Application of arm support training in sub-acute stroke rehabilitation: first results on effectiveness and user experiences

GB (Gerdienke) Prange, PhD, AIR (Anke) Kottink, PhD, JH (Jaap) Buurke, PhD, PT, JS (Hans) Rietman, MD, PhD
Roessingh Research and Development
Enschede, the Netherlands
g.prange@rrd.nl

***Abstract*—A multi-center randomized clinical trial was performed in 7 Dutch rehabilitation centers, in the context of an implementation project (ROBAR), to compare the effect of an arm support (AS) training device to equally intensive conventional reach training (CON) on recovery of arm-hand function in sub-acute stroke. The Fugl-Meyer assessment (FM) and user experiences of therapists and patients were examined in both groups. An improvement of 10 and 8 points on the FM was found for respectively the CON and AS group. Both therapists and patients reported positive experiences on several aspects of user acceptance. These findings indicate that a low-tech system for arm support results in similar gains in arm function as conventional reach training in equal intensity, and is suitable for application in clinical practice.**

Keywords—arm support, gravity compensation, arm function, user experience, stroke, rehabilitation, upper extremity

I. INTRODUCTION

Almost half of all stroke patients have a limited arm function and only 5-20% of stroke survivors have functional use of the arm in daily life at 6 months post-stroke [1]. One of the mechanisms playing a role in the reduced coordination of arm/hand movements is the occurrence of involuntary, abnormal coupling between movements over multiple joints. This is translated to a limitation of elbow extension during reach, which affects the execution of activities of daily living to a large extent [2]. Optimal restoration of motor function is essential to maximize independence in daily life. It is known that active initiation and execution of arm movements in meaningful environments with a high intensity of practice are crucial elements for optimal motor relearning of the hemiparetic arm after stroke [3-5]. Currently, intensive arm therapy is mainly provided through (semi-) individual therapy (1 therapist for 1 or a few patients). Possibilities for further intensification of therapy are difficult because of a limited availability of therapists, due to graying of the population [6]. To enable such intensive treatment, the application of robotic systems in rehabilitation is promising.

Several systematic literature reviews have shown that robot-aided therapy has a positive effect on arm function of stroke patients [7-9], applying a combination of several types of robotic support. One of the aspects that many robotic devices have in common, is that the arm is being supported during movement [10]. As previous research has shown that arm support positively influences work area and facilitates active movements of the hemiparetic arm [11, 12], this may provide a relatively simple application of rehabilitation technology that would be suitable for clinical practice. In chronic stroke patients, this instantaneous influence of arm support is translated to improved unsupported arm movements after a period of training with arm support, as shown in previous research by our and other groups [13-15] [16-18].

Although research so far indicates that for chronic stroke patients arm support training is promising for use in clinical practice, the crucial target population in rehabilitation is sub-acute stroke patients. Therefore, within the multi-center ROBAR project the effectiveness of arm support training is studied in sub-acute stroke patients in a clinical setting, in comparison with conventional training in equal intensity. To stimulate actual adoption of such technology in regular rehabilitation, one of the additional aims of the ROBAR project was enhancing use of arm support devices in clinical practice of participating rehabilitation centers through an implementation process. In this process, participating rehabilitation professionals were educated and instructed in how to work with the arm support device in practice, with specific attention to prerequisites for implementation on technical, clinical, organizational and cultural aspects. Therefore, user experiences of stroke patients and rehabilitation professionals in terms of user acceptance were evaluated in addition to clinical effectiveness.

II. METHODS

A. Participants

Across 7 Dutch rehabilitation centers (Roessingh Rehabilitation Center, Enschede; Groot Klimmendaal, Arnhem; Sint Maartenskliniek, Nijmegen; de Hoogstraat, Utrecht; UMCG/Beatrixoord, Haren; Reade, Amsterdam; Rijndam, Rotterdam), 70 sub-acute stroke patients were included in the study. All subjects had to suffer from a first ischemic or hemorrhagic stroke, between 2-12 weeks ago, had

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to be medically stable, have limited arm function ($2 \leq MRC \leq 4$ for shoulder and elbow), and without shoulder pain or co-morbidities. All participants provided written informed consent and the study was approved by the local medical-ethical committee.

B. Study design

The study was conducted as a multi-center randomized controlled trial (RCT). All participants received 6 weeks of reach training, block randomized per 2 subjects over two groups; intensive conventional reach training (CON) or arm support training (AS). Assessments were performed before and after training by testers blinded for treatment allocation and each subject was tested on both occasions by the same person. In both groups, three regular 30-minute physical/occupational therapy sessions, that are part of the usual rehabilitation program, were replaced by either AS or CON training programs each week to achieve equal training intensity.

1) Arm support training

Arm support training was supervised by experienced physical or occupational therapists, instructed in the use and application of the device for arm support. The arm support device (ArmeoBoom; Hocoma, Switzerland) has an overhead sling suspension system with low inertia to provide an adjustable amount of arm weight support at the wrist and elbow (Fig. 1). This device is based on the previously developed Freebal device [19], which has an ideal spring mechanism to counteract the forces of gravity acting on the arm at the elbow and wrist. In the ArmeoBoom device, the arm support is combined with a laptop on which interactive rehabilitation exercises (games) are played by moving the affected arm (using an integrated webcam and potentiometer). The exercises were structured according to a categorization of the games for increasing difficulty, to maintain challenge throughout training. In addition, at the start of each session the workspace within the game environments were scaled to the maximal active workspace of the patient. The amount of arm support was reduced by one level on the integrated scaling system when a subject had improved elbow extension with the previous support level by about 60 degrees, as judged by the therapists following a standardized protocol defined a-priori in consensus with experienced therapists.

2) Conventional reach training

Conventional reach training was supervised by experienced physical or occupational therapists instructed in the application of a structured program of conventional upper extremity exercises. A standardized set of exercises was developed, based on usual conventional arm therapy applied in the local rehabilitation centers, in consensus with therapists, before the start of the study. In general, all exercises required reaching for targets, positioned on a table top or using specific equipment (bow, pegs in holes, placing disks, etc.; Fig. 2). In a similar way as for the AS group, the conventional exercises were categorized with increasing difficulty.

C. Outcome measures

Evaluation assessments took place 1 week before (T1) and after (T2) 6 weeks of training. The upper extremity motor section of the Fugl-Meyer assessment (FM; max. 66 points) was used to measure changes in arm/hand function [20]. For standardization across rehabilitation centers and testers, a uniform scoring approach was followed according to Deakin et al. [21].

User experience of both physical and occupational therapists that have worked with the ArmeoBoom was assessed at T2 in terms of user acceptance using a custom written questionnaire, based on the Unified Theory of Acceptance and Use of Technology (UTAUT) framework [22]. The questionnaire consisted of statements on the following domains: preferences, usability, expectations of use, attitude towards technology, social norms, perceived effectiveness, satisfaction, cultural context. Each statement had to be rated on a 7-point Likert scale (1 – strongly disagree; 4 – neutral; 7 – strongly agree), to reflect personal experience of working with the ArmeoBoom. The resulting score indicates either negative (<4) or positive (>4) experience, while 4 denotes neutral. In addition, stroke patients who participated in either AS or CON groups rated their overall experience with the training they had received on a scale of 1 to 10, at T2. Furthermore, they were asked to rate ease of use of the exercises and preference for continued use of the training type on a 7-point Likert scale, with the same scoring indication as for therapists mentioned above. Scores on all questionnaires were averaged per domain per participant.

Fig. 1. Arm support device

Fig. 2. Example of a conventional arm exercise

D. Statistical analysis

Individual scores were averaged across subjects (per group). Repeated measures ANOVA was used for FM to determine the effect of AS on the recovery of arm-hand function when compared with intensive conventional reach training. Group (between-subjects), Time (within-subjects) and Group x Time (interaction) were entered as factors in the model. The significance level α was set at 0.05 and the statistical analysis was performed with SPSS 18 for Windows.

III. Results

A. Participants

In total, 68 subjects completed the study protocol and evaluations, of which 33 in the CON group and 35 in the AS group (see Table 1 for characteristics).

TABLE I. PATIENT CHARACTERISTICS

	CON group	**AS group**
Subjects, *n* (drop outs)	33(0)	35(2)
Age, *years* (mean (sd))	58(11.4)	60.3(9.7)
Affected side, *n* (R/L)	16/17	25/10
Stroke type, *n* (ischemic/hemorrhagic)	25/8	28/7
Time after stroke, *years* (mean (sd))	6.8(3.1)	7.3(3.4)

B. Arm/hand function

The CON and AS groups improved respectively 10 (from 27 to 37) and 8 (from 22 to 30) points on the FM assessment (Fig. 3), which was significant in both groups (p=0.04). The improvement in the AS group was not different from the CON group (p=0.85).

C. User experience

The UTAUT questionnaire was completed by 20 therapists who had experience with treating patients using the ArmeoBoom. On each domain the mean score was above 4 points (Fig. 4), indicating positive ratings in terms of user acceptance. They could operate the device well, even though some technical issues had to be resolved (usability, perceived effectiveness), had a positive attitude towards this type of technology along with their colleagues and supervisors (social norm), and appreciated the possibilities for treatment and its relevance for continuing application in stroke rehabilitation (expected value, preferences, satisfaction). Specifically, they valued the new and additional treatment options especially for more severely affected stroke patients.

In terms of user experience by stroke patients, both groups (n=28 in CON; n=32 in AS) rated the training they received to be quite high (on a scale from 1 to 10), with 7.9 (± 1.5) in the CON group and 7.8 (± 1.4) in the AS group. Furthermore, both groups perceived the training to be quite easy to do and expressed their preference to continue their type of training during the remainder of their rehabilitation process, as scores were around 5 up to 6 on the 7-point Likert scale (Fig. 5). These subjective ratings didn't show marked differences between CON and AS groups.

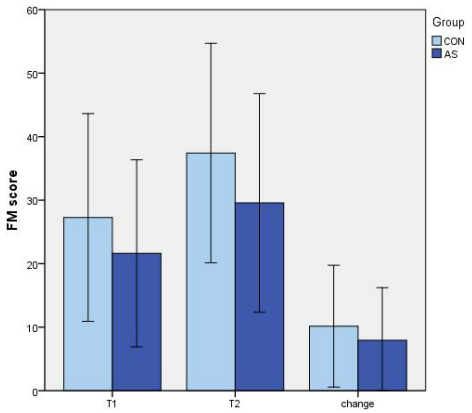

Fig. 3. Mean (sd) Fugl-Meyer scores (±sd) before (T1), after (T2) and change during training per group

IV. Discussion

The ROBAR project aimed, on one hand, to enhance the use of arm support devices in clinical practice of participating rehabilitation centers through an implementation process. In this process, 2-4 rehabilitation professionals per center were taught how to work with the arm support device (teach-the-teacher) and supervised in how to organize practical issues to allow application in clinical practice for the specific situation in their center. This resulted in the arm support device being embedded within regular care pathways of all 7 rehabilitation centers, and continued use of the device in clinical practice (even up to the present time, 1 year after the end of the project). All 20 involved therapists reported positive experiences in terms of user acceptance, indicating that they highly appreciated the arm support device in terms of operating the device and applying arm support to treat hemiparetic arm function. Especially the new and additional treatment options for more severely affected stroke patients with arm support were highly valued by therapists. Stroke patients in both groups expressed a positive experience during training, with AS training being valued equally high as CON training.

During this implementation process, several practical issues had to be resolved before such rehabilitation technology could be successfully embedded in clinical practice. This resulted in several recommendations, briefly highlighted below in order to add to the general understanding of issues associated with applying technology in clinical practice. On executing level recommendations predominantly regard the choice of location (in an easily accessible but lockable room, coherent with existing workflow), and the possibility to replace existing regular treatment sessions (more independent training by patients, relieving the pressure on therapist availability). Strategic and management recommendations concern mainly nurturing a positive attitude towards technology within the entire organization (through timely communication between all parties involved, including managers, clinicians and supporting departments), and identifying potential financial and organizational benefits (in terms of more efficient planning of personnel, enabling more treatment time per patient and strategic profiling of the center).

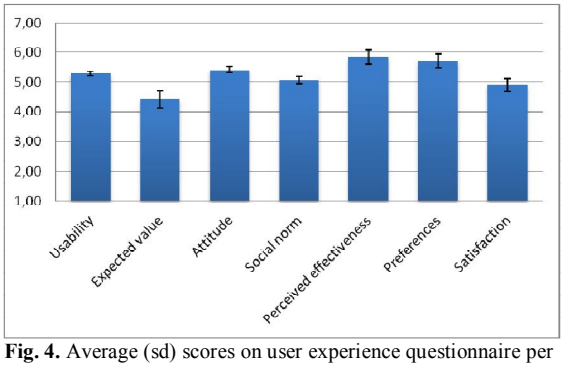

Fig. 4. Average (sd) scores on user experience questionnaire per domain by 20 therapists

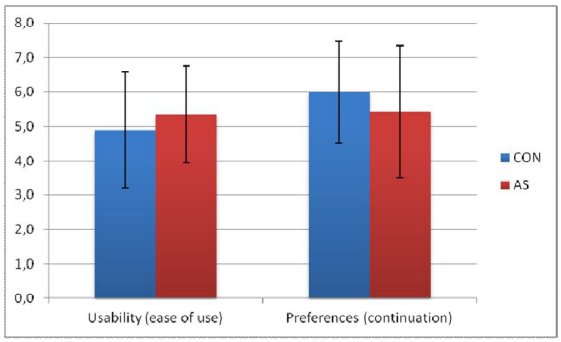

Fig. 5. Average (sd) scores on user experience questionnaire by stroke patients

After successful implementation in clinical practice, the effect of arm support training was compared to conventional training in a RCT design involving 68 sub-acute stroke patients across 7 rehabilitation centers. This RCT showed that FM score had improved significantly by 8 to 10 points after training in both groups, which did not differ between the two groups. As training intensity is a key determinant of improvement of arm function after stroke in itself [23], comparison of equal intensity interventions is essential to assess the actual effect of arm support training. To enable CON training in equal intensity as the AS group, the CON group received a standardized exercise program, which was more intensive then usual rehabilitation, in terms of more time dedicated specifically to arm training. In this light, the present findings indicate that gains in arm/hand function after training with arm support are at least as large as after conventional training. Subsequently, transfer of these gains to the activity level is being investigated.

When comparing arm support with conventional exercises in chronic stroke, improvements in FM score after training were comparable between both groups [17], in line with the findings of the present study in sub-acute stroke. Remarkably, improvements in arm function after arm support training were even similar to those after robot-aided therapy in another study involving chronic stroke patients [16]. Although Lo et al. found that improvements in arm function after robot-aided therapy in chronic stroke patients were larger than conventional therapy as provided in a regular clinical setting (comparing a higher training intensity with a lower training intensity), results after robot-aided training were comparable to conventional therapy when provided in equal intensity [24]. Abovementioned findings underline high(er) intensity of training as one of the key aspects for improvement of arm function [23]. Moreover, it emphasizes that rehabilitation technology would be a suitable tool to achieve this high(er) training intensity. Besides total training duration, training intensity can also reflect number of movement repetitions or effort during movement, which may also be influenced positively using such tools. Future studies should therefore include other aspects of training intensity in order to specify an optimal schedule of providing arm support training after stroke.

Although the specific effect of arm support hasn't been investigated up to now in the sub-acute stroke population, as far as we could discern, robot-aided therapy has been applied in the early phase after stroke, and has shown positive effects [7-9]. The amount of improvement in arm function (as measured by FM) in the present study was similar to recent RCT's on robot-aided therapy involving sub-acute stroke with 8 [25] and 7 points [26] increase. Remarkably, the arm support group in the present study received considerably less hours of treatment (9 hours) than provided in the robot-aided therapy studies with 15 [26] to 20 hours [25]. When comparing the relatively low-cost option of arm support versus more expensive and complex rehabilitation robots in the context of literature reporting similar gains after robot-aided therapy as after arm support therapy [16], arm support seems to be a highly promising tool to enable intensive hemiparetic arm training, in a way that is suitable for actual application in clinical practice.

The present RCT showed that improvements in arm/hand function of sub-acute stroke patients after arm support training using a low-tech, relatively simple device matched the gains after conventional therapy in equal intensity. Nevertheless, some aspects from this multi-centre RCT require that findings have to be interpreted with care. Potential differences in training or evaluation between centers can't be excluded, even though standardization was addressed at instruction meetings and by following specific written guidelines and procedures for training and assessment distributed to all centers. In addition, although a single-blinded design was used (e.g., the testers were not involved in training), it can't be avoided that colleagues talked amongst each other (although advised against it), or that other arrangements had to be made in case of unforeseen absence of a therapist (either trainer or tester). Besides this, the patients were aware of the type of treatment they had been receiving.

V. Conclusion

Training with a low-tech system for arm support during sub-acute stroke rehabilitation resulted in similar improvements in arm/hand function as equally intensive conventional arm training. This application enables active, high intensity, task-oriented training by sub-acute stroke patients in a motivating environment. Moreover, independent training, without one-to-one supervision by a therapist, may relieve some of the strain on healthcare.

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