

Statistical Analysis Plan

Study Title: Cyclical muscle vibration in multiple sclerosis to improve walking

Last update: 01/29/2020

The within subject experimental design was used for this feasibility study because it requires fewer subjects with more statistical power while reducing the potential for systemic error or selection bias to test the effect of training with vibration on walking. While practice and carryover effects are major disadvantages of this study design, proper precautions including rest periods between tests and randomization of testing order for walking with or without vibration was instituted to minimize them at baseline and post-treatment¹. In this study design, any improvements at baseline with vibration compared to volitional gait can be attributed to short term effects of vibration. Improvements in volitional gait *post* training with vibration compared to volitional baseline gait can be attributed to long term effects of vibration. While this feasibility study design has limited generalizability due to the small number of subjects and inhomogeneity of the selected population, it can be quite useful for developing and refining future vibration intervention studies.

Means and standard deviations were calculated for all outcome measures for each subject. Differences in means were determined via a two-way analysis of variance ($p < 0.05$). A statistical power of 90% was used to determine the number of trials with VICON motion analysis system required for the testing and comparison of gait parameters. The results indicated a requirement of 30 strides of data or roughly 6 trials (approximately 5 strides per trial) for each condition (volitional or with vibration).

¹ Greenwald AG. With-in subject design: to use or not to use? *Psychological Bulletin*, 83(2):314-320, 1976.