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Official Title of the study: Individualized Vestibular Rehabilitation for Elderly With Self-Management and Gaming Elements

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Study Protocol

This experiment will test the app for proof of concept on older subjects with dizziness in a clinical environment (laboratory or clinic) under the supervision of a clinician. The aim is to test whether when using the app older patients perform rehabilitation in a similar manner as when directly instructed by a clinician. A secondary goal is to evaluate usability and enjoyment of the app. Data will be collected on 40 subjects (20 male and 20 female). Subject inclusion criteria are to be aged between 60 and 75, able to walk and get up from a chair independently, free of musculoskeletal disorders, and not taking any medication that may affect balance. Each participant will be asked to take part in two visits. One for the experimental trial and the other for a focus group follow up.

The subject age, body height and mass and vestibular condition will be recorded. They will also be asked to answer a Dizziness Handicap Inventory (DHI) as well as an Activities-specific Balance Confidence (ABC) scale questionnaire to assess how much they are affected by their vestibular condition.

Each subject will perform a rehabilitation session with the prototype app and one session without the app. The session will be setup on the app by the clinician for each participant specifically. The session without the app will include the same exercises at a similar recommended speed and range of motion. These will be performed without any feedback as they would typically be performed by a patient doing their at-home exercises. The order in which the sessions occur will be randomized to avoid learning effects. Subjects are encouraged to take a break between the sessions and can take a break at any time if desired. Each session will start with the participant practicing the games and exercises using the slower speed practice games and proceed when they feel ready. A physical therapist will be present to assist if needed. This is to simulate first use of the app. It is envisioned that the first time a patient will use the app this will be under supervision and assistance of a physical therapist. Patients will perform a full rehabilitation session, lasting about 20 minutes after that.

The real-time feedback during the exercises will be tested. A clinician who is blinded to the feedback the patient receives (as in they cannot see the screen and will be listening to music on headphones in the case of auditory feedback) will identify each error the patient makes and will make notes whether this error continues or is corrected by the patient. This will be coded with numbers and recorded on video. Errors identified by the ML algorithm will be stored in the app as well with a time stamp for comparison. Raw sensor data will be stored and analyzed to test the efficacy of the feedback and see if exercise execution improves after feedback.

IMU data will be collected during both sessions (with and without the app) for comparison. Outcome measures, including range of head motion, movement velocity, and the number of repetitions performed, will be calculated. Data will be compared between the two sessions to investigate whether patients performed exercises similar with and without the app.

Questionnaires will be answered to rate usability and enjoyment while using the app, as well as open ended questionnaires to identify areas of improvement.