

ID:
STUDY00011386

Early Powered Mobility for Toddlers With
Cerebral Palsy Using the Permobil® Explorer
Mini and a Modified Ride-On Car

NCT04684576

Statistical Analysis Plan
Document Date: 12/1/2020

Data Analysis:

All statistical analyses will be conducted using SPSS (version 26.0 IBM, Armonk, NY). Descriptive participant characteristics (e.g., age, sex, race/ethnicity, CP subtype, GMFCS-level) will be summarized as categorical variables.

Aim 1: Developmental, activity and participation outcomes

Sample size justification: Since the current proposal is a pilot study, there are no previous data to conduct a power analysis on the potential change of developmental, activity and participation outcomes as a result of using different powered mobility devices.

Analysis for measures assessed in Aim 1 will include descriptive statistics. Data will be assessed for normality and symmetry. If normality assumptions are met, we will use parametric statistics to examine between- and within-subject effects. If assumptions are not met, we will use the non-parametric equivalent of the planned analyses. We will calculate three separate analyses to examine changes in developmental, activity and participation outcomes. (1) Separate 2 (group: 1, 2) x 3 (time: T0, T1, T2) repeated measures MANOVAs will be calculated to determine between- and within-subject changes on mean scores of developmental, activity and participation outcomes. (2) Stratification into low and high usage groups will occur based on mean device use data. We will use these stratified groups to run our analyses to determine if device use is related to developmental, activity and participation outcomes. Separate 2 (group: low usage, high usage) x 3 (time: T0, T1, T2) repeated measures MANOVAs will be calculated to determine between- and within-subject changes on mean scores of developmental, activity and participation outcomes. Post-hoc analyses (i.e. Bonferroni correction) will be used for the above analyses to control for the type I error rate and determine where the significant differences exist. (3) We will also use visual analysis to determine if clinically significant differences exist.

Aim 2: Use patterns (frequency, duration, environment) & families' perspective and experiences

Sample size justification: A power analysis based on preliminary data was used to determine the number of participants (*N*) necessary to satisfy statistical assumptions for the current study. Power was calculated from the results of the total time (minutes) a modified ride-on car was used between two groups: (1) Families who received bi-weekly support via in-person researcher visits (Mean minutes = 1,060; SD = 783.8), and (2) Families who received no support throughout a 3-month intervention period (Mean minutes = 171.4; SD = 206.1). Beta was set at .80 and alpha at .05 to calculate *N* which is standard practice. Analysis indicates that a sample of 6 participants in each group (modified ride-on cars, Explorer Mini) will produce meaningful treatment differences. This power analysis is appropriate given our hypothesis that the Explorer Mini will be used more frequently and more often than a modified ride-on car based on design features. Also, the above power analysis from previous data is based on between-group differences whereas the current study will examine within-group differences of use patterns between devices, resulting in less variability and greater likelihood of observing differences, if differences exist.

95% confidence intervals and mean number of driving sessions, mean duration (minutes) of driving sessions, and summed total duration (minutes) of driving sessions will be summarized by device type. Variable distributions will be examined to (1) identify appropriate response variable distributions, (2) screen for outliers, and (3) characterize patterns of data missingness. If assumptions for parametric statistics are met, we will use parametric statistics to examine within-subject effects. If assumptions for parametric statistics are not met, we will use the non-parametric equivalent of the planned analyses. A 2

(group: 1, 2) x 2 (time: T1, T2) repeated measures MANOVA will be calculated to determine within-subject changes on the dependent measures of the mean number of driving sessions, mean duration (minutes) of driving sessions, and summed total duration (minutes) of device use. Significant differences will be followed-up with appropriate post-hoc analyses such as the Bonferonni correction to control for the type I error rate and determine where the significant differences exist.

Analysis of caregiver logs and quantitative device use data will include descriptive statistics to describe home and community use trends for both devices (mean distance traveled, speed, number of mobility bouts, number of controller activations, etc.) across all users, and describe differences in use parameters for children stratified by device type.

Interview recordings will be transcribed verbatim and coded using constant comparison until thematic saturation is reached. NVivo Qualitative Coding Software (QSR International, Melbourne, Aus) will be used for data analysis. Preliminary themes will be shared with participants as a form of member checking. We will also use the Linguistic Inquiry and Word Count (LIWC 2015) program to analyze caregiver interviews. LIWC 2015 is a text-analysis program developed on the premise that the words people use reflect their physical and mental health and can be used to learn about their beliefs, thinking patterns, emotions, social relationships, and personalities. LIWC 2015 examines each word in a transcript against an internal dictionary of more than 6,000 words to place the word into the appropriate linguistic and psychological categories; it can objectively evaluate a transcript on the basis of four summary language variables: Analytical Thinking, Clout, Authenticity, and Emotional Tone. These variables will be used to compare each caregiver's perceptions of their child, reflected in their use of words at the beginning of the study, with their perceptions (again reflected in their use of words) at the end of the study. Our team has had past success with this program in compliment to traditional qualitative interview coding procedures.