Statistical analysis plan - Version 3, 17/10/2020

The effect of training on brain activity during postural control tasks in older adults

Protocol identification number

S62917

Study type

Interventional

Principle investigator

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Brief summary:

Older people show deficits in dynamic weight-shifting, as we found that more time is needed to perform weight-shifts and the movements become less fluent and accurate in older versus younger adults. Deficits with weight-shifting in the mediolateral (left-right) direction has been linked to balance and falls in ageing. Balance control can be improved with training. Virtual reality (VR) based training programs for improving balance are gaining ground, as it can provide both fun and challenging balance tasks, enhancing motivation. We demonstrated earlier that older adults show an overloaded neural activation pattern compared to young adults when performing the same VR-based mediolateral weight-shifting task (wasp game). What is yet unclear, is whether improved balance capacity can be gained with training and whether such an intervention impacts the underlying neural mechanisms. Using a combination of behavioral assessments and functional Near-Infrared Spectrocopy (fNIRS), the primary aim of this study is to investigate the effects of a VR-based weight-shift training and its underlying neural imprint in older adults. Furthermore, as our previous study also showed that adding an extra cognitive task in a so-called dual-task (DT) negatively affects weight-shifting performance, a secondary aim will be to test whether weight-shift training will enhance performance during such DT conditions. The results of this study may contribute to the future design of technology-based rehabilitation programs.

Primary outcome:

For the primary behavioral outcome, weight-shifting speed in the mediolateral direction will be used. Participants will shift their weight to 80% of their stability limits within the Wasp Game. As people tend to slow down when reaching the 80% limit in order to aim for the wasp, mediolateral weight-shifting speed will be determined from the 80% limit on the right side the 80% limit on the left side and vice versa. Mediolateral weight-shifting speed will be determined and compared between the three test moments (pre, post, retention) and between the two groups (training, control) during the Wasp Game ST and DT.

Secondary outcomes:

1. Outcomes of the Wasp task

The number of wasps hit (#wasps) and the anterior-posterior weight-shifting error (error from the ideal trajectory) will be used within the Wasp Game. The trajectory error will be determined similar to the primary behavioral outcome measure. #wasps hit and trajectory error will be compared between the three test moments (pre, post, retention) and between the two groups (training, control).

2. Functional limits of stability.

These will be determined in eight different directions (anterior, anterior-right, right, posterior-right, posterior, posterior-left, left, anterior-right) and compared between the three test moments (pre, post, retention) and between the two groups (training, control).

3. fNIRS-outcomes

For the neural outcome, cortical oxygenated hemoglobin (HbO2) will be measured with functional Near-Infrared Spectroscopy (fNIRS) in the prefrontal cortex (PFC), frontal eye fields (FEF), premotor cortex (PMC), supplementary motor area (SMA) and the somatosensory cortex (SSC) . HbO2 levels will be determined and compared between the three test moments (pre, post, retention) and between the two groups (training, control) during the Wasp Game ST and Wasp Game DT.

Tertiary outcomes:

1. Clinical balance outcome

The MiniBEST will be administered to assess general balance. The scale consist of 4 subscales: 1) anticipatory postural control; 2) reactive postural control; 3) sensory orientation; 4) dynamic gait. Total score (range 0-28) will be compared between the two days (pre, retention) and between the two groups (training, control).

2. fNIRS-outcomes

Cortical deoxygenated hemoglobin (HHb) will be measured with functional Near-Infrared Spectroscopy (fNIRS) in the same regions as HbO_2. HHb levels will be determined and compare between the three test moments (pre, post, retention) and between the two groups (training, control) during the Wasp Game ST and Wasp Game DT.

Main analysis:

Primary, secondary and tertiary outcomes will be compared between training and control group and pre, post and retention test using linear mixed models. We will determine the best model based on standard fitting criteria. . We will consider cognitive and balance skills as possible covariates, depending on between group differences and determined by a blind review of the data. Post-hoc testing will be corrected for multiple testing by Bonferroni corrections.

Depending on data normality, Pearson and/or Spearman correlation analysis will be performed between neural and behavioral outcomes within groups and test moments. Bonferroni corrections for multiple testing will be applied when necessary.

Secondary analysis:

A planned secondary analysis will be performed within the control group to investigate fNIRS test-retest reliability using a three-way repeated measures ANOVA (pre, post, retention). Here we will also calculate the intraclass correlation coefficient (ICC) and standard error of measurement (SEM) .