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Review

Telerehabilitation: Review of the State-of-the-Art and Areas of Application

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Abstract

Background: Telemedicine applications have been increasing due to the development of new computer science technologies and of more advanced telemedical devices. Various types of telerehabilitation treatments and their relative intensities and duration have been reported.

Objective: The objective of this review is to provide a detailed overview of the rehabilitation techniques for remote sites (telerehabilitation) and their fields of application, with analysis of the benefits and the drawbacks related to use. We discuss future applications of telerehabilitation techniques with an emphasis on the development of high-tech devices, and on which new tools and applications can be used in the future.

Methods: We retrieved relevant information and data on telerehabilitation from books, articles and online materials using the Medical Subject Headings (MeSH) “telerehabilitation,” “telemedicine,” and “rehabilitation,” as well as “disabling pathologies.”

Results: Telerehabilitation can be considered as a branch of telemedicine. Although this field is considerably new, its use has rapidly grown in developed countries. In general, telerehabilitation reduces the costs of both health care providers and patients compared with traditional inpatient or person-to-person rehabilitation. Furthermore, patients who live in remote places, where traditional rehabilitation services may not be easily accessible, can benefit from this technology. However, certain disadvantages of telerehabilitation, including skepticism on the part of patients due to remote interaction with their physicians or rehabilitators, should not be underestimated.

Conclusions: This review evaluated different application fields of telerehabilitation, highlighting its benefits and drawbacks. This study may be a starting point for improving approaches and devices for telerehabilitation. In this context, patients’ feedback may be important to adapt rehabilitation techniques and approaches to their needs, which would subsequently help to improve the quality of rehabilitation in the future. The need for proper training and education of people involved in this new and emerging form of intervention for more effective treatment can’t be overstated.

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KEYWORDS

telerehabilitation; rehabilitation; telemedicine; health care; remote rehabilitation assistance

Introduction

In the last few years, telemedicine applications have been increasing due to the development of new computer science technologies and of more advanced telemedical devices.

Long-distance communication can be easily achieved by videoconferencing, email, and texting, to name a few. Today there is the possibility of controlling robots, robotic arms, or drones at a distance. Thanks to these advancements, the course of human action has been considerably transformed [1]. During

the last 20 years, demographic changes and increased budget allocation in public health have improved new rehabilitative practices [2]. Rehabilitation is an old branch of medicine, but in the last few years, new telecommunication-based practices have been developed all over the world. These particular approaches in the field of rehabilitation are commonly defined as telerehabilitation, which should be considered as a telemedicine subfield consisting of a system to control rehabilitation at a distance [3].

Telerehabilitation has been developed to take care of inpatients, transferring them home after the acute phase of a disease to reduce patient hospitalization times and costs to both patients and health care providers. Telerehabilitation allows for treatment of the acute phase of diseases by substituting the traditional face-to-face approach in the patient-rehabilitator interaction [4]. Finally, it can cover situations in which it is complicated for patients to reach traditional rehabilitation infrastructures located far away from where they live.

Controlled studies on rehabilitation have demonstrated that quick management of an injury or a disease is critical to achieve satisfactory results in terms of increasing a patient's self-efficacy. Hence, a rehabilitation program should start as soon as possible, be as intensive as possible, be prolonged, and continue during the recovery phase. A major factor is the initiation time, which, in general, should begin as soon as possible. In most cases, the initial stages of rehabilitation, after the occurrence of a disease or injury, could be performed by patients at home even if they need accurate and intensive treatment. For these reasons, telerehabilitation was developed to achieve the same results as would be achieved by the normal rehabilitation process at a hospital or face to face with a physiotherapist. Various types of telerehabilitation treatments and their relative intensities and duration have been reported [5].

The first scientific publication on telerehabilitation is dated 1998 and, in the last few years, the number of articles on the topic has increased, probably because of the emerging needs of people and due to the development of exciting new communication and computer technologies. Figure 1 shows the number of patients treated through telerehabilitation from 1998 to 2008 according to studies published in the international literature [2].

A remarkable increase in the number of patients treated by telerehabilitation is noticeable from 2002 to 2004. After a subsequent decrease, the number of patients assisted by telerehabilitation increased starting from 2007, probably due to the support of new technologies and the overcoming of the initial skepticism to which every new technology is subjected.

Telerehabilitation is primarily applied to physiotherapy [6,7], and neural rehabilitation is used for monitoring the rehabilitative progress of stroke patients [8]. Telerehabilitation techniques mimic virtual reality [9-12] and rehabilitation for neurological conditions by using robotics and gaming techniques [13]. Quite often, telerehabilitation has been associated with other nonrehabilitative technologies such as remote monitoring of cardiovascular parameters, including electrocardiogram (ECG), blood pressure, and oxygen saturation in patients with chronic diseases [14]. These technologies belong to another telemedicine branch called telemonitoring, which has been widely developed and used in recent years. A few studies were also centered on the economic aspects of the use of telerehabilitation to reduce the costs of hospitalization [15]. We reviewed the status and future perspectives of telerehabilitation by analyzing their impact on patients' everyday life. The main topics taken into account were (1) the status of telerehabilitation and analysis of the main medical specialties where it is being applied, (2) quality-of-life improvement due to telerehabilitation, and (3) the future of telerehabilitation.

Figure 1. Number of patients treated from 1998 to 2008 through telerehabilitation techniques.

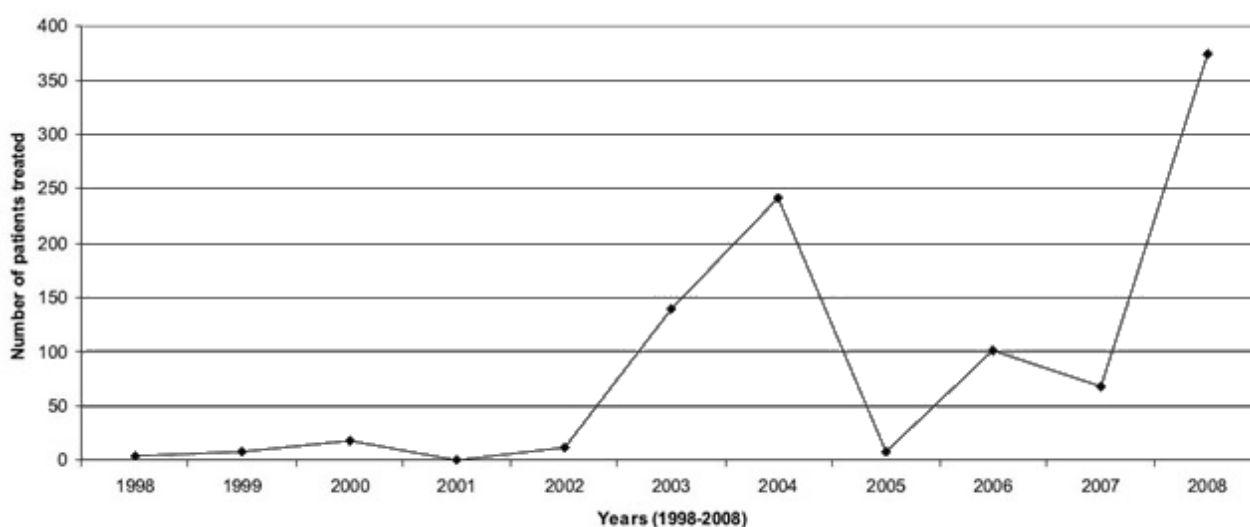


Table 1. Characteristics of studies on telerehabilitation reviewed.

First author, date, reference	Type of article	Rehabilitation area	Sample size	Article key points	Positive aspects	Barriers and limitations
Ackerman, 2010 [1]	Original research	Multiple rehabilitation areas	Literature review	Next-generation telehealth tools	Devices are available at home; electronic health record available for each person; interaction of multiple systems.	People and technological systems are not ready (data flow and incompatibility between telerehabilitation systems).
Rogante, 2010 [2]	Review article	Multiple rehabilitation areas	Literature review	Overview of telerehabilitation literature	Provides some techniques at a distance.	Health care providers are not ready; comprehensive studies are lacking.
Zampolini, 2008 [3]	Review article	Multiple rehabilitation areas	Literature review	Overview of telerehabilitation literature and a study	The possibilities of using telerehabilitation as standard in the future.	Technologies, patients, and health care providers are not ready.
Carey, 2007 [4]	Original research	Physiotherapy	Literature review	Cortical reorganization after stroke	Telerehabilitation may be effective in improving performance in patients with chronic stroke.	No clear advantage produced over the same amount of practice of random movements.
Parmanto, 2008 [5]	Review article	Multiple rehabilitation areas	Literature review	Telerehabilitation from informatics perspective	Information technology and telerehabilitation are the future.	Health care providers are not ready to manage an everyday telerehabilitation approach.
Mani, 2016 [6]	Review article	Physiotherapy	Literature review	Telerehabilitation in musculoskeletal disorders	Telerehabilitation-based physiotherapy assessment is technically feasible.	Telerehabilitation-based physiotherapy assessment was not feasible or reliable for lumbar spine posture, orthopedic special tests, neurodynamic tests, and scar assessment.
Gal, 2015 [7]	Original research	Physiotherapy	Literature review	Kinect-based system in physiotherapy	Kinect can greatly help people in rehabilitation.	Not present.
Jagos, 2015 [8]	Clinical trial	Cardiac rehabilitation	5 patients	Rehabilitation after stroke	The system used could be used for further analysis.	Not present.
Keshner, 2007 [9]	Original research	Multiple rehabilitation areas	Literature review	VR ^a as a treatment intervention	VR should be used more in the future.	People are not ready.
Larson, 2014 [10]	Review article	Multiple rehabilitation areas	Literature review	VR treatment	VR is effectively used for telerehabilitation.	Further studies are needed to optimize the techniques.
Kenyon, 2004 [11]	Review article	Multiple rehabilitation areas	Literature review	VR treatment	The virtual environment can be a valuable tool for therapeutic interventions that require adaptation to complex, multimodal environments.	Not present.
Lewis, 1997 [12]	Review article	Multiple rehabilitation areas	Literature review	VR treatment and human factors	VR has many potentialities in health care.	Some users experienced adverse effects during and after exposure to VR environments (ocular problems, disorientation and balance disturbances, and nausea).
Burdea, 2013 [13]	Case study	Physiotherapy and neurological rehabilitation	Literature review	Cerebral palsy motor control improvement	Game-based robotic training of the ankle benefits gait in children with cerebral palsy.	Additional studies are needed to quantify the level of benefit and for comparing different approaches.
Busch, 2009 [14]	Clinical trial	Cardiac rehabilitation	4 patients	Electrocardiography, blood pressure, and oxygen saturation in cardiac patients	The system shown is acceptable.	Electrocardiogram connection (27%) and blood pressure reading problems (23%); more reliability is needed.
Dinesen, 2012 [15]	Case study	Multiple rehabilitation areas	60 patients	Telehealth in pulmonary disease patients	Not present.	Future work requires large-scale studies of prolonged home monitoring with more extended follow-up.

First author, date, reference	Type of article	Rehabilitation area	Sample size	Article key points	Positive aspects	Barriers and limitations
Giansanti, 2013 [18]	Original research	Multiple rehabilitation areas	Literature review	Validation of a portable care system	Very low costs compared with optoelectronic solutions and other portable solutions; very high accuracy, also for patients with imbalance problems; good compatibility with any rehabilitative tool.	Not present.
Kairy, 2016 [19]	Clinical trial	Physiotherapy	104 patients	Upper limb through VR	This approach can enhance continuity of care once patients are discharged from rehabilitation.	Not present.
Myers, 2003 [20]	Original research	Cardiac rehabilitation	Literature review	Cardiology overview	Not present.	Not present.
Piotrowicz, 2012 [21]	Clinical trial	Cardiac rehabilitation	75 patients	Home-based cardiac rehabilitation in heart failure patients	The system used is reliable.	Further studies are required.
Fletcher, 2001 [22]	Original research	Cardiac rehabilitation	Literature review	Exercise standards for testing and training	Not present.	Not present.
Piotrowicz, 2010 [23]	Clinical trial	Cardiac rehabilitation	152 patients	Home-based tele-monitoring system	The system is effective and usable.	Not present.
Rose, 2005 [24]	Review article	Neurological rehabilitation	Literature review	VR in brain damage	VR has the potential to assist current rehabilitation techniques and will be an integral part of cognitive assessment and rehabilitation in the future.	Brain damage rehabilitation is still a relatively undeveloped field.
Satava, 1995 [25]	Original research	Multiple rehabilitation areas	Literature review	VR	Not present.	Not present.
Rizzo, 2005 [26]	Original research	Neurological rehabilitation	Literature review	VR, brain, and therapy	VR has many potentialities in medicine.	VR rehabilitation is still in an early phase of development characterized by successful proof of concept.
Linder, 2015 [27]	Clinical Trial	Neurological rehabilitation	99 patients	Improving quality of life and depression after stroke	A robot-assisted intervention may be a valuable approach for improving quality of life.	Not present.
Holst, 2017 [28]	Original research	Neurological rehabilitation	Literature review	Depression treatment	Internet-mediated cognitive behavioral therapy is an attractive alternative for some, but not all, patients with depression in primary care.	Lack of face-to-face meeting and human contact.
Vaughan, 2016 [29]	Review article	Neurological rehabilitation	Literature review	State-of-the-art of VR	VR could be used to treat neurological patients.	Not present.

^aVR: virtual reality.

Methods

Data Sources and Study Selection

We systematically searched the literature in the PubMed and Medline databases, *British Medical Journal*, Oxford Journals, Biomed Central, and CINAHL using the Medical Subject Headings (MeSH) “telerehabilitation,” “telemedicine,” and “rehabilitation,” as well as “disabling pathologies”. Parameters applied were English language, at least one keyword corresponding to the search terms in the title or abstract, and study based on the evaluation of clinical trials. An additional evaluation criterion was the publication of articles in

peer-reviewed journals. The search was carried out in 2016 for the years January 1996 to January 2016. Moreover, we selected and examined 45 books and other online materials through Google search, university of Camerino E-database, and the central library of University of Camerino. We retrieved more than 400 articles on telerehabilitation or related topics. A further analysis performed by 2 researchers independently reading article titles and abstracts reduced the results to less than the 25% of articles.

Exclusion Criteria

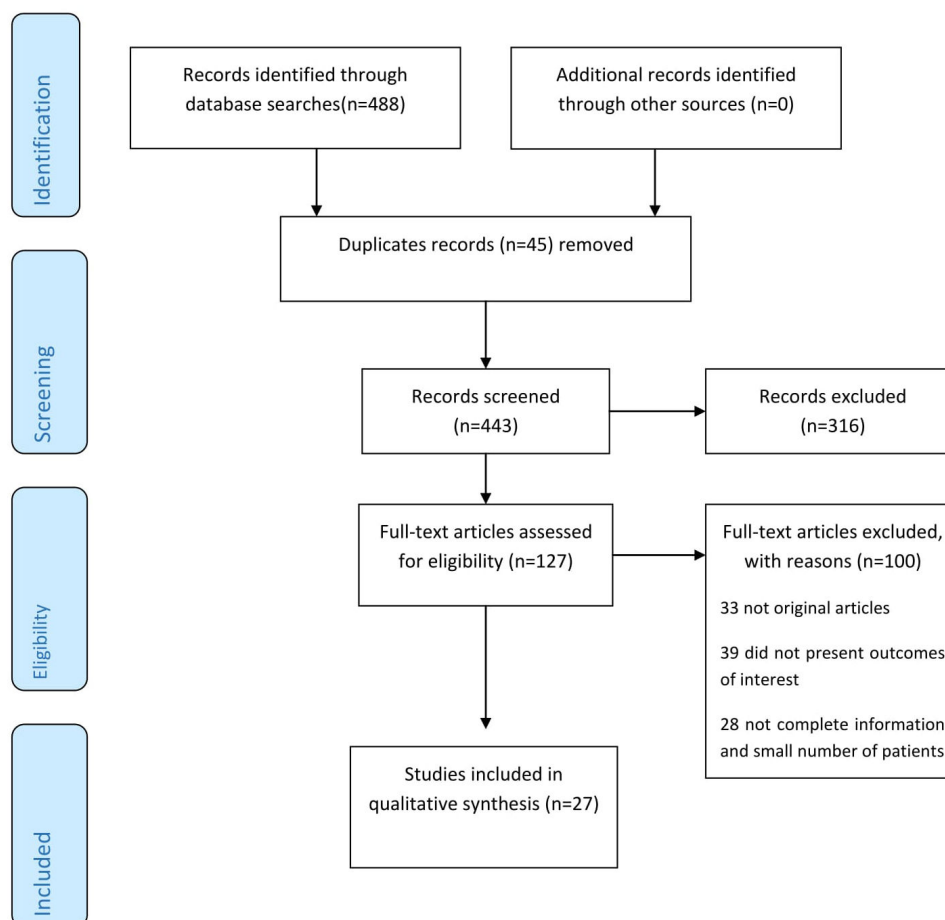
We excluded studies or other materials published before 1996 from our analysis. This is because, as [Figure 1](#) shows, the first

effective telerehabilitation procedures started in 1998. Therefore, the selected articles were published between 1996 and 2016. We also excluded articles published in nonpeer-reviewed journals, as well as pilot studies, due to the small number of patients investigated. Only English-language articles were selected. Finally, we discarded articles without the terms telerehabilitation, disabling pathologies, telemedicine, or rehabilitation in the title or keywords.

Quality Assessment

We evaluated the relevant articles with the standard criteria of the Newcastle-Ottawa Scale for assessing the quality of nonrandomized studies in meta-analyses [16]. Overall study quality was defined as poor (score 0-4), moderate (5-6), or good (7-9). The score was based on the following filters that could be attributed to a review article: comparability, and desired outcome. In addition, we analyzed various parameters of each article. The scores depended on these parameters.

Figure 2. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart.



Results

Evaluation Outcomes

The literature search identified 488 abstracts, 127 of which we analyzed in detail. Among these 127 articles, we excluded 100 in a full-text analysis (Figure 2 [17]). The search analysis showed that, although all these articles matched with the keywords we used, most of them were pilot studies evaluating the response of the system in the real environment in a small sample group of patients. We did not discard these articles because pilot studies are also a valuable source of information, but we considered them as an experience in relation to the patients involved. Finally, we chose only a few of articles (n=27) to assess applications of telerehabilitation to meet patients' needs in everyday life [18,19].

From our literature analysis, we identified that telerehabilitation was used primarily in cardiac, neurological, and physiotherapy

rehabilitation. Table 1 summarizes data derived from the literature and supplemented by additional information when available [1-15,18-29].

Cardiac Telerehabilitation

In chronic cardiac diseases, rehabilitation is one of the main tools used to improve the quality of life of patients, along with a drastic reduction of cardiac risk factors, mainly through lifestyle changes. Inpatient rehabilitation is in general effective and efficient, whereas in outpatients the quality of rehabilitation is limited. Only 13% to 40% of the total cardiac patient population in Germany performed cardiac rehabilitation in a supervised and controlled-phase program [14]. Some studies showed that at least 5 to 30 minutes of aerobic sessions per week reduce cardiac risk factors [20]. Patients do not join supervised and controlled-phase rehabilitation programs due to scheduling conflicts, difficulties in reaching the training phase, and a reluctance to perform the exercise in a group. Another

study showed that home-based telemonitored cardiac rehabilitation (HTCR) is a new method of rehabilitation for stable heart failure patients [21]. For at-home exercise, transtelephonic ECG could be a good substitute for outpatient visits [22] and probably HTCR produces quality-of-life improvements similar to those obtained by standard outpatient-based cardiac rehabilitation [23].

An example of telerehabilitation applied to cardiovascular diseases is the SAPHIRE system [14]. It consists of a bicycle with a touch screen and wireless sensors to check the patients' ECG, blood pressure, and oxygen saturation in real time. At the hospital, the supervising staff can connect remotely to the patient's computer touch screen to customize the exercises based on the results of a previous exercise stress test. They can monitor the patient's health condition in real time during the rehabilitation, and they can stop the exercises if abnormal sensors values are detected. In particular, the system has three different training forms: constant load, intervals, and heart rate control. If any limits are exceeded, the patient is alerted through an icon to reduce the load or to immediately abort the exercises. The SAPHIRE system was used in 4 patients with 13 staff members. During the experimental phase, no serious events related to heart disease occurred, but some difficulties were observed regarding sensor operation. In the 39 training sessions completed, in 27% of them the ECG connection could not be established and in 23% blood pressure measurement failed.

The more important advantage of this kind of telerehabilitation system is common to other telehealth systems. Patients can follow their rehabilitation program at a distance (eg, at home) saving time and money, and avoiding unnecessary travel and discomfort to the patient. The disadvantages are also common among different telerehabilitation systems. These include limited flexibility in the use of the various medical devices appropriate to patients' differing needs.

Neurological Telerehabilitation

In the case of neurological diseases such as brain injury or cognitive problems, the best rehabilitation for patients is to stimulate the brain with adequate environmental interactions. Probably due to the short history of neurological rehabilitation techniques, neurological telerehabilitation approaches are not clearly defined at this point and have no concrete theoretical bases [24]. Recent research in human-computer interfaces has improved the effectiveness of virtual reality. Virtual reality consists of simulations through dedicated machines such as personal computers with specific graphical features of a real environment. The machine could be interfaced with devices such as robotic arms, robotic legs, data gloves, and smart glasses. Such smart devices can be used in a 3-dimensional environment simulation, and they can allow for a greater sense of immersion in the virtual environment [10].

The first conference on virtual reality applied to medicine was the Medicine Meets Virtual Reality conference [25]. Advantages of this new type of approach over standard care were discussed. The positive results encouraged the use of this smart technology. Performing exercises inside a laboratory (ie, in front of a computer) avoids the unnecessary risk that comes with performing the same exercises in a real and dangerous

environment, can establish the simulated environment in relation to the patient's condition, and optimizes the difficulty of the environment according to the patient's neurological severity [26].

Health care treatment closer to the needs of the specific pathologies of the patient improves the quality of life and often decreases the duration of treatment. It has been shown that virtual reality can be used for the assessment and rehabilitation of specific disabilities resulting from brain injury, executive dysfunction, memory impairments, spatial disability, attention deficits, and unilateral visual neglect. A virtual urban environment for the treatment of 27 patients with moderate and severe brain injuries was developed in which patients needed to navigate in the simulator. However, this study showed no improvement due to the number of repetitions [24].

Another example of a telerehabilitation system is the Rehab@Home framework used to perform rehabilitation in the domestic setting for stroke patients [8]. The framework consists of instrumented insoles connected wirelessly to a third-generation tablet computer, a server, and a graphic Web interface for medical experts. Rehabilitation progress is automatically analyzed after assessment tests are executed in the tablet computer. Both the systems (Rehab@Home, virtual urban environment) were accepted by patients and doctors because of good results obtained. Perhaps the systems described above will not be used widely in the future, but they will contribute to improve these approaches in the future, with better cardiac telerehabilitation applications.

A telerehabilitation system was applied to 99 poststroke patients to evaluate their quality of life. The authors observed a statistically significant change in both interventions (normal and robotic rehabilitations). Actually, both modalities were effective in improving quality of life and depression outcomes for participants at less than 6 months after their stroke. The goal of this study was to obtain better results for robotic rehabilitation, but the findings obtained did not show significant differences between the 2 groups [27].

A telerehabilitation project called H-CAD was developed from 2003 to 2005. H-CAD is a system for patients with multiple sclerosis, stroke, or traumatic brain injury for performing upper limb rehabilitation treatment, at home. A help desk was developed to guide the patients in developing a proper exercise regimen by evaluating the performance periodically. Patients had the possibility to interact with doctors at the hospital through a teleconferencing system. The process was carried out in 2 test phases. The first phase was to test the results of the system with volunteers inside a hospital. The second phase was to test the system at home with ad hoc patients. The results were encouraging, and the doctors observed a marked improvement in patients using this system [3].

More recently, the use of a telerehabilitation approach in the management of patients with depression was studied [28]. Here, the authors used an Internet-mediated cognitive behavioral therapy (iCBT) system to treat depression remotely. Unfortunately, considering that depression is an important, modern, and widespread psychiatric disorder, these results were not conclusive [28]. Eventually an individual treatment design

seems to be preferred, and elements of iCBT could be included as a complement when treating depression in primary care. These procedures may be economically important because they could relieve the overall treatment burden of depression.

Physiotherapy Applied to Telerehabilitation

Musculoskeletal disorders have a high impact on health care provision. A controlled study was conducted to assess the effectiveness of a telerehabilitation approach instead of standard face-to-face practice. A literature review analyzed 898 studies on the validity and reliability of Internet-based physiotherapy assessment for musculoskeletal disorders. Most of the telerehabilitation approaches were valid if they were applied for some physical diseases, except for lumbar spine posture, where the final score was not conclusive. In fact, results showed that the intervention had effectiveness scores from low to moderate [6].

Another study demonstrated the use of Microsoft Kinect, a motion-sensing input device, to detect patients' posture and movement, and it enabled caregivers to develop custom exercise patterns for each patient. Tests confirmed that the intervention had several benefits, particularly in creating a customized physical exercise program for physical rehabilitation [7].

Discussion

The application of telemedicine to cardiology, neurology, and rehabilitation is growing fast. For instance, its use in neurology in emergency departments is particularly critical because so many of them do not have a full-time neurologist. In 2016 it was reported that about 125,000 patients who had a stroke or symptoms of stroke used telemedicine-based technology in one form or another during treatment or rehabilitation. Telerehabilitation is a young field of telemedicine (Figure 1), and it may cover different areas of medicine [2]. As a new field, it is still undergoing research and development, and all the applications available are being tested with only a limited number of patients (Table 1). Every system analyzed is a basic one used to check the effectiveness and the responsiveness of

patients and doctors to this new approach. It is easily observable that the technology is ready to be used for telerehabilitation. With the support of wireless sensors, microcomputers, and communications systems, it is possible to develop a telerehabilitation system, but further research is required to determine the effectiveness of these systems.

Advantages and Disadvantages

Like every technology, telerehabilitation has some advantages and disadvantages. In terms of advantages, home telerehabilitation systems are cost effective if the intervention is just used to monitor or evaluate patients during corrective therapy [14,29]. The possibility to stay in touch with telematic technologies allows patients with serious pathologies, such as severe cognitive deficits, to perform physiotherapy at home without having to make tiring journeys. In terms of disadvantages, a problem could be the loss of human contact (face-to-face interaction) with the doctor. Moreover, for each patient, system operators are required to optimize the teletherapy according to the type of disease, and sometimes this is not possible due to high costs.

Conclusion

This review evaluated different application fields of telerehabilitation, highlighting its benefits and drawbacks. In conclusion, this analysis has shown that telerehabilitation is a new and interesting field but, unfortunately at present, there are no standard procedures or protocols, and different telerehabilitation facilities are being used for pilot studies only. Herein, we suggest the need for further research to improve the electronic equipment and devices, and to make their application as flexible as possible. This approach should significantly increase the reliability and effectiveness of telerehabilitation equipment to treat specific patient problems. Furthermore, in this context, feedback from patients may be important to update rehabilitation techniques to improve the quality of the rehabilitation itself. On the other hand, an important aspect of the future success of telerehabilitation involves proper training of people involved in these new forms of intervention, which may lead to more effective rehabilitation.

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Conflicts of Interest

None declared.

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Abbreviations

ECG: electrocardiogram

HTCR: home-based telemonitored cardiac rehabilitation

iCBT: Internet-mediated cognitive behavioral therapy

MeSH: Medical Subject Headings

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Original Paper

Mobile Phone–Supported Physiotherapy for Frozen Shoulder: Feasibility Assessment Based on a Usability Study

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Abstract

Background: Patients with frozen shoulder show limited shoulder mobility often accompanied by pain. Common treatment methods include physiotherapy, pain medication, administration of corticosteroids, and surgical capsulotomy. Frozen shoulder often lasts from months to years and mostly affects persons in the age group of 40 to 70 years. It severely reduces the quality of life and the ability to work.

Objective: The objective of this study was to evaluate the feasibility of a mobile health (mHealth) intervention that supports patients affected by “stage two” frozen shoulder. Patients were supported with app-based exercise instructions and tools to monitor their training compliance and progress. These training compliance and progress data supplement the patients’ oral reports to the physiotherapists and physicians and can assist them in therapy adjustment.

Methods: In order to assess the feasibility of the mHealth intervention, a pilot study of a newly developed app for frozen shoulder patients was conducted with 5 patients for 3 weeks. The main function of the app was the instruction for exercising at home. Standardized questionnaires on usability such as System Usability Scale (SUS) and USE (Usefulness, Satisfaction, and Ease of use), and Technology Acceptance Model-2 (TAM-2) were completed by the study participants at the end of the study. Additionally, a nonstandardized questionnaire was completed by all patients. The correctness of the exercises as conducted by the patients was assessed by a physiotherapist at the end of the study. The mobility of the shoulder and pain in shoulder movement was assessed by a physiotherapist at the start and the end of the study.

Results: The pilot study was successfully conducted, and the app was evaluated by the patients after 3 weeks. The results of the standardized questionnaires showed high acceptance (TAM-2) and high usability (SUS) of the developed app. The overall usability of the system as assessed by the SUS questionnaire was very good (an average score of 88 out of 100). The average score of the TAM-2 questionnaire on the intention to further use the app was 4.2 out of 5, which indicated that most patients would use the app if further available. The results of the USE questionnaires highlighted that the patients learned how to use the app easily (an average score of 4.2 out of 5) and were satisfied with the app (an average score of 4.7 out of 5). The frequency of app usage and training was very high based on patient reports and verified by analysis of the usage data. The patients conducted the exercises almost flawlessly.

Conclusions: Our results indicate the feasibility of the mHealth intervention, as the app was easy to use and frequently used by the patients. The app supported the patients' physiotherapy by providing clear exercising instructions.

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KEYWORDS

telemedicine; mobile health; mHealth; frozen shoulder; adhesive capsulitis; physiotherapy (techniques); home health aides; mobile phone

Introduction

Shoulder stiffness is a condition associated with the restriction of active and passive range of motion. A variety of conditions are classified according to underlying pathologies, which could be intrinsic (pathology inside the joint), extrinsic (pathology outside the joint), and systemic (related to systemic diseases) in nature. All these conditions are summarized under "secondary shoulder stiffness." In contrast to these, the onset of primary idiopathic shoulder stiffness, also known as frozen shoulder, occurs without any apparent reason. The incidence for a frozen shoulder is reported to be 2% to 3.5% in the general population [1,2]; people in the age group of 40 to 70 years are affected more frequently [1,2]. Additionally, 10% to 36% of diabetics are affected by frozen shoulder at least once in their lifetime [3,4]. The occurrence of thyroid diseases is also linked with a fourfold increase in the risk of developing frozen shoulder [3]. In the diagnostic classification systems, International Classification of Diseases, Tenth Revision (ICD-10) and ICD-9-CM (Ninth Revision, Clinical Modification), frozen shoulder is included in the class "adhesive capsulitis" and no distinction is made between primary, idiopathic, and secondary causes. However, the term "adhesive capsulitis" does not describe the pathological process accurately [5] and thus, the term "frozen shoulder" is used consistently in our work to refer to primary idiopathic adhesive capsulitis. Frozen shoulder commonly lasts 2 to 3 years, yet the course of a frozen shoulder can vary greatly and symptoms may persist [6]. The process of a frozen shoulder is divided into three stages. It starts with a painful freezing stage characterized by an inflammatory process in the synovia and the capsule of the shoulder joint. The freezing stage is followed by a frozen stage, in which pain slowly subsides, but restriction in active and passive mobility develops. Abduction and external rotation are the most affected directions of movement, followed by internal rotation and flexion. This condition can last for several months up to several years. In the final stage, the thawing stage, mobility improves, yet for up to half of the patients limitations in mobility remain to some degree [7].

The annual treatment cost for a patient affected by frozen shoulder is estimated between \$7000 and \$8000 [3]. These treatment costs do not include the costs associated with the loss of productivity due to work disability and sick leaves. The negative effect of the patients' reduction in quality of life is not considered by costs at all. While frozen shoulder is a common disease with a large morbidity, high quality evidence for successful treatment methods is still missing [1,8-15]. Most common treatments are pain medication, physiotherapy, and surgery [16].

Physiotherapy, including mobilization and strength exercises, is a common treatment in the early painful phase as well as the resolution phase [16]. In most cases, these exercises are performed at home and not under the constant supervision of a physiotherapist, due to financial and time constraints. Exercising at home presents two difficulties for patients: training compliance and exercise correctness. Training frequency and duration at home is not maintained as intended. Noncompliance rates as high as 70% have been reported [17]. In a previous study, only 8 of 20 patients were reported to be fully compliant to physiotherapy during therapy sessions, and only 7 of 20 were reported fully compliant after the therapy ended [18]. A main factor for compliance is the successful inclusion of exercising into daily life [18]. The other main issue of home-exercise-based physiotherapy is that the majority of patients were not performing exercises at home correctly after 2 weeks of receiving their initial instructions [19]. Compliance and exercise correctness can be tackled by motivational tools and better instructions that are accessible at home. Mobile phones have become common and, therefore, a mobile phone app aiming to support patients with frozen shoulder through motivational tools and improved home instructions can be a viable contribution in the treatment of this disease.

The aim of this study was to conduct a pilot study to evaluate the feasibility of a mobile phone-based mobile health (mHealth) intervention for frozen shoulder.

The main research question was whether the mHealth intervention was feasible, that is, whether the app could be successfully employed in a field study. Evaluated measures for success were app usability, training compliance, and exercise correctness.

The organization of the study follows the guidelines for evaluation studies in health informatics [20].

Methods

Study Context

Organizational Setting

The initiative to develop an app was taken by the head of shoulder surgery at the University Hospital Salzburg (Salzburger Landeskliniken, Universitätsklinikum Salzburg, SALK), Department of Orthopedics and Trauma Surgery of the Paracelsus Medical University, Salzburg, which is a level one trauma center. The app was developed and tested at the Department of Multimedia Technology at the Salzburg University of Applied Sciences (SUAS). The study was conducted at the educational facility of the Department of

Physiotherapy of the SUAS, which is located at the main facility of the SALK.

A Mobile Phone App to Support Patients With Frozen Shoulder

The app for frozen shoulder patients was developed in a co-creation process, which included a training mode with detailed instructions on exercise conduct, an exercise calendar, and a mobile phone sensor-based mobility measurement (see [Multimedia Appendix 1](#)). The exercises were demonstrated by means of a three-dimensional (3D) avatar, which performed the exercises as intended.

The Unity3D game engine was used to implement the app. The exercises were first recorded with a 3D capturing system (OptiTrack) and on video. The OptiTrack recordings and videos were used by a 3D modeler to create accurate animations of the exercises. Several interface concepts were tested and evaluated by the authors and their colleagues (see Acknowledgments). App development was an iterative process of analysis, conceptualizing, and prototyping in a focus group. This prototype was evaluated in a focus group consisting of 8 potential patients typical for the target group and 5 physiotherapists. The final prototype for the pilot study is explained in detail in the following sections.

The main screen of the frozen shoulder app for the patients in the pilot study had 4 buttons to access four functions (see [Figure 1](#)):

1. Training Mode
2. Mobility Assessment
3. Calendar
4. Info

The training mode included instructions for four exercises (selected by a team of physiotherapists and the physician), which are shown in [Figure 2](#). In the first exercise, the shoulders are moved up and down (see first screen of [Figure 2](#)). In the second exercise, the affected arm is mobilized on a table (see second screen of [Figure 2](#)). For the third exercise, the patient is lying down and laterally moving the affected arm, while the other arm is used for support (see third screen of [Figure 2](#)). The fourth

exercise involves the use of doorframe for external rotational stretching (see fourth screen of [Figure 2](#)). The app recommends three sets with 20 repetitions for each exercise.

Mobility assessment is useful for monitoring the progress of the effect of the treatment of frozen shoulder. For mobility assessment, two options were implemented, which can be freely chosen by the patient for each mobility assessment (see [Figure 3](#)). One mode employs manual input of the range of motion with a slider, whereas the other employs the built-in sensors of modern mobile phones. Mobility is assessed in four ways: lateral arm lift, frontal arm lift, lateral external rotation, and back rotation/scratch (see [Figure 4](#)). For sensor-based measurements, the patient uses a wrist band to attach the mobile phone to the upper arm for the lateral and frontal arm lift and on the forearm to the lateral external and back rotation. Then, the user presses the “measurement” button in an arbitrary position (see [Figure 5](#)). The patient moves the arm in a neutral (hanging) position. After 3 seconds, the measurement starts (as indicated by an audible beep) and the patient moves the arm as far as possible without any pain in the measured plane. The measurement is automatically stopped if the user moves back to the initial position. The maximum angle to the neutral position is automatically computed without any user input. After reaching the maximum position, the patient can move his or her arm into any comfortable position and examine the measurement, which is also illustrated on the avatar (see [Figure 6](#)). The patient can always repeat the measurement by pressing the “retry” button. By pressing the “ok” button, the measurement is saved. The recommendation was to conduct mobility measurement once a week. The overview screen shows a monthly calendar with a progress overview. A smiley on a day indicates that the training was carried out. Measurement results are visualized as bar charts in percent of maximum possible range of motion. [Figure 7](#) shows the results of an overview screen of a patient included in the pilot study.

The information screen gives a brief definition of frozen shoulder and mentions the common treatment options, pain medication, and mobilization exercises. Furthermore, the most important functions of the app are briefly explained and contact information for the physician who supervised the study is given.

Figure 1. Start menu view.



Figure 2. Training mode.

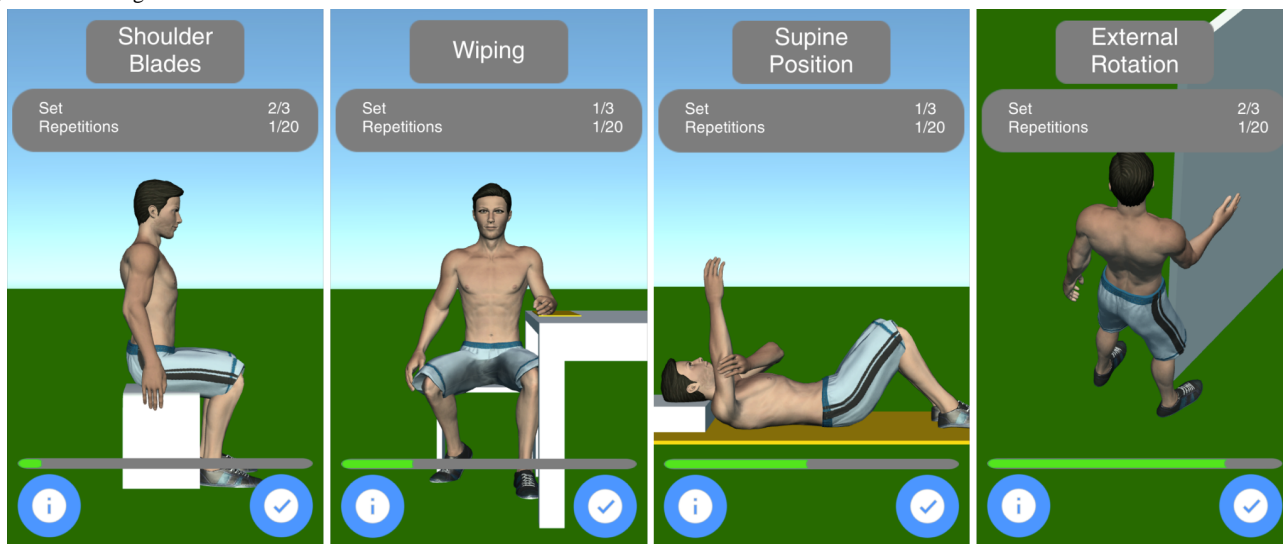


Figure 3. Start screen of mobility assessment.

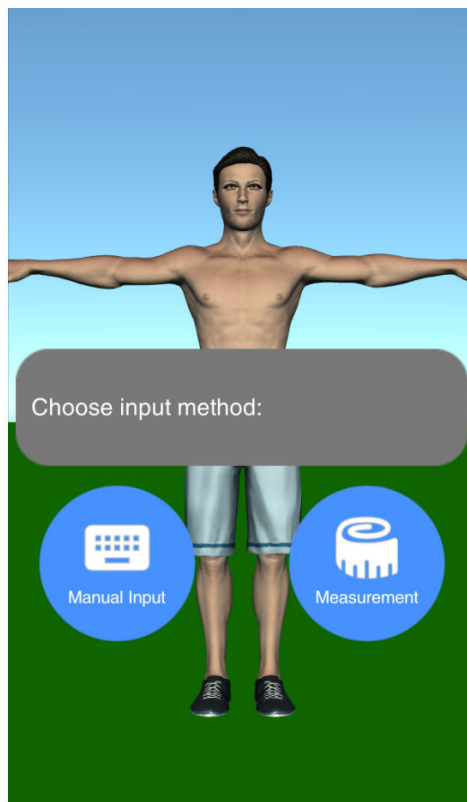


Figure 4. Mobility assessment.

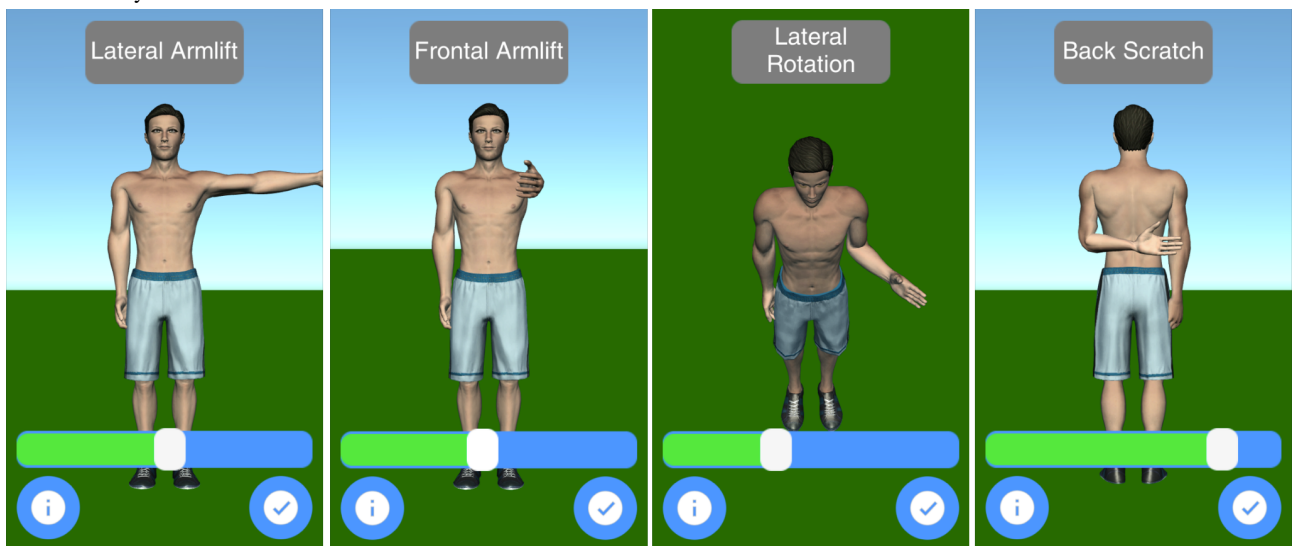


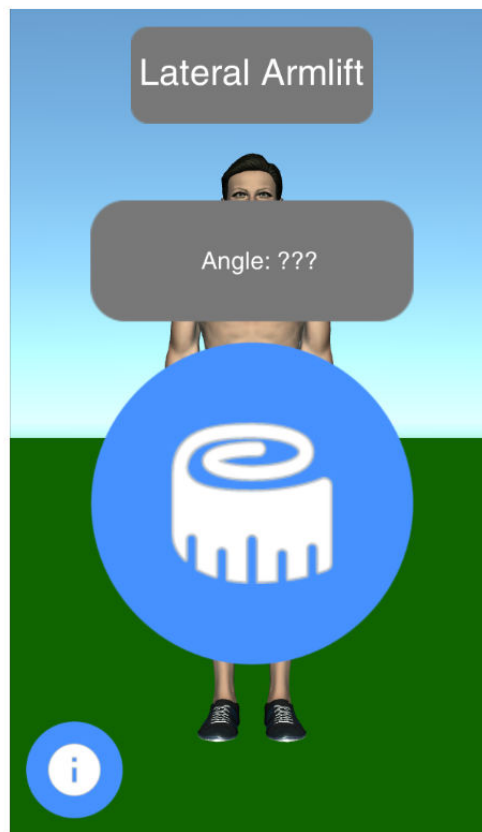
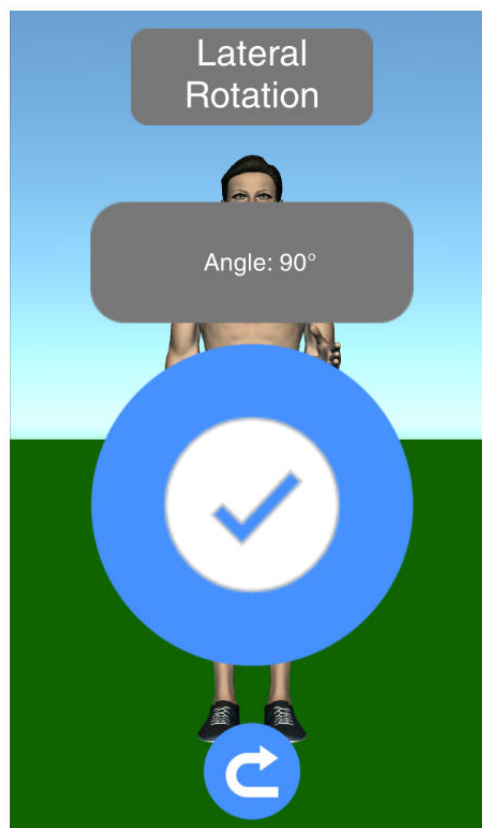
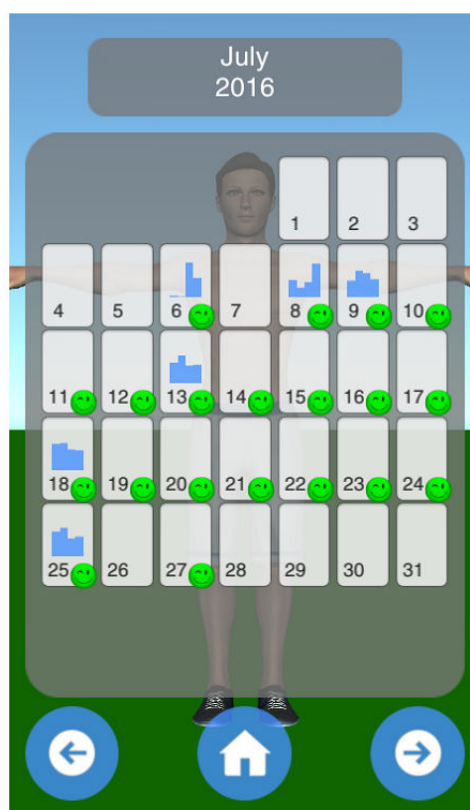
Figure 5. Start screen sensor-based mobility assessment.**Figure 6.** Result screen of sensor-based mobility assessment.

Figure 7. Overview screen.



Study Design

The study was designed to gather data on the feasibility of a mobile phone-based mHealth intervention for frozen shoulder. Therefore, the main focus was on usability of the app and the technology acceptance of the patients. Good usability and high technology acceptance were required for the feasibility of the intervention. Due to the limited number of available patients, a quasi-experimental design with no control group was chosen. Since the actual usage of the app at home was most relevant for the feasibility of the intervention, an ambulatory assessment of the app usage was included and app usage data was collected. In addition to usability, technology acceptance, and app usage analysis, we included an assessment of correctness of the exercise conduct. Several other outcome measures were evaluated as well (such as pain) to provide a context for the interpretation of the results and to gain an insight into their applicability in future studies.

The study design did not alter the standard physiotherapy for frozen shoulder (given as therapy order by the medical doctor). In the study, the app was employed to assist patients at home to conduct their exercises, comparable to an improved paper pamphlet. Thus, a formal approval of the federal ethics committee was not required by Austrian law. The study complied with the declaration of Helsinki [21], with the exemption of §35, which states that the study must be registered in a public database before the recruitment of the first subject.

Participants

Inclusion criteria were a diagnosis of “stage two” frozen shoulder (frozen stage) and the willingness to voluntarily participate in the study. The participants were recruited by the physician and shoulder surgery expert, NM.

Study Flow

The study duration was 3 weeks. Patients gave informed consent by signing a patient information sheet, including study goals and details, the voluntary participation, the data collected by the app, and a privacy statement, which informed patients that only pseudonymous information was collected during the study.

The study started with a personal meeting of each patient with a physiotherapist and a computer scientist. The exercises were explained by a physiotherapist and the app usage by a computer scientist. The patients were provided with the app either on their own phone or on a mobile phone that was provided to them. Three Android mobile phones with the preinstalled app were prepared. It was expected that the app could be installed on at least 2 patient mobile phones. Pain and movement impairments were assessed by the physiotherapist.

The patients were instructed to use the app daily to log the training, and to conduct at least one mobility assessment per week. Training and measurements were done at home and without guidance of the physiotherapist. Patients were instructed to stop training and mobility assessment in case of pain.

After 3 weeks, a second personal meeting was scheduled. Pain and movement impairments were assessed again. In this second

meeting, usability questionnaires were completed by the patients. Questions about technical aspects of the interaction with the app and the study optimization from the patients' point of view were asked as well. All questionnaires in German and English are provided in [Multimedia Appendix 2](#). The app usage log files were collected.

Outcome Measures and Evaluation Criteria

The outcome measures and evaluation criteria consisted of usability and acceptance questionnaires for the app, additional questions on the technical aspects of the intervention and the app, and an assessment of the correctness of the exercises, pain assessments, and mobility assessments.

Usability and Acceptance Evaluation

For the usability and acceptance evaluation of the app, several standardized questionnaires were employed that included selected parts (intention to use, perceived usefulness, perceived ease of use) of the revised Technology Acceptance Model (TAM-2) [22,23], the System Usability Scale (SUS) [24], and the USE (Usability, Satisfaction, and Ease of use) questionnaire, which were employed in a previous study [25]. For the interpretation of SUS scores, refer to the study by Bangor et al (2008) [26].

App Usage Data

The app automatically collected usage data, namely the time and date when the app was started and ended, the time and date and interaction type with the app (button push), and the results of the mobility measurement.

The duration of a single training set (20 repetitions of single exercise) were computed on the basis of these data.

Technical Aspects of the Intervention and the App

Furthermore, each patient was asked what they liked and what they disliked about the app. Questions on technical aspects of user interactions were asked as well, that is, whether they viewed the exercise from different angles and distances, whether they read the instructions, and whether they listened to the audio instructions. These questions were contrived by the human-computer interaction (HCI) expert and tested for understandability by the other authors.

Questions on further improvements in the overall conduct of the study and whether the initial personal instructions about how to use the app were necessary were asked.

Assessment of Correctness of the Exercises

In the second meeting, the physiotherapist reassessed the correctness of the exercises. The patients performed the conducted exercises under supervision of a single physiotherapist, and correctness was rated on a scale of 1 to 5:

1. No recollection of the exercise
2. Major errors, no effect of the exercise can be expected

3. Errors, effect of exercise limited
4. Minor errors, effect of exercise as presumed
5. Perfect execution

Assessment of Perceived Pain

The perceived pain on the first meeting (introduction of the exercises and the app) and the second meeting (interviews and evaluations) was recorded. The pain was recorded on a numeric rating scale (NRS), where 0 indicated no pain and 10 indicated the highest level of pain. Minimum pain levels (Did you experience even pain free episodes in the last days?), maximum pain (What was the worst pain you had in the last days?), and current pain levels at the time of the interview were assessed (What is your level of pain right now?). The occurrence of nightly pain was recorded as well.

Assessment of Mobility

In addition to the mobility assessment in the app, the ability to perform two movement tasks was assessed qualitatively by one physiotherapist at the start and at the end of the study:

1. Movement of the arm to the neck
2. Movement of the arm to the lower back

The physiotherapist explained and demonstrated the movement and recorded the ability of the patient to perform the task ("Able," "Hardly able," "Unable").

Results

In the following, the results of a 3-week pilot study with 5 patients affected by frozen shoulder are presented. The raw data are provided in [Multimedia Appendices 3 – 5](#). The R scripts used for analysis are contained in [Multimedia Appendix 6](#).

Demographics and Patient Characteristics

The pilot study included 5 patients: 4 female patients and 1 male patient. The app was installed on his or her mobile phone. All patients were diagnosed with "stage two" frozen shoulder. An overview of their baseline characteristics is given in [Table 1](#). The frozen shoulder affected the left shoulder in 3 patients and the right shoulder in 2 patients. Four patients were already treated with physiotherapy at the time of the first meeting. The patients' participation was voluntary.

Four of the 5 patients were mobile phone users; one patient did not own and use a mobile phone but was aided by the partner, who did own a mobile phone. The partner was present in the first and second meeting and was included in the usability results, as they used the app together. Two of the 5 patients were iPhone users. Four of the 5 patients stated that they used the mobile phone for calls and text messages. Four of the 5 patients stated that they used the mobile phone for social media or messaging services. One of 5 patients also used the mobile phone for Web surfing, other apps, and health apps.

Table 1. Patient baseline characteristics (sorted).

Age, years	Diagnosis	Shoulder
48	February, 2014	Left
49	October, 2014	Left
56	April, 2015	Left
57	November, 2015	Right
58	November, 2015	Right

Unexpected Events During the Study

At the first meeting, patients were provided with the app, and 3 mobile phones with the app preinstalled were prepared for users who did not have a suitable Android mobile phone. We expected that at least 2 patients owned a suitable mobile phone. However, the app could not be installed on 2 Android devices, as the devices were not satisfying the minimum system requirements (enough free space and a suitable graphic hardware). Furthermore, 2 patients were iPhone users and only a version of the app for Android at the time was provided. Thus, one patient could not use the app directly starting from the first meeting. This patient started app usage later and the study duration was only 10 days for this patient. These data are included in the analysis.

Study Findings and Outcome Data

In the following, the results on the changes of perceived pain, app usage, and compliance; the correctness of the exercise conduct; technical aspects of the app; and usability questionnaires are presented.

Table 2. Results of the usability questionnaires (n=6). Technology Acceptance Model-2 (TAM-2) and Usefulness, Satisfaction, and Ease of use (USE) scores range from 1 to 5 (best score). System Usability Scale (SUS) ranges from 0 to 100 (best score). SUS score above 80 indicate highly usable systems.

Questionnaire	Mean	Standard deviation
TAM-2 ^a : Intention to use	4.2	1.5
TAM-2: Perceived Usefulness	3.9	0.8
TAM-2: Perceived Ease of Use	4.4	0.5
USE ^b : Ease of Learning	4.2	0.8
USE: Satisfaction	4.7	0.8
SUS ^c	88	6

^aTAM-2: Technology Acceptance Model-2.

^bUSE: Usefulness, Satisfaction, and Ease of use.

^cSUS: System Usability Scale.

Compliance and Quantitative Usage Data

All patients reported that they used the app. The patient statements were verified by the log files of the app; the overview screens of the patients are shown in Figures 8-12. A green smiley refers to a training session. A blue bar plot represents the result of a mobility assessment (the higher the bar, the more mobile the patient's shoulder joint). The patients performed the

Usability Questionnaires

The results of the usability questionnaires are summarized in Table 2. TAM-2 answers were given on 5-point Likert scale, from 1 (negative/disagree) to 5 (positive/strongly agree). The TAM-2 results are summarized in Table 2. The users (5 patients and the partner of 1 patient) showed strong intention to further use the app (4.2 on an average); only one patient reported that she/he did not like regular usage of mobile phones at all and she/he would not like to use such apps. The users considered the app useful. The average score for perceived usefulness was 3.9. The users considered the app easy to use. The average score for perceived ease of use was 4.3.

The questions of the USE questionnaire were rated on a 5-level Likert scale as well. The users considered the app easy to learn. The average score for ease of learning was 4.2. The users were satisfied with the app. The average score for satisfaction was 4.7.

The app achieved an average SUS score of 88 (on a 0 to 100 scale), which indicates a very usable system [26].

training on every day of the study (green smileys), but one patient started later (see Figure 11). All patients except one assessed their mobility at least once a week during the study (a bar plot in the Calendar represents a mobility assessment).

In the further analysis of the quantitative usage data, the first day (instruction day) and the last day (end of study) were excluded in order to omit the instruction and reporting usage

cases of the app. Especially interesting is a closer investigation of the mobility measurements with the app. [Figure 13](#) shows all measurement results per patient; each circle visualizes one distinct mobility measurement. We excluded one patient (PID 02), who did not record any mobility measurements after the first meeting. One patient (PID 03) repeated the mobility measurements multiple times until she/he was satisfied. Overall, 139 single mobility assessments were successfully completed, 32 mobility assessments were interrupted (eg, by pressing the “home” button, an incoming call), and for 21 mobility assessments, the slider was not touched at all.

Another interesting question is how the training mode of the app was used. Namely, did the patients just quickly mark the exercises as done, or did they use the training mode to guide them through the exercises?

The avatar executes a single repetition of an exercise within 3.5 seconds, that is, 70 seconds for a set of 20 repetitions, and the time for the relaxation phase between sets was not specified. The minimum plausible time for a set when using the app during exercising was 20 seconds, as a single repetition of one exercise requires at least one second based on practical tests by the research team. The maximum plausible time for using the app during exercising was set to 200 seconds, that is, about 3 minutes for 20 repetitions and a relaxation phase.

Our analysis shows that for more than half of the time (624 out of 1145), the patients used the app during training and did not just tick off the exercises. [Figure 14](#) shows a histogram of the duration of a single set of an exercise. Many durations of a single set are close to zero; in these cases, the patients used the app often just to tick off exercises. A smaller peak at 125 seconds can be observed, which corresponds to the recommended set time (70 seconds) and less than a minute of relaxation between the sets.

The patients were instructed to conduct the four exercises with three sets each on a daily basis (4 patients for 20 study days and 1 patient for 9 study days), that is, for perfect compliance 1068 exercise sets were expected. As 1260 exercise sets were recorded, training compliance was excellent. Of these 1260 exercise sets, 78 sets had durations of above 200 seconds and were therefore excluded. 37 exercise sets were interrupted (eg, by pressing the “home” button, turning off the phone, or receiving a call) and were therefore excluded as well.

Four hundred and sixty sets had durations shorter than 7 seconds, that is, in these cases it was concluded that the app was only used to mark the exercises as completed. In addition, 61 set-durations were too long for just checking the exercise sets as done, and too short to properly conduct the exercise set. An explanation could be that the patients showed the exercises to someone.

[Figure 15](#) shows the set duration per patient and day of study. One patient (PID 05) stopped to use the app during training, and started to use the app only for confirmation after a week.

[Figure 16](#) shows the usage patterns of the app over time. Green bars illustrate the sets that have likely been completed using the app during the exercise (set durations between 20 and 200 seconds), whereas blue bars illustrate the percentage of sets that used the app just to tick off the exercises (confirmation, set durations below 7 seconds). Gray bars (label “unknown”) refer to set durations above 7 seconds and below 19 seconds. Overall, compliance stayed high during the study. For perfect compliance, each patient had to perform 12 exercise sets per day, that is, 48 exercises for the 4 patients of the first 11 days of the study and 60 exercise sets for the 5 patients for the rest of the study.

Figure 8. Overview screen of patient with PID 01.

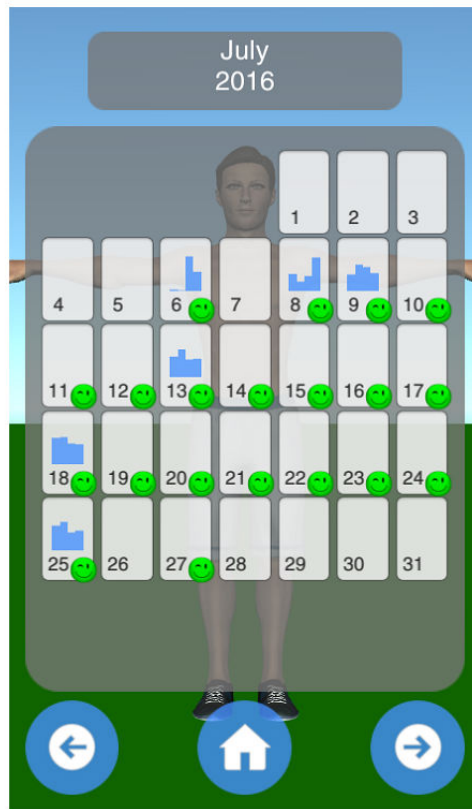


Figure 9. Overview screen of patient with PID 02.

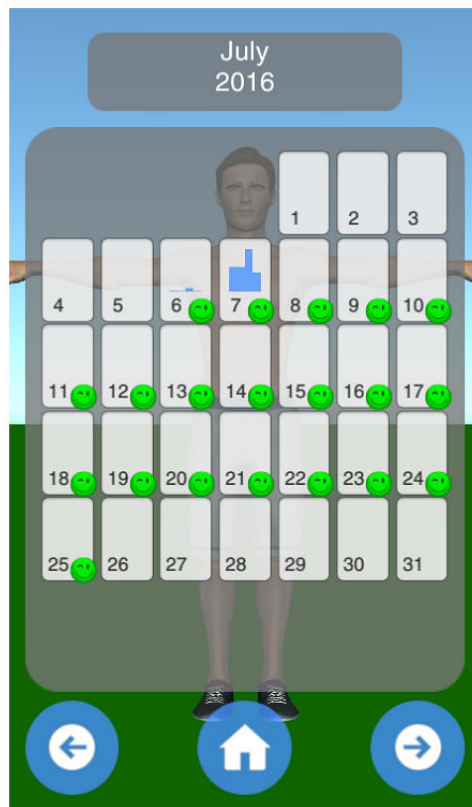


Figure 10. Overview screen of patient with PID 03.

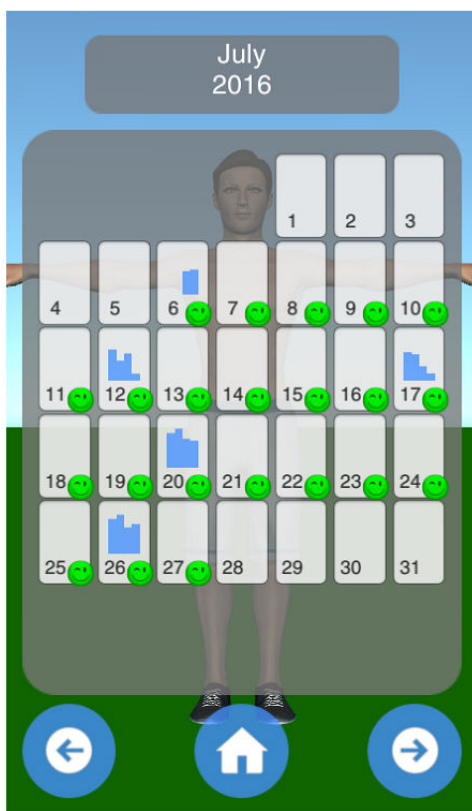


Figure 11. Overview screen of patient with PID 04.

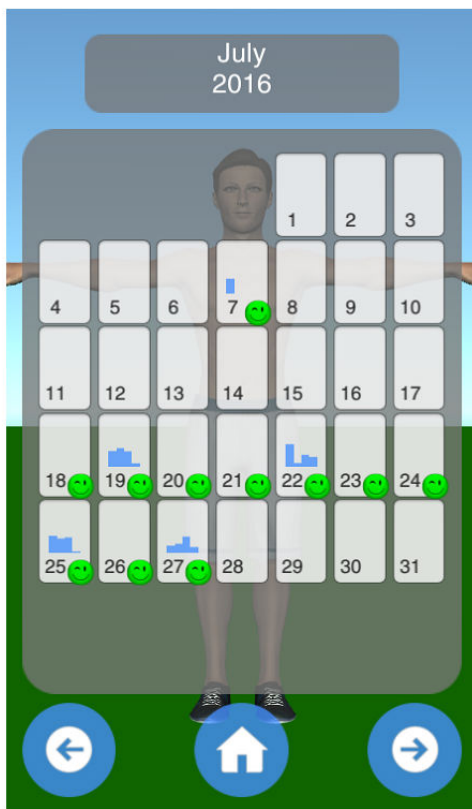


Figure 12. Overview screen of patient with PID 05.

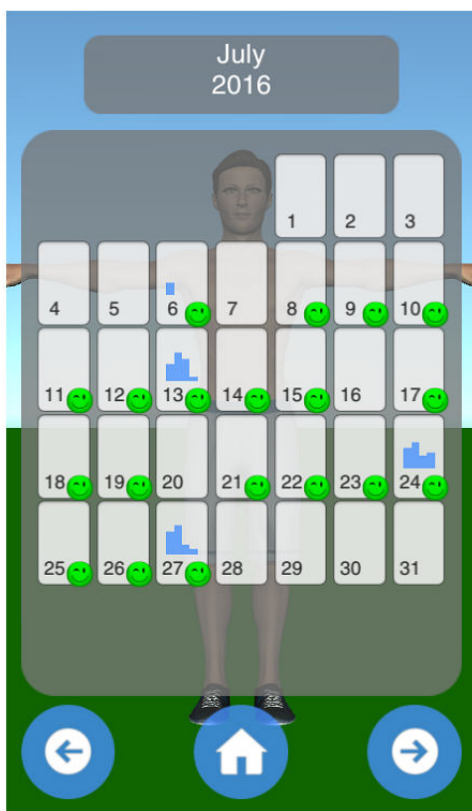


Figure 13. All mobility measurements for each patient and all four mobility assessments (n=4, N=139). Each square contains the measurements for a certain patient and a certain assessment method, that is, Lateral Arm Lift. The mobility measurement is given in percent of the maximum possible mobility range and plotted against the day of study.

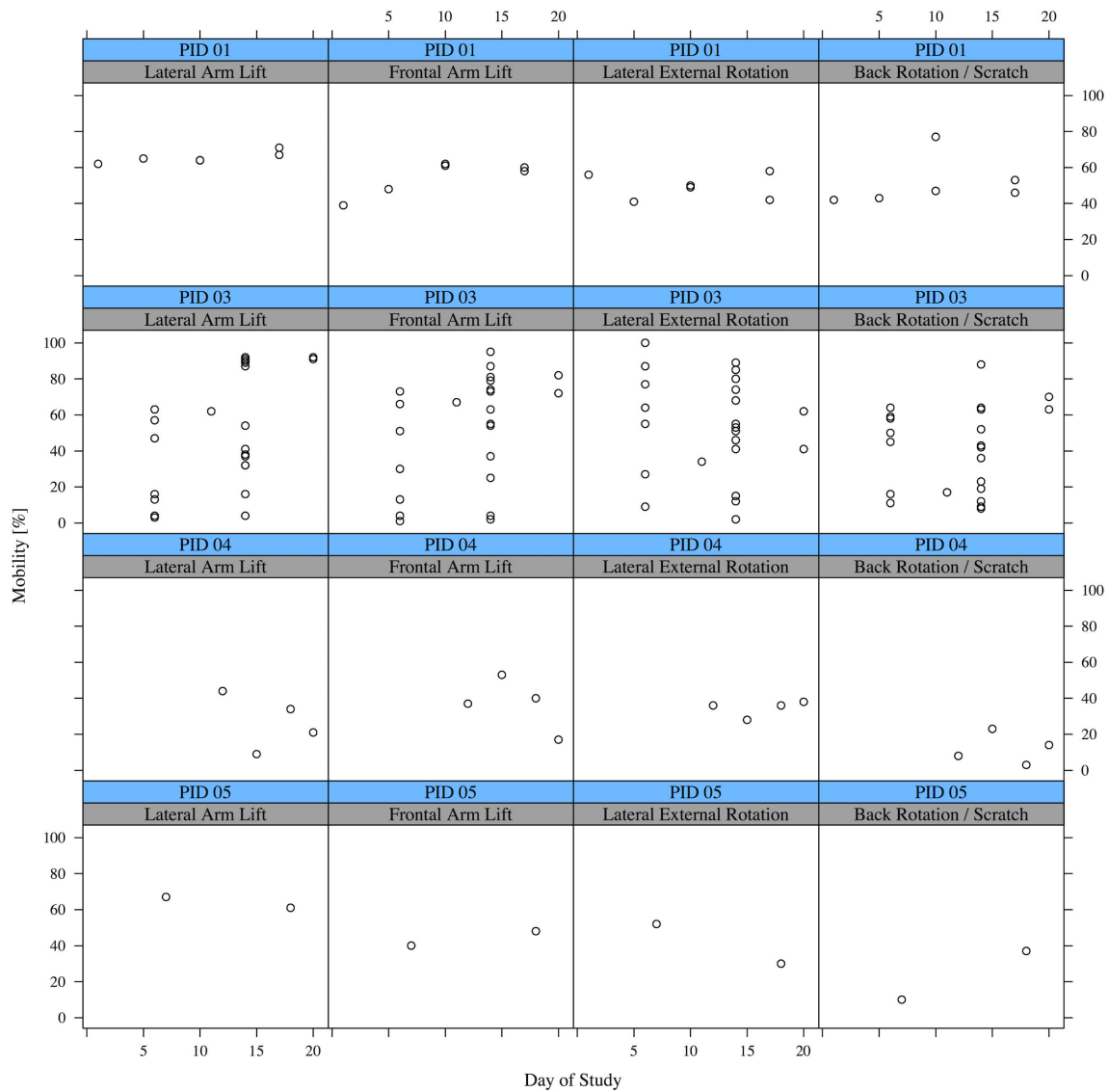


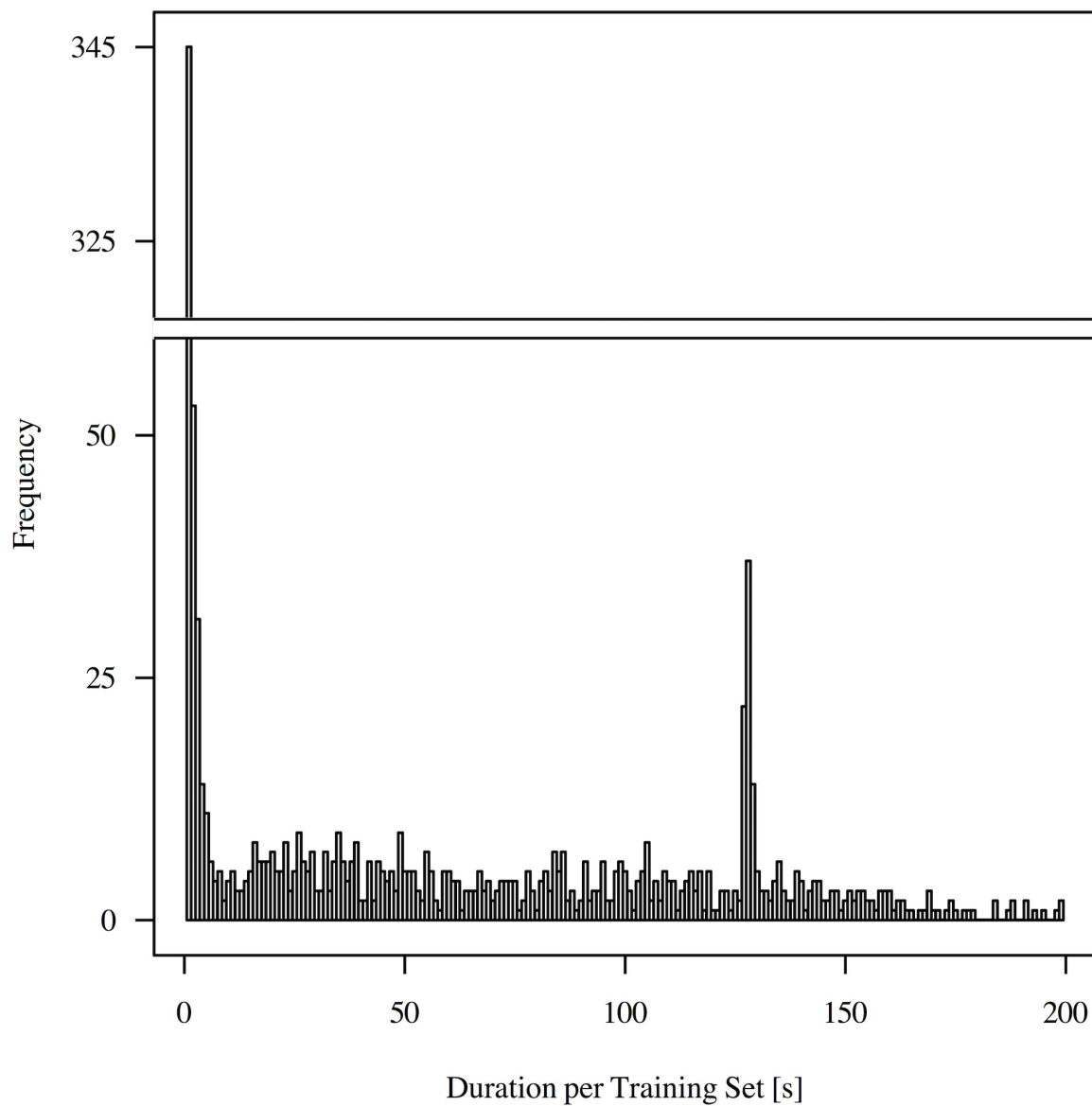
Figure 14. Histogram of training set durations (n=5, N=1145).

Figure 15. Training set durations per patient (N=1145).

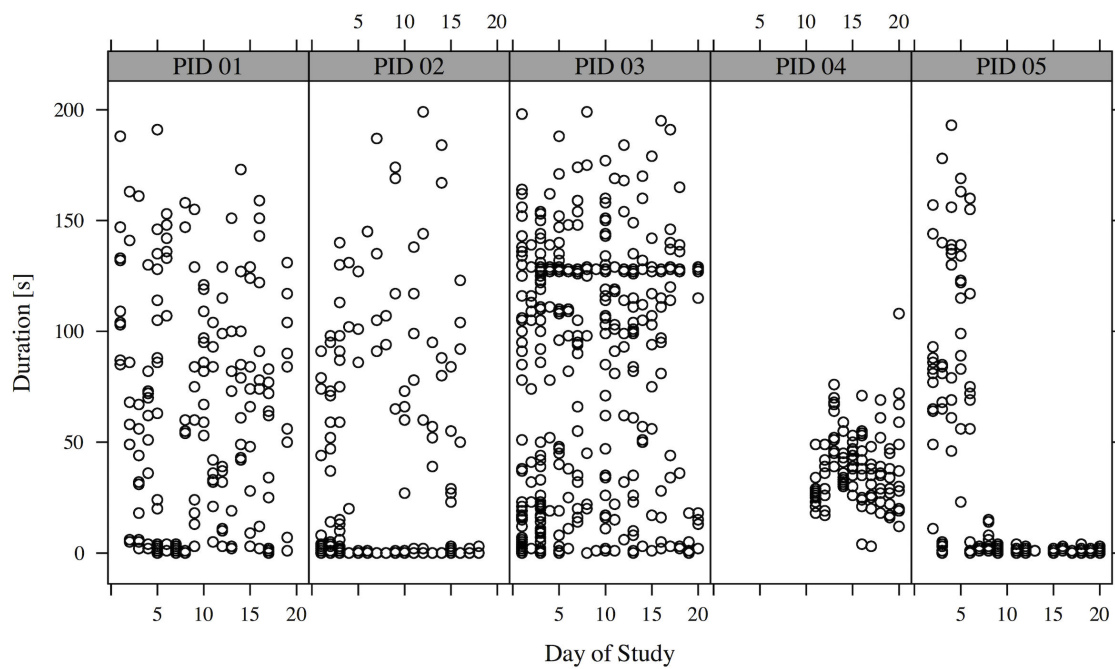
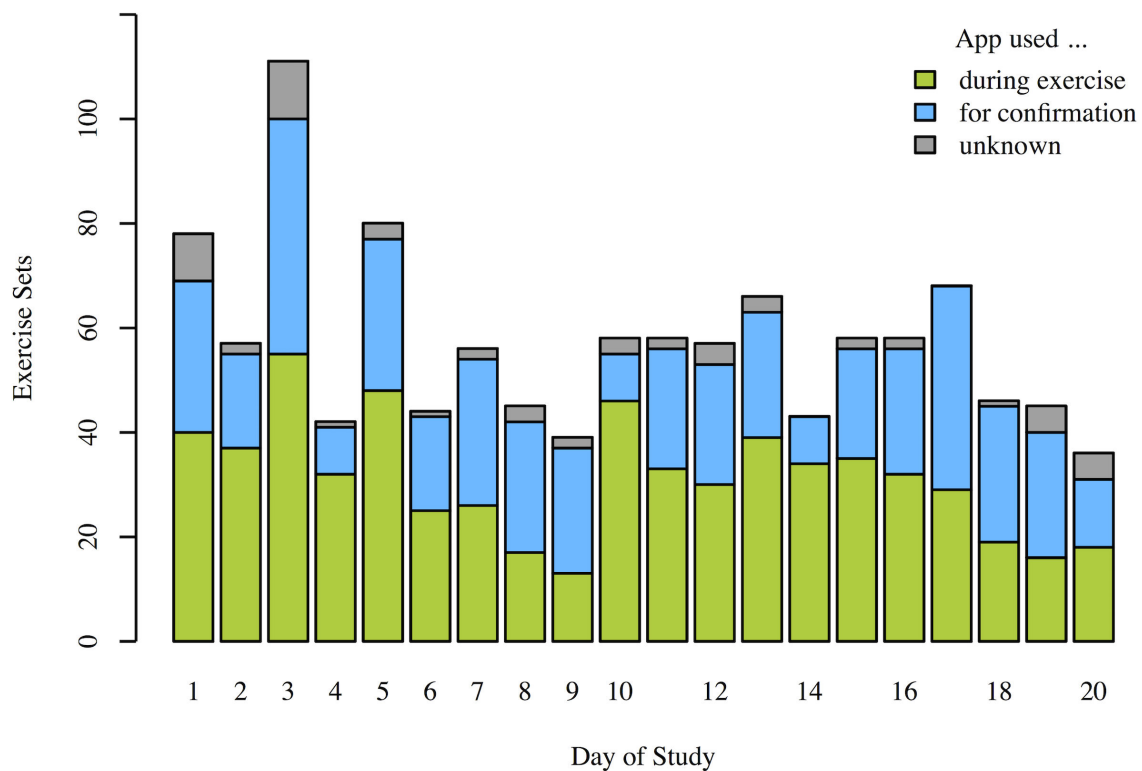


Figure 16. Training mode usage pattern per study day (n=5, N=1145).



Technical Aspects of the Intervention and the App

In the following, the feedback to each question about technical aspects of the app is summarized. In order to preserve the privacy of the patients, all information is given as generally as possible.

Q1: What Did You Like About the App and the Intervention?

One patient said that he/she liked that the app motivated her to regularly and properly conduct the exercises. One patient reported that he/she especially liked a certain exercise (stretching in the door). The partner of one patient reported that they

conducted the manual mobility assessment (without sensors) together and that the joint usage of the app was enjoyable. One patient reported that she/he liked the simplicity of the program and that the app would even be usable for someone with no mobile phone usage experience. The introduction to the app and the exercises in the first meeting were mentioned as well. Furthermore, the possibility to contact the physician during the trial was positively noted.

Q2: What Did You Not Like About the App and the Intervention?

Two patients and the partner of one patient reported that there was nothing they did not like. One patient deemed the instructions for the mobility assessment as insufficient. One patient said that despite owning a mobile phone, she/he does not like to use it and does not like to report on a daily basis. One patient reported that a different choice of wrist bands should be considered, as due to the design of the distributed wrist bands, these had to be tediously adjusted for the measurements on the upper and the lower arm. One patient said that the current manual mobility assessment required a second person.

Q3: Did You Change the Viewpoint of the Avatar?

All the patients and the partner reported that they changed the view point, in order to view the exercises from different angles and to have better control of their own conduct of the exercise.

Q4: Did You Read the Exercise Text Instructions?

Only 2 patients reported that they did not read the instructions at all; 3 patients and the partner of one patient used the text instructions.

Q5: Did the Audio Explanation of the Exercises Help?

Three patients said the audio was helpful. Two patients and the partner of one patient did not find the audio instructions helpful.

Q6: Did You Use the Mobility Assessment With the Mobile Phone Sensors?

Three patients used the assessment with the sensors. One did not know how to conduct the measurements and one mobile phone did not support the sensor measurement. Furthermore,

one patient slightly misunderstood the measurement process, which made the measurement process more cumbersome, as she/he thought she/he had to press the “accept measurement” button at the maximum angle of movement.

Q7: Would You Like to Document the Pain With the Mobility Assessment?

Three patients and the partner of one patient did not like to document pain. Two patients would have liked to document the pain, but did not have a suggestion on how they would like to do it.

Q8: What Could the Study Organizers Have Done Better?

Two patients reported that the sensor-based mobility assessment would benefit from better instructions in the first meeting and in the app. One patient recommended that at least one measurement should be done by the patient in the first meeting. Furthermore, one patient suggested more exercises (also for back pain) and a selection of exercises more specifically chosen to the individual patients’ condition and impairment.

Q9: Did You Need the Personal Instructions for the App?

Three patients and the partner reported that they needed the instructions. One patient said that only the mobility assessment needs instructions and that patients should be encouraged to perform a self-measurement during the initial instructions. One patient said that the personal instructions were not necessary.

Assessment of Correctness of Exercises

All the patients reported that no improvements of the exercise instructions were necessary. All of them thought that they conducted the exercises correctly (4, 4, 5, 5, 5; with 1 having no memory how to perform the exercise and 5 being totally correct). Four of the 5 patients could participate in the second meeting in person; one patient was ill and was interviewed by telephone. Thus, the correct conduct was only assessed for 4 patients. The assessment of the physiotherapist confirmed the correctness of the conduct of the exercises. Only minor differences to the optimal exercise conduct were present (see [Table 3](#) for detailed comments).

Table 3. Assessment of the correctness of exercises.

Patient	E1 ^a	Comment	E2	Comment	E3	Comment	E4	Comment
PID 01	4	Seat to high	4	Seat to high	5		4	Elbow not bent enough
PID 02	5		4	Upper body slightly too upright	4	Legs not bent	4	Elbow bent too much
PID 03	4	Sometimes small circular movements	5		4	Legs not bent	5	
PID 04	5		5		4	Legs not bent	5	

^aThe exercises 1 to 4 (E1 to E4 in the heading) were assessed by a physiotherapist on a scale of 1 (no recollection) to 5 (perfect execution).

Pain and Mobility Assessments

The results for the grades of pain are summarized in [Table 4](#). Decreased pain levels are colored in green; increased pain levels are colored in red and with a horizontal stripe pattern. Minimum pain levels (NRS min in [Table 4](#)) increased slightly for Patient PID 02 (from 0 to 1.5). Patient PID 05 had a decrease in minimum pain from 3.5 to 2. Maximum pain levels (NRS max in [Table 4](#)) were reduced in 4 patients (decreased by 2.5, 0.5, 1

and 0.5, respectively) and increased by 0.5 in patient PID 05. All patients reported reduced current pain levels. Pain during the night remained constant for all patients (three were affected by nightly pain, two did not).

Additionally, two movement tasks were tested, namely moving the hand to the neck and moving the hand to the lower back ([Table 5](#)). For one patient, an improvement for the first movement was recorded (from hardly possible to possible), and

for another patient, an improvement for the second movement was noticeable (from not possible to hardly possible).

Table 4. Grades of pain at the start and the end of the study in a numeric rating scale (NRS).

Patient	NRS min ^a		NRS max ^b		NRS current ^c		Nightly pain	
	Start	End	Start	End	Start	End	Start	End
PID 01	0	0	5	2.5	1	0	No	No
PID 02	0	1.5	9	8.5	2.5	1	Yes	Yes
PID 03	0	0	2.5	1.5	1.5	0	Yes	Yes
PID 04	0	0	2.5	2	0	0	No	No
PID 05	3.5	2	3.5	4	3.5	2	Yes	Yes

^aNRS values range from 0 (no pain) to 10 (high pain). NRS min refers to the minimum perceived pain in the last days.

^bNRS max refers to the maximum perceived pain in the last days.

^cNRS current refers to the pain level during the interview.

Table 5. Performance on movement tasks at the start and the end of the study.

Patient	Task 1		Task 2	
	Start	End	Start	End
PID 01	Able	Able	Hardly able	Hardly able
PID 02	Able	Able	Unable	Able
PID 03	Able	Able	Hardly able	Hardly able
PID 04	Hardly able	Able	Able	Able
PID 05	Able	Able	Hardly able	Hardly able

Unexpected Observations

Two patients reported joint usage of the app with their partner. One patient was no mobile phone user, and used the app together with the partner on the partner's device. One patient reported that the partner assisted in the mobility assessment.

Discussion

Answer to the Study Questions

The main research question of this work was whether the mobile phone app-based mHealth intervention is feasible. Considering the satisfying results in the usability evaluation and the fact that the patients actually used the app at home and could correctly perform the exercises, a strong case for the feasibility of the mHealth intervention can be made. On the basis of the analysis of the quantitative app usage data, the conclusion is drawn that excellent compliance was achieved for both training mode and the assessment of mobility. The designed app was shown to be a suitable support tool that was accepted by the majority of the small study population. The exercise instructions worked well and the 3D interaction was a beneficial and frequently used feature. The problem of uncertainty regarding how to perform an exercise (a common reason to avoid exercising [27]) was solved for the selected frozen shoulder exercises.

Overall, the app tackled important obstacles for physiotherapy at home via comprehensible and easily accessible exercise instructions, compliance, exercise correctness, and progress monitoring [28,29].

Strengths and Weaknesses of the Study

Our usability evaluation was based on a 3-week ambulatory assessment with real patients using the app at their real home and not in a controlled laboratory setting, which can raise many issues that are not illuminated in a lab or hypothetical setting [30]. Therefore, we believe that our evaluation and system are close to the actual requirements of home-based physiotherapy [28,29]. However, only 5 patients took part in the pilot study and a certain positive bias might have been introduced by the study design.

Results in Relation to Prior Work

There has been a significant interest of the research community and the industry in technology assistance for rehabilitation and health and fitness.

Apart from general health and fitness, which have become topics for major companies such as Google (Google Fit) and Apple (Apple Health), several specific medical and rehabilitation issues have been addressed in the HCI and the medical community. Among these issues were stroke rehabilitation [31], Parkinson disease [32], cerebral palsy [33], autism [34], and most importantly, for the focus of this study, musculoskeletal disorders (MSDs) [28,29], including the disorders of the knee [35] and the shoulder [36,37].

Previous studies on technology assistance for rehabilitation and health and fitness can be classified in terms of the used technology and hardware, which range from the application of professional tracking hardware [38] over virtual and augmented

reality HMDs (head mounted displays) [39] and mainstream gaming hardware [40] to everyday mobile phones [41-43].

Non-Mobile Phone–Based Systems

Professional tracking systems are capable of precisely tracking patient motion during exercises and use these data to provide feedback. A Vicon tracking system was used to implement a prototype for physiotherapy at home [44,38].

Virtual reality (VR) HMDs offer the efficient simulation of training environments. VR systems were used to simulate situations of everyday life (eg, a virtual kitchen) where patients with cognitive disabilities could relearn daily living skills [45]. VR exer-game, in which the user controls the avatar movement with an ergometer, was proposed as well [46]. However, as compared with a mobile phone app, a VR system is not as suitable for home exercising and wide deployment, as it requires expensive hardware to be installed at the home of the patient.

Augmented reality (AR) systems with HMDs (such as the Microsoft HoloLens) allow to graphically overlay the visual perception with additional information, which would be well-suited to provide patients with feedback on exercise performance. The design of AR games for upper extremity motor dysfunctions was investigated [47] and in a follow-up study, an AR game for an HMD system was evaluated [39]. However, as compared with a mobile phone, AR HMDs are expensive and not widely available at the moment.

Off-the-shelf game console hardware has been proposed to support physiotherapy. The accuracy of Microsoft's Kinect body tracking for rehabilitation purposes was quantitatively assessed [48]. Kinect-based systems for physiotherapy have been proposed [40,49]. A Kinect-based system for shoulder impingement therapy was presented as well [36]. The Nintendo Wii system includes a game controller that allows pointing at screen positions and contains an accelerometer. Rehabilitation of cerebral palsy with a system running on the Nintendo Wii was investigated [33]. Off-the-shelf Nintendo Wii Fit games were employed and evaluated with respect to the retention of motor skills of patients with Parkinson disease [32].

However, as compared with mobile phones, even gaming consoles are not as widely deployed, especially for individuals in the age group of 40 to 70 years. Furthermore, the small movements of the exercises for frozen shoulder are hard to track with off-the-shelf hardware. Even recordings of our exercises with a professional motion capturing system (OptiTrack) required manual corrections by a 3D animator.

Accelerometers and gyroscopes, that is, inertial measurement units (IMUs), have been widely used in previous studies on technology-assisted rehabilitation. An IMU-sensor-based system to deliver balance and strength exercises to the elderly was proposed [50]. Knee rehabilitation supported by IMUs was proposed [35,51]. A cap with an IMU (Sense-Cap) to monitor balance exercises was proposed and evaluated [30]. A more complex IMU-based system to provide motion guidance was also proposed [52]. Compared with our system, additional hardware (IMUs) needs to be distributed to the patients.

Mobile Phone–Based Systems

Mobile phone apps for general health and fitness have moved from research to practice. The application of mobile phone apps in medical and rehabilitation contexts is currently heavily researched.

Early studies [41,53] proposed a context-aware and user-adaptive mobile system for fitness training. A 3D avatar was used as a mobile trainer and to show the exercises. It was pointed out that the use of a 3D avatar allowed the user to perform the exercises more accurately.

The use of conversational interfaces for health and fitness companions was discussed [54]. User-tailored activity coaching systems were reviewed [55]. Mobile phone apps were investigated for physiotherapy [43]. A reminder app for stroke patients was proposed [56]. A mobile phone app to encourage activity in patients with chronic obstructive pulmonary disease was evaluated [25].

There are a large number of commercial fitness and training apps. In these apps, exercises are presented using animated videos (no view point change is possible). None of the commercially available mobile phone applications use an interactive 3D avatar, which our system offers.

Physiotherapy over video communication was discussed and evaluated [57]. It was highlighted that information of bodily cues is limited in two-dimensional videos.

Compared with most of the previous contributions from academia, which have mainly focused on special not widely available hardware (especially in the age group of 40 to 70), our proposal only requires a standard mobile phone.

Previous studies show, that new technology is hardly accepted by many elderly patients [58] and especially, hardware that has to be installed at home is problematic [31].

Although our app is not the first app to target MSDs, it is the first that specifically tackles frozen shoulder and presents an evaluation on the basis of a pilot study.

Meaning and Generalizability of the Study

Treatment options of frozen shoulder have not been assessed conclusively so far, and our contribution cannot provide this assessment. However, our results indicate that the frozen shoulder app can play an important role in patient motivation, exercise instruction, and shoulder mobility progress assessment. Therefore, the frozen shoulder app may also be employed in the evaluation process of other treatment options for frozen shoulder (mobility monitoring). The presented app can be considered the first part of a system for a thorough and standardized evaluation of home-exercise-based physiotherapy for frozen shoulder. Such a system can support the assembly of high quality evidence for the treatment options of frozen shoulder.

New Questions and Future Research/Improvements

Overall, the positive patient feedback and the results justify further work on the app to support the treatment of frozen shoulder. In the course of the study, the physiotherapists

proposed the integration of a training's planning mode, which offers more exercises and the adaptation of the number of sets and the iterations per set. The training's planning mode also enables to adapt the app more to the specific requirements of a single patient. Furthermore, physiotherapists proposed to include the possibility to add personalized information for the patient (text, audio, video). As 2 patients reported joint usage of the app with their partner, the further integration of the social contacts (partners, friends) in the app usage and training could be investigated.

Our analysis also highlights that instructions for the mobility measurement need to be improved and the repeatability and reliability of the self-measurement process of the patients need

to be carefully investigated. Users with no mobility limitations achieved almost perfect repeatability of the measurements. Given that in over 50% of the exercise sets the app was used while training but the set durations varied greatly, the inclusion of explicit timing information (a counter) should be considered.

Conclusions

A mobile phone app to support the therapy of patients with frozen shoulder was developed. Overall, the proposed mobile phone-based mHealth intervention was shown to be feasible. Main obstacles of home-based physiotherapy could be tackled, as the mobile phone-supported intervention resulted in correct exercise conduct and high compliance. The patients reported high technology acceptance and very good usability.

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Authors' Contributions

TS was responsible for writing the paper; he was the project leader and responsible for overall development of the app and the pilot study. He implemented prototypes of the app and assisted in the analysis of the log files. NM was responsible for the medical aspects of the app and the paper, literature research, patient acquisition, and the overall idea for an app for frozen shoulder patients. DH conducted the instructions for physiotherapy, developed the pain and movement assessment, and conducted parts of the interview. GE was responsible for the final version of the app and conducted the analysis of the log files. MD conducted the analysis of the log files, helped in the polishing of the paper, and advised on HCI issues. MT helped with the implementation of the app. SG initialized the project and contributed in the write-up of the paper. GJO and UF helped with the literature research, the proofreading of the paper, and as test users for the app.

Conflicts of Interest

None declared.

Multimedia Appendix 1

FrozenShoulder app.

[[APK File, 30MB - rehab_v4i2e6_app1.apk](#)]

Multimedia Appendix 2

All questionnaires (original German and English translation).

[[PDF File \(Adobe PDF File\), 150KB - rehab_v4i2e6_app2.pdf](#)]

Multimedia Appendix 3

Excel-sheets of results of all questionnaires.

[[XLS File \(Microsoft Excel File\), 72KB - rehab_v4i2e6_app3.xls](#)]

Multimedia Appendix 4

Application log file.

[[CSV File, 17KB - rehab_v4i2e6_app4.csv](#)]

Multimedia Appendix 5

Application log file.

[[CSV File, 92KB - rehab_v4i2e6_app5.csv](#)]

Multimedia Appendix 6

Evaluation scripts for log files.

[[R File, 9KB - rehab_v4i2e6_app6.R](#)]

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Abbreviations

- AR:** augmented reality
- HCI:** human-computer interaction
- HMD:** head mounted displays
- ICD:** International Classification of Diseases
- IMU:** inertial measurement units
- mHealth:** mobile health
- MSD:** musculoskeletal disorders
- NRS:** numeric rating scale
- SUS:** System Usability Scale
- TAM-2:** Technology Acceptance Model-2
- 3D:** three-dimensional

USE: Usefulness, Satisfaction, and Ease of use

VR: virtual reality

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Original Paper

Mobile App to Streamline the Development of Wearable Sensor-Based Exercise Biofeedback Systems: System Development and Evaluation

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Abstract

Background: Biofeedback systems that use inertial measurement units (IMUs) have been shown recently to have the ability to objectively assess exercise technique. However, there are a number of challenges in developing such systems; vast amounts of IMU exercise datasets must be collected and manually labeled for each exercise variation, and naturally occurring technique deviations may not be well detected. One method of combatting these issues is through the development of personalized exercise technique classifiers.

Objective: We aimed to create a tablet app for physiotherapists and personal trainers that would automate the development of personalized multiple and single IMU-based exercise biofeedback systems for their clients. We also sought to complete a preliminary investigation of the accuracy of such individualized systems in a real-world evaluation.

Methods: A tablet app was developed that automates the key steps in exercise technique classifier creation through synchronizing video and IMU data collection, automatic signal processing, data segmentation, data labeling of segmented videos by an exercise professional, automatic feature computation, and classifier creation. Using a personalized single IMU-based classification system, 15 volunteers (12 males, 3 females, age: 23.8 [standard deviation, SD 1.8] years, height: 1.79 [SD 0.07] m, body mass: 78.4 [SD 9.6] kg) then completed 4 lower limb compound exercises. The real-world accuracy of the systems was evaluated.

Results: The tablet app successfully automated the process of creating individualized exercise biofeedback systems. The personalized systems achieved 89.50% (1074/1200) accuracy, with 90.00% (540/600) sensitivity and 89.00% (534/600) specificity for assessing aberrant and acceptable technique with a single IMU positioned on the left thigh.

Conclusions: A tablet app was developed that automates the process required to create a personalized exercise technique classification system. This tool can be applied to any cyclical, repetitive exercise. The personalized classification model displayed excellent system accuracy even when assessing acute deviations in compound exercises with a single IMU.

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KEYWORDS

exercise therapy; biomedical technology; lower extremity; physical therapy specialty

Introduction

Background

Exercise rehabilitation for the treatment of musculoskeletal conditions such as osteoarthritis, following an injury or orthopedic surgical procedures, is accepted as an essential treatment tool [1-3]. Resistance training may also be used to improve one's muscular strength, hypertrophy, and power in nonpatient populations [4-6]. However, many people completing exercise programs encounter a variety of difficulties when performing their exercises without the supervision of a trained exercise professional such as a physiotherapist or strength and conditioning (S&C) coach. One such difficulty is that in many circumstances, people may execute their exercises incorrectly [7,8]. Incorrect alignment during exercise, incorrect speed of movement, and poor quality of movement may have an impact on the efficacy of exercise and may therefore result in a poor outcome [7,8]. It is therefore essential that accurate assessment of exercise performance is available to ensure that people perform their exercises properly. This is particularly necessary in cases where an individual completes their exercise program in the absence of an exercise professional's supervision, for example, during home-based rehabilitation programs or S&C programs where the person performing the exercises cannot afford a personal trainer.

Recent research has shown inertial measurement unit (IMU)-based biomechanical biofeedback systems to be an accurate exercise assessment tool. Biomechanical biofeedback involves (1) the measurement of one's movement, postural control, or force output and (2) the provision of feedback to the user regarding these measurements [9]. IMUs are able to acquire data pertaining to the linear and angular motion of individual limb segments and the center of mass of the body. They are small, inexpensive, and easy to set up, and facilitate the acquisition of human movement data in unconstrained environments [10]. Research in this field has shown the ability of multiple body-worn IMUs to evaluate exercise quality for a variety of exercises [11-14]. These range from early-stage rehabilitation exercises such as heel slides and straight leg raises [15] to more complex late-stage rehabilitation exercises or S&C exercises such as bodyweight squats [16], lunges [17], and single-leg squats [18-20]. More cost-effective and practical systems using a single body-worn IMU have also been shown to be effective in the analysis of exercise technique [17,18,21,22]. Systems that are based on a single IMU are considered preferential, as they can provide equivalent exercise analysis quality to multiple IMU setups at a lower cost.

However, in a number of cases, a single IMU setup achieves lower quality exercise analysis levels than multiple IMU setups. The ability of a single IMU setup to detect acute naturally occurring technique deviations in compound late-stage rehabilitation and S&C exercises such as deadlifts, lunges, and squats is also largely unknown; although this has been shown as possible for single-leg squats [18], the reported findings on lunges and squats pertain to detecting deliberately induced exercise technique deviations [16,17]. There is also a need to iteratively improve the accuracy, sensitivity, and specificity of

IMU-based exercise technique biofeedback systems and increase the number of exercises that can be analyzed with IMUs. IMU-based exercise biofeedback systems should be able to assess technique for a comprehensive range of exercises, both accurately and in a manner that is practical for people completing the exercises.

There are a number of considerable challenges in the creation of such biofeedback systems. First, for machine learning classification algorithms to produce desirable results, they require large volumes of training data. As such, it is difficult to collect IMU data on a large variety of exercises in a research environment. Subsequently, current research has mainly assessed very commonly completed exercises that span the scope of musculoskeletal screening, rehabilitation, and S&C. There remain thousands of exercises for which the ability of IMUs to assess their technique is unknown. Classification algorithms such as random forests and logistic regression also require balanced training datasets, where each class (eg, acceptable or aberrant) has the same amount of instances in the training data [23-25]. This provides a huge challenge in creating systems that aim to detect natural technique deviations that occur idiosyncratically and at greatly differing frequencies. This challenge is heightened in circumstances where the intersubject variation of completing an exercise with acceptable form exceeds the intrasubject variation between one's acceptable and aberrant form.

One solution to combatting the aforementioned challenges may be to create individualized exercise classification systems. In this circumstance, a classifier is created using training data solely from the person whose exercise is to be assessed. Preliminary research has shown that such classifiers can produce superior accuracy as compared with global classification systems [26,27]. Additionally, some global classification systems have only been developed and evaluated with deliberately induced technique deviations [16,17]. Personalized systems may allow for many more exercises to be evaluated for a particular person performing the exercises and could allow for acute naturally occurring technique deviations to be detected with a single body-worn IMU where this has not been previously possible. The classifiers would also be less memory intensive and more efficient, as they are developed using smaller training datasets. However, to the best of the authors' knowledge, there is a lack of tools currently available to efficiently capture and label IMU data during exercise to enable the efficient development of personalized exercise technique classification systems.

Objectives

Therefore, the purpose of this investigation was to create a tablet app that enabled efficient creation of personalized single IMU-based exercise biofeedback systems. We also sought to investigate the accuracy of this personalized system in a real-world evaluation using a sample of 4 compound lower limb exercises (lunges, single-leg squats, squats and deadlifts) in 15 participants. In this paper, an overview of the developed app is first presented. An experimental evaluation of the system in the real world is then described.

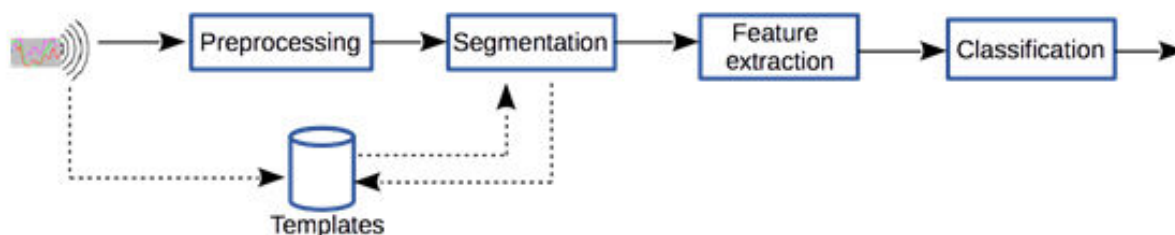
Methods

System Overview

In exercise classification with IMUs, there exist a number of universal steps that allow for the development of exercise biofeedback systems [28]. First, IMU data must be collected from participants as they exercise. Each repetition of each exercise must be labeled by an exercise professional. The signals collected from the IMU must be filtered to eliminate unwanted noise, and additional signals may be computed that, for instance, describe the IMU's three-dimensional (3D) orientation. The signals are segmented into epochs, each of which pertains to

one repetition of an exercise. Features are computed from these segmented signals as described in the upcoming "Feature Computation and Classifier Creation" section. Finally, a classification model is trained using both the labels provided by an exercise professional and the features computed from the sensor signals that pertain to the same repetitions (Figure 1). The tablet app, presented in this paper, allows for simultaneous IMU and video data capture. It then allows labeling of each IMU data epoch through reviewing its associated video epoch. Features are then automatically computed from the IMU signal epochs, and classifiers are built using these features and the labels provided by the exercise professional.

Figure 1. Steps involved in the development of an inertial measurement unit (IMU)-based exercise classification system.



Overview of Data Collection Tool

The tablet app was developed using Android Studio (Android, Google) and ran on a Samsung Galaxy S2 tablet. It contains a number of tabs that enable a vast degree of functionality to enable the automated creation of personalized classification systems. Figure 2 demonstrates the processes involved and highlights the need for data labeling from an exercise professional. The various tabs within the app are demonstrated in Figure 3. The system can connect to a maximum of 5 Shimmer (Shimmer sensing) IMUs [29] and stream synchronized data from them simultaneously. All IMUs were automatically configured to stream triaxial accelerometer (± 2

g), gyroscope ($\pm 500^\circ/s$), and magnetometer (± 1.9 Ga) data at 51.2 Hz. These values were chosen, as they have previously been shown to be appropriate for the analysis of rehabilitation exercise with IMUs [15,18,19]. However, the sampling rate and sensor ranges may be insufficient for faster exercises such as jumping or plyometric exercises. Future iterations of the system will address this by allowing the exercise professional to select sampling rate and sensor ranges based on exercise type before data collection. For this study, the IMU was calibrated by the lead investigator of this study. This took roughly 10 min.

The app then allows for the automation of all the aforementioned steps in the development of an exercise technique classifications system as shown in Figures 1 and 2.

Figure 2. Schematic demonstrating the flow and functionality of the tablet app.

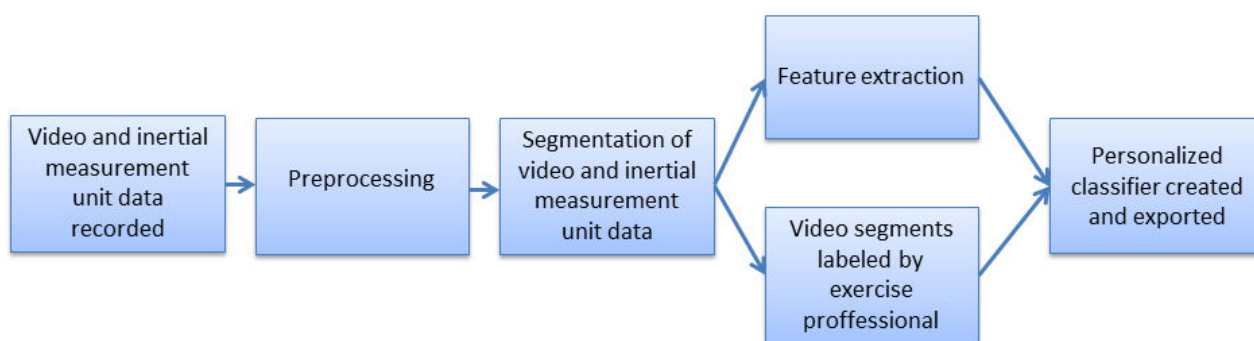
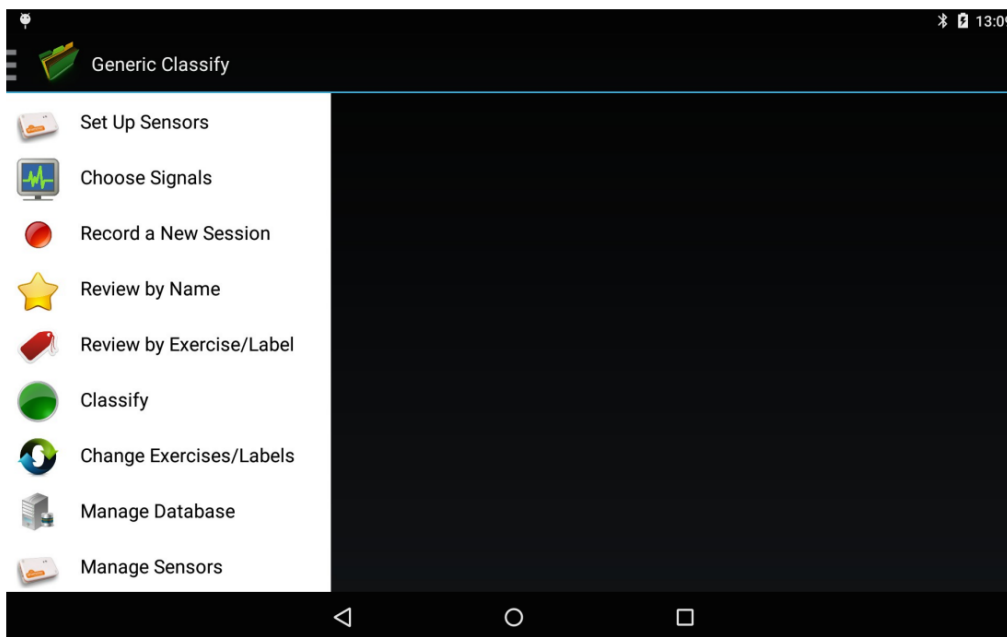


Figure 3. Home screen of tablet app, demonstrating its variety of functions.

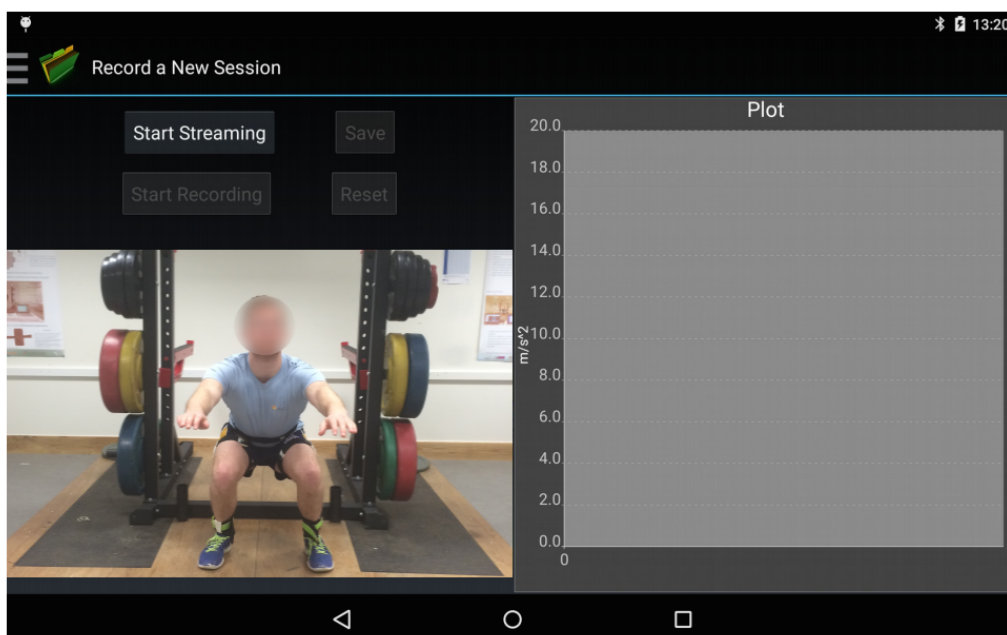


Video and IMU Data Collection

Following sensor set up, navigating to the “Record a New Session” tab allows an exercise professional to take a video of their client as they exercise, as data from the IMUs are

simultaneously collected. The video is captured at the tablet’s natural sampling rate, and IMU data are collected at 51.2 Hz (Figure 4). The exercise professional may choose to record their client from the frontal or sagittal plane depending on the exercise being evaluated.

Figure 4. Data capture part of the app that allows IMU (inertial measurement units) data and video to be captured simultaneously.



Signal Processing and Segmentation

Following the recording of a set of a particular exercise, a number of steps were completed by the app in processing the IMU data. To ensure that the data analyzed applied to each participant’s movement and to eliminate unwanted high-frequency noise, 6 signals were low-pass filtered at $f_c=20$ Hz using a Butterworth filter of order $n=8$. Nine additional signals were then calculated. The 3D orientation of the IMU

was computed using the gradient descent algorithm developed by Madgwick et al [30]. The resulting quaternion values (W, X, Y, and Z) were then converted to pitch, roll, and yaw signals. The pitch, roll, and yaw signals describe the inclination, measured in radians, of each IMU in the sagittal, frontal, and transverse planes, respectively. The magnitude of acceleration was also computed using the vector magnitude of accelerometer x , y , and z . The magnitude of acceleration describes the total acceleration of the IMU in any direction. This is the sum of the

magnitude of inertial acceleration of the IMU and acceleration due to gravity. Additionally, the magnitude of rotational velocity was computed using the vector magnitude of gyroscope x , y , and z . Although these magnitude signals do not allow for specific body segment planes to be analyzed, they can aid in capturing detection of aberrant movement when deviations are very pronounced or occur in multiple planes.

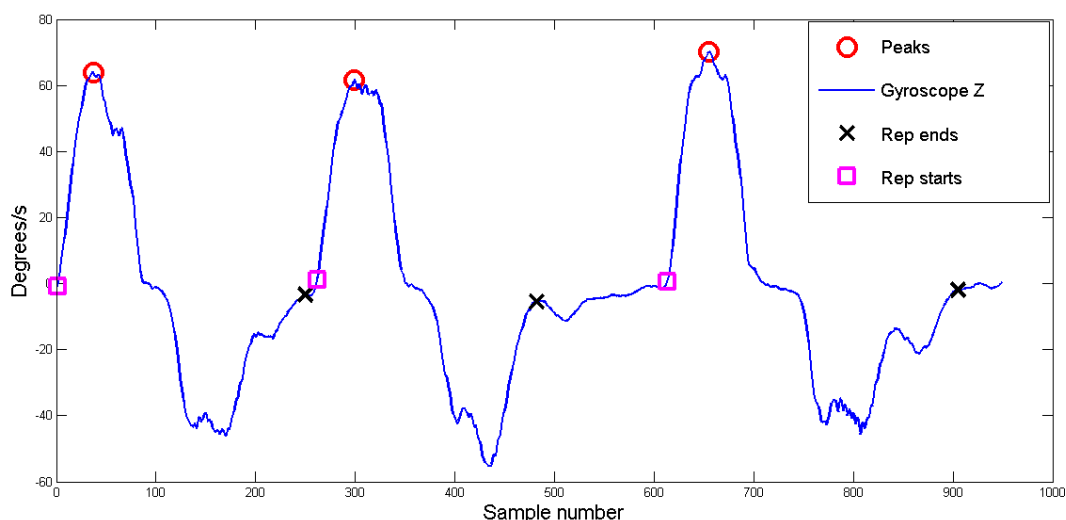
The signals and video data were then programmatically segmented into epochs that relate to single full repetitions of the completed exercises. Many algorithms are available to segment human motion for rehabilitation exercises, including the sliding window algorithm [31]; top-down, bottom-up algorithms [32]; zero velocity-crossing algorithms; template-base matching methods [33]; and the combination algorithms of the above [34]. These algorithms have advantages and disadvantages. For the purpose of the creation of a functioning classifier creation tool, a simple peak-detection algorithm was used on the gyroscope signal with the largest amplitude for any particular exercise. The start and end points of each repetition can then be found by looking for the

corresponding zero-crossing points of the gyroscope signal leading up to and following the location of a peak in the signal. Figure 5 demonstrates example results of the segmentation algorithm used on the gyroscope Z signal, from an IMU positioned on the left thigh during 3 repetitions of the deadlift exercise.

Following the signal processing and segmentation of the IMU data, the video was cut into epochs based on the start and end points of repetitions found in the IMU data. The session name, exercise name, repetition number, IMU data, and video data for each individual exercise repetition were stored as objects in a database.

The specific signal processing and segmentation processes selected were chosen based on their demonstrated capability in similar research [16-19]. In future iterations of the app, a variety of additional signal processing and segmentation options may be presented to the exercise professionals using the system, or the functions will be updated to match the emerging state of the art.

Figure 5. Plot showing detection of peak, start, and end points of repetitions through identifying neighboring zero-crossing values to the peak locations. The signal shown is the gyroscope Z signal from the left thigh during 3 repetitions of a deadlift.

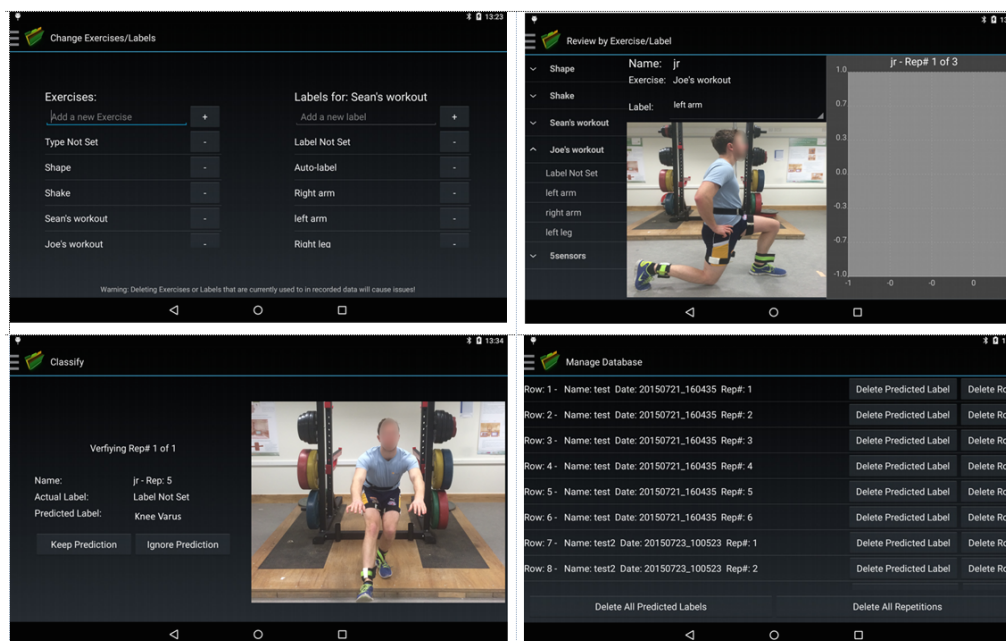


Data Labeling

The app enables a number of different functionalities regarding data labeling. The exercise professional using the tablet app first has the ability to add new exercises and technique deviations as possible labels for the stored and segmented data. These labels also become available to the exercise professional when they record new exercise sessions.

The exercise professional then has the option of labeling the videos, repetition-by-repetition, through viewing them according to the filter criteria “session name” or by “exercise type.” The default class for all repetitions is “Acceptable” until they are labeled as “Aberrant” or as a specific deviation from an acceptable technique. An unlimited number of possible labels can be created for each exercise.

Once data have been collected for each exercise, there is also an “Auto-label” function. This function uses data already labeled by the exercise professional to build a random forests classifier, which estimates the class for currently unlabeled data. As shown in Figure 6, the app then presents the classifier’s predicted label with the video of the repetition and allows the exercise professional to either keep the prediction or ignore the prediction. If the prediction is ignored, the repetition can then manually be labeled in the “review by exercise” or “review by session” tab. The database can also be manually updated at any time, allowing the exercise professional to remove particular repetitions or edit the current label for it. Figure 6 highlights the app’s various data-labeling functionalities.

Figure 6. Various data labeling functionalities of the app.

Feature Computation and Classifier Creation

Once the data have been labeled as desired by the exercise professional, the app can then build the personalized exercise technique classification objects for each client and each exercise they completed. A separate classifier is created for each different exercise.

Time-domain and frequency-domain descriptive features are computed to describe the pattern of each of the 18 signals when the 5 different exercises were completed. These features were, namely, “Mean,” “RMS,” “Standard Deviation,” “Kurtosis,” “Median,” “Skewness,” “Range,” “Variance,” “Max,” “Min,” “Energy,” “25th Percentile,” “75th Percentile,” “Level Crossing Rate,” “Fractal Dimension” [35], and the “variance of both the approximate and detailed wavelet coefficients using the Daubechies 5 mother wavelet to level 7.” This resulted in 17 features for each of the 18 available signals, producing a total of 306 features per IMU. Training data are balanced to ensure the developed classifiers are unbiased. This is done by removing random observations of overrepresented classes until all classes have an equal number of observations. For instance, if a labeled dataset of squat repetitions has 50 “acceptable” repetitions and 40 “aberrant” repetitions, 10 “acceptable” repetitions, which are chosen randomly using a programmatic method, will not be used to train the classifier. Finally, the app builds random forests classifier objects with 400 trees.

The choice of features computed, balancing of training data, and use of a random forests classifier all replicate recently published work in the field [15-18]. Similar to signal processing and segmentation, these processes can be updated in future iterations of the app to match the emerging state of the art in exercise technique classification with IMUs.

The developed classifier objects can then be exported from within the tablet app to individual’s exercise biofeedback apps on their mobile phones for use in monitoring their rehabilitation exercise programs.

System Evaluation

Participants

Fifteen volunteers currently not undergoing any rehabilitation participated, whereby no participant had a current or recent musculoskeletal injury that would impair their exercise performance. Participants were recruited via poster advertisements on notice boards in the local area and were, therefore, a sample of convenience. Of these, 5 participants were beginner exercisers who had been screened to have naturally aberrant technique and were untrained in the exercises in the study, whereas 10 participants were experienced with the exercises and were required to deliberately mimic aberrant technique at appropriate times during the experiment. Each participant signed a consent form before completing the study. The University College Dublin Human Research Ethics Committee approved the study protocol.

Experimental Protocol

The testing protocol was explained to the participants upon their arrival at the research laboratory. Their gender was recorded and their weight was measured using a weighing scale. Height was then measured with a stadiometer. All participants completed a 5-min warm-up on an exercise bike, during which they were required to maintain a power output of 100W and cadence of 75 to 85 revolutions per minute. Following the warm-up, an investigator placed a single IMU on the participant at the midpoint of the left femur (determined as halfway between the greater trochanter and lateral femoral condyle). The orientation and location of the IMU was consistent across all study participants. The IMU sampling rate and sensor range settings used were identical to those described in the “Overview of tool” section.

Video and IMU data were then simultaneously collected as the participant completed 4 of the following exercises: bodyweight left leg, single-leg squats; bodyweight lunges; bodyweight or barbell squats; and barbell deadlifts. These exercises were

chosen pragmatically, as they represent compound lower limb exercises that span both the late-stage rehabilitation (knee, hip, and ankles) and S&C domains. They also cannot be easily analyzed by any existing systems. Forty repetitions of each exercise were collected; 20 repetitions were completed with “acceptable” form, whereas 20 repetitions were completed with “aberrant” form. The “aberrant” repetitions from the 5 beginners were naturally occurring, whereas the 10 experienced participants deliberately induced their “aberrant” form. Following these data collection, the IMU was removed from the participants’ left thigh.

As the participant rested, the exercise professional then used the segmented videos to label all exercise repetitions of the 4 exercises as being “acceptable” or “aberrant” technique (160 repetitions per participant). For each participant, 4 binary random forests classifiers were then created, each pertaining to 1 of the 4 aforementioned exercises. These random forests objects were imported into a biofeedback app. The data labeling and classifier creation took a maximum of 30 min per participant. The biofeedback app entitled “Formulift” (Figure 7) allows a person performing the exercises to connect to a Shimmer IMU, select each of the above exercises, and have their repetitions of each exercise be classified as “acceptable” or “aberrant.”

Following the creation of their personalized biofeedback system, the participants first secured the IMU to their left thigh by

themselves and connected the wireless Shimmer IMU to the mobile app. These steps took roughly 1 min. They then completed 2 sets of 10 repetitions for each of the 4 exercises. In the first set of each exercise, they were instructed to exercise with their best possible technique, and in the second, they were asked to try and replicate the mistake they had made before being coached by the exercise professional. The video of the whole session was simultaneously taken, and the classifier’s predictions of the participants’ technique were stored in the background storage folders on the tablet.

Data Analyses

Following the participants’ use of their personalized biofeedback app, the system’s predicted labels (acceptable or aberrant) for each repetition of each exercise were stored. The videos of each repetition of each exercise were then labeled by an S&C coach with more than 5 years’ experience in visual analysis of the exercises. They were labeled as acceptable or aberrant in a systematic format. The S&C coach could view the repetitions as many times as necessary to make a clear judgment on the label. Labeling all data for each beginner participant took under 25 min and was quicker for the experienced participants as their aberrant form was deliberately induced. Example types of aberrant form that the exercise professional was looking for included knee valgus, knee varus, and asymmetry as used in similar recent research [16-19].

Figure 7. Screenshot from the “Formulift app,” which uses the classifiers developed from the tablet app to analyze whether a person’s exercise technique is acceptable or aberrant as they complete squats, deadlifts, lunges, and single-leg squats.

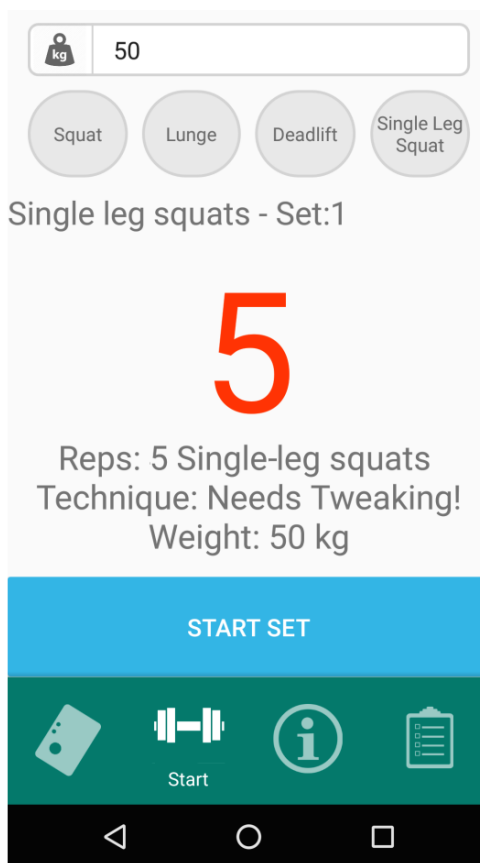


Figure 8. Formulae for: a) accuracy, b) sensitivity, and c) specificity.

$$a) \text{ Accuracy} = \frac{TP+TN}{TP+FP+TN+FN}$$

$$b) \text{ Sensitivity} = \frac{TP}{TP+FN}$$

$$c) \text{ Specificity} = \frac{TN}{TN+FP}$$

The personalized, classifiers-predicted labels were then compared with the exercise professional's labels, which were considered to be ground truth for each repetition of each exercise from each participant. Where the exercise professional had labeled a repetition as "acceptable" and the classifier predicted "acceptable," this was counted as a true positive (TP). However, if the classifier predicted "aberrant," in this circumstance a false negative (FN) was counted. If the exercise professional and classifier both deemed a repetition to be "aberrant," it was counted as a true negative (TN). However, if the exercise professional deemed a repetition to be "aberrant" and the classifier predicted it as "acceptable," this was counted as a false positive (FP). The scores used to measure the quality of classification were total accuracy, sensitivity, and specificity. Accuracy is the number of correctly classified repetitions of all the exercises divided by the total number of repetitions

completed. This is calculated as the sum of the TPs and TNs divided by the sum of the TPs, FPs, TNs, and FNs. Sensitivity measures the effectiveness of a classifier at identifying a desired label, whereas specificity measures the classifier's ability to detect negative labels. These three metrics were used to assess the classification quality of each individual participant for each of the 4 exercises completed. The formulae for accuracy, sensitivity and specificity are shown in [Figure 8](#).

Results

Participant Demographics

The demographics of the participants were as follows: 12 males, 3 females, age: 23.8 [standard deviation, SD 1.8] years, height: 1.79 [SD 0.07] m, body mass: 78.4 [SD 9.6] kg. Each participant's characteristics are shown in [Table 1](#).

Table 1. Participant characteristics.

Type	Gender	Age, in years	Height, in meters	Weight, in kilograms
Beginner	Male	20	1.68	66.5
Beginner	Male	25	1.75	68
Beginner	Male	22	1.76	76
Beginner	Female	26	1.74	86
Beginner	Female	26	1.7	65
Experienced	Male	23	1.85	85
Experienced	Female	21	1.77	72.5
Experienced	Male	24	1.88	86
Experienced	Male	25	1.83	74
Experienced	Male	26	1.7	63
Experienced	Male	23	1.75	83
Experienced	Male	25	1.805	84
Experienced	Male	22	1.93	86
Experienced	Male	24	1.775	84
Experienced	Male	25	1.88	97
Mean (SD ^a)		23.8 (1.8)	1.79 (0.07)	78.4 (9.6)

^aSD: standard deviation.

System Evaluation Results

Table 2 demonstrates the mean accuracy, sensitivity, and specificity scores for all participants using their 4 personalized classifiers for each exercise under study, in the real-world evaluation as described in the “System Evaluation” section. The mean results for the 5 beginner participants who had naturally aberrant technique and for the more experienced participants who had deliberately induced technique mistakes are shown.

The system was more accurate for the experienced exercisers’ group (98.59%) than the beginners’ group (88.00%) for the deadlift exercise but was otherwise more accurate for the beginners. This is particularly interesting as the beginner’s technique aberrations were naturally occurring, and the experienced group’s aberrations were deliberately induced. The system was least accurate for lunges (84.14%) and most accurate for single-leg squats (97.26%) across all participants. Accuracy

varied considerably for each individual in the lunge and squat exercises, as can be seen in the presented standard deviations (Table 2). The range of accuracies across all participants was less variable for the single-leg squat and deadlift exercises.

For the single-leg squat exercise, the mean sensitivity was 98% and the mean specificity was 93%. This means the system was better at detecting acceptable single-leg squat technique than aberrant technique or that 7% of aberrant exercise repetitions were misclassified as acceptable. The system had relatively similar sensitivity and specificity in classifying lunges and deadlifts. Therefore, it would not appear biased to either the “acceptable” or “aberrant” class to an exerciser using the system. However, for the squat exercise there was a 13% chance that an acceptable repetition may be classified as aberrant and a 17% chance that an aberrant repetition may be classified as acceptable.

Table 2. Mean accuracy, sensitivity, and specificity of personalized classifiers for the binary evaluation (acceptable or aberrant technique) of each exercise and each participant.

Exercise	Participants	Accuracy, mean (SD) ^a , %	Sensitivity, mean (SD), %	Specificity, mean (SD), %
Single leg squats				
	Beginners (N=5)	99.17 (1.86)	100.00 (0.00)	98.33 (3.73)
	Experienced (N=10)	95.98 (6.69)	97.00 (4.83)	90.41 (15.24)
	All (N=15)	97.26 (5.54)	98.00 (4.00)	93.03 (19.09)
Lunges				
	Beginners (N=5)	92.63 (10.5)	96.67 (7.45)	88.70 (16.36)
	Experienced (N=10)	77.77 (21.26)	74.07 (3.19)	83.82 (32.17)
	All (N=15)	84.14 (18.96)	83.11 (27.49)	85.78 (20.85)
Squats				
	Beginners (N=5)	84.83 (16.58)	75.00 (35.47)	95.00 (5.00)
	Experienced (N=10)	82.71 (15.43)	90.98 (15.25)	74.44 (32.01)
	All (N=15)	84.53 (16.38)	87.06 (27.53)	82.67 (29.00)
Deadlifts				
	Beginners (N=5)	88.00 (8.16)	84.00 (16.25)	90.00 (2.00)
	Experienced (N=10)	98.59 (2.71)	98.15 (3.55)	98.99 (2.86)
	All (N=15)	94.81 (7.93)	93.10 (13.35)	95.78 (14.35)

^aSD: standard deviation.

Discussion

System Development

The tool described in this paper successfully automates the process of creating personalized IMU-based exercise technique classification systems. The previously laborious sequence of data collection, data labeling, and data analyses in software such as MATLAB (MathWorks, Natwick) has been streamlined as an Android tablet app that can be used by an exercise professional. The app eliminates the need for a data analysis professional to develop the classification systems by automating the common steps in the development of such systems (Figure 1). A key benefit of this tool for exercise professionals is that it allows rapid development of personalized exercise feedback

systems tailored to their client’s exercise needs and specific movement patterns.

There are a number of notable benefits to taking an individualized analysis approach to the development of IMU-based exercise technique analysis systems. Recent work has shown such systems to be more accurate and computationally efficient than global classifiers [27]. The development of global classifiers is extremely time-intensive and requires hundreds of hours of data collection and analysis by researchers. Data must be collected in such fashion for any exercise for which a technique classifier is desired. This means that, currently, there exist only a handful of exercises that have been proven to be possible to assess with IMUs. The system described in this paper should allow for the creation of a

personalized exercise classifier for any rehabilitation or S&C exercises that are cyclical and repetition based. Therefore, clinicians would not be limited in their exercise choices when designing specific programs to meet their clients' needs. The app described in this paper could be conceivably used by a clinician during a patient's visit to their clinic, and then the data labeled from this session could be used to create a functioning analysis tool for their program, which they may complete in the absence of professional supervision.

System Evaluation

The preliminary evaluation of the system also suggests that the accuracy, sensitivity, and specificity of the personalized exercise technique classifiers may exceed that of global exercise technique classification systems. This reflects other similar research that compared sensor setups and classification methodologies for the barbell squat and deadlift exercises [27]. Although it is difficult to make direct comparisons with the previous research, it can be noted that a single IMU positioned on the left thigh has been demonstrated as capable of assessing acceptable or aberrant lunge technique with 77% accuracy [17] and single-leg squat technique with 75% accuracy [18]. These values were computed using leave-one-subject-out cross-validation. The personalized systems, evaluated in the real world, achieved 84% and 97% accuracy for the same analysis of lunges and single-leg squats, respectively. The binary classification of squat technique has previously been shown to be 80% accurate in a global classification system using a single lumbar-worn IMU [16]. The individualized systems described in this paper ranged from 50% to 100% accuracy and had a mean value of 85% across the 15 participants. It can also be noted that the deviations collected from the 5-participant beginner group used for analysis in this paper were naturally occurring, whereas in the aforementioned lunge and squat global classifiers, the deviations from correct technique were deliberately induced by study participants. This may make individualized classifiers more functional and usable in the real world. This paper's deadlift accuracy result of 95% exceeds recently published work on binary classification of the deadlift with a left thigh IMU where 84% accuracy was achieved [27]. This is likely because there was more training data for each individual in this study. The personalized classification systems used in this preliminary evaluation of the tablet app were developed using 4 sets of each exercise (a total of 40 repetitions). Increasing the amount of training data used for each individual would likely further improve the accuracy of their personalized exercise technique evaluation system [24,25].

Limitations

There are a number of contextual factors to this study that should be considered. Most notably, although the tool described allows for the efficient creation of an IMU-based exercise technique classifier for any cyclical, repetition-based exercise, it is not as simple as using a global classification system for exercises for which they exist. The tool described requires at least one recorded session with an exercise professional and requires the exercise professional's time and expertise to label the video data. However, the tool described could be conceivably used to fill in the gaps in a client's exercise program where a global

classifier is not yet available. Moreover, the labeled data can all be stored in a database, and the data that were initially used to create individualized classifiers can be pooled together to make a global classifier. The exercise professional could switch to this global classifier when they deem it accurate enough to negate the benefits of creating an individualized classifier for each of their clients.

A key area that limits the findings of the evaluation study is that it was small scale, and the participants were not balanced in experience or gender. Moreover, the study participants were relatively homogenous in the evaluation study, and it is not yet understood whether the results found would be generalizable to other populations such as older, obese, or underweight people. In particular, the system evaluation was completed with individuals not currently undergoing rehabilitation. Future work should investigate the system with individuals undergoing rehabilitation. It is foreseen that it should still work, provided the exercise professional can label the data appropriately for each individual's needs. The authors also acknowledge that more work is required to assess the capabilities of classifiers created with this new tool, particularly in the detection of exact deviations in exercise technique. The capabilities of a multiple IMU setup must be examined. However, the results presented show excellent potential for a single IMU setup to assess complex compound lower limb exercises when using personalized classifiers.

Future Work

It should be noted that this paper only describes the development of this new tool and its first evaluation. It is not yet fully understood how it will be incorporated into clinical practice. Future work should investigate the influence of the exercise professional's experience level, when labeling the data, on system accuracy. The usability of the system and how it may best be incorporated into a clinician's use of time should also be investigated. Only 1 exercise professional labeled the data in the evaluation study. The coding was not compared with other professionals; this should be investigated in future studies. Finally, the tool described only replicates current state of the art in the field, and the signal processing, feature computation, and classification methods ought to be iterated as the field progresses.

Conclusions

In this paper, a tablet app that streamlines the creation of IMU-based exercise technique analysis systems is presented. The tool replicates the data analysis pathways that have been used in recently published research [16-19]. It also allows an exercise professional to record video data simultaneously to IMU data and label it efficiently, following a session with a client. The app then creates personalized exercise technique classifiers for the client based on the labeled IMU data. These personalized classifiers are less memory-intensive and more accurate than equivalent global classifiers for the exercises used in this study. In addition to this, data collected with the tool could ultimately be used to train new global classification systems with increased accuracy because of the increased amount of training data available.

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Conflicts of Interest

While this work was cofunded by Shimmer, the developer of the IMU used in this study, we believe the results are generalizable to any IMU with the same sampling rate and on-board sensor ranges as described in this study. We can clarify that there was no outside business interest or other biasing factors from Shimmer during this study's design and execution.

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Abbreviations

- FN:** false negative
- FP:** false positive
- IMU:** inertial measurement unit
- S&C:** strength and conditioning
- SD:** standard deviation
- 3D:** three-dimensional
- TN:** true negative
- TP:** true positive

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Original Paper

Treatment of Low Back Pain with a Digital Multidisciplinary Pain Treatment App: Short-Term Results

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Abstract

Background: Even though modern concepts of disease management of unspecific low back pain (LBP) postulate active participation of patients, this strategy is difficult to adapt unless multidisciplinary pain therapy is applied. Recently, mobile health solutions have proven to be effective aides to foster self-management of many diseases.

Objective: The objective of this paper was to report on the retrospective short-term results of a digital multidisciplinary pain app for the treatment of LBP.

Methods: Kaia is a mobile app that digitalizes multidisciplinary pain treatment and is in the market as a medical product class I. For the current study, the data of anonymized Kaia users was retrospectively analyzed. User data were evaluated for 12 weeks regarding duration of use and effect on in-app user reported pain levels, using the numerical rating scale (NRS), depending on whether LBP was classified as acute, subacute, or chronic back pain according to current guidelines.

Results: Data of 180 users were available. The mean age of the users was 33.9 years (SD 10.9). Pain levels decreased from baseline NRS 4.8 to 3.75 for all users at the end of the observation period. Users who completed 4, 8, or 12 weeks showed an even more pronounced decrease in pain level NRS (baseline 4.9 [SD 1.7] versus 3.6 [SD 1.5] at 4 weeks; baseline 4.7 [SD 1.8] versus 3.2 [SD 2.0] at 8 weeks; baseline 4.6 [SD 2.2] versus 2.6 [SD 2.0] at 12 weeks). In addition, subgroup analysis of acute, subacute, or chronic classification revealed no significant main effect of group ($P > .30$) on the reduction of pain. Conclusions: This retrospective study showed that in a pre-selected population of app users, an app digitalizing multidisciplinary rehabilitation for the self-management of LBP reduced user-reported pain levels significantly. The observed effect size was clinically relevant. Ongoing prospective randomized controlled trials (RCTs) will adjust for potential bias and selection effects.

Conclusions: This retrospective study showed that in a pre-selected population of app users, an app digitalizing multidisciplinary rehabilitation for the self-management of LBP reduced user-reported pain levels significantly. The observed effect size was clinically relevant. Ongoing prospective RCTs will adjust for potential bias and selection effects.

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KEYWORDS

lower back pain; app; mHealth; retrospective study; self-management

Introduction

In spite of recent developments in diagnosis and treatment of low back pain (LBP), the burden of disease for patients and

health economy remains outstanding. LBP is not only the leading cause of years lived with disability globally, but shows a 1-month prevalence of about 30% of the global population. The vast majority of patients are affected by non-specific LBP

rather than by back pain with a specific cause that can be targeted by a specific treatment [1].

Recently, treatment paradigms have shifted from a merely somatic disease concept of LBP towards a bio-psycho-social model; a more comprehensive approach that encompasses somatic findings as well as psychological and environmental factors. Current treatment of LBP in primary and secondary care is often limited to a monocausal somatic approach and thus disregards current guidelines [2]. Multidisciplinary pain treatment (MPT), a combined program comprising educational, physical, and psychological exercises, has been proven to be effective in the treatment of LBP with positive effects on pain level, functionality, and other outcomes parameters including quality of life [3]. As such, MPT is part of treatment recommendations for chronic LBP in a variety of international guidelines [4-6].

Multidisciplinary programs are comparably expensive and limited to specialized centers, which restricts their widespread use. Only recently, electronic health (eHealth) and mobile health (mHealth) Web apps have emerged as new treatment options for non-pharmacologic interventions in a variety of conditions [7]. Guidelines for the development of mHealth apps are under development and the rapidly progressing field awaits constant adjustments in structure, composition, and content [8,9]. Especially in chronic conditions, which require adequate strategies of self-management for optimal treatment results, mobile- or Web-based solutions show great potential and sometimes even more desirable outcomes than current—often pharmacologic—standard therapies [7].

Several mHealth or Web-based solutions have been designed for the self-management of LBP; however, only few of them have been subjected to prospective clinical trials [10]. Two recent reviews considered 9 and 6 clinical studies relevant, respectively [11,12]. However, all of them represented a vast variety of different approaches, many of them based on cognitive behavioral strategies. Due to the heterogeneity of the included interventions and primary endpoints, the authors found the evidence inconclusive [11]. The clinical standard of LBP treatment considers physical activity and activation [1,5,6]. Recent appraisals of commercially available apps revealed that the vast majority of apps available in app stores are not based on a scientific framework [13]. Surprisingly, physical activity was only included as a key component in 1 app and study [12].

Here, we reported on the efficacy of an LBP app that is based on a comprehensive multidisciplinary treatment concept, including patient education, video-guided physiotherapy, and mindfulness training. The content of the app is in line with current German guidelines for the management of LBP [5]. The study investigated the in-app reported pain levels of users in their pain diaries to elucidate the development of pain levels over a period of 3 months after download of the app.

Methods

Study Design and Users

The study was designed as a retrospective analysis of the user database of Kaia. All users agreed to the collection of data

presented in this publication by signing the terms and conditions for use of Kaia. All data used for the study were anonymized before submission to the Technical University of Munich for statistical analysis.

The study cohort was recruited via online channels (Facebook, Google Ads, company homepage) in Germany, Austria, and Switzerland. The criteria for participation were age 18 years and older, declaration of medical treatment of back pain, no history of indicators for specific causes of back pain (red flags), and sufficient level of physical fitness (self-report). The study sample consisted of all users in the user database of the company fulfilling the inclusion criteria.

Users included in the study had to be users of the Pro version, as non-Pro users are limited to 1 week of usage only. Only subscribers before March 2017 were included. The Institutional Ethic Committee of the Medical Faculty of the Technische Universität München approved the study design (study number 273-17s).

Data Collection

All data analyzed in this study were entered by app users as part of their self-test or in-app diaries and stored on company servers in Frankfurt, Germany. Only anonymized data were extracted from the user database via reporting criteria and no personal data were submitted for scientific evaluation. The data protection officer of the University Hospital of the Technische Universität München approved the concept for protection of personal data of the current study.

Statistical Analysis

Primary analysis referred to the comparison of baseline pain levels and the pain levels on the last day of use. For this purpose, mean baseline pain levels and mean last day of use pain levels were subjected to a paired-sample *t* test. In addition, for the purpose of investigating if completing the program (12 weeks) is advantageous compared to quitting the program at an earlier point of time, the following tests were conducted: (1) baseline pain level and pain level after 12 weeks were compared for those users completing the program using the paired-sample *t* test and checked effect sizes for differences (completers versus all users); and (2) a between-subject *t* test was computed in order to compare final pain levels of the completers (12 weeks) and all users.

Secondary analyses were also performed. In order to investigate the development of pain levels over time, 3 paired-sample *t* tests (Bonferroni-corrected) were computed in order to compare the baseline pain level with the pain level after 4 weeks (test 1), the pain level after 8 weeks (test 2), and the pain level after 12 weeks (test 3).

Furthermore, in order to detect potential differences between subgroups with different durations of LBP, baseline pain ratings, as well as pain ratings after 4 weeks, 8 weeks, and 12 weeks of training were subjected to 3 separate split-plot analysis of variances (ANOVAs) with the 3-level between-factor duration of symptoms (less than 6 weeks [acute], versus 6 to 12 weeks [subacute], versus greater than 12 weeks [chronic]), and the 2-level within-factor time ANOVA 1 (baseline versus 4 weeks),

ANOVA 2 (baseline versus 8 weeks), and ANOVA 3 (baseline versus 12 weeks).

Overall Description of the App

Kaia (Kaia Health Software GmbH, Munich, Germany) is a multiplatform app for iOS, Android, and native Web solutions. Kaia came to market September 2016 and is classified as a medical product class I. It is available via the App Store (iOS), the Google Play Store, or as a native website. Download of the app is free, but to remain active in the app for longer than 7 days, and to unlock the full functionality, users need upgrade to the Pro version via an in-app purchase.

The Kaia program was available on a monthly subscription during the timeframe of the study at costs of €9.99/per month. Multimodal offline programs in Germany have costs ranging from €2500 to €5000 depending on duration and program structure.

After registration in the app, users performed a mandatory self-test. During the first stage, users confirmed that they were not suffering from any complaints that may be indicative of a potentially specific cause of pain (red flags). The potential hints for red flags in a patient's history that are included in the app were based on a corresponding list in the current German guidelines [5]. Furthermore, users were required to confirm that they had already visited a physician because of their LBP and that there was no contraindication for physiotherapy. The self-test furthermore assessed pain distribution, pain duration (acute LBP of less than 6 weeks, subacute LBP of 6 to 12 weeks, and chronic LBP of less than 12 weeks, based on German guidelines [5]), pain intensity, and overall fitness.

Depending on the results of this initial test, exercise regimen and content were tailored to the individual user from a pool of 120 exercises based on an algorithm.

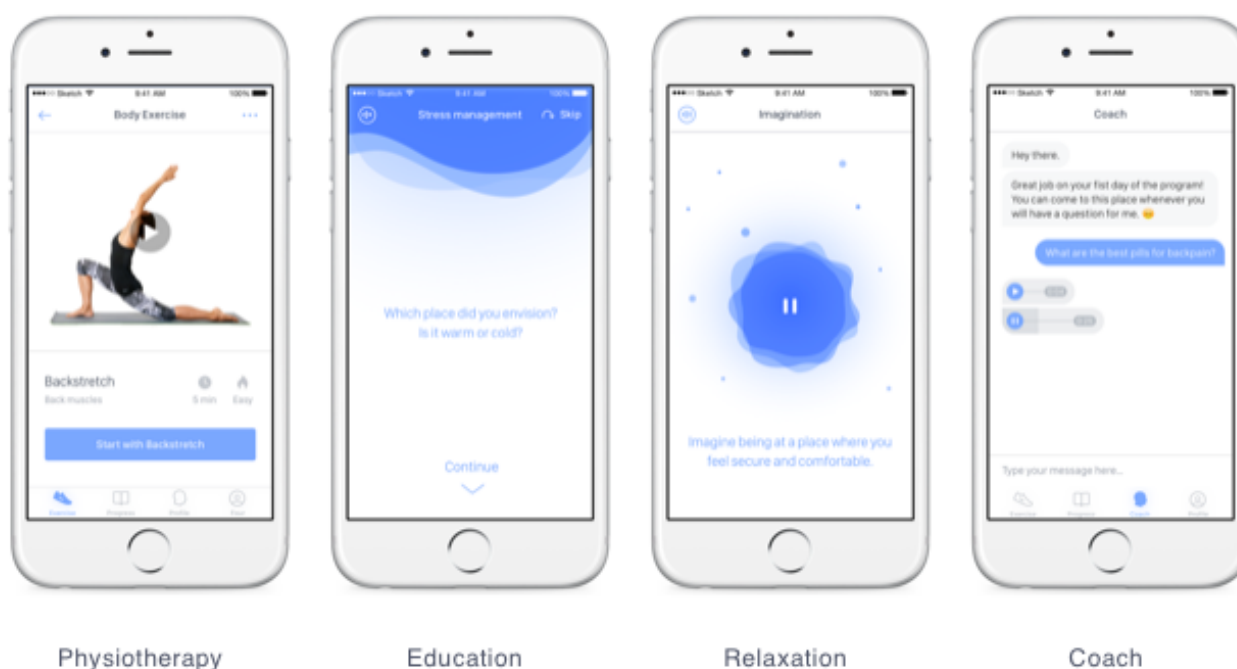
Users recorded their levels of pain and sleep using numerical rating scales (NRSs) at the end of each day of therapy in a pain diary as a separate function of the app. Pain was recorded from 0 to 10 (worst imaginable pain) whereas sleep was recorded from 0 (worst imaginable sleep) to 10 (best imaginable sleep). User progress within the app from day to day of practice and the development of user-reported pain and sleep were constantly visible in a screen. There is also a chat function in the app that connects users to a coach (physiotherapist or sport scientist) for motivational and exercise-related questions.

App Content

The Kaia app involves the following pillars: (1) back pain-specific education, (2) physiotherapy, and (3) mindfulness techniques. Daily content consists of all 3 pillars. The content for an individual patient is compiled and updated from day to day (or upon each login) from a large background of exercises and skills archived in the app. Depending on the patient's status of knowledge, practice, and progress this is adapted from day to day. Each section is comprehensive as a stand-alone—there is no obligation to perform all 3 sections in a single session.

Content in the educational section covers a broad spectrum of general pain-related and back pain-specific education (Figure 1). There are over 30 different educational units in the app. Content is based on current German or international guidelines [5,6] and standard textbooks in the field. Educational content was authored by board-certified physicians with relevant expertise in the field of back pain (ie, neurology, orthopedic surgery, and pain medicine) or clinical psychologists with experience in pain psychotherapy.

Figure 1. Examples of daily content from the app for each of the categories and design of the coach chat.



The single exercises and the individual composition of exercises for every user per day (up to 5 exercises) were designed by physiotherapists of the Pain Center Technische Universität München according to guidelines and curricula of the German Pain Society. A pool of 145 exercises is subdivided into 5 classes (front side, lower back, upper back and shoulders, lateral muscles, and legs), and is individually applied in relation to the users body region with most pain. Furthermore, exercises within each class are ranked depending on exercise difficulty and strain. Depending on the self-test and ongoing user feedback, exercises are continuously adopted to the user's fitness level.

Mindfulness and relaxation techniques are an integral part of multidisciplinary in- and outpatient LBP rehabilitation. The Kaia app contains units of breathing techniques, body scan, visualization, and progressive muscle relaxation. The value of the various techniques is explained in the education part of the app. Mindfulness content is generally broadcasted as audio content only.

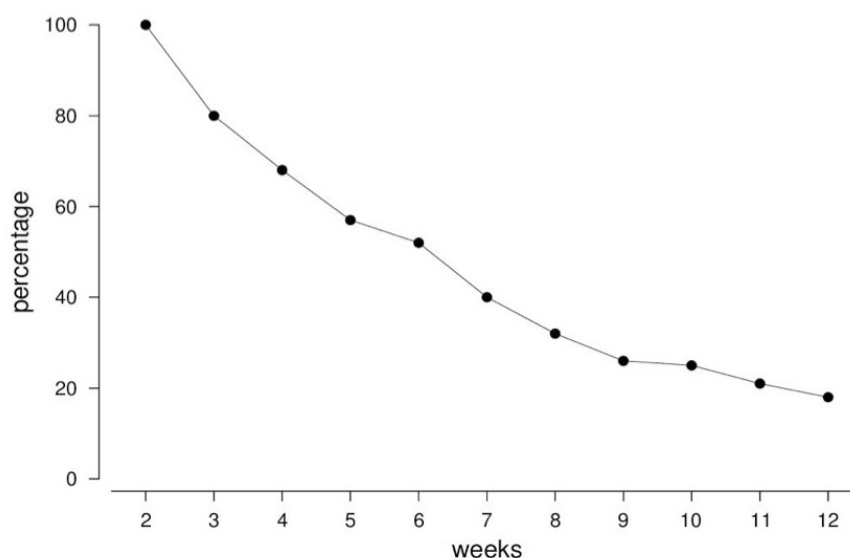
Results

Sample Characteristics and Dropout of Users Over Time

Data of 180 users of the Pro version were available, of which 105 were female (58.3%, 105/180). The mean age of the users was 33.9 years (SD 10.9). Of the users, 25 (13.9%, 25/180) reported pain for less than 6 weeks, 23 (12.8%, 23/180) between 6 and 12 weeks, and 132 (73.3%, 132/180) patients reported pain for more than 12 weeks before starting the program.

As expected, there was a substantial dropout over time. After 4 weeks, the number of users decreased to 123 (68.3%, 123/180). After 8 and 12 weeks, 58 (32.2%, 58/180) and 32 (17.8%, 32/180) still participated in the program, respectively. The dropouts are illustrated in [Figure 2](#).

Figure 2. Development of user numbers over time.



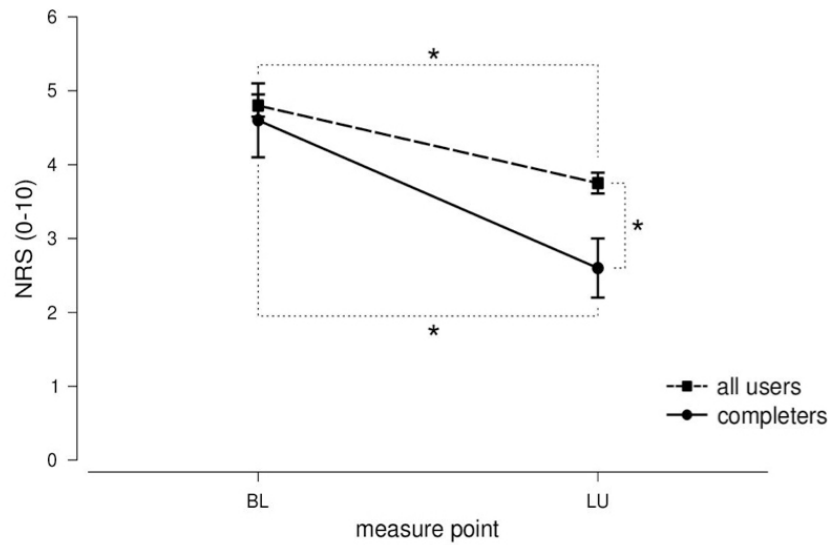
Development of User-Reported Pain Levels Until Last Reported Use

A significant reduction in pain level from the baseline (mean 4.80 [SD 1.95], median 5) to the last day of use (mean 3.75 [SD 1.76], median 4) was found ($t_{158}=6.21$, $P<.001$, $d=0.56$). Moreover, in order to check if completers of the program (12 weeks, $N=20$) showed a better pain outcome, baseline pain levels (mean 4.60 [SD 2.21], median 4) and pain levels after 12 weeks (mean 2.60 [SD 1.98], median 3) of the completers were tested for differences. The paired-sample t test revealed a significant reduction in the pain level also in this group ($t_{19}=3.75$, $P=.001$), with a bigger effect size compared to the overall comparison ($d=0.95$ versus $d=0.56$, see above). In addition, a between-group t test confirmed a significant better pain outcome for the program completers (2.60 versus 3.75) compared to all users, ($t_{177}=2.71$, $P=.007$).

In addition, 2 ex-post-analyses were performed. Firstly, in order to analyze differences in baseline pain levels of completers and non-completers, a between-group t test was performed, which did not reveal significant differences (NRS 4.6 for completers versus 4.8 for non-completers, t less than 1). Secondly, to analyze whether users with lighter baseline pain levels had a different outcome than users with lower baseline pain levels, a median split was applied to the baseline pain level data and 2 paired-sample t tests were performed in order to compare baseline versus last day of use pain levels separately for users above and below median. A significant reduction in pain levels was found only in the above-median group (baseline 6.2 versus last day of use 4.2, -33% , $P<.01$). No significant baseline-last day of use differences were detected in the below-median group except a rather slight descriptive increase in pain levels (baseline 3.1 versus last day of use 3.3; $+7\%$; t less than 1).

These analyses revealed (1) a significant pain reduction over time through using the app; and (2) an even better pain outcome for completers of the program. All effects were of medium to large size ([Figure 3](#)).

Figure 3. Mean (SE) baseline (BL) pain levels and pain levels of the day of the last use (LU) both for completers of the program (12 weeks) and all users. NRS: numeral rating scale.



Development of Pain Levels Over Time

As the previous analysis revealed that users who remained in the app for 3 months had lower NRS scores at last use than users who quit at earlier points in time, we analyzed whether the decrease in NRS levels was larger over time using 3 follow-up measures (4, 8, and 12 weeks of use). The analysis revealed significant reductions in pain levels in all 3 follow-up measures relative to baseline: baseline versus 4 weeks follow-up ($t_{70}=6.10$,

$P<.001$, $d=0.84$), baseline versus 8 weeks follow-up ($t_{29}=3.64$, $P=.001$, $d=0.76$), and baseline versus 12 weeks follow-up ($t_{19}=3.75$, $P=.001$, $d=0.95$). The results of this analysis are depicted in Figure 4.

Pain level was reduced during app use regardless of the anamnestic duration of complaints. The duration of complaints was further analyzed whether the duration, as classified in the self-test (acute versus subacute versus chronic LBP), determined the pain reduction over time (Figure 5).

Figure 4. Development of mean (SD) pain levels both for the baseline (BL) and the 3 follow-up measures (4 weeks, N=71; 8 weeks, N=30; 12 weeks, N=20).

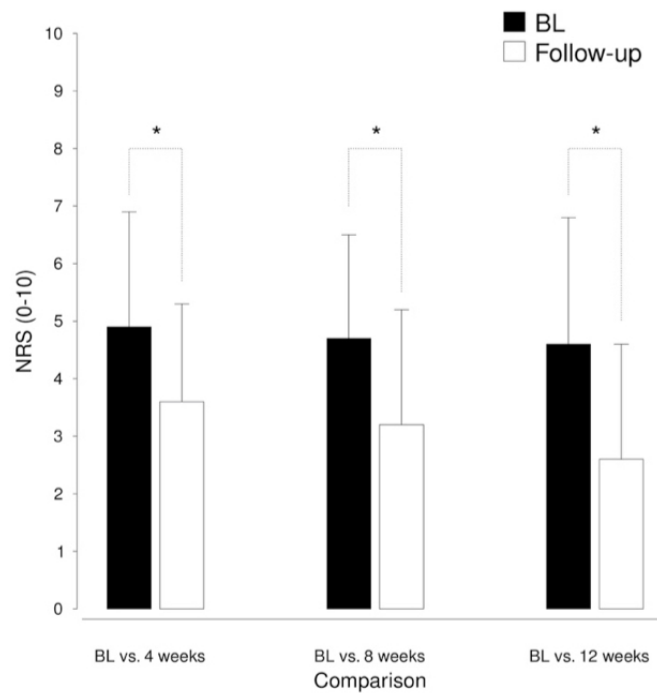
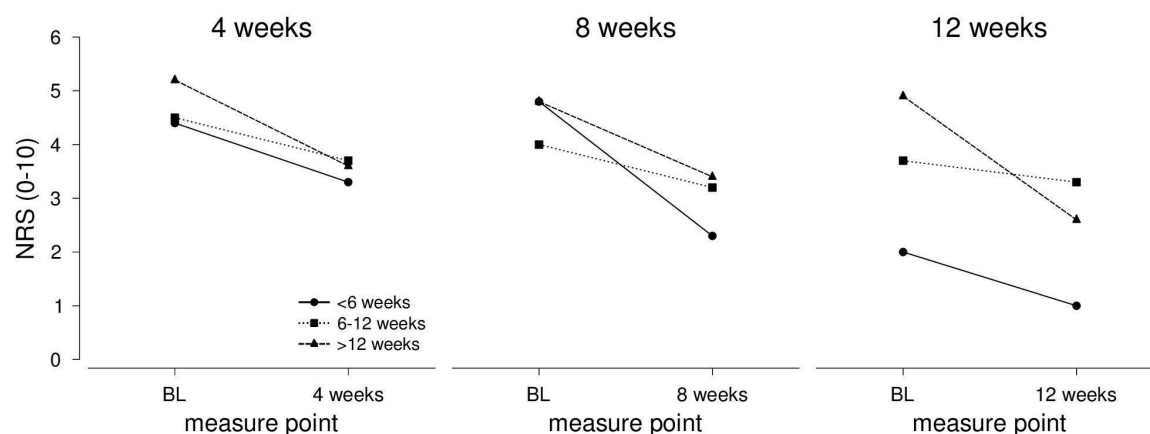


Figure 5. Development of pain levels over time (baseline versus 4, 8, and 12 weeks) for the 3 chronification groups (stratified by duration of their complaints). Less than 6 weeks: 4 weeks, N=12; 8 weeks, N=4; 12 weeks, N=1. Between 6 and 12 weeks: 4 weeks, N=10; 8 weeks, N=4; 12 weeks, N=3. More than 12 weeks: 4 weeks, N=49; 8 weeks, N=21; 12 weeks, N=16.



The ANOVAs for the pain ratings after 4 weeks and 8 weeks both revealed significant main effects of time ($F_{1,68}=17.28$, $P<.001$, $\eta=0.203$; $F_{1,27}=8.99$, $P=.006$, $\eta=0.250$), while there was no main effect of time in the ANOVA for the pain ratings after 12 weeks ($F_{1,17}=1.74$, $P=.205$, $\eta=0.093$). In addition, no significant main effect of group and no significant interaction of group and time were found in any of the ANOVAs (all P values less than .30). Taken together, an overall pain reduction was found in each of the groups after 4 weeks and after 8 weeks, but not after 12 weeks, suggesting that the effect of app use was equally effective regardless of the duration of complaints at start.

Discussion

Principal Findings

The application of a digital multidisciplinary back pain app reduced pain ratings in patients with LBP. The retrospective analysis of user data revealed stable pain reduction, independently of the duration of back pain (acute, subacute, chronic LBP) and demonstrated an increased level of pain reduction in relation to the duration of app application. Thus, the treatment of back pain can potentially be complemented with self-management via a digitalized version of a multidisciplinary biopsychosocial rehabilitation program. However due to its limitations, this retrospective set of data should only serve as a first pilot study and the effects should be confirmed with further prospective trials.

Recently, a large randomized controlled trial (RCT) of a mobile Web app by Irvine et al reported a significant decrease in pain burden following long-term use of a medical app [10]. And yet, another recent study confirmed that non-supervised exercise exerted a beneficial effect on pain levels and muscle strength as compared to patients on a wait-list [15]. Thus, the finding that self-management of LBP with an app reduced user reported pain levels fits well with these earlier observations and published data.

Recent reviews have not yet found conclusive evidence for the beneficial effects of digital solutions to support self-management of back pain [11,12]. This ambiguous view might be due to

limited controlled trials [11,12]. The differences in the underlying concepts and also in the design of the interventions make it especially hard to generalize from results with one app to another. Of note, not one app explicitly based on a multidisciplinary setting was reported in these publications. Furthermore, this retrospective analysis did not reliably determine which section of the Kaia app (pain education, physiotherapy, or mindfulness training) was the key factor for pain improvement. The analysis of user log files and detailed feedback analysis (via path analyses) may help answer this question in future studies.

While apps utilized in clinical investigations related to back pain cannot be found in app stores, the ones found in app stores have not been applied in clinical investigations. It was also found that retrospective data for solutions was unavailable in app stores [13]. Thus, this current retrospective analysis is one of the first to bridge the gap between commercialized support interventions for back pain and scientific evaluation.

The dropout rate over 12 weeks was high. Of note, this is an early report and other similar publications also reported significant dropouts over time in digital interventions for self-management of musculoskeletal conditions while showing reduced pain levels in users still engaging in the app [16]. Future design of the app has addressed users' feedback and included reminders like emails and push mails. Increasing interaction between patients and the app and personnel has been shown to contribute to user engagement of pain patients in a recent study [17].

The clinical potential of mHealth and eHealth to support the patient's self-management and adoption of new behavioral patterns is not in question. This is underlined by increasing evidence and positive connotations in numerous disease conditions [7]. However, searches for apps in app stores that are intentionally designed for the self-management of pain often present with uncertain validity of content and are missing in scientific framework [13,18]. Establishing digital solutions based on current clinical concepts for self-management of LBP seems to be highly desirable, especially when considering that many patients seek online advice and support of self-management. The quality of content on self-management

for back pain does not to reflect current medical knowledge for back pain treatment, as evidenced in several studies [19,20]. And, seemingly, the concept of self-management and active self-involvement in rehabilitation of pain has not reached a substantial level of awareness in patients suffering from LBP [21]. This preserves a passive attitude of patients and prevents new strategies of rehabilitation. On the other hand, this insight makes innovative methods, like apps, so important to spread the concept of self-management in LBP, especially given that the app is based on relevant concept and content.

Most previous online interventions in eHealth and mHealth apps for LBP have focused on cognitive behavioral therapy [10,11]. Only little scientific information is available for online interventions focused on exercise and relaxation techniques. However, trials with interventions focusing on the relevance and applicability of physical exercise and mindfulness are underway and currently ongoing [14,22,23].

Limitations

Limitations of the current study arose from the uncontrolled, retrospective analysis. This did not allow adjustment of the reported decrease in pain levels for any potential spontaneous improvement of pain levels. The high rate of dropouts over time

posed a significant limitation of the current study. Reasons for dropout are not known due to the study design, but across all users there was a substantial improvement in their pain levels from baseline to the last reported value, suggesting that overall users improved their pain levels during use of the app. However, whether this is caused by the app or spontaneous improvement will only be known after future RCTs. Furthermore, demographics of users included in the current study were not representative of the heterogeneous group of patients suffering from persistent back pain and represented only a selection of patients especially prone to profit from the digital intervention. This is valid since only limited data on the study collective are available due to the retrospective nature of the study—important information like the physical activity level at baseline was not known.

Conclusions

The current retrospective study showed that in a pre-selected population of app users, an app digitalizing multidisciplinary rehabilitation for the self-management of LBP reduced user-reported pain levels significantly. The observed effect size was clinically relevant. Ongoing prospective RCTs will adjust for potential bias and selection effects.

Conflicts of Interest

SH declares to have an advisory contract with Kaia Health Software.

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Abbreviations

ANOVA: analysis of variance
eHealth: electronic health
LBP: low back pain
mHealth: mobile health
MPT: multidisciplinary pain treatment
NRS: numerical rating scale
RCT: randomized controlled trial

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Original Paper

Exploring Determinants of Patient Adherence to a Portal-Supported Oncology Rehabilitation Program: Interview and Data Log Analyses

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Abstract

Background: Telemedicine applications often do not live up to their expectations and often fail once they have reached the operational phase.

Objective: The objective of this study was to explore the determinants of patient adherence to a blended care rehabilitation program, which includes a Web portal, from a patient's perspective.

Methods: Patients were enrolled in a 12-week oncology rehabilitation treatment supported by a Web portal that was developed in cooperation with patients and care professionals. Semistructured interviews were used to analyze thought processes and behavior concerning patient adherence and portal use. Interviews were conducted with patients close to the start and the end of the treatment. Besides, usage data from the portal were analyzed to gain insights into actual usage of the portal.

Results: A total of 12 patients participated in the first interview, whereas 10 participated in the second round of interviews. Furthermore, portal usage of 31 patients was monitored. On average, 11 persons used the portal each week, with a maximum of 20 in the seventh week and a drop toward just one person in the weeks in the follow-up period of the treatment. From the interviews, it was derived that patients' behavior in the treatment and use of the portal was primarily determined by extrinsic motivation cues (eg, stimulation by care professionals and patient group), perceived severity of the disease (eg, physical and mental condition), perceived ease of use (eg, accessibility of the portal and the ease with which information is found), and perceived usefulness (eg, fit with the treatment).

Conclusions: The results emphasized the impact that care professionals and fellow patients have on patient adherence and portal usage. For this reason, the success of blended care telemedicine interventions seems highly dependent on the willingness of care professionals to include the technology in their treatment and stimulate usage among patients.

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KEYWORDS

telemedicine; rehabilitation; patient portals; treatment adherence; compliance

Introduction

Over the last couple of years, the use of telemedicine applications within health care has increased. The term telemedicine refers to health services that enable patients to receive treatment in their daily living environment, whereby distance between health care professionals and patients is bridged by information and communications technologies (ICTs) [1]. Therefore, telemedicine can be used as a stand-alone treatment, or it can be combined with face-to-face treatments to form so called blended care treatments [2]. Telemedicine is believed to provide opportunities to increase the efficiency and effectiveness of health care services, resulting in improved health outcomes [3,4]. However, telemedicine applications often do not live up to these expectations and often fail once they have reached the operational phase [5,6]. Especially in cases where users need to use telemedicine over time, declined usage is prevalent [1,5]. Why is it so difficult to successfully implement telemedicine applications in health care treatments and to avoid nonusage over time? And why is it so hard to make patients use technologies—that are designed to improve their treatment outcomes over time?

One of the possible explanations could be found within the concept of patient adherence, which is the extent to which the patient's behavior matches the agreed recommendations of the prescriber. As with more traditional treatments, telemedicine requires patients to be active users over time to be successful and have a chance of positive clinical outcomes [3,7,8]. In traditional health care, patient adherence is known to be an important factor when it comes to the success of health care treatments and medication intake [9]. Low patient adherence is known to lead to increased health care costs and negative health outcomes [8,10]. As far as we know, there has not been a lot of research exploring the determinants of patient adherence in blended care treatments in which a lot of interaction between off- and online factors are likely to be at play. In this study, the determinants of patient adherence to a blended care rehabilitation program, including a Web portal, were explored from the perspective of both patients and care professionals. This paper focuses on the patient's perspective.

Methods

Context

This study was set around a portal designed for a blended care rehabilitation program aimed at supporting cancer survivors who got out of primary care to cope and live with the consequences of the disease on their life. In an intensive 12-week program, patients were supervised by a multidisciplinary team of care professionals such as social workers, rehabilitation physicians, and physiotherapists. Patients were assigned to groups with fellow patients and participated in a variety of group activities and sessions. Besides group sessions, which took place three times per week at the rehabilitation center, patients were required to do additional individual activities and exercises at home.

These home activities were supported by a telemedicine intervention in the form of an online portal. To make the portal as fitting to the needs of patients and care professionals as possible, the modules in the portal were designed and developed following a user-centered approach in close cooperation with care professionals and patients from the program. Before introduction, the usability of both the patient's and the care professional's side of the Web portal was evaluated and improved.

The primary goal of the portal was to support the rehabilitation treatment and to facilitate self-management by patients. Therefore, the portal contained the following modules: (1) information about the program and the disease; (2) activities and exercises, with video instructions about individual exercises to enable patients to do their exercises independently at home; (3) self-report diaries (see [Figure 1](#)), which enabled monitoring of physical and mental progress during the program; and (4) a message function, enabling patients to leave messages for care professionals and enabling care professionals to effectively target their care to the needs and wishes of patients during sessions at the rehabilitation center. Usage of the portal was not mandatory, although it was strongly advised to patients to use the information from the portal for home exercises. After the rehabilitation program ended, the Web portal remained available for several months to patients without explicit support by care professionals.

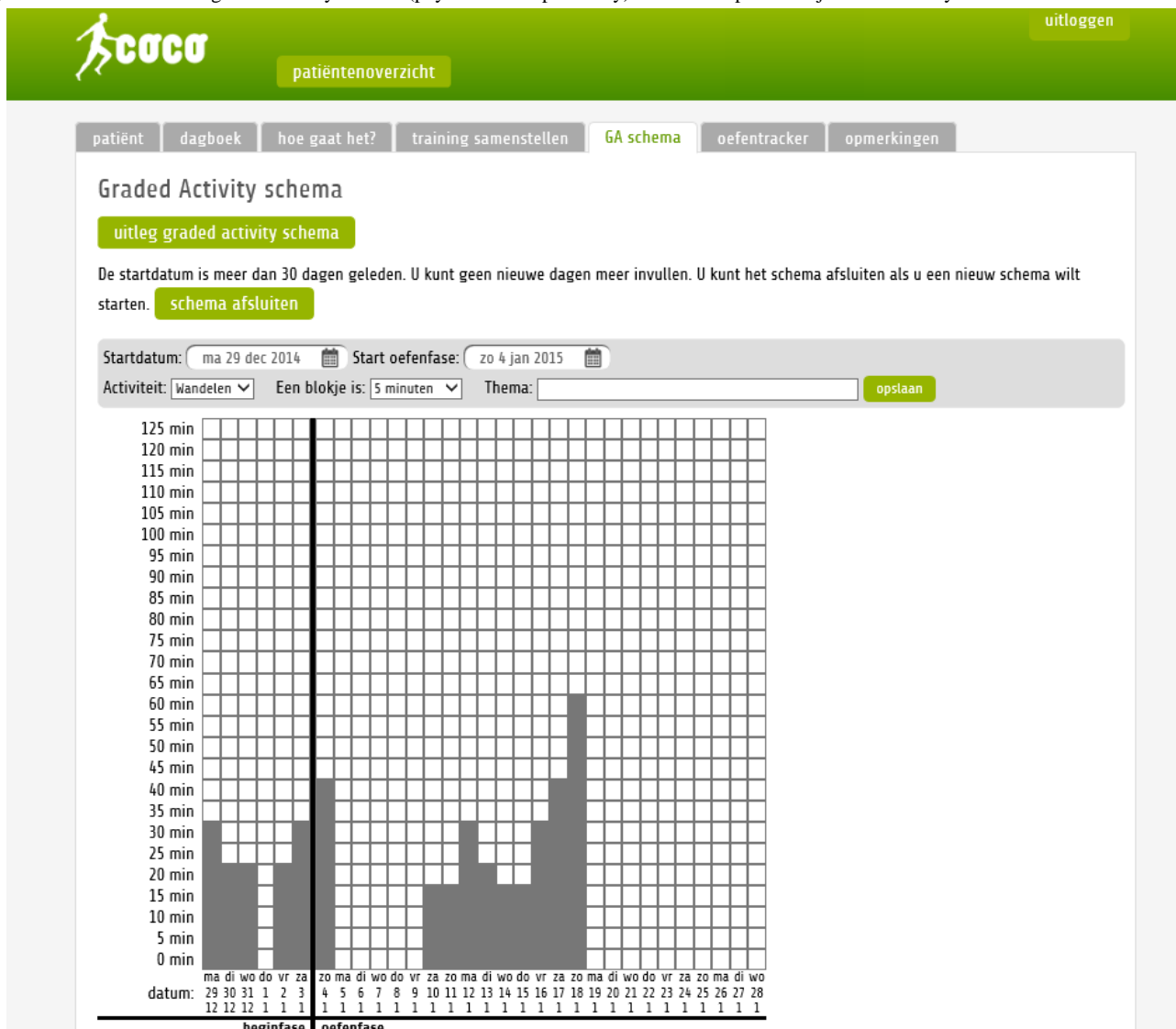
Participants

There were 2 groups of participants in this study: patients and care professionals. This paper focuses on determinants of patient adherence to the portal from the perspective of patients. All patients enrolled in the oncology program in the period of September 2014 to February 2015 were approached to participate in the study. Participation in the study was voluntary, and an informed consent was obtained before participation. The study was approved by a medical ethical committee. A total of 12 patients agreed to participate in the study; 11 of the participants were females, with an average age of 53.8 (standard deviation [SD] 7.2) years. Furthermore, portal usage data was analyzed of 31 patients, of which 29 were females and 2 males, with an average age of 52.4 (SD 8.5) years, who gave permission to use their data upon log-in to the portal for the first time.

Procedure

To explore the behavior within the program, 2 rounds of open interviews were conducted among the participating patients and care professionals. A list of topics (see [Textboxes 1](#) and [2](#)) was used to structure the open interviews. The first interview took place within 3 weeks after the start of the program, whereas the second interview was scheduled toward the end of the program. In addition to the interviews, logged usage of the portal was analyzed to determine the actual use of the portal during the 12-week program. Because the portal was available to the patients after the rehabilitation treatment had ended at the center, it was decided to collect usage data over a 10-week follow-up period too.

Figure 1. Screenshot of the graded activity scheme (physical self-report diary) on the Web portal subject to this study.



Textbox 1. The topics addressed in interview 1 conducted with patients.

- Living with the disease
 - Impact on daily life
- Treatment
 - Goals
 - Expectations
 - Influence on others
- Role of the portal
 - Acceptance of technology
 - Expectations
 - Goals
- Near future
 - Behavioral intention treatment
 - Behavioral intention portal usage
 - Expectations

Textbox 2. The topics addressed in interview 2 conducted with patients.

- Recap
 - Impact on daily life
 - Treatment
 - Influence of others on treatment
- Role of the portal
 - Portal usage
 - Perceived usefulness
 - Influence on others on portal usage
- Preview on future
 - Self-efficacy
 - Portal usage after treatment

Instrument

The aim of the first interview with the patients was to gain insights in their behavioral intentions for the treatment, including their use of the portal. According to the theory of planned behavior (TPB) [11,12], behavioral intentions are indications of how much an individual is willing to perform a particular behavior. The second interview focused more on actual behavior and experiences with the rehabilitation program and the portal. To do so, health behavior was explored from the perspective of 3 different human behavior models used to identify determinants of health behavior within the treatment. Additional determinants were derived from literature describing patient adherence in various health care contexts. This was done to ensure a comprehensive overview of behavioral determinants. The determinants derived from the TPB were used to explore the behavioral intention of the patients. The TPB is built on the assumption that all behavior is intentional and is determined by one's attitudes, normative beliefs, and perceived behavioral control [11,12]. It is known to be applicable to health care contexts. We also explored determinants derived from the health belief model (HBM) to take preventive health behavior topics into account, such as perceived susceptibility, perceived seriousness, perceived benefits and barriers to taking action, and cues to action [13,14]. Patients in this study had received primary care for their disease before, making the latter three factors from the HBM applicable and useful within the context of this study. Third, determinants derived from the technology acceptance model (TAM), such as perceived ease of use and usefulness, were used to explore reasons for usage and nonusage of the portal, which was an essential element of the treatment [15,16]. Finally, various determinants used in this study were derived from the model of supported accountability (SA) [5], which describes how patient adherence is enhanced by human support from care professionals and moderated by a patient's motivation and the type of communication technology used. This theoretical background resulted in the topic list that can be found in [Textboxes 1](#) and [2](#), as well as in themes for analyzing the interviewee's responses (see [Table 1](#)).

Data Analysis

Usage Data

Portal usage was determined by counting and analyzing sessions focusing on the individual page visits, which were categorized into one of 3 categories (information, activities and exercises, and self-report diaries). It was not possible to count usage of the message function, as this function was implemented into the various other functionalities, and the number of messages sent back and forth was not available. Furthermore, it was decided to monitor one of the activity self-management tools, being the graded activity scheme, separately. The number of page visits was analyzed to determine how much the 4 categories were used during each week of the program.

Interviews

The interviews with patients and care professionals were recorded with a voice recorder. The audio files were transcribed and divided into short episodes. All episodes were coded into different categories following a thematic analysis method [17,18]. The initial code list of determinants was based on the TPB [11,12], HBM [13,14], and TAM [15,14], theoretical models, complemented with possible determinants of health behavior derived from literature that explains possible determinants for patient adherence, such as the model of supportive accountability (SA) [5], which includes (among other determinants) patient's expectations, motivation, and voluntariness to accept the influence of the care professional [5]; perceived disease severity [13,19]; and patients-to-care professional communication [5,8,13,20-22]. Coding of the episodes was done by 2 independent coders who reached consensus considering the assigned codes after a low agreement at first sight.

Results

Usage of the Portal

How much was the portal used by the patients? The data were collected from 31 anonymous patients who logged in to the portal at least once, including the respondents of the study; 2

of the interviewees never succeeded in getting into the portal. **Figure 2** shows the number of patients who logged in to the portal in each week of the rehabilitation treatment and during a 10-week follow-up period after the treatment. The graph shows that patients used the Web portal more during the treatment phase, whereas after the treatment their usage drops. The number of persons who logged in to the portal increased in the first weeks of the treatment and decreased from week 7.

As mentioned before, the Web portal included 4 functionalities, addressing different tasks within the treatment: graded activity scheme (a physical self-report diary; 21 different individuals), Web-based exercises (30 different individuals), information (30 different individuals), and self-report diaries (20 different individuals). It was not possible to analyze the message function.

Figure 3 shows the number of sessions for each functionality per week. The graph shows a similar pattern as **Figure 2**, with higher use in the first weeks and a decreased use over time in which the graded activity (average of 15 sessions per week) and exercises (average of 22.9 sessions per week) were the most visited functionalities.

Important findings that the usage data showed were the limited use of the portal, declined usage over time, and the fact that almost no one was inclined to use the portal after the treatment had ended (even though it was deliberately kept available to patients after the 12-week program). These findings led us to explore the determinants for usage and nonusage of the portal from the interviews that were conducted among patients.

Figure 2. Overview of the number of individual users per rehabilitation treatment week (N=31).

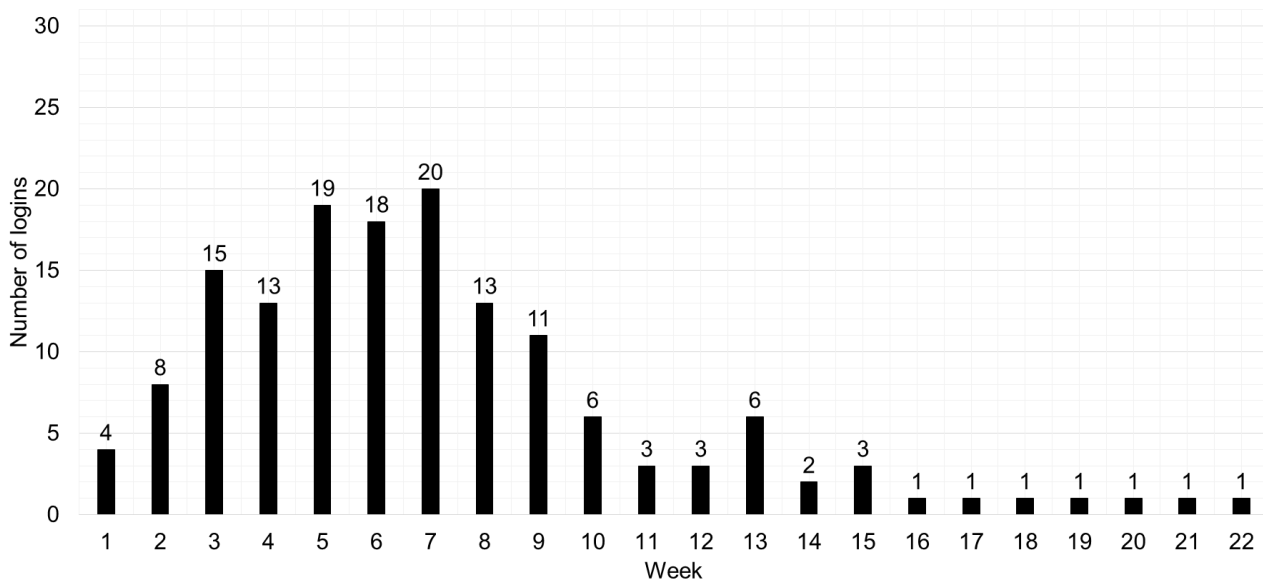


Figure 3. Overview of the number of sessions ordered by functionality.

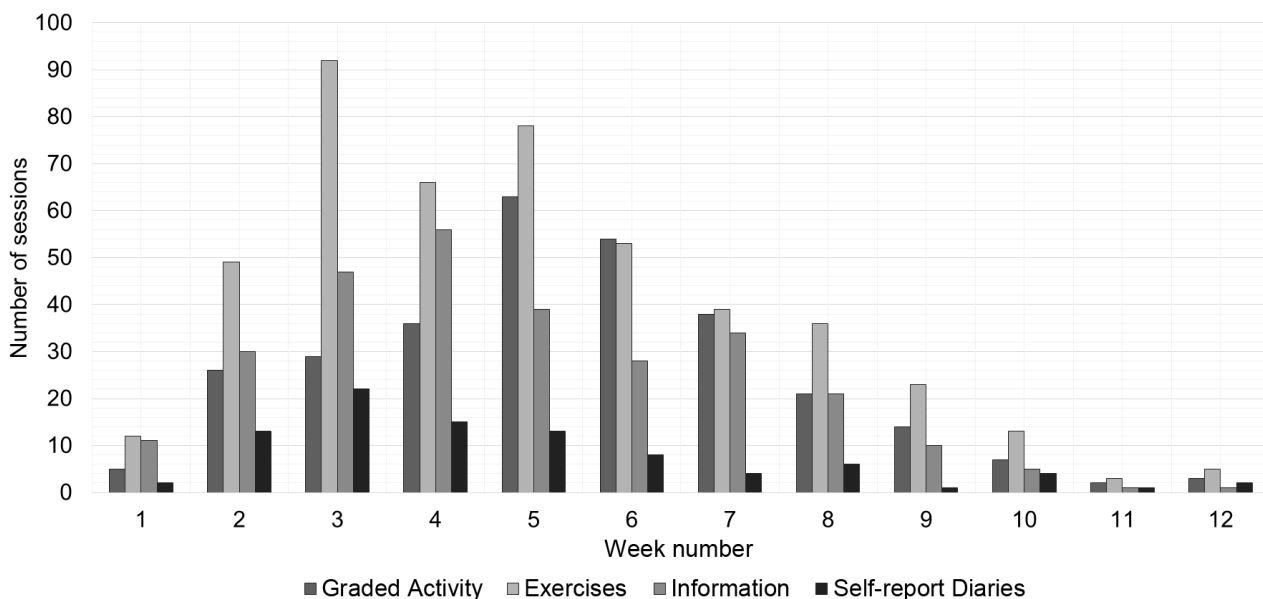


Table 1. Determinants of adherence. Overview of the number of codes assigned to relevant episodes in the interviews. Descending from the most often to the least mentioned themes.

Theme of episode	Derived from	Total codes (N=1010) n (%)
Extrinsic motivation cues	TPB ^a [11,12]	181 (17.92)
Expected benefits of the treatment	HBM ^b [13,14]	118 (11.68)
Adherence to the portal ^c	TAM ^c [15], TPB [11,12]	111 (10.99)
Perceived impact of the disease	HBM [13,14]	95 (9.41)
Perceived ease of use	TAM [15]	87 (8.61)
Perceived usefulness of the portal	TAM [15]	79 (7.82)
Adherence to the treatment ^c	TPB [11,12], HBM [13,14]	64 (6.34)
Intrinsic motivation cues	TPB [11,12]	63 (6.24)
Expectations of the portal	-	44 (4.36)
Expectations of the professional	SA ^d [5]	40 (3.96)
Situational motivation cues	SA [5]	37 (3.66)
Usefulness of other technologies	TAM [15]	19 (1.88)
Facilitating conditions	TAM [15]	15 (1.49)
Voluntariness	TAM [15], SA [5]	15 (1.49)
Previous experience with technology	TAM [15]	13 (1.29)
Attitude toward technology	TAM [15]	10 (0.99)
Trust in technology	-	10 (0.99)
Perceived responsibility	-	9 (0.89)

^aTPB: theory of planned behavior.

^bHBM: health belief model.

^cTAM: technology acceptance model.

^dSA: supported accountability.

^e*Adherence to the treatment* and *adherence to the portal* codes were used to classify whether episodes were related to portal or treatment related behavior.

Interviews

What exactly were the reasons for the decline in usage that was found? In the interviews, the determinants for behavior and how it reflected within the treatment were explored. Interviews were transcribed and divided into episodes. The 12 patients made 763 episodes that were considered relevant over the 2 interviews conducted. Table 1 shows an overview of the number of episodes made for each theme and how this relates to the total number of episodes.

The determinants that were referred to in more than 50 episodes (5%) are described in detail in the following sections. Reported in order; perceived impact of the disease, expected benefits of the treatment, motivational cues, perceived ease of use and perceived usefulness of the portal, ultimately leading to conclusions about adherence.

Perceived Impact of the Disease

What was the impact of the disease of the patients on their daily lives before the treatment and how did this impact change over the course of the treatment? All persons included in the rehabilitation treatment have had some form of cancer, of which the majority had breast cancer. During the first interview, 44

episodes were coded as disease, 13 of which were negative, and 3 were positive. Seven respondents stated that the biggest impact of the disease, after receiving primary care treatment, was the fact that they were tired all day, both mentally and physically:

It [the disease] has a lot of influence, as I am tired the entire day. With everything I do, I am easily tired, which is frustrating. [48, female]

After the 12-week program, the majority reported to have made progression in the way they perceive the impact of their disease. Most of the health problems discussed in the first interviews were also mentioned in the second interview, although respondents perceived they had improved their ability to accept their changed self and perceived an improved physical condition. On the other side, there were some respondents who experienced a decline in their health, which limited their ability to fully engage in the treatment. A 68-year-old male respondent explained that he was planning to use the portal, together with others, after the treatment at the center had ended because he felt that he had much more physical progress to make before he would be satisfied. On the other hand, a 57-year-old female respondent stated that she had not used the portal over the last

week because she was ill and had some issues with herself, and a 58-year-old female patient emphasized that the portal "...should to be supportive and not a challenge, because we have enough challenges already while we are here." Therefore, the perceived impact of the disease that influenced both the physical and mental condition of the patients seemed to have an influence on patient adherence both in the off- and online treatment.

Expected Benefits From the Treatment

The second possible determinant that was discussed with the patients concerned their goals and expectations from the treatment. When asked about the expectations about the treatment, all respondents responded positively. Every patient expected to be able to achieve the goals that they had set before initiating the treatment. In total, 70 episodes were coded into this theme, of which 29 were positive, and 5 were negative. The most important goals that patients had set for themselves considered improvement of physical condition, mental health, and acceptance of themselves after going through an impactful disease:

Not desperately trying to get back to how it used to be, because that is not...But just getting used to the new setting, new situation, with my new body, my new head. I have to find my place and feel comfortable again. [47, female]

Respondents were confident that with the help of the care professionals and their fellow patients, they would be able to achieve those goals.

By the end of the rehabilitation program, the respondents remained very positive about the treatment and largely believed their expectations were met (48 episodes, 3 negative vs 26 positive). Respondents were particularly positive about the multidisciplinary approach of the treatment team, physiotherapists, social workers, and psychologists:

I have gained a lot from sports. And the wise lessons from social workers, [...], the conversations with each other and the psychologists. The combination of everything was really good for me. [58, female]

Furthermore, the fact that the treatment was offered in groups made it a lot easier for patients to cope with the treatment and the challenges alongside it

The main strength of the treatment was the group. If I had to do it on my own, then I would not have made so much progress. [47, female]

Finally, and most importantly, all respondents felt that they had achieved, and in some cases even surpassed, their expectations. The most often mentioned achievements are increased awareness on how to cope with the disease and an increased physical condition:

I have learned to cope better with it. I did learn that you should not always attempt to do everything at once, but that you spread tasks over the entire day. [48, female]

None of the respondents mentioned the portal used in the intervention as a positive feature of the treatment, which was no surprise considering the quick decline of use of the portal.

Extrinsic Motivation Cues

What was the influence of others on the behavior of patients within the treatment? Extrinsic motivation cues were most often discussed in both interviews, and based on the responses, it is fair to conclude that others had an influence on the behavior of the respondents within the rehabilitation treatment. Seven respondents were referred to, or enrolled in, the treatment by their primary care providers. After being asked about the influence of being enrolled for the treatment, a 58-year-old female respondent stated that this "...makes it more special, which makes you think, I am going to do it."

Respondents expected that during the treatment, both their fellow patients as well as care professionals would be able to influence their behavior:

Yes, I really feel like I belong here, being in a group of 8 who all have the same disease. And that there is a lot of experience, that everyone knows...The social worker, motor therapist, they know how it works, and what is on your mind and what is tough [47, female]

Respondents had the intention to follow instructions provided by the care professionals, and some were expecting such instructions to occur:

But I am not like I do that [look at the portal] every day. I really need someone to tell me to do some exercises. In that case I have a driving force that makes me do so. [57, female]

Furthermore, the treatment group, existent of patients who have a shared medical background, was often mentioned as a very positive feature of the treatment. Especially the fact that patients have common understanding of the impact that the disease had on their lives was perceived as a positive thing:

Being together with others who suffer the same disease, although in different ways, but...cancer is cancer. You learn to talk about it. It is easier with fellow patients than with outsiders, or your partner. In such cases, you have the feeling they have heard it all. [48, female]

During the second round of interviews, however, an example arose of the negative influence a strong group feeling might have on patient adherence and in this case, usage of the portal. Two patients were unable to log in to the portal, which influenced both care professionals and patients associated to their treatment group:

We collectively quit using the portal, because 2 persons could not join in. Two persons who cannot login on 7 participants is a lot. It drove them crazy, as they reported the issues and felt nothing was done about it. [...] And then we decided together to drop it! [58, female]

One respondent even stated that the portal became a topic that was avoided during group sessions because there were some patients who got annoyed by the fact that there were some who could not use the portal at all. Thus, besides the direct impact on the 2 persons that could not use the portal, this inability to use the portal resulted in a lower willingness to use the portal

across their entire treatment group. Luckily, there were also some positive signals. A 46-year-old female respondent reported that “if someone told me they had watched a functionality, I would check it at home too.” And she was not alone in this. Others also stated they would have used the portal more if usage would have been stimulated more by the care professionals. The findings from these interviews really emphasize the impact that both care professionals and fellow patients have on the willingness to use the portal within the treatment. Especially, stimulation by care professionals and a positive attitude within the group toward the portal seem to be positive determinants for patient adherence.

Intrinsic Motivation Cues

According to the literature, patients who are more intrinsically motivated required less stimulation [5]. So how was the intrinsic motivation of the patients included in this study? A total of 36 episodes across 11 interviews were assigned to intrinsic motivation cues. The general intrinsic motivation of the respondents was positive (18 positive vs 6 negative episodes in the first round of interviews). Respondents were highly motivated to actively participate within the treatment to get back into full participation within the society:

I think this treatment is so beautifully set up, this is a chance that I get to get my life back on track. Of course, I will seize to grab this opportunity with both hands. [47, female]

One person even stated he had already put effort into training to strengthen his physical condition before signing up for the treatment, which is proof of his strong intrinsic motivation to get better. In line with the first round of interviews, participants within the treatment remained intrinsically motivated during their entire treatment (63 episodes, 5 negative vs 12 positive):

I was full engaged, and still am. [...] I you want to achieve something, you will give your 100%. [60, female]

However, as a 47-year-old female respondent stated, it did vary how people translated this motivation into action:

I believe everyone was seriously engaged within the treatment. Though I was a bit surprised that some participants took a week or a weekend off and missed treatment days because of it. I decided that during these 12 weeks all appointments associated with the treatment received highest priority. [...] I felt it was a now or never kind of story.

The responses to the questions concerning intrinsic motivation were quite uniform, in the sense that everyone seemed to be intrinsically motivated to engage in the treatment. Although this might be a very strong determinant for their willingness to engage in group- and other offline sessions, it is unlikely that this was an important determinant for usage of the portal.

Perceived Ease of Use of the Portal

Could it be that the determinants for the usage patterns that were found are originating from the TAM [15]? First, the responses considering the ease of use of the portal were mixed. Over a total of 49 coded episodes, 12 were negative and 11 were

positive. Positive remarks were made about the easiness with which the contents of the portal could be found and used, whereas negative remarks primarily focused on difficulties accessing the portal. First, there were 2 respondents who reported difficulties to log in to the portal. The second, and more prevalent problem, was the fact that the portal was only designed for usage from a laptop or desktop computer. This was experienced as a barrier to use the portal by 5 respondents, who explicitly stated they preferred using such a portal from a tablet:

I prefer to use it on the tablet. Some parts do work, while others do not. Those parts do not fit on the screen properly. [...] A tablet is a bit easier to pick up. [47, female]

During the second round of interviews, responses considering the ease of use of the portal were mixed. Out of 87 quotes, 15 were negative and 11 were positive. As mentioned before, 2 persons dropped out of the treatment as they were unable to log in to the portal and felt insufficiently supported to resolve those issues. On the other hand, many respondents who could log in described the portal as easy, simple, and “easier than the information folder,” 48, female. The primary critique on the portal remained the inaccessibility of the portal on devices other than laptops and computers:

I would like to be able to use the portal on my tablet. It is a shame that I have to grab the laptop to use it, which makes it less convenient to use it. [47, female]

Another important comment, stated by 2 respondents, is the fact that users of the portal were unable to see how the content presented on the portal was related to specific parts of the treatment. In other words, it is important that the content on the portal has a strong link to the treatment:

All the content is present, but you are forced to find it yourself. [...] I do not take the time to figure everything out, because I am mentally unable to do so. [49, female]

Finally, it is important to understand that the patients who were included had faced a lot of mental and physical challenges and were not willing to accept a telemedicine intervention as another challenge within their treatments:

I only go for the easy way now, if I am honest. I do not take time to figure everything out, because I am not up for it now. [49, female]

The interviews with patients showed that the perceived ease of use is very likely to determine the willingness of patients to use a portal in the treatment, especially if the portal is perceived as difficult to use. This emphasized the need for a portal that is easy to access from different devices, provides information that is easy to find and to understand, and is backed up by sufficient facilitating conditions to resolve any issues that patients encounter while using it.

Perceived Usefulness of the Portal

During the first interviews, some patients already had some brief experience with the portal, and mostly positive comments were made about the usefulness of the portal with 19 positive and 4 negative quotes. However, there were already 2

respondents who did not feel the need for the portal within the treatment. The other respondents were positive about the usefulness of the portal and its functionalities. Some important reasons for a positive perceived usefulness were the fact that the portal can be used as reference material for exercises and information, a way to monitor progress, a way to communicate with care professionals (although there was a person who wished for more communication abilities), and to find treatment schedules:

It supports the activities that we do here at social work, occupational therapy, and group sessions. It enables you to watch instructions at home. We also have a folder with information, which I do read, but the video instructions on the portal are much easier.

[47, female]

During the second interviews, respondents were largely positive about the usefulness of the portal (46 codes, 5 negative vs 21 positive). Functionalities that were perceived as useful were the message function (“It was fun to see that these notes were read by care professionals and that they responded or asked questions about the remarks,” 47, female), the graded activity scheme, and the video instructions (“I use the portal daily, especially the mindfulness exercises,” 49, female). A 47-year-old female respondent was overwhelmed by the amount of available information and advised to “...make content on the portal available in doses,” which might help to guide users of the portal to the content that is required in a particular week and increase the earlier discussed fit with the treatment. Furthermore, the blended care caused for some confusion. Because information was both available in traditional information folders and the portal, some respondents were confused as to what was expected from them:

It has to be either the portal or the information folder.

[48, female]

Several respondents, including a 47-year-old female respondent, emphasized that they intended to visit the portal on a regular basis after the treatment had finished to print and save information that she thinks could be useful in the future. Another reason to visit the portal after the treatment was to see the video exercises that could be found on the portal. However, the fact that on average only 1 patient per week visited the portal makes it unlikely that all patients who said so did. It can be concluded that the portal was perceived as useful by the participants, although that this was not the main determinant to use it or not.

Adherence to the Overall Treatment

How do the previously mentioned determinants influence actual adherence within the treatment? The overall adherence to the treatment seemed to be sufficient. Patients were eager to participate in the offline part of the treatment, of which they had very positive expectations beforehand. After the treatment, patients reported positive experiences about the treatment plan that was followed while visiting the rehabilitation center. Intrinsic motivation (getting life back on track), the perceived impact of the disease (both physically and mentally), expected benefits from the treatment (multidisciplinary results and care professionals), and the intensity of the contact with fellow patients were reasons to stay adherent to the treatment.

Adherence to the Portal

On the contrary, the analyzed portal usage of patients was rather low. How is it possible that if patients were intrinsically motivated and had positive expectations about the treatment in general, their interest in using the portal was generally low? The 4 most important determinants of portal usage found in this study were (perceived) impact of the disease (being physically or mentally unable to use the portal), extrinsic motivation cues (strong or poor stimulation from care professionals and fellow patients to use the portal), perceived ease of use (especially the ease with which the portal could be visited), and perceived usefulness (influenced by the fit of the portal its content with the general treatment program and communication about usefulness and application from care professional to patient).

Discussion

Principal Findings

The main objective of this study was to explore determinants for patient adherence to portal-supported rehabilitation treatments from the perspective of both patients and care professionals, where this paper focused on the patients’ perspective. When it comes to the offline part of the treatment, patients were generally positive and willing to engage in the treatment. All respondents were intrinsically motivated to get their lives back on track after suffering from a life-threatening disease and wanted to fully participate in society again. Participants were very positive about the multidisciplinary approach of the treatment, had positive expectations about the treatment, intended to fully engage to the program, and had good hopes to get their lives back on track with the support of care professionals.

At the start of the treatment, patients had the intention to use the portal offered alongside it. However, when it comes to portal usage, adherence seemed to be much lower. Whereas an increase in portal usage was seen over the first weeks of the rehabilitation program, it quickly declined after the seventh week of the treatment. After the treatment at the rehabilitation center had ended, on average, only 1 of 31 patients visited the portal.

Even though the portal was designed and developed in close cooperation with care professionals and patients and patients seemed to be generally motivated to stay adherent to the treatment, the usage of the portal remained low. How can this be explained? From the interviews, it appeared that 4 determinants were particularly influencing adherence to the portal: perceived impact of the disease, extrinsic motivation cues, perceived ease of use, and perceived usefulness. Although the 4 determinants were described separately earlier in the manuscript, analyses learned that they were strongly intertwined.

First and foremost, the study showed how important it is for a portal to be truly embedded into the overall program design for it to be used by patients in the treatment. We would like to emphasize the role that care professionals play, as extrinsic motivators, when it comes to increasing awareness among patients about the importance and usefulness of the portal. This is in line with earlier studies that emphasized the role of the care professionals and human support as a strong motivator for

health behavior [5,8,21]. The behavior of care professionals and their off- and online communication with patients was reported by patients as a strong incentive to use the portal. In the few weeks that usage of functionalities on the portal was stimulated, portal usage increased. This finding emphasizes the crucial role that care professionals play in the potential success of portal applications in rehabilitation programs. Clear communication from care professionals to patients about the usefulness of, and benefits derived from the portal, by emphasizing a strong link with the offline program, might increase awareness of the usefulness of the portal and stimulate active usage of a portal in the treatment [19,20]. These observations strengthen the suggestion that a telemedicine intervention will not be successful unless care professionals are to increase the awareness among patients about the importance and usefulness of the ICT within the treatment.

A second group that influenced behavior in the treatment and willingness to use the portal were the fellow patients. Because there was such a strong focus on the group during the treatment, the attitude held within the group toward group activities and usage of the portal influenced the intended behavior. Patients could stimulate each other to engage in group sessions and inform each other about information to be found on the portal. On the contrary, the group also showed negative influence on the behavior of patients, which was showed in the case where 2 persons of a group could not use the portal. They felt insufficiently supported to resolve these issues, leading to a bad attitude toward the portal within the group, which ultimately led to a group decision to quit using the portal.

Finally, the perceived impact of the disease, which was derived from the HBM [13,14], mostly seemed to be a barrier toward portal usage. Patients indicated that the severity of their disease influenced their ability to engage in the treatment and their willingness to use the portal. Some explained that they were physically and mentally unable to use the portal. Patients explicitly stated they did not want to commit to a portal that was perceived as an additional burden to their already intensive rehabilitation program, which is in line with findings of earlier research [19]. This emphasized the need for a portal that is easy to access and use. Where earlier studies found disease severity

to be a determinant for general health behavior [13,19], this study showed it is also likely to determine willingness to use a portal supportive to the treatment.

Strengths and Limitations

What are the strengths and weaknesses of our study? The study was conducted with a low number of participants because the influx in the rehabilitation program was low. Furthermore, many of the approached patients perceived participation in the study as an extra burden to the treatment, and they did not want to commit their precious time to it. The portal did not fully fit the needs of the patients and care professionals involved in the rehabilitation treatment. This resulted in the fact that care professionals were not always willing to apply the portal in the treatment. This made them unsuitable candidates for stimulating usage of the Web portal among patients. Finally, 2 patients that enrolled in the treatment encountered issues with the portal and felt unsupported when trying to address and resolve these issues. Furthermore, the portal was offered rather independent from the treatment and appeared to be insufficiently incorporated within the treatment. It would be interesting to investigate the determinants once these problems are taken care of.

Conclusions

In this paper, the determinants for patient adherence to portal-supported rehabilitation treatments were explored from the perspective of patients. Where hardly any adherence issues were reported considering the offline elements of the treatment program, the usage of the portal applied within the treatment remained low. Although various determinants for adherence were identified, the most important barrier toward portal usage seemed to be uncertainty among patients about the fit of the portal within the treatment program and the importance of using it. From the determinants identified in the study, it seems that extrinsic motivation by care professionals plays an important role in countering these issues. The findings suggest that, to increase portal usage, the portal needs to be truly embedded in the overall treatment program, with a strong link to the activities scheduled in the offline sessions, and usage of the portal by patients should be actively stimulated by care professionals.

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Authors' Contributions

HB contributed to the study design, conducted the interviews, analyzed the data, and was the lead writer for the manuscript. MT contributed to the study design and reviewed the manuscript. LvV contributed to the study design and reviewed the manuscript. TvdG contributed to the study design and coauthored the manuscript. HH contributed to the study design. All authors approved the final version of the paper.

Conflicts of Interest

None declared.

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Abbreviations

HBM: health belief model

ICT: information and communications technology

SA: supported accountability

SD: standard deviation

TAM: technology acceptance model

TPB: theory of planned behavior

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Original Paper

Activity Recognition in Individuals Walking With Assistive Devices: The Benefits of Device-Specific Models

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Abstract

Background: Wearable sensors gather data that machine-learning models can convert into an identification of physical activities, a clinically relevant outcome measure. However, when individuals with disabilities upgrade to a new walking assistive device, their gait patterns can change, which could affect the accuracy of activity recognition.

Objective: The objective of this study was to assess whether we need to train an activity recognition model with labeled data from activities performed with the new assistive device, rather than data from the original device or from healthy individuals.

Methods: Data were collected from 11 healthy controls as well as from 11 age-matched individuals with disabilities who used a standard stance control knee-ankle-foot orthosis (KAFO), and then a computer-controlled adaptive KAFO (Ottobock C-Brace). All subjects performed a structured set of functional activities while wearing an accelerometer on their waist, and random forest classifiers were used as activity classification models. We examined both global models, which are trained on other subjects (healthy or disabled individuals), and personal models, which are trained and tested on the same subject.

Results: Median accuracies of global and personal models trained with data from the new KAFO were significantly higher (61% and 76%, respectively) than those of models that use data from the original KAFO (55% and 66%, respectively) (Wilcoxon signed-rank test, $P=.006$ and $P=.01$). These models also massively outperformed a global model trained on healthy subjects, which only achieved a median accuracy of 53%. Device-specific models conferred a major advantage for activity recognition.

Conclusions: Our results suggest that when patients use a new assistive device, labeled data from activities performed with the specific device are needed for maximal precision activity recognition. Personal device-specific models yield the highest accuracy in such scenarios, whereas models trained on healthy individuals perform poorly and should not be used in patient populations.

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KEYWORDS

activities of daily living; machine learning; wearables; rehabilitation; orthotic devices

Introduction

Activity recognition (AR) has become an active area of research in the past decade, largely driven by the availability of low-cost wearable sensors and general purpose machine learning algorithms [1,2]. A promise of such systems is to unobtrusively

track and quantify daily physical activities or other physiological parameters and ultimately provide personalized recommendations to prevent health problems or tailor exercise or rehabilitation programs.

Rehabilitation is an area of health care that can largely benefit from AR [3]. By monitoring functional activities of individuals

with disabilities, clinicians and researchers can rely on quantitative data to evaluate the effectiveness of a treatment or an assistive device and optimize them to improve patient outcomes. This need is fueled by the rapid development of novel prostheses, orthoses, and wearable robots that can recognize the user intentions or the environment properties and adapt the device's mechanical properties accordingly [4,5]. In order to justify reimbursement of such devices from health insurance companies, clinical studies need to provide quantitative evidence that this technology significantly improves a patient's quality of life, compared with conventional assistive devices. Therefore, AR systems can overcome the limitations of current clinical tests in collecting such data.

The majority of wearable- and mobile phone-based AR studies have been conducted using healthy individuals, whereas relatively fewer studies are focused on people with disabilities [6], such as those resulting from stroke [7-9] or Parkinson disease [10,11]. Some of these studies showed that a model trained on young healthy individuals will yield poor performance when used with a different population [9,11-13], including those who need an assistive device for walking [14]. These differences arise due to the fact that movements are unique to individuals, and movements in people with a disability are different from that of able-bodied individuals [15]. As a result, AR systems are still of limited use in health care applications [16].

Furthermore, gait patterns of individuals with disabilities can change significantly from that of healthy individuals, and additional variability can arise when disabled individuals who walk with an assistive device switch to a new device. The source of such variability can be due to differences in the mechanical design or in the way the new device is controlled, which often requires the person to learn new movement strategies [4]. These differences could affect the reliability of an AR model and should be considered when deploying an AR system for clinical purposes.

In general, an AR model can be user specific (*personal* model) or it can be trained on data from other individuals to predict the activities of a new individual (*population* or *global* model). Global models are arguably easier to deploy, as they do not require labeled data from every new user; in addition, they can be trained on a larger dataset, as data from many users are aggregated to train the model. However, their lack of specificity can affect accuracy [17], due to the variability that exists between individuals. Personal models, in contrast, are trained on data from each new subject, with the advantage of being highly specific. However, collecting labeled data from each new subject is expensive. Thus, it is important to understand under which conditions a model will perform well.

Studies comparing personal with global models showed mixed results [2], with some emphasizing the need of using personal

models [18] whereas others reporting that global models can be flexible enough to generalize to new users [19]. Few approaches attempted to enhance the performance of global models with unlabeled [20] or labeled [21] data from the new user or by combining activity models from other users with similar characteristics [22]. However, it is unclear how all these results will apply to patient populations, specifically those using different assistive devices.

Here we focus on identifying physical activities using a waist-worn accelerometer in people walking with a leg orthosis, namely a knee-ankle-foot orthosis (KAFO). A KAFO is normally used by individuals who suffered a traumatic or neurological injury, as well as a neuromuscular disease causing weakness or partial paralysis of one or both legs [23]. In our scenario, the persons with disabilities are testing a novel computer-controlled hydraulic KAFO (OttoBock C-Brace) that substitutes their control KAFO. We ask whether an AR model has to be trained with labeled data from the person performing physical activities with the C-Brace or whether data obtained from the control device or from other individuals will suffice. We analyze how the specificity of the training data affects the performance of the model as we move from a model trained with data from other subjects (global model) to one specific for each subject and brace (personal device-specific model).

Methods

Study Design

After being consented, 11 individuals with disabilities (3F, mean age 56.4 [SD 12.9] years) and 11 age-matched, able-bodied individuals (5F, mean age 49.2 [SD 19.4] years) participated in this study. Northwestern University's Institutional Review Board approved the experimental procedures for the study, which took place at the Rehabilitation Institute of Chicago. For the sake of convenience, in the following, we will also refer to our pool of participants with disabilities as "patients."

All patients required the use of a unilateral KAFO to ambulate due to either a neurological or traumatic injury or a neuromuscular disease causing muscular weakness in one leg (see Table 1). The recruited participants were part of a larger study that investigated whether a microprocessor-controlled KAFO (C-Brace) helps differently abled persons to better perform functional everyday activities and to have a more active lifestyle. All patient participants were able to transfer to sitting and standing and walk independently or with the supervision of a caregiver. Out of the 11 patients, 2 were not able to safely manage going up and down a flight of stairs and did not require stair climbing in their homes. The speed of walking and daily distance of walking varied within the patient population.

Table 1. Demographics of participants with disabilities.

Subj #	Gender	Age, in years	Diagnosis	Control assistive device
1	M	64	Poliomyelitis	Freewalk - Ottobock
2	F	59	Spinal cord injury	SPL2 - Fillauer
3	M	40	Poliomyelitis	E-MAG - Ottobock
4	M	64	Poliomyelitis	E-MAG - Ottobock
5	F	41	Poliomyelitis	E-MAG - Ottobock
6	M	35	Spinal cord injury	E-MAG - Ottobock
7	M	72	Poliomyelitis	E-MAG - Ottobock
8	M	68	West Nile meningitis	E-MAG - Ottobock
9	F	44	Peripheral neuropathy	Becker Stride - Becker
10	M	65	Poliomyelitis	E-MAG - Ottobock
11	M	68	Spinal cord injury	E-MAG - Ottobock

Each patient was fitted and effectively trained at using a passive stance-control KAFO as their control device and a microprocessor-controlled hydraulic KAFO as their novel device, namely the C-Brace (Ottobock, Duderstadt, Germany). Each device was used by the participants at home and in the community. Unlike traditional KAFOs, the C-Brace embeds a computer-controlled hydraulic unit that dynamically changes the impedance of the knee joint by using sensors in the knee and ankle joint that infer the slope of the ground surface and the user intent [4]. This stance and swing impedance feature assists the user in performing stand-to-sit movements as well as walking on a variety of surfaces and descending stairs.

All subjects wore a triaxial accelerometer (Actigraph wGT3X-BT; Actigraph LLC, Pensacola, FL) that recorded data at a sampling frequency of 30 Hz and was strapped around their waist on the right side with a belt. We aimed at detecting the following 5 functional activities: sitting, stair climbing and descent, standing, and walking. All subjects performed a scripted sequence containing the 5 activities, over 3 different sessions, which took place on separate days. Here, we define a single repetition of the sequence as a "session." The total time of the recordings for each patient lasted an average of 35 minutes.

During each session, subjects were asked to sit comfortably while talking, gesturing, or checking their phone. They were then asked to stand while washing their hands or pouring and drinking water. Participants then walked at a self-selected, comfortable pace, and finally ascended and descended at least one flight of stairs at a self-selected pace. Each activity was performed for at least 30 seconds to ensure that enough data were collected. For safety purposes, all individuals with disabilities were supervised by a physical therapist.

Healthy subjects performed the scripted activities 3 times during 1 session. Patients performed the scripted activities during

clinical training. For this data analysis, 3 sessions using the control assistive device and 3 using the novel assistive device were used. The sessions took place over a 3-week period on average. Due to comfort and safety issues related to their disability when using the new device, 2 patients could not ascend or descend stairs. A researcher observed the sessions and recorded the length of the activities for subsequent data labeling. Furthermore, all patients were administered the Orthotics Prosthetics Users Survey self-report questionnaire for lower extremity functional status (OPUS-LEFS) at the end of the study, to rate their level of comfort in using each KAFO. On average, all participants rated both the control and the novel device equally comfortable.

Activity Recognition

Accelerometer data were downloaded on a personal computer using the Actigraph ActiLife software (Actigraph LLC, Pensacola, FL). Data windows of 6 seconds with 75% overlap were extracted from the raw acceleration data and a set of 131 features (Table 2) were computed on each window. Both time and frequency domain features were used, as in previous studies [24]. The window length was selected based on previous AR studies that aimed at recognizing functional daily activities, such as walking or stair climbing [2,25] using wearable sensors. A random forest classifier [26] was used to predict the activity given a vector of features calculated on each window (Figure 1).

We selected random forest as it does not suffer from overfitting, performs well in activity recognition problems [27], and it has fewer hyper-parameters to optimize as compared with other classification models (eg, support vector machines). The number of trees was optimized to maximize the balanced accuracy (see the section "Performance Metric"), which resulted in 10 trees for the *Healthy* model and 50 trees for all the other models.

Table 2. List of features computed on the accelerometer data used for activity classification.

Description	Number of features
Mean, range, interquartile range (x, y, z)	9
Moments: standard deviation, skew, kurtosis (x, y, z)	9
Histogram: bin counts of -2 to 1 z-scores (x, y, z)	12
Derivative of moments: mean, standard deviation, skew, kurtosis (x, y, z)	12
Mean of the squared norm	1
Sum of axial standard deviations	1
Pearson correlation coefficient, $r(xy), r(xz), r(yz)$	3
Mean cross products (raw and normalized), xy, xz, yz	6
Absolute mean of cross products (raw and normalized)	6
Power spectra: mean, standard deviation, skew, kurtosis (x, y, z)	12
Mean power in 0.5 Hz bins between 0 and 10 Hz (x, y, z)	60

We trained 5 classification models (Figure 2) to compare how the training data affected classification accuracy when predicting each patient's activities performed with the novel assistive device. Classification models are divided into 2 categories:

global models, which are trained on data from subjects other than the one being tested, and *personal models*, which are trained and tested using data from the same subject.

Figure 1. A. The two types of assistive devices (knee-ankle-foot orthosis, KAFO) used in the study. Patients performed activities with their control KAFO (passive stance-control orthosis) and then with the novel KAFO (OttoBock computer-controlled C-Brace). B. Experimental setup, data processing, and activity recognition steps (adapted with permission from [14]). A patient performed a set of activities while wearing a KAFO and a triaxial accelerometer. Windows of 6 seconds were extracted from the raw acceleration data (sampled at 30 Hz) yielding a matrix $[a]$ of size 3×180 . A set of 131 features were computed on each window, and the resulting vector f was inputted to a random forest classifier, which predicts the performed activity.

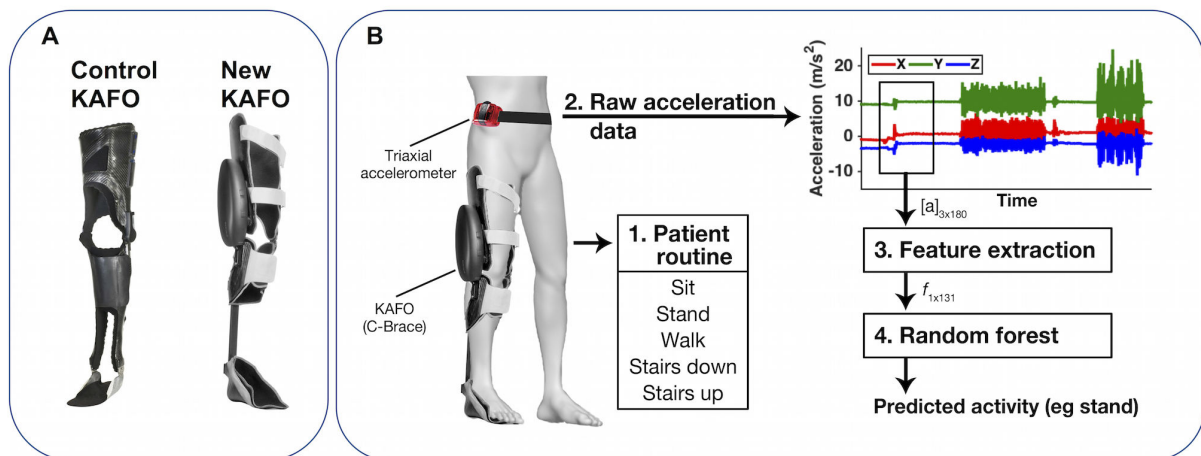
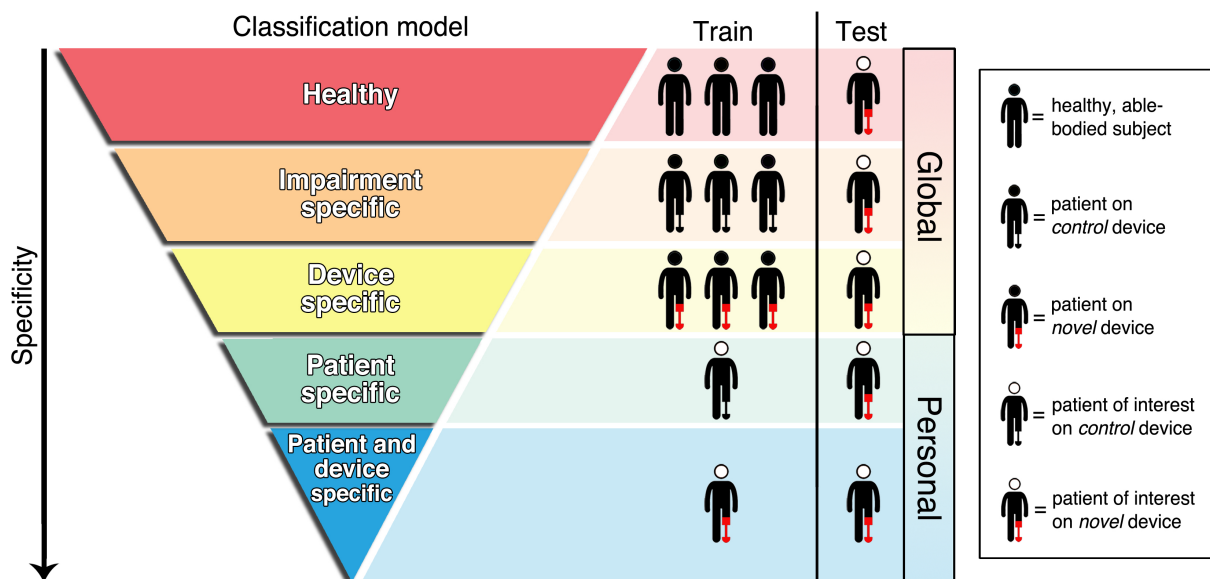


Figure 2. Diagram depicting increasing specificity of classification models in terms of what groups of individuals (able-bodied or individuals with disabilities/patients) they are trained on. Patients are depicted using their control (black) or novel (red) assistive device. Each classification model is used to predict activities for the patient of interest (Test), walking with the novel assistive device. The top 3 layers of the pyramid contain global models, which are trained on individuals other than the one used to test the model. The 2 bottom layers of the pyramid contain personal models, which are trained and tested with data from the same individual.



Global Models

Healthy model: a classifier is trained on data collected from the healthy subjects (~9000 data points) and evaluated on each patient while using the novel device.

Impairment-specific model: a classifier is trained on data from other patients while using their control device (~16,000 data points), and evaluated on the patient of interest while using the novel device.

Device-specific model: a classifier is trained on data from other patients while using the novel device, and evaluated on the patient of interest while using the novel device.

Personal Models

Patient-specific model: each personal classifier is trained on a patient’s own control device data and evaluated on their novel device data (~1500 data points).

Patient- and device-specific model: each personal classifier is trained on a patient’s own novel device data and evaluated on their data using a leave-one-session-out cross-validation (~1000 data points).

Performance Metric

As stair-climbing data are largely underrepresented, there is a significant class imbalance in the dataset. Because of that, we used the balanced accuracy (mean recall) as the metric to assess classifier performance, such that the error in each class receives equal weight. In scenarios with class imbalance, it is important to use an unbiased performance metric, such as the balanced accuracy or balanced error rate, to prevent drawing erroneous conclusions about the performance of the AR model [28].

$$\text{Balanced accuracy} = 1 / C \sum_{i=1:C} (TP_i / n_i)$$

where C is the number of activities (5 in our case), TP_i the number of true positives for activity i , and n_i the number of data points for activity i . Put simply, the balanced accuracy averages the prediction accuracy for each activity and, consequently, is not affected by the presence of more data for some activities. Class imbalance stems from the fact that patients using a KAFO can have difficulty ascending and descending stairs. However, these 2 activities are still performed by patients to some extent and, thus, are important in the assessment of a clinical AR system.

To compare performances across models we performed 4 Wilcoxon-signed rank tests to account for the non-normality of one of the distributions (Shapiro-Wilk test). These 4 tests were performed sequentially, such that each classification model was compared with the next more specific model, with $\alpha=.05$.

Training Data Size in Global Models

Whereas personal models are trained on data from a single subject, global models are trained on data from multiple subjects. As the number of subjects in the training dataset increases, the amount of training data increases, and the classification error of a global model will likely decrease. Therefore, we evaluated the balanced accuracy of both global models (healthy and impairment-specific) as a function of the number of training subjects. For each selected number of subjects, we ran 1000 training iterations, where in each iteration we randomly picked subjects to train on and one patient’s novel device data to test on. We chose 1000 iterations to account for a sufficient number of combinations of training and test subjects and for minor fluctuations in performance of the random forest. The largest number of training subjects for the impairment-specific model is 1 minus the total number of patients, as 1 patient is always set aside for testing. For each set of models trained on a selected

number of subjects, we inferred the mean and 95% confidence interval of the median balanced accuracy by bootstrap using 1000 repetitions.

Results

We compared the performance of global and personal classifiers trained with either data from patients who used their control KAFO assistive device or the novel C-Brace assistive device. A global model trained on healthy subjects was included in the comparison, representing the least specific classification model. Models were compared based on their balanced accuracy. Global models were then compared in terms of the amount of training data (number of subjects) used to reach a certain level of accuracy.

Classifier Specificity

To understand whether training data from the novel assistive device will improve performance of a global model, we compared the classification accuracy across the 3 global models (Figure 3). A classifier trained with only healthy subjects' data yielded the lowest balanced accuracy, with a median of 53%, for predicting the activities of a patient using the novel assistive device. A global model trained on patients using their control KAFO (impairment-specific) only performed marginally better ($P=.03$) than the healthy model, with a median balanced accuracy of 55%. In contrast, a global model trained using data from the novel device (device-specific) boosted the balanced accuracy significantly over the former 2 models ($P=.006$), reaching a value of 61%. Thus, data from activities performed with the specific assistive device used should be collected to achieve the highest accuracy with an AR system.

We then examined whether training data from the novel device affected the accuracy of personal models. The patient-specific model, which is a personal model trained with a patient's control device data and tested on the patient's own novel device data, yielded a median balanced accuracy of 66%. However, the performance of this model varied drastically across patients (interquartile range, $IQR=[47\%-72\%]$), and overall there was no statistically significant improvement over the global device-specific model ($P=.29$). Model accuracy did not correlate with how comfortable patients felt using the novel device, as measured by the OPUS-LEFS questionnaire ($r=0.14$, $P=.69$), indicating that the variable performance of the model is not related to the perceived comfort in using the device. This suggests that a personal model might overfit to the data from the control assistive device, and therefore, it does not confer an advantage over a global device-specific model.

Conversely, a personal model trained with the novel device data (patient- and device-specific) yielded the highest median

balanced accuracy (76%), providing a significant advantage over all the previous models ($P=.01$). Of notice, this model was trained with the least amount of data (~1000 samples) across all models, which is about one-third less data than the patient-specific model. Therefore, regardless of whether a model is global or personal, the resulting classifier will perform significantly better if trained on data from the specific assistive device used by the patient.

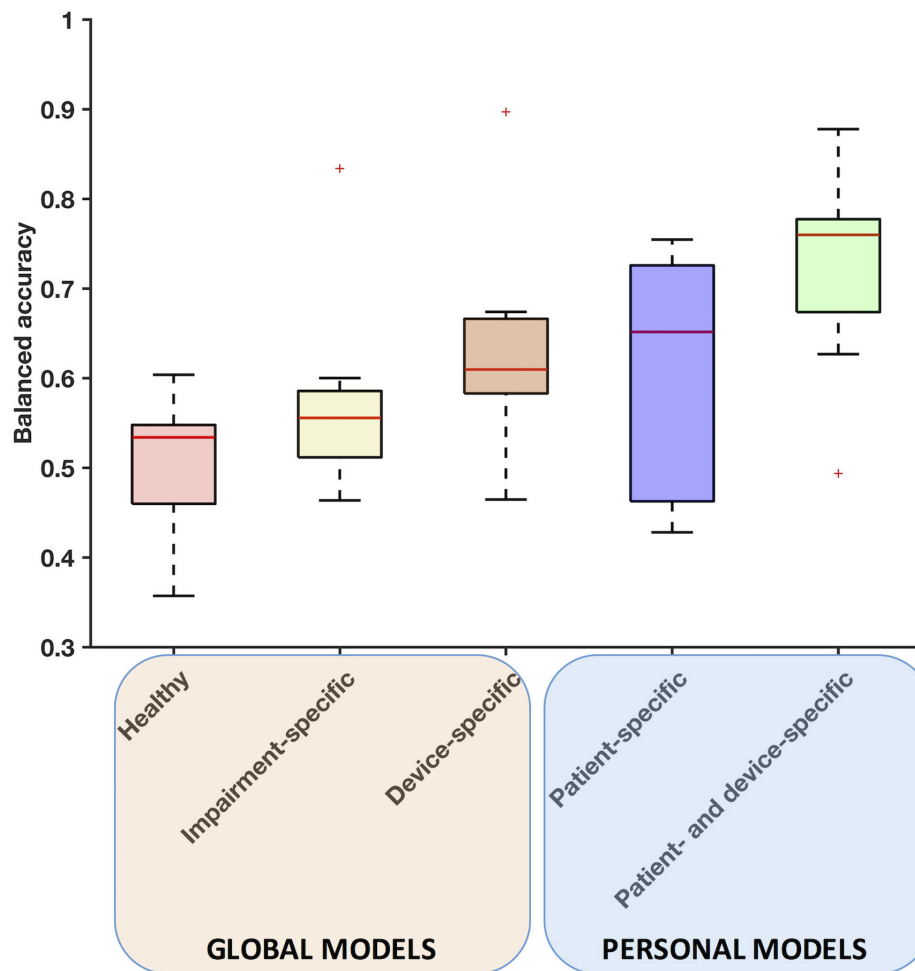
As the results on the balanced accuracy do not reveal which activities are misclassified by each model, we analyzed the accuracy per class (recall) across the 5 activities for all models (Figure 4). The recall for sedentary/stationary activities (sitting and standing) was overall high for all models ($>70\%$) and did not change dramatically across them. This is not surprising, as features used by each model to identify these activities are not expected to depend on the patient population, nor on the assistive device used.

The global healthy model had the lowest recall for predicting walking (27.13%, 1337/4928), which was mostly misclassified as climbing upstairs (Figure 4, top-left). Interestingly, recall for climbing upstairs had the highest value (53.1%, 331/623) compared with all other models, suggesting that features describing climbing upstairs might be similar between healthy subjects and patients walking with the novel device. In contrast, recall for climbing downstairs was quite low (7.7%, 45/582). This is surprising in that the C-Brace allows the knee to bend and support the user in a step-over-step stair descent similar to the pattern used by the healthy subjects. Thus, models trained on able-bodied displayed poor performance for capturing dynamic activities in patients.

On the other hand, recall for walking was significantly higher (79.26%, 3906/4928 and 91.61%, 4514/4928, respectively) in the impairment-specific and device-specific models (Figure 4, top-center and top-right), although both models misclassified most of the stair-climbing data ($\leq 21.8\%$, 127/582) as walking. Consequently, global models trained on patients generalized well to walking data but were still poor at capturing stairs ascend and descend activities.

Patient-specific models performed in between the global-healthy model and the global-patients' models, with a recall of 64.33% (3170/4928) for walking and of 43.8% (273/623) for stair climbing up. Recall for stair climbing down was still low (17.2%, 100/582). Recognition of both stair-ascend and descend activities only improved with the patient- and device-specific model (43.1%, 83.7/194 and 48.0%, 99.7/207.7), although the recall was well below that for walking or other activities. Therefore, the main gain achieved by personal models trained with the new device data was on the recognition of stair-climbing activities.

Figure 3. The distribution of balanced accuracies for the 5 models. Each model is tested on each patient using the novel assistive device (C-Brace). Boxes represent the interquartile range (IQR), red lines are medians, and whiskers show 1.5 IQR. Red crosses are outliers.



Effect of Number of Subjects on Global Models

As global models are trained with data from multiple subjects, we evaluated how many subjects are required to achieve a desired level of performance for each global model. As expected, the median balanced accuracy increased with the number of subjects for all 3 global models (Figure 5). The median accuracy of the impairment-specific models seemed to plateau already with 11 subjects. However, trends for the Healthy and

device-specific models suggest a further increase in accuracy if additional subjects are added. Nevertheless, the device-specific model showed a net advantage over the healthy and impairment-specific model, as a model trained on 1 patient performed as well as a model trained on 11 healthy individuals. Therefore, device-specific global models require significantly less data from patients to achieve the same performance, as compared to the other global models.

Figure 4. Confusion matrices for the 5 classification models, grouped by global and personal models. Numbers represent percentage of instances in that class.

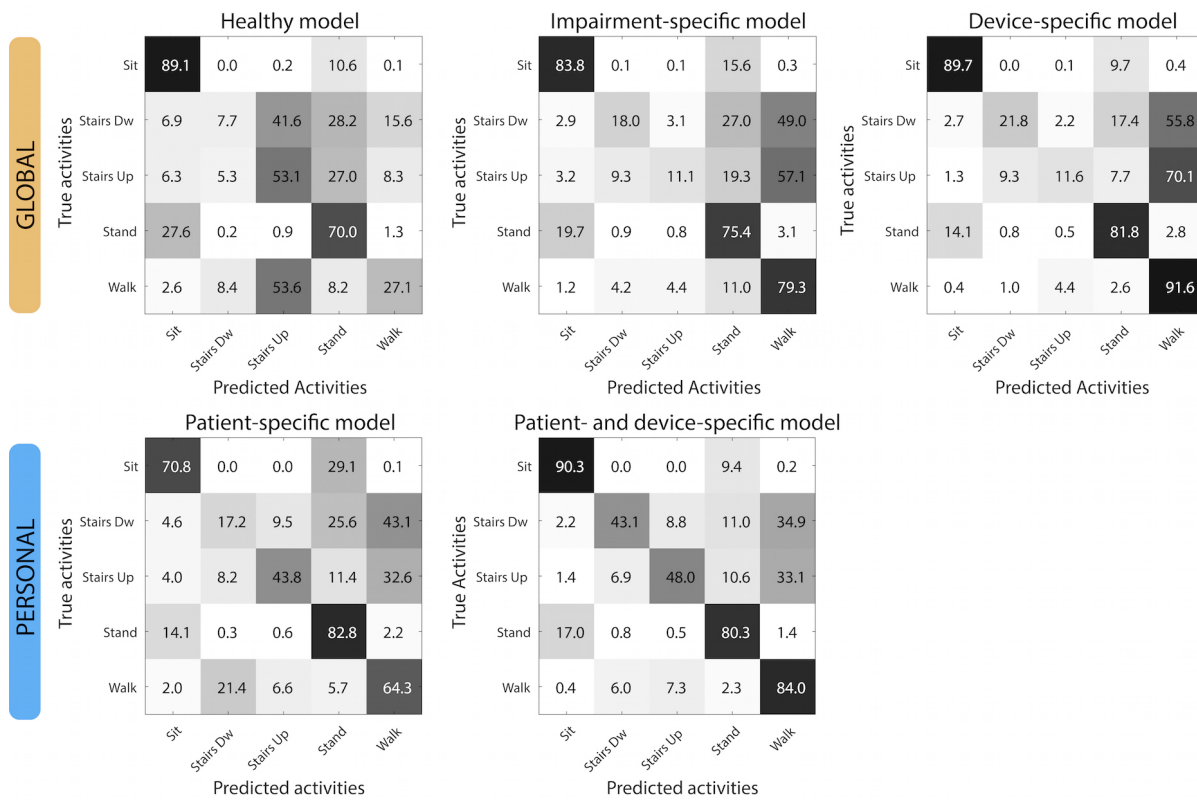
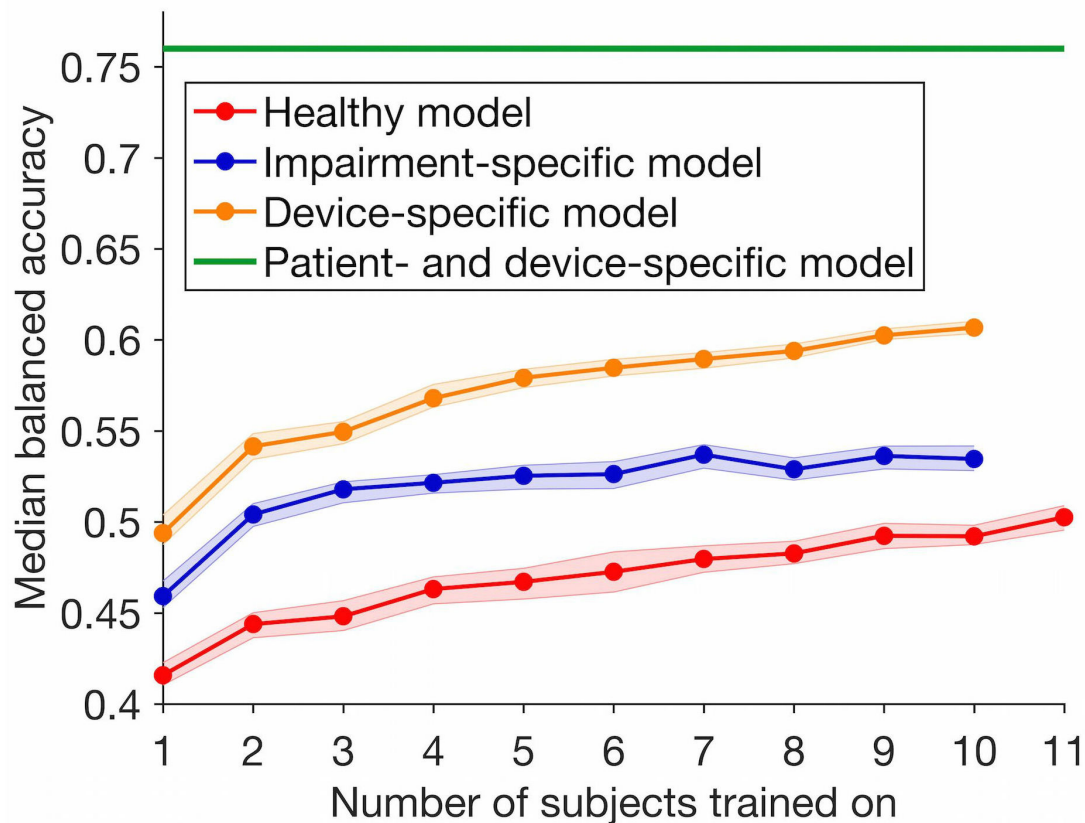


Figure 5. Effect of number of subjects used to train each global model on the median accuracy for healthy (red), impairment-specific (blue), and device-specific (orange) global models. The maximum number of subjects for patient models is 10, as 1 patient is left out for testing (leave-one-subject-out cross-validation). Shaded areas represent the 95% confidence intervals on the medians obtained by bootstrap. The green line represents the median accuracy of the patient- and device-specific models (personal model).



Discussion

Principal Findings

We asked whether AR models for individuals walking with an assistive device (KAFO) require training data from the new KAFO (C-Brace) or whether data from their control KAFO will suffice. We found that both global and personal models performed significantly better when trained with data from the novel KAFO used by the subjects to perform the functional activities. Therefore, an AR system has to be trained with data specific to the assistive device used to maximize classification accuracy.

We examined both global and personal models. Although global models were trained with about 16 times more samples than personal models, a personal model trained on the novel KAFO data (patient- and device-specific) largely outperformed all global models. Interestingly, this was not the case for a personal model trained on the control KAFO data (patient-specific), as the accuracy of this model was highly variable across subjects and overall not better than that of a global device-specific model. Therefore, in this scenario, a personal model might only help if trained with data from the specific assistive device used.

On the other hand, global models are arguably easier to deploy, as they do not require collecting data on each and every new patient [14]. Interestingly, in our scenario, personal device-specific models surpassed global models only for identifying stair-climbing activities, while being equally accurate at detecting walking. This suggests that when stair climbing is not a predominant daily activity that needs to be identified for a patient, a global device-specific model will equal the mean accuracy of a personal model.

Although the performance of the global-healthy model increased with the number of training subjects, this model was outperformed by global models trained on patients using the novel KAFO (device-specific). One reason is that gait patterns in individuals with disabilities can be markedly different from those of able-bodied subjects [15], and the algorithms could use different sensor features to identify activities in different populations [9,29]. Indeed, former studies found that activity recognition models trained on a population of young able-bodied individuals generalize poorly to patient populations, such as the elderly or patients of stroke or Parkinson's disease [9,11-13]. Our findings are in line with these results and show that additional variability can be introduced by the use of different KAFOs. Therefore, a model trained on able-bodied individuals will likely be inaccurate when applied to a population that uses a KAFO to walk.

Limitations

There were certain limitations to our study that we need to acknowledge. We only had a sample of 11 individuals with disabilities (patients) for training the global models; adding more subjects could increase the performance of these models, and should be explored in future studies. It has to be noted though that the accuracy of global models was dramatically lower than that of personal device-specific models. As reported by some prior studies, global models might not reach the

performance of personal models even when a large number of subjects are used [18]. On the other hand, a global device-specific model equaled the performance of a patient-specific personal model, which suggests that personal models may suffer from overfitting to the specific assistive device used, and therefore, not generalize well across different assistive devices.

We asked our subjects to perform a structured set of activities in a lab setting and under the supervision of a clinician. Although specific instructions on how to perform activities were not provided (eg, washing hands or checking the phone), this scenario is still different from a natural environment. Previous studies showed that the accuracy of AR can drop significantly when the data collection is performed outside of a lab-controlled condition [30], and therefore, these findings should be validated outside of the lab. However, collecting labeled data in naturalistic environments remains a challenge, particularly with patient populations.

We compared performance of global models to that of personal models. However, one can also use intermediate approaches, where both data from other subjects and personal data are combined to train a new model. For example, activity-specific personal models from other subjects can be combined to fit a small dataset of labeled data from the target subject (semipopulation models) [31]. Such an approach can be guided by individual characteristics of the target individual, such as height and weight [32]. Transfer learning methods can also be employed: here, features learned in one domain, where data are abundant (eg, healthy or patient), are modified to fit the data in the target domain (eg, new patient or new assistive device), where labeled data are scarce or expensive to collect [28,33]. While we are investigating the application of these methods, further validation in a larger pool of subjects is needed, before they can be implemented in our scenario.

We only used one sensor (accelerometer) attached to the participants' belt to detect the activity performed. This solution is unobtrusive and well suited for a long-term monitoring scenario, particularly in disabled or elder populations [34]. Using additional inertial sensors (eg, gyroscope or barometer) could improve the model performance, although at the cost of increased power requirements [35]. Similarly, the placement of the sensor on the body can affect the prediction accuracy for certain activities, as the optimal location is often a function of the activity to recognize [36]. Using multiple sensors on different body parts is also known to increase the accuracy [25], although it is likely to decrease patient compliance. Future studies should explore how these factors influence the accuracy of AR when patients use an assistive device.

Conclusions

Guidelines on how to use wearable technology to track functional activities in populations other than young able-bodied are still lacking [37]. Our results suggest that AR models need to be validated on both the specific patient population and assistive device used and that personal models may confer an advantage only when trained on the specific assistive device used. Maximizing the reliability of AR models is a key enabling factor that will allow clinicians performing informed decisions

based on the data. This is a necessary step to favor the deployment of such technology into the clinic.

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Conflicts of Interest

None declared.

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Abbreviations

AR: activity recognition

IQR: interquartile range

KAFO: knee-ankle-foot orthosis

OPUS-LEFS: orthotics prosthetics users survey for lower extremity functional status

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Original Paper

Caregiver Input to Optimize the Design of a Pediatric Care Planning Guide for Rehabilitation: Descriptive Study

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Abstract

Background: Participation and Environment Measure Plus (PEM+) is a guide that is compatible with the YC-PEM and may expedite care plan development and strengthen a patient's engagement in discussions and decisions about their values, needs, and desires that shape meaningful care (ie, patient-centered care).

Objective: The objective of this study was to examine the feasibility of a stepwise process for building on a baseline assessment of young children's participation in activities to develop a care plan relevant to pediatric rehabilitation.

Methods: A cross-sectional descriptive study design was employed using qualitative methods. Data were collected via Web-based technology and by telephone. Twenty-five caregivers of young children (9 with developmental delays, 16 without delays) and between 1 and 7 years were recruited from a subsample of parents who had previously enrolled in a Web-based validation of a PRO on children's participation and provided consent for future contact. Each caregiver completed a demographic questionnaire and Young Children's Participation and Environment Measure (YC-PEM) online, followed by a 20- to 60-min semistructured and audiotaped phone interview to review and build upon PRO results as summarized in an electronic report. Interview data were content coded to the interview guide and reviewed by multiple research staff to estimate feasibility according to stepwise completion rates, perceptions of difficulty in step completion, and perceptions of overall utility.

Results: Half of the participants in the final study sample (N=25) fully completed a stepwise process of building on their baseline PRO assessment to develop an initial care plan for their child. In most cases, similar stepwise completion rates and trends in the approaches taken for step completion were found regardless of the child's disability status. However, more parents of children with disabilities reported difficulties in rank ordering their priorities for change and identified child-focused strategies for goal attainment. Nearly 77% (19/25) of users were willing to use the process to develop and communicate intervention priorities and strategies with professionals, family, and friends.

Conclusions: Results informed revisions to the care planning guide before usability and feasibility testing of an initial Web-based prototype that is now underway.

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KEYWORDS

pediatrics; social participation; goals; patient-reported outcome; eHealth

Introduction

Background

Pediatric occupational therapists typically play a direct role in helping children with developmental disabilities and delays to participate in activities of daily life [1]. They are key members of pediatric rehabilitation teams who strive to deliver evidence-based and tailored therapies targeting functional outcomes [2] so as to mitigate social disparities in rehabilitation service use [3]. Occupational therapists rely on self or proxy report to monitor a child's participation as compared with observing the child's performance of discrete tasks [4,5]. Hence, providers need access to valid and feasible patient-reported outcome (PRO) assessments to gather caregiver input about young children's participation for planning and delivering care that is responsive to patient priorities [6].

Due to time and resource constraints, pediatric rehabilitation providers need efficient ways to gather PRO data. For example, service eligible families in early intervention [7] need to have a care plan that is developed within 45 days of referral and reflects family priorities. Semistructured and face-to-face interviews with parents and primary caregivers are not routinely completed because of time and resource constraints. For example, the Routines-Based Interview (RBI) takes up to 120 min and 2 trained providers to complete [8].

Advances in rehabilitation assessment and technology [9] may afford for valid and more feasible family assessment. For example, the Young Children's Participation and Environment Measure (YC-PEM) is a newly developed electronic assessment of children's participation. The YC-PEM content, scaling, and layout decisions were informed by caregiver input [10-12] and are intended to offer several user benefits, which are as follows: (1) comprehensive assessment of participation in home, school, and community settings; (2) assessing multiple dimensions of a child's participation (frequency, involvement, change desired); (3) assessing for environmental impact on participation in each setting; and (4) Web-based format affording feasible self-administration. Initial psychometric evidence suggests that the Web-based YC-PEM provides valid, reliable, and feasible assessment of participation and environmental impact on participation among young children with and without developmental disabilities [13]. Validation has focused on establishing the validity of known-groups [14] and modeling environmental impact on participation when applied to younger children [15]. The YC-PEM is now a recognized common data element for studies involving children with cerebral palsy and other neurological disorders [16]. Culturally adapted versions will increase instrument uptake in clinical research contexts [17] and afford for additional psychometric validation.

Recent work has been undertaken to explore the utility of deploying the YC-PEM within an intervention context [18-20]. For individual families, YC-PEM results may be helpful as a

springboard for collaborative care planning with providers, supporting patient-centered care. As YC-PEM assessment results will not automatically produce a viable care plan, caregivers will need to complete additional work to synthesize their assessment results to develop goals with focused and feasible action plans to improve their child's participation. However, caregivers often manage this complex task of improving their child's participation with limited or delayed intervention support while balancing competing time demands. For this reason, electronic health (eHealth) technologies that help caregivers organize a plan-of-care flexibly, on their own schedule, may enhance caregiver-provider collaboration during care-planning activities.

Participation and Environment Measure Plus (PEM+) is a guide that is compatible with YC-PEM and may expedite care plan development and strengthen patient's engagement in discussions and decisions about their values, needs, and desires that shape meaningful care (ie, patient-centered care) [21]. Caregivers are expected to complete PEM+ to specify their priorities for change, generate goals for their child, and design initial intervention strategies for goal attainment. PEM+ was designed with caregiver and provider input [18-20].

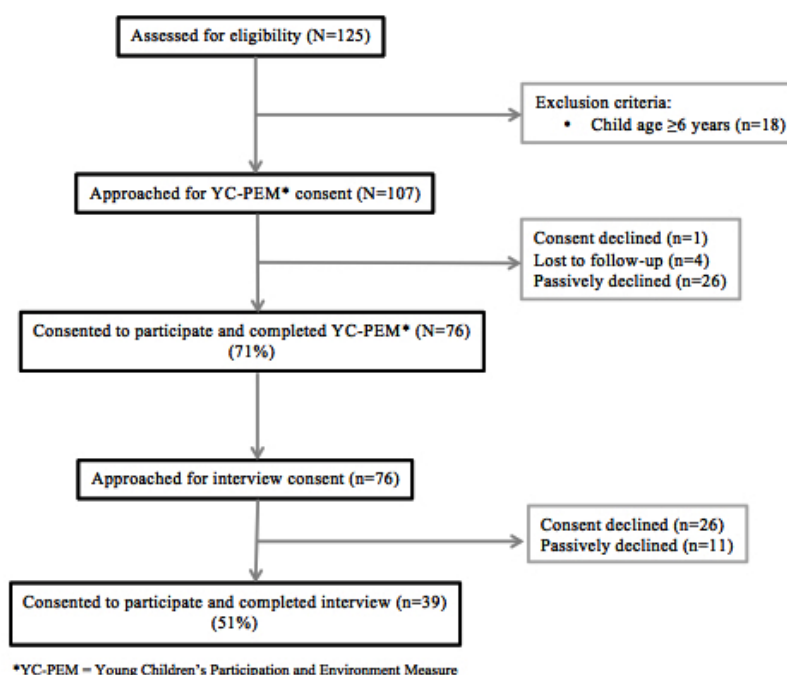
Objective

The purpose of this study was to examine the feasibility of a revised PEM+ prototype for use within an early childhood-care-planning context. Study results will guide assessment of whether to build and test PEM+ usability as an eHealth technology for use in rehabilitation.

Methods

Participants

This observational study employed a cross-sectional descriptive design. Data were drawn from a convenience sample of 125 caregivers of children with and without developmental disabilities and delays. They had initially consented to future contact during a Web-based YC-PEM validation study when their children were in the age group of 0 to 5 years (Time 1: June 2013-October 2013) and then enrolled online in a longitudinal cohort study 1 year later when their children were between the ages of 1 and 6 years (Time 2: October 2014-March 2015). At the Time 1 enrollment, all caregivers met the following inclusion criteria: (1) could read and write in English; (2) resided in the United States or Canada; (3) were 18 years or older; (4) were parents or legal guardians of a child aged between 0 and 5 years; and (5) had Internet access. For this study, a total of 76 caregivers enrolled in Time 2 data collection. These caregivers accessed a Web-based platform to consent to complete the YC-PEM online. After YC-PEM completion, 39 of these 76 caregivers also consented for a phone interview to discuss and build on their YC-PEM results using PEM+ (see Figure 1).

Figure 1. Enrollment Consort (Consolidated Standards of Reporting Trials) flow diagram.

Measures

Demographic Questionnaire

Caregivers were asked to report on family factors (eg, employment status, annual income, and respondent education) and child factors (eg, age, gender, receipt of and reason for early intervention or early childhood special education services, and functional issues [no problem, little or big problem]).

Young Children's Participation and Environment Measure (YC-PEM)

The 27-item YC-PEM evaluates the caregivers' perceptions of their young child's participation in various activities that take place at home (13 items), daycare or preschool (3 items), and within the community (12 items). Upon completion of the participation items for a setting, caregivers were asked to evaluate the effect of environmental features and resources on their young child's participation (13 items for home, 16 items for daycare or preschool, and 17 items for community). A 3-point scale (3=no impact or usually helps to 1=usually makes harder) was used to assess the perceived effect of environment on participation.

The YC-PEM has three participation scales and one environment scale, which have shown fair to excellent internal consistency for the home (Cronbach alpha=.82-.96), daycare or preschool (Cronbach alpha=.67-.92), and community (Cronbach alpha=.68-.96). Test-retest reliability of the YC-PEM has also been established, using intraclass correlation coefficient (ICC) for the home (ICC=.57-.91), daycare or preschool (ICC=.31-.92), and community (ICC=.52-.94) settings. For this study, setting summary scores [12] were calculated to describe sample trends in current participation. The YC-PEM item responses were also

summarized in a case report and sent electronically to caregivers to guide data collection via phone interviews.

Data Collection

Eligible and interested participants created a user account to enroll online and complete a demographic questionnaire and the YC-PEM for the second time. Following survey completion, participants provided their contact information and availability for a semistructured phone interview to experience and provide feedback on PEM+. Before each phone interview, research staff generated a graphical YC-PEM report summarizing their responses at two time points (see [Multimedia Appendix 1](#)), which was cross-checked and sent to the participant electronically 1 to 2 days before the scheduled interview.

During the phone interview, participants were asked to review and provide feedback on the content and layout of the YC-PEM report and then try a stepwise process of building on the information in their report to specify priorities for change and to formulate goals and action plans for goal attainment. For feasibility, each participant completed the PEM+ process once during the interview. The interview guide (see [Multimedia Appendix 1](#)) was informed by formative work with community-based providers working with children and youth with developmental disabilities in a small-town community [18]. Probes in the interview guide were used to increase the likelihood of data saturation with respect to feasibility.

Data Analysis

Sample characteristics and trends in current participation were first summarized for the total sample and subgroups (disability, no disability) using the Statistical Package for Social Sciences version 24.0 (SPSS 24.0; IBM Corp). Data were first screened via visual inspection (histogram) and normality statistics (absolute values of >2 for skewness and >7 for kurtosis) to

examine whether data met assumptions of normality. Normality assumptions were also confirmed using a series of Shapiro–Wilk tests for YC-PEM participation and environment summary scores. Participation frequency scores did not deviate significantly from normal, $D(25) = .867-.949$, $P = .09-.24$. Daycare or preschool involvement and environmental support scores as well as home desire change did not deviate significantly from normal, $D(25) = .877-.932$, $P = .10-.12$. However, home and community involvement and environmental support summary scores, as well as daycare or preschool and community desire change scores, were significantly non-normal, $D(25) = .632-.895$, $P < .001$. Therefore, parametric tests were used for select subgroup comparisons only.

For main analyses pertaining to feasibility, a total of 39 phone interviews were audiotaped. The audiotaped case recordings were each reviewed independently by 2 research assistants to determine whether the recording was viable for analysis based on two criteria: (1) the recording had audible content coverage and (2) the recording contained pertinent content relative to each main question, indicating fidelity to the interview guide. Upon case review, 25 of the 39 cases (25/39, 64%) were deemed viable for analyses and therefore transcribed verbatim. A third research assistant checked each transcript with its respective digital recording to ensure accuracy before being imported into QSR International's NVivo 11.0 for analysis.

Transcripts were content coded to the main questions in the interview guide in five phases [22]. Analytical deductive coding was used whereby relevant text (eg, words, phrases, and quotes) from each interview was sorted to a priori, which corresponded to the interview questions. Two research assistants independently coded an initial transcript that underwent code-by-code review by the principal investigator to ensure the following: (1) each excerpt included participant wording; (2) there was a match between the coded text and corresponding label; and (3) there were no missed opportunities to code interview content pertaining to one or more codes. The research assistants then proceeded to code six more transcripts, followed by another round of review by the principal investigator. Inter-coder agreement was estimated to range from 80% to 95% by the third transcript.

The second research assistant proceeded to code the remaining 18 transcripts that were randomly assigned to one of four phases. Following each phase, one coded transcript was selected at random for review by the principal investigator. Discrepancies were resolved through discussion. Following analyses of all 25 cases, the second research assistant randomly selected a second coded transcript from each of the five phases for review to ensure accuracy. The principal investigator conducted a final review of all coded data to establish a final study dataset. To estimate feasibility, frequency counts were then calculated to describe PEM+ stepwise completion rates, perceived difficulty with step completion, perceived utility and report sharing preferences. Mean completion time was calculated based on start and end times for phone interviews as documented by study staff. Most findings were reported for total sample and disability subgroups, including exemplars to illustrate main findings.

To ensure credibility of the main findings, multiple researchers with different disciplinary backgrounds reviewed coded data from 13 (13/25, 52%) of the cases. To ensure dependability of main study findings, the first seven transcripts (7/25, 28%) were independently coded by 2 research staff and reviewed by the principal investigator. The principal investigator continued to review one case at random in each subsequent phase of analysis to ensure match between each code label and corresponding text. Once all the cases were analyzed, a second staff member and the principal investigator randomly selected and reviewed eight cases (8/25, 32%).

Self-reflexivity involves acknowledgement of experiences and understandings by a research member that may impact study approach and expected findings, which in turn provides authenticity and trustworthiness to the findings [22]. The first research assistant had worked at a therapeutic recreation center for children with disabilities. Her work there had exposed her to identifying participation-focused goals that do not hinge on a child's level of independence, as well as both child and environmental strategies that parents might generate for goal attainment. During phase 1 analyses, she was closely partnering with a parent to advocate for a child, whom she had tutored, so the child could obtain interventions to address academic performance concerns that hindered his school participation. Her concurrent experience working with this family may have sensitized her to code data on parenting priorities and strategies. The second research assistant had prior experience working alongside occupational therapists, who emphasized compensatory techniques to improve patient recovery in their homes. These experiences may have sensitized her to identifying environmentally focused strategies specific to the home environment during analyses.

Results

Caregiver and Child Characteristics

Caregiver respondents were white mothers who were mostly married (22/25, 88%) and non-Hispanic (23/25, 92%). More than two-thirds of the families sampled were residing with multiple children in the home. As shown in Table 1, nine of the children sampled were eligible for early intervention or early childhood special education services at the time of enrollment. The most common reason for service referral was diagnosis (6/25, 24%) versus developmental delay or risk for delay. The latter indicates that a child has (or is at the risk of) an established delay in development, based on standardized developmental assessment scores, but does not have a diagnosed condition (eg, autism spectrum disorder). The most common form of rehabilitation addressing functional issues was speech and language therapy (7/25, 28%), ranging from 30 min to 3 hours per week, followed by occupational therapy (4/25, 16%) and physical therapy (2/25, 8%). There were no significant disability group differences in sociodemographic characteristics of the study sample.

Table 1. Sample characteristics (N=25).

Characteristic	n (%)
Caregiver's education^a	
Some college or technical training	3 (12)
Associate's degree	2 (8)
Bachelor's degree	8 (32)
Graduate degree	11 (44)
Employment status	
Does not work for pay	12 (48)
Part-time	7 (28)
Full-time	6 (24)
Household income, in US dollars (\$)	
<\$50,000	5 (20)
\$50,000-100,000	10 (40)
>\$100,000	10 (40)
Child's age (in years)^{a,b}	
1-3	14 (58)
4-5	8 (33)
6-7	2 (8)
Child's gender^a	
Male	13 (52)
Female	11 (44)
Service receipt	
Yes	9 (35)
No	16 (64)
Reported functional problems^a	
Managing emotions	14 (58)
Controlling behavior	11 (46)
Paying attention	10 (42)

^aindicates missing values.

^bconfirmed at the time of the interview.

Children, on average, participated once or more each week in home activities (mean=5.67, range=2.15) and daycare or preschool activities (mean=5.77, range=2.67) and once each month in community activities (mean=3.00, range=2.58). Children were somewhat to very involved in activities across home (median=4.20, interquartile range [IQR]=3.83-4.45), daycare or preschool (mean=4.6, range=1.33), and community (median=4.27, IQR=3.71-4.62) settings. Caregivers, on average,

wanted their young child's participation to change in more than half of home (13/25, 52%) and daycare or preschool (18/25, 72%) activities but not community (8/25, 32%) activities. Significant group differences between young children with and without developmental disabilities and delays were found with respect to the child's current participation (frequency, involvement, desire change) in home and community settings (see [Table 2](#)).

Table 2. Disability group differences in young children's participation and environment.

Young Children's Participation and Environment Measure (YC-PEM) scales	Disability, mean (range)	No disability, mean (range)	<i>t</i> (degrees of freedom)	<i>P</i> value
Home frequency	5.21 (1.62)	5.91 (1.85)	-3.264 (23)	.004
Home involvement ^a	3.82 (1.93)	4.25 (0.54)	-	.36
Home desire change	68.38 (84.62)	43.59 (69.23)	2.157 (23)	.04
Home environmental support ^a	82.05 (16.67)	97.44 (5.13)	-	.11
Daycare or Preschool frequency	5.50 (2.00)	5.94 (1.33)	-0.882 (8)	.40
Daycare or Preschool involvement	4.38 (1.33)	4.67 (1.00)	-0.953 (8)	.37
Daycare or Preschool desire change ^a	100.00 (33.33)	100.00 (100.00)	-	-
Daycare or Preschool environmental support	93.23 (12.50)	98.61 (2.08)	-1.780 (8)	.17
Community frequency	2.62 (2.00)	3.13 (2.25)	-1.736 (22)	.10
Community involvement ^a	3.57 (2.04)	4.38 (.53)	-	.11
Community desire change ^a	81.82 (72.73)	9.09 (27.27)	-	.03
Community environmental support ^a	84.31 (21.57)	98.04 (7.84)	-	.03

^aindicates median (range).

Feasibility of PEM+ for Care Plan Development

Mean PEM+ completion time as denoted by phone interview length was 38 minutes.

PEM+ Step 1: Identify Priorities for Change

All 25 caregivers were able to complete the first step of PEM+ in one of the two ways. Most caregivers opted to rank order the list of activities in which they had reported wanting their child's participation to change. Only one parent opted to sort the activities according to whether the activity should be worked on now versus later.

Nearly 80% of the parents opted to rank based on importance rather than how feasible it would be to implement change to improve the child's participation in that activity. To do this, parents' often considered the following: (1) the extent to which the activity was challenging for their child and (2) the extent to which the activity was valued by the parent. Two parents acknowledged both considerations to arrive at their respective priorities in rank order:

I guess I put...his greatest challenges first, and that the interactive and organized play he's very rigid...[it's] a skill that he can use in any, in every context. The socializing with friends and family, well that's for me kind of an obvious one because we want him to take pleasure in that.

I'd rate houseguests one because I feel like she needs that interaction with people. Probably two, I would rate meal prep because I want her to be able to...help me and get that interaction with me and that bonding time with me. I would say three for the personal care because she's still 2 and she'll learn that as we go along.

Whereas all caregivers were able to complete this first step, 3 out of 25 caregivers (3/25, 12%) expressed some difficulty in

rank ordering their priorities for change, particularly in cases where there were a large number of situations warranting change because:

...[the activities] all kind of run together.

According to another parent:

I would say it's kind of hard. I mean, I can pick...the top one or two pretty easily, and the bottom one or two pretty easily, but the ones in the middle all kind of [blend together].

PEM+ Step 2: Formulate Activity-Specific Goal for Child

A total of 22 out of 25 caregivers (88%) were able to develop a goal to improve their child's participation in their top-ranked activity or one that was sorted into the "now" category. Caregivers most often chose to focus on improving their child's participation in a home-based activity.

Within the home setting, goals were commonly focused on improving the young child's participation in a nondiscretionary activity such as personal care management (9/25, 36%) and cleaning up (3/25, 12%). For example, a mother of a 5-year-old boy with reported attention, communication, and sensory processing difficulties described the importance of her child's participation in nondiscretionary activities:

...his self-care, dressing, getting clean...those are big things for him, um, to go into kindergarten.

She further elaborated on her goals for him to be more helpful in these activities:

...it could be, uh, initiating going to the bathroom on his own without being asked to go...And, uh, resting in the morning.

Similarly, a working mother described wanting her 32-month-old daughter to help clean up at home:

...when you make a mess it's your responsibility to pick that mess up. It's not my job to come behind you and pick it up all the time.

Whereas parents tended to describe their goals in their own words, their descriptions closely aligned with their child's current level of participation. For example, parents described goals related to their child being more helpful or interactive in cases where their child was only somewhat involved in the activity.

PEM+ Step 3: Appraise Current Strategies for Goal Attainment

A total of 24 out of 25 caregivers identified strategies for goal attainment. Parent-reported strategies to improve the child's participation focused on the child, the child's environment, or both the child and the child's environment.

The most common type of strategy identified by 96% (24/25) of families who had completed the YC-PEM related to modifying the child's environment, regardless of whether or not the child had a disability. Across a broad range of home-based activities, parents described their attempts to change the physical layout of the home environment to promote the child's engagement. For example, several parents described placing a step stool and toothbrush within reach so that the child could participate in personal care routines such as brushing teeth. Similarly, parents described setting the house up, so their child has "a place for his clothes so he knows where they go." This type of environmental strategy extended to discretionary activities, whereby parents described placing toys and books within reach as well:

I recently like kind of reorganized his toys and like the crafts and things...and everything kind of has a place so he knows where to look and where to go. And kind of where he can see it so it's not...all like covered up. I just think he, if he can see something he can go play with...then he doesn't...ask for a show 'cause he has something else that he's doing.

I mean even on a simple level...we used to keep our son's books up so he couldn't reach them...so we moved them to his level and it's amazing how often he goes out and picks a book and flips through it.

Apart from modifying the physical space, parents described changing the cognitive and social demands of home-based activities by setting reminders or by modeling behavior:

...having his...outfit completely laid out...in the proper way for him to be able to put it on easily without having to figure out which one's front, which one's back.

...reminders for her to clean up the toys.

...having the other people there and then she's kinda watching what we're doing and kinda copying whatever we're doing...that's beneficial.

Whereas the environmentally focused strategies were most common, close to one-third of families (32%) described strategies that involved having the child practice skills as preparation for engaging in the activity. This type of strategy

was reported on by 56% (5/9) of caregivers raising young children with disabilities as compared with 19% (3/16) of caregivers raising young children without disabilities.

One-third of the families identified strategies for goal attainment that were directed at the child and the child's environment. The most common type of strategy involved reinforcement strategies during mealtime. For example, 2 caregivers of children receiving services for developmental delay described offering their children desired food as an incentive for trying a new food at mealtime:

Usually if she doesn't like what's for dinner then she has a choice to just have cereal. She has to take a certain number of bites and then she does that and she's still hungry and then she can just eat cereal.

So, with food, ya know, to keep out of line of sight, ya know...so, ya know, he loves yogurt. And we might do yogurt as part of lunch but yogurt doesn't come out until he's eaten the first part of his lunch.

PEM+ Step 4: Develop New Strategies for Goal Attainment

Out of 25 caregivers, 19 were able to generate new strategies for goal attainment. A vast majority of the new strategies focused on additional ways to change qualities of the child's environment to improve participation. For example, one caregiver identified multiple strategies for allotting adequate time for cleaning up toys at home. She described allocating more time for cleaning up by pushing back the schedule, as well as by regularly going through and removing select toys to ensure that there would be a reasonable number of toys to clean up in the designated time. Another caregiver made the room darker and quieter to help her son get adequate rest, as both light and sound hindered his ability to sleep. Furthermore, a working mother of a 21-month-old girl identified ways to adjust the height of the sink and the location of her daughter's toothbrush and toothpaste:

...an area where she could actually reach them on her own, um, and do it, she would probably be more successful. So maybe getting a table and standing next to her until she learns how to, or is tall enough to actually reach it herself.

Finally, caregivers also adjusted how children were invited to join home-based activities. For example, a mother of a 4-month-old boy could "organize the laundry in a fun way" and recalled a method where she could put her son in the laundry basket and "pull him around the house...and afterwards start folding."

PEM+ Step 5: String Steps Together to Create Activity-Specific Action Plan

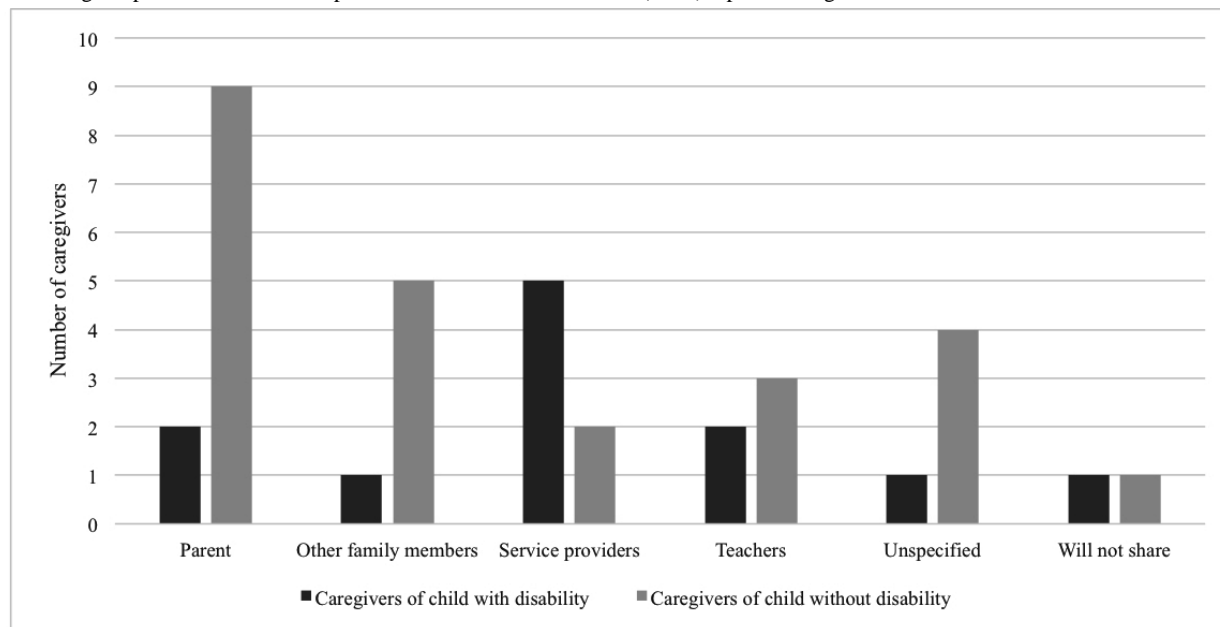
A total of 12 out of 25 (48%) of caregivers were able to communicate the results of the first four steps completed via phone. These caregivers could specify which activity they wanted their child to focus on first, set a goal, and identify strategies for goal attainment. However, only 4 caregivers defined a clear time frame that they considered actionable for goal attainment.

PEM+ Completion Time, Perceived Utility, and Report Sharing Preferences

Mean PEM+ completion time as denoted by phone interview length was 38 min. Nearly 77% (19/25) of the users perceived

the PEM+ process as useful to develop and communicate intervention priorities and strategies. Caregivers described a number of people with whom they would share their PEM report, including professionals, family, and friends (see Figure 2).

Figure 2. Caregiver preferences for Participation and Environment Measure (PEM) report sharing.



Discussion

Principal Findings

Patient-centered care hinges on patients having ways to collaboratively engage in designing and monitoring their care [23]. Technology may afford for more accessible provider–patient interaction [9,24] when planning and monitoring patient care. In pediatric rehabilitation, electronic PROs have emerged as one way to feasibly elicit caregiver input about the child’s functional status when the child receives care. As rehabilitation is designed to improve children’s functioning in activities of daily life, caregiver input about the child’s functional status can be used to ensure patient-centeredness in monitoring outcomes of service provision [25,26]. Pilot data on the feasibility of electronic PRO data collection within routine care suggest that they can be feasibly completed in entirety within or outside an early intervention home visit [27].

To our knowledge, this is one of the first studies to examine the feasibility of a stepwise process (PEM+) for caregivers to build on a baseline assessment of their young child’s participation and actively develop an individualized care plan for their child. Provider and caregiver input helped to characterize PEM+ as a process, whereby a caregiver can establish their intervention priorities, develop goals related to each priority, and create action plans for goal attainment [18,19]. Main findings of this study suggest that 88% (22/25) or more of the caregivers sampled could engage in 4 out of the 5 parts to the PEM+ process by telephone and viewed it as an accessible way to help plan care for their young child. Several trends in stepwise completion rates and the approaches taken for step completion

suggest that PEM+ can be built as an eHealth solution and are discussed.

Caregivers in this study benefited from multiple options to complete the first step of PEM+, whereby they were instructed to weigh their priorities for change and identify a top priority. Some parents expressed difficulty when rank ordering problematic activities for their child, and one parent opted to sort the activities instead. Although less common, sorting problematic activities may be a viable approach to weighing priorities for change. Sorting may be a particularly valuable approach in cases where the caregiver has identified a large number of activities in which change is desired. Patient choice is a key indicator of patient-centeredness [25] and is a common feature of eHealth technologies specific to planning care [28,29]. Both ranking and sorting options are programmable core requirements to afford for parental choice during PEM+ completion.

Since parents' expectations and priorities for change vary by context [30], future studies should examine whether providing caregivers with choice about ranking or sorting problematic activities helps in planning care outside of the home context. In this study, caregivers commonly focused on improving their child’s participation in nondiscretionary activities at home, perhaps because home is where children spend a large amount of time [31,32], or because they have greater self-efficacy in improving conditions for participation in the home environment that they typically set up for their child and where their child receives services [15]. Alternatively, this trend in step 1 completion may have been because of the home PRO results appearing first in the PEM summary report and so were reviewed first by each caregiver during the phone interview.

Regardless, generalizability of this part of the PEM+ process to out-of-home contexts warrants further study. Future studies could alter the order in which PRO results are presented in the PEM report, as well as probe to understand caregiver rationale for setting selection. Although there are fewer activity categories in the daycare or preschool section, the home and community sections of the YC-PEM PRO contain similar number of items and so would afford for stronger comparisons around trends in PEM+ step 1 completion.

Environmentally focused strategies were most commonly identified for goal attainment during PEM+ completion. This finding could be reflective of the strong environmental focus during PRO completion, as the YC-PEM involves comprehensive caregiver assessment of environmental impact on participation for each setting. Alternatively, caregivers of young children in this study may have prior experience with adapting their home environment to meet the child's needs rather than preparing the child for the activity. This alternative hypothesis is congruent with emerging evidence about environmental impact on young children's home participation [15,33] and the efficacy of environmentally focused interventions involving children with disabilities [34]. However, PEM+ stepwise completion rates may vary by setting. Recently, Benjamin et al [14] reported on greater caregiver knowledge and use of child-focused strategies to improve participation in daycare or preschool activities. Therefore, future studies should examine PEM+ stepwise completion rates when applied to out-of-home contexts such as the daycare or preschool setting.

New environmental strategies were also generated with phone-based intervention support for 76% (19/25) of families. These results suggest that one of the major contributions of PEM+ may be to increase parental efficacy in developing environmentally focused plans for goal attainment. This feature of PEM+ may be particularly valuable for families of young children with disabilities who receive rehabilitation services that are not functionally focused, and in turn, have increased exposure to strategies that address specific underlying impairments and prepare their child to participate in activities [35]. In this study, caregivers of young children with developmental disabilities and delays who completed PEM+ perceived their environments as providing less support for participation as compared with caregivers of young children without disabilities. These caregivers also tended to have identified child-focused strategies for goal attainment. Small sample size and lack of service use data did not allow for subgroup analyses examining the effect of service use on care plan development but warrants consideration in future studies.

Technology may enhance PEM+ functionality by affording for visualizations to help caregivers envision how to change their child's environment. Users can also conduct queries to access data from other PEM+ users on environmental strategy use, if the content is tagged and banked by setting or activity of interest. These technological features may provide for tailored intervention support and are commonly employed in eHealth technologies for patient education [36] and emerging technology-based interventions within rehabilitation [34,37].

Trends in PEM+ completion time and report sharing lend important insight into the feasibility and use of a programmable care planning option for use by caregivers within a service context. Caregivers of children with and without developmental disabilities and delays completed PEM+ during a single phone conversation that was on average of less duration when compared with more established family assessments during a face-to-face visit [38,39]. Caregivers identified formal and informal ways to share the PEM report, although caregivers of children with disabilities most often chose to share the report with service providers who are typically tasked with soliciting for caregiver input during care plan development [40].

Limitations

Results of this study should be considered in light of several limitations, some of which are opportunities for future study. First, approximately 34% (26/76) of families actively declined phone interviews, yet data on their reason or reasons for decline were not gathered because of feasibility. Similarly, approximately 36% (14/39) of families were excluded because of poor recording quality and fidelity. PEM+ usability testing is underway and will include tracking of enrollment trends to identify issues of sampling bias that may limit the generalizability of study results. Second, caregivers gave input on a provider-informed process [18], and PEM+ was completed by phone versus online. This level of provider involvement may have resulted in higher stepwise completion rates because of increased provider contact, as well as lower estimates of perceived difficulty and higher estimates of perceived utility due to social desirability bias. Alternatively, these higher estimates may also be due to lack of a diverse sample according to race and ethnicity and caregiver gender, or the fact that participants had completed the YC-PEM twice and were therefore familiar with its content and able to build on it during PEM+ completion. Third, we only ascertained whether and with whom the caregiver would share their PEM report, which limits our understanding of when and how they might use the information to guide decision making during rehabilitation treatment planning. Subsequent testing of a Web-based PEM+ prototype is underway and includes access to large early intervention and early childhood agencies whose routine care is undergoing change. Hence, we anticipate enrollment of a larger and more heterogeneous sample according to race and ethnicity of the caregiver, child disability status, and family socioeconomic status to extend the generalizability of findings from this study.

Conclusions

This study extends prior knowledge about the accessibility of electronic assessment and care planning for use by caregivers who want to consider child-focused and environmentally focused ways to improve their young child's participation in activities of daily life. Further studies are needed to investigate how caregivers prioritize settings and whether the order in which PRO results are presented influences decision making about high priority settings. Additionally, stepwise completion rates of PEM+ when applied to out-of-home-contexts should also be examined. Work is now underway to conduct usability testing of an initial Web-based PEM+ prototype with visualizations

and tiered coaching support. This testing will involve caregivers intervention services of young children aged 0 to 3 years who receive early

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide and sample PEM report.

[[PDF File \(Adobe PDF File\), 884KB - rehab_v4i2e10_app1.pdf](#)]

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Abbreviations

- eHealth:** electronic health
ICC: intraclass correlation coefficient
IQR: interquartile range
PRO: patient-reported outcome
RBI: routines-based interview
PEM: participation and environment measure
PEM+: participation and environment measure-plus
YC-PEM: young children's participation and environment measure

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Corrigenda and Addenda

Correction: Caregiver Input to Optimize the Design of a Pediatric Care Planning Guide for Rehabilitation: Descriptive Study

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The article “Caregiver Input to Optimize the Design of a Pediatric Care Planning Guide for Rehabilitation: Descriptive Study” (*JMIR Rehabil Assist Technol* 2017; 4(2):e10) had several errors. These errors have been corrected as follows:

Introduction:

In the “Background” subsection, fifth paragraph, the text should read: “Participation and Environment Measure Plus (PEM+) is a guide that is compatible with the YC-PEM and may expedite care plan development and strengthen a patient’s engagement in discussions and decisions about their values, needs, and desires that shape meaningful care (ie, patient-centered care).” This sentence was corrected to be grammatically correct.

Results:

In the “PEM+ Step 3: Appraise Current Strategies for Goal Attainment” subsection, fourth paragraph, the text should read: “This type of strategy was reported on by 56% (5/9) of caregivers raising young children with disabilities as compared with 19% (3/16) of caregivers raising young children without disabilities.” This was corrected to denote the correct denominator for the corresponding subgroup.

The text of the last subsection should read: “PEM+ Completion Time, Perceived Utility, and Report Sharing Preferences”. This header is corrected to accurately reflect the content of this subsection in results.

Discussion:

In the “Principal Findings” subsection, second paragraph, the text should read: “Provider and caregiver input helped to characterize PEM+ as a process, whereby a caregiver can establish their intervention priorities, develop goals related to each priority, and create action plans for goal attainment [18,19].” This sentence was corrected so that it aligns with the two references that are listed as supporting this statement.

In the “Principal Findings” subsection, fourth paragraph, the text should read: “Since parents’ expectations and priorities for change vary by context [30], future studies should examine whether providing caregivers with choice about ranking or sorting problematic activities helps in planning care outside of the home context.” This sentence was corrected as it contained a typographical error.

In the “Limitations” subsection, the text should read: “Subsequent testing of a Web-based PEM+ prototype is underway and includes access to large early intervention and early childhood agencies whose routine care is undergoing change.” This sentence was corrected as it contained a typographical error.

The corrected article will appear in the online version of the paper on the JMIR website on December 21, 2017, together with the publication of this correction notice. Because this was made after submission to PubMed or Pubmed Central and other full-text repositories, the corrected article also has been re-submitted to those repositories.

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