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

University of Washington
Consent form
Up and Down: Use of a Dynamic Partial Body Weight Support Play Environment to Encourage Upright Mobility and Exploration in Infants with Down Syndrome

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We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

Study Purpose

To explore the effects of Partial Body Weight Support (PBWS) within an enriched play environment for infants with Down Syndrome (DS), who are not yet walking, to better understand how PWBS may impact their mobility; exploration; and overall activity level.

Study Materials and Procedures

You and your child will come to our research lab in the CHDD for 9 weeks. The procedures will take place within our portable play area, which includes toys and a partial body weight mobile harness system to assist your child in moving and exploring safely within the play area. See figure (1). Your child will always play and explore in this same area during the study but sometimes they will wear the PBWS harness and sometimes they will not wear the harness. During the intervention play sessions, your child will have the harness on. During the control play sessions, your child will play in the play area without the harness on. Your child will participate in the intervention play sessions (using the harness) for 3 weeks, and in the control play sessions for 3 weeks. Before the first visit, we will decide at random which group (intervention or control) your child will start with. Your child will switch groups after week 5 of the study.

Figure (1) Partial Body Weight Mobile Harness System and Play Area

- Week 1: assessment week, single session for 1 hour. At this first session, we will do a developmental test on your child to see how they move around. This test will be videotaped. We will also ask you to fill out a survey which asks you questions about the motivation of your child and how your child learns and plays.
- Week 2-4: play sessions, three times/week for one hour each. At each play session, we will videotape your child playing and also place a small activity monitor on one wrist and one ankle. The session will end when your child has played in the play area for 30 minutes or your child has been present for 60 minutes, whichever comes first.
- Week 5: assessment week, single session for 1 hour. The tests and surveys from the first week will be repeated. Your child will then switch groups to or from the intervention group or the control group.
- Weeks 6-8: play sessions, 3 times/week for one hour each. Your child will participate in the same activities as described above but in the opposite group in which you began.
- Week 9: assessment single session for 1 hour. The tests and surveys from week 1 and week 5 will be repeated a final time. The study will be over after this visit.

During all play and testing sessions, your child will be given breaks as needed or if you request one. You will be able to play and interact with your child as you usually do throughout the play session and will be present in the play area with your child at all times.

Risks, stress, or discomfort

There is some potential risk for physical injury when using the harness, though this is low. This study is designed to minimize known physical risks. All research team members who will lead intervention sessions are trained pediatric physical therapists who interact routinely with these types of support technologies for children with disabilities. Further, the session will stop if there is a safety concern, harness slippage is noted, or the child becomes upset and cannot be re-directed. There is a risk of loss of confidentiality if someone outside the study team got access to your family's information.

Your Benefits from this Study

A direct benefit to you and your child will be to receive play sessions geared to promote mobility and exploration and led by pediatric physical therapists. You will also receive education and trial use of a partial-body weight support harness to support play and mobility. This research will also benefit other people by sharing gained knowledge about your child's experiences with this device.

Research Funding

The researcher for this study Heather Feldner is receiving payment from the Academy of Pediatric Physical therapy (APTA Pediatrics).

Privacy and Confidentiality

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The researchers will do their best to keep the study information private and confidential. We will label your research information with a study number and assign you a false name in written transcripts. We will keep any information that might identify you separate from the research information in a secure location. Video recordings will also be included in this study to score the mobility behavior and developmental test. You and your child's image may be recognizable on the video recording. Video recordings of the developmental test will be deleted after scoring is completed. Videos of mobility behaviors will be kept and may be used in educational or scientific presentations or publications. The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

Although we will protect your confidentiality, if we learn of or suspect child abuse, we are obligated to report that to authorities.

Using your Data in Future Research

The information and/or specimens that we obtain from you for this clinical trial might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether we need to get additional permission from you.

Leaving the Study

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form. Research staff may tell you not to continue the study if the study activities are causing you stress. If you leave the study, the research team will keep and use data that has already been collected, unless you ask in writing to remove this data.

Costs to You

There are no costs to you to participate in this study other than your time. Parking expenses to come to the research lab at UW will be reimbursed.

Compensation to You

You may receive a total of $50.00 Tango gift cards, which can be used at a variety of retail stores. The first $25 card will be given to you during week 5 of the study, and the second $25 is after the study completion. Gift cards will be delivered electronically immediately following each study milestone. In order to receive the gift card, you will need to provide some personal information to the research team. Your child will receive a small, age-appropriate toy upon completion of the study.

In case of Injury/harm

If you think your child has been harmed from being in this research, promptly contact the primary research investigator, Heather A. Feldner, e-mail: hfeldner@uw.edu, daytime telephone number: 847-630-6993 (cell) 206-543-3721 (office). Dr. Feldner will refer you to resources for support or treatment.

The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Participant Rights

Being in this study is voluntary. You and your child do not have to be in this study if you do not want to.

- You have the right to change your mind and leave the study at any time without giving any reason. Nothing bad will happen if you leave the study.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent and permission form to keep for your records.
- You do not lose any of your legal rights by giving your consent and permission to be in the study.

Consent Presenter Statement

I have provided this participant and/or their legally authorized representative (LAR) with information about this study. The participant/LAR has been given sufficient time to consider participation and I have answered any questions they had. The participant and/or their LAR indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of study staff obtaining consent Date

Participant's statement

This study has been explained to me. I volunteer for myself and my child to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I or my child have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

_____

Printed name of participant

_____

Participant signature Date

If the participant is unable to sign:

_____

Printed name of the witness Signature of the witness Date

Copies to:

- Researcher
- Participant/ parent