Active and Repetitive Robot Assisted Training Improves the Functional Recovery of the Arm in Sub-Acute Stroke Patients: A single-blinded, randomized and controlled study

Samuel Faran, Stefanie van Kaick, Christel Eichert, Karl-Heinz Mauritz

1. Institute for Medical Psychology and Behavioral Neurobiology, University of Tübingen, Tübingen, Germany 2. Motricity Medical Ltd., Caesarea, Israel 3. Charité - Berlin University Medical School, Department of Neurological Rehabilitation, Clinic Berlin, Berlin, Germany

Background and Objective

Loss of arm functionality is one of the most devastating consequences of a stroke as it can lead to severe limb disability.

The purpose of this study was to test the hypothesis that repetitive robot-assisted unilateral movement training can significantly improve upper limb motor function in sub-acute stroke patients.

Methods

Design

A single-blinded, controlled and randomized study design was used. Patients who met the inclusion and exclusion criteria participated in the trial during their sub-acute stage. Clinical evaluations were performed by an independent assessor who was blind to the patient’s group allocations and from the patient treatment (SWK). Scoring and preliminary data analysis of all patients and assessments occurred only at the end of the study.

Subjects

Twenty (20) sub-acute stroke patients with a 1st ischemic stroke onset between 3 weeks and 3 months prior to the treatment finished the study. All the patients had upper limb muscle strength grades between 2 and 3 on the Medical Research Council (MRC) motor power scale. Both groups were comparable in age, sex and in average number of days between the stroke and trial entry.

Interventions

In addition to daily physiotherapy and occupational therapy sessions, each patient received 20 one hour sessions of upper extremity treatment with either the Reo Therapy System or air splint therapy for a period of 4 weeks. During the Reo sessions, patients were instructed to perform goal-directed “reach” movements to basic targets on a computer screen (Reo 3D, Motricity Medical (Israel) Ltd). During the treatment the patients were instructed to either actively reach pre-defined reach points, or be guided while the robotic arm led their arm towards the reach points (see Fig. 1). Participants in the splint group were customized splints for one hour daily during the 4-week intervention period, and were asked to sit quietly for 60 minutes.

Main Outcome Measures

The blindly assessed Fugl-Meyer (FM) test, the Motor status score and the Action Research Arm Test (ARAT), were performed at baseline, at the end of the treatment, and at follow-up 3 months later.

Results

The Fugl-Meyer Test

All patients improved during the treatment period. However, the Reo group showed greater improvements before and after therapy compared to the control group. The control group improved from mean = 30.7 to mean = 40.3 (p = 0.002 sig), whereas the Reo group improved from mean = 34.9 to mean = 68.1 (p = 0.001 sig). The Reo group showed greater improvement after treatment (from mean = 18.7 to mean = 34, p = 0.038 sig), in comparison with the control group (from mean = 16.1 to mean = 24, p = 0.017 sig). The results imply a difference of 7.8 points and 14.3 points in favor of the Reo group.

Repeated measures model with Motor Power Score (MPS) at baseline

The repeated measures model included the MPS (Motor Power Score) at baseline and ran for each assessment ARAT and FM. A significant interaction existed between the baseline MPS and the treatment group. Improvement resulting from the Reo therapy was considerably higher for patients entering the therapy with higher motor power (for Fugl-Meyer F = 5.579, p = 0.039, for ARAT F = 4.872, p = 0.05).

Conclusions

The results of the study indicate that motor recovery of the upper limb in hemiplegic stroke patients can be significantly improved through additional sensor-motor training in the sub-acute phase. The scores of the Fugl-Meyer in the Reo group improved by 82.2%, a difference that can be considered to be clinically relevant. The results of the ARAT indicate that the positive effect of the Reo treatment on the impairment level was generalized to the level of functional disability. Whereas the Reo group improved by 14.3 points (+25%), the splint group improved by 7.9 points (13.8%). Although the Reo intervention consists of repeated muscle training of shoulder and arm, the improved motor activity probably provides a necessary basis for training of finer motor activities as grip and grasp. These results also show that patients who entered the study with higher MPS scores in baseline benefitted significantly more from Reo treatment than patients with high scores in the control treatment. The results presented here are based on small number of patients (20). This study serves as an initial indication prior to the next stage, which should aim to further establish the clinical magnitude of Reo therapy in a larger population of sub-acute stroke patients.