THREE-DIMENSIONAL, TASK-SPECIFIC ROBOT THERAPY OF THE ARM AFTER STROKE: A MULTICENTRE, PARALLEL-GROUP RANDOMISED TRIAL.

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ABSTRACT

BACKGROUND: Arm hemiparesis secondary to stroke is common and disabling. We aimed to assess whether robotic training of an affected arm with ARMin—an exoskeleton robot that allows task-specific training in three dimensions—reduces motor impairment more effectively than does conventional therapy.

METHODS: In a prospective, multicentre, parallel-group randomised trial, we enrolled patients who had had motor impairment for more than 6 months and moderate-to-severe arm paresis after a cerebrovascular accident who met our eligibility criteria from four centres in Switzerland. Eligible patients were randomly assigned (1:1) to receive robotic or conventional therapy using a centre-stratified randomisation procedure. For both groups, therapy was given for at least 45 min three times a week for 8 weeks (total 24 sessions). The primary outcome was change in score on the arm (upper extremity) section of the Fugl-Meyer assessment (FMA-UE). Assessors tested patients immediately before therapy, after 4 weeks of therapy, at the end of therapy, and 16 weeks and 34 weeks after start of therapy. Assessors were masked to treatment allocation, but patients, therapists, and data analysts were unmasked. Analyses were by modified intention to treat. This study is registered with ClinicalTrials.gov, number NCT00719433.

FINDINGS: Between May 4, 2009, and Sept 3, 2012, 143 individuals were tested for eligibility, of whom 77 were eligible and agreed to participate. 38 patients assigned to robotic therapy and 35 assigned to conventional therapy were included in analyses. Patients assigned to robotic therapy had significantly greater improvements in motor function in the affected arm over the course of the study as measured by FMA-UE than did those assigned to conventional therapy (F=4.1, p=0.041; mean difference in score 0.78 points, 95% CI 0.03-1.53). No serious adverse events related to the study occurred.

INTERPRETATION: Neurorehabilitation therapy including task-oriented training with an exoskeleton robot can enhance improvement of motor function in a chronically impaired paretic arm after stroke more effectively than conventional therapy. However, the absolute difference between effects of robotic and conventional therapy in our study was small and of weak significance, which leaves the clinical relevance in question.

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