



Safe Toddlles

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Research Study: Investigation of the Use of Pediatric Belt Canes with Young Children with who are blind or mobility visually impaired

Principal Investigator: Grace Ambrose-Zaken, Ed.D., COMS
Research Director

Research Sponsor: Safe Toddlles

You are being asked to participate in a research study because you have self-identified as having a child diagnosed with a vision impairment resulting in mobility visual impairment or blindness (MVI/B).

The purpose of this research study is to evaluate families of children with visual impairments use of the Pediatric Belt Cane with the child with MVI/B. We will be asking these families to provide us with video documentation about their experiences before and after introducing the Pediatric Belt Cane.

This consent document is being sought for research and your participation is voluntary. The purposes of the research is to observe and measure children's outcomes before and after introducing the Pediatric Belt Cane to children with MVI/B. Your participation is expected to be for three months, during which time you will be asked to respond to emails about your experiences and provide videos of your child engaged in play and walking activities.

Participants may experience minimal risks or discomforts through participation, the most likely is the discomfort of adopting a new tool into daily activities.

Participants may experience benefits of participation by seeing gains in independent walking, self-confidence, improved concept, language and social skills when your child is encouraged to consistently wear of the Pediatric Belt Cane during recommended daily physical activity time.

Participants are encouraged to continue with all therapies and other activities used to encourage age-appropriate independent walking and play.

Procedures:

Families are being asked to participate by providing regular feedback and weekly videos for three months. If you volunteer to participate in this research study, we will ask you to do the following:

Getting started:

- Families will be asked to sign this informed consent document.
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- Families will provide the correct size of the child.

Project activities:

- The families will be asked to have their children wear the Pediatric Belt Cane every day with increasing time each day, per recommended daily physical activity for their child.
- Families will be asked to send email feedback about their child’s progress.
- Families are encouraged to seek project support when any difficulty using the Belt Cane.
- Families will be asked to submit approximately 3 minutes of smart phone videos of their children engaged in those walking and play activities each week wearing Belt Cane.
- If the child begins to use a different mobility tool. Families are asked to submit videos of their child using that mobility tool to demonstrate the transition away from needing to wear their tool (super important 😊)

Video Recording:

We are collecting family created video recordings of the motor and play activities for three months. These are essential for analyzing your child’s response to wearing the Pediatric Belt Cane. You cannot participate in this study if you do not consent to submitting video recordings.

Time Commitment:

Your participation in this research study is expected to last for a total of three months.

Potential Risks or Discomforts:

Activity	Discomfort/risk
Attaching the pediatric cane frame to the belt using the built-in magnetic clips.	Some discomfort may be encountered with introducing the frame for the first time, learning to connect and disconnect it correctly might cause performance stress.

Potential Benefits:

Wearing pediatric belt canes provides an almost immediate benefit to young children who are severely visually impaired and blind, as it provides them with essential information about the path ahead. Toddlers who are blind are better able to balance and stand quietly without holding on to furniture or people. The benefits include reduced stress, anxiety and fear of independent ambulation. Improved motor skills (gait, pace) reduced tactile defensiveness, increased concepts, improved language, and social skills.

The addition of this new easy to use safe mobility tool for young blind and severely visually impaired children will provide teachers and families with an effective means to improve developmental outcomes for young children born blind and severely visually impaired.

Alternatives to Participation:

Alternative mobility tools can be tried with your child instead of participation in this project. These include hand-held mobility tools such as human guide, push toys, rectangular cane, rod canes. As these are not effective alternatives for children younger than three or who are not walking well above the age of three, we are hoping videos of these attempts will also be provided. All participants always have the option not to participate in this study.

Payment for Participation:

Participants will receive a free Pediatric Belt Cane, free access to the Fast Forward curriculum and on-going project support in using the Belt Cane, as needed.

New Information:

You will be notified about any new information regarding this study that may affect your willingness to participate in a timely manner.

Confidentiality:

We will make our best efforts to maintain confidentiality of any information that is collected during this research study, and that can identify you. We will disclose this information only with your permission or as required by law. We may be using part or all the videos on social media platforms and in our curriculum for the purposes of educating parents and professionals working with learners who are blind or mobility visually impaired.

We will protect your confidentiality by keeping all recordings on a password protected computer. The computer will be housed in the project office behind a locked door with restricted access.

The research team authorized Safe Toddles staff, and government agencies that oversee this type of research may have access to research data and records to monitor the research. Research records provided to authorized, non-Safe Toddles individuals will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Participants' Rights:

- Your participation in this research study is entirely **voluntary**. If you decide not to participate, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.
- You can decide to withdraw your consent and stop participating in the research at any time, without any penalty.

Questions, Comments or Concerns:

If you have any questions, comments, or concerns about the research, you can talk to one of the following researchers:

- Grace Ambrose-Zaken, O&M instructor, project leader 845-244-6600

Participant Signature for Audio/Video Recording

If you agree to video recording, please indicate this below.

_____ I agree to video recording

_____ I do not agree to video recording and do not wish to Participate.

Signature of Participant:

If you agree to participate in this research study, please sign and date below. You will be given a copy of this consent form to keep.

Printed Name of Participant

Signature of Participant

Date

Signature of Individual Obtaining Consent

Printed Name of Individual Obtaining Consent

Signature of Individual Obtaining Consent

Date