STUDY PROTOCOL & ANALYSIS PLAN

Protocol Title: A Novel Parent Education Program for Early Intervention
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PURPOSE

The purpose of this pilot clinical trial is to determine whether parent education impacts daily parent-infant handling and positioning activity or infants' developmental outcomes.

PARTICIPANTS

We will enroll twenty participants 1-5-months-old who are not yet rolling and are of any gender. To be included, infants and their parents must be able to safely and independently engage in the data collection activities and be available for data collections. Infants with medical equipment that restricts movement or positioning will not be included. Infants who are blind will also be excluded. Participants will be recruited via advertisement in the local community.

Participation in the study is voluntary and there is no compensation for participation. During the first contact made with potential participants, written information explaining the study will be provided that details in simple terms, a) criteria for participation, b) purpose of the research and procedures involved, c) right to withdraw at any time without penalty of any kind, and d) assurance of confidentiality (via number ID representation vs. name). If the individual meets the criteria for participation and is interested, the information just described will be reviewed, questions will be answered and an informed consent form will be signed in the presence of a witness. Parents of the participants will be reminded by the researcher that this signature does not bind them to participate and that they are free to withdraw at any time.

PROCEDURES

This study will involve 3 data collections that occur in the home. Informed consent will be obtained prior to the first data collection. Parents will be provided the opportunity to read the consent form, the contents will be reviewed with the family, and any questions or concerns will be discussed prior to obtaining consent.

After families consent, they will be asked to complete a Health & Demographic Form. Based on the information in this form, infants will be assigned to one of 4 risk categories: No health or socioeconomic risk; Only health risk; Only socioeconomic risk; or Health *and* socioeconomic risk. Health risk will include infants who were born very preterm, infants who had a documented neurologic or respiratory problem at birth, and infants who spent more than 1 week in the neonatal intensive care unit after birth. Socioeconomic risk will include infants whose families report combined income levels below poverty level or report middle or high school completion as the highest level of parental education. Blocked random assignment will then be performed within risk categories so that infants are assigned to the Milestone Education Group or the Positioning Education Group.

The total time commitment for participants in this study involves three data collections 30-75 minutes in duration; the baseline data collection happens at the time families enroll with infants at 1-5 months of age and the second data collection happens one month later. Families will also be asked to allow researchers to contact them monthly to collect milestone attainment data through the time infants begin walking independently (typically occurs between 10 and 18 months of age). The final data collection will happen when infants are between 16 and 24 months of age.

The first data collection will begin with infants donning the Get Around Garment, a smart garment that collects valid, reliable data about the position of infants (i.e., supine, reclined, upright, inclined, or prone). Then, the data collection will consist of: 1) one 2.5-minute *Structured Play Assessment* during which the infant will be placed by the experimenter for 15-30 seconds into each of the following 5 positions: supine, prone, inclined about 45 degrees from upright, reclined about 45 degrees from upright, and seated upright; 2) one 60 minute *Free Play Assessment* during which parents will be encouraged to go about their typical daily activities as if the experimenter were not there; and 3) a second 2.5-minute *Structured Play Assessment.* Accelerometer data from the garment will be collected simultaneously with video data throughout these assessments. Accelerometer data will be saved on a memory card or transmitted to a research computer via Wi-Fi. The entire visit will be video recorded. By comparing data from the garment and the video throughout the entire visit within each infant, we can determine whether the garment provides valid position data throughout the wearing session. The garment will be left with families, and they will be asked to have their infants wear t for 2 days during awake periods when with an adult but not during periods of sleep or periods without supervision. Families will be asked to log the times the sensor belt was worn and infants' general activity. Sensor data will be stored so we can better understand infants' activity across a typical 2-day period. We will leave 2 garments just in case one gets dirty. We will inform families they can wash the garments as they would typical clothing except that they should first remove the sensor unit. Note that garments that are in good condition (no stains) may be re-used for other babies after we wash them. After the 2-day period, the researchers will collect the garment from the family, will collect the Sensor Wearing Log and ensure the data on the log are complete and correct, and will ask parents to complete the Garment Perception Survey. They will also assess infants using the Alberta Infant Motor Scale and the Bayley Scales of Infant Development III to show their developmental abilities at the start of the study.

After the first data collection, parents will receive education in relation to their group assignment. The written information will be sealed in envelopes to ensure the assessor remains masked to group assignment. Participants will be reminded at each data collection not to discuss their group assignment of activities with the masked assessor. The Milestone Education Group will receive written information regarding developmental milestones expected based on the age of their infant. This information will be based on data from the Centers for Disease Control and Prevention (https://www.cdc.gov/ncbddd/actearly/milestones/index.html) and The American Academy of Pediatrics (www.healthychildren.org). This type of education will help parents understand the milestones that are typically observed at the their child's age and reflects the typical education parents receive. The Positioning & Play Education Group will receive written information regarding handling, positioning, and play activities they can engage in with their infants. These activities aim to provide infants safe opportunities to explore new ways of moving and controlling their bodies and interacting with objects to learn about their bodies and objects around them. These activities are safe and have been shown to advance development for typically developing infants when compared to a social control group that only involved parents talking to babies. The activities have not been tested in comparison to Milestone Education, which represents business as usual care. In addition, no one has previously been able to measure the impact of this type of education on everyday positioning practices by caregivers. The Get Around Garment will allow us to do that. Parents in both groups will be asked to provide their infants with opportunities to engage in the behaviors they have received education on for 20 minutes daily across 1 month. Parents will be informed that missing some days is acceptable

but they should try to engage in the activities as many days as possible. Parents will be asked to log their activities.

The second data collection will occur after a 4-week period of requested daily activity engagement according to the education received. The researchers will collect the Activity Logs and ensure data on them is complete and correct. Then the researchers will repeat all procedures from the first data collection, as described above, including a second, 2-day wearing period for the garment. Parents will be informed that daily activity engagement is no longer expected. At this data collection, parents will be taught how to keep track of their infant's milestones using the Milestone Checklist. The research team will contact families monthly through the onset of walking (typically between 10-18 months of age) to gather information about infants' performance on this checklist.

The third and final data collection will serve as a follow-up visit when infants are 16-24 months of age. Infants will be assessed using the Alberta Infant Motor Scale to show how their developmental abilities have changed since the start of the study and whether there are differences between the two education groups. Parents will be asked to complete the Dimensions of Mastery Questionnaire (DMQ 18) to evaluate each child's intrinsic motivation to move and explore so we can determine if and how this relates to our early measures of development and interaction.

RISKS AND BENEFITS

The risks associated with participation in this study are minimal. The assessment procedures are safe, and are similar to movement and play activities experienced by infants on a regular basis. The measurements are non-invasive, play- or functionally-based, and have been used in past research with infants.

There is a risk that participants may experience fatigue or be upset during the visits. If the infant cries or shows facial expressions suggesting fatigue or upset, we will take a break from the activities. We will not continue again until the infant has his/her needs met (sleeping, eating, diaper changing, etc) and appears happy and eager to join the testing again based on his/her affect and facial expressions. We will reschedule for another time if that better meets the infant's and family's needs.

The garment could be uncomfortable for infants. The sensor unit could rub the infant's skin. The garment has been designed with the sensor unit on the lateral aspect of the infant's trunk since infants do not typically place weight on this part of their body before they begin rolling over. Infants will not be enrolled in the study if they are already rolling. In addition, the sensor unit is quite small (2.44" long x 1.47" wide x 0.7" thick) so should not interfere with parents carrying infants. Researchers will check and parents will be asked to check infants' skin for redness after removing the garment. If we note irritation or redness that lasts more than 20 minutes, we will work on better fitting the garment and sensor. If the problem persists for an infant, we will discontinue that aspect of the experiment for that infant.

The sensor unit is made of small parts and uses a low level battery for energy supply. These parts could cause a choking risk if exposed. The garment is designed so that the sensor unit is secured within a 3D printed case, which is housed within a snug fabric enclosure to avoid small parts of the sensor unit from breaking off. As an added precaution, the garment will be used under the supervision of researchers or under the advised supervision of parents in the home.

Infants and parents may benefit from receiving education on development and learning the results of infants' developmental assessments.

Early handling, positioning, and play activities have been linked to future motor and cognitive abilities. It is helpful to understand the ways infants and parents are engaging in early movement activities and

how we can change those practices to positively impact development, especially for infants with health or socio-economic risks.

DATA ANALYSIS PLAN

All assessments and data coding will be conducted by trained experimenters masked to group assignment. Coders will be trained to ensure they are reliable before conducting official data coding. 20% of all data will be recoded to ensure high levels of intra- and inter-rater reliability are maintained. Double data entry will be conducted where applicable.

Primary outcome: To determine whether the change in AIMS score from Visit 1 to 2 differs between the two education groups, Wilcoxon tests will be performed for intra-group, Mann-Whitney for inter-group comparisons, with Bonferroni corrections.

Secondary outcomes:
To determine whether changes in parent-child interaction behavior or positioning practices (sensor data) differ from Visit 1 to 2 between the two education groups, Wilcoxon tests will be performed for intra-group, Mann-Whitney for inter-group comparisons, with Bonferroni corrections.