Study Protocol and Statistical Analysis Plan

Study Title: Performing Dynamic Weight-Shifting Balance Exercises With a Smartphone-Based Wearable Telerehabilitation System for Individuals With Parkinson's Disease

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Objective

This study examines static/dynamic balance performance, daily activities, and confidence in less fear of falling for people with Parkinson's disease (PD) performing in-home balance exercises with a smartphone-based wearable telerehabilitation system (intervention group). Twenty-two subjects with idiopathic PD will be potentially recruited.

Study Design

The experimental design will include laboratory assessments (i.e., pre-assessment baseline at the beginning of week 1, post-assessment at the end of week 6, and retention-assessment 1 month after week 6) and in-home balance exercises. Participants will perform in-home balance exercises (3 days per week for 6 consecutive weeks) with the Smarter Balance System (SBS).

Laboratory assessments: Subjects will be quantitatively assessed for static/dynamic balance performance using a measure for the range of limits of stability (LOS) in both anterior-posterior (A/P) and medial-lateral (M/L) directions. After completion of the pre-assessment, a member of the research team will train all participants to use the SBS's smartphone, and all participants will be additionally trained in the use of the custom belt and the walker and multimodal biofeedback for in-home dynamic weight-shifting balance exercises (WSBE) guided by the SBS. After completion of the post-assessment, all participants will complete a usability and acceptability questionnaire (UAQ) for the SBS.

In-home balance exercises: All participants will use the SBSs for 6 consecutive weeks, and they will complete in-home WSBE (i.e., physical therapists' recommended dynamic balance exercises) with the SBS (3 days per week) in both A/P and M/L directions. All participants will perform in-home dynamic WSBE by standing inside a walker (no wheels). The instructional video provided by the SBS will show how to perform dynamic WSBE in both A/P and M/L directions by standing inside the walker without touching or holding onto it unless the subject experiences loss of balance. After each trial, the SBS's smartphone app will store exercise-related data.

Performance metrics: Measured data from the SBSs will be analyzed using MATLAB (The MathWorks, USA). Statistical analysis will be performed using SPSS (IBM Corp., Armonk, NY, USA). As a function of the pre/post/retention-assessments, two primary outcome measures (range of LOS) will be used to evaluate static/dynamic balance performance. Ranges of LOS in degrees correspond to the furthest deviations of the body tilt in both A/P and M/L directions. The UAQ score (Likert scale) will be used to assess the usability and acceptability of the SBS, and the participants' compliance with the in-home balance training regimens, total exercise time, and number of completed exercises will be quantitatively analyzed.

Name	Time Frame	Brief Description
Range of limits of stability	Pre-assessment (baseline at the beginning of week 1), post-assessment (at the end of week 6), and retention-assessment (1 month after week 6)	Limit of stability refers to the outermost range in anterior-posterior and medial-lateral directions at which the subject can lean from the vertical without changing the base of support.
Usability and acceptability questionnaire (UAQ)	Post-assessment (at the end of week 6)	The UAQ is a self-reported questionnaire used by subjects to assess the usability and acceptability of the proposed SBS.

Statistical Analysis Plan

The primary outcome measure for evaluating balance performance is the range of Limits of Stability (LOS) in both the anterior-posterior (A/P) and medial-lateral (M/L) directions. LOS represents the maximum angular excursion that a participant can achieve while maintaining a stable base of support without stepping or losing balance. LOS will be measured at three time points: baseline (Week 1, prior to intervention), post-intervention (Week 6), and retention (Week 10, one month after the intervention ends). These measurements will be obtained using the SBS smartphone application, which quantifies participants' dynamic balance capacity by analyzing trunk sway and range of controlled movement.

To assess the efficacy of the SBS-guided intervention, Repeated Measures Analysis of Variance (ANOVA) will be used with time (baseline, post, retention) as a within-subject factor and group (intervention vs. control) as a between-subjects factor. Main effects of time and group, as well as the interaction effect (time × group), will be evaluated to determine whether balance performance improved differentially over time depending on the assigned intervention. A significant interaction effect would suggest that the SBS system had a unique impact on improving LOS relative to the paper-based control regimen.

As a measure of user experience and technology acceptance, the Usability and Acceptability Questionnaire (UAQ) will be administered at the post-assessment time point (end of Week 6). The UAQ consists of self-reported Likert-scale items that evaluate perceived ease of use, clarity of instructions, comfort of the wearable system, motivation to exercise, and willingness to continue using the SBS. Responses will be summarized using descriptive statistics (mean, standard deviation) for each item. Between-group differences in total UAQ scores will be analyzed using independent samples t-tests to determine whether the intervention group rated the SBS as more usable and acceptable than the paper-based regimen.

All analyses will be conducted using IBM SPSS Statistics v29 (IBM Corp., Armonk, NY, USA), with the significance level set at $\alpha = 0.05$.