Vestibular Rehabilitation utilizing Virtual Environments to Train Sensory Integration for Postural Control in a Functional Context

NCT04268745

ANALYSIS PLAN

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The ***specific aims*** of this pilot project are:

Aim #1: Determine the extent to which sensory integration strategies differ between individuals with unilateral vestibular hypofunction and age-matched peers. Participants' head sway will be recorded as they experience two levels of moving stars[10] and white noise, while standing on the floor or a compliant surface. Our working hypothesis is that patients with vestibular hypofunction utilize substitution strategies such that they will demonstrate greater visual and auditory reliance compared with controls, particularly when somatosensory cues are reduced via the support surface. We will then explore whether these mechanism changes after training.

Aim #2: Develop the protocol and establish the feasibility of a randomized controlled trial (RCT) comparing C.S.I. training to standard vestibular rehabilitation. Following the assessment, the patients will be randomized into standard vestibular rehabilitation vs. C.S.I. training. This pilot study will enable us to test the feasibility of our recruitment, randomization procedures, establish attrition rate, and test the training protocol.

Aim #3: Generate pilot data for sample size calculation for a properly powered RCT. The follow up RCT will test the effect of C.S.I. training on: Visual Vertigo Analog Scale (VVAS), Functional Gait Analysis (primary); balance confidence, overall disability (descriptive). In our preliminary study, 8 patients met the inclusion criteria for the current proposal. Following the C.S.I. training, they had a large effect size of 1.17 on the VVAS. The current study will allow us to identify the between-group effect size for the VVAS and for a functional gait outcome.

Description of Outcome Measures:

FGA: A functional test designed to assess individual's ability to perform various motor tasks, such as: walking with eyes closed, walking backwards, climbing stairs. There are 10 items, each is scored by a therapist on a scale of 0 (severe impairment) to 3 (normal). Intraclass correlation coefficients of .86 and .74 were found for interrater and intrarater reliability of the total FGA scores in vestibular disorders. Internal consistency was .79.

VVAS: The VVAS is a visual analog scale where a participant rates the intensity of their dizziness in 9 situations of visual motions that typically provoke dizziness.[50] The VVAS is the second primary outcome measure because the intervention was designed to improve symptoms and function in sensory complex environments. Indeed, the VVAS has shown the largest changes from pre to post training changes in our preliminary work.

ABC: A subjective measure of confidence in performing activities without falling. Each item is scored from 0% (no confidence in one's balance) to 100% (full confidence in one's balance).

***DHI*:** The DHI has 25 items involving the functional, emotional, and physical domains. Each item is scored as 'no', 'sometimes' or 'yes' to evaluate self-perceived disability imposed by dizziness.

Head Root mean square velocity in the medio-lateral and anterior-posterior direction: the difference in position between two consecutive data points divided by the average time interval. The velocity at each point is squared and summed. The square root of the sum is then divided by the number of data points.

Data Analysis:

Aim 1: For each of the measures of interest we will fit a linear mixed effects model to compare the age-matched controls to patients with vestibular hypofunction while accounting for the inherent multi-level study design (person, conditions, repetitions). The models will include main effects of group, visual condition, auditory condition, surface condition, as well as their interactions, while adjusting for age. *P*-values for the fixed effects will be calculated through the Satterthwaite approximation for the degrees of freedom for the T-distribution. We will repeat the analysis following the intervention, adjusting for group assignment and pre-intervention values. ABC and DHI will be used to describe the sample.

Aim 2: No statistical analysis needed.

Aim 3: First, following the intent-to-treat principle, a linear regression model will be fit with the VVAS and FGA as the primary dependent variable, on treatment group, controlling for baseline covariates (age and other self-reported questionnaire measures) to improve the precision of the treatment effect estimate, as well as pre-test scores. The potential efficacy of the intervention will be assessed based on a significant coefficient for treatment status. Second, as described above, we will fit a pattern mixture model to multiply impute any missing values, and use Rubin's rules to pool coefficients and their standard errors from the regression models fit to each imputed dataset. Data generated from this pilot randomized trial will be used to calculate the sample size needed for future, adequately powered, randomized controlled trials by estimating the difference in means for the treatment groups (i.e. a future expected effect size) as well as the variance of the primary outcomes and the values of other parameters necessary to compute the power function.