Study Protocol

Fast Arm Motor Skill Training (FAST)

NCT05013762

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Protocol Synopsis

4.1. Brief Summary

The primary objective of this study is to determine whether fast arm movement training on a tracking task ("Speed-training"), in chronic stroke survivors with mild to moderate paresis, will generalize to improve arm function better than dose-equivalent accuracy training on the same task.

This will be measured through the primary outcomes of 1) movement time and 2) smoothness (defined as number of peaks in hand velocity profile) in a reaching task and secondary outcomes of 1) Arm Research Action Test and 2) Box and Block test.

The secondary objectives are: 1) To determine whether speed training induced improved feedforward control in a fast elbow task, as measured by improved acceleration scaling to movement amplitude and by improved anticipatory timing of pectoralis surface EMG activity and 2) To determine whether improvement due to training correlates with the integrity of the cortico-cerebellar networks.

4.2. Study Design

4.2.a. Narrative Study Description

Design and Outcomes
The main design of this study is a two-group parallel, randomized design with 2 interventions (speed and accuracy training), and 3 repeated testing sessions: A baseline pre-test, 1 post-test (3 days post-treatment), and 1 retention test (1 month post treatment). The therapists administering tests will be blinded to treatment.

Interventions and Duration
Two interventions will be compared: Speed and accuracy training with a tracking task. The 4 training sessions will be approximately 2 hour long. Training on the tracking task will consist of 300 trials per session, given in 6 blocks of 50 trials each. Blocks will be separated by rest periods of at least 5 minutes.

Participants in both conditions will receive training on a complex tracking task, which we previously tested for individuals with mild to moderate impairments post-stroke. The task will be identical for both group except for the instructions and the computations of reward feedback.

Sample Size and Population
The participant group will be 48 severely paretic chronic stroke patients, who do not experience severe activity limiting pain in their paretic shoulder. Patients will be randomized after screening and the first testing session to ensure inclusion criteria.

4.2.b. Primary Purpose: Treatment

4.2.c. Interventions

Type	Name	Description
Behavioral	Speed training	In the speed- training condition, participants will be instructed to move as fast as possible, while keeping their hand in the track. They will receive 1 of 5 possible reward points based on their movement time.
Behavioral	Accuracy training	In the Accuracy- training condition, participants will be instructed to be

		as accurate as possible, while keeping their hand in the middle of the track. They will receive 1 of 5 possible reward points based on their movement accuracy.

4.3 Outcome measures

Type	Name	Time Frame	Brief Description
Primary	Kinematic measures of movement time over workspace	A baseline pre-test, 1 post-test (3 days post-treatment), and 1 retention test (1 month post treatment).	Average movement time for 15 planar reaching movements to target arrayed on a planar workspace
Primary	Kinematic measures of movement smoothness	Same as above	Average movement smoothness for 15 planar reaching movements to target arrayed on a planar workspace. Smoothness is computed by number of peaks in hand tangential velocity profiles.
Primary	Kinematic measures of speed accuracy trade off	Same as above	We will compute the "Fitts" slope between "index of difficulty" of reaching movements and movement time, for targets at 3 distance and of 3 diameters.
Secondary	Arm Research Action Test (ARAT)	Same as above	The ARAT assess specific changes in limb function among individuals who sustained a stroke. It assesses the ability to handle objects differing in size, weight and shape.
Secondary	Box and Block Test	Same as above	The Box and Block Test (BBT) measures unilateral gross manual dexterity. It is a quick, simple and inexpensive test and is commonly used in stroke.