upper extremity; grasp; rehabilitation

Introduction

Individuals with motor function deficits of their arm (eg, individuals with stroke and a hemiparetic arm) often involuntarily avoid using their weak arm during the activities of daily living (ADL)[1,2], leading to an inevitable and gradual degradation of their ability to move their arm. Published studies have shown that increasing the use of a person's weak arm is believed to be an important factor for a successful recovery [3]. Technologies that provide objective feedback to the individual on the use of their arm could potentially encourage them to be more proactive in using their affected arm [4], and consequently gradually improve their arm motor functions.

Some studies have used accelerometer-based devices to capture gross movements of the arm [3,5,6] and provide that information as activity feedback to the individual. However, such devices generally cannot discern between movements that are functional and believed to be relevant for the recovery [7,8] (ie, grasping a glass and drinking) from those that are not functional (ie, arm movements induced by movements of the body, such as turning, walking, moving during sleeping) [1,3]. Therefore, accelerometer-based devices could provide inaccurate and potentially counterproductive feedback [1].

Devices with the ability to detect grasping motions, which is generally required during functional arm movements, could potentially provide a more suitable indication of functional use of the upper limb [2,9]. Studies showed that exercising the arm by grasping an object has the potential to greatly improve rehabilitation outcomes [10,11]. Hence, detecting the number of grasping actions performed by an individual during ADL could be used as feedback to facilitate rehabilitation. In addition to uses for rehabilitation, the ability to unobtrusively detect grasping motions could be used in applications such as monitoring the repetitive hand activity level of a worker for load transfer tasks [12], or could be used in identification of hand-held objects [13]. Hence, innovative solutions to detect grasping motions are, therefore, in need.

Currently, commercial devices capable of detecting grasping motions do exist. They are mostly based on either a vision-based approach or using a wearable technology approach such as wearing data gloves. The vision-based systems, such as Microsoft's Kinect [14], Leap Motion Controller [15], and Optotrak [16], have to be mounted externally to the user's body and are generally used in well-controlled indoor environments such as a rehabilitation center or clinic. They cannot be used to monitor ADL, especially when the individual is in an outdoor setting. On the other hand, the use of a data glove, such as the CyberGlove [17], can be used for monitoring grasping motions outdoors. However, data gloves are generally not practical for use by individuals with a clutched hand, as in the case of individuals with a hemiparetic arm resulting from stroke. In fact, they require a considerable effort to be donned and doffed. Furthermore, they cannot be used in many ADL, such as washing dishes, taking a shower, etc, as they are not waterproof or are simply uncomfortable. Data gloves also reduce the tactile sensation of the hand and fingers, which poses a further barrier for being accepted by the users [18,19].

In addition to the above-mentioned commercially available technologies, the academic community has investigated different approaches to classify grasping and other hand gestures. One of these approaches is based on surface electromyography (sEMG) recorded from the forearm [20]. While such an approach could potentially be used in a large variety of environments, including outdoors, its signal quality may degrade due to many environmental factors, such as sweating and electrical noise, which has been shown to drastically affect its performance [21]. Furthermore, medical-grade sEMG systems capable of capturing low noise sEMG signals generally cost thousands of US dollars (eg, Noraxon sEMG system), which makes them unsuitable for being implemented in practice.

An alternative approach to detect grasping is force myography (FMG). FMG is a technique that uses sensors to capture displacements of muscles, skin, and tendons [22]. This technique was also referred to as topographic force mapping [21], residual kinetic imaging [23], or muscle pressure distribution mapping [24]. Although the FMG technique is relatively unexplored and less standardized compared with sEMG, it presents different potential advantages over the latter. Specifically, FMG signals do not degrade due to sweating or electrical noise [21]. As a consequence, the related hardware for the signal acquisition is also less sophisticated and expensive. While FMG devices are currently not commercially available, an experimental prototype of an FMG signal acquisition device costs less than US $50 [25].

The use of FMG can be dated back as early as the 1960s, when FMG was proposed for controlling a single-degree prosthetic terminal device [26]. Since then, the use of FMG for controlling hand prosthesis has gained some interest in the research community [27-33]. At the same time, researchers also explored the use of FMG for individuals with intact limbs for various applications. For example, FMG signals taken from healthy individuals were studied for regressing isometric force applied by the fingers [22,25], as well as for recognizing different hand gestures and finger movements [24,31,34,35]. Also, a preliminary test performed by Yungher and Craelius showed that regressing the grasping force through the forearm FMG of individuals with poststroke condition was viable [36]. Recently, robotic orthosis with FMG sensing capability were proposed for potential stroke rehabilitation applications [37,38].

FMG signals to detect hand movements are generally extracted from the middle of the forearm where large radial displacements can be recorded [22,24,25,31,34,39-42]. Recent studies have, however, explored the possibility of estimating hand movements by processing FMG signals recorded at the wrist. For instance, Morganti et al proposed a wrist strap consisting of four force-sensing resistors (FSRs) to detect wrist positions [43]. Dementyev and Paradiso subsequently developed a wrist strap that was capable of deciphering 6 static hand gestures [44]. The

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works of both Morganti and Dementryev showed the potential of embedding FMG sensors inside a watch strap, which could make the technology acceptable for users, especially those who may highly value the cosmetics of the device.

The large majority of studies on FMG for the upper extremities presented in the literature considered exploratory tests in very controlled scenarios, where healthy volunteers were asked to move their hand or wrist while maintaining a fixed elbow position [21,22,24,25,29,31,35,43-46]. Despite being able to obtain high prediction accuracy, this approach does not truly reflect the capability of FMG for detecting hand action in a practical scenario, in which arm movements are generally present. To the best of the authors' knowledge, the only studies that included arm movements with the use of FMG are the ones performed by Ogris et al [47] and Sadarangani and Menon [48]. Both of their studies used FMG in conjunction with inertial measurement unit (IMU) to decipher various ADL. The result of Ogris's work showed that FMG improved classification accuracies of some ADL; however, the capability of using FMG to decipher hand action was not fully investigated. In the other study, Sadarangani and Menon's work focused on the investigation of detecting hand actions, but only for 3 limited scenarios.

As a fundamental step toward the development of a technology suitable to detecting grasping motions in the presence of arm movements as an indirect estimation of functional arm movements, this study investigates the ability of using FMG to count the number of grasping motions during a series of pick-and-place (PAP) actions. Two wireless FMG straps were prototyped and placed close to the wrist and on the forearm of 10 healthy individuals for this study.

Methods

FMG Signal Extraction and Data Transmission

Figure 1 shows the 2 FMG strap prototypes used in this study. The strap in the left of the figure is 28 cm long and it was designed to be donned on the forearm while the strap in the right is shorter (19 cm) and was designed to be donned on the wrist, like a watch. Each strap had 8 FSR sensors (FSR 402 from Interlink Electronics), which were evenly distributed on the straps' inner surface (see Figure 1).

A single FSR sensor has 2 terminals: one terminal is connected to a common analog input pin of a microcontroller (Atmega 328p from Atmel) with an internal pull-up resistor (37.5 kΩ) equipped, and the other terminal is connected to a digital control pin as shown in Figure 2.

The analog input pin takes the reading of the signal and converts it into a 10-bit unsigned integer value. Since only 1 analog pin was used for sampling, the signal of each FSR was sampled sequentially. The order of sampling was determined by the digital control pin. When the selected FSR signal was ready to be sampled, the corresponding control pin was set to low, and the other control pins were set to be in high impedance states. At any single moment, only 1 control pin would be set to low and others would be changed to high impedance state in order to guarantee independent sampling. This configuration used a single analog pin with internal pull-up resistor in order to obtain the most simplified design under the constraints of the selected inexpensive microcontroller.

The sampled data were transmitted wirelessly to a personal computer using a generic Bluetooth module (HC-05). A custom-made application with real-time signal display was developed in LabVIEW on a personal computer for querying and storing the sample data. When sampling began, the application sent a command to the microcontroller to retrieve a set of FSR data at every 100 milliseconds (10 Hz) as proposed by Amft et al [40].

Experimental Protocol

An experimental protocol was designed to capture both wrist and forearm FMG signals simultaneously during a PAP exercise. Before the experiment, the forearm FMG strap was donned on the belly of the right forearm of a volunteer with the help of the research assistance. The wrist FMG strap was instead donned on the distal end of the forearm (next to the ulna styloid process, see Figure 3). In order to reduce signal inconsistency due to the placement of the strap for different volunteers, the first sensor near the tail end of the forearm strap (see Figure 1) was always placed on the bulk of the flexor carpi ulnaris, and the wrist counterpart was always placed near the ulna styloid process. However, it should be noted that the rest of the sensors were not positioned on specific muscles or tendons (the FSR were evenly distributed in the strap). This approach was intentionally followed to avoid personalization of the strap and provide a generic strap that could be used by a layperson at home. Finally, another FSR sensor (FSR 400 Interlink Electronics) was taped to the pulp of the thumb to obtain the true label for investigational purposes.

Once the straps were donned, the volunteer was asked to fully extend the fingers and then make a fist 3 times, while the research assistant monitored the raw signal through visual feedback from the display of the LabVIEW application. This hand action was shown to be able to generate a clear and visually distinguishable FMG pattern for healthy individuals [29,40,44], and therefore, the action was used to ensure the strap was able to register muscle-tendon movement activities. If this action did not generate a clear FMG pattern, the research assistant would readjust the tightness of the sensor. Also, the assistant would ensure the strap did not block blood circulation or cause discomfort to the volunteer through his or her oral feedback. On average, this calibration procedure took less than 3 minutes for each volunteer.

In the experiment, the volunteers sat in front of a table as illustrated in Figure 4. They were then asked to pick up and place a cylindrical object from and to 6 locations following different sequences. The object used in the experiment was a 12-cm high hollow cylinder with a radius of 3 cm. It weighed only 73 g so that the participants did not need to apply a large force to lift the object. The 6 locations included 1 start location (Location 0) and 5 other target locations (Locations 1-5). Locations 1-5 were placed around Location 0, at a distance of 40 cm. Using Location 0 as the reference, each of the 5 locations were 30 degrees apart from the adjacent one. The elevations of the 5 target locations were 30 cm, 1 cm, 40 cm, 10 cm, and

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20cm from the table, respectively. Each location had a circular area with a 5-cm radius, such that the upper limb joints of the volunteer must be highly coordinated in order to successfully place the object on the target locations.

In order to capture FMG signals in the presence of various arm movements, 3 PAP sequences were designed for the participants to perform. These PAP sequences required the coordination of the shoulder, the elbow, wrist, and hand. Therefore, the FMG patterns that were associated with some of the elbow flexion/extension, forearm pronation/supination, wrist flexion/extension/abduction/adduction, hand opening/closing, and the overall arm motion would be captured. Some examples of the captured movement during the PAP sequences are shown in Figure 5.

In the first sequence, the participant was asked to pick up the object from the start location and place it onto the target locations at a pace comfortable for them. Then the participant retrieved their hand to the start location without the object. Next, the participant picked up the object from the current location, and returned it to the start location. Finally, the participant released the object completely before starting the next PAP action. In total, each participant performed 10 PAP actions for the first action sequence as shown in the left picture of Figure 6. In the second sequence, the participants performed an additional 10 PAP actions following the order shown in the middle of Figure 6. In the third sequence, the participants repeated the path of the second sequence but in a reversed order, as shown in the right of Figure 6. Each participant was asked to repeat the 3 sequences (30 distinct PAP actions in total) 5 times. With 3 sequences and 5 repetitions, a total of 150 PAP actions were recorded.

Figure 1. Wireless FSR straps: (a) wireless FSR strap for the forearm and (b) wireless FSR strap for the wrist.

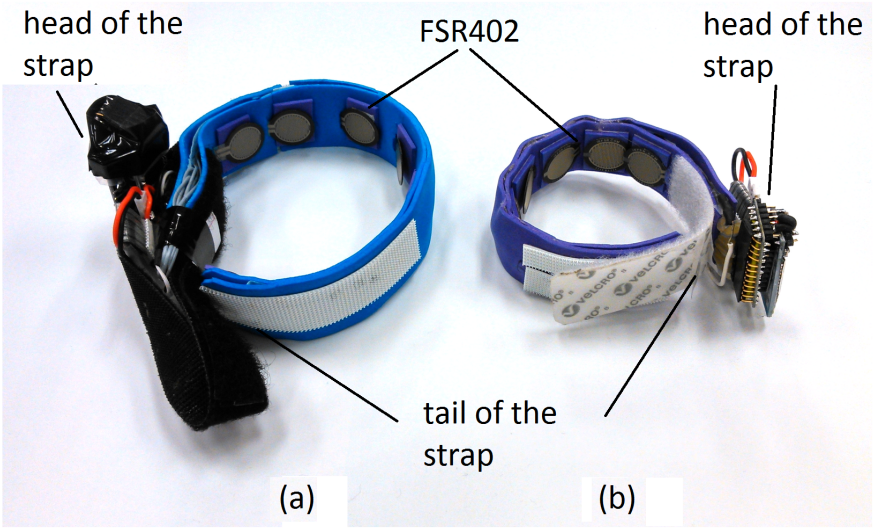

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Figure 2. Schematic for FMG signal extraction and data transmission. The microcontroller sampled the signal from 8 FRS sensors, and the data were sent wirelessly to the computer through the Bluetooth transmitter module.

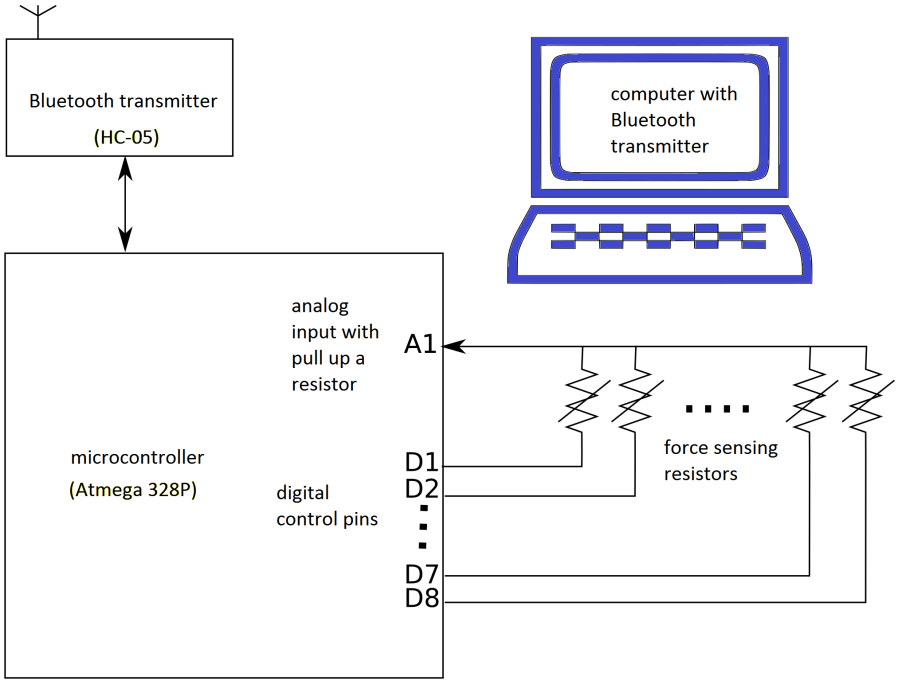

Figure 3. FSR straps placement: (a) forearm supinated view and (b) forearm pronated view.

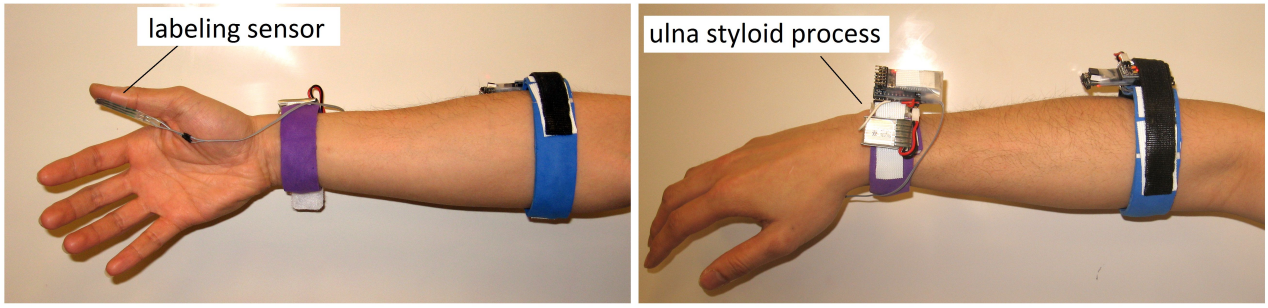

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Figure 4. Experimental setup. The start location is shown in gray, the five target locations are shown in green, and the object for grasping is shown in yellow.

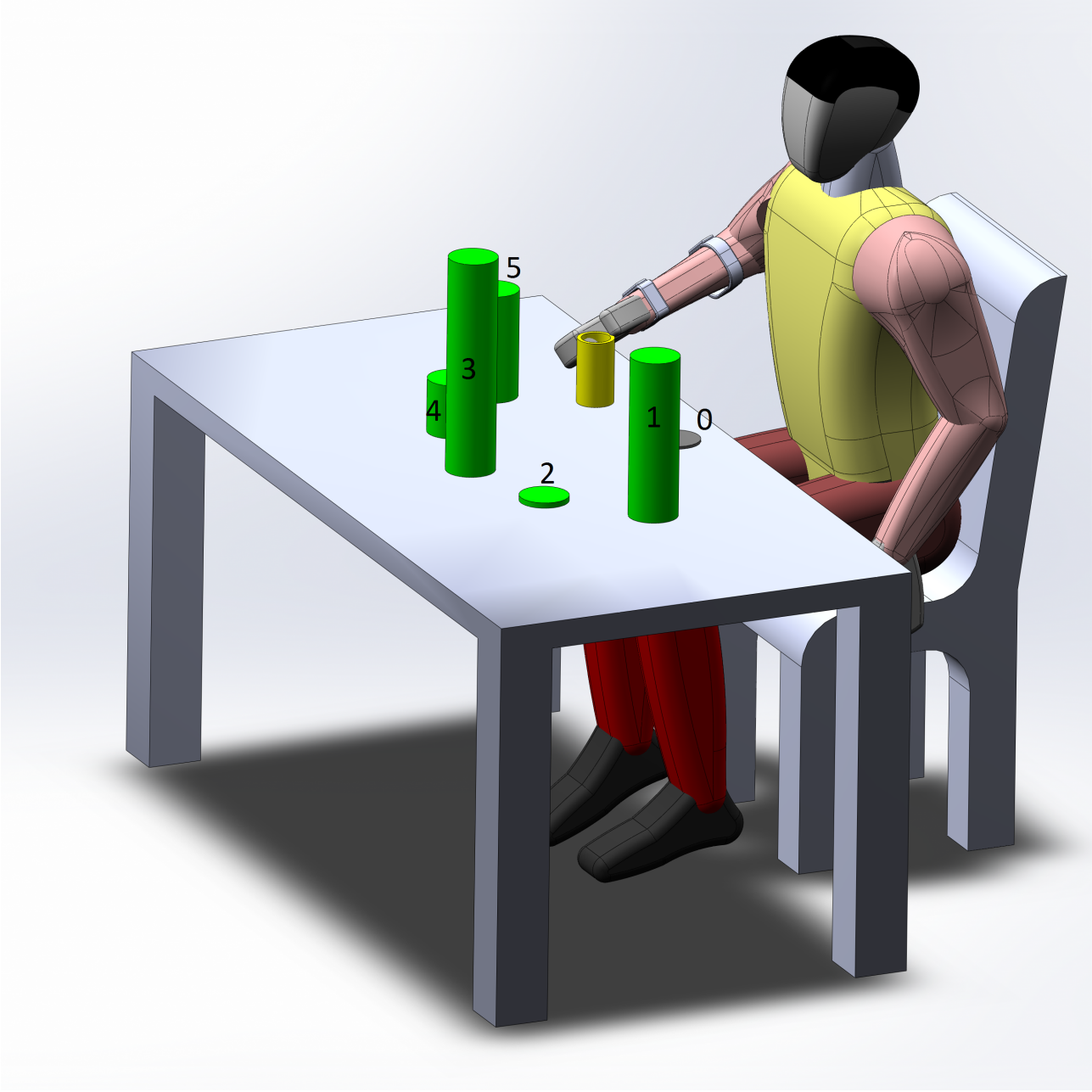

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Figure 5. Examples of upper limb position during the PAP sequence: (a) grasping the object from start position; (b) transporting the object from start position to target location 4; and (c) transporting the object from target location 2 to 4.

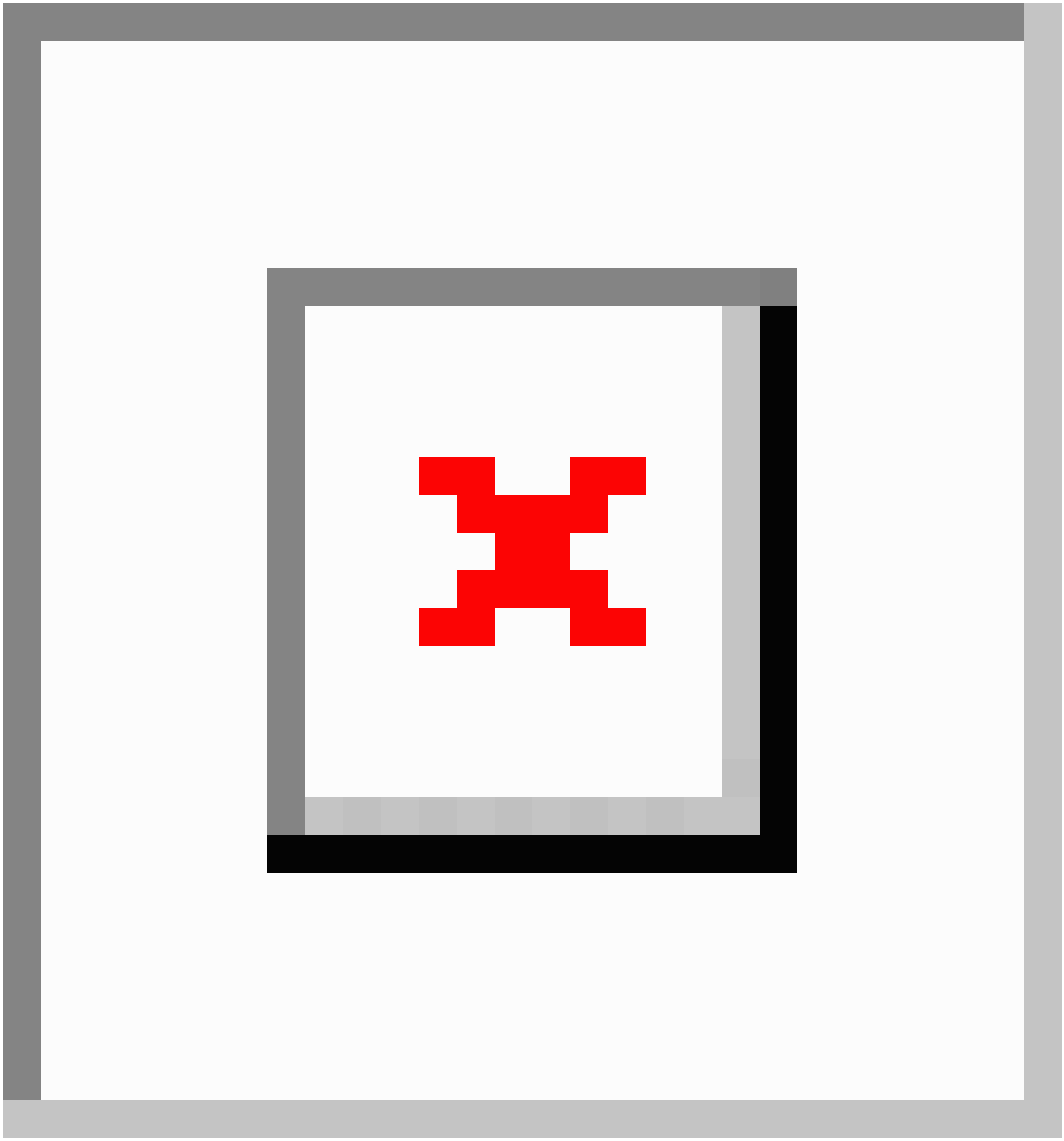

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Figure 6. PAP action sequence. The red circles indicate the target positions, the arrows indicate the direction of the PAP actions, and the numerical labels indicate the orders of the steps in each sequence: (a) first PAP action sequence; (b) second PAP action sequence; and (c) third PAP action sequence.

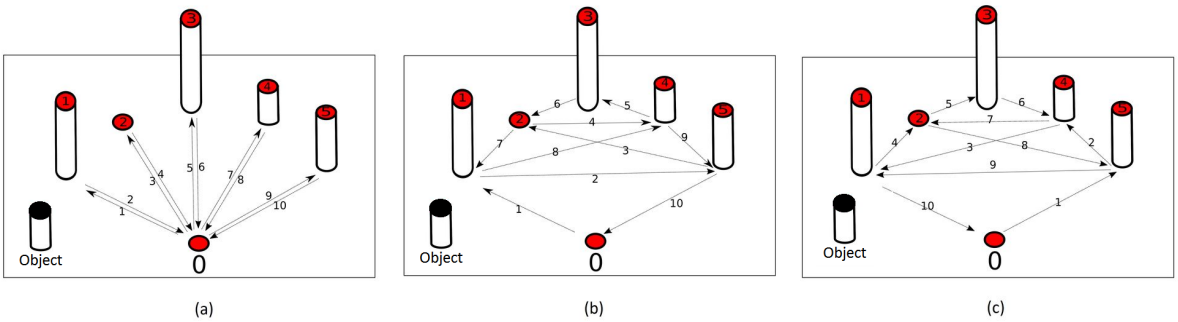
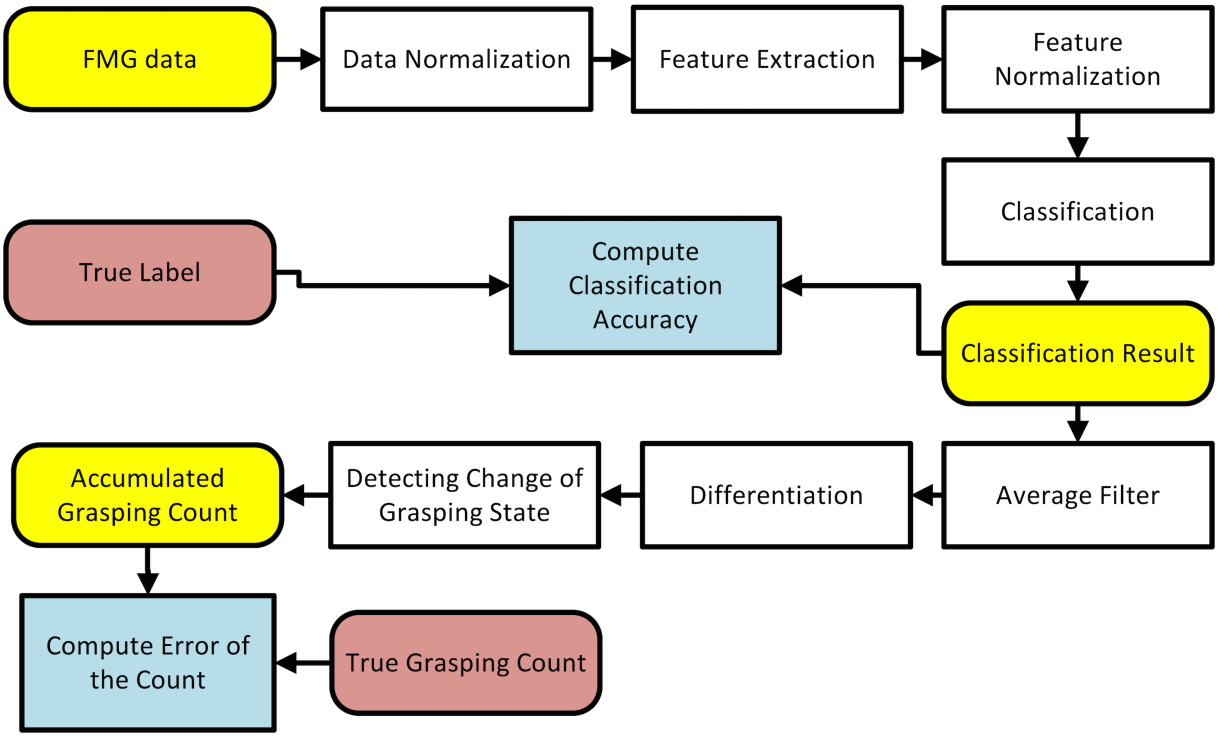


Figure 7. Data processing sequence.



Participants

Ten healthy volunteers aged between 21 and 42 years participated in the experiment. Each participant signed an informed consent form (approved by the Office of Research Ethics, Simon Fraser University) before entering the study. Their wrist and forearm belly circumferences were recorded for performance analysis and are shown in Table 1.The average circumference of the wrist and forearm belly are 16.81 cm (SD 1.11) and 26.2 cm (SD 3.15), respectively.

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Table 1. Participant statistics.

ID	Wrist circumference (cm)	Forearm belly circumference (cm)
1	16.5	28
2	19	27
3	17.5	27
4	16	27
5	17.6	28.5
6	15.5	27
7	16	17
8	18	26
9	16.5	26.5
10	15.5	28
Average	16.81	26.2
SD	1.11	3.15

Data Processing

The data collected from each participant consisted of both wrist and forearm FMG positions. The 2 streams of data were processed through identical but independent treatments. The collected data were first divided into training and testing sets. The training set data consisted of the first 30 PAP actions, and the testing set consisted of the rest of the 120 PAP actions data sets. The training set was used for extracting relevant statistical information about the signals and for generating a classifier model. The testing set was used for examining the generalized performance of the classifier for detecting grasping. The overall data processing sequence is shown in Figure 7.

As shown in Figure 7, the raw FMG data of each channel was first centered by subtracting its mean and then normalized using its standard deviation. Both the mean and standard deviation parameters were obtained from the training set.

Next, feature extraction was performed. The raw FMG data were considered as primary feature of the signal. Three additional signal features, namely the root mean square (RMS), waveform length (WL), and window symmetry (WS), were extracted from the raw data with a 300 ms window and a step size of 100 ms.

RMS is the averaged signal magnitude of each window and its equation is shown in Figure 8. In the equation, x_i is the value of the i^{th} sample in the processing window and N is the window size, which in our case was 3.WL is the sum of the change of the input samples within the processing window, which provides speed-related information to the classifier. The formula for computing WL is shown in the middle of Figure 8.

WS is the difference between the average of the first N data points and the one of the last N data points, which can provide directional information of the change of the input samples. The formula for computing WS is shown in the bottom of Figure 8. A total of 4 features were extracted from each channel including the normalized raw input signal magnitude. Since there were 8 input channels for each of the wrist and forearm FMG straps, a total of 32 features were extracted, respectively. Each of the extracted features were once again centered and normalized based on their mean and standard deviation obtained from the training set before being classified using the supervised classification scheme.

Under the supervised classification scheme, the classifier needs to be trained using true label obtained from external source. In our case, the labeling signal was the one recorded by the FSR sensor placed on the thumb. This signal measured the amount of contact force between the object and the thumb. If the contact force was less than 2% of the maximum, then the corresponding FMG data was labeled as nongrasping (class 1); otherwise, the FMG data was labeled as grasping (class 2).

Among different supervised classifiers, linear discriminant analysis (LDA) classifier using Fisher discriminant criteria is one of the most widely used for analysis. LDA fits a multivariate normal density to each class with a pooled estimate of covariance. It is capable of revealing linear separability of the signal features. Additionally, LDA is computationally efficient and suitable to be implemented in a microcontroller [49]. Therefore, it was selected for use in this study.

The output of the LDA classifier was the predicted state of the hand. In order to count the number of grasping actions, the transition from nongrasping to grasping state needed to be identified. This transition could be detected by subtracting the current state output with the previous one. A positive result indicated a grasping action has occurred. However, the accuracy of such a counting method could be sensitive to any small glitches (misclassifications over a short period, eg, <1s) in the classification data output stream. Hence, an average filter was applied to smooth out the output stream of the classifier. The window size of the filter could affect the overall performance in terms of the counting accuracy and the delay. Therefore, the effect of different window sizes on the counting performance was examined (see Results section).

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Figure 8. Equations for FMG feature extraction: (a) Root mean square, (b) Waveform length, and (c) Window symmetry.

(a)
$$RMS = \sqrt{\frac{\sum_{i=1}^{n} x_i^2}{N}}$$

(b)
$$WL = \sum_{i=1}^{N} |x_i - x_{i-1}|$$

(c)
$$WS = \frac{1}{\left\lfloor \frac{N}{2} \right\rfloor} \times \left(\sum_{i=1}^{\left\lfloor \frac{N}{2} \right\rfloor} x_i - \sum_{i=\left\lceil \frac{N}{2} \right\rceil + 1}^{N} x_i \right)$$

Figure 9. Boxplot for FMG classification accuracies of the 10 participants. The bottom and top of each box are the first and third quartiles of the data set, respectively. The band inside the box is the median. The ends of the dashed lines (whiskers) are the minimum and maximum of the data. The red and blue boxes indicate classification accuracies related to FMG collected from the wrist and forearm, respectively. (a) Accuracies computed using training set data. (b) Accuracies computed using testing set data.

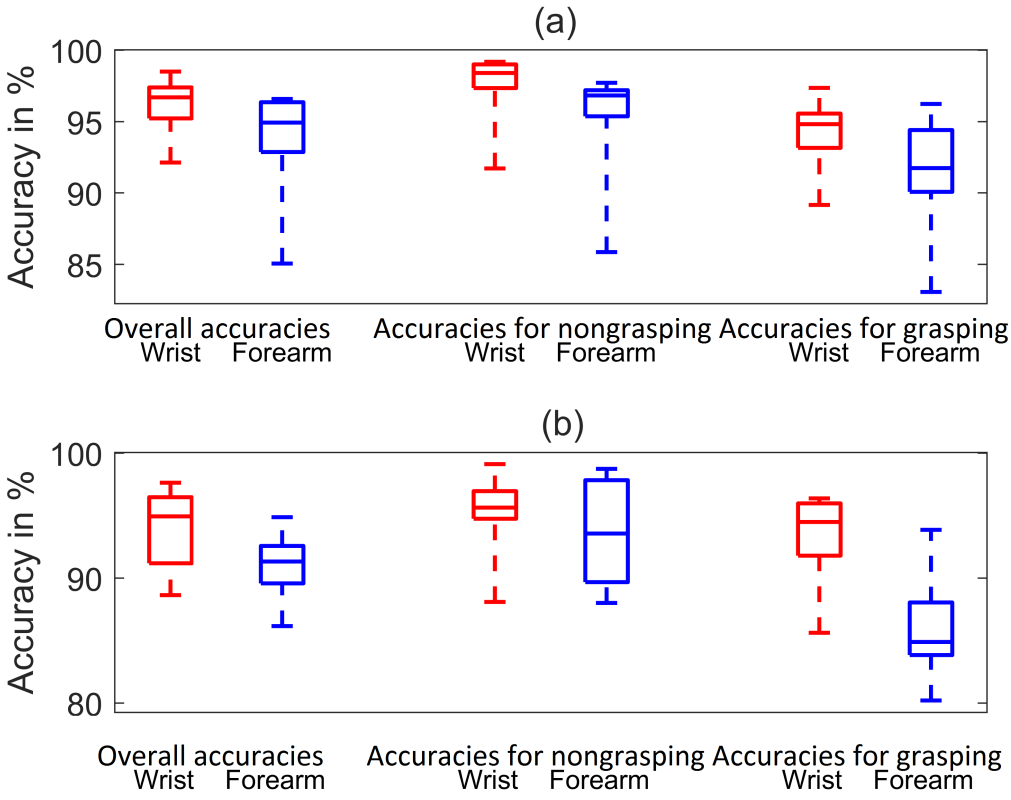

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Figure 10. Classification result comparison: (a) accuracy comparison using wrist FMG and (b) accuracy comparison using forearm FMG.

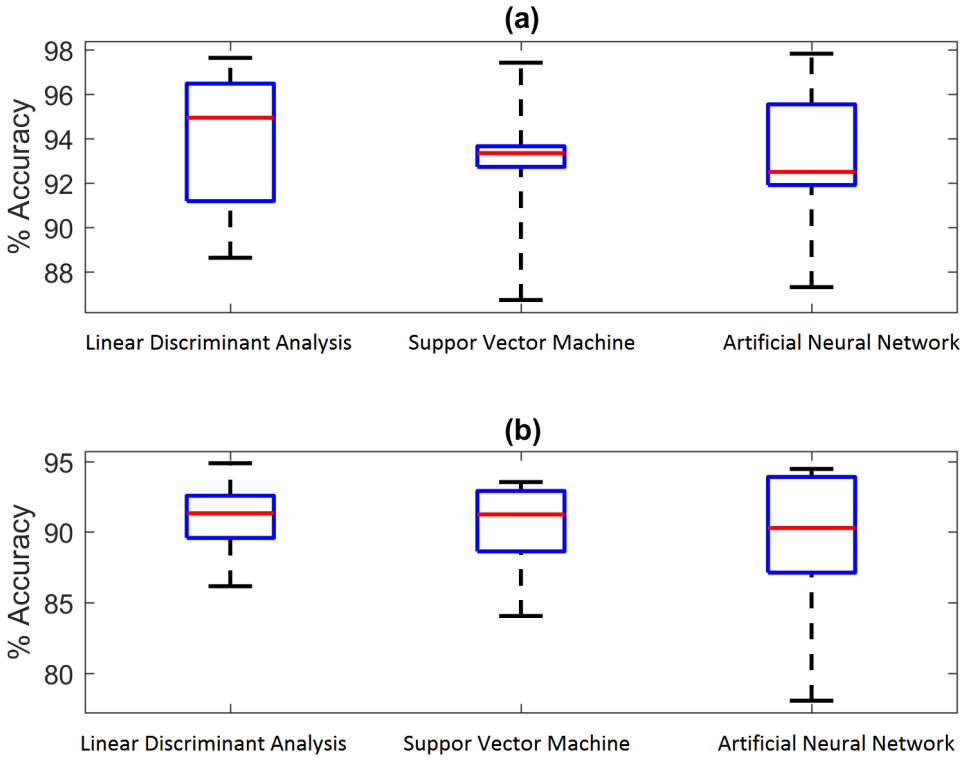

Figure 11. Regression plots for force-myography (FMG) classification accuracies of the 10 participants: (a) wrist FMG classification accuracies versus wrist circumference; (b) forearm FMG classification accuracies versus wrist circumference; (c) wrist FMG classification accuracies versus time per action; and (d) forearm FMG classification accuracies versus time per action.

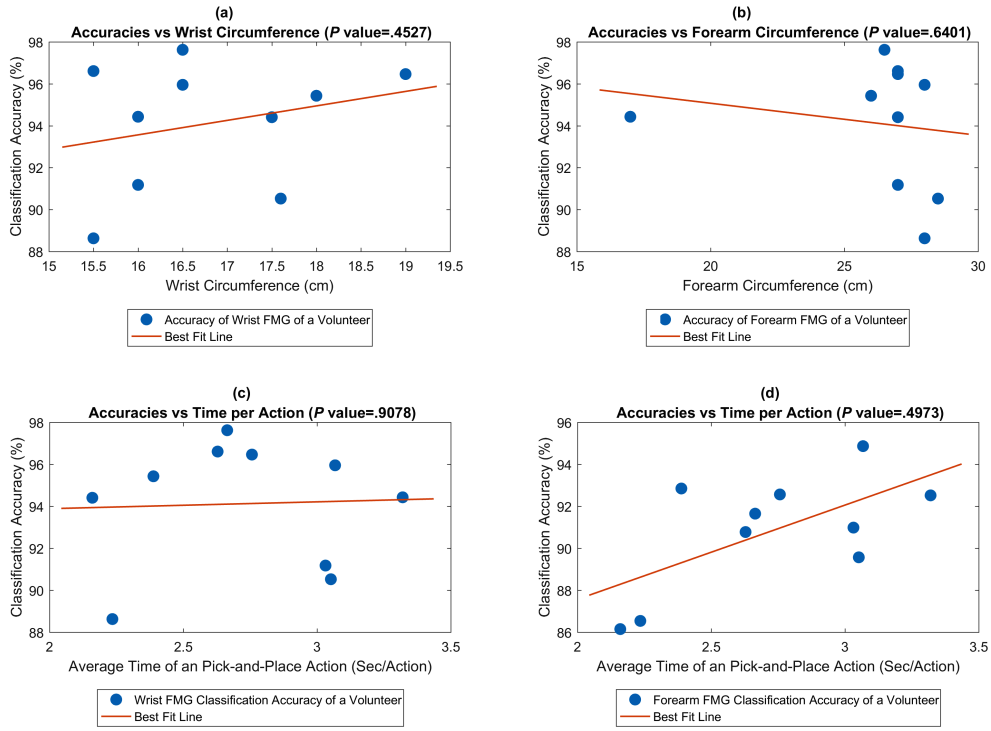

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Figure 12. Boxplots for grasp counts versus number of filtered samples: (a) result generated using wrist FMG and (b) result generated using forearm FMG.

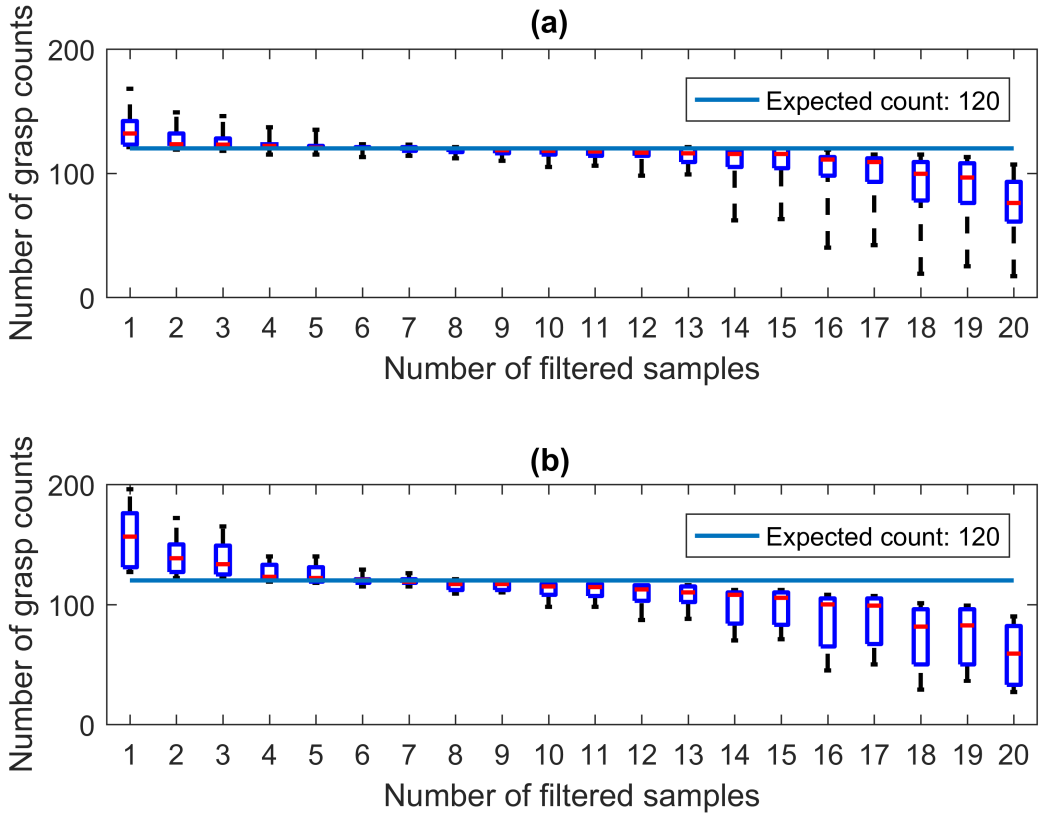

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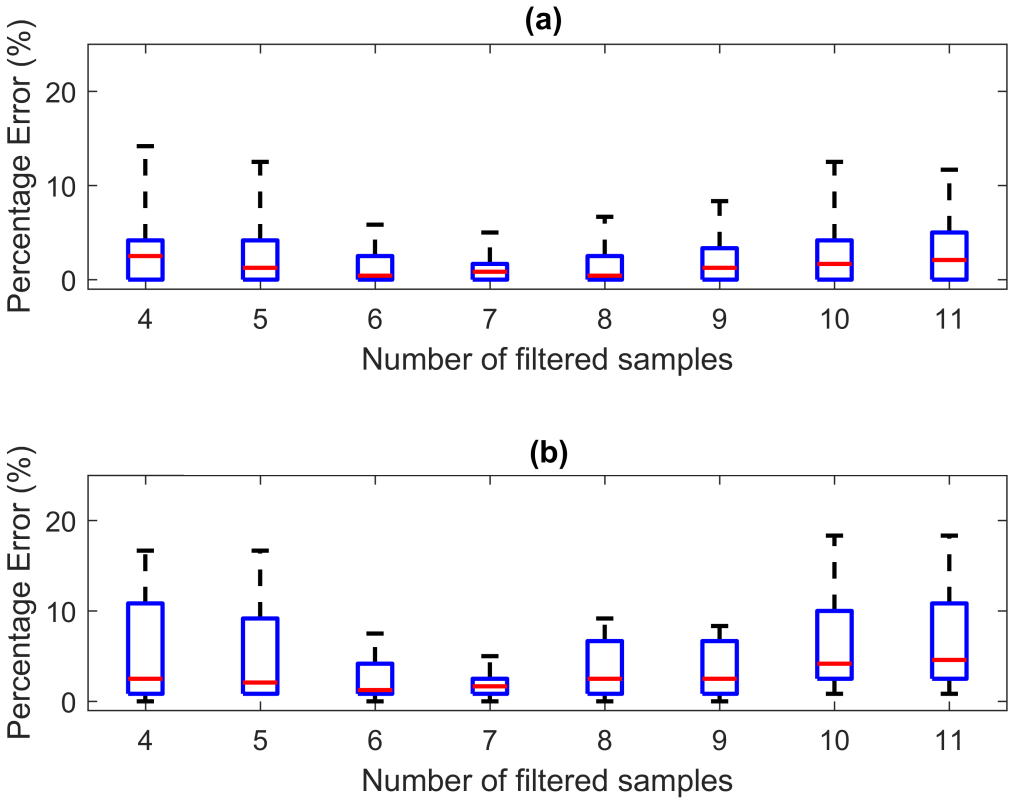
Figure 13. Boxplots for percentage error of grasp counts versus number of filtered samples: (a) result generated using wrist FMG and (b) result generated using forearm force-myography.



Performance Evaluation

The overall performance of the proposed method was evaluated based on 2 metrics: the classification accuracies and percentage errors of the grasp count obtained from the test set.

The classification accuracy was calculated based on the sum of the correctly classified sample over the total number of samples. The difference of classification accuracies between wrist and forearm FMG using LDA was evaluated. Also, the performance of LDA was compared with other 2 popular classifiers, namely the Radial Basis Function kernel Support Vector Machine (RBF-SVM) and the 2-layer Artificial Neural Network (ANN). In addition, the correlations between the accuracies and action speeds, as well as the size of the wrist or forearm were assessed using a regression method.

The percentage error of the grasp count was based on the result of the absolute difference between the predicted and the expected counts over the expected one. The expected count for the test set was 120 in this study. The difference between the errors of the wrist and forearm FMG approaches was also assessed.

Paired sign test and Kruskal-Wallis test were used for examine the statistical significance of the obtained results. All the statistical analysis was performed using the same significance level (alpha) of .05.

Results

LDA Classification Results

The LDA classification accuracies of the 10 participants for nongrasping (class 1) and grasping (class 2) an object are shown in Figure 9. The combined accuracies of the 2 classes are shown in the first pair of results on the left of this figure (see “Overall accuracies”). Due to the fact that the results were not normally distributed, the median accuracy was used as the indicator for classification performance.

For the FMG recording from the wrist, the median training accuracy (see the top of Figure 9) was 97% and the corresponding interquartile range (IQR) was 2%. These high training accuracies suggest that FMG patterns recorded from the wrist are suitable to detect grasping and nongrasping during PAP actions. The median accuracy for the testing data set (see the lower plot of Figure 9) was 95% and the corresponding IQR was 5%. The high accuracies for both the training and testing data suggested that the training data was a good representation of the testing data set; no under- or overfitted phenomena was observed.

Similar results were obtained for FMG data recorded from the forearm: the median training accuracy was 95% and the corresponding IQR was 4%. The median testing accuracy was 91% and the corresponding IQR was 3%.

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The difference between the medians of the wrist and forearm FMG testing accuracies was 4%. With a *P* value less than .001, the paired right-tailed sign test showed that the prediction using wrist FMG had a statistically significantly higher median accuracy than the one using forearm FMG.

The second pair of results in Figure 9 (see "Accuracies for nongrasping") shows the prediction accuracies when the participants did not grasp the object. For FMG recorded from the wrist, the median testing accuracy was 96% and the corresponding IQR was 2% (see the lower plot of Figure 9). For FMG recorded from the forearm, the median testing accuracy was 94% and the corresponding IQR was 8%. With *P* value equals to .94, the paired right-tailed sign test did not show that the prediction accuracy of using wrist FMG was statistically different from the one using the forearm FMG for the nongrasping state.

The third pair of results in Figure 9 (see "Accuracy for grasping") shows the prediction accuracies while the participants grasped the object. For FMG recorded from the wrist, the median testing accuracy was 95% and the corresponding IQR was 4%. For FMG recorded from the forearm, the median testing accuracy was 85% and the corresponding IQR was 4%. With a *P* value less than .001, the paired right-tailed sign test showed that FMG recorded from the wrist yielded a better prediction accuracy for grasping than FMG recorded from the forearm.

Classification Result Comparison Between LDA and Other Classifiers

The performance of using LDA was compared with the ones of RBF-SVM and ANN. Standard model generation procedures for SVM and ANN, which are described in [50] and [51], were followed. For training the SVM model, a ten-fold cross-validation procedure was used to obtain best RBF parameters. For training the ANN model, a 2-layer network with 100 hidden nodes was trained based on a back-propagation algorithm. The obtained testing accuracies from all 3 classifiers are shown in Figure 10. For both wrist and forearm FMG classifications, no statistically significant difference among the results could be established using the Kruskal-Wallis test. The *P* values obtained from the test were .5 for wrist FMG classification and .9 for forearm FMG classification.

Classification Results and Participants' Physical and Performance Factors

In order to examine if the size of the participants' limbs and action speeds influence the classification accuracies, 4 regression plots were generated and shown in Figure 11.

The first row of Figure 11 shows the regression plots of accuracies versus the wrist and the forearm circumference, respectively; the second row shows the regression plots of accuracies of the wrist and the forearm FMG classification versus the average time for the participant to complete a PAP action, respectively. With all *P* values larger than the specified significance level (alpha=.05), no statistically significant correlation could be established between accuracies and the 2 factors.

Grasping Count Result

In order to assess the effect of the filtering window, the grasp counts of the participants were recomputed using different window sizes. Figure 12 shows the corresponding grasping count using box plot for the window sizes of 1-20 samples. The expected counts are shown as a solid line, which was 120 in this experiment.

Without averaging (sample size equals 1), the numbers of grasping were overestimated by a large margin for all the participants' data. As the size of the averaging window increased, the counts were closer to the expected value in general. However, when the size continued to increase, the count became increasingly underestimated. On the basis of the result shown in Figure 12, medians of the counting error smaller than 5% were obtained when the number of filtered samples ranged between 4 and 11. The counting errors within such a range of filtered samples are shown in Figure 13.

As shown in Figure 13, the smallest maximum percentage errors were obtained by using 7 filtered samples for both wrist and forearm FMG counts (5% maximum percentage errors for both cases). Under such conditions, the median percentage error for wrist FMG was 1%, and the corresponding IQR was 2%. For the forearm FMG, the median percentage error was 2%, and the corresponding IQR was also 2%. A *P* value of .29 was obtained by using the paired 2-side sign test. Despite the wrist FMG having a smaller median, the statistical significant difference between the 2 FMG counts could not be established.

Discussions

Primary Findings

The LDA classifier was selected as the main classifier for this study, and its performance was as good as the more computational-intensive SVM and ANN classifiers. The LDA classification result (see Figure 9) shows that the wrist FMG band produced significantly higher classification accuracies than the forearm FMG band for detecting a grasping state, but no statistical difference was found for detecting a nongrasping state. This result could be associated to the fact that the grasping action occurred closer to the wrist than the forearm. During the object manipulation, movement of the thumb could be better registered by the wrist strap as the tendon and the nearby skin movements contributed to a more distinct FMG pattern. In addition, the FMG from the forearm also captured the pattern related to elbow movement [34], which was a confounding factor for grasp classification. Nevertheless, both FMG methods were capable of producing high classification accuracies (>85%) for all participants. These results confirmed that FMG was an effective method to detect hand grasping even with the presence of complex arm movements. The scope of this study focuses on the capability of FMG only, however, other wearable sensors such as an IMU should be considered along with FMG to further improve accuracy.

The regression method was used to test if the size of the participants' limbs and action speeds influence the classification accuracies. The results of the test showed there were no statistically significant correlation between the accuracies and

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the 2 factors. These results suggested the performance of the FMG method was independent of the limb size and action speed in this study. However, since the participants in this study were healthy individuals, the variations of their physical status and action performance were expected to be insignificant. For future investigation, grasping at various speeds by individuals with different limb sizes should be considered.

The grasping counts were extracted from the filtered output of the LDA classifiers. As shown in Figure 12, the size of the filtering window largely influenced the accuracies of the counts. Suitable window sizes (medians of the counting error smaller than 5%) were identified to be from 4 to 11 samples, and such window sizes could add 300 ms to 1000 ms of delays to the system. Combined with the delay introduced by the feature extraction process (300 ms), a grasping could be registered by the system after at least 600 ms from the start of the action. While such a delay might be problematic for some real-time human machine interfaces [52-54], it is not considered to be of concern for the targeted activity monitor application, as the user's instant action does not depend on the feedback [55-57]. Under the optimal settings, which was based on the smallest maximum percentage error, a median percentage error of 1% with IQR of 2% for the grasping count using the wrist FMG was obtained. Compared with the results obtained using forearm FMG, no statistically significant difference was established using the paired sign test. These results show great potential for both FMG approaches.

This study investigated the capability of using FMG to predict and count grasping actions with healthy individuals. Therefore, the knowledge obtained from this study can be directly applied to the applications in which healthy individuals are the wearers of the FMG bands. An example of such an application could be for monitoring the repetitive hand activity level of a worker during load transfer tasks. However, for rehabilitation applications, as the targeted population will be the people with a weak arm, such as individuals recovering from stroke, further studies are needed to examine the transferability of the result of this study. For example, in poststroke rehabilitation, the targeted wearers are often seniors with limited mobility and range of motion. Their muscles are normally much weaker than the ones of healthy individuals, and may even have significantly deteriorated if the individuals are chronic stroke patients. These characteristics posed questions on whether the proposed FMG method could be used with such a population. Currently, there is lack of in-depth studies that examine the FMG pattern characteristic of stroke patients or people with a weak arm. However, the pilot investigation of Yungher and Craelius showed that the grasping force could be regressed from the forearm of stroke patients (n=4) with mild to moderate spasticity [36]. This study indicated some useful FMG information could still be extracted as long as the patients had some range of motion on the limb. For object manipulation task, this type of patient tends to produce larger grip force, but with less control when compared with the healthy counterpart [58,59]. In such a scenario, distinct FMG patterns associated with some movements are still expected to be captured; however, the consistency of the patterns is likely to be less. The inconsistency due to muscle fatigue may also become more prominent, which might require modification of algorithms to adjust the training parameter of the classifier (eg, normalization parameters of the FMG signals) in order to compensate for the change. In addition, the FMG pattern can be very different among patients due to the different degree of impairment. Because of these conditions, the classifier model may need to be very user- and task-specific in order to tailor for the needs and obtain high prediction accuracy. In order to examine the transferability of the proposed FMG approach for rehabilitation, testing on the stroke population or individuals with weak arm should be the next logical step.

Conclusions

The possibility of detecting and counting grasping in the presence of arm movements (PAP exercise) was explored using wrist and forearm FMG strap prototypes. The 2 main performance parameters that were considered were classification accuracy for detecting grasping and percentage error for counting grasping. A high median grasping prediction accuracy was obtained from 10 subjects (95% and 91% for FMG recorded from the wrist and forearm, respectively). A low median grasping count error was also found (1% and 2% for wrist and forearm, respectively). These results provide evidence that FMG-based straps could be used to monitor grasping activities during functional arm movements in a controlled environment. This work poses the foundation for future studies investigating the applicability of using FMG to detect grasping in activities of the daily living first with healthy participants and then with individuals with a weak arm (eg, seniors, individuals with a hemiparetic arm resulting from stroke).

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Authors' Contributions

ZGX prototyped the FMG straps, implemented data collection software, performed experiments, analyzed the experimental results, and participated in the manuscript preparation. CM, Principal Investigator of this research, contributed to the design of the study, supervised the work, participated in the interpretation of the results and contributed in writing the manuscript. All authors read and approved the final manuscript.

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Conflicts of Interest

The Principal Investigator, Carlo Menon, and members of his research team have a vested interest in commercializing the technology tested in this study, if it is proven to be successful and may benefit financially from its potential commercialization. The data are readily available upon request.

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Abbreviations

ADL: activity of the daily living
ANN: artificial neural network
FMG: force myography
FSRs: force-sensing resistors
IMU: inertial measurement unit
IQR: interquartile range
LDA: linear discriminant analysis
RBF-SVM: Radial Basis Function kernel Support Vector Machine
RMS: root mean square
sEMG: surface electromyography
WL: waveform length
WS: window symmetry

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Original Paper

Translating Comprehensive Conservative Care for Chronic Knee Pain Into a Digital Care Pathway: 12-Week and 6-Month Outcomes for the Hinge Health Program

Peter Smittenaar[1], PhD; Jennifer C Erhart-Hledik[2], PhD; Rose Kinsella[1], MEng; Simon Hunter[1], PhD; Gabriel Mecklenburg[1], Mphil; Daniel Perez[1], BSc

[1]Hinge Health Inc, San Francisco, CA, United States

[2]Department of Orthopaedic Surgery, Stanford University, Stanford, CA, United States

Corresponding Author:
Peter Smittenaar, PhD
Hinge Health Inc
818 Mission Street
San Francisco, CA,
United States
Phone: 1 7823770826
Fax: 1 7823770826
Email: peter@hingehealth.com

Abstract

Background: Chronic knee pain (CKP) affects a large number of adults, many of whom do not receive best-practice care and are at high risk for unnecessary surgery.

Objective: The aim of this study was to investigate the effect of the Hinge Health 12-week digital care program (DCP) for CKP on knee pain and function, with secondary outcomes of surgery interest and satisfaction, at 12 weeks and 6 months after starting the program.

Methods: Individuals with CKP were recruited onto the 12-week program, comprising sensor-guided physical exercises, weekly education, activity tracking, and psychosocial support such as personal coaching and cognitive behavioral therapy (CBT). We used a single-arm design with assessment of outcomes at baseline, 12 weeks, and 6 months after starting the program. We used a linear mixed effects model with Tukey contrasts to compare timepoints and report intention-to-treat statistics with last observation carried forward.

Results: The cohort consisted of 41 individuals (32 female, mean age 52 years, SD 9 years). Between baseline and week 12, participants reported clinically significant improvements in the Knee Injury and Osteoarthritis Outcome Score (KOOS) pain and Knee Injury and Osteoarthritis Outcome Score-Physical Function Short Form (KOOS-PS) function scales of 16 points (95% CI 12-21, $P<.001$) and 10 points (95% CI 6-14, $P<.001$), respectively. Significant reductions of 57% (mean difference 30, 95% CI 21-38, $P<.001$) and 51% (mean difference 25, 95% CI 16-33, $P<.001$) in visual analog scale (VAS) knee pain and stiffness, respectively, were observed at 12 weeks, as well as a 67% reduction in surgery interest (mean reduction 2.3 out of 10, 95% CI 1.5-3.1, $P<.001$). Average satisfaction at week 12 was 9.2 out of 10. Critically, all improvements were maintained at 6 months at similar or greater magnitude.

Conclusions: Participants on the Hinge Health DCP for CKP showed substantial clinical improvements that were maintained 6 months after enrolling in the program. This shows that DCPs carry strong potential to deliver evidence-based, cost-effective care to those suffering from CKP.

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KEYWORDS

chronic pain; osteoarthritis, knee; digital health; conservative management

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Introduction

Background

Chronic knee pain (CKP) is one of the most common health conditions [1] and is a characteristic presenting symptom of knee osteoarthritis (OA) [2]. People living with CKP experience a reduced quality of life [3] and are at risk of developing concomitant musculoskeletal and mental health conditions [4,5]. CKP is most effectively treated by comprehensive chronic pain programs, comprising not only physical exercise but also education, psychosocial support, and weight loss [6-9]. Such programs have shown clinically relevant reductions in pain that last up to 5 years [10,11] and medical cost savings due to a reduced need for injections, drugs, and surgery [8], with one intervention for CKP due to knee OA showing a 75% (8/41 had knee replacement in control vs 2/42 in treatment) reduction in rate of total knee replacements [12]. Comprehensive care for CKP due to knee OA is also more effective at reducing pain in the long-term compared with physical therapy only [13-16]. However, chronic pain programs are rare for CKP, and over 80% of individuals with CKP due to knee OA receive suboptimal conservative care [17]. Furthermore, CKP patients show poor adherence to existing treatments [18].

The lack of widespread best-practice conservative care for those suffering from CKP drives patients toward total knee arthroplasty (TKA), an expensive intervention which almost doubled in rate between 2000 and 2010 in the United States [19]. Further exacerbated by an aging population, TKAs now represent one of the main cost drivers for self-insured employers and the largest in-patient cost for Medicare, alongside hip replacements. Despite the popularity of the procedure, many patients undergoing TKA may have avoided or at least delayed surgery through comprehensive conservative care [12], with 34% of TKAs performed in the United States regarded as inappropriate [20]. For those that do undergo TKA, the benefits are partly offset by serious adverse events [21,22]. Even more wasteful are arthroscopic debridement surgeries, which have no discernible effect on the patient beyond placebo yet remain one of the most common interventions with 500,000 procedures every year in the United States alone [23]. As such, there is huge scope for effective nonsurgical treatment solutions to improve patient outcomes and drive down the surging costs associated with CKP.

A digital care program (DCP), whereby each facet of evidence-based care is digitized, aims to deliver care more efficiently, effectively, and in a way that would improve outcomes while decreasing costs. In particular, a DCP for CKP administered remotely would allow patients access to the program at any time and place, provide a single touchpoint for every aspect of care, enable rich data collection on patient behavior and progress, and drastically reduce the marginal cost of additional patients receiving treatment. Furthermore, as poor adherence can limit long-term effectiveness of a program for CKP [18], a DCP incorporating remote sensing would enable very precise monitoring of adherence levels to exercise therapy, affording personalized and timely interventions during the course of treatment. Digital health is moving into many different domains of health care, ranging from cognitive behavioral therapy (CBT) for pain and depression to remote monitoring of heart patients [24-26]. In diabetes prevention, a digital health program has shown positive outcomes that persisted up to 2 years after completion of the program [27], and a digital sleep therapy program was found to be effective in a randomized controlled trial [28]. However, the musculoskeletal field has seen relatively little digital innovation and was judged to be “in its infancy” in this regard [29].

The American College of Rheumatology recommends those suffering from CKP to participate in cardiovascular and strengthening exercise, self-management training, psychosocial intervention, and weight loss for overweight patients [7]. In line with these recommendations, we have developed a 12-week DCP for CKP. The program builds on previous work in digital musculoskeletal care, which studied individual components of digital care in isolation, such as diagnosis [30], CBT [25], exercise with telephone-based coaching [31], exercise with pain coping training [32], and behavioral change approaches [33].

Aims of This Study

The aims of this study were to (1) determine the change in pain and function between baseline and follow-up (week 12 and 6 months) in participants in the 12-week Hinge Health DCP and (2) assess changes in surgery interest and patient satisfaction between baseline and follow-up.

Methods

Research Design

We used a single-arm design with patient-reported outcome measures (PROMs) collected before starting the program (“baseline”), at the end of the 12-week program, and at 6 months after starting the program.

Participants

The 12-week Hinge Health DCP was deployed at two sites in the United States, both of which compensated Hinge Health for the deployment. All potential participants were employees of a self-insured employer, covered by their medical plan. Potential participants were recruited by email, letters mailed to their home address, and fliers posted in the workplace, and were screened for inclusion by Web-based questionnaire. For inclusion, subjects had to provide written informed consent, have lived with knee pain for at least 3 months in the past 12 months, and had to meet at least 2 of the following additional inclusion criteria derived from the American College of Rheumatology criteria for OA of the knee [2]: morning stiffness lasting less than 30 min, crepitus on movement, bony tenderness, bony enlargements, lack of warmth of the knee to the touch, and age of 50 years or older. Exclusion criteria were knee surgery or trauma in the past 3 months. We obtained ethical approval to conduct a research study as part of these deployments from the Western Institutional Review Board (WIRB 20160949).

An a priori sample size calculation was performed for comparing the primary outcomes of pain and function. Using an alpha level of .05, a power of 0.8, and a medium effect size of 0.5, 33 subjects were needed. Recruitment of 41 participants accounted

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for a potential dropout rate of 20% over the course of the study. As there were a limited number of places available on the program, we invited eligible applicants on a first come, first serve basis. Users were not compensated for their time, but could participate in the program free of charge.

Intervention

The Hinge Health DCP is a 12-week program (Figure 1) which aims to equip participants with the knowledge and tools to self-manage their condition without prescription drugs and surgery as long as possible. The program comprises sensor-guided physical exercise, education, CBT, psychosocial support through teams and personal health coaches, weight loss, and activity tracking. In the week before the official start of the program, each invited participant was assigned to a team of 15-20 participants and taken through a 30-min in-person onboarding session led by a trained Hinge Health representative. During this session, the participant was provided with a tablet computer preloaded with the Hinge Health app as well as wearable bands with motion sensors to be used during guided exercises (Figure 2), and shown how to use the main features of the app and perform sensor-guided exercise therapy. This was followed within a few days by a 30-min call with a personal coach, who was an employee of Hinge Health trained for interaction with participants. The purpose of the call was for the coach to establish themselves as the primary touchpoint for the participant throughout the program, orient the participant to the program, help set goals, and identify and alleviate practical barriers to adherence. Every week on the program participants had to complete a number of goals. These components of the program are discussed below. Participants were allowed to keep their tablet computer and movement sensors after completion of the 12-week program, and they could continue to interact with the program as desired to access education, communicate with teammates, log symptoms, and track activities; however, no activities were required of participants during this maintenance phase.

Figure 1. User flow in the Hinge Health digital care program. (a) Every odd-numbered week. (b) Only for those with a starting body mass index (BMI) of 25 kg/m2 or greater. (c) Only on a subset of weeks and only for those users who qualified for the respective cognitive behavioral therapy module (see "Methods" section).

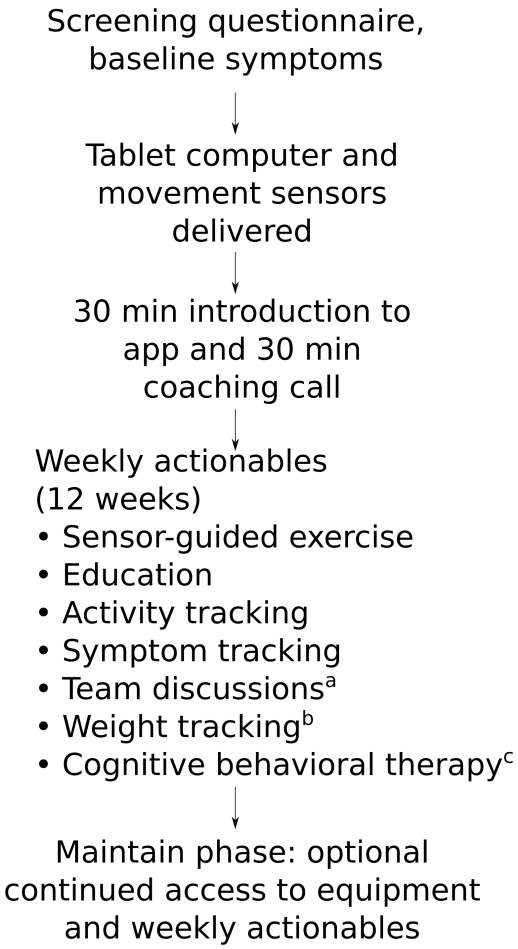

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Figure 2. Tablet computer and sensors as part of the Hinge Health kit. (a) A screenshot of the home screen. Weekly actionables are indicated by stars, followed by an overview of fellow team members and the team discussion feed. Further functionality—including a progress screen, education articles, and private communication channel with the coach—are available through the menu. (b) Placement of sensors for exercise therapy.

Exercise Therapy

Participants had a weekly exercise repetitions goal for sensor-guided exercises, which increased over the course of the program. Approximately 15 min of stretching and strengthening exercise for 3-4 days per week was sufficient to reach their weekly goal. Specifically, we provided the following sensor-guided exercises: standing quad stretch (pulling heel toward buttocks), seated quad stretch (pull leg toward chest), half squats, forward lunges, leg raise (raising lower leg behind the body until parallel with floor while holding chair), seated leg raise (raising lower leg to horizontal while seated), and hamstring stretch (foot on raised object, reach to touch toes with straight leg). The app tracked the execution of the exercises and provided real-time feedback to the user to ensure that the exercises were performed correctly. Before starting a new exercise, a narrated video showed correct execution, and this video remained available to the participant throughout the program. Crucially, the sensors afforded an objective avenue to monitor adherence.

Education

Education articles were presented once per week, for a total of 12 education articles, each requiring approximately 10-20 min of reading. Each article consisted of approximately 6 pages, and we tracked consumption of each page. A piece of education was marked complete if the participant reached the final page of the article.

Symptom Logging

Participants were asked to log their pain and stiffness symptoms on a visual analog scale (VAS) at least twice a week, alongside any treatments they had been using for their knee. Participants were prompted to fill out questionnaires at predetermined timepoints in order to track PROMs. The specific timepoints for each PROM are outlined below.

Activity Tracking

A self-report activity tracker helped log any physical activity they performed during the week, encouraging at least three 30-min sessions per week of low-impact exercise.

Cognitive Behavioral Therapy

CBT modules were provided. One was provided to all users (*pacing activity levels*), whereas others were provided based on data provided by users: the *weight loss* CBT for participants with a body mass index >25 kg/m^2; the *coping with pain* CBT for users with a score greater than 30 on the pain catastrophizing scale; the *low mood* and *anxiety* CBT for participants with a score of 10 or higher on the Hospital Anxiety and Depression Scale (HADS), respectively.

Team and Coach Interaction

The coach facilitated in-app team discussions, while encouraging team members to discuss anything of interest with their teammates on the team feed (accessible via the app). Participants communicated with the coach through the tablet app, phone, SMS, or email. The participants could initiate a conversation

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at any time and the coach would respond within the same day. Moreover, the coach sent weekly messages to introduce the week's education, provide feedback on completed CBT modules, send an overview of the participant's performance in the previous week, and encourage the user to attend to their weekly goals on Wednesdays and Fridays, if the participant was behind on their goals.

Primary Outcomes: Pain and Function

We used the Knee Injury and Osteoarthritis Outcome Score (KOOS) 9-question pain subscale [34,35], as well as the 7-question Knee Injury and Osteoarthritis Outcome Score-Physical Function Short Form (KOOS-PS) to assess function [36]. KOOS questionnaires were asked at baseline (screening) as well as at week 4, 8, and 12 of the program, and scored from 0 (no symptoms) to 100 (extreme symptoms). Both questionnaires were also administered at the 6-month timepoint.

Secondary Outcomes

Participants reported on their knee pain and function by completing VAS questions at baseline (screening) and twice per week during the program, asking "Over the past 24 h how bad was your knee pain?" and "Over the past 24 h how bad was your knee stiffness?" respectively. The left pole was set to 0 and contained the text "none," and the right pole was set to 100 and contained the text "worst imaginable." Unlike other PROMs, VAS reports were optional in the app. To assess overall satisfaction with the program, we asked "On a scale of 0-10, how likely is it that you would recommend the Hinge Health program to a friend or colleague?" at week 6 and week 12. We tracked participants' self-reported likelihood of undergoing knee surgery at baseline (screening), week 6, and week 12 of the program by asking "On a scale from 0 to 10, how interested are you in knee surgery?" All secondary outcomes were also assessed at 6-month timepoint.

Statistical Analysis

We report *intention-to-treat* statistics with last observation carried forward. We used a linear mixed effects model implemented through LME4 [37] and implemented Tukey contrasts to compare timepoints through the "multcomp" package [38] in the statistical computing software R (version 3.3.2, The R Project for Statistical Computing). We modeled a single within-subject factor "time" (levels: baseline, 12 weeks, 6 months), and a separate baseline for each participant. We modeled time as a categorical factor and therefore do not assume a linear relationship between time and outcome measures. We report the contrast estimate, 95% CI on the estimate, and *P* value. *P* values <.05 were considered significant. We also examined the *per protocol* results. Due to the low dropout rate, these results were not meaningfully different from the *intention-to-treat* results and are therefore not reported here.

Results

Participants

Demographics of participants are presented in Table 1. On average, participants were aged above 50 years, had a BMI over 25 kg/m^2, and predominantly female. At baseline, 66% (27/41) of users were not doing any physical therapy-style exercise and 54% (22/41) were active 90 min or less per week including walking, suggesting a predominantly sedentary lifestyle. There were no significant differences in any of the demographics or baseline data between those who completed the PROMs at 6 months and those who did not (*P*>.05 for all).

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Table 1. Demographics and relevant baseline data.

Metric	All Participants	Completed 12 week PROMs[a]	Completed 6 month PROMs	Did not complete 12 week	Did not complete 6 month
n (% of all participants)	41 (100)	37 (90)	33 (80)	4 (10)	8 (20)
Age in years, mean (SD[b])	52 (9)	52 (9)	54 (8)	54 (4)	47 (9)
BMI[c] (kg/m^2), mean (SD)	29 (7)	28 (7)	29 (7)	32 (6)	27 (7)
Height (cm), mean (SD)	169 (10)	169 (10)	168 (8)	171 (4)	176 (13)
Weight (kg), mean (SD)	82 (17)	80 (17)	81 (17)	92 (15)	83 (19)
Female, n (%)	32 (78)	29 (78)	28 (85)	3 (75)	4 (50)
PT-like exercise[d] at baseline, n (%)	14 (34)	13 (35)	11 (33)	1 (25)	3 (38)
Active 90+ min per week at baseline, n (%)	19 (46)	19 (51)	18 (55)	0 (0)	1 (12)
Pain catastrophizing scale[e], mean (SD)	14 (9)	13 (10)	13 (10)	19 (5)	16 (8)
Had knee surgery in past, n (%)	17 (41)	15 (41)	15 (45)	2 (50)	2 (25)
Arthritis diagnosed by doctor, n (%)	18 (44)	17 (46)	17 (52)	1 (25)	1 (12)

[a]PROMs: patient-reported outcome measures.

[b]SD: standard deviation.

[c]BMI: body mass index.

[d]PT-like exercise: answer to screening question “Do you currently do any physical therapy-style exercises?”

[e]Pain catastrophizing scale: from 0 (no catastrophizing) to 52 (extreme).

Intervention Engagement

Engagement across each of the relevant goals provided to participants in the program are shown in Table 2. Participants performed sensor-guided physical exercises on 42.9 days on average, or 3.6 days per week—in line with the goal of 3-4 days exercise per week. On such an average active day, participants performed 39 repetitions across various exercises. Participants also completed the majority of their education articles, consuming education on 89% (10.7/12) of weeks. The average participant completed 1.9 (SD 0.8) of the 3.3 (SD 0.8) CBT sessions offered.

Primary Outcomes: Pain and Function

Participants reported highly significant improvements on the KOOS pain subscale (Figure 3; improvement at week 12 from baseline: 16 points, 95% CI 12-21, P<.001) that were maintained at 6 months (improvement from baseline: 18 points, 95% CI 14-23, P<.001). Knee function also significantly improved at 12 weeks (KOOS-PS, Figure 3; improvement at week 12 from baseline: 10 points, 95% CI 6-14, P<.001) and was maintained at 6 months (improvement from baseline: 14 points, 95% CI 9-18, P<.001).

Table 2. Engagement with the Hinge Health digital care program (DCP) for chronic knee pain (CKP).

Metric	All Participants	Completed 12 week PROMs[a]	Completed 6 month PROMs	Did not complete 12 week	Did not complete 6 month
Days with sensor-guided exercise, mean (SD[b])	42.9 (16.1)	44.8 (15.2)	46.7 (14.5)	26 (16.1)	27.4 (13.3)
In-app physical exercise repetitions, mean (SD)	1685.5 (1150)	1772.6 (1163.1)	1881.2 (1175)	880.2 (665.1)	878.1 (565.8)
Offline activities logged in hours, mean (SD)	24.9 (11.5)	26 (11.4)	27.2 (11.3)	14.8 (5.8)	15.4 (5.8)
Education articles read, mean (SD)	10.7 (2.1)	10.9 (1.6)	11.1 (1.5)	8.5 (4.4)	8.9 (3.1)
CBT[c] session completed, mean (SD)	1.9 (0.8)	1.9 (0.8)	2 (0.7)	1.5 (1)	1.4 (1.1)
Team posts and comments, mean (SD)	12.3 (7.7)	12.9 (7.7)	13.9 (7.4)	6.2 (3.2)	5.4 (3.9)

[a]PROM: patient-reported outcome measure.

[b]SD: standard deviation.

[c]CBT: cognitive behavioral therapy.

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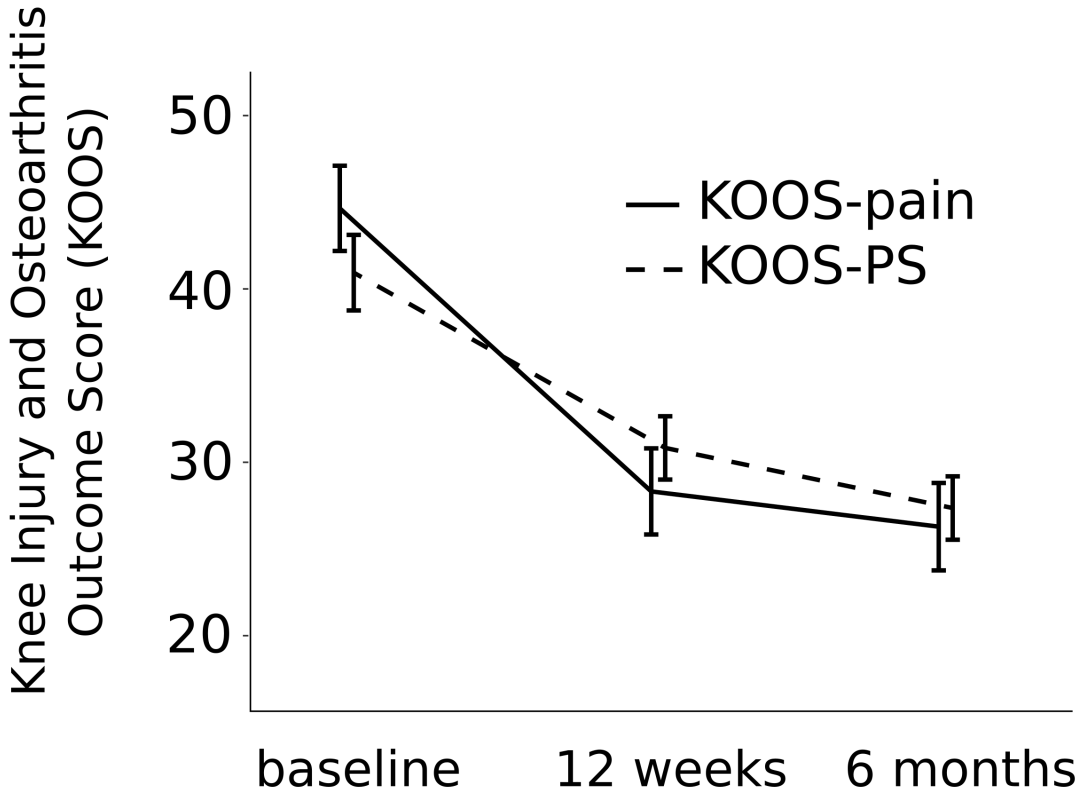
Figure 3. Knee Injury and Osteoarthritis Outcome Score (KOOS) pain subscale and Knee Injury and Osteoarthritis Outcome Score-Physical Function Short Form (KOOS-PS)—which measures knee function—over the course of the 6-month assessment period. Error bars indicate standard error of the mean (SEM).

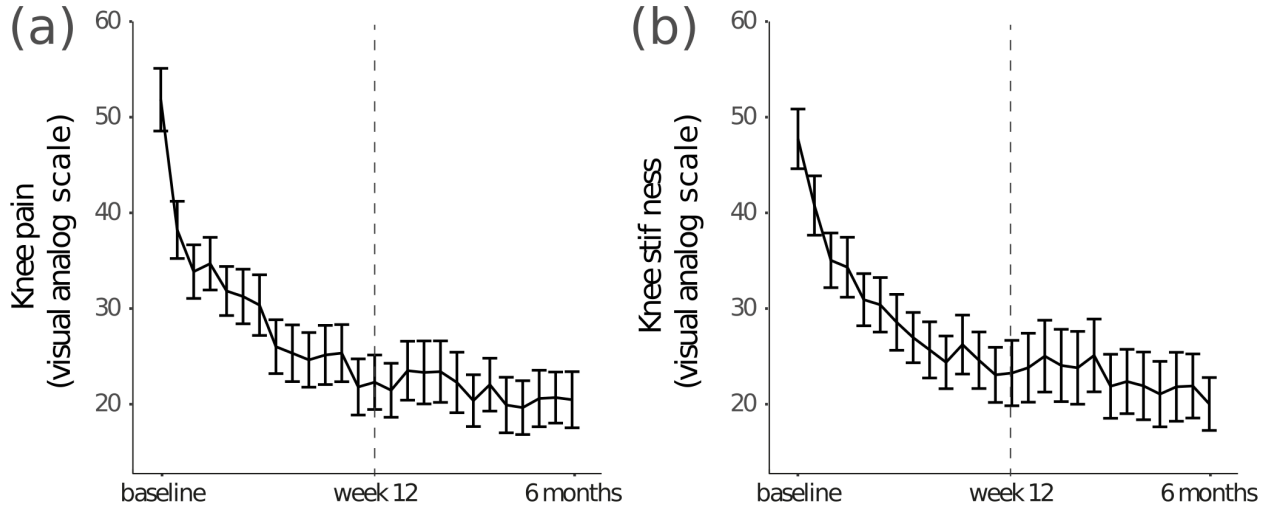


Secondary Outcomes

Visual Analog Scales

Between baseline and week 12, participants reported a 57% reduction in knee pain (Figure 4; from 52 to 22 points; mean difference 30, 95% CI 21-38, *P*<.001) and 51% reduction in knee stiffness (Figure 4; from 48 to 23; mean difference 25, 95% CI 16-33, *P*<.001). These improvements were maintained at 6 months for both knee pain (mean improvement 31, 95% CI 23-40, *P*<.001) and stiffness (mean improvement 28, 95% CI 20-36, *P*<.001).

Figure 4. Visual analog scale assessment of (a) knee pain and (b) knee stiffness over the course of the 6-month assessment period. The dotted line indicates the last week of the 12-week program. Error bars indicate standard error of the mean (SEM).



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Surgery Intent

Surgery interest significantly decreased over the course of the program from 3.5 out of 10 at baseline to 1.2 out of 10 at 12 weeks (67% reduction; mean reduction 2.3, 95% CI 1.5-3.1, *P*<.001). At 6 months participants still expressed low interest in surgery (69% reduction; mean reduction: 2.4, 95% CI 1.6-3.2, *P*<.001). Of the 17 participants at high risk of surgery at baseline—defined as a surgery interest of 5 or higher—by week 12 only 3 remained at high risk. At 6 months, still only 3 remained at high risk for surgery, 2 of whom also were at high surgery risk at week 12, and 1 of whom had moved into the high-risk category between week 12 and 6 months.

Satisfaction

Participants expressed high satisfaction with the program. At week 12, on average participants rated the program 9.2 out of 10 (SD 1.3). By 6 months, the average rating was 9.3 (SD 1.1).

Discussion

Principal Findings

Although CKP is a common cause of severe chronic pain and disability affecting millions of individuals, accessible comprehensive treatment programs that address multiple components of care are lacking. The challenges to effectively delivering a program involving physical therapy, education, and psychosocial support are diverse and substantial—including time constraints on primary care appointments, paucity of reimbursement for education, and lack of awareness of the psychosocial risk factors that impact outcomes for CKP. Moreover, there are significant practical and cost barriers faced by the patient—such as traveling to physical therapy appointments, large patient costs, sourcing and paying for childcare, or having to seek out education and psychosocial support on their own. Finally, tracking outcomes and program adherence is difficult if not impossible in the traditional outpatient setting, and there is a distinct lack of technology-enabled solutions for patients. The results of this study demonstrated that the Hinge Health 12-week DCP for individuals with CKP produced clinically and statistically significant improvements in knee pain, stiffness, and function that lasted over a period of 6 months following initiation of the 12-week program, and were accompanied by a significant reduction in surgery interest as well as high satisfaction. Furthermore, the digitization of exercise therapy allowed for precise tracking of participation and adherence, showing that on average participants completed exercise therapy between 3 and 4 days each week.

Participants' KOOS pain and function scores improved by clinically significant 16 and 10 points, respectively, at the end of the 12-week program. Similarly, VAS pain and stiffness scores improved by clinically significant 58% and 50% at the end of the 12-week program. These improvements are greater than or of similar magnitude to other treatment programs that have shown efficacy for CKP, including a 12-week graded physical activity exercise program which found improvements in WOMAC pain and function of 25% and 22%, respectively, immediately after program completion [39]; an 8-week exercise and education program which found improvements in WOMAC pain, stiffness, and function scores of 23%, 17%, and 23%, respectively, immediately after the completion of the program [40]; and a 6-week exercise, education, and self-management program which found improvements in WOMAC pain and function of 31% and 26%, respectively, immediately at the end of the program [10]. Deyle et al [41] found greater improvement in WOMAC score at the end of a 4-week program of manual therapy and supervised exercise (52%) versus a home-based exercise program (26%). However, the clinical intervention was more expensive than the home-based intervention and did not lead to better long-term outcomes [41], and the home-based intervention did not include any program components such as education or behavioral therapy which may improve long-term outcomes. The format of the program also did not allow the researchers to track adherence to the home exercise.

The clinically significant improvements in KOOS pain and function in this study were maintained at 6 months after starting the program, with improvements of 18 and 14 points, respectively. Similarly, the improvements in VAS pain and stiffness scores were maintained, with improvements of 60% and 58% at the 6-month timepoint, respectively. These results suggest strong maintenance of effect of the program. Similar long-term effects have been reported in other intervention programs of similar length [10,12,39-41], with clinical improvements reported to be maintained as long as 30 months after completing the programs. Although the long-term effect of the Hinge Health DCP, in particular the effect related to exercise, may in part be dependent on continued adherence to the program [42], the behavioral, educational, and psychosocial components of the program may improve the potential for long-term effects [10]. Furthermore, the comprehensive conservative care program incorporating exercise may also influence the need for future surgical treatments, as a previous treatment program incorporating exercise and manual physical therapy found a 75% reduction in TKA after participation in the program [12]. Similarly, comprehensive pain management programs for chronic back pain demonstrate a reduced need for surgery of 67% as compared with alternative medical care [6]. Surgical interventions such as TKA are effective at improving pain and symptoms following surgery, with studies finding between approximately 50% and 75% of patients experience improvement after surgery [43,44]. However, even in individuals with CKP that have all indications to warrant surgery, afflicted individuals are often reluctant to consider invasive surgical procedures, with data showing only 15-32% are willing to consider surgery for their knee pain [45,46]. In this study, surgery interest significantly decreased over the course of the 12-week program, with no participant increasing in intent for surgery. These improvements in pain and function could be maintained over the long-term, thereby circumventing surgery and its cost. However, the follow-up period of this study was too short to draw a definitive conclusion on the matter, and future research will be needed to more fully understand the economic effects of the program.

Strengths and Limitations

The results of this study demonstrate that the Hinge Health DCP shows promise for providing participants with a program to

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effectively manage their CKP condition. However, this study has several limitations. This was a single-arm study without blinding of the participants, and thus any placebo effect, for example, due to simply being accepted into the program, or regression to the mean was not able to be evaluated. Future work with a more rigorous study design such as a randomized, controlled trial as compared with standard care or multiple baseline trial will be needed to better understand the effect of the program as compared with standard care. Although the sample size was relatively small, the results demonstrated large effect sizes for primary outcomes which showed highly significant results and should be confirmed in larger future studies.

The study enrolled participants with self-reported CKP, but did not require a physician-diagnosis of knee OA. However, our recruitment questionnaire utilized questions specific to clinical diagnosis for knee OA derived from the American College of Rheumatology criteria for OA of the knee [2], and our inclusion criteria are similar to those of other knee OA studies [12,39-41]. Furthermore, participants included in this study showed typical demographics and characteristics of people living with CKP (Table 1). Our participants were predominantly female, and although a higher prevalence of knee OA and knee pain are reported in female versus male [47,48], future work should include a larger male participant population to better understand potential differences in program response due to sex.

Study results showed good subject engagement with exercise and education. However, due to the comprehensive nature of the program, it is not possible to determine if all components of the program are integral to the study results. As shown in Figure 4, we noted a substantial drop in knee pain and stiffness between baseline (screening) and the first VAS score reported, potentially as a positive consequence of the exercises performed as part of onboarding, regression to the mean, and perceived improvements due to the positive news of being accepted onto the program. To confirm that the program achieved improved outcomes not just between baseline and the first VAS, we also compared the average VAS ratings in weeks 1-4 of the program against those in weeks 9-12, and observed highly significant reductions in pain (9.3 points, 95% CI 5.7-12.8, $P<.001$) and stiffness (8.4 points, 95% CI 4.8-12.0, $P<.001$). Deyle et al [12] also noted a rapid reduction in symptoms of 20-40% after only a few treatment sessions, which was attributed to improvement from the initial therapy. Although other treatments of similar duration have found lasting effects [10,12,39,40,49], the relatively short time frame of this study, to 3 months follow-up after completion of the program, or 6 months after enrollment, requires future work to evaluate the potential of the program for long-term improvement in symptoms.

Conclusions

The results of this study demonstrated clinically and statistically significant improvements in pain, function, and stiffness following a 12-week digitally based program designed to address multiple components of care for CKP. Although the initial results with this program are promising, future research will be needed to understand the long-term effects of the program. Due to the adaptability of the system, future work may also investigate the effect of a similar program on other chronic pain conditions such as lower back pain.

In conclusion, the results of this pilot study of the 12-week digital Hinge Health DCP demonstrate improvements in knee pain, stiffness, and function which were maintained to 6 months after enrollment into the program. The program greatly reduced surgery interest in participants, providing strong evidence that the program may be an effective intervention to delay or significantly reduce the incidence of more invasive and costly treatments for CKP such as surgery.

Acknowledgments

The authors would like to thank all participants and collaborators at the study sites. The authors also thank Karl Rosenberg for expert advice on the content of the 12-week program. This study was funded by Hinge Health, Inc, the company that developed the 12-week program tested here.

Conflicts of Interest

All authors except JCE-H work at Hinge Health. JCE-H is a paid domain expert consultant.

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Abbreviations

CBT: cognitive behavioral therapy
CKP: chronic knee pain
DCP: digital care program
HADS: Hospital Anxiety and Depression Scale
KOOS: Knee Injury and Osteoarthritis Outcome Score
KOOS-PS: Knee Injury and Osteoarthritis Outcome Score-Physical Function Short Form
OA: osteoarthritis
PROM: patient-reported outcome measure
TKA: total knee arthroplasty
VAS: visual analog scale

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Original Paper

Technologies to Support Community-Dwelling Persons With Dementia: A Position Paper on Issues Regarding Development, Usability, Effectiveness and Cost-Effectiveness, Deployment, and Ethics

Franka Meiland[1], PhD; Anthea Innes[2], PhD; Gail Mountain[3], PhD; Louise Robinson[4], PhD; Henriëtte van der Roest[5], PhD; J Antonio García-Casal[6], DClinPsy; Dianne Gove[7], PhD; Jochen René Thyrian[8], PhD; Shirley Evans[9], PhD; Rose-Marie Dröes[1], PhD; Fiona Kelly[10], PhD; Alexander Kurz[11], MD, PhD; Dympna Casey[12], PhD; Dorota Szcześniak[13], PhD; Tom Dening[14], MD, FRCPsych; Michael P Craven[15,16], PhD; Marijke Span[17], PhD; Heike Felzmann[18], PhD; Magda Tsolaki[19], MD, PhD; Manuel Franco-Martin[20], MD, PhD

[1]Department of Psychiatry, VU University medical centre, Amsterdam, Netherlands
[2]Universities of Salford and Stirling UK, Manchester, Stirling, United Kingdom
[3]School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, United Kingdom
[4]Institute for Ageing, Newcastle University, Newcastle, United Kingdom
[5]Department of General Practice and Elderly Care Medicine, VU university medical centre, Amsterdam, Netherlands
[6]Iberian Research Psychosciences Institute, Psychosocial Rehabilitation Centre, Intras Foundation, Zamora, Spain
[7]Alzheimer Europe, Luxembourg, Luxembourg
[8]German Center for Neurodegenerative Diseases (DZNE), Site Rostock, Greifswald, Germany
[9]Association for Dementia Studies, University of Worcester, Worcester, United Kingdom
[10]Centre for Person-centred Practice Research, Queen Margaret University, Edinburgh, United Kingdom
[11]Technische Universität München, Munchen, Germany
[12]School of Nursing and Midwifery, National University of Ireland Galway, Galway, Ireland
[13]Department of Psychiatry, Wroclaw Medical University, Wroclaw, Poland
[14]Division of Psychiatry & Applied Psychology, University of Nottingham, Nottingham, United Kingdom
[15]NIHR MindTech Healthcare Technology Co-operative, Institute of Mental Health, University of Nottingham Innovation Park, Nottingham, United Kingdom
[16]Bioengineering Research Group, Faculty of Engineering, University of Nottingham, Nottingham, United Kingdom
[17]Windesheim University of Applied Sciences, Zwolle, Netherlands
[18]National University of Ireland Galway, Galway, Ireland
[19]Memory and dementia outpatient clinic, 3rd Department of Neurology, Aristotle University of Thessaloniki, Thessaloniki, Greece
[20]Iberian Research Psychosciences Institute, Psychiatric Department in Zamora Hospital, Salamanca University, Zamora, Spain

Corresponding Author:
Franka Meiland, PhD
Department of Psychiatry
VU University medical centre
AJ Ernststraat 1187
Amsterdam, 1081 HL
Netherlands
Phone: 31 207885623
Fax: 31 207885623
Email: fj.meiland@vumc.nl

Abstract

Background: With the expected increase in the numbers of persons with dementia, providing timely, adequate, and affordable care and support is challenging. Assistive and health technologies may be a valuable contribution in dementia care, but new challenges may emerge.

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Objective: The aim of our study was to review the state of the art of technologies for persons with dementia regarding issues on development, usability, effectiveness and cost-effectiveness, deployment, and ethics in 3 fields of application of technologies: (1) support with managing everyday life, (2) support with participating in pleasurable and meaningful activities, and (3) support with dementia health and social care provision. The study also aimed to identify gaps in the evidence and challenges for future research.

Methods: Reviews of literature and expert opinions were used in our study. Literature searches were conducted on usability, effectiveness and cost-effectiveness, and ethics using PubMed, Embase, CINAHL, and PsycINFO databases with no time limit. Selection criteria in our selected technology fields were reviews in English for community-dwelling persons with dementia. Regarding deployment issues, searches were done in Health Technology Assessment databases.

Results: According to our results, persons with dementia want to be included in the development of technologies; there is little research on the usability of assistive technologies; various benefits are reported but are mainly based on low-quality studies; barriers to deployment of technologies in dementia care were identified, and ethical issues were raised by researchers but often not studied. Many challenges remain such as including the target group more often in development, performing more high-quality studies on usability and effectiveness and cost-effectiveness, creating and having access to high-quality datasets on existing technologies to enable adequate deployment of technologies in dementia care, and ensuring that ethical issues are considered an important topic for researchers to include in their evaluation of assistive technologies.

Conclusions: Based on these findings, various actions are recommended for development, usability, effectiveness and cost-effectiveness, deployment, and ethics of assistive and health technologies across Europe. These include avoiding replication of technology development that is unhelpful or ineffective and focusing on how technologies succeed in addressing individual needs of persons with dementia. Furthermore, it is suggested to include these recommendations in national and international calls for funding and assistive technology research programs. Finally, practitioners, policy makers, care insurers, and care providers should work together with technology enterprises and researchers to prepare strategies for the implementation of assistive technologies in different care settings. This may help future generations of persons with dementia to utilize available and affordable technologies and, ultimately, to benefit from them.

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KEYWORDS

dementia; technology; evaluation studies; diffusion of innovation; ethics

Introduction

Due to our aging societies, dementia has become a 21st-century global public health concern, placing considerable burden on not only the individual and their family but also current and future service provision [1]. Worldwide prevalence is around 46 million, a figure predicted to treble to 131.5 million by 2050, with current care costs recently estimated at US $818 billion [2]. Among all chronic diseases, dementia is one of the most important contributors to dependence, disability, and care home placement [3]. Despite a global policy push toward more timely diagnosis and earlier intervention, considerable geographical inequalities in the provision of post-diagnostic care and support services exist [4]. One aspect of postdiagnostic support, which may enable persons with dementia to remain independent for a longer time and thus potentially leading to cost savings by delaying entry into care and nursing homes [2,3], is assistive technology. Assistive technology for persons with dementia can be defined as “Any item, piece of equipment, product or system driven by electronics, whether acquired commercially, off-the-shelf, modified or customized, that is used to help persons with dementia in dealing with the consequences of dementia” (see also Marshall [5]; Assistive Technology Industry Association [6]; ISO9999 [7]). The technology does not necessarily need to be “purposely designed” [8] for persons with dementia, as many mainstream technologies can be adapted to their changing needs. Important need areas in dementia are memory support, information, company, reducing psychological distress, and engaging in daytime activities [9,10]. Various technologies have been developed to address these needs, such as electronic calendars, Web-based information systems, video-calling, and electronic activity support systems [11-13].

Evaluation studies have found that persons with dementia are positive about using electronic devices to facilitate their independence and reduce family stress [11,14]. Furthermore, small-scale studies have found that assistive technologies improve independence [15], behavioral symptoms in persons with dementia [16], and quality of life [15], and stress in carers [16].

Despite the promising benefits of technological support systems, several issues remain before they will really make a difference in the field of dementia care. For example, the predominant use of technological solutions for safety and security and carer reassurance rather than for lifestyle in general [17]; the slow uptake and implementation of assistive technologies; the lack of high-quality scientific research into the effectiveness and cost-effectiveness of assistive technologies in dementia care [18,19], the lack of successful commercialization of prototype technologies; and the limited attention to aesthetics, which can make many technological support systems feel stigmatizing [20]. Furthermore, professionals and society also seem to lack an applied understanding of the potential of assistive technology in dementia because it is not being integrated into mainstream dementia care practice [20,21].

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The need to address these issues has been widely acknowledged. For example, joint research efforts on assistive technologies in dementia were identified via a taskforce on Assistive Technology setup within INTERDEM (an interdisciplinary European research network of more than 160 members, collaborating to develop and carry out pan-European research on early, timely, and quality psychosocial interventions in dementia [22]). Experts from this taskforce worked together to discuss and reach consensus regarding the current state of affairs regarding (assistive) technologies for community-dwelling people with dementia. This resulted in this position paper.

Based on literature and expert opinions, key areas were considered including development issues, usability, effectiveness and cost-effectiveness, deployment, and ethics of (assistive) technologies for community-dwelling people with dementia. The term "assistive technology" included a wide range of aids, appliances, and whole-system applications; consequently, discussions were focused on technologies that addressed the following 3 areas of global need:

1. Devices intended to help persons living with dementia to manage their everyday life across the disease journey, such as electronic calendars and reminders for activities, medication reminders, aids to perform activities of daily life, robots, and navigation systems.

2. Technologies to help people engage in meaningful and pleasurable activities such as cognitive stimulation and physical activities, as well as technologies to improve social participation, contact, and support.

3. Health care technologies that aim to support professional organizations and systems within dementia health and social care, such as behavior monitoring, shared decision making, and Global Positioning System (GPS) tracking systems.

We concluded with a set of recommendations for key stakeholders including the research community, technology developers (industry and business), care commissioners, and care providers to better prepare them to ensure the ongoing delivery of high-quality, efficient care and support to the growing numbers of persons living with dementia and their families.

Methods

Literature reviews were performed by members of the taskforce Assistive Technology, who met twice (Ljubljana, September 2015; Berlin, October 2015) to discuss the aim and methodology of this study and divide the work. Each subsequent section was led by 2 taskforce members and prepared by a subgroup of the taskforce Assistive Technology.

The section on technology development was based on expert opinion and relevant literature, among other previous reviews of taskforce members [23,24]. For the sections on usability, effectiveness and cost-effectiveness, and ethical issues, separate literature searches were conducted in PubMed, CINAHL, PsycINFO, and Embase databases. Common search terms were used for dementia ("Dementia"[Mesh]) OR (dement* OR alzheimer* OR lewy OR CJD OR JCD OR creutzfeldt OR binswanger OR korsakoff OR frontotemporal OR FTD OR "vascular dementia" OR VaD OR "pick disease" OR "picks disease") and technology ((assistiv* OR orthotic* OR supportiv* OR electronic*) AND (technolog* OR device*)) OR telecare OR "Self-Help Devices"[Mesh] OR ("information communication technology" OR ICT), added with specific terms for the sections on usability ((usability AND (computer OR technology OR software OR virtual reality)) and ethics (ethic*). Inclusion criteria were reviews in English, reporting (partly) on persons with dementia living in the community, and technologies in 1 or more of the 3 selected areas (daily living, meaningful and pleasurable activities, and health care technology). There was no restriction on publication dates, and the searches were finalized in January 2016.

All records from the searches were reviewed by at least two independent researchers in each section to check whether they should be included. Another researcher was involved to reach consensus in cases of disagreement. Reviews that met the inclusion criteria were included, and the results of the reviews (or single studies in the reviews if relevant) were summarized. For the section on deployment, searches were conducted in specific Health Technology Assessment databases, using the search terms: assistive technology dementia.

Results

Development Issues Regarding Assistive Technologies for Daily Living, Meaningful and Pleasurable Activities, and Health Care Technology

In the past, devices for older people were generally created by technologists with little attention to the specific needs of older end users, and thus the users' requirements of devices. Nowadays, there is wider understanding of the importance of engaging end users at all stages of technology development to ensure their needs are addressed and to promote acceptance of technological aids. However, challenges in the development of technological devices were identified as follows: How can technologies address the heterogeneous needs of persons with dementia? Should technologies be designed specifically for dementia or adapted from mainstream technology? What methods are more efficacious when developing technologies for persons living with dementia? Finally, we addressed what challenges are to be faced regarding developmental issues in the 3 selected application areas of assistive technology.

Technologies to Address the Heterogeneous Needs of Persons With Dementia

To develop technologies that are useful and valuable for persons with dementia, it is important to know what kind of assistance is needed. This requires a thorough understanding of the different types of dementia and associated impairments, individual experiences and coping mechanisms, and the continuous changing situation during the dementia "journey." It is also important to be attentive to needs such as a sense of self-esteem and feeling respected, which are related to higher levels of well-being and quality of life, as highlighted in Maslow's "hierarchy of needs" [25,17]. People with dementia can express their needs [26] and preferences [27] consistently,

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even in an advanced stage of dementia [28]. Therefore, to really understand what it is to live with dementia and which needs should be addressed, people with dementia should be asked about their needs and experiences and be involved early in the process of development of supportive tools and interventions. Till now, very few technologies have actually been designed to meet the specific needs of people living with dementia [29], and only few of these prototypes have been adopted for commercial development.

Technologies Designed Purposively for Dementia or Adapted From Mainstream Technology

Technologies can be divided into those designed specifically for persons with dementia as opposed to technologies that have been developed in the mainstream and lend themselves well to support people with cognitive difficulties. For example, the functionality of some forms of telecare technology, such as GPS, webcams, and apps (Joint Improvement Team, 2016), is being superseded by readily accessible off-the-shelf devices that can successfully assist people to navigate their day. Also, recent work has confirmed that persons with dementia can be supported to use touchscreen computing for leisure and recreation in line with the rest of society [29]. Nevertheless, the complex sensory, perceptual, and cognitive changes caused by dementia can make using mainstream devices problematic for some persons with dementia, and therefore for the foreseeable future, some demand for bespoke devices will continue.

Methods of Technology Development in Dementia

In developing assistive technologies in health care, there has been a shift from expert- and technology-led design toward a user-driven approach, and it is more common to now involve end users.

Examples of methods that support end user involvement and aim for sustainable eHealth innovations are the holistic approaches of the roadmap of the Centre for eHealth Research and Disease Management (CeHRes) [30] and Contextual Design [31]. Both methods are rooted in human-centered design (HCD) and emphasize 3 interrelated components: technology, people, and organization (health care environment). The CeHRes roadmap focuses, in particular, on the health domain and combines HCD principles with business modeling.

For dementia, the drive to ensure engagement at all stages of technology development is underpinned by the principles of person-centered care and, in a broader perspective, by a social inclusive society. This includes the coproduction of new innovations for research and for practice, with the involvement of end users from the outset [32,33]. In practice, however, people with dementia have rarely been involved in technology development, with user acceptability tending to be assessed via family carers and others [11,24,34]. Successful examples of collaborative working with people with mild-to-moderate dementia are emerging [14,33,35-37]. However, people with more severe dementia are less often included in development of assistive technologies.

Challenges in the Development of Assistive Technology

Challenges in the development of assistive technology include the need for personalized and tailored technologies in dementia. A “one size fits all” is not an optimal solution because of the individual variations in needs and abilities. The development of sustainable assistive technology for persons with more severe dementia is a challenge, as is how to develop technologies in a way that will help to make the world a more “dementia-friendly” place [38]. Examples of assistive technologies that can help persons with dementia in their daily life are simple aids such as calendars and reminders but also more complicated devices such as robots that perform a social role or augment individual human capabilities through cognitive prosthetics [39]. There are companies who anticipate providing inclusive assistive technology solutions for older people, including those with dementia, for example, Alcove [40]. One research challenge is how to develop assistive technologies that address the emotional state of persons with dementia during everyday tasks [41]. One of the challenges in the field of health care technology, which supports organizational and supportive systems of dementia care, is to integrate technology into the built environment, such as lighting, floor coverings, and improved way-finding (eg, via improved signage), taking into account the varying and changing needs of the residents [42,43]. Another challenge is to integrate technology into the routine health care, using information and communication technology (ICT) in the clinical assessment of cognitive, behavioral, and physical functioning of persons with dementia [44].

Conclusion on State of Affairs Development of (Assistive) Technologies in Dementia

Research has revealed that persons with dementia are enthusiastic about using assistive technology to remain independent and also about taking part in technology design [23,33]. At the same time, some challenges remain, such as how to personalize and tailor technologies to the individual and changing needs and abilities of persons with dementia. We envisage that the involvement of end users in developing new assistive technologies will continue to grow, and that more applications of existing technology using mobile phones or apps will be put to use to benefit persons with dementia.

Usability of Assistive and Health Technology in Dementia

The International Organization for Standardization defines usability as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use” [45]. Thus, usability refers to the capability of the technology to be understood, learned, and used under specified conditions. The literature review on usability issues in dementia resulted in 89 papers (Figure 1). The main results are discussed in the following sections.

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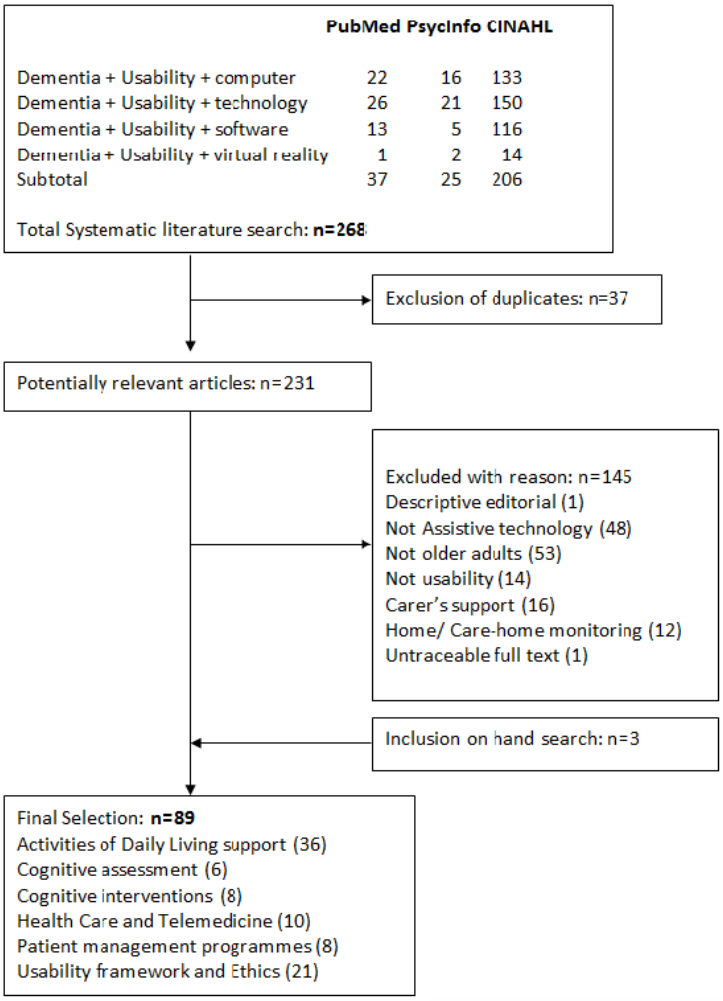
Figure 1. Flowchart of systematic review on usability.



Usability of Technologies to Support Persons With Dementia in Everyday Life

Little research so far has been conducted in the field of assistive technologies in community dementia care and support, with only 3 studies exploring usability in supporting everyday life with a Day Navigator [46], a GPS [47] and a timer device [48]. In the study by Meiland et al, 42 participants and carers considered the Day Navigator to be mainly user-friendly, but conclusions about usefulness were limited due to insufficient duration of the testing period [46]. The GPS system was tested among 33 dyads, with only 1 leaving the study because of technical reasons. Participants with dementia who went outside unaccompanied took the GPS with them 67% of the time. Also, 80% (20/25) of the caregivers said that the use of the technology was not difficult, and almost all of them felt that they were in control of the secured website where they could track and trace their relatives (92%; 23/25). The study does not provide specific information about usability outcomes apart from ease and frequency of use and the fact that the participants with dementia did not seem to mind that they heard a voice from their GPS without notification [47]. The timer device was used for a stove and tested with 9 older adults with cognitive impairment or dementia and 5 relatives. The authors found that end users scarcely participated in the process of choosing and adapting the device. Although the device provided increased safety, there were also some unforeseen problems, such as not fully understanding how the device worked. The authors stressed the importance of actively involving users in home modifications with assistive technologies and providing medium- and longer-term follow-up of the technological support [48].

Usability of Technologies to Support Participation in Meaningful and Pleasurable Activities

In research on technology to participate in meaningful and pleasurable activities, for example, cognitive interventions for persons with dementia, usability issues are often not mentioned. Jelcic et al [49] reported a positive perception of technology-based cognitive therapy, as participants would recommend it to others and were satisfied with the utility and appeal of this intervention. Zaccarelli et al [50] found that the educational level of users was important, as results of the studies on people with Alzheimer's disease, mild cognitive impairment and healthy adults showed that participants with a higher education level found it easier to learn how to use the ICT platform. Lee et al [51] reported that the usability of their computer-based cognitive intervention was good. Persons with dementia were highly motivated in using it, and their sense of achievement was enhanced; they took pride in showing others that they could operate the computer [51]. Gillespie et al [52] suggested that large-scale studies of assistive technology to improve cognition should also focus on functional areas, for

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example, prompting, navigating, and reminding, rather than on the specific content of the devices itself.

Factors Influencing Usability

Over time, persons with dementia may have reduced ability for new learning, which may impact actual use of technology because learning and technology use are inseparable and proceed together [53]. Understanding how persons with dementia access and embrace technology is vital in order to develop usable and acceptable technological solutions. Technology use by older adults has been criticized for not eliciting and including their interests [54]. Devices should be adjusted to each individual, achieving better tailored interventions, and assistive technologies should be embedded in a person-centred model [55]. A good example of this is the provision of feedback sessions to ensure that the person with dementia and carer understand the assistive technologies, to answer questions, and to collaboratively discuss recommendations for improvement [56]. A recent review (not limited to dementia) on mHealth applications suggested the adoption of automated evaluation mechanisms to improve the empirical methods to assess usability [57].

Furthermore, a good match between the person and the technology is required because if this is not achieved well from the end user's perspective, the technology may be ignored or not be used optimally [58]. Bardram et al [59] emphasized the importance of deploying assistive technologies in a real-world setting, outside the laboratory, and also the need to perform longitudinal studies that assess the evolution of the relationship between the end user and the technology [59]. A person's acceptance of assistive technologies can vary during the course of dementia. For example, acceptance can improve when symptoms start to threaten the independence of the person [60]. The ability to use assistive technology may also vary. Over time, a decreasing use of technology is seen in people with cognitive impairment [61].

It has been suggested that usability studies of assistive technologies should be designed in several stages: predeployment (observation sessions, focus groups with people with dementia, carers, and professionals); deployment (carrying out long-term observations and quantitative and qualitative assessments in real settings); and postdeployment (feedback sessions) in close partnership with end users, carers, and specialists [62].

Usability in the Area of Computer Technologies

In the area of computer technologies, usability of interfaces has received special attention. Research on the preferences of persons with dementia has indicated that touchscreen devices are preferred over mouse or keyboard input devices [63]. Direct response devices using a touchscreen reduce the distance between the subject (seeing the stimuli) and the causal effect (providing the answer), which enhances the person´s involvement in the task. The previous experience of people with dementia with computers affects which type of interface device they prefer, with experienced users preferring the mouse. However, although the mouse is the most demanding device in terms of cognitive and motor demands, there can also be problems with touchscreens in terms of accuracy that may be frustrating for the end user [64]. Computer literacy has an important role in usability: lack of computer experience was reported to decrease the odds of successful use of technology [65]. Thus, pretest, treatment, or intervention training sessions could be used to enable persons with mild cognitive impairments and early dementia to become familiar with novel technologies [66-69]. The need for including performance tests to enhance the ecological validity of assistive technologies has been highlighted, such as measuring the user's motivation [54]. Although there is a prejudice that assistive technologies are not "elderly friendly," in fact the evidence points in the opposite direction: when older adults get the opportunity to use computers, they regard them as a "status symbol" often associated with youth; as a consequence, the use of computers could have a positive effect on self-confidence and self-esteem [70].

Regarding the assessment of the usability of assistive technologies and user satisfaction, various tools were used, for example, the usefulness, satisfaction and ease of use questionnaire [71]; the Everyday Technology Use Questionnaire [72]; the Quebec User Evaluation of Satisfaction with Assistive Technology [51]; and the model of technology acceptance, specifically developed to test the acceptance of assistive social agents by older adults [73]. There is a lack of tools to evaluate the usability of assistive technologies in persons with severe dementia.

To conclude, despite advances in the field of technology-based interventions for persons living with dementia, few applications have been analyzed for their usability. Technologies can be used by many persons with dementia, but additional support is often needed from informal caregivers or professionals. To promote better utilization of technologies in dementia care, a better understanding is needed of their usability for persons with dementia, people's preferences for specific interfaces, and their acceptance of different technologies.

Effectiveness and Cost-Effectiveness of Assistive and Health Care Technologies in Dementia

The flowchart in Figure 2 illustrates the literature retrieved on effectiveness and cost-effectiveness of assistive and health care technologies. Eighteen reviews met our inclusion criteria, most of which (n=10) described a combination of the 3 technology domains we focused on in this study. One review focused on technologies to support persons with dementia in everyday life, 3 on technologies for engagement in pleasant and meaningful activities, and 4 on health care technology to support organizational and supportive systems. From the selected reviews, 55 individual studies described the effects of technologies on persons with dementia, the results of which are described in the following sections. None of the empirical studies described the cost-effectiveness of assistive and health care technologies for community-dwelling persons with dementia.

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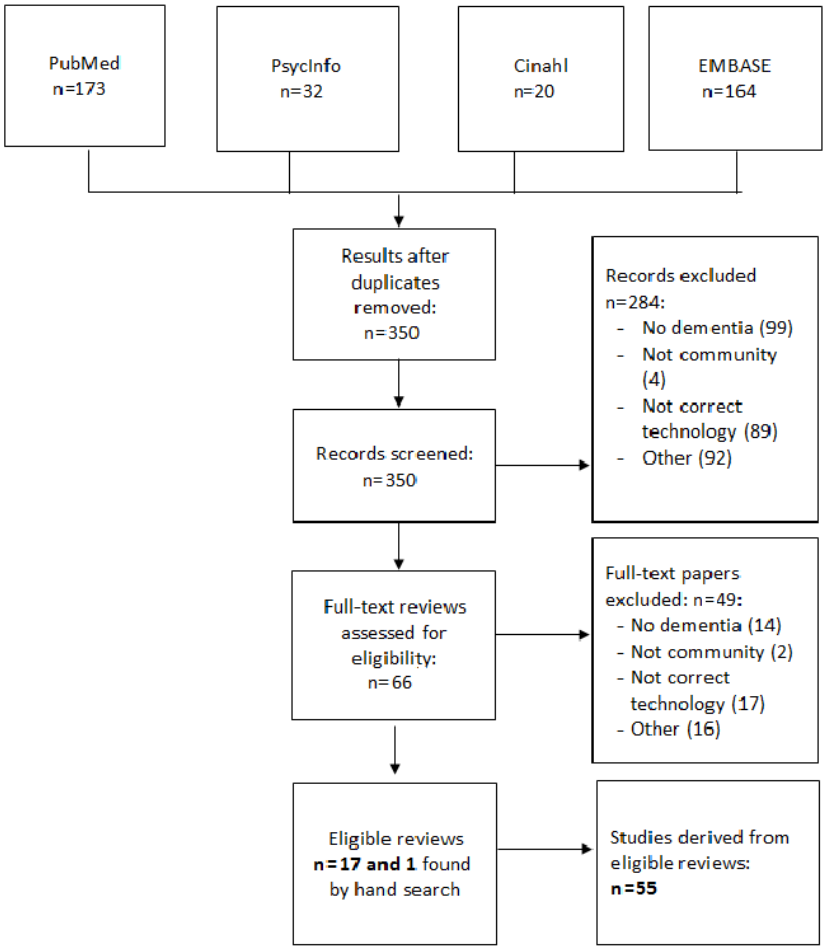
Figure 2. Flowchart of systematic review on effectiveness and cost-effectiveness.



Assistive Technologies to Support Persons With Dementia in Everyday Life

Within this domain, many devices have been tested for their effectiveness. For example, a calendar was positively evaluated by more than half of the 21 participants [74]; a training device (based on errorless learning) to guide people with dementia in using a mobile phone was reportedly effective [75]; prompting devices to support in activities of daily life or in memory were found useful [76,77] and effective [76-80]; and prompts were found effective for traveling [81-84]. However, another prompting device found no impact on quality of life [85], which might have resulted from the many technological problems encountered during the effect pilot study. The NeuroPage [86] was tested in a randomized controlled trial (RCT) and showed a significant reduction in memory and planning failures by providing prompts; however, this study included patients with brain injury, and only a small number had dementia. Although tracking devices are said to be effective [87,88], 1 study showed that only a minority used such devices successfully, and 1 patient was injured by a passing vehicle [89]. Two studies also identified positive effects of tracking devices for caregivers (relief or reduction of emotional distress) [87,90].

Assistive Technologies to Support People With Dementia in Meaningful and Pleasurable Activities

Within the domain of technologies for meaningful or pleasurable activities, computer programs with cognitive training applications showed improvements in task performance or cognition in persons with Alzheimer's dementia [70,91], recall [92], global cognitive functioning, and emotion [93,94]. However, devices with prompts for creative activities were found to be not effective [95,96], although participants liked the activities with an ePAD (Engaging Platform for Art Development) [95]. Social robot therapy for stimulating interaction showed an improvement in brain activity in half of the 14 participants [97]. Research into the use of multimedia tools to support people with dementia has reported improvements in well-being [98,99], mood [100], psychological stability [101], and social interaction and engagement [100,102-107]. In another study, a music tool was enjoyed by its users, but the prompts proved difficult to understand for the person with dementia [96]. Telephones or videophones have been reported as being easy to use for persons with dementia and helpful for maintaining social contacts, and they positively affected self-esteem [108-110].

Health Care Technologies

Health care technologies to facilitate health care delivery for people with dementia included sensors to monitor behavior,

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virtual reality, and video conferences. Sensors and smart home technologies are said to provide a good image of performed activities [111] and were reportedly successful in preventing major incidents [48,112,113]. Reported effectiveness of these tools in helping persons with dementia to live longer in the community varied [114,115]. One large controlled study [15] concluded that smart home technologies helped persons with dementia by improving confidence, ability to maintain community living for a longer time, and reducing need for care visits. A single case study found a reduction in required support, perceived anxiety, and confusion by the person with dementia [116]. Comparison of the use of video conferences for, for example, clinical assessment showed no differences compared with face-to-face assessments [117-119]. Clinical improvements were found for almost half of the study sample that received telecare, which consisted of telemedicine, tele-education, and telecounseling services [120], and this kind of telecare could be promising for rural populations [119].

Conclusion of Effectiveness and Cost-Effectiveness Assistive and Health Technology in Dementia

To summarize, various benefits of assistive technologies for persons with dementia have been reported. However, the results described need to be interpreted with caution because the majority of the included studies were uncontrolled studies with relatively small sample sizes. Reviews on cost-effectiveness studies of assistive and health care technologies in dementia were not found.

Deployment of Assistive and Health Technology

Results regarding deployment were based on (1) recommendations for deployment of health technology identified by an expert panel and (2) a literature search using databases regarding health technology assessments (HTAs) and health services or technology assessments (HSTAs). These databases were chosen because they are specifically designed to give evidence-based recommendations and are directed at a nonscientific audience, for example, stakeholders who want to deploy health technology. The search resulted in 17 papers, of which 5 were relevant for the issues under consideration.

Deployment Issues

According to the Ambient Assisted Living Association (AALA) [121], “the market is growing beyond its traditional boundaries and this is attracting a growing interest by potential investors, the ICT industry and all service and care providers.” The landscape of the market will be deeply modified by a combination of a demand pull (by the rapidly growing population of older persons) and a technology push (through development of new ICT solutions and services) ([121], p. 76). A key recommendation of the AALA was to develop a European observatory with the mission to become the main source of trusted and high-quality information and data on the market to inform all stakeholders.

The next 3 paragraphs consider factors that influence deployment related to demand pull of stakeholders in general, health care professionals, and persons living with dementia.

Deployment Factors: Stakeholders in General

Stakeholders need trusted and high-quality information from HTAs or HSTAs. However, reviewing the current situation of HTA or HSTA delivers disappointing results in that these data, mainly provided by national bodies, are often incomplete, with many variations in definitions, information provided, and quality and reliability of the data [121].

The users of these data include health care providers, health service researchers, policy makers, funders, consumers, and information professionals (eg, in United States [122]; United Kingdom [123]; Germany [124]). Solely searching the HTA databases that provide English literature with the search term “assistive technology dementia” reveals few results (ie, United States: 14 books; United Kingdom: 3 items). Two of them provide facilitators and barriers (expanded upon later) to the deployment of technology: Jimison et al [125] and Finkelstein et al [126]. One is a systematic review on the effectiveness of assistive technology which does identify some of the barriers that are also mentioned in Jimison et al [125] and Finkelstein et al [126], and the other is a bibliographic record of an ongoing health technology assessment being undertaken [127]. One result was a Cochrane protocol focusing on the efficacy of assistive technology for memory support in dementia [128]. The other results were either not related to dementia or were not focusing on assistive technology.

Deployment Factors: Health Care Professionals

A range of constraints limiting deployment and related to the technology and health care sectors were identified at a workshop (2014) involving Ambient Assistive Living (AAL) and Joint Programme for Neurodegenerative Diseases (JPND) stakeholders; 25% of the projects funded by AAL and JPND are about developing ICT-based solutions for support and care of older adults with cognitive impairments [129]. These constraints came from a range of sectors including health and social care and business, covering aspects such as open standards, finance and business models, skills, and simply knowing what is available and where there are gaps in the market.

When assistive technology is used to enable support and care processes, barriers include the following: lack of usability; problems with access to the health IT application, low computer literacy in patients and clinicians, insufficient basic formal training in health IT applications; physicians’ concerns about more work; workflow issues; problems related to new system deployment, including concerns about confidentiality of patient information; depersonalization; incompatibility with current health care practices; lack of standardization; and problems with reimbursement [121]. Facilitators for the utilization of health IT included ease of use, perceived usefulness, efficiency of use, availability of support, comfort in use, and site location [126].

Deployment Factors: Persons Living With Dementia

Barriers for deployment of assistive technologies for the end user, which might also apply to a wider audience than dementia, include the following: usability problems, unreliable technology, the lack of consumers’ perceived benefit from using the system, inconvenience, data entry being cumbersome, and the

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intervention not fitting into the user's daily routine. Deployment appeared to be more successful if the intervention could be delivered by technology that consumers already use daily for other purposes, and that satisfactorily meet their needs [125].

In conclusion, to promote successful deployment of assistive and health technologies in dementia care, it is essential that the technologies are reliable, user friendly, and useful; and that there is a single centrally funded access point to high-quality information regarding assistive technology products relating to dementia for all stakeholders. The Assistive Technology Dementia website [130] provides such a platform but is reliant on short-term funding (donations and grants), which means that optimization of information and sustainability are compromised. Furthermore, education and training in the field of technologies in dementia care should be available for all stakeholders.

Ethical Considerations

The analyses of the literature search regarding ethical considerations resulted in 33 references in which ethical issues were discussed linked to the use of assistive technology by or for persons with dementia living at home (see flowchart in Figure 3). The documents reviewed all covered at least one of the 3 assistive technology domains in the following numbers: technologies to support people in managing everyday life (13), to support in pleasurable and meaningful activities (1), health care technologies (1), and a combination of domains 1 and 2 (5), domains 1 and 3 (1), and all 3 domains (12). There was variation in the terminology used to cover ethical issues in relationship to assistive technology and in the coverage and the depth of consideration of such issues. Table 1 shows 7 categories of ethical issues resulting from the analysis and the reference numbers of the articles or studies in which they were addressed.

Figure 3. Flow chart of systematic review on ethics.

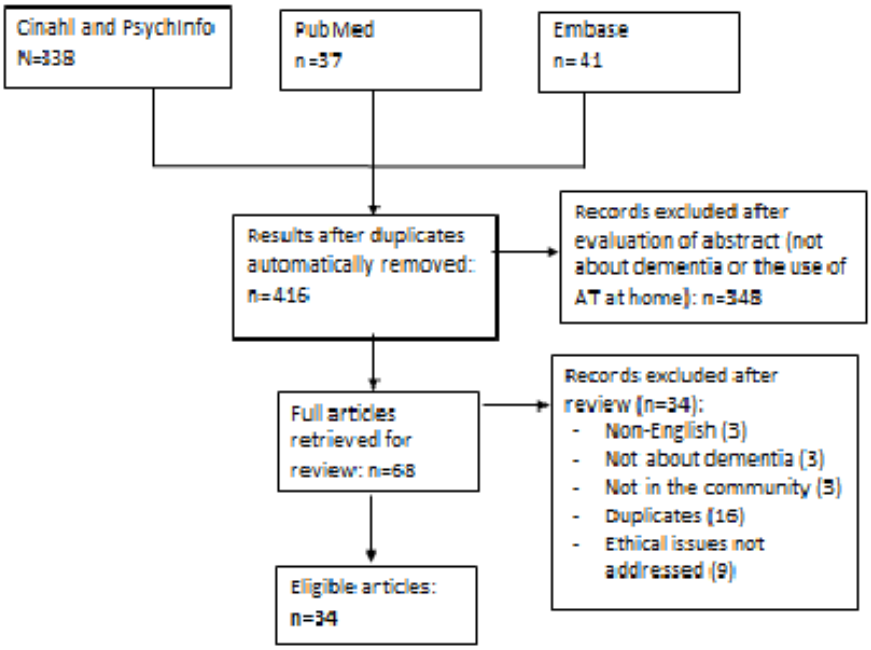

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Table 1. Ethical issues addressed in the articles reviewed.

Category of ethical issue	Additional topics included	Articles or studies that addressed these ethical issues
Autonomy, freedom // paternalism, disempowerment	Informed consent, independence, the right to take risks, individuality, self-esteem and identity versus the use of restraint and coercive measures, over-protection	Cash [131]; Kang et al [132]; Landau et al [133]; Landau et al [134]; Landau et al [135]; Landau and Werner [136]; Lindqvist et al [137]; Mahoney et al [138]; Mao et al [139]; Martin and Cunningham [140]; McCabe and Innes [141]; McKinstry and Sheikh [142]; Mehrabian et al [143]; Miskelly [88]; Olsson et al [144]; Pino et al [145]; Plastow [146]; Pot et al [47]; Rauhala and Topo [12]; Robinson et al [14]; Robinson et al [147]; Robinson et al [148]; Siotia and Simpson [149]; Sorell and Draper [150]; Van Berlo [151]; Welsh et al [152]; Werner and Landau [134]; White and Montgomery [153]; Zwijsen et al [154]
Dignity, personhood // stigma, discrimination	Devaluation	Hughes et al [155]; Kang et al [132]; Landau et al [135]; Landau and Werner [136]; Mahoney et al [138]; Mao et al [139]; Marshall [156]; McCabe and Innes [141]; Plastow [146]; Robinson et al [14]; Robinson et al [147]; Robinson et al [148]; Sorell and Draper [150]; Werner and Landau [157]; White and Montgomery [153]; Zwijsen et al [154]
Social inclusion // replacement or loss of human contact	Simulated presence, staffing issues, and deception	Cash [131]; Kang et al [132]; Landau [133]; Landau et al [135]; Mahoney et al [138]; Marshall [156]; Martin and Cunningham [140]; Pino et al [145]; Plastow [146]; Robinson et al [147]; Siotia and Simpson [149]; Van Berlo [151]; Welsh et al [152]; Werner and Landau [157]; Zwijsen et al [154]
Privacy and data security	Confidentiality	Frisardi and Imbimbo [158]; Kearns and Fozard [159]; Landau et al [133]; Landau et al [134]; Landau et al [135]; Landau and Werner [136]; Mahoney et al [138]; McCabe and Innes [141]; McKinstry and Sheikh [142]; Mehrabian et al [143]; Rauhala and Topo [12]; Sorell and Draper [150]; White and Montgomery [153]; Zwijsen et al [154]
Overreliance on technology, new risks, false security		Landau et al [135]; Mao et al [139]; Marshall [156]; Martin and Cunningham [140]
Beneficence // nonmaleficence	Wellbeing, minimizing distress and harm (not only for people with dementia), for whose benefit the AT is used	Cash [131]; Hughes et al [155]) Kang et al [132]; Landau et al [133]; Landau et al [135]; Landau and Werner [136]; Lindqvist et al [137]; Mahoney et al [138]; Marshall [156]; McCabe and Innes [141]; Mehrabian et al [143]; Pino et al [145]; Pot et al [47]; Robinson et al [147]; Robinson et al [148]; Siotia and Simpson [149]; Sorell and Draper [150]
Equity or justice	Issues related to the individual and society (including costs)	Cash [131]; Mahoney et al [138]; Martin and Cunningham [140]; Mehrabian et al [143]; Rauhala and Topo [12]; Siotia and Simpson [149]; Van Berlo [151]; Welsh et al [152]; Werner and Landau [157]; Zwijsen et al [154]

A wide range of ethical issues were addressed but with a focus primarily on 3 of the 4 biomedical ethical principles (respect for autonomy, beneficence, and nonmaleficence) as well as on issues associated with care ethics and human rights (eg, social inclusion, human contact, personhood, dignity, and discrimination). Most researchers addressed a comprehensive range of ethical issues in the introduction to their article (ie, to contextualize their study or argument), but some gave much less attention to them when reporting their findings.

Several researchers (eg, Hughes et al [155]; Landau et al [133,135]; and Pino et al [145]) demonstrated a nuanced understanding of various ethical issues associated with the use of assistive technologies specifically for or by persons with dementia. This involved, for example, reflection on opposing concepts and concerns, such as social inclusion versus loss of human contact, or respect for autonomy versus concerns about safety (touching on coercion and paternalism). Some authors (McCabe and Innes [141]; Robinson et al [14]) emphasized that ethical issues are related to the way assistive technologies are used rather than inherent in particular devices or systems (eg, a device is not inherently stigmatizing; tracking devices may, depending on the situation and the individual, be experienced as either promoting or reducing freedom and autonomy).

Issues were frequently described in terms of ethical dilemmas of which 2 are notable. The first is about privacy and respect for autonomy versus safety and minimizing risks. The more safety a person with dementia wishes to have, the more it may be necessary for them (or others on their behalf) to accept some loss of privacy or autonomy and with various possible negative consequences (eg, safety at the expense of reduced quality of life, some risk but possibility to delay entry into residential care, deterioration of carer's quality of life or health). The second ethical dilemma is about obtaining informed consent from persons with dementia due to possible difficulties understanding complex technology and loss of awareness over time of the presence or purpose of assistive technology, or that data is being collected on them.

Discussion

Principal Findings

The aim of our study was to describe the state of the art regarding development issues, usability, effectiveness and cost-effectiveness, deployment, and ethics of (assistive) technologies for community-dwelling persons with dementia, and based on that, to recommend a roadmap for development, research, and practice to support and promote the use of assistive

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technology, thus preparing society for the growing number of people with dementia.

A literature review was performed in the fields of usability, effectiveness and cost-effectiveness, and ethics. Most reviews were found in the field of usability, with the majority of these papers evaluating technologies to support daily living. In the field of effectiveness and cost-effectiveness, most reviews described a combination of the 3 technology domains we focused on in this study, and in the field of ethics, topics were addressed that were less related to the domain of technology, but rather to the way technology was used and the consequences for the user regarding, for example, autonomy and dignity.

Based on the results of the literature reviews and expert opinions, the following can be concluded about the state of the art of assistive technology for persons with dementia:

Development issues: Research has revealed that people with dementia are enthusiastic about using assistive technology to remain independent and also about taking part in technology design [23,33]. It is envisaged that the involvement of end users in the development of new assistive technologies will continue to grow, and that more applications of existing technology, using, for example, mobile phones and apps, will be put to use to benefit persons with dementia. We also anticipate that more companies will show an interest in this market, thus promoting the daily use of assistive technologies in dementia care. However there are also challenges such as how to personalize and tailor technologies to the individual needs and abilities of the person with dementia, how to address the emotional state of persons with dementia during everyday tasks [41], and how to integrate technology into the built environment and routine health care.

Usability issues: Little research so far has been conducted in community dementia care and support, with only a few studies exploring the usability of assistive technology in supporting everyday life [37,47,48]. The results showed that people with dementia were able to use the technology, but that additional support by informal caregivers or professionals was often needed. Furthermore, research showed that successful use of technology was related to computer literacy [65], and level of education of the users [50]. In the field of meaningful and pleasurable technology-based interventions, such as cognitive interventions for people with dementia, usability is generally not mentioned. However, a recent review showed promising findings for these activities using touchscreen technologies [160]. More research on usability in all areas of assistive technology is needed.

Effectiveness and cost-effectiveness: Various benefits of assistive technologies for people with dementia have been reported, such as cognitive and social functioning, mood and well-being, and reduction in service use. However, these findings need to be interpreted with caution because the majority of the included studies were uncontrolled, with half of them having included less than 10 persons with dementia. Most of the controlled studies included between 10 and 30 participants, and there were only 2 RCTs (1 with 46 and 1 with 143 participants of which less than 8% were people with dementia). No studies were found on the cost-effectiveness of assistive technologies or health technology interventions.

Deployment: Many barriers were identified ranging from a lack of knowledge about technology solutions, lack of usability and training, low computer literacy to incompatibility with current health care practices and reimbursement issues. Future projects should therefore focus more on the deployment of assistive technology, and appropriate business plans and scenarios need to be developed for bringing these technologies to the market. Looking to the future of the implementation of assistive technology in general, Peterson et al [161] concluded that future assistive technologies would be more integrated into the environment, combined with ambient and intelligent technologies, the potential of cloud computing, and the Internet of Things (a global network of physical objects that contain embedded technology to communicate and sense or interact with their internal states or the external environment). Assistive technologies will also become more personalized to individual needs and user requirements. These developments, however, will bring new challenges (see below).

Ethical issues: Many ethical issues were addressed by authors in the introduction of their papers, but less were described in the description of the results. With regard to assistive technologies in dementia, several authors stressed that ethical issues were not in the first place related to the technologies themselves but rather to how people use them. Ethical issues that were often described in this field are the dilemmas between autonomy and risk versus privacy reduction and increased safety and difficulties obtaining informed consent when persons with dementia do not understand or are not aware of the presence of the technology.

The Identified Challenges

We identified several challenges for research into the selected research topics in the next few years.

Challenges in the development of assistive technology include how to develop these technologies in a way that meets individual variations in needs and abilities of persons with dementia, so that they really help to maintain autonomy, provide meaningful activities, and promote social inclusion. Another challenge is how to develop assistive technologies that address the emotional state of persons with dementia during everyday tasks [41]. A challenge in the field of health care technology supporting organizational systems and services in dementia care is to integrate the technology into the built environment, such as lighting, floor coverings, and improved way-finding [42,43], and into the routine health care, for example, by using ICT in the clinical assessment of cognitive, behavioral, and physical functioning of persons with dementia [44].

A challenge regarding usability lies in identifying those applications that have particular relevance for people living with dementia. A reiterated theme out of each of the literature reviews is the essential requirement to involve those with a diagnosis of dementia in identifying which needs technologies should meet, and in the development and usability testing of technology that is intended for people with dementia.

A challenge in effectiveness and cost-effectiveness research is to conduct methodologically sound scientific research in this field comparing assistive technology with care as usual. To

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conduct RCTs with large enough samples may be difficult because the assistive technologies may be expensive or it may be invasive to have them implemented in one's home, for example, with sensors and cameras installed. Another challenge is to select adequate outcome measures that reflect the results of assistive technology interaction [161]. A third challenge is rooted in the fact that technology is an ever-moving target [20]. Everyday devices are continually developing with newer technologies coming to market, rendering evaluation of any one device obsolete within a short time frame. There is a clear need for new methods of rapid technology appraisal and evaluation to inform deployment [162].

Regarding deployment, the challenge lies in overcoming the barriers that will be faced as a result of the expected further integration of technologies within the built environment. These are challenges concerning, for example, data storage, system integrity, privacy and security, networked architecture, and service provision. Furthermore, having a good source of trusted and high-quality information on assistive and health care technologies to inform relevant stakeholders who may further implement them will be another challenge.

As for ethical issues, a challenge will be obtaining informed consent of participants with dementia for research on assistive technologies. This may have to do with difficulties in understanding what the technologies encompass and a lack of awareness over time of the presence and use of technology, or with data that are collected on people with dementia. Another challenge is to ensure that ethical issues are considered an important topic for researchers to include in their evaluation of assistive technologies.

Limitations

The interpretation of assistive technologies used for the evidence reviews embraced bespoke devices developed to support persons living with dementia to manage their everyday life and participate in meaningful and enjoyable activities and health care technology. However, these reviews can only provide a retrospective snapshot of what has been researched rather than reflecting the current picture and what the future might hold. Also, the literature reviews were limited to (systematic) reviews rather than single studies because we aimed to get a global overview of the state of art. Furthermore, we did not consult persons living with dementia regarding their experiences and priorities.

Recommendations

Our work underscored the challenge of determining the current "state of the art" in technology development and deployment given the dynamic definitions and various understandings of what assistive technologies are. This complexity is magnified when assistive technologies are situated within dementia. Nevertheless, based on the current literature, we recommend the following actions for development, usability, effectiveness and cost-effectiveness research, deployment, and ethics of assistive and health technologies across Europe and suggest that they are included in national and international calls for funding and assistive technology research programs in the coming decade (Textboxes 1-4).

Textbox 1. Actions to improve the development and usability of assistive technologies.

- Persons with mild-to-moderate dementia or their supporters must be involved in all projects that aim to develop or test technologies for their ultimate benefit; this must be a prerequisite for project funding.
- Researchers involved in such technology development for persons with dementia must have adequate knowledge of dementia and, if not, receive specific training and support to enable full and meaningful engagement with persons with dementia; this should also be a prerequisite for funding.
- Steps must be taken to ensure that unnecessary replication of technology development that is proven unhelpful or ineffective does not occur.

Textbox 2. Actions regarding research into the effectiveness of assistive technologies.

Research into the effectiveness of assistive technologies should move beyond explorative studies and include more and larger RCTs.

The focus should be on how technological services succeed in addressing individual needs of persons with dementia, as the population is heterogeneous and many face comorbid conditions.

Many different outcome measures are used in effect studies, making it difficult to synthesize the results of individual studies. Consensus on the use of outcome measures in this field is recommended [163]. Also, other designs such as randomized block designs with sufficient power can be considered to study these effects.

Research is needed on the cost-effectiveness of assistive technologies.

New methods of technology evaluation are required so that the results can be rapidly obtained and translated into practice, such as logging use and electronic ecological momentary assessments.

Textbox 3. Actions regarding the deployment of assistive technologies.

Persons living with dementia and those involved in providing treatment and support need clear information about what already exists, for whom, and in what situations (eg, via the websites of national Alzheimer associations). They also need examples of how everyday devices can be used effectively by persons with dementia to enable appropriate deployment.

The benefits of new forms of technologies for persons with dementia have to be considered before they are brought on the market or disseminated; examples include robots for care and companionship and ubiquitous computing in the home and in society.

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Textbox 4. Actions regarding ethics in using assistive technologies.

Our review has demonstrated 3 important issues of relevance to researchers in this domain that ask for the following action:

There should be greater consistency among researchers regarding the terms used to describe ethical issues. This will facilitate the comparison of findings and recommendations.

Guidelines on ethical issues related to assistive technology use by or for people with dementia are available [164,165]. However, they are not widely applied in research exploring the role of assistive technology for community-dwelling persons with dementia. Researchers working in this area are advised to review and engage with these guidelines that provide a structured approach to addressing ethical dilemmas in the context of dementia care [165] rather than simply highlighting such ethical dilemmas. This should ensure that not only the conduct of the research complies with ethical principles but that the future use of devices also promotes ethical practice.

Researchers should strive to ensure that emerging reflection and findings on the ethical use of assistive technologies reach the general public, persons with dementia, informal carers, and health care professionals, and that for this wider dissemination, terms and explanations are understandable and meaningful to these targeted groups.

Conclusions

Although this study shows that further research into the development and evaluation of assistive technologies for persons with dementia is needed, it also shows that they are enthusiastic about using technologies to remain their independency, that assistive technologies can improve cognition, mood, and social functioning and decrease service use, and that the use of technology is expected to improve with the increase in computer literacy and level of education, which will be the case in future generations of older people. It is therefore recommended that policy makers, care insurers, and care providers together with technology enterprises and researchers prepare strategies for the deployment of affordable assistive technologies in different care settings, to ensure that future generations of persons with dementia can derive benefit from this.

Conflicts of Interest

None declared.

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Abbreviations

AALA: Ambient Assisted Living Association
CeHRes: Centre for eHealth Research and Disease Management
GPS: Global Positioning System
HCD: human-centered design
HSTA: health services or technology assessment
HTA: health technology assessment
ICT: information and communication technology
RCT: randomized controlled trial

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Original Paper

Design and Development of a Telerehabilitation Platform for Patients With Phantom Limb Pain: A User-Centered Approach

Andreas Rothgangel[1,2,3*], MSc; Susy Braun[1,2*], PhD; Rob Smeets[2,4*], PhD; Anna Beurskens[1,2*], PhD

[1]Research Centre for Autonomy and Participation of People with a Chronic Illness, Faculty of Health, Zuyd University of Applied Sciences Heerlen, Heerlen, Netherlands

[2]CAPHRI School for Public Health and Primary Care, Maastricht University, Maastricht, Netherlands

[3]Kaasa health, Duesseldorf, Germany

[4]Libra Rehabilitation and Audiology, Eindhoven/Weert, Netherlands

[*]all authors contributed equally

Corresponding Author:
Andreas Rothgangel, MSc
Research Centre for Autonomy and Participation of People with a Chronic Illness
Faculty of Health
Zuyd University of Applied Sciences Heerlen
Nieuw Eyckholt 300
PO box 550
Heerlen, 6419 DJ
Netherlands
Phone: 31 45 400 6273
Fax: 31 45 400 6039
Email: andreas.rothgangel@zuyd.nl

Abstract

Background: Phantom limb pain is a frequent and persistent problem following amputation. Achieving sustainable favorable effects on phantom limb pain requires therapeutic interventions such as mirror therapy that target maladaptive neuroplastic changes in the central nervous system. Unfortunately, patients' adherence to unsupervised exercises is generally poor and there is a need for effective strategies such as telerehabilitation to support long-term self-management of patients with phantom limb pain.

Objective: The main aim of this study was to describe the user-centered approach that guided the design and development of a telerehabilitation platform for patients with phantom limb pain. We addressed 3 research questions: (1) Which requirements are defined by patients and therapists for the content and functions of a telerehabilitation platform and how can these requirements be prioritized to develop a first prototype of the platform? (2) How can the user interface of the telerehabilitation platform be designed so as to match the predefined critical user requirements and how can this interface be translated into a medium-fidelity prototype of the platform? (3) How do patients with phantom limb pain and their treating therapists judge the usability of the medium-fidelity prototype of the telerehabilitation platform in routine care and how can the platform be redesigned based on their feedback to achieve a high-fidelity prototype?

Methods: The telerehabilitation platform was developed using an iterative user-centered design process. In the first phase, a questionnaire followed by a semistructured interview was used to identify the user requirements of both the patients and their physical and occupational therapists, which were then prioritized using a decision matrix. The second phase involved designing the interface of the telerehabilitation platform using design sketches, wireframes, and interface mock-ups to develop a low-fidelity prototype. Heuristic evaluation resulted in a medium-fidelity prototype whose usability was tested in routine care in the final phase, leading to the development of a high-fidelity prototype.

Results: A total of 7 categories of patient requirements were identified: monitoring, exercise programs, communication, settings, background information, log-in, and general requirements. One additional category emerged for therapists: patient management. Based on these requirements, patient and therapist interfaces for the telerehabilitation platform were developed and redesigned by the software development team in an iterative process, addressing the usability problems that were reported by the users during 4 weeks of field testing in routine care.

Conclusions: Our findings underline the importance of involving the users and other stakeholders early and continuously in an iterative design process, as well as the need for clear criteria to identify critical user requirements. A decision matrix is presented

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that incorporates the views of various stakeholders in systematically rating and prioritizing user requirements. The findings and lessons learned might help health care providers, researchers, software designers, and other stakeholders in designing and evaluating new teletreatments, and hopefully increase the likelihood of user acceptance.

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KEYWORDS

telerehabilitation; telemedicine; self care; software design; phantom limb; imagery (psychotherapy)

Introduction

Phantom limb pain is a frequent and persistent problem following amputation. Despite many pharmacological and nonpharmacological interventions, up to 80% of patients still suffer from phantom limb pain many years after the amputation [1-3]. According to a recent trial [3], 63% of a sample of 3234 amputees with an average time since amputation of 33 years, were still suffering from phantom limb pain. These data illustrate the chronic nature of this disorder, which is accompanied and maintained by a wide range of changes in the peripheral [4] and central nervous system [5]. Achieving sustainable favorable effects on phantom limb pain requires therapeutic interventions such as mirror therapy [6] that target these maladaptive neuroplastic changes in the central nervous system.

Two recent systematic reviews [7,8] reported that despite the potential merits of mirror therapy, the quality of evidence for patients with phantom limb pain is still low and a detailed description of how to deliver the intervention is lacking. Therefore, we recently developed an evidence-based clinical framework for mirror therapy for patients with phantom limb pain [9] that is currently being tested for effectiveness in a multicenter randomized controlled trial [10]. Given the chronic nature of phantom limb pain, continuous training with at least one session a day over a period of several weeks to months seems to be needed to achieve sustainable treatment effects [7]. However, resources in clinical practice are generally scarce, which necessitates unsupervised training by patients to achieve the desired training intensity. Unfortunately, patients' adherence to unsupervised training is generally poor [11], implying the need for effective strategies to support long-term self-management by patients with phantom limb pain.

One possible strategy might be the use of information and communication technology such as telerehabilitation, which allows patients to continue their treatment program independently at their own homes. Furthermore, therapists can create tailored exercise programs, improve their guidance for self-administered exercises, and monitor phantom limb pain. Problems that occur during self-management can be discussed with the supervising therapist and the treatment program can be modified according to patient's preferences to increase long-term adherence to self-administered exercises [12,13]. The use of telerehabilitation has been shown to enhance treatment intensity [14], self-efficacy [15,16], and compliance with self-administered exercises, that in turn correlates positively with the effects of the intervention [17]. Moreover, the implementation of these potential time- and cost-saving strategies might lead to increased accessibility and enhanced continuity of care [18]. Data regarding the effects of telerehabilitation in patients with phantom limb pain is sparse. In a recent study [19], a teletreatment for 2 patients with phantom limb pain using mirror therapy was described. This teletreatment solely consisted of email instructions by a physician on how to deliver self-administered mirror therapy. Both the patients reported complete recovery from phantom limb pain after daily exercises for 4 and 8 weeks, respectively. However, the teletreatment was restricted to email instructions, and it remains unclear as to how the content of the teletreatment was developed and whether the end users were involved during the design of the system.

To facilitate user acceptance, such teletreatments have to be easy to use [20], match the requirements and preferences of the end users [21], and fit in their personal context [22]. This is supported by theoretical models such as the technology acceptance model (TAM) [23,24] and the unified theory of acceptance and use of technology (UTAUT) [25,26] that assume that user acceptance and the intention to use a telemedicine service is predicted by factors such as perceived usefulness, perceived ease of use, as well as intrinsic motivation and social influence. Therefore, it is essential to involve the end users in the design and development of any new telerehabilitation platform. In the PAtient Centered Telerehabilitation (PACT) project [10], we developed an innovative mobile telerehabilitation platform using mirror therapy for patients with phantom limb pain following lower limb amputation. Patients and physical and occupational therapists were involved throughout the entire platform development process.

The aim of this study was to describe the user-centered approach that guided the design and development of the telerehabilitation platform.

The following research questions were addressed:

Which requirements are defined by patients with phantom limb pain following lower limb amputation and the occupational and physical therapists treating these patients regarding the content and functions of a telerehabilitation platform, and how can these requirements be prioritized to develop a first prototype of the platform?

How can the user interface of the telerehabilitation platform be designed so as to match the predefined critical user requirements, and how can this interface be translated into a medium-fidelity prototype of the platform?

How do patients with phantom limb pain and their treating therapists judge the usability of the medium-fidelity prototype of the telerehabilitation platform in routine care, and how can the platform be redesigned based on their feedback to achieve a high-fidelity prototype?

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Our description of this process and the lessons learned along the way aims to offer insights into the complexity of the user-centered design process and illustrates the necessity to address the needs of different stakeholders to achieve a platform that is easy to use and fits in with the daily routines of the users. Our findings might help health care providers, researchers, software designers, and other stakeholders in designing and evaluating new teletreatments.

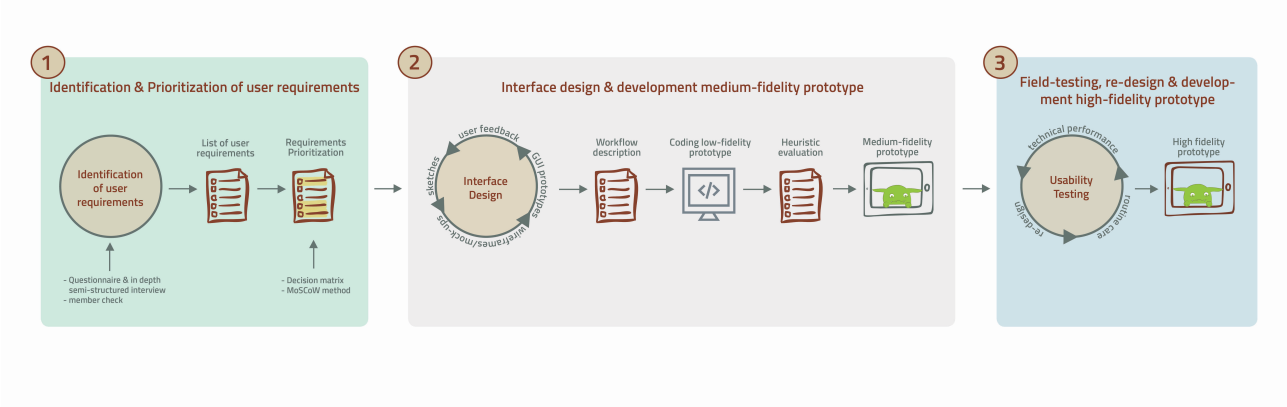
Methods

Study Design

The framework to improve the uptake and impact of eHealth technologies [27] and the method of agile software development [28] were used in an iterative user-centered design process to develop the telerehabilitation platform in 3 phases (Figure 1).

Important topics that are mentioned in the framework of van Gemert-Pijnen [27] such as a participatory development and design approach, value specification through identification of user requirements, as well as persuasive design techniques and continuous evaluation cycles were also addressed in this study.

Figure 1. Overview of the 3 phases and methods used throughout the user-centered approach.



Recruitment of Patients

We used purposive sampling to achieve a wide range of patient characteristics (eg, age, gender, reason for amputation, time since amputation) to obtain a rich data collection. The principal investigator (AR) identified eligible patients by contacting patient support groups and orthopaedic technicians and placing Web-based advertisements in Germany. In addition, the therapists who participated in the interviews selected patients whom they had treated in the past or whom they were currently treating. Adult patients with unilateral amputation of the lower limb and sufficient cognitive and linguistic capacities to participate in a 1-hour interview were included. In addition, patients needed to have sufficient experience in using mirror therapy, which was defined as having attended at least five treatment sessions during the past 12 months. Selection of patients was based on the judgment of the recruiting principal investigator or therapists.

Recruitment of Therapists

The principal investigator identified physical and occupational therapists by email or phone via existing networks in Germany. The professionals needed to have sufficient experience in using mirror therapy for patients with phantom limb pain, which was defined as having treated at least three patients during the past 12 months. Again, we tried to include a wide range of therapist characteristics (eg, profession, age, experience, work setting) to obtain a rich data collection.

Phase 1: Identification and Prioritization of User Requirements (Research Question 1)

In the first phase, a questionnaire followed by a semistructured interview was used to identify the user requirements of both the patients suffering from phantom limb pain and the physical and occupational therapists. The reported requirements were then prioritized using a decision matrix.

Collection and Analysis of Data

We developed a structured questionnaire for patients and therapists that contained questions on patient and therapist characteristics such as level and side of amputation, a case description of a patient with phantom limb pain to illustrate the principle of telerehabilitation, and 3 general items regarding the content and functions of the platform (eg, which information, content or functions should be included in the telerehabilitation platform enabling tailored support of your patients regarding self-delivered exercises?"). In addition, 3 therapist respectively 6 patient questions regarding user acceptance, barriers and facilitators, and context of use were included (eg, which aspects are relevant to increase patient and therapist acceptance of the telerehabilitation platform?). The questionnaire was checked on integrity and comprehensibility by 5 therapists and 1 patient representative. After some minor text revisions and after participants gave informed consent, the principal investigator sent the questionnaire by email to all patients and therapists who were to participate in the interviews 2 weeks before the interview took place. The completed questionnaire was to be returned at least one day before the interview. The principal investigator checked the data regarding the telerehabilitation platform before the interview took place

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to prepare for the interview and refined in-depth questions on the various topics.

All interviews were conducted by the principal investigator in a quiet room at the patient's home or at the professional's clinic. The interviews lasted approximately 1 hour and were digitally audio-taped and subsequently transcribed using the f4 software (audiotranskription, Marburg, Germany). In addition, the principal investigator took field notes after each interview describing the context of the interview. After 6 interviews had been transcribed, the principal investigator used data analysis to check which topics emerged, and recruited additional patients and therapists until data saturation was achieved.

The data regarding patient and therapist characteristics were extracted from the questionnaires and displayed in a frequency table. Data regarding the topics relating to the telerehabilitation platform were analyzed using directed content analysis [29]. The initial coding scheme was based on the topics of the questionnaire. This scheme was extended as new topics emerged from the data analysis. After each interview, the data were summarized by topic in a table and were subsequently sent to the interviewee, who was asked to check the data for integrity and correctness (member check). The interviewees returned the adjusted summary of the data to the principal investigator by email. A sample of 2 patient and 2 therapist interviews was independently analyzed by another researcher (SB) and the results were discussed with the principal investigator to reach consensus about the data analysis. Finally, all data from the interviews were clustered into topics and the user requirements regarding each topic were specified in a table to create a requirements catalog.

Requirements Prioritization

The user requirements were subsequently prioritized to decide which requirements from the requirements catalog were critical to include in the first prototype of the telerehabilitation platform. We developed a decision matrix incorporating 3 different criteria to reflect the views of various stakeholders in the project (patients, therapists, researchers, and software development team, see also Table 2):

Best available evidence: A systematic literature review regarding the clinical framework of mirror therapy for patients with phantom limb pain was conducted in a preliminary stage [9]. Literature was screened to identify studies supporting the relevance of each reported user requirement.

Technical complexity: Members of the software development team were also asked to rate the different requirements in order to determine the technical complexity of each requirement. They were asked whether implementation of each requirement would be time-consuming or expensive. The technical complexity of each requirement was assessed by 3 engineers from the software development team (Kaasa health, Duesseldorf, Germany) using an 11-point numeric rating scale (0=very low, 10= very high complexity).

Importance of requirements: The importance of the requirement was primarily defined by the number of respondents who mentioned the requirement and whether or not there was agreement between patients and therapists (eg, the more respondents mentioned the same requirement, the more important the requirement). However, an exception was made for requirements that were only mentioned by a minority of users but were nevertheless regarded as important by the research team that rated the priority of requirements.

Based on these criteria, 3 members of the research team (RS, AJB, AR) rated the priority of each user requirement independently on a 4-point numeric rating scale according to the MoSCoW prioritization method (1=Must have, 2=Should have, 3=Could have, 4=Won't have at this time) [30].

Only requirements that were scored as priority stage 1 or 2 by at least two of the 3 raters were defined as critical for the first prototype of the telerehabilitation platform.

Phase 2: Interface Design and Development of Medium-Fidelity Prototype (Research Question 2)

Based on the critical user requirements defined in phase 1, the interface of the telerehabilitation platform was designed using design sketches, wireframes, and interface mock-ups (Balsamiq Mockups, version 2.2.10, Balsamiq Studios, Sacramento). All critical user requirements belonging to 1 specific category were used to build the first design sketches incorporating these requirements. In the next step the interface designer of the software development team converted these mock-ups into graphical user interface (GUI) prototypes. The GUI prototypes were shown in several iterative phases, on screen or paper, to a sample of 6 patients and 5 therapists who had been interviewed in phase 1, to provide feedback regarding the content and design of the prototypes. Their feedback was summarized and discussed with the interface designer, to refine the GUI prototypes. Evaluation of GUI prototypes continued until the majority (>50%) of patients and therapists made no further comments, and the final interface design emerged. For each category of user requirements, a workflow description was composed in which the final GUI was used to illustrate the sequential steps to be taken by the users when operating the application. Based on this workflow description, the source code was programed for each application to develop a low-fidelity prototype of the telerehabilitation platform.

Heuristic Evaluation

The usability of the low-fidelity prototype was tested in a laboratory situation by 3 therapists who had already been involved in phase 1, as well as 10 physical therapy students and 4 evaluators from the software development team, using the criteria of Nielsen [31]. Typical user tasks such as logging in and recording a pain score or selecting a tailored exercise program were developed, to enable the evaluators to rate the prototype in terms of existing usability principles (heuristics"). We developed a criteria matrix (Table 2) in which each evaluator noted their feedback on each heuristic. Subsequently, the severity of each usability problem was rated on a 5-point numeric scale (1= I don't agree that this is a usability problem at all, 5=Usability catastrophe) according to the frequency and persistence of the usability problem and its impact on the workflow [32]. The results of the heuristic evaluation were reported to the software development team, who fixed usability

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problems with a minimal severity score of 3 to create a medium-fidelity prototype of the telerehabilitation platform.

Phase 3: Field-Testing in Routine Care, Redesign and Development of High-Fidelity Prototype (Research Question 3)

Following the heuristic evaluation, the medium-fidelity prototype was tested for usability and technical performance in routine care by 2 physical and 3 occupational therapists who had already taken part in phase 1 and also participated in the multicenter trial [10]. Each therapist was asked to select 2 patients with phantom limb pain whom they were currently treating. The participating therapists were trained regarding the content and application of the telerehabilitation platform. Subsequently, each therapist was asked to instruct patients with phantom limb pain on how to use the telerehabilitation platform before patients were discharged from the rehabilitation center. After discharge, patients and therapists used the telerehabilitation platform for a period of 4 weeks. During this period, the users were encouraged to use various aspects of the telerehabilitation platform (eg, personal communication with patient or therapist or other patients, exercise programs, monitoring of phantom limb pain) and were asked to note any usability problem by means of an in-app feedback system that automatically transferred the user feedback to the software development team. In addition, patients and therapists were phoned once a week by the principal investigator to assess usability problems that were not automatically recorded through the in-app feedback system. All usability problems were listed in a standardized bug log and scored by the principal investigator for priority (low, medium, high). The technical performance of the prototype was evaluated using data logging. The issues mentioned in the bug log were continuously forwarded to the software development team that redesigned the prototype until the users reported no more major bugs and a high-fidelity prototype of the telerehabilitation platform had been achieved.

Ethical Approval

This study has been approved by the Ethics Committee of the Medical Faculty of Cologne University, Cologne, Germany (approval no. 12-029).

Results

Phase 1: Identification and Prioritization of User Requirements (Research Question 1)

In total, 11 patients (6 female) and 10 therapists (8 female) were recruited for the interviews until data saturation was achieved. The sample of patients was very heterogeneous as shown in Table 1.

Table 1. Characteristics of patients participating in the interviews.

Patient	Age (years)	Gender[a]	Work status	Time since amputation (months)	Side of amputation	Level of amputation	Reason for amputation	Information and communications technology experience
1	22	F	Student	15	Left	TT[b]	Trauma	High
2	49	M	Part-time	12	Right	TT	Trauma	Medium
3	56	F	Retired	5	Right	TT	Vascular	Low
4	64	M	Retired	116	Right	HE[c]	Vascular	High
5	49	F	Retired	27	Right	HE	Vascular	High
6	70	M	Retired	36	Left	TF[d]	Vascular	Low
7	39	F	Retired	39	Left	HE	Infection	High
8	49	M	Retired	328	Right	HP[e]	Trauma	High
9	47	M	Retired	35	Right	TF	Vascular	Medium
10	59	F	Full time	3	Right	TF	Vascular	Low
11	24	F	Student	45	Left	F[f]	Trauma	High

[a]F: Female, M: Male.

[b]TT: Transtibial.

[c]HE: Hip exarticulation.

[d]TF: Transfemoral.

[e]HP: Hemipelvectomy.

[f]F: Foot.

The occupational (n=5) and physical (n=5) therapists (age range 23-57 years) had extensive work experience in treating amputees ranging from 5 to 28 years. Three therapists worked in a hospital, 4 in a rehabilitation center and 3 in a private practice. Three therapists reported a low level, 3 reported a medium, and 4 reported a high level of experience in using information and communication technology.

Requirements Defined by Patients and Therapists

A total of 63 patient requirements and 64 therapist requirements were identified. After the prioritization process, 24 patient

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requirements and 35 therapist requirements remained that were classified as critical for the first prototype of the telerehabilitation platform (Table 2). Seven categories of patient requirements were identified: Monitoring (eg, monitoring of phantom pain and self-administered exercises), training programs (eg, mirror therapy, mental practice), communication (eg, text messages, videoconferencing), settings (eg, personal data, reminder), background information (eg, phantom pain, training programs), and log-in and general requirements (eg, privacy, gamification). With respect to the requirements of therapists, 1 additional category emerged: Patient management (eg, creating a new patient, patient overview).

We decided to develop a mobile app of the telerehabilitation platform as the majority of the patients and therapists preferred mobile access to the platform in order to be more flexible regarding the time and place of platform use.

Table 2. Prioritization of user requirements using the decision matrix (example shows 4 out of 64 therapist requirements from the category monitoring").

ID	Category 1: Monitoring Description of requirement (number of entries)	Decision criteria Literature[a] (+ or − or ?)	Defined by majority of users[b] (+ or −)	Consensus patient therapist[c] (+ or −)	Complexity 0= very low 10= very high	Priority[d] 1=high 4=low	Notes
1[e]	The system must be able to monitor the intensity of phantom limb pain, so that the therapist is able to evaluate its course over time (10/10)	+ Barbin et al [8] Rothgangel et al [9]	+	+	5	1 1 1	
2	The system has to record the perceived position and range of motion of the phantom limb (1/10)	+ Schmalzl et al [33] Mercier and Sirigu [34] Moseley [35] Sumitani et al [36]	-	-	8	3 4 3	Consider for clinical trial
3[e]	The system must enable the therapist to control the frequency and quality of self-delivered exercises (eg, video recording, text messages) (10/10)	+ Darnall and Li [11] Beaumont et al [37] MacIver et al [38]	+	+	8	1 1 2	Camera of tablet has no wide angle—poor display window
4	The system has to record the perceived difficulty of self-delivered exercises (3/10)	+ Mercier and Sirigu [34] Beaumont et al [37] Giraux and Sirigu [39]	-	-	5	3 2 3	

[a]+= yes, −= no, ?=unclear.

[b]+=Requirement defined by >50% of users.

[c]+=consensus between at least one patient and one therapist.

[d]1=must have, 2=should have, 3=could have, 4=won't have this time.

[e]Based on the decision criteria and priority rating only requirements with ID 1 and 3 were defined as critical for the first prototype.

Phase 2: Interface Design and Development of Medium-Fidelity Prototype (Research Question 2)

Based on the 7 categories of user requirements identified, a mobile app was developed for each category, incorporating all user requirements belonging to this category, using an iterative design process. The development process is illustrated in the following section using the example of phantom limb pain monitoring.

Ten patients and all therapists agreed that the telerehabilitation platform should be able to monitor the frequency, duration, type, and intensity of phantom limb pain. These aspects were integrated in the first userface design sketches and mock-ups of the mobile app for monitoring of phantom limb pain (Figure 2).

These mock-ups resulted in the first graphical user interface (GUI) prototypes (Figure 3). The feedback from patients and therapists regarding the GUI prototypes showed that 6 patients and 5 therapists required a more compact and comprehensive overview of the most important aspects of phantom limb pain. In addition, 7 patients wished to integrate some gaming elements to enliven the use of the application. In response to this, a little monster symbolizing the phantom limb pain was introduced (Figure 3). The final interface design of the mobile app for

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monitoring phantom limb pain emerged after 7 iterative rounds with patients and therapists.

Figure 2. First design sketches and mock-ups of phantom limb pain monitoring.

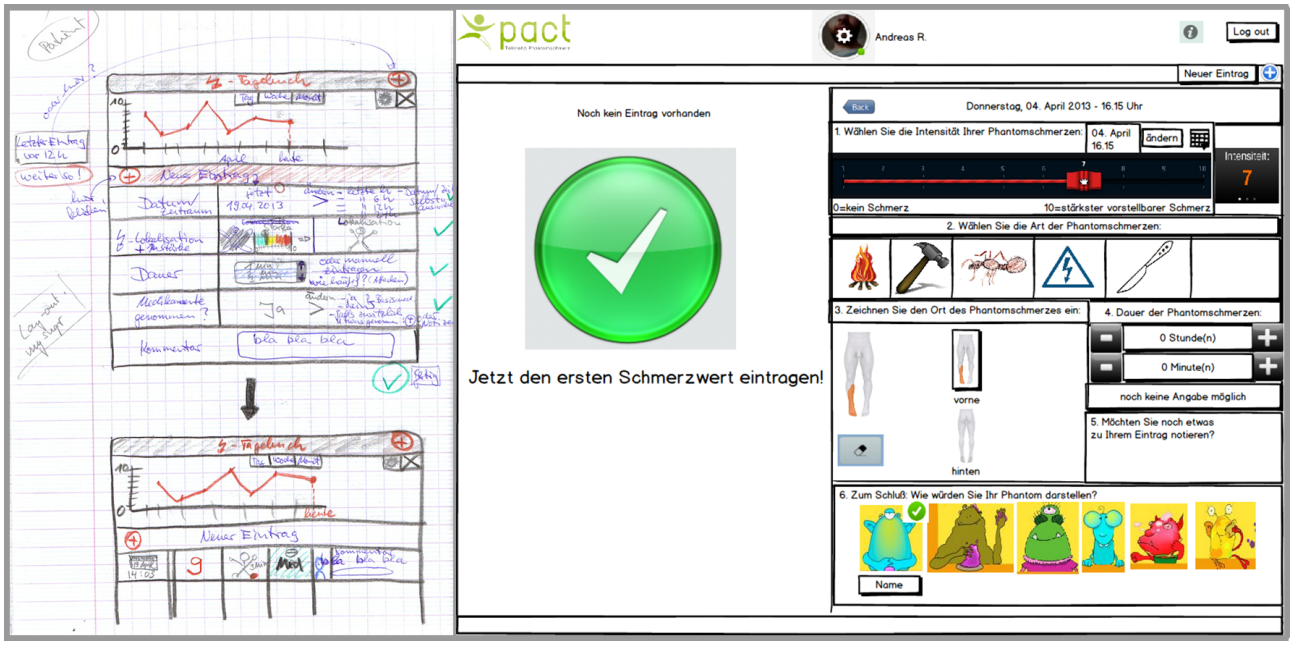

Figure 3. First graphical user interface (GUI) prototype and final interface design of phantom limb pain monitoring after 7 iterative rounds.

From Low to Medium-Fidelity Prototype

The coding process based on the workflow description resulted in a low-fidelity prototype of 5 different individual applications that were included in the main menu of the patient interface of the telerehabilitation platform (Figure 4): monitoring phantom limb pain, traditional mirror therapy, mobile mirror therapy facilitated by augmented reality using the tablet-integrated camera (Figure 5; Multimedia Appendix 1), mental practice including relaxation exercises and limb laterality recognition training.

The main menu was also coded as 1 individual application and featured additional functions such as an overview of exercise programs and training history, background information, personal settings, or communication with a personal therapist and other patients (eg, short message system, videoconferencing).

The main menu of the therapist interface of the low-fidelity prototype integrated 4 different applications in a coherent overview, to enable easy access for the professional: personal and medical data of patient, monitoring of phantom limb pain and self-administered exercises, creation of individual exercise programs, and communication with individual patients (Figure 4). In addition, the main menu contained personal settings for the therapist and a patient management system with an overview of patients currently being treated by the therapist, as well as options for searching and adding new patients.

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Figure 4. Low-fidelity prototype of patient and therapist interfaces of the telerehabilitation platform.

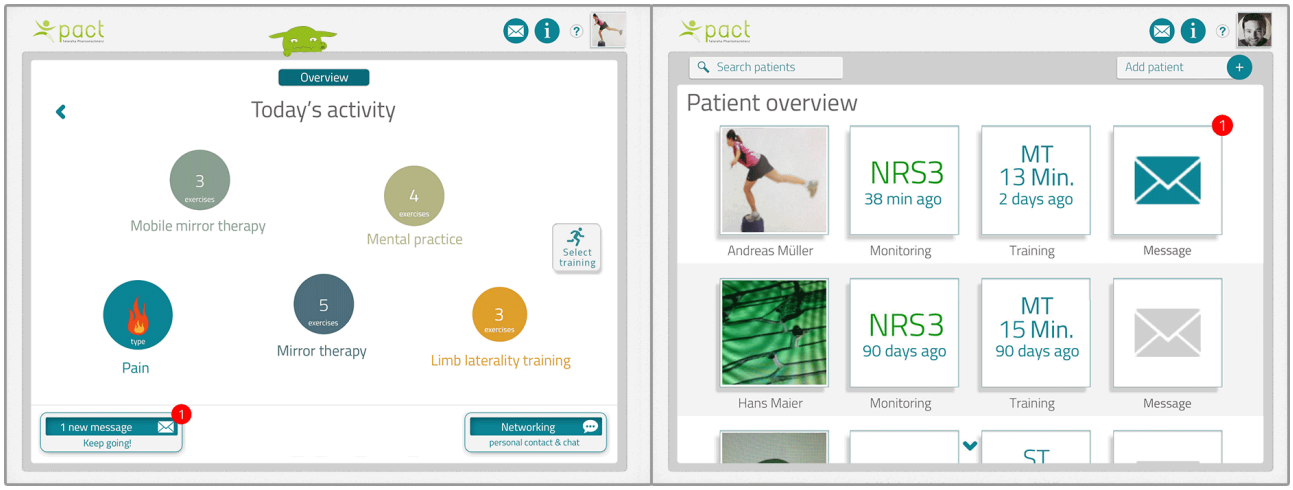

Figure 5. Mobile mirror therapy facilitated by augmented reality using the tablet-integrated camera.

Heuristic Evaluation

The group of evaluators who rated the usability according to Nielsen criteria identified several usability problems in the low-fidelity prototype, as shown in Table 3. Usability problems were found to occur in different areas of the prototype (eg, log-in, profile settings, exercise programs). For example, the software did not provide sufficient information about the system status during various tasks such as sending messages.

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Table 3. Results of heuristic evaluation of the low-fidelity prototype (one example per heuristic shown).

Type of heuristic	Description of usability problem	Frequency of problem 0= never 10=very often	Impact on workflow 0= low 10=very high	Persistence low or medium or high	Severity rating 1-5[a]
Visibility of system status	The system provides no feedback about whether a message has successfully been sent or not.	7	5	High	4
Match between system and the real world	If the user takes a profile picture the system shows it upside down.	3	3	Medium	3
User control and freedom	It is not clear where the user can log out.	10	7	Low	4
Consistency and standards	It is not clear whether the phrase video training means the same as the phrase mental practice.	2	0	Low	2
Error prevention	The system does not provide feedback on how to get back to the main menu after the training has been completed.	10	8	Medium	4
Recognition rather than recall	There is no tutorial that guides the user through the different sections of the application.	2	3	High	3-4
Flexibility and efficiency of use	There is no option to skip the instruction videos in the training programs.	10	5	Medium	4
Aesthetic and minimalist design	The text in the video selection frame is redundant as it is a repetition of the title.	8	0	Low	2
Helping users recognize, diagnose, and recover from errors	There is no error message when the Internet connection is timed out or a wrong password is used during log-in.	10	10	Medium	4
Help and documentation	The help icon in the limb laterality recognition training does not work.	2	1	High	2

[a]Severity rating: 1= I don't agree that this is a usability problem at all, 2=Cosmetic problem only: need not be fixed unless extra time is available, 3=Minor usability problem: fixing this should be given low priority, 4=Major usability problem: important to fix, so should be given high priority, 5=Usability catastrophe: imperative to fix this before product can be released.

All usability problems that were rated with a minimal severity score of 3 were fixed by the software development team in order to build a medium-fidelity prototype of the telerehabilitation platform.

Phase 3: Field Testing in Routine Care, Redesign and Development of High-Fidelity Prototype

During the 4 weeks of field testing of the medium-fidelity prototype in routine care, patients and therapists reported additional usability problems through the in-app messaging system and during the weekly telephone calls regarding the following topics: (1) Problems related to the Internet connection (eg, delayed data transfer and log-in); (2) Messaging system (eg, message is not completely visible in the text fields, no confirmation if the message was successfully sent, message not received by user); (3) Data management (eg, system displays wrong dates and patient scores); (4) Patient management (eg, failure to add new patients and save a tailored exercise program); and (5) Interface design (eg, overlap of text and icons, missing icons).

The software development team continuously redesigned the medium-fidelity prototype. As soon as a new version of the telerehabilitation prototype was available, the software for patients and therapists was updated so they were able to test it in routine care.

High-Fidelity Prototype

After all major bugs had been fixed, additional graphics such as a home button were added to the patient interface. In addition, some elements to facilitate patient compliance (eg, group challenges using high scores, awards) were incorporated in the high-fidelity prototype (Figure 6). The button to select a training program was replaced by a button immediate action" to enable patients to immediately start mobile mirror therapy in case of an acute attack of phantom limb pain. Tapping on the colored circles starts the individual exercise programs. A new tutorial on how to use the different functions of the platform was also included in the main menu for patients and therapists. A new button to add and delete patients was included in the therapist interface (Figure 6).

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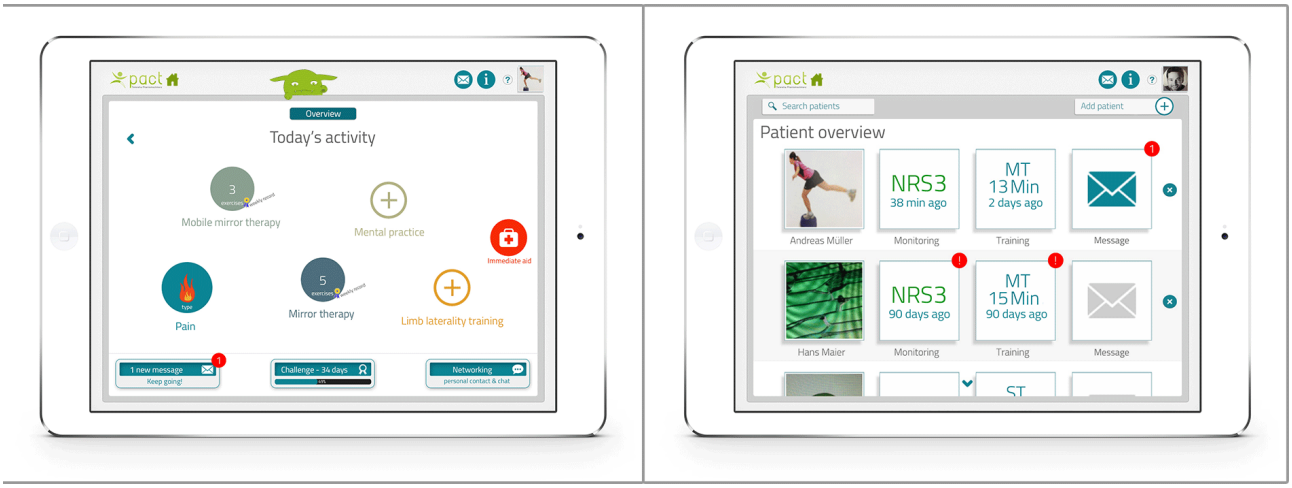
Figure 6. High-fidelity prototype of patient and therapist interfaces of the telerehabilitation platform.



Discussion

In this project, an interdisciplinary software development team consisting of several stakeholders (patients, health care professionals, researchers, and information technology [IT] experts) took part in designing and developing a mobile telerehabilitation platform for patients with phantom limb pain by means of an iterative user-centered design process. Each of the 3 research questions was answered in a separate phase of the process.

Principal Findings

The first phase of the study aimed to identify the requirements defined by patients and therapists regarding the content and functions of a telerehabilitation platform and how these requirements could be prioritized to develop a first prototype of the platform.

The users defined an extensive list of requirements (N=127) regarding the topics of monitoring, training programs, communication, settings, background information, log-in, general requirements, and patient management. The limited time and budget available meant that not all requirements could be incorporated in the platform. Hence, it was essential to have a decision aid based on clear criteria that enabled systematic prioritization of user requirements and ensured the identification of the most critical requirements to include as a starting point in the first prototype of the telerehabilitation platform. To this end we developed a decision matrix reflecting the views of various stakeholders based on 3 different criteria: best available evidence [9], importance of the requirement, and the technical complexity (time or money) of implementing the requirement in the platform.

The first 2 criteria were clear and straightforward to use. The last criterion, however, required frequent discussion with the software team and turned out to be an important and restricting factor in deciding whether or not a requirement was implemented. Some user requirements such as monitoring the phantom limb pain" were technologically easy to develop and implement, whereas some others, such as perceived position and range of motion of phantom limb" were technologically complex to design. It has to be mentioned that depending on the user characteristics (eg, age, experience in using IT) it was difficult for some users to provide reasonable information regarding the content and functionalities of the platform. For this reason some requirements were only mentioned by 1 or 2 users, nonetheless providing valuable information. In order to also meet the needs that were mentioned by a minority of users, 3 members of the research team that rated the priority of requirements decided whether these requirements provided important information that should be taken into account. Overall, the decision matrix was very helpful and enabled us to systematically rate and prioritize all requirements.

The second phase of the study was used to assess how the user interface of the telerehabilitation platform could be designed to match the critical user requirements and how the interface could best be translated into a medium-fidelity prototype.

It appeared to be crucial to involve the users and other stakeholders early and often in the design process, that is in line with results from a recent scoping review [40]. The potential future users were shown mock-ups and prototypes of graphical user interfaces of the low and medium-fidelity prototypes of the platform, incorporating the predefined user requirements. During this iterative process, the users were able to check whether their requirements had been sufficiently addressed. They highly appreciated the possibility to cocreate the application with the interdisciplinary software team. In particular, participants were enthusiastic about discussing with other users their ideas regarding the functions and interface design, and to see how their feedback was incorporated in the subsequent prototypes. In addition, some functions and interface design issues that were suggested by the software team, such as adding a Facebook sign-in button, were rejected because the users did not consider them relevant. As soon as the final interface design emerged, it was important to provide the software developers with a structured and logical workflow description so that they were able to code a first prototype matching the critical user requirements. However, continuous redesign of the first prototype was required to achieve a medium-fidelity prototype, as several usability problems were identified through heuristic evaluation.

This close cooperation with the users and other stakeholders gave us valuable insights into critical requirements and resulted

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in a telerehabilitation platform that will most likely fit the main requirements and wishes of the end users.

Phase 3 of the project assessed the usability of the medium-fidelity prototype of the telerehabilitation platform in routine care as judged by patients with phantom limb pain and their treating therapists. This information was necessary to redesign the platform into a high-fidelity prototype.

An important step during the iterative design process was field testing the platform in routine care, which contributed greatly to improving the usability of the platform. During this process the users continuously identified additional problems that had not been detected before through heuristic evaluation. When field testing started, the users rated the usability of the medium-fidelity prototype as poor because of several problems such as delayed data transfer or problems regarding the login process. It was important to discuss the usability problems continuously with the software development team and to regularly provide the users with an improved version of the platform, to gradually increase its usability to achieve a high-fidelity prototype. However, at a certain point in the development process we had to stop improving the platform and start the multicenter trial in order to evaluate the effects of the platform [10]. This time was difficult to set as there are no formal criteria to decide when to stop the prototype design process. Development of the platform stopped after all critical issues had been resolved and time and budget restrictions did not allow any more reported bugs to be addressed, despite the fact that less critical malfunctions kept occurring. The latter implies that in the platform that is currently being evaluated in a multicenter trial [10], there could still be some minor malfunctions which can potentially influence user acceptance.

Strengths and Limitations

In our experience it is important to take sufficient time for the different stakeholders to get to know and understand each other. It is necessary that the different stakeholders learn to speak each other's language in order to work effectively together and correctly transform the wishes and requirements of the users into the design of the tool. Even though the involvement of the users and other stakeholders made the process time-consuming, we believe that it is a crucial factor in building an eventually successful and user-friendly platform.

A potential limitation of this study could be that the same sample of patients and therapists (except for the patients who were recruited for usability testing in routine care) was used throughout the development process of the telerehabilitation platform. This enabled patients and therapists to check whether the requirements, which they defined, were sufficiently addressed in the first prototypes of the platform. However, using the same sample also carries the risk that the views of novel users without prior knowledge regarding the platform are insufficiently addressed. This may have resulted in a lower number of reported usability problems. This potential underestimation of usability problems was tackled by including novel patients who were not familiar with the technology during field-testing in routine care.

Patients and therapists who participated in field testing had limited time to practice in using the telerehabilitation platform. However, this time frame seemed appropriate to evaluate the usability and ease of use of the system as it reflected the situation of a first-time user [41]. Field testing does not provide sufficient insights into user compliance with and acceptance of the platform. This will be further analyzed in our multicenter trial [10], in which patients use the telerehabilitation platform over a period of 6 months.

Comparison With Prior Work

Prioritization of user requirements is still a challenge in software engineering [42]. Recently, it has been recommended that requirements should be prioritized from a user point of view [42]. There are many difficulties in defining which factors should be taken into account when setting the priorities. For example, Moisiadis [43] argues that prioritizing requirements should involve representatives from different stakeholders with a vested interest in the success of the development project. To our knowledge ours is one of the first studies to use a decision matrix incorporating the views of different stakeholders to systematically rate and prioritize user requirements within a telehealth project.

A recent study [19] described a teletreatment for patients with phantom limb pain using mirror therapy. In contrast to our study, this teletreatment consisted solely of email instructions by a physician on how to deliver self-administered mirror therapy. In our experience, however, users have many other requirements regarding the functionalities of a telerehabilitation platform, such as monitoring the phantom limb pain, communication with a personal therapist and other patients, as well as tailored management of the training programs.

In recent years, several telerehabilitation platforms have been developed for different patient groups, such as those with musculoskeletal [44], neurological [45], or pulmonary conditions [46]. However, it remains unclear whether these platforms were developed following a strict user-centered approach. Lack of user acceptance is one of the major barriers to the deployment of services in many telehealth projects [47,48], mainly because relevant user preferences and usability issues have not been taken into account [41]. Early and frequent involvement of end users in the design process, as presented in this study, could prevent some of the problems described previously. We followed the human-centered design principles [49] with the goal of designing a system that is modeled in accordance with the characteristics, tasks, and requirements of the end users. However, in software engineering there are numerous methods for designing software applications [41,49] and using another design and evaluation method might therefore have led to different results.

Recommendations for Future Research

Given the limited research efforts being invested to systematically involve the end users in the design of new teletreatments, the findings of this study (eg, the use of a decision matrix) could be applied in future telehealth projects. Sharing the experiences with tools for human-centered design processes will eventually lead to a better understanding of ways

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to develop user-friendly teletreatments, will enable comparison with products and the efficacy of different methods, and will ultimately lead to higher degrees of user acceptance for eHealth solutions. Mirror therapy has shown promising results in reducing phantom limb pain in 3 controlled studies, however, the evidence is still limited [7,8]. It is still not clear which patients may respond more favorably to mirror therapy than others, but at least some patients who experience no effect through mirror therapy could be more suitable for alternative methods such as virtual or augmented reality [50]. Compared with the mirror therapy approach, these treatment strategies are able to adapt the visual image to the perceived position and length of the phantom limb thereby making the visual illusion more vivid and real, which has been shown to be correlated with the effects of the treatment [6]. The results of our multicenter trial [10] will yield information about the potential effects of mirror therapy and the telerehabilitation platform in treating phantom limb pain in routine care, and will indicate further points for improvement of the platform. Within this trial we will also assess user acceptance of the service using a questionnaire based on the technology acceptance model [23,24].

Conclusions

This study involved developing a mobile telerehabilitation platform for patients with phantom limb pain through an iterative user-centered design process. Our findings underline the importance of involving the users and other stakeholders in an iterative design process by our project, as well as the need for clear criteria to identify critical user requirements. The decision matrix presented here incorporates the views of various stakeholders and might help others systematically rate and prioritize user requirements. The reported findings and lessons learned might be of interest to health care providers, researchers, software designers, and other stakeholders when designing and evaluating new teletreatments. They may also potentially increase the likelihood of user acceptance of these applications.

Acknowledgments

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Conflicts of Interest

AR was partially funded by Kaasa health through a grant of the State of North Rhine-Westphalia (NRW, Germany) and the European Union through the NRW Ziel2 Program as a part of the European Fund for Regional Development. Kaasa health is a for-profit organisation, which might commercialise an improved version of the technology described here.

Multimedia Appendix 1

Video demonstrating the use of the telerehabilitation platform.

[MP4 File (MP4 Video), 67MB - rehab_v4i1e2_app1.mp4]

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Original Paper

Designing a Mobile Health App for Patients With Dysphagia Following Head and Neck Cancer: A Qualitative Study

Gabriela Constantinescu[1,2], MSc-SLP; Irene Loewen[1], MSc-SLP; Ben King[1,3], MDes; Chris Brodt[3], BDes; William Hodgetts[1,2], PhD; Jana Rieger[1,2], PhD

[1]Department of Communication Sciences and Disorders, University of Alberta, Edmonton, AB, Canada

[2]Institute for Reconstructive Sciences in Medicine (iRSM), Covenant Health, Misericordia Community Hospital, Edmonton, AB, Canada

[3]Department of Industrial Design, University of Alberta, Edmonton, AB, Canada

Corresponding Author:
Jana Rieger, PhD
Department of Communication Sciences and Disorders
University of Alberta
2-70 Corbett Hall, University of Alberta
Edmonton, AB, T6R 3T5
Canada
Phone: 1 780 492 4992
Fax: 1 780 492 9333
Email: jana.rieger@ualberta.ca

Abstract

Background: Adherence to swallowing rehabilitation exercises is important to develop and maintain functional improvement, yet more than half of head and neck cancer (HNC) patients report having difficulty adhering to prescribed regimens. Health apps with game elements have been used in other health domains to motivate and engage patients. Understanding the factors that impact adherence may allow for more effective gamified solutions.

Objective: The aim of our study was to (1) identify self-reported factors that influence adherence to conventional home therapy without a mobile device in HNC patients and (2) identify appealing biofeedback designs that could be used in a health app.

Methods: A total of 10 (4 females) HNC patients (mean=60.1 years) with experience completing home-based rehabilitation programs were recruited. Thematic analysis of semi-structured interviews was used to answer the first objective. Convergent interviews were used to obtain reactions to biofeedback designs.

Results: Facilitators and barriers of adherence to home therapy were described through 6 themes: patient perceptions on outcomes and progress, clinical appointments, cancer treatment, rehabilitation program, personal factors, and connection. App visuals that provide feedback on performance during swallowing exercises should offer an immediate representation of effort relative to a goal. Simple, intuitive graphics were preferred over complex, abstract ones. Continued engagement with the app could be facilitated by tracking progress and by using visuals that build structures with each use.

Conclusions: This is a detailed documentation of the initial steps in designing a health app for a specific patient group. Results revealed the importance of patient engagement in early stages of app development.

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KEYWORDS

app design; dysphagia; games for health; gamification; head and neck cancer; mHealth; mobile health; patient adherence; patient engagement

Introduction

Background

More than half of the patients treated for head and neck cancer (HNC) experience swallowing difficulties also known as dysphagia [1-4]. The inability to swallow safely can have serious consequences on the health and psychosocial well-being of these patients, such as malnourishment, dehydration, aspiration pneumonia, and depression. Although research has shown that individualized, intensive therapy achieves lasting changes to swallowing anatomy and physiology [5], limited clinical

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resources result in the majority of swallowing therapy prescribed as home programs. Home programs have been reported to have low adherence rates [6] and require clinicians to rely on patient report to measure effectiveness. These limitations render existing approaches to dysphagia treatment inadequate. Technological advancements such as mobile health (mHealth) devices can be combined with existing effective therapies to help address this clinical gap and remotely monitor adherence to treatment regimens.

mHealth and Swallowing Exercises

The purpose of this study was to obtain patient opinions to inform the design of an mHealth app for swallowing therapy. This app is used together with a wireless mobile device and uses surface electromyography (sEMG) sensors to provide patients with real-time feedback during the exercise. Although it has been recognized that patients prefer more appealing and intuitive displays over signal tracings, the process and research used to select visuals for mHealth apps is rarely reported.

Before this study, 6 design concepts for sEMG biofeedback were generated by considering a typical saliva swallow as well as the technique and clinical goals (eg, peak amplitude and duration of contraction) for the 2 swallowing exercises targeted by the app: the effortful swallow and the Mendelsohn maneuver. Two elements were varied in these 6 designs: (1) the level of visual complexity (simple, complex, abstract) and (2) the presence of a character (eg, coach or third person game; Figure 1).

Smeddinck et al (2013) identified visual complexity as an important element to consider in the design of games for health. They surmised from previous work and anecdotal evidence that whereas complex graphics can increase a sense of immersion and motivation in the user, they also can distract patients from their own movements resulting in injury or overexertion [7]. In their study, Smeddinck et al systematically manipulated visual complexity using a taxonomy for common levels of computer graphics ranging from simplified to realistic. The authors found that although visual complexity had no influence on player experience, the older adults perceived greater exertion when realistic visuals were used [7]. The presence of a character (ie, third person games) or a coach is another important element to present to patients as a visual option. The presence of a coach may help patients transition from one-on-one therapy with a clinician to home-based sessions and has been used with other health apps such as My Fitness Coach from Wii. Third person games offer a familiar and predictable game setting and have been successfully used with games for health with pediatric and young adult cancer patients [8].

This study had 2 primary goals, both aimed at contributing to the development of a swallowing therapy app that is engaging to patients with HNC. The first part of patient interviews focused on identifying the determinants of successful adherence to home-based swallowing therapy, information that will be used to select app features (eg, reminders). The second part of the interview focused on obtaining reactions to designs for the visual biofeedback. This aspect of the app was selected because the real-time biofeedback is what participants will rely on as an indicator of correct exercise completion in the absence of a clinician.

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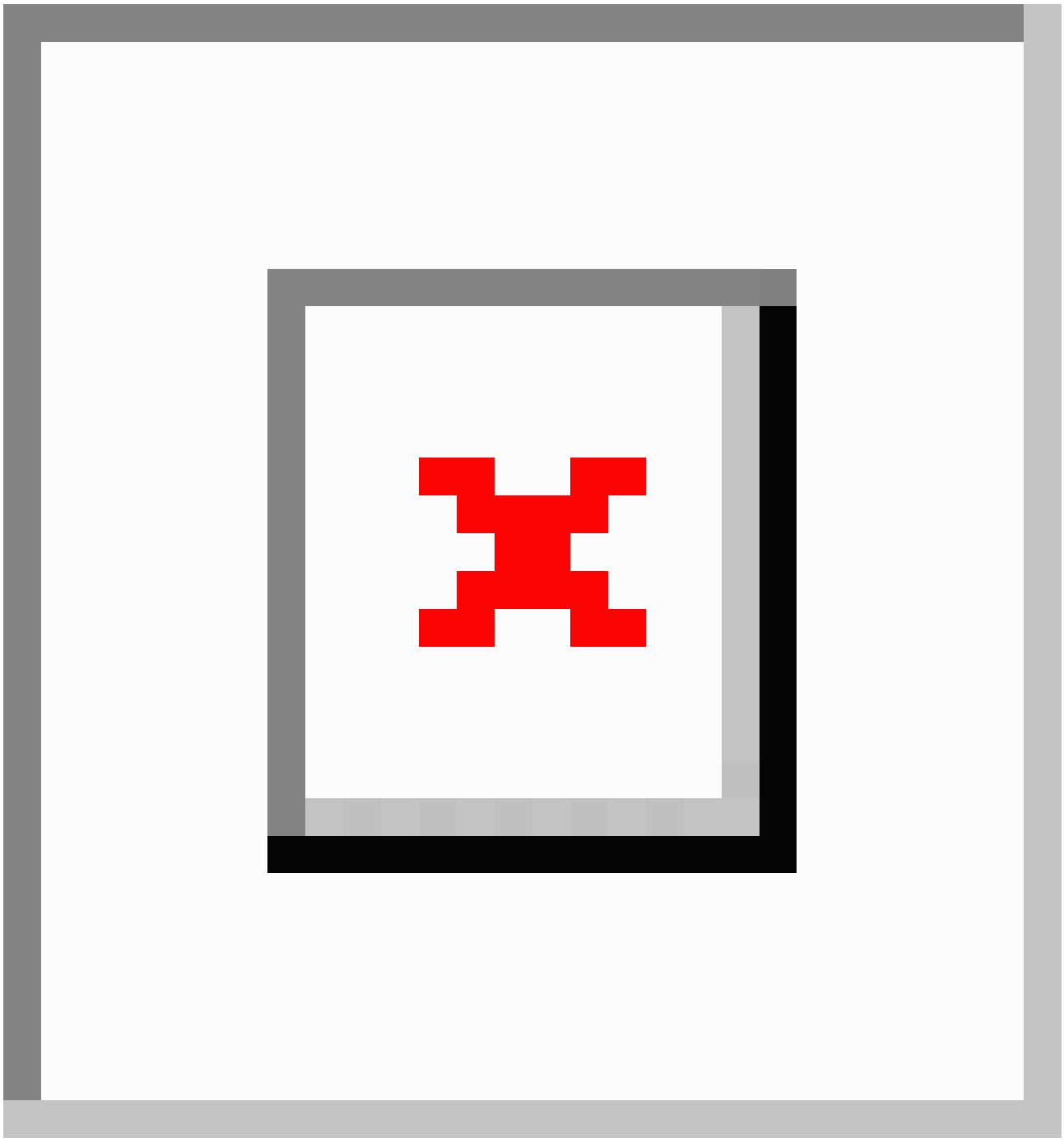
Figure 1. Screenshots of design concepts for visual biofeedback, distinguished across 2 features: the type of visuals (simple, complex, abstract), and the presence or absence of a character. An example for each of the swallow exercises was created for all 6 categories and explained to patients in a video.



Objectives

The following are our study objectives:

1. What are self-reported determinants for adherence to conventional home therapy (ie, without a mobile device) in patients with dysphagia following treatment for HNC?
2. When shown concepts of visual biofeedback for swallowing therapy exercises that could be used with a mobile device, what are some key design elements that patients with dysphagia feel are important?

Interviewing techniques were selected based on the aim of each objective. Therefore, although each participant took part in a single interview, 2 distinct methods were employed in succession.

Methods

Participants

The health research ethics board at the University of Alberta, Edmonton, Alberta, Canada approved this study. Patients with a history of HNC were recruited through tertiary care centers in Edmonton. Participants were included in the study if they reported difficulties with swallowing of any kind and if they had experience with home-based, unsupervised therapy

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following cancer treatment. This experience was not limited to swallowing exercises, as it is possible that not all participants received home programs for swallowing therapy, but may have had other rehabilitation exercises, such as physiotherapy, prescribed.

Procedures

Participants were approached either in person or by phone once consent to be contacted by the research team was provided. Participants were booked for an individual appointment, which was split up into 2 parts and videorecorded. Part 1 used a semi-structured approach to explore the facilitators and barriers of adherence to conventional home therapy, without a mobile device. This style of interview allowed for the flexibility to understand individual and unanticipated ideas, but still retained the structure needed for interparticipant comparison [9]. Part 2 of the appointment determined patient preference for visual biofeedback using a convergent interviewing approach. Convergent interviewing is a structured process for explorative research in an emerging field [10,11]. This process has 2 distinguishing features: (1) participants are systematically selected to reflect a wide range of opinions and (2) the process is progressive whereby the initial interview questions, at first unstructured, are used to identify key issues; these findings help focus the questions for subsequent sets of interviews. In this way, converging key issues can be identified [10-12]. Convergent interviews were analyzed in sets of 3; the first 3 interviews (ie, first set) were analyzed for uniting themes, which were then used to guide the interview questions for the subsequent set of 3 appointments. Given that 10 participants were recruited, the first set of convergent interviews comprised 4 participants. An effort was made to ensure that each set of 3 interviews contained participants of different ages and sex. Demographic and past swallowing therapy information was collected at the beginning of the appointment. HNC treatment variables were collected from a chart review. All the participants who were contacted for the study participated.

Interviews were conducted by the first author, a speech-language pathologist with clinical expertise in interviewing this population. As these were her first interviews conducted for research purposes, several pilots were conducted. Recordings took place at 2 locations, each with an identical setup. All participants were told that this study was part of a larger research goal to develop an mHealth device for swallowing therapy with sEMG sensor technology.

Semi-structured Interviews (Part 1)

Participants were comfortably seated in a room with the interviewer. To explore patient perceived barriers and facilitators to completing conventional swallowing exercises at home, an open-ended question was asked to all participants: “Throughout your cancer treatment, you may have been given some exercises by your speech therapist or your physical therapist. What is your honest opinion about having to do these exercises?” Questions that followed were composed using the Rogers et al theoretical framework for physical activity behavior in patients with HNC [13] as a guide (Multimedia Appendix 1). During the interviews, follow-up questions were used to obtain more in-depth information from participants; as such, no 2 interviews were identical.

The interviews were transcribed verbatim, and identifiers such as names of family, friends, or clinicians were removed [9,14]. Thematic analysis was data-driven and semantic themes (ie, using the surface meaning of data) were sought [9]. Two investigators (GC, IL) coded the transcripts independently, using NVivo for Mac, version 11.1.1 (QSR International Pty Ltd). Lab notes were kept in NVivo and the study binder. Once consensus was reached, transcripts were recoded using the mutually agreed upon set of codes. Codes were grouped into themes and subthemes [15] using Coggle (coggle.it, Cambridge, England).

Convergent Interviews (Part 2)

During this part of the interview, a second interviewer was called in the room to participate with the first 3 participants. This was done to ensure that questions specific to design were addressed and that design ideas for biofeedback were interpreted correctly for participants (eg, what will happen if the exercise target is unmet in a given design concept). Once the clinician felt comfortable addressing all topics independently, the second interviewer no longer took part. Each participant was introduced to, and asked to try the effortful and the Mendelsohn maneuver swallowing exercises to gain a sense of the effort and focus required to complete them. Next, they were introduced to visual biofeedback and its potential to aid in completing the demonstrated exercises. Participants were presented a short video displaying the 6 distinct visual biofeedback concepts. Patients were then asked a series of questions (Multimedia Appendix 1) to identify distinct visual biofeedback elements of importance to them with respect to swallowing exercises. This approach, like the first part, required broad and open initial questions to encourage interviewees to share as much information as possible without biasing prompts [10]. On occasion, questions were posed again to allow participants to reflect on what had already been shared.

Three groupings of participant appointments were booked. Interviews in the first set were transcribed and analyzed to determine key design themes. These were defined as a topic or element that was brought up by at least two participants in a set of interviews. It did not matter if participants in the set agreed or disagreed on the theme. When an issue was brought up by only 1 interviewee, it was noted, but not regarded as key [10]. Two researchers (GC, CB) independently analyzed the transcripts and identified key design themes through consensus.

In subsequent sets of interviews, the interviewer sought to expand on and to clarify these key design topics. Once new interview questions were generated, the industrial designers and a second clinician vetted them before the start of a new set of interviews. Rao et al (2003) point out that as interview data are collected, new insights may emerge, prompting reexamination of the literature and reshaping ideas for subsequent interviews. If a participant in the second or third group of interviews raised a new topic, it was noted, but not further probed in subsequent discussions unless at least one other interviewee in that set also brought up that topic (Figure 2). Following analysis of all

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convergent interviews, themes were once again analyzed to determine if they were suitably categorized.

Figure 2. Fragment of notes taken during the analysis of convergent interviews. The following codes were used: (✓) participant agreed with issue; (✗) participant disagreed with issue; (-) participant did not raise this issue, or issue was not probed by clinician; (A) issue actively probed for by interviewer in subsequent set and participant agreed; (D) issue actively probed for by interviewer in subsequent set and participant disagreed; (U) issue actively probed for by interviewer in subsequent set and participant undecided or gave contradicting statements throughout the interview; (.) not a converging theme from previous set and not specifically probed for by interviewer. Highlighted issues were deemed convergent.

Round	1				2			3		
Participant	1	2	3	4	5	6	7	8	9	10
A. Biofeedback function										
1. Feedback should only show the amount of effort exerted (not too much information)	✓	-	-	✗	D	D	-	A	✓	✓
2. Feedback should be immediate	✓	-	-	✓	-	A	-	A	A	A
3. Feedback should mimic what muscles are doing (eg, lift)	✓	-	-	-	•	•	•	•	•	•
4. Feedback should be contingent on effort, but also show patient progress relative to a goal	✓	-	-	✗	A	A	-	D	A	✓
5. Feedback should only tell patients whether or not they met a target	-	-	-	✓	•	•	•	•	•	•
6. Feedback should be simple and straightforward	✓	-	-	✓	✓	✓	-	A	A	A
7. Third person player feedback is not a good measure of what is happening	✓	-	-	✗	✓	A	-	A	D	✓
8. Third person player feedback is not an obvious indicator of whether or not the exercise was completed correctly	✓	-	-	✗	✓	D	-	U	A	A
9. Patients did not find sEMG biofeedback helpful in past swallowing therapy sessions	-	-	-	-	-	-	A	•	✗	•
10.If patients do not understand biofeedback, they may complete the exercise incorrectly	-	-	-	-	-	-	-	-	✓	-
11.Immediate feedback can assist patients experience success with the exercise	-	-	-	-	-	-	-	-	-	✓
B. Having choices is important (e.g., game, how much information to display, sound)	✓	-	-	-	•	•	•	•	✓	•

Results

Demographics

The study sample comprised a convenience sample of patients visiting the center for various reasons. Descriptive statistics are summarized in Table 1. Although 9 patients complained of dysphagia, only 7 reported having been prescribed swallowing exercises to do at home. One participant reflected mostly on his shoulder rehabilitation exercises, whereas another on his voice therapy. One participant had just begun his radiation therapy at the time of the interview and reported reduced taste sensation. Although this participant had experienced mild pain with swallowing at the time of recruitment, this had resolved. Six participants had prior experience with sEMG as an adjuvant to swallowing therapy in the clinic.

Semi-structured interviews were on average 41 minutes in length (range 19 to 67 minutes), whereas convergent interviews lasted on average 40 minutes (range 27 to 57 minutes). As these 2 interviews addressed different objectives, they will be reported on separately.

Table 1. Participant information.

Sex[a]	Age	T-stage	Education	Annual household income (Can $)	Dysphagia history	Past swallowing therapy
Female	45	T2	University	> 80,000	8 months	Yes
Male	64	T1	High school	< 20,000	7 years	No
Male	57	Tx	College	(left blank)	6 months	Yes
Male	66	T1	College	> 80,000	Not applicable	Yes
Female	61	T2	High school	60,000-79,999	5 years	Yes
Female	60	T2	University	> 80,000	8 years	Yes
Male	70	T3	University	(left blank)	5 years	Yes
Female	68	T4	(left blank)	(left blank)	1 year 2 months	Yes
Male	60	T3	High school	< 20,000	16 years 3 months	Yes
Male	50	T2	College	> 80,000	7 years 10 months	Yes

Semi-structured Interviews (Part 1)

A total of 74 mutually agreed upon set of codes were identified; 5 of these codes were used to mark important information, but were not relevant to the research question (eg, frequency and format of home exercises). Codes were organized into 6 distinct themes: (1) perceptions on outcomes and progress, (2) role of clinical appointments, (3) cancer treatment, (4) rehabilitation program, (5) personal factors, and (6) connection. Facilitators and barriers of adherence to unsupervised home therapy, as explained by these themes, are summarized in Table 2.

The first theme, perceptions on outcomes and progress , revealed a potential link in adherence to the gap perceived by patients between their current function and their goal, or their progress toward that goal. Both facilitators and barriers to adherence were evident in this theme. The second theme, role of clinical appointments, included comments on how clinical appointments and clinicians serve to promote adherence. Clinical appointments

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provided a place for patients to receive education on the anatomy and physiology of a swallow and on how prescribed exercises could improve current function. The use of technology such as biofeedback and modified barium swallow videos facilitated education. These appointments also served as an opportunity to build confidence; patients welcomed reassurance from clinicians if they felt guilty about not completing the full treatment regimen and if they second-guessed their exercise performance. Patients also appreciated clinical appointments as they provided an opportunity to have exercise prescriptions tailored to their needs and abilities. Finally, appointments provided reminders and accountability for doing the exercises. Only facilitators were identified in this theme, although 2 participants brought up a wish for better access.

The third theme, cancer treatment, described various barriers to adherence that relate to surgery, radiation therapy, or chemotherapy. Patients mentioned difficulties with memory and focus as well as a sense of being overwhelmed with information and recommendations. Another perceived barrier was lack of energy or weakness, expressed as either general exhaustion or as rapid muscle fatigue when completing the exercises. Various other side effects mentioned included pain, discomfort, swelling, fibrosis, scarring, postradiation hypothyroidism, and depression. The fourth theme, rehabilitation program, revealed that although there were some facilitators and barriers general to the way the rehabilitation regimen had been set up, some factors also depended on the exercises themselves (eg, novelty, complexity) and some were patient-dependent (eg, time of day when exercises would be completed). Some patients preferred to continue to try new types of exercises and asked peers on social media to share their recommendations, whereas 1 patient reported wanting to wait until a technological solution (ie, prosthetic throat) would exist.

The fifth theme, personal factors, revealed that patients were, at least in this context, generally positive and grateful to be alive. They revealed coping skills through their self-talk and self-compassion, respect for the extent of efforts made by their health care workers, and a wish to help others. Only facilitators to adherence were identified in this theme. The last theme, connection, explained the impact made by a patient's social context (ie, other patients, friends, family) on adherence and on perceptions of current function. On one hand, interactions with other HNC patients provided support; however, it also facilitated peer comparison of function, a code found in 9 out of the 10 participants in this study. If a patient found his or her function to be better than that of other HNC patients, this made that patient feel good. Although this comparison was not explicitly stated as a facilitator of adherence to home-based treatment, it did influence how patients perceived their current function. This shift in perception may be considered an indirect facilitator or barrier of adherence.

In addition to these themes, it became apparent during the interviews that patient perspectives varied on what home-based swallowing therapy was. When answering interview questions, participants referred to a number of different activities, such as stretches (eg, neck, jaw), maneuvers (eg, head tilt, head turn), and rehabilitation exercises (eg, Mendelsohn maneuver, effortful swallow). Two participants considered swallowing in general as the exercise, making questions on adherence difficult to analyze because these patients felt that they were constantly exercising.

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Table 2. Summary of facilitators and barriers to adherence identified in each theme.

Theme	Factor	Sample quote
Theme 1: Perceptions on outcomes and progress		
Facilitators	Perceived regression in function or fear of poor outcomes	"I need to work harder at it. And, because, I've already been pretty sick, I don't want to get sick again."
	Perceived benefit as a result of the exercise	"I did stick with it because I went, 'Wow, I'd do this.' Any improvement in swallowing, being able to maybe eat a little faster cuz it's going down quicker, I want. I really want it."
Barriers	No swallowing problem or restored function	"I told myself, oh I'm in the clear!"
	Perceived little or no progress	"I don't see any more progress, I'm not doing this anymore."
	Unrealistic postcancer treatment outcome expectations	"(...) you realize okay well this is gonna take time."
	Pessimistic adjustment in outcome expectations	"I just resigned myself to the fact that I don't think my situation is really gonna change."
Theme 2: Role of clinical appointments		
Facilitators	Education	"Now, now I see where you-, what you're getting at, when you invent these exercises."
	Building confidence	"I was always second-guessing really my technique. So I found the technique a little bit difficult to actually maintain. Um, especially after (...) I would leave the in-house session and try to do them at home."
	Tailored prescriptions	"But she said if it's too difficult and you find an issue then just at least continue on with the other ones. Just don't stop"
	Accountability	"(...) you slide into bad habits pretty fast. If you're not constantly monitored."
Barrier	Access	"So so if I was doing something wrong, I didn't have the feedback to tell me try this or try that. I had to wait till my next appointment."
Theme 3: Cancer treatment		
Barriers	Memory and focus	"I'd get home and you'd hand it to me, like do this, this and this, and I'd go, 'Well that's so simple' Good God. And I'd get home and go (face palm) 'What, what (...) oh man, I don't remember, I don't know what this means, and I'm not gonna phone because this is grade 3 instructions' know what I mean?"
	Sense of overwhelm with information and recommendations	"(...) this type of cancer is very complex in its requirements for support and therapy, yeah, some days, it's just like whoa, it's a lot to keep on track, I can't keep it all up."
	Low energy and fatigue	"So sometimes all I had time for or energy in the day was a 1 hour visit with somebody. Maybe half an hour only. And then exercises, even eating sometimes would fall off because I wanted to go nap and sleep."
	Other side effects	"You're tired. You're tired of choking. You're miserable. You're isolated. You can't communicate as it is except by writing a lot of places. Like for months. After the radiation burns your throat and that, it makes it harder to swallow, your throat's raw. For so many reasons that make it easy not to, to swallow. And to take the food, there's just an endless list of reasons why you can say, 'Well, it's too hard!'"
Theme 4: Rehabilitation program		
Facilitators	General: tracking progress, providing reminders, routine, setting goals	"So then I was tracking my swallow exercises at home, which, yeah, helped, I think. Helped to motivate me, to remind me that those were really critical. And helped me to also track how was how well I was doing."
	Patient-specific: adjusting the practice environment, customizing the exercise schedule	"At first, I'd get up in the morning and do them, kind of when I did my meds and stuff and try and get rid of all that at the same time."
	Exercise-specific: novel, interesting, easy, tackle multiple goals at once	"(...) but some of the ones were very unique, so there (were) more complex ones where you held (...) your breath. I thought, 'Oh, actually this is kind of cool' So it was kind of intriguing for a while."
Barriers	General: no structure, distractions, length of time in rehabilitation program	"(...) But it's not official, it's not regimented, it's not programmed (...)"

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Theme	Factor	Sample quote
	Exercise-specific: too complex or difficult, feeling self-conscious, misinterpreting other activities as exercise	"(...) but after a while the complex ones fell off rather quickly" "So there is an embarrassment factor that you have to get over. But I just go down into in my room in the basement and sortta, I guess isolate myself a lot to do certain exercises."
Theme 5: Personal factors		
Facilitators	Positive and grateful	"But then after I started feeling better again, then I thought, 'Well, the rest of me is getting better, this part might as well come along too' so, I kind of got back into doing them a little more."
	Coping, through self-talk and self-compassion	"I would think, 'Just stop, stop whining, get get up and get better'". "I would forgive myself that day. And then I would (unintelligible) tomorrow."
	Sense of personal obligation to health care workers involved in extended treatment	"The thing is to (...) keep it in your mind that the surgeons and the therapists and the nurses and the whoever are the ones that are the reason why you're here. And you owe it to them and to yourself to, (unintelligible) and to be strong (...)."
	Wish to become a role model or helper	"I think more like, I want to be a role model for my friends. Yeah. I want to show them that if you put your mind to it, you can do it."
Theme 6: Connection		
(Potential indirect) facilitator	Patient perceives his or her function to be better than that of peers	"It's not fair, but then there's others where, like there's for example the guy that can only eat cream of wheat, I'm going 'Wow, I'm miles ahead of him!'"
(Potential indirect) barrier	Patient perceives his or her function to be worse than that of peers	"(...) and it got really depressing, because all these people they would be put on the peg, taken off the peg, off they go. New norm! (...) and they would come in and, 'Today I ate half a hamburger!' Well, I ate my first half of hamburger the other day. And this was within 3 months of their treatment (...)."

Convergent Interviews (Part 2)

A total of 84 issues and 11 preliminary themes were found across all 10 interviews. Of these, 21 were found to be convergent (Table 3). These topics were first explored for level of agreement. All participants who had an opportunity to discuss the following issues agreed that biofeedback should be immediate, simple, and straightforward; noting improvement over time is important and builds confidence; competition with oneself is preferred over competition with peers. Most participants (5 or more) agreed that: feedback should be contingent on effort, but also show user progress relative to a goal; having a third person character is not a good measure of what is happening during the swallow exercise; education is important for uptake and adherence; tracking progress over time is important; and visuals where structures are built over time are engaging. Most participants (5 or more) disagreed with issues raised by some of the participants in the first set of interviews, namely that: visuals with a medical look, such as raw signal, are unappealing; progress graphs are difficult to interpret; completing all assigned swallow trials is important; and that they felt concern for a third person character in the game (ie, did not want character to get hurt if the swallow exercise was not completed well). A split in opinion was noted for the following issues: feedback should only show amount of effort (ie, not overwhelm the user with too much information), that the third person character feedback does not make it obvious if the exercise was completed correctly, that the third person player game is engaging, that more complex visuals are better than simplistic ones, that built-in reminders are beneficial, and finally that failure motivates one to keep trying.

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Table 3. Convergent themes.

Key issue	Agreed	Disagreed	Undecided or not addressed
Feedback should only show amount of effort (not too much information)	4	3	3
Feedback should be immediate	6	0	4
Feedback should be contingent on effort, but also show progress relative to goal	5	2	3
Feedback should be simple and straightforward	7	0	3
Third person player feedback is not a good measure of what is happening	5	2	3
Third person player feedback does not make it obvious if user completed exercise correctly	4	2	4
Education is important to get patients to do the exercises	6	1	3
Visuals that look medical do not look good (eg, graphs)	2	5	3
Visuals that are more complex are better that those that are too simple	4	4	3
Graphs are difficult to interpret	1	5	4
Artistic creations using biofeedback were nice, but too soft and boring	3	0	7
Completing the number of swallow trials is important	3	5	2
Built-in reminders are beneficial; patients have a lot of time demands	2	2	6
Failure motivates users to keep trying again and work harder	4	3	3
Improvement over time is important; building confidence in swallowing ability	6	0	4
Building structures over time is engaging	5	2	3
Concern expressed for third person player in the game	1	7	2
Third person player game is engaging	3	4	3
Tracking progress over time is important	8	1	1
Tracking progress should include a baseline	3	0	7
Competition with self is better than that with others	5	0	5

Discussion

Principal Findings

This study obtained detailed patient feedback on past experiences with home programs and on preferences for app visuals, findings that may generalize to other apps for HNC patients, and apps that use visual biofeedback. The study also offers a detailed documentation of our approach to designing a mobile swallowing therapy app, a methodology that may be applied when developing for other patient groups.

The exploration of determinants for adherence to home therapy revealed a number of elements that could be incorporated in future mHealth apps for swallowing therapy. First, aside from an objective approach to documenting adherence, mHealth apps would provide an opportunity for clinician remote monitoring. Fluctuations in adherence or nonadherence could alert clinicians so that they may target those patients who struggle most. Adjustments to the therapy regimen could be made remotely or in conversation with the patient, retaining an individualized quality to the therapy. For example, this is an existing feature of SwallowSTRONG, an mHealth device and app for tongue strengthening exercises (Swallow Solutions, LLC, Madison, WI). Finally, remote monitoring also provides an avenue for accountability to a clinician.

Second, apps may address any existing or anticipated gaps in access to swallowing therapy or educational information. A mobile device also provides an opportunity for HNC patients to complete exercises during high-energy periods in the day or to customize exercise programs according to medication schedule, rather than to clinician availability.

Third, mHealth devices and apps for swallowing therapy can furthermore address adherence by providing education, instructions, and biofeedback. The app could include educational screens highlighting the importance of regular exercise, and the expected impact that specific exercises are expected to have on swallow physiology. Education on how progress may change throughout the course of cancer treatment also may be important, as some patients reported neglecting their exercises when function appeared to improve. Information that can be accessed multiple times, at the user's convenience, should address concerns raised around the shame of asking for help. The app could track progress over time and use that information to demonstrate incremental improvements.

Two additional important elements that should be considered in a swallowing therapy mHealth app relate to biofeedback and social engagement. First, the biofeedback should be accurate and precise enough so that appropriate techniques are reinforced and frustration is minimized. Second, although leaderboards and status shares are important elements in many other health

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apps, our findings suggest that these are not recommended for swallowing therapy in HNC patients. Peer-to-peer comparison of performance may result in poor self-efficacy and lead to depression; however, social engagement in the app may take on other forms such as an anonymous patient-to-patient exchange of motivational messages.

Finally, some aspects of adherence appeared to be best mediated during clinical appointments. These included forming realistic expectations, building hope, and managing treatment side effects such as pain.

With respect to the development of our app, the following design recommendations were made once converging themes were synthesized. Visual biofeedback should be immediate and relative to the level of muscle activity detected. It should be represented simply so that it is easily understood. Since mixed opinions occurred with respect to displaying a reference target during each trial, perhaps this visual can be set to on or off based on user preferences.

With respect to visuals in the app, there was no real or perceived aversion to the raw signal. Whereas the participants agreed that it looked medical, most preferred it because they found it easy to interpret. An interesting finding was that typical game-play (ie, third person character jumping or ducking over obstacles) was not meaningful to the patients in this study and should be avoided for swallowing therapy apps. However, the act of constructing something over time was deemed engaging and even more entertaining than simpler visuals. When biofeedback was represented through expanding shapes and colors, participants felt that the visuals were too soft and uninteresting. Furthermore, irrespective of the visual theme, failure should be presented in a sensitive way. Whereas a few participants felt that failure in the app would be a strong motivator (eg, character falls down a cliff if target is not met), the majority of participants shared that failing in the game would be upsetting: “I would feel defeated. Like oh yeah, don’t even know how to do this.” Finally, tracking improvements over time within the game have the potential to build confidence with the user’s swallowing ability outside of the app.

With respect to app features, participants agreed that education was important, particularly to build an understanding on the importance of completing all trials with maximum effort. Connecting with other HNC patients in the app for the purpose of competition should be avoided. Built-in reminders may help some users, but could be postponed to later app versions as some participants stated that they would not use this feature.

Limitations

This study consisted of a convenience sample of 10 participants recruited over a period of 6 months. Since these interviews were conducted to inform the design of an app, it is possible that data saturation was not achieved. A time frame of 6 months was deemed a reasonable delay in the development of our mHealth app in order to engage end-users early. Furthermore, although the sample size was small, it was heterogeneous enough (eg, in duration of dysphagia, length of time from cancer treatment, and level of adherence to swallowing exercises) to represent most types of patients using the future mHealth app. In addition, 3 of the 10 participants reported no prior experience with home-based swallowing therapy and had to reflect on other types of rehabilitation exercises. Therefore, the reader is cautioned when interpreting these findings, as the themes identified here may not generalize to all HNC patients or swallowing apps.

Additional limitations include self-selection and recall bias. Two participants were noted to wear a FitBit and 1 participant wore a smartwatch; participants varied in their experience with dysphagia (6 months to 16 years). In addition, we were unable to quantify the strength of a participant’s opinion. For example, how does one distinguish between a participant who has a preference, but not a strong one, and someone who may not complete the exercise program at all if a particular design were selected?

Additional details on the study were compiled with the assistance of the consolidated criteria for reporting qualitative research (COREQ) checklist [16] and are summarized here to assist readers in assessing the level of bias present in this work. The interviewer (GC) and the second coder in part 1 (IL) are female, both with clinical experience in HNC; the industrial designers who assisted with part 2 (BK and CB) are both male. Although the interviewer had prior expertise conducting clinical interviews, this was her first time doing so in a research study. The researchers could not approach patients directly for study recruitment until consent to be contacted by the research team was provided. Therefore, it is unknown how many patients were approached, but declined to be contacted. A prior relationship existed with some patients as the primary interviewer also worked as a clinician. Furthermore, participants did not provide feedback on the transcript accuracy or findings.

Conclusions

The collection of patient perspectives is an important step in the development of mHealth technologies for a patient population that has not been extensively targeted by this industry. Although a laborious process, the themes identified in this study informed how mHealth apps could be used as an adjuvant to home rehabilitation following treatment for head and neck cancer. This approach also revealed that visuals that appeal to the development team, such a complex graphics with game elements, might not necessarily be intuitive to users.

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Multimedia Appendix 1

Semi-structured interview questions.

[PDF File (Adobe PDF File), 27KB - rehab_v4i1e3_app1.pdf]

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Abbreviations

HNC: head and neck cancer
mHealth: mobile health
sEMG: surface electromyography

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