Official Title: A Randomized Control Trial to Compare the Effects Between Wearable Robotic System and Robotic Mirror Therapy in Patients With Spastic Hemiplegia Post Botulinum Toxin Injection: Neurophysiological and Behavior Outcomes.

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Background:

Botulinum toxin type A (BoNT-A) injection is an effective treatment for upper-limb spasticity, but lacks in effects on arm-hand capacity. Adding a rehabilitation program after BoNT-A injection was suggested as a way to optimize spasticity treatment outcomes. However, the optimal adjunct treatment, especially for hand function, remains to be established.

Aims:

This randomized single-blind pilot study aimed to investigate and compare the effects between Exoskeletal Robotic Hands therapy (RT) vs Exoskeletal Robotic Hands Training Integrating with Mirror Therapy (RMT) after Botulinum Toxin A Injection for Post-stroke Spastic Fingers.

Participants

Participants with stroke were recruited from a rehabilitation department of a tertiary referral hospital. Patients who had spastic finger flexors, at least 1+ with the Modified Ashworth Scale (MAS) (R. W. Bohannon & M. B. Smith, 1987), interfering with hand function, and needed BoNT- A injections, were screened for eligibility to join the study. The inclusion criteria were: (1) clinical and imagine diagnosis of a first or recurrent unilateral stroke ≥ 6 months; (2) the MAS of finger flexors ≥ 1+; (3) initial motor part of UE of FMA score ranging from 10 to 55, indicating moderate to severe movement impairment; (4) Mini Mental State Exam score ≥ 20; (5) age ≥ 18 years ; and (6) could provide written informed consent. The exclusion criteria were (1) bilateral hemispheric or cerebellar lesions; (2) fingers had fixed contracture; (3) severe aphasia or cognition impairment; (4) significant visual field deficits or hemineglect; (5) treatment with BoNT-A ≤4 months before recruitment or (6) history of orthopedic or other neurologic diseases or medical conditions that would prevent adherence to the rehabilitation protocol.

Methods:

A randomization scheme was used to randomize participants. To minimize possible confounding effects of upper limb motor ability, we stratified participants into groups based on upper limb motor function (FMA UE score: 10-35 or a FMA UE score: 35-55) (Pamela W Duncan, Larry B Goldstein, David Matchar, George W Divine, & John Feussner, 1992) A person who did not involve the other study procedures did the randomization to decide new participants' group allocation when they enrolled, and inform the trainer to conduct their intervention. After BoNT-A injection patients were randomly allocated to 2 groups: RT group, and RMT group,

both groups underwent 24 training sessions (60 minutes /session, 3 sessions/week for 8 consecutive weeks). Assessments were performed before training (T0), after training (T1), and 3 months after training (T2). The primary outcomes were changes in the FMA–Upper Extremity score (FMA–UE, total and distal scores) at T1 from T0. The other measures, including Modified Ashworth Scale (MAS), and Medical Research Council scale (MRC), Action Research Arm test (ARAT), Box and block test (BBT) and Motor Activity Log (MAL) at T1 and all measures at T2 were secondary outcomes.

Data Analysis

The Mann–Whitney U test was used to analyze differences between groups. Wilcoxon's signed-rank test was performed to assess differences in the parameters between baseline and post-training points. All tests were executed using the SPSS software version 25 (International Business Machines Corp., Armonk, NY) at the $\alpha = 0.05$ level of significance.