

**Up and Down: Use of Dynamic Partial Body Weight Support
Play Environment to Encourage Upright Mobility and
Exploration in Infants with Down Syndrome (DS)**

NCT number:

Date: 1/06/2022

Statistical Design and Power

Data Analysis:

All statistical analyses will be conducted using SPSS (version 27.0 IBM, Armonk, NY). Descriptive participant characteristics (e.g., age, sex, race/ethnicity, DS type) will be summarized as categorical variables. The dependent variables for this study are exploratory behavior activity counts, exploratory behavior coding counts, GMFM sections D and E raw scores, and DMQ-18 raw scores. Descriptive statistics will be reported for each variable. To test whether there is a difference in conditions for each dependent variable, paired t-tests will be performed comparing the control post-tests to the intervention post-tests. Prior to statistical analysis, we will test the data for normality. If the data is not normally distributed, differences will be determined using the Wilcoxon Rank Sum test. Alpha will be set at 0.05.

Movement counts will be analysed using the Actilife 6 software (ActiGraph, Pensacola, FL). Each intervention session will be video recorded, and exploratory activity will also be coded from the recordings. Coding will be conducted using a momentary time sampling strategy from the videos of the first session of week 2 and week 6 (first exposure to the play environment in each condition) and the last session of week 4 and week 8 (last exposure to the play environment in each condition). Coding metrics will include physical activity, classified according to the Observational System for Recording Physical Activity in Children- Preschool version, social interactions, classified according to the Code for Active Student Participation and Engagement- Revised (CASPER-III), and object-related actions, classified by whether a child is touching, holding, or using a portable object with their hands using a categorical yes/no binary²⁸. Inter- and intra-rater reliability of at least 90% agreement will be established for each exploratory behavior on 10% of the video recordings using the ratio of [agreements/ (agreements + disagreements) X100] to establish a percentage of agreement.