Chief Science Officer

NCT04516343

Title: Evaluation of the Safety and Efficacy of a Lower Extremity BiOMOTUM Exoskeleton in the Pediatric Population with Cerebral Palsy

2/6/2025

Statistical Analysis Plan

Gait Training with RAAD *assistance* statistical analysis:

The RAAD <u>assistance</u> training protocol took place under the supervision of Dr. Schwartz at Gillette Children's Specialty Healthcare. We completed the protocol with 12 participants for this arm of the study. Participants completed a pre-training assessment and then 12 sessions (roughly 3 per week for 4 weeks) of RAAD assistance over-ground walking training. Walking speed was measured using a gait timer; the distance in meters was divided by the completion time in seconds. Walking distance was measured using a distance wheel measuring tool. To calculate the metabolic cost of transport, the standing baseline metabolic rate for each participant and each trial was subtracted from their walking metabolic rate to estimate the net metabolic rate of walking. Next, we normalized the net metabolic rate of walking by each participant's body mass and walking speed to calculate the metabolic cost of transport. Outcomes were assessed during walking without the RAAD before and within one week after the last training session. We checked outcome measures data for normality using a Shapiro-Wilks test. For data that were normally distributed, we tested for statistical differences using paired Student's T-tests (two tailed, alpha set to 0.05).

Gait Training with RAAD *resistance* statistical analysis:

The RAAD <u>resistance</u> training protocol took place under the supervision of Dr. Jayaraman at the Shirly Ryan Ability Lab. We completed the protocol with 16 participants for this arm of the study (Table 5). Participants completed a pre-training assessment and then 12 sessions (roughly 3 per week for 4 weeks) of RAAD resistance treadmill walking training with plantar pressure biofeedback. The resistance level was gradually increased to ensure progression. Walking speed was measured using a gait timer; the distance in meters was divided by the completion time in seconds. Walking distance was measured using a distance wheel measuring tool. To calculate the metabolic cost of transport, the standing baseline metabolic rate for each participant and each trial was subtracted from their walking metabolic rate to estimate the net metabolic rate of walking. Next, we normalized the net metabolic rate of walking by each participant's body mass and walking speed to calculate the metabolic cost of transport. Outcomes were assessed without the RAAD before and within one week after the final training session. We checked outcome measures data for normality using a Shapiro-Wilks test. For data that were normally distributed, we tested for statistical differences using paired Student's T-tests (two tailed, alpha set to 0.05).