Study Protocol and Statistical Analysis Plan

for

FitMi Plus: Smart Functional Modules for Practicing Activities of Daily Living after Stroke

ClinicalTrials.gov Identifier: NCT03935425

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Background

Stroke is the leading cause of chronic disability in the United States, with over 700,000 people experiencing a new stroke each year. Other conditions that lead to chronic disability are spinal cord injury, hand and wrist trauma, multiple sclerosis, traumatic brain injury, muscular dystrophies, back injury, and cerebral palsy. In all these conditions the human motor system retains substantial capacity for plasticity, and thus intensive rehabilitation exercise can reduce long-term movement impairment. Unfortunately, access to intensive rehabilitation is limited due to cost and therapists' time constraints, preventing many individuals from receiving the amount of therapy required to maximize their potential recovery. There has been a recent surge in the development of technologies, services, and methodologies for enabling individuals to practice on their own at home. However, existing technologies for home therapy have not been widely adopted in actual practice. The most common approach to home-based therapy is simply providing patients with printed sheets of exercises. This approach is not motivating, does little to incorporate current theories on effective rehabilitation, and is associated with low compliance and high dropout rates.

Flint Rehab's existing FitMi system has demonstrated success in motivating individuals with stroke to perform moderately intense therapy with relevant feedback, individually tailored exercises, and an appropriate challenge level. However, FitMi does not encourage the functional practice of activities of daily living. Recognizing this, we developed an expanded version of FitMi called FitMi Plus that combines objects commonly used during activities of daily living into distinct Functional Modules, allowing users to practice specific functional tasks while engaging with a motivating software platform.

Trial Design

This study was a double-site, single-blind randomized controlled trial evaluating the efficacy of home-based functional training with FitMi Plus compared to non-functional exercise (FitMi Basic) with individuals with chronic stroke (N=50). This randomized controlled trial was carried out at two separate study sites: the University of California, Irvine, and Rancho Los Amigos National Rehabilitation Center in Downey, CA, with the specific objective of enrolling 25 participants at each study site by the end of the project period. Participants were invited for an initial assessment to confirm they met the inclusion criteria and to establish baseline measures. Participants provided informed written consent. Qualifying participants were randomly assigned to either the FitMi Plus group or non-functional exercise (FitMi Basic) group. Participants in both groups were instructed to perform self-guided therapy for at least 3 hours/week for three consecutive weeks. Appropriate exercise movements for each participant were selected in collaboration with each participant by a trained therapist.

After the three-week exercise period, participants returned for a post-therapy assessment. At this assessment, participants returned their devices. Participants also returned one month later for a one-month follow-up assessment. The trial was pre-registered on ClinicalTrials.gov (NCT03935425) and approved by the Rancho Research Institute, Inc. Institutional Review Board at Rancho Los Amigos National Rehabilitation Center and University of California, Irvine Institutional Review Board.

Participants

Inclusion criteria included experiencing one or more strokes >6 months prior, Upper Extremity Fugl-Meyer (FM) Score >=15 and <=55 out of 66, absence of moderate to severe upper extremity pain (<= 4 on the 10 point visual-analog pain scale), ability to understand the instructions to operate FitMi, and age <= 85 (as older age could be a confounding variable). Exclusion criteria included having other concurrent

severe medical problems, visual deficits, severe neglect or apraxia, or enrollment in other therapy studies. After obtaining consent, participants received a 30-minute training session on how to set up and use their device to perform a prescribed list of exercises. Recruitment aimed to balance the age, ethnicity, and gender of the study participants to be representative of Los Angeles and Orange County in California, USA. All participants provided informed consent.

Using an estimated effect size (Cohen's *d*) of 0.9 based on long-term follow-up data from a previous study (N=18) of functionally oriented home-based exercise with MusicGlove, 22 participants in each group would provide a 90% chance of detecting a significant difference between groups at the 0.05 significance level (one-tailed t-test). To account for 10% dropout, we will recruit 25 participants in each group.

Adaptive randomization was used to ensure matched levels of impairment between the FitMi Plus and FitMi Basic groups. Specifically, subjects were stratified by their UE FM Score into two levels (i.e. 15-35, 36-55) and then randomized by alternating block allocation.

Intervention

Participants randomized to the FitMi Plus group were given a FitMi Plus system with custom 10" touchscreen tablet. Participants randomized to the FitMi Basic group were given a FitMi Basic system with custom 10" touchscreen tablet. For both groups, a supervising rehabilitation therapist selected the exercises for each participant based on their specific impairments and functional goals. All participants received 30 minutes of training from the therapist on how to perform the selected exercises correctly.

Participants in both groups were instructed to perform self-guided therapy for at least 3 hours/week for three consecutive weeks. After the 3-week exercise period, participants returned for an end-of-therapy assessment. At this assessment, participants returned their FitMi Plus or FitMi Basic systems. Participants returned one month later for a follow-up assessment.

Outcomes

The primary outcome measure was the change in Motor Activity Log (MAL) score from baseline to one-month post-therapy to assess increases in self-reported functional use of the upper extremity. MAL was assessed at baseline and one-month follow-up. The secondary outcome measure was the change in Upper Extremity Fugl-Meyer (FM) Score from baseline to one-month post-therapy to assess changes in motor impairment. These measures are widely used in stroke rehabilitation research and have good sensitivity and reliability. All assessments were performed by a blinded, trained evaluator.

Statistical Methods

Statistical analyses were performed using Matlab R2020 software. Change in Motor Activity Log (MAL) from baseline assessment to one-month follow-up was compared between FitMi Plus group and FitMi Basic group using an unpaired two-tailed t-test. We recruited 50 total participants across both study sites. Two participant did not return for long term follow-up and were excluded from final analysis, leading to a final n=48 (13 female, 35 male), with 24 participants in the FitMi Plus group and 24 participants in the FitMi Basic group. Similarly, change in Upper Extremity Fugl-Meyer Score from baseline to one-month post-therapy was compared between groups using an unpaired two-tailed t-test.