Passive Tactile Stimulation for Stroke Rehabilitation

NCT number: NCT03814889

Unique Protocol ID: 49330

8/26/2022

Protocol

PHASE 1, PHASE 2, and PHASE 3 are pilot studies not included in the clinical trial.

Acute Testing (PHASE 2b): All participants try on several wearable prototypes in our laboratory that provide vibration to the arm. Sensors or electrodes taped onto the arm and hand will sense muscle activity and record any changes during periods of vibration and periods with vibration turned off.

Longitudinal Testing (PHASE 4): This study takes 3 or 6 months. 1) If the patient gets Botox injections in their hand and arm, their arm function will be measured for three months during this standard care. 2) Next, all patients will be given a wearable device to take home. The patient will wear the device while feeling vibrations for 3 hours during the day while awake for two months. During this time and 1 month after this intervention, arm function will be tested.

Statistical Analysis

Wilcoxon Signed-Rank tests were performed for paired comparison on ordinal data (Modified Ashworth) and paired t-tests were performed on paired continuous variables (Active Range of Motion). Intervention adherence was analyzed by processing device logs using an algorithm.

Acute Stimulation: Our sample size calculations were based on a two-sided paired t-test, which should have adequate power for the Wilcoxon Signed Rank test. For pattern 1 stimulation, we expected the mean change on the Modified Ashworth scale to be -2.3 and the standard deviation to be 0.5. We found that we can achieve 80% power with 4 samples. For pattern 2 stimulation, we expected the change to be -1.1 and the standard deviation to be 0.6. We found that we can achieve 80% power with 6 samples. For pattern 3 stimulation, we expected the change to be -1.0 and the standard deviation to be 0.75. We found that we can achieve 80% power with 9 samples. We enrolled 5 additional participants to account for those who may become lost to follow-up, leading to the sample size of 14 participants.

Longitudinal Stimulation: We expect the average change to be -1.44 in Modified Ashworth scale ratings and the standard deviation to be 1.1 based on prior work [Seim, 2021]. We can achieve 80% power with 16 samples. We aimed to enroll 20 patients to account for drop outs during the study.