Condensed and Distributed Robotic Therapy in Spastic Stroke Post Botulinum Toxin Injection

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Spasticity, a common impairment after stroke, has a profound impact on activity and participation for patients. According to the result of our ongoing study, we found Botulinum Toxin A (BoNT-A) injection combined with robot-assisted training is recommended to enhance functional recovery for patients with spastic hemiplegic stroke. However, the optimal program as considering the Robotic Therapy (RT) frequency is unknown.

The aims of this study are to determine and compare the immediate and longer-term effects between condensed and distributed programs of RT following BoNT-A injection in subjects with spastic hemiplegic stroke.

Methods

Participants with stroke will be recruited from a rehabilitation department of tertiary referral hospital. Patients who have spastic hemiplegic stroke are screened for eligibility to join the study. The inclusion criteria will be: (1) clinical and imagine diagnosis of a first or recurrent unilateral stroke ≥ 3 months; (2) upper limb spasticity (modified Ashworth scale of ≥ 1+ for elbow flexor and/or forearm pronator and/or finger flexor muscles and/or wrist flexor muscles (Bohannon & Smith, 1987); (3) initial motor part of UE of FMA score ranging from 12 to 56, indicating moderate to severe movement impairment (Duncan, Goldstein, Matchar, Divine, & Feussner, 1992; Fugl Meyer, Jaasko, & Leyman, 1975; Park, Wolf, Blanton, Winstein, & Nichols-Larsen, 2008); (4) no serious cognitive impairment (i.e., Mini Mental State Exam score > 20) (Teng & Chui, 1987); (5) age ≥ 18 years ; and (6) willing to provide written informed consent. Participants will be excluded if they are pregnant, or with bilateral hemispheric or cerebellar lesions, sever aphasia, significant visual field deficits or hemineglect, contraindication for BoNT-A injection, treatment with BoNT-A within 4 months before recruitment, any fixed joint contracture of the affected upper limb, or a history of orthopedic or other neurological diseases and/or medical conditions that would prevent adherence to the rehabilitation protocol.

Participants with will be recruited and randomly assigned to either condensed or distributed RT groups post BoNT-A injection. Each training session included 40 minutes RT, followed by 40-minute functional training. The condensed group will receive 4 sessions per week, for 6 weeks, the distributed group 2 sessions per week, for 12 weeks. Body function and structures outcome measures include Fugl-Meyer Assessment, Modified Ashworth Scale, actigraphy. Activity and participation measures include Wolf Motor Function Test, Motor Activity Log, and Canadian Occupational Performance Measure. In addition, to directly reflect a patient's unique needs and goals, Goal Attainment Scaling will be assessed. Evaluators will be blind to group allocation. The outcome will be measured at pre-treatment, mid-treatment,

post-treatment, and 6-week follow-up.

Data Analysis

To examine the baseline differences among 2 groups, we use the chi-square test and independent-sample t tests to compare participants' baseline characteristics between groups. To examine the therapeutic effects of the RT, we use mixed ANOVA to test the differences within groups across 4 measurement time points (time effect) and to test the differences between groups (condensed intervention group and distributed intervention group) and to test interaction effect between time and group. Pairwise comparison with Bonferroni adjustments is used to examine the differences between measurement time points. All tests are executed using the SPSS software version 25 (International Business Machines Corp., Armonk, NY) at the $\alpha = .05$ level of significance.