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Study Title: Tracking Post-stroke Walking Improvements From the Clinic Into the Home

Document Type: Protocol / Statistical Analysis Plan

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Study Design: Prospective repeated-measures study with step symmetry training

Primary Outcomes: Step-length asymmetry, step-time asymmetry, gait speed

Population: Adults with chronic stroke; non-stroke comparison group (Aim 1 only)

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Study Protocol

Tracking Post-stroke Walking Improvements from the Clinic into the Home

Overview

This protocol describes a prospective repeated-measures study with two distinct study components. Aim 1 compares clinic-based walking capacity with home-based walking performance in two groups: adults with chronic stroke and neurologically intact adults. Aim 2 evaluates the transfer and durability of walking improvements after step symmetry training only in participants with chronic stroke.

Study Design

Aim 1 includes a two-group observational comparison using baseline clinic and home walking recordings. The two groups are adults with chronic stroke and neurologically intact adults. Aim 2 is an intervention follow-up component limited to participants with chronic stroke group, who complete a single step symmetry training session and repeated home recordings after training.

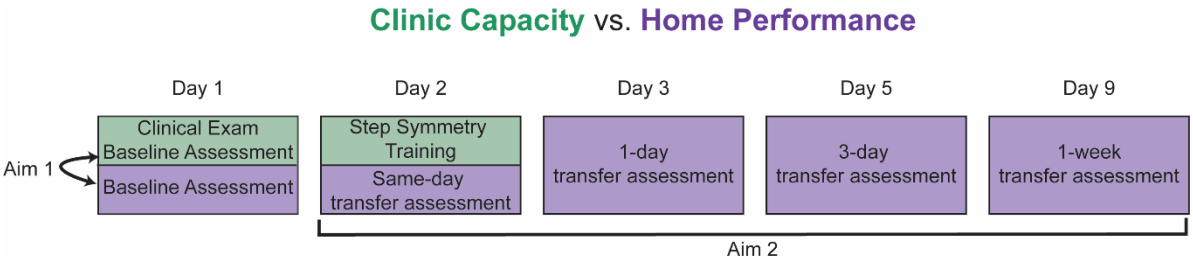


Figure 1 Study Design. Participants will engage in 5 total sessions. Assessment: bouts of video-recorded over ground walking; Step symmetry training: 30 minutes of split-belt treadmill training; Green blocks: portions of the experiment that take place in the clinic or laboratory; Purple blocks: portions of the experiment that take place in the home.

Participants

Group 1: adults with chronic stroke who are community dwelling, able to ambulate independently or with modified independence, and meet study eligibility criteria. Group 2: neurologically intact adults who are community dwelling, able to ambulate independently or with modified independence, and meet study eligibility criteria. Aim 2 includes only Group 1.

Procedures

Aim 1: both groups complete standardized clinical examination, clinic walking video recording, and home walking video recording. Aim 2: only the chronic stroke group completes step symmetry training (five 2-minute blocks of adaptation-based weighted limb training) followed by same-day and delayed home video recordings at the planned follow-up time points.

Video Recording: For assessments of walking capacity, we will record videos (~30 Hz) of frontal views of participants as they walk overground on a level tile surface in a well-lit and distraction-free clinical setting. For assessments of walking performance, participants or members of their household will use the same video-recording device sampling at 30 Hz to record the participant as they walk in their homes (also frontal view). For a given transfer recording, participants will perform a 2-minute walking trial at their preferred walking speeds.

Pose Estimation: We will use pose estimation workflows for human gait analysis using the freely available pose estimation algorithm OpenPose17. These workflows can provide accurate estimates of many spatiotemporal and kinematic gait parameters from both sagittal and frontal viewpoints and have been validated against ground-truth three-dimensional motion capture measurements for adults with and without stroke. These validation steps have also been performed for both overground and treadmill walking.

Outcomes

Primary outcomes for Aim 1 are step-length asymmetry, step-time asymmetry, and gait speed measured in clinic and home in both groups. Primary outcomes for Aim 2 are same-day transfer and persistence of step-length symmetry improvements in the chronic stroke group only.

Statistical Methods

Aim 1 analyses compare clinic and home gait metrics within each group and between groups using correlation and group-comparison methods as appropriate.

Aim 2 analyses are restricted to participants with chronic stroke and evaluate change across post-training time points relative to baseline and same-day transfer.

Statistical Analysis Plan

Tracking Post-stroke Walking Improvements From the Clinic Into the Home

Purpose

This SAP specifies analyses for two distinct components. Aim 1 compares clinic and home gait outcomes in adults with chronic stroke and neurologically intact adults. Aim 2 evaluates the effect of split-belt treadmill training only in the chronic stroke group.

Analysis Populations

Aim 1 population: all participants with baseline clinic and home data, analyzed separately for the chronic stroke group and the neurologically intact group, with between-group comparisons where planned. Aim 2 population: only participants with chronic stroke who complete training and at least one post-training home assessment.

Power Analysis

25 participants will be recruited for this study. This sample size was determined via a power analysis using data from previous work that had the same participant population and the same objectives of measuring changes in step length asymmetry. Using parameters alpha = 0.05, beta = 0.80, effect size = 0.67 for a two tailed t-test, it was determined that 20 participants are needed to detect a difference. We plan to recruit an additional 5 participants to account for attrition.

Data Processing

We have developed pose estimation workflows for human gait analysis using the freely available pose estimation algorithm OpenPose. These workflows can provide accurate estimates of many spatiotemporal and kinematic gait parameters from both sagittal and frontal viewpoints and have been validated against ground-truth three-dimensional motion capture measurements for adults with and without stroke. These validation steps have also been performed for both overground and treadmill walking. The video recordings and pose estimation workflows will be used to capture our three variables of interest.

Three different walking variables will be assessed during each bout of walking, for each participant. These include:

1) step length asymmetry: The normalized difference between short step length and long step length; a spatial parameter
   (short step length - long step length / short step length + long step length)
2) step time asymmetry: The difference between short step time and long step time; a temporal parameter
   (short step time- long step time)
3) gait speed: the speed at which a participant is walking (meters/second).

Primary Analyses

Aim 1 primary analyses assess associations between clinic and home values for step-length asymmetry, step-time asymmetry, and gait speed within each group, followed by within-setting and between-group comparisons.

Aim 2 analyses assess change from baseline through same-day, next-day, 3-day, and 1-week time points in the chronic stroke group only.

Statistical Methods

Correlation analyses are used for clinic-home relationships in each group. Paired or nonparametric within-person tests are used for clinic-home differences. Group comparisons use t tests or nonparametric alternatives depending on assumptions.

Aim 2 We will conduct a one-way repeated measures ANOVA with each variable of interest as the dependent variable and an independent variable of timepoint. This will allow us to detect changes across time. Post hoc tests (paired t-test with Bonferroni correction) will be conducted if indicated.

Missing Data

Missing data are handled within each aim separately. Participants missing a clinic or home value are excluded from the specific Aim 1 comparison requiring that value.

Aim 2 analyses use available repeated measures and maximum-likelihood estimation when mixed models are applied.

Interpretation

Aim 1 is intended to determine whether clinic measures of gait reflect home performance in both adults with stroke and neurologically intact adults.

Aim 2 is intended to determine whether a clinic-derived improvement in step symmetry transfers and persists in the chronic stroke group only.