A Randomized, Crossover Clinical Trial of Exoskeletal-assisted Walking to Improve Mobility, Bowel Function, and Cardio-Metabolic Profiles in Persons with SCI

NCT02314221

09/28/2023

A Randomized, Crossover Clinical Trial of Exoskeletal-assisted Walking to Improve Mobility, Bowel Function and Cardio-Metabolic Profiles in Persons with SCI

Statistical Plan and Data Analysis:
The best value achieved for each walking test during sessions 5 to 12 (T1) and from 13 to 36 (T2) will be recorded separately to be used for comparative analysis. These best T1 and T2 scores will be used to determine percent of occurrence with the hypothesized goals. Achievement of the hypothesized goals in the WALK intervention group for the primary outcomes (10mWT, 6minWT and TUG at the 12- and 36-session time points) will be reported as categorical data and presented as a percent of occurrence with the 95% upper and lower confidence intervals (CI). Continuous variables for the Secondary outcomes of the body composition and bowel function variables will be presented as mean ±SD. For the continuous variables, a difference score or percent change from pre to post will be calculated for the WALK and UA arms of the study. Comparisons between WALK (Pre-Post) vs. UA (Pre-Post) difference scores will be performed using paired t-tests. Pre to post comparisons for variables that are not normally distributed will be performed by non-parametric tests such as the Wilcox signed rank test or the paired sign test.

Walking outcomes (10mWT, 6minWT, and TUG): Achievement of the hypothesized goals in the WALK intervention group will be reported as categorical data and presented as percent occurrence with 95% confidence intervals (CI). For each of these outcomes, the best value achieved during the T1 period (sessions 5-12) and the T2 period (sessions 13-36) will be recorded separately and compared to the hypothesized goals, as listed below:

Primary Hypothesis (are tested pre and post the WALK arm only):

1. By session 36, 70% of the participants compared with 10% at session 12 will be able to perform the 10mWT ≤40 seconds (≥0.25 m/s);
2. By session 36, 70% of the participants compared with 10% at session 12 will be able to perform the 6minWT distance ≥80 m (≥0.22 m/s); and
3. By session 36, 60% of the participants compared with 20% at session 12 will be able to perform the TUGin ≤90 seconds.

Power Calculation: A one-sample method was chosen to test the observed proportion against the expected proportion determined from the preliminary data of the percent of those who achieved these goals. Using the most stringent criteria above of 20% (session 12) versus 60% (session 36) who achieve the TUG goal, there is 100% power (alpha=5%, double sided Z-power=5.6) with 13 of 63 (20%) versus 38 of 64 (60%) achieving the goal. If the attrition rate is as high as 25%, then the power is still 100%, (alpha=5%, double sided Z-power=4.53), with 10 of 48 (20%) at session 12 versus 29 of 48 (60%) of the participants achieving the goal at session 36.

Secondary Hypotheses

1. Bowel function will improve as demonstrated by 25% improvement on the Ten-question bowel survey.
2. Total body fat mass is hypothesized to be reduced by 2.0±1.2 kg

Power Calculation: The preliminary data demonstrated a total score change of 31.5±7.1 to 22.5±5.3, N=8 and a total body fat mass change from 24.14±8.45 to 22.22±8.19, N=9, alpha=0.05, using a pairwise method, the power for both was 100%. Allowing for 25% dropout, the power is still 100% for 48 participants at an alpha=0.05.
Please note, that both the primary and secondary hypotheses are well powered due to the huge effect observed in the preliminary data. However, performing this study in fewer participants will not permit us to ask many of the exploratory questions. There is no empirical data to support an appropriate power calculation for the exploratory hypotheses.