

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

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Research objective

Children with Down syndrome (DS) experience delayed mobility, which decreases their opportunity for exploration and impacts the development of their cognitive, communication, and social-emotional skills. Physical therapy interventions for infants with DS frequently focus on the development of postural control and body weight support to enhance the development of motor skills. Partial body weight supported (PWBS) intervention, where part of the child's body weight is offloaded through the use of a harness and allows for easier movement through space, is an effective intervention for infants with DS, leading to earlier onset of independent mobility and increased physical activity. We are combining PWBS support for infants with DS who are not yet walking, within an enriched play environment to better understand how PWBS may impact their mobility, exploration, and overall activity level.

Research Design

This is a randomized, crossover pilot study design with the sampled children serving as their own controls

Methods

Participants will include children of all genders, with Down Syndrome (any form) diagnosis, under 36 months of age, able to sit independently and one parent or legal guardian of all genders ages 18 and above. Inclusion criteria for the study: 1) The child will have a medical diagnosis of DS (any form); 2) be under 36 months old; 3) able to sit independently; 4) one parent must be able to read proficiently enough in English to complete a written assessment. Children will be excluded from the study if: 1) they can walk independently; 2) have uncontrolled seizures; 3) have known medical precautions that would prohibit them from wearing a harness; 4) have other developmental disability diagnoses. Participants will be recruited by the research team via social media postings, emails to known rehabilitation professionals in the Seattle region, and via fliers hung-up and passed out at local healthcare clinics and hospitals. The research team will also send emails to past research participants who had shared their email address and had agreed to be contacted for future studies. Potential participants will self-elect to call or email the research team to hear more about the study to determine whether or not they are interested in participating. Interested potential participants would then be screened for eligibility by a member of the research team.

We will conduct our work in this pilot study using a randomized, crossover design with children serving as their own controls. Study activities for each child will take place over 9 weeks in the PI's research lab on UW campus (CHDD buildings). After successful recruitment, children baseline assessment will be conducted during week one. On the first visit, parents will be asked to review and sign informed consent documentation to participate and baseline assessments will be completed. Then randomization assignment into 2 groups for intervention either play sessions using the PBWS (harness) or control play group (no harness, 3 sessions per week) for 3 weeks (weeks 2-4 of the study and weeks 6-8), with a washout and reassessment period during week 5 prior to crossover. A final reassessment session will be done during week 9.



Figure 1. (Left) Portable PUMA system for Partial Body Weight Support in an Enriched Environment; **(Right)** Close up photo of the harness attachment and portable frame components.

Equipment: Each child will be introduced to an 81 square foot play environment with dynamic enrichment (PEDE). The PEDE will consist of a **Portable Mobility Aid for Children (PUMA) system and a PBWS harness** that offers 1, 2, 4, or 8 lb counterweighting (Enliten, Newark, DE, USA, images of the system at <https://www.enlitenllc.com/puma.html>) as well as toys and toy placement that facilitates upright exploration. A **standardized set of toys and equipment** will be used at each site for consistency. The **PEDE** will be set up over bi-colored 12" x 12" interlocking floor tiles to provide a firm yet padded play surface and also allow for straightforward measurement of movement trajectories across the play space. Standardized toys will include but not be limited to a set of four nesting benches, a crawl-in play cube, a manipulative activity cube that can be accessed in seated or standing positions, cause and effect toys, and sensory play items such as a Montessori Busy Board. (See Appendix B for photos of proposed standardized toys).

In the control condition, children will be placed in the PEDE but not attached to the PUMA or harness. In the experimental condition, children will be placed in the harness and attached to the PUMA, which acts as a partial body weight support. In both conditions, the children will be placed in sitting initially, and though the researchers will encourage the children to stand through placement of toys and verbal/visual cues, position changes will not be imposed by researchers or caregivers. While in the PEDE, children will play for up to 30 minutes within a 60-minute appointment. Children will be given breaks as needed based on the following criteria: the child cannot be redirected, distracted, or calmed by parent/researcher for more than 1 min with repeated attempts to engage/distract; the child falls asleep; there is a safety concern or harness slippage; or the parent requests a break for their child. Once a child reaches 30 minutes of exposure to the PEDE or the 60-minute appointment time ends, the child's intervention session will end for the day. The amount of time in the harness and PUMA system will be documented at each study visit.

Dependent Measures:

Aim 1: Explore the effects of a harness-based intervention on exploratory behavior among infants with DS

Exploratory behavior expressed as activity counts during all intervention and control play sessions will be measured using **wrist and ankle mounted accelerometers (Actigraph GT3X+)**. These passive sensors will be placed on the child's right-side wrist and ankle and covered with wrist bands. The sensors will be

set to capture data in 1 second epochs. 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 binary. (See Appendix A for a detailed description of the behavioral coding scheme). 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.

Aim 2: Explore the effects of a harness-based intervention on gross motor skill acquisition among infants with DS

Standardized study assessments will occur at the initial study session, during week 5 (midpoint), and during week 9 (post-test). The **Gross Motor Function Measure-88 (GMFM)** will be used to assess gross motor development. Specifically, we will use sections D (Standing), and E, (Walking, Running & Jumping). The GMFM-88 is a reliable measurement tool and is valid for children with Down syndrome. The GMFM-88 will be administered by the site investigator but will be scored by a single, blinded, trained assessor via video recording.

Aim 3: Explore the effects of a harness-based intervention on parent-reported mastery motivation among infants with DS

Mastery motivation will be measured via parent report using the **Revised Dimensions of Mastery Questionnaire (DMQ-18) Infant version**. The DMQ-18 has one general competence scale and six mastery motivation scales including: cognitive/object persistence, gross motor persistence, social persistence with adults, social persistence with children/peers, mastery pleasure, and negative reactions to challenge in mastery situations. The test-retest reliability of parent ratings of children with typical development and cerebral palsy is good. The DMQ has been validated for children with DS.