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Successfully Implementing a Clinically-Used Therapy Device in a Home-Therapy Setting

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Abstract. Telerehabilitation has the potential to improve the outcomes of rehabilitation. To expand tele-rehabilitation, the REHA2030 project aimed to integrate medical devices in therapy. To use medical devices in an unsupervised setting within a telerehabilitation system, requirements, processes and control mechanisms need to be defined. In a field trail with four patients and seven therapists, the REHA2030 system with an integrated hand rehabilitation device was evaluated. The aim of including the hand rehabilitation device in combination with a serious game was to increase hand strength and sensor-motor function and to test the feasibility in a home setting. From the four included patients two used the hand rehabilitation device within the field test and trained with it in average 5,8 respectively 5,2 times per week over a period of 10 respectively 5 weeks. The statements of the participants indicate an increase in exercise intensity and frequency and an increase in motivation to practice independently. Easy handling of the system by therapists and patients could also be demonstrated. Further results with more study participants over a longer period of time are needed to validate the results.

Keywords. Telerehabilitation, Stroke, Universal Design, Professional-Patient Relations, Pablo

1. Introduction

Telerehabilitation has the possibility to improve outcomes of rehabilitation after various illnesses and achieves equal results in terms of rehabilitation of daily life activities, motor and upper limb function as conventional rehabilitation [1, 2]. In order to improve the possibilities of tele rehabilitative care, one of the goals of the REHA2030 project was to integrate medical devices into a telerehabilitation system to support stroke patients. In addition, a service model and a technology platform were developed to support patients in regaining functions, improve self-efficacy through controlled practice and enable low-threshold access to therapeutic care, also in rural areas. When using medical devices in an unsupervised setting, that were initially designed for clinical usage, challenges arise and requirements need to be clearly defined. Therefore, required processes, prerequisites and control mechanisms for therapists were conceptualized and elaborated as well as evaluated within two studies that are presented in this work.

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1.1. REHA2030 project

In the project REHA2030, a service model to provide telerehabilitation and a technology platform to support this service model were developed. The technology platform consists of a web-based interface for the therapists and an app for patients. Therapists can set up individual exercises, monitor data, document the therapy, perform therapy sessions face-to-face or via video calls and adjust therapy devices settings. The patients can use the system via an application on a tablet, where they have access to exercise programs, including serious games, the possibilities to monitor their progress within the therapy and to communicate with the assigned therapists via chat or video calls. The system can be used in direct face-to-face therapy, in video calls, but also in unsupervised settings. To include medical devices into the REHA2030 system, processes and requirements were discussed, that they can then be used in the therapy process and software to achieve maximum benefit for therapists and patients within the telerehabilitation setting.

1.2. Requirements for hand rehabilitation equipment for home use

In workshops in Slovenia and Austria with 21 experts (therapists and physicians), requirements for a hand rehabilitation device for stroke patients were assessed. These were used to set up the telerehabilitation system in such a way that it can be used in home setting without constant supervision, considering technical understanding, social factors and life experience of the end-users. Essential requirements are the possibility for repetitive unsupervised training between therapeutic interventions, training of hand and finger strength, safety, handiness, ease of use for home usage, low-cost, usage in acute phase and later rehabilitation process, support in assessments and individual adjustable settings. The listed requirements are also in line with other studies that aimed at a device integration in teletherapy in home use [3, 4].

2. Methods

Through the Human Centered Design (HCD) approach, relevant stakeholders were involved in the system conceptualization, requirement analysis, initial evaluation stages, usability and friendly user tests and a field trail. The requirements from the therapist workshops for the integration of a hand rehabilitation device into a telerehabilitation system in an unsupervised setting, were included into the system and improved in an iterative process with recurring workshops and settings were tested in an initial study with 10 healthy participants. The RHEA2030 system including the hand rehabilitation device was evaluated in a field test with 4 patients.

2.1. Pablo Settings

Based on the requirements, the Pablo handheld rehabilitation device from Tyromotion was selected to be used in this project, as it is already established, safety-certificated therapeutic device, meeting most of the requirements. For the best use of the Pablo, the gold standard for hand strength measurement was used and digitized, using Pablo [5]. The app prompts the patient to perform three maximum hand strength measurements, and the maximum strength value is used for further applications. It serves as a progress

control for patients and therapists and the maximum value is used as baseline to calculate the force ratio which is used to control the serious game. The force ratio is a percentage of the maximum strength and can be adjusted by the therapist within the telerehabilitation-interface.

2.2. Initial study

An initial study was conducted with 10 people, 4 female and 6 male healthy participants, randomly recruited at the Carinthia University of Applied Sciences (CUAS). Participants performed 3 maximum hand-strength measurements with the hand rehabilitation device Pablo from Tyromotion. Followed by playing a serious game, which is implemented in the REHA2030 system, three times for 3 minutes each. The first round with a force ratio of 50% and the next two rounds with self-selected force ratio values. At the end of the three rounds, the participants were asked to specify their preferred force setting, which should be stored in the system as the default value.

2.3. Service Model & Platform Test

The REHA2030 system was tested after a positive decision by the Ethics Committee at CUAS, the Private Clinic Laßnitzhöhe (PKL) and the University Rehabilitation Institute Soča (URI). Four patients received outpatient care from 7 therapists over a period of 5-10 weeks. In the field test, 3 of the 4 patients used both, the REHA2030 system and the Pablo. One patient out of the 3, had to be excluded from further Pablo analyses because only one measurement with the Pablo was performed. The therapy contained face-to-face sessions, synchronous sessions and the patient practiced additional independently.

The participating patients were selected based on the inclusion criteria: stroke, use of a tablet possible, referral to therapy from a physician, mobile internet at home, center of live in a private home setting. The exclusion criteria were limitations of both arms/hands or high grade communication impairment, dementia, severe hearing or visual impairment or a lack of compliance.

Physiotherapy, occupational and speech therapists participated in the study. Inclusion criteria were access to a PC with internet including webcam and microphone and willingness to use digital media. Therapists were approached regarding participation by employees of CUAS or the respective clinic management. Patients were asked by the medical staff to participate in the field test and signed an informed consent.

2.4. Data Collection

Through the tele-rehabilitation platform, digital data was recorded such as exercise-selection, -number, -duration and whether exercises were selected from the therapist's exercise program or in addition to the program. When using the Tyromotion Pablo, the three initial maximum force measurements were saved and for the serious games, the force ratio, game -duration, -level and -score. In addition, questionnaires were distributed to therapists and patients before and after the field test. The questionnaires in the beginning of the field test participation, contained personal and demographic data, affinity to technology and therapy and rehabilitation questions. The questionnaires after participation contained questions about the usability in teletherapeutic use and about the therapy with REHA2030.

3. Results

3.1. Results initial study and REHA2030 settings

In the initial study, the default value of 50% of the maximum force, which was estimated in therapist workshops, was confirmed. 7 out of 10 healthy participants preferred a force ratio of 50% to be used as the default setting for the field test. The therapist can increase or decrease the force ratio within the software depending on the level of the patient and the therapy goals. They also can change the duration and difficulty level of the serious game individually to the patients' needs and progress. Therefore, all adjustments of Pablo in the system are managed by the therapists. To track the therapy progress, an activity monitoring was implemented. Therapists get an overview of all planned and performed exercises, training duration, exercise minutes planned and performed and the patient feedback to the exercise programs. For therapy process with Pablo, the therapist gets an overview of the force progression, including the force average of the three initial force measurements and the reached maximum force. Shown as a summary is also the achieved game scores in relation to the game level. The patient gets an overview of the performed exercises in relation to the planned trainings per week, training duration, and an exercise counter. In addition, a detailed list of all the exercises which were carried out is available.

3.2. Pablo statistics of Service Model & Platform Test

Figure 1 shows the frequency of the Pablo exercises. This chart contains planned and patient-initiated additional Pablo exercises. In both patients, an increase in frequency is seen at the beginning, followed by a drop where it remained at a constant high frequency. For Pat1, a lower frequency can be seen in the first week of the field test.

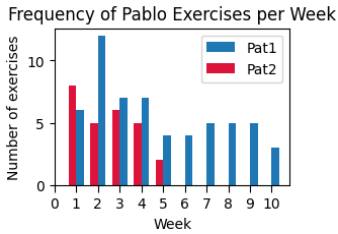

Figure 1. Pablo exercises per week

Table 1. Overview of force measurements Pat1 and Pat2

Patient	Number of Measure-ments	Mean force [kg]	Mean of SD	Meas2 >Meas1 [%]	Meas3> Meas2 [%]	Meas2>Meas1 &Meas2>Meas3 [%]	Time [weeks]
Pat1	58	22,48	2,31	84,5	63,8	31,0	10
Pat2	26	31,94	2,35	84,6	42,3	50,0	5

In **Table 1** the force measurement data of Pat1 and Pat2 is presented. Pat1 trained for 10 weeks and performed 58 Pablo exercises, Pat2 trained for 5 weeks and performed 26 Pablo exercises. The average force over all the exercises was 22,48kg for Pat1 and 31,94kg for Pat2. Across the three measurements (Meas1-Meas3), the mean of standard deviation was 2,31 for Pat1 and 2,35 for Pat2. In the three measurements, both patients showed higher force in Meas2 compared to Meas1 in 84% of cases. For Pat1, Meas3 was larger than Meas2 in 63,8% of the cases, but this occurred for Pat2 only in 42,3% of cases. Meas2 was larger than the two other measurements in 31% of cases for Pat1 and in 50% of cases for Pat2.

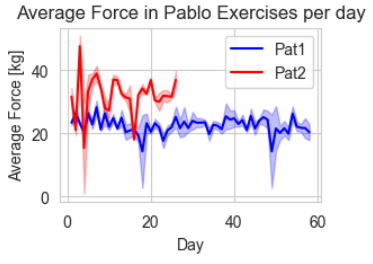

Figure 2. Average force in Pablo Exercises

Figure 2 displays the average forces which were assessed in the force measurements. Pat1 had two outliers in the lower force range. Pat2 shows three outliers, one outlier in the upper force range and two outliers in the lower force range. The outliers in the lower force can be traced back to very low force in the first measurements. In both patients, a constant force curve is evident over the field test period.

3.3. Questionnaires patients

Pat1 stated that the combination of tele-rehabilitation and integration of the Pablo significantly increased the motivation for exercising. Through the collected metrics via the Pablo, the patient was able to control the rehabilitation process better and had the chance to make the progress visible. The easy handling of the Pablo and the interaction with the serious game were also mentioned. REHA2030 offered the patient a good additional support and motivation to the standard attendance therapy and therefore increased the exercise intensity and duration. Pat2 stated, that additionally to the exercise programs in the system, he mainly exercised with the Pablo. By using the system with the Pablo, the exercise time was extended by about one hour per day, therefore the motivation to practice was significantly increased. By combining the therapeutic exercises, the Pablo exercises and the control through the activity monitoring by the patient and therapists, the patient would like to continue using the system.

3.4. Questionnaires therapists

Pat1 therapist stated that the combination of teletherapy and Pablo significantly increased the patient's motivation. It led to a doubling of the patient's training time and frequency compared to previous therapies. Activity monitoring made it easier to show progress in the therapy and by the combination of teletherapy, device integration and standard therapy, an improvement in sensor-motor function and hand strength could be achieved. The therapist saw potential by integrating further serious games to increase long time motivation. The Pablo should also collect movement data for the control of serious games and should be applied to orthopedic patients without cognitive impairments to achieve even more positive effects. Pat2 therapist stated, that the motivation to practice in the home setting has significantly improved and it was noted that long-term care, which is often necessary for neurological patients, could be facilitated. It was noticeable that the exercises with the Pablo were completed much more often in addition to the planned exercise program. Critically noted was that possible evasive movements, when using the Pablo unsupervised, cannot be controlled precisely. With regard to the Pablo, both therapists stated that the settings were easy and clear to make.

4. Discussion

With the REHA2030 system in combination with the Pablo, an increase in motivation, exercise- frequency and time in patients with stroke were indicated in the questionnaires. As displayed in Figure 1, the two patients who used the Pablo had a peak of the frequency in the beginning of the field test but remained at a constant high level after the middle of the test phase. The feedback from the therapists was positive, they even recommended further use and expansion with other patient groups. Therapists as well as patients emphasized the ease of use of the telerehabilitation system and Pablo. Still the results of

this paper are limited, as only two patients could be treated with the REHA2030 system including the Pablo over the time in the field test and the third patient had to be excluded due to the one-time use. Regarding the system processes, the Force ratio value of 50%, collected via the initial study was used by the therapists in the field test. But it is evident that therapists had made a few changes to the force ratio and the game levels. Therefore, it must be critically questioned whether the settings in the system were easy to use or whether the settings were needed by the therapists. All the therapists stated that the overall system was easy to use, only one therapist mentioned that the strength data in the activity monitoring is difficult for her to find. With the force values from **Table 1** it is questionable if the increase in force from the first to the second measurement was dependent on the system and its graphic announcement or on the habituation effect. The three outliers in the lower force range, which can be seen in **Figure 2** in the two patients, can be traced back to very low force values in the first force measurement. These outliers could speak for an application error as it only occurred in the first measurements. The outlier in Pat2 in the upper force range could not be clarified exactly retrospectively, as all three force measurements here are clearly above the remaining level. An increase in strength during the test period could not be shown, but this is not to be expected with neurological patients in such a short period of time. The handling of the Pablo by the patients and therapists worked well, there were no negative conspicuities in the questionnaire surveys, except for the comment of a therapist who was unable to view the complete activity data at the beginning. Further results with more participants over a longer period of time would be needed to validate the results.

Declarations

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Ethics: The project was approved by the Ethics Committee of Carinthia. EK number M2021-29, chair Dr. med. univ. Martin C. Spendel.

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