

**Therapeutic Dance Intervention for Children with
Cerebral Palsy**

NCT03681171

June 2, 2021

Protocol

This is a pilot study that is being conducted to evaluate the feasibility of the proposed intervention and to collect pilot data from up to 10 participants that will be used to design a subsequent larger study. Data from this study will be used to identify hypotheses to be tested and for estimating the means(s) and standard deviations of outcome measurements that will be used to conduct a power-based determination of a minimal, adequate sample size for the subsequent study.

Aim 1 – To evaluate baseline anthropometric, physiological, psychological, and physical functioning in a sample of children with cerebral palsy.

Aim 2 – To systematically measure for the first time in children with cerebral palsy the effects of a short-term ballet intervention. We will recruit up to 10 boys and girls (ages 9-15) who have cerebral palsy and enroll them in a 7-week intervention, which will include three 60-minute sessions of therapeutic dance intervention (ballet) per week. We will measure: • Gait and physical functioning • Executive functions • Social and emotional functioning • Body composition • Bone density • CBC and lipid panel • Muscle strength • Habitual physical activity

Aim 3 – To evaluate the feasibility of measuring the acute effects of a session from the therapeutic dance intervention on executive functions and enjoyment in children with cerebral palsy. We will measure executive functions before and after a single session of intervention.

As this is a very small pilot study, we will not have a control or comparison group and will not use randomization. The study is pre and post intervention design, with an added follow-up assessment. In other words, prior to intervention, we will collect baseline measurements on the domains of interest. Then there will be an intervention period, which will be followed with a post-intervention assessment on the same outcomes. To study whether any potential improvements are maintained, we will have another assessment at a follow-up period after a brief phase of no intervention. It is our goal to eventually conduct a fully randomized clinical trial, but in this first pilot study, the study design is appropriate to the goals of piloting the intervention and evaluating the feasibility and acceptability of the research procedures and intervention.

Means and standard deviations at each assessment point will be provided for each outcome collected according to the measurement schedule. To evaluate impact of the intervention, degree of change between the pre-intervention and post intervention points will be measured. To determine if potential gains seen across the intervention period are maintained, degree of change between post-intervention and the follow-up assessment will be measured. For each type of comparison (pre/post, post/follow-up, and acute), means and standard deviation of the change score, as well as within-subject effect sizes will be calculated and presented. We will examine this data both for the group as a whole as well as for subgroups (younger, older participants).