

The Effect of an Arm Support Device on Recovery of Arm-Hand Function in Sub-acute Stroke: A Randomized Controlled Trial*

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Abstract. A multi-center randomized clinical trial was performed in 7 Dutch rehabilitation centers to compare the effect of an arm support (AS) training device in combination with interactive rehabilitation games to intensive conventional reach training (CON) on recovery of arm-hand function by the Fugl-Meyer assessment (FM). An improvement of 10 and 8 points on the FM was found for respectively the CON and AS group. These preliminary results indicate that a low-tech system for arm support in rehabilitation is equally effective as intensive conventional reach training.

1 Introduction

After a stroke, many patients suffer from impaired motor function of the arm [1]. Optimal recovery of arm function is important for stroke patients to perform independent activities of daily life. From literature is known that intensive and task-specific training is important to stimulate optimal recovery of arm function [2]-[4]. To establish this aim, the application of robotic systems in rehabilitation may be promising. More specifically, previous research by our group showed that active movements are facilitated by the use of arm support [5], [6]. One of the biggest advantages of a gravity compensation device is the possibility for patients to train more independently, allowing one therapist to treat multiple patients simultaneously. This may aid in increasing productivity of healthcare and reducing associated costs.

In recent years, collaboration between RRD, the University of Twente and BAAT Medical resulted in the development of a device (the Freebal) which can

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support the arm in a smart way [7]. In the commercialized version (ArmeoBoom, Hocoma, Switzerland) arm support is combined with rehab games (Fig. 1). By adding augmented feedback through these specially designed interactive games, recovery of arm function can be further enhanced. This will result in higher motivated patients with higher attention, which could promote motor relearning [8].

The ArmeoBoom was implemented in 7 rehabilitation centers throughout the Netherlands (Roessingh Rehabilitation Center, Enschede; Groot Klimmendaal, Arnhem; Sint Maartenskliniek, Nijmegen; de Hoogstraat, Utrecht; UMCG/Beatrixoord, Haren; Reade, Amsterdam; Rijndam, Rotterdam). The aim of the present study was to examine the effect of AB training compared to intensive conventional reach training on recovery of arm-hand function.



Fig. 1 ArmeoBoom device

When training using such a device shows at least similar improvements as conventional arm training, opportunities arise to lower the burden on therapists and to improve the quality of physical therapy after stroke (intensify treatment).

2 Methods

2.1 Participants

Across 7 Dutch rehabilitation centers, 70 sub-acute stroke participants were included in the study (10 participants by each center). Participants had to fulfill the following criteria for inclusion: between 2-12 weeks post-stroke, limited arm function with no pain symptoms or other limitations of the arm that are not related to their stroke. All participants provided written informed consent and the study was approved by the local medical-ethical committee.

2.2 Study Design

The study was conducted as a multi-center randomized controlled trial (RCT). All participants received 6 weeks of reach training, randomized 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.

In both groups, three regular arm therapy sessions, as part of regular rehabilitation, of 30 minutes per week (physical and/or occupational therapy sessions) were replaced by either AS or CON training to achieve equal training intensity. The AS training consisted of reaching exercises displayed on a computer screen, while the arm was being supported by the ArmeoBoom device. CON training consisted of a rather intensive, standardized program of reaching exercises commonly applied in physical and occupational therapy.

2.3 Outcome Measure

The upper extremity motor section of the Fugl-Meyer assessment (FM) was used to measure changes in arm-hand function before and after training (max. 66 points).

2.4 Statistical Analysis

Repeated measures ANOVA was used to determine the effect of AS on the recovery of arm-hand function when compared with intensive conventional reach training. Group, time and the interaction between group and time were entered as terms in the model. The significance level α was set at 0.05 and the statistical analysis was performed with SPSS 18 for Windows.

3 Results

3.1 Participants

Of the 70 sub-acute stroke patients, 68 completed the entire study protocol. Table 1 shows the characteristics of the participants.

Table 1 Participants characteristics

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

3.2 Arm-Hand Function

CON and AS groups improved respectively 10 (from 27 to 37) and 8 (from 22 to 30) points on the FM assessment (Fig. 2). Over time, a significant difference was found in arm- and hand function within both groups ($p=0.04$). However, no significant difference was found between both groups ($p=0.85$).

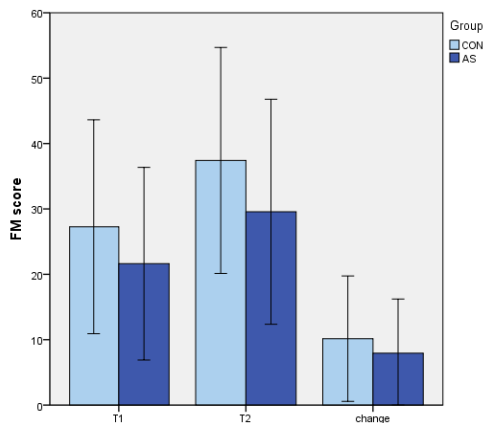


Fig. 2 Mean Fugl-Meyer scores (\pm SD) before (T1) and after (T2) training per group, including averaged change scores per patient

4 Discussion

This RCT showed no significant difference in outcome of the FM between both groups over time, which indicates that gains in arm-hand function after training with a low-tech system for arm support in rehabilitation are at least as large as after a rather intensive program of conventional arm exercises.

In terms of robot-aided training, Lo et al. found that improvements were larger than conventional therapy as provided in a regular clinical setting, which was less intensive than robot-aided training [9]. However, results after robot-aided training were comparable to conventional therapy when provided in equal intensity. This is in line with the findings of the present study, indicating that predominantly the opportunity to provide high intensity training is one of the key values of such rehabilitation technology.

With the graying of the population, it is expected that the prevalence of stroke survivors will increase rapidly, while the amount of therapists will decrease. These demographic changes will cause a substantial increase in pressure on the healthcare systems. The use of biomechanical technology like robotics in clinical practice could be to some extent a solution for this problem.

5 Conclusion

Training with a low-tech system for arm support during sub-acute stroke rehabilitation resulted in similar improvements in arm-hand function as intensive conventional arm training. This application enables active, high intensity, task-oriented training by sub-acute stroke survivors 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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