Statistical Analysis Plan for

Effects of a Soft Robotic Exosuit on Exercise Capacity, Biomarkers of Neuroplasticity, and Motor Learning after Stroke

NCT05138016

PI: Louis N. Awad, PT, DPT, PhD

louawad@bu.edu

617-358-3043

January 15, 2020

The Shapiro-Wilk test and visual inspection were used to assess data normality. Student's t-tests were used to investigate an order effect of training session (i.e., exosuit versus no-exosuit) on primary outcomes. Paired t-tests were used to evaluate between-session differences in the study's primary outcomes of VO_2 peak and training duration. With a sample size of 11, the study was powered to detect a large effect size (d = 0.98) with 80% power and an alpha of 0.05. Paired t-tests were also used to evaluate within-session differences (i.e., pre- vs. post-training) in serum BDNF levels and interlimb peak propulsion symmetry. Individual-level analyses were used to describe individual subject outcomes. For these analyses, VO_2 responders were defined as those whose VO_2 peak in the exosuit-augmented training condition was larger than in the no-exosuit control condition by at least the 2.2 mL O_2/kg/min MDC (95%CI 1.3–3.1 mL O_2/kg/min). Training duration responders were defined as those who walked longer during exosuit-assisted walking, regardless of the magnitude of difference. BDNF responders were determined for each training condition and defined as those whose difference in pre- to post-training BDNF levels increased above the 9.15 ng/ml MDC-UCL_{95}. Given propulsion symmetry is a metric that combines individual limb propulsive forces, we also explored the contribution of changes in individual limb peak propulsion to the differences observed in post-training propulsion symmetry. A change in limb peak propulsion above the 0.80 %bw MDC was interpreted as meaningful. To explore differences in secondary exercise characteristics between exosuit and no-exosuit training, we used paired t-tests. Finally, differences in the reasons for stopping training are described. Data are presented as average ± standard error unless otherwise specified. Alpha was set at 0.05. All statistical analyses were performed using RStudio software (version 1.3.1056).