

## **Cover page**

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

**NCT number (if available):** STUDY00148324

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## Statistical Design and Power

Number of subjects expected to enroll: 40

Expected effect size and power:

The expected effect size in head range of motion outcome measures (Flexion angle, Extension angle, Left angle, Right angle) is  $5^\circ$ . This is based on the mean and standard deviations of the data that were collected on 6 older vestibular patients in Phase I.

Using an estimated standard deviation of  $7.5^\circ$  and a desired power of 80% and a  $p < 0.05$ , this resulted in an estimated 36 subjects being required to reach this power.

The expected effect size in head velocity outcome measures (Flexion angular velocity, Extension angular velocity, Angular velocity left, Angular velocity right) is  $20^\circ/\text{s}$ . This is based on the mean and standard deviations of the data that were collected on 6 older vestibular patients in Phase I.

Using an estimated standard deviation of  $30^\circ/\text{s}$  and a desired power of 80% and a  $p < 0.05$ , this resulted in an estimated 35 subjects being required to reach this power.

Since effect size of the balance related outcome measures are unknown (these were not calculated in phase I), as well as the differences that will occur due to feedback (hypothesis 6) being unknown, a total number of 40 subjects was decided upon.

Statistical methods:

All outcome measures will be tested for normal distribution using a Kolmogorov-Smirnov test and if required non-parametric tests will be used. Statistical significance will be defined as  $p < 0.05$ .

Hypothesis 3 will be test for significant difference for outcome measures for the exercises between performing the exercises with and without the app. This will be tested using a paired t-test. The two different conditions for the paired t-test are the exercises performed with and without the app. The outcome measures that will be compared between the two conditions are: Flexion angle, Extension angle, Left angle, Right angle, Flexion angular velocity, Extension angular velocity, Angular velocity left, Angular velocity right, Balance excursion medio-lateral, and Balance excursion anterior-posterior.

If any variable shows a non-normal distribution a Wilcoxon signed rank test will be used instead of a t-test.

Hypothesis 4 will be tested using the following outcome measures: Ease of use rating, Enjoyment rating, Motivation rating, Use intention rating, and Usefulness rating. It will be tested whether the mean and median for each of the outcome measures is a positive response (value  $< 4$ ).

Hypothesis 5 will be tested similar to hypothesis 1 by calculating the accuracy of identifying the errors using the identification by the clinician as gold standard. The goal is to get a minimum accuracy of 90% for each specific error. This does not involve any specific statistical tests.

Hypothesis 6 will be using a paired t-test with pre- and post-feedback as conditions. Dependent variables will be average head range of motion and velocity and standard deviation of velocity over a time window pre- and post-feedback. This will be calculated for each common error separately. It will be tested if head motion is altered for the error of moving the body versus the head, it will be tested whether head motion slows down or speeds up as instructed by the

feedback and if movement velocity standard deviation reduces when feedback is given on an inconsistent speed.