Critically Appraised Paper

Robot assisted upper limb therapy combined with upper limb rehabilitation was at least as effective on a range of outcomes, and cost less to deliver, as an equal dose of upper limb rehabilitation alone for people with stroke

Synopsis 1

Objective: Evaluate effectiveness of group based robot-assisted therapy (RAGT) with individual arm therapy (IT) for people with moderate to severely affected upper extremities following stroke.

Design: Single-blind randomised trial. PEDro scale: Criteria met for random allocation, allocation concealment, baseline comparability, blind assessors, adequate follow-up, intention to treat, reporting between-group comparisons, point estimates/variability.

Settings: Two in-patient stroke rehabilitation settings in Germany.

Participants: Adults with first-occasion stroke (supratentorial) < 8 weeks with non- or minimally functional upper extremity, in an in-patient programme ≥ 6 weeks. Fifty randomised, 23 analysed per group (reasons given); adequate power estimated at N = 40. RAGT n = 25, 13 male, mean age 71.4 years; IT n = 25, 15 male, mean age 69.7 years.

Interventions: Both groups participated in comprehensive rehabilitation programmes. In addition IT completed 2 × 30 minutes of individual arm therapy per workday for four weeks which included task-oriented motor re-learning provided by centre-based therapists. The RAGT group completed 30 minutes of individual arm therapy per day plus arm studio group therapy assisted by one supervised therapy assistant for 30 minutes per day. Bi-ManuTrack, Reha-Digit, Reha-Slide, and Reha-Slide duo provided passive mobilisation and repetitive training of isolated shoulder, elbow, wrist, and finger movements.

Outcome measures: Blinded assessment of Fugl-Meyer Assessment (FMA) upper extremity score (range 0–66; primary outcome) at baseline, post-intervention and three months. Secondary outcomes (un-blinded): Action Research Arm Test, Box and Blocks, Modified Ashworth Scale (MAS), Medical Research Council scale (muscle strength), and Barthel Index (activities of daily living). Costs per treatment were calculated.

Main findings: No significant between group differences for any measure at any time point. Within group differences demonstrated significant improvements at each time point on each measure except MAS. Clinically significant mean differences at four weeks on FMA: RAGT +11.1 (SD: 10.6); IT +14.6 (SD: 11.2); three months FMA: RAGT +16.8 (SD: 16.0); IT +20.6 (SD: 14.6). No major adverse events; fingertip blisters in two RAGT participants. 17/24 RAGT participants provided favourable feedback for use as adjunct to individual arm therapy. Costs per treatment session were 4.15 € RAGT and 10.00 € IT.

Authors’ conclusions: When combined with individual arm therapy, robot assisted group training or an equal dose of individual arm therapy alone were equally effective to improve upper extremity outcomes. Robot assisted therapy cost less to deliver.

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Synopsis 2

Objective: Evaluate outcomes of adults in the post-acute stroke phase participating in standard upper limb rehabilitation (SULR: 100%) compared with a group having partial substitution (35%) of Neuro-Rehabilitation-roBOT (NeReBot) within SULR.
**Design:** Dose-matched, assessor blinded, randomised trial. PEDro scale: Criteria met for random allocation, baseline comparability, blind assessors, adequate follow-up, intention to treat, and reporting between-group comparisons and point estimates/variability.

**Settings:** Stroke unit, Italy.

**Participants:** Adults following first unilateral stroke in the post-acute stage who were incapable of active upper limb movement against gravity or weak resistance. Thirty-four participants were randomised; 30 analysed (NeReBot: n = 14, mean age 65.6 years (SD: 9.2), 10 males; SULR: n = 16, mean age 66.8 years (SD: 7.9), 10 males).

**Interventions:** Both groups completed 5 weeks of intervention (120 minutes/day, five days per week: total 3000 minutes). SULR group spent 80 minutes/day completing conventional functional rehabilitation (Bobath, functional re-education, wrist/hand mobilisation) and 40 minutes/day active upper limb exercise. The NeReBot group completed 80 minutes/day conventional rehabilitation and 40 (2 × 20) minutes/day of physiotherapy supervised NeReBot training to actively contribute to shoulder flexion, extension, adduction, abduction and circumduction exercises in sitting or supine.

**Outcome measures:** Blinded evaluators measured outcomes at baseline, post-intervention and three and seven months post-intervention. Primary outcomes: Fugl-Meyer Assessment (FMA), Functional Independence Measure and Frenchay Arm Test. Secondary measures: Medical Research Council Scale for Muscle Strength, Modified Ashworth Scale, Box and Blocks Test, tolerability and acceptability of NeReBot training.

**Main findings:** No significant between group differences existed for the primary or secondary outcome measures. Within group, statistically significant improvements existed in post-intervention and follow up for all measures, e.g. FMA increased baseline to three months: NeReBot median 36–64; SULR 25–57. NeReBot training was well accepted and tolerated.

**Authors’ conclusions:** Partial substitution of NeReBot training of the upper arm for adults in the post-acute stage following stroke was at least as effective as an equivalent dose of SULR. NeReBot is portable and, with one therapist simultaneously supervising multiple patients for NeReBot training, may be a cost effective means of delivering upper limb intervention.

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**Combined commentary**

Occupational therapists working with stroke survivors dedicate a large proportion of their time attempting to remediate upper limb impairments (Gustafsson, Nugent & Biros, 2012). Robotics have emerged as a treatment approach which may be used by therapists to augment usual care. The purported benefits of using robotics are that they provide the opportunity to perform intensive, repetitive arm movements and independent exercise (Mehrholz, Hadrich, Platz, Kugler & Pohl, 2012). Data from the National Stroke Foundation audit of rehabilitation services show that 9% of rehabilitation facilities in Australia have robotic equipment; all of these facilities were part of the public health system (National Stroke Foundation, 2012). The randomised controlled trials published by Hesse, Heß, Werner, Kabbert and Buschfort (2014) and Masiero, Armani, Ferlini, Rosati and Rossi (2014) provide useful new information regarding the efficacy, cost and clinical utility of robotics.

Both trials are of high methodological quality (PEDro criteria achieved: Masiero = 6; Hesse = 7). It should be noted that assessment of secondary outcomes in the trial conducted by Hesse et al. (2014) was conducted by an assessor who was not blind to group allocation. Participants in both studies were recruited in the subacute phase of rehabilitation whereas previous studies have tended to examine the efficacy of robotic use for stroke survivors more than six months after stroke. Hesse et al. recruited participants within eight weeks of stroke and Masiero et al. (2014) recruited within two weeks of stroke. Targeting intervention at this time may be most effective as evidence suggests there is enhanced potential for neuroplasticity in the first month following stroke (Murphy & Corbett, 2009).

The nature of robotic intervention was somewhat different between the studies. The NeReBot intervention studied by Masiero et al. (2014) provided assistance in performing unilateral movements of the shoulder and elbow. The ‘arm studio’ evaluated by Hesse et al. (2014) appeared to be more amenable to offering a program tailored to the needs of the individual. The studio comprised four types of robotic devices which had the capacity to deliver both unilateral and bilateral movements and target movements of the shoulder, elbow, wrist and fingers. Both studies applied the robotic intervention in combination with usual care.

The results of both studies suggested that there were no between-group differences following intervention. The authors, therefore, concluded that robotics can be used in addition to usual care as a resource-efficient way of providing therapy. Hesse et al. (2014) reported that the ‘arm studio’ was associated with an annual cost of AUS$17,000 per year. They calculated that a therapy session using the robotics was significantly less expensive than usual therapy session as the ‘arm studio’ was supervised by a therapy assistant and able to offer therapy to multiple patients at once. It is important to note that the ‘arm studio’ used at the study site serviced a median of 35 patients per day. Masiero et al. (2014) reported that the costs of robotic training could be compensated by the savings derived from three hours of therapy substitution with 1:3 supervision; precise costs were not reported in the paper. It seems that offering robotic therapy may only be cost effective when
there are a large number of patients within the rehabilitation service for whom robotic therapy is appropriate. Stroke survivors in the studies were excluded when they presented with spasticity or shoulder pain. Hesse et al. reported that of 399 patients screened, only 50 met their eligibility criteria and consented to participate in the study. Based on these figures, robotic therapy appears to be appropriate for approximately 12% of stroke survivors in rehabilitation settings.

Robotic therapy appeared to be well received by participants in the studies when provided as an adjunct to individual therapy. Hesse et al. (2014) reported that 17 of the 24 participants in the intervention group provided positive feedback. There were few drop-outs in the studies and study withdrawal appeared to be unrelated to the intervention. Approximately one-third of the intervention group reported that robotic therapy was uncomfortable, demanding and of little relevance to their rehabilitation goals (Hesse et al.). Therapists using robotics need to ensure that they clearly describe their role in relation to achieving their therapy goals.

In conclusion, these studies provide more robust evidence that robotic therapy appears to be a useful way of increasing therapy dose, encouraging large numbers of repetitions and enabling semi-independent practice. These factors have been found to be important in improving outcomes in people after stroke (Veerbeek et al., 2014). Robotic therapy may be suitable for a relatively small number of stroke rehabilitation clients; those with moderate to severe motor impairments appear more likely to benefit as patients with milder impairments can be challenged with independent practice of more active and functional tasks. The upfront costs of robotics are prohibitive in many settings and may only be justified in larger settings where there are a large number of patients that may benefit and systems in place to ensure resource efficient use (such as therapy assistants and group-based treatment). Robotics will hopefully become more sophisticated and affordable in the future as they are one of the few therapy approaches appropriate for stroke survivors with moderate to severe upper limb impairments.

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References
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