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Otteroo Case Series
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Protocol

Significance and justification for use

The goal of this project is to measure overall developmental status before and after Otteroo experience in pre-locomotor infants and young children for whom a healthcare provider or caregiver has identified concerns about potential developmental delay. We are proposing that the Otteroo may be a good "tool" to facilitate early movement and exploration of the ability to move and control one's body. The Otteroo is a widely-available commercial floatie marketed to families as "a floatie for babies ages 8 weeks +" (https://otteroo.com/).

The Otteroo is a floatie which supports an infant or young child with their head above and their body in water. The Otteroo allows them to move around in water under direct caregiver supervision and within arm's reach without the need for the caregiver to physically support the infant or child. As water provides a reduced-gravity environment, it allows infants and young children an opportunity to explore their ability to move and control their bodies more easily than when they are in a 'typical gravity' environment. Research has shown that infants are initially able to move their limbs against gravity in a stepping pattern, then go through a period of rapid weight gain that is not matched by a concurrent strength gain, and thus 'lose' the ability to step against gravity as they are not strong enough to lift their heavier limbs. Supporting them in water, however, allows them to perform stepping movements during the period when they otherwise would not be strong enough (1). While typically-developing infants move through this developmental progression, infants with motor delays can get 'stuck' in this period. As a result of their difficulty moving, they continue to physically grow but may not gain the requisite strength and may not optimally explore their ability to move and control their bodies during this foundational early developmental period (2). Children with developmental delays and disabilities are often recommended to participate in aquatic therapy to supplement clinic, early intervention, or school-based physical therapy or occupational therapy. One study with 37 children ages 6-30 months found that the aquatic therapy plus standard early intervention group demonstrated significantly greater gains in functional mobility than the comparison group of children who received standard early intervention only (3). Further, aquatic therapy has been explored as a useful intervention in clinically stable newborns of gestational age less than 36 weeks who were hospitalized in a neonatal intensive care unit (4). We propose that using the Otteroo to allow movement practice in a reduced-gravity environment will allows infants to perform leg movements they otherwise would not be strong enough to perform, and this increased exploration and movement practice may have a positive impact on their development.

Approach

A pilot study sample of up to 4 infants/young children will participate. A single-subject research design will be used: measures of infant development will be collected across a 4-week baseline period (standard care), 4 weeks of intervention (standard care and Otteroo use), and 4 weeks of reversal/retention period (standard care).

Inclusion Criteria: Infants and young children who are pre-locomotor and for whom a healthcare provider or caregiver has identified concerns about potential developmental delay (see appendix 1).

Exclusion Criteria: Infants younger than 8 weeks of age or with body weight of more than 35 lbs will be excluded per the specifications of use of the Otteroo floatie. Children who are able to locomote independently more than 4 feet will be excluded as prelocomotor infants and young children are the target. Children older than 66 months of age will be excluded do to restrictions of the Ages and Stages measurement tool. Infants or children with a diagnosis of Down syndrome or with a clinical presentation of ligamentous laxity will be excluded due to concerns about atlanto-axial instability. Infant or children without access to an appropriate water source (bathtub or pool depending on the size of the child) will be excluded. Infants or children with prior experience using Otteroo will be excluded.

Participant Recruitment:

The infants will be recruited using fliers distributed at Starfish Therapies, an early intervention therapy provider in San Mateo, CA. Starfish therapies may give handouts to potential participants they identify through looking at their own clinic's medical records or by looking at their own clinic logs. They are a pediatric clinic with 6 physical therapists, and see approximately 10 patients per week who meet our inclusion criteria. The caregivers will be asked to contact the research staff by phone or email for further information about the research study, including discussion of the exclusion criteria. When caregivers contact the research staff, the staff will give more specific information about the study and answer any questions. If the caregivers choose to participate after the initial contact, a written consent form will be provided to them. This will allow them to discuss their participation with others before signing the written consent. A parental consent form will be signed by a parent or legal guardian at the first visit, before any study procedures occur.

Procedures: Visits will take place at Starfish Therapies and last approximately 30 minutes.

At the first visit (week 0), the researcher will measure the participant's weight, overall development, and motor development. The researcher will assess and quantify motor development by administering the Alberta Infant Motor Scale, a standardized, norm-referenced observational scale of motor development (5). The researchers will assess and quantify overall development using the Ages and Stages Questionnaire,

a standardized, norm-referenced caregiver-report scale of development (6). This is standard of care.

At the second visit, after a 4-week baseline period (week 4), the researcher will measure the participant's weight and administer the Alberta Infant Motor Scale and the Ages and Stages Questionnaire. This is standard of care. The researcher will provide an Otteroo floatie to the family, along with an activity log to track it use. Caregivers will report date of use, duration of use, activities performed, and child's response. The researcher will refer the family to the Otteroo website for some ideas of potential activities, as well as discuss and determine potential activities with the family. The researcher and family will use the Canadian Occupational Performance Measure (7), a standardized method for setting an individual goal, to set a goal relating to Otteroo use. The researcher will document therapy services received, and briefly describe the amount and type of any therapy received. This is for research purposes.

After 4 weeks of Otteroo use (week 8), the researcher will collect the Alberta Infant Motor Scale, the Ages and Stages Questionnaire (all standard of care), and the Canadian Occupational Performance Measure (research purposes). The researcher will collect the activity log (research purposes). The researcher will document therapy services received, and briefly describe the amount and type of any therapy received (research purposes). The family will answer survey questions about their experience with Otteroo (research purposes). The family will keep the Otteroo floatie.

After 4 weeks of reversal/retention period (week 12), the researcher will administer the Alberta Infant Motor Scale and the Ages and Stages Questionnaire. This is standard of care.

Data Analysis. We will calculate descriptive statistics (mean, range, coefficient of variation) for all measures and describe the participants over time. The Alberta Infant Motor Scale is the primary outcome. We will relate the participant's performance at each time point to norm-referenced results for their age. We will compare rate of change of Alberta Infant Motor Scale between weeks 0 and 4, 4 and 8, and 8 and 12. The Canadian Occupational Performance Measure is a secondary outcome measure, and we will report whether or not goals are met between weeks 4 and 8.

Potential risks

The infant or young child may become distressed during data collection or Otteroo use. The caregiver may stop any activity at any time and soothe the infant or child.

There is a small risk that the Otteroo will deflate while the child is using it (due to leaks or seams breaking), and being in water carries risk of drowning. The caregiver must directly supervise and be within arm's reach of the child while he or she uses the floatie. If it starts to deflate, the caregiver has been instructed in the consent form to stop using it and re-inflate it before resuming use. If it deflates again, we will replace it.

Protections

Loss of confidentiality will be minimized by identifying all research data with the participant's study identification number, and allowing only those authorized to have access to the data. REDCap, a university supported, secure data collection and storage site will be used for collecting and storing the participant's randomly generated study identification code number and identifying information and health information. All other files will be identified by code numbers only, not by name or by any other information which might identify the parent or participant. All data will be on secured, password protected, backed up USC servers at all times.

References

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