Title: Operant Conditioning of Loading Response During Locomotion in Able-bodied Individuals and People After Stroke

NCT number: Not available

Date: April 11, 2022

Statistical Design and Power

Sample Size. 15 individuals with no known neurological conditions or history of orthopedic injuries will be studied in Aim 1. For the primary measure (soleus EMG response), the difference between the non-perturbed and perturbed EMG will be assessed by Student's *t*-test. In the previous study [29], a group analysis with a s.d. of 0.87% change (% non-perturbed EMG) was observed in the soleus EMG in response to 1 deg/s joint motion perturbation during the mid-late stance phase (i.e., the variation in the soleus EMG is linearly related to the velocity and/or amplitude of the perturbations [29]). Assuming similar s.d. for the proposed study, the sample size of N=15 allows us to estimate, with a two-sided 95% confidence level each, the soleus EMG response to perturbation within a margin of error of 5.4% non-perturbed EMG.

A sample size of 5 participants with hemiparesis and gait deficits due to a stroke will be studied in Aim 2 to examine the feasibility of the proposed algorithms and device. Due to the lack of availability of data with post-stroke participants, s.d. change % unperturbed soleus EMG cannot be defined prior to conducting testing with individuals after stroke. Hence, the pilot will provide preliminary results to characterize the soleus EMG due to the applied perturbations in people post-stroke, which will facilitate hypothesis testing and inform our sample size of stroke survivors in our subsequent study.

Statistical Analysis. All statistical analyses will be performed using SAS® 9.4. For descriptive purpose, continuous data will be summarized with the number of non-missing values, mean, and standard deviation, minimum, median, and maximum and categorical data will be summarized with the number of nonmissing values and the numbers (frequencies) of values equal to each of the possible categories, unless stated otherwise. All statistical tests will be two-sided with a significance level of alpha=0.05. Unless otherwise stated, no multiplicity adjustment will be applied, and no missing values will be imputed. Mixed effects model will be used as needed to assess whether the effect of our algorithm depends on other related factors, such as age