IMMEDIATE EFFECTS OF EARLY ENVIRONMENTAL ENRICHMENT ON INFANT MOTOR BEHAVIOR THROUGH THE USE OF AN OPEN-AREA BODY-WEIGHT SUPPORT SYSTEM

by

Elena Kokkoni

A dissertation submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Biomechanics and Movement Science

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Approved: ____
Samuel C.K. Lee, PT, MPT, Ph.D.
Director of the Biomechanics & Movement Science Program

Approved: ____
Kathleen S. Matt, Ph.D.
Dean of the College of Health Sciences

Approved: ____
Ann L. Ardis, Ph.D.
Senior Vice Provost for Graduate and Professional Education

I certify that I have read this dissertation and that in my opinion it meets the academic and professional standard required by the University as a dissertation for the degree of Doctor of Philosophy.

Signed: ____

James (Cole) Galloway, Ph.D., FAPTA
Professor in charge of dissertation

I certify that I have read this dissertation and that in my opinion it meets the academic and professional standard required by the University as a dissertation for the degree of Doctor of Philosophy.

Signed: ____

Darcy S. Reisman, PT, Ph.D.
Member of dissertation committee

I certify that I have read this dissertation and that in my opinion it meets the academic and professional standard required by the University as a dissertation for the degree of Doctor of Philosophy.

Signed: ____

Samuel C.K. Lee, PT, MPT, Ph.D.
Member of dissertation committee

I certify that I have read this dissertation and that in my opinion it meets the academic and professional standard required by the University as a dissertation for the degree of Doctor of Philosophy.

Signed: ____

Anna Y. Klintsova, Ph.D.
Member of dissertation committee

I certify that I have read this dissertation and that in my opinion it meets the academic and professional standard required by the University as a dissertation for the degree of Doctor of Philosophy.

Signed: ____

Jennifer M. Buckley, Ph.D.
Member of dissertation committee

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TABLE OF CONTENTS

Appendix

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Exposure to an Enriched Environment (EE) that involves various levels of motor, sensory, and cognitive stimulation has been shown to enhance neuroplasticity, memory function, and motor ability in animals.[1–4] Neurobehavioral research has demonstrated the capacity of the developing human brain to adjust to environmental changes,[5,6] and has emphasized the positive role of early experiences on development.[7,8] Despite the apparent link between EE exposure, experiences, and development, EE paradigms have not been adequately applied in human studies. Thus, the effect of such exposure on the motor behavior and learning of infants is still not well studied. Especially for an atypical population, like that of infants diagnosed with Down syndrome (DS), incorporating EE exposure in their early interventions may be critical for advancing their development.

Infants with DS achieve their motor milestones significantly later than their typically developing (TD) peers,[9–11] and their immobility lessens the opportunities for forming early experiences, which in turn may affect early brain changes[12] as well as perception, cognition, and language development.[13,14] One common intervention approach to address immobility involves body weight supported treadmill (BWSTT) training.[15–17] BWSTT does not typically include an EE.

The focus of this dissertation work was to bridge EE exposure and body weight support devices. More specifically, this project was an initial attempt to combine an EE paradigm and an innovative “open-area body weight support system” (BWSS) to enhance motor behaviors beyond an infant’s current level of ability. The feasibility and short-term effects of this new paradigm application in non-walking TD and infants with DS was assessed. Aims 1 and 2 were directed toward the evaluation of the immediate change in performance of TD infants in and out of the BWSS in the lab EE. Aim 3 explored the change in the performance of infants with DS in and out of the BWSS in the lab EE. Aim 4 assessed the feasibility of the paradigm in the home and evaluated the new paradigm from the family’s point of view. The latter is important since the future goal is to move beyond the lab and into the community including the home (aka Harness House).

The results suggest this paradigm is feasible for application in both populations in the lab and potentially in home settings. All infants and their families successfully completed the study and happily participated in every session. Effects on certain tasks were observed in and out of the BWSS even within one session emphasizing the capability of young infants to rapidly adapt to changes in the environment. In addition, effects were observed after the short-term exposure when infants were out of the BWSS. These short-term effects were more evident for the TD infants than the infants with DS.

Three factors are discussed which, in part, may explain the capacity of infants to display rapid changes in the EE: 1) infants’ current level of ability, 2) infants’ previous experiences, and 3) the level of complexity the task imposes. More formal group studies are required to further describe the impact of these and other factors on infants’ behavior within the EE.

This study improved our understanding of infants' performance in EEs and how BWS can be used to enhance their performance. Next steps include a) the long-term application with a much larger sample of infants, b) the examination of the effect that this paradigm may have on the onset of motor skills, and c) the testing of this paradigm on other populations that present mobility delays.

Chapter 1

BACKGROUND AND SIGNIFICANCE

1.1 Motor Development of Infants With and Without Down Syndrome

The transformation from a limited movement repertoire early in life to the sophisticated control of complex behaviors of a toddler is visible and dramatic.[18] During the first four months, typically developing (TD) infants explore themselves and their nearest environments in supine and prone.[19] In parallel, they learn how to control their head, which is essential for the transition to the first vertical posture, supported sitting, that emerges at around four months of age. Eventually, infants learn to control and coordinate the different segments of the upper body, head, trunk, and pelvis, and acquire independent sitting at around seven months.[20] Infants then learn to stand -- a very challenging posture that requires even more effort as they learn to coordinate their whole body with respect to gravity -- while they progress from stationary to mobile through actions like crawling, climbing, and finally walking typically by 15 months of age.[21,22]

This general developmental pattern emerges from a complex, individualized learning process and is not nearly as rigid in timing or sequence as once believed (see more detail in section 1.2). And for certain infants, such as those diagnosed with Down syndrome (DS), this process may be even more challenging, as shown by the markedly different general rate of displaying the aforementioned key behaviors.

The most striking different with young children with DS is the increasing delay in the emergence of the so called "motor" milestones.[9–11,23] On average, infants with DS sit four months later, they pull themselves to standing position nine months later, and they need almost double the time of a typical infant to being able to stand and walk independently.[23] In fact, 40% of infants with DS do not walk independently (defined as taking 3 consecutive steps) by 24 months of age.[11] These delays are particularly disturbing as they are thought to be related to delays in other domains, such as the emotional, social, cognitive, and language.[24]

1.2 A Multi-factorial Approach to Motor Development

Historically, the emergence of infant motor behaviors was thought to reflect brain maturation processes in isolation. Maturational theory grew out of neurobehavioral animal studies, such as Coghill's classic work with salamanders who associated changes in movement patterns to growth of certain parts of the nervous system as seen in histological samples.[25,26] The observed cephalocaudal pattern in the expansion and progression of motor behaviors was attributed to the connections of motor neurons developed in the associated body parts which followed the same temporal direction.[25,26] Inspired by Coghill's work, Gesell and McGraw were early pioneers in the study of the development of infants. Likewise, they related behavioral changes in posture and mobility to isolated neural maturation.[27,28] This theory and the data supporting it were ground-breaking at the time. Modern theories, such as the dynamical systems theory, include brain maturation as one factor along with other factors within the body and extended environment.

Thelen and colleagues introduced, through a series of experiments, a more dynamic, non-linear, and multiple-factor approach to the study of development.[18,29–33] This approach simultaneously challenged the exclusive explanation of neuro-maturational progression and placed movement within environments as a critical set of causal factors in developmental change. In one experiment, Galloway and Thelen (2004) followed non-reaching infants (starting at 8-15 weeks of age) longitudinally up to the point they became consistent in grasping. Every week, infants were tested on reaching for objects that were presented separately at their shoulder and hip height while straddled in an inclined position. Infants' first object contact and the emergence of consistent contacts were both with their feet, and preceded the ones from the hands by four weeks. In addition, contact time with the feet was larger than that of the hands for every week, up to the onset of consistent grasping. The same effect was evident even if the toy was presented in the usual area of infants' limb movement (and not in midline), in a standardized toy-to-limb distance (4 inches), within a single session, as the same researchers found in another experiment.[34] The above results demonstrated that voluntary control of legs was present earlier, and in clear violation of a rigid cephalocaudal rule.[34]

But how could the earlier observed behavior of legs be explained? They proposed that body anatomy and resulting biomechanics contributed to the differences in the earlier emergence of feet reaching. Specifically, the different anatomy of the respective limb joint and the muscle-to-fat ratio provide different "constraints" in the range of movement and movement against gravity, which probably affected the development of the behavior with time. The term “constraints” in this case refers to the way some factors may detain movement within a range by increasing the effort to produce it.[34] Thus, the “dynamical systems approach” purposes that infants’ observed behaviors emerge from the ongoing, non-linear interactions of constraints across a seemingly endless array of factors including biomechanical, environmental, and task-related factors.[18,32,35]

To further support this approach, Thelen’s team assessed infants’ behavior under altered biomechanical, environmental, and task-related constraints. For example, the muscle strength-to-weight ratio effect on the “disappearance” and the re-emergence of the “stepping reflex” was examined by adding weights on the legs and by placing infants in water respectively.[36] In the first experiment, 12 newborns (<1 month old) were tested with and without the weights for a minute each. The amount of weight corresponded to the gain of weight infants typically acquire later in their development. All infants showed a significant decrease in their stepping frequency when weights were added. In the second experiment, another sample of 12 newborns were tested in and out of a water tank up to the waist that decreased the weight of the legs. All infants showed a dramatic increase in their stepping frequency in water. These observations could explain the “disappearance” of the stepping pattern in infants older than one month and the re-appearance later on.[33,36,37] This behavior does not disappear, rather it is hindered by the biomechanical constraints, as infants’ muscle strength needs time to “catch up” the rapid leg mass gain. However, when environmental constraints are altered (i.e. placed in water), a self-initiated change in the specific task (i.e. stepping) is observed. The above results suggest that infants have the ability to adapt and "self-organize" given the ongoing interactions of biomechanical, environmental, and task constraints.[18,32,35] In general, the feet reaching and stepping work reminds us that multiple factors, including body mechanics, brain development and environmental forces such as gravity interact as behavior emerges.

1.3 Environmental Enrichment

The daily lives of infants constantly expose them to a variety of stable and changing biomechanical, environmental, and task constraints. These constraints shape activity-dependent plastic changes in the infants' brain as well as advance the complexity of future behaviors. Environments that induce positive brain and behavioral changes are often called 'enriched environments'.[38–40]

Much of the research into the relationship between an enriched environment (EE) and brain development comes from non-human work. Hebb (1947) first described the potential effects of EEs when he noticed that the behavior of the rats that were freely wandering in his house was different to that of rats living in his laboratory cages.[41] He argued that the free rats had the opportunity to explore a varied environment, gain experiences, and advance their problem-solving ability.[41] Later, an EE was formally defined as the one that involves " a combination of complex inanimate and social stimulation".[42] The housing setup of the EE does not include specific parameters or static features. In fact, EEs have the opposite features -- conditions that include high levels of complexity and variability. For example, EEs contain platforms, tunnels and toys, which are typically changed every few days to introduce new challenges, require active memory, and promote learning.[40,43,44]

Translating EE paradigms for human work has been less studied, yet is of significant interest to our lab. The first EE-related studies, similarly to Hebb's first method, examined the detrimental impact of 'under-enrichment' of institutionalized environments and orphanages. These environments are now notoriously associated with delayed and impaired behaviors including walking, social and cognitive delays.[45]

More recently, studies of enrichment for infants raised in typical and atypical environments focused broadly on motor, cognitive, and social outcomes.[46–49] Not surprisingly, the results were positive at all levels. The infant brain is capable of adapting to, learning from, and ultimately controlling the environment through neurogenesis and activity-dependent mechanisms.[5–7] Along these lines, modern childcare as well as federal programs such as Head Start and Early Head Start are based, in part, on providing enrichment to children as soon as possible – especially those at economic risk.[50,51]

There is limited research focusing on the effects of EEs on the emergence specifically of 'motor' behaviors and formation of movement patterns (described previously in section 1.2) in typical and even less in atypical development. An extensive review found that the few studies of EE applications on movement of children with cerebral palsy (CP) supported EEs impact on gross motor development overall.[46] This review also highlighted a surprising lack of detailed EE descriptions and little standardization of EE paradigms across studies.[46]

Research suggests two basic factors in order for an EE to provide opportunities for meaningful behavioral change. First, the EE needs a certain level of *complexity, familiarity, and novelty*. Second, the *dosage* of experience, learning and activity during EE exploration is thought to be important.[40,44,52] These factors were important to the current study for designing the EE, choosing the tasks for the infants, and building the technology to support them moving about the EE. These factors were also important to the interpretation of the results and for planning for future studies that build upon the current study findings.

1.4 Early Intervention

1.4.1 Standard of Care

Conventional wisdom is that current "early intervention" (aka "EI" in the US, treatment for children birth to three years of age) lacks the proper type of training, the high dosage of training, and the technology necessary to impact children's long-term activities of daily living.[53–55] This is not reassuring given the above review of the factors that may significantly shape infant development.

One common goal for EI therapists is to apply a broad range of treatment activities and implementation strategies that address the different modes and rates of learning of these infants.[56] Standard of care in EI is not well known but is thought to vary widely with geographical region and even with medical providers within the same region.[57,58] That said, the oldest and most well-known formalized type of training currently in use in EI is the "neurodevelopmental treatment approach" (aka NDT).

In its most traditional form, NDT involves passive movement “facilitation” and “inhibition”, as well as infant handling and postural positioning by the therapist.[59,60] Many critics have written about the limitations of traditional NDT.[55,60–63] Two commonly discussed limitations are that NDT: 1) does not enhance self-initiated actions by the infant, as the dynamic systems approach supports, and 2) can only be applied when the therapist is present – thus at a very low dose compared to the total activity of typical infancy.[64] Even if the therapist trains the caregiver on these activities, the type and training of NDT is very likely not enough to significantly minimize the delay in the motor milestones.[59] To be clear, limited training options and low dosage are not a critique solely of NDT. These issues are active areas of discussion across both pediatric and adult rehabilitation.

With respect to technology used for training and assisting movement during EI, low-tech orthoses and assistive devices that move with the individual, such as walkers, canes, positioning devices, and crutches have been used for literally thousands of years to assist ambulation. Using these devices leads to an improvement of functional mobility for 3 out of 4 children.[65] However, children that require technology with more support simply do not community-ambulate until their motor ability improves adequately as a result of development and/or training.[66]

Although the federal legislation has been promoting the use of assistive devices, the unmet need for mobility aids has only been increasing throughout the years according to the National Survey of Children with Special Health Care Needs. The 4.7% of children with unmet need for mobility aids reported in 2004 has increased to an estimated 7.7% as reported in 2016.[67,68] Although the American Physical Therapy Association has developed guidelines on promoting professional training programs for pediatric therapists,[69] therapists may still lack the hours and expertise on the use of assistive devices. Survey studies on pediatric therapists' perception of technology knowledge and use support this statement.[70,71] For example, 33% to 59% of the respondents reported that that they don't feel adequately trained on assistive technology applications and related services (e.g. working with families regarding assistive technology, legislation and policies related to assistive technology services, etc.), whereas 7% to 18% have received no formal training on these areas.[70] It seems that there is a clear gap in the technology available as well as the use of available technology by clinicians. Mobility research studies have begun to target the aforementioned deficiencies in the standard of care by advancing the type and dosage of training, as well as the technology used in EI.

1.4.2 Research on Early Mobility

The first major mobility related intervention study for infants with DS was done by Ulrich and colleagues in 2001 and involved treadmill training.[15] The primary focus of this pioneering work was to reduce the delay of the onset of independent walking (defined as three steps). Training involved daily stepping on small motorized treadmills with physical support from their parent. Starting at an average age of ten months, just 8 minutes per day (5 days per week) of training reduced average walking onset of about three months, thus achieving an average walking onset at around 20 months of age.[14–16]

Ulrich's next series of studies built on this evidence and aimed to further explore the effects of treadmill training towards maximization of walking performance.[15–17,72,73]

For example, infants that received treadmill training presented better adapting strategies when walking across obstacles.[73] In another study, they examined the effects of different intensities of treadmill training on walking performance and on the acquisition of other motor milstones.[17] The first group of 14 infants received the same protocol as in the 2001 study (8min/day, 0.15m/s belt speed), and the other group of 16 received high intensity training by adding weights on the legs (up to 125% of calf mass), increasing belt speed (up to 0.30m/s), and increasing daily duration of use (up to 12 min/day). The results showed a dramatic increase in treadmill stepping throughout the study for the high intensity group as well as early raising to stand and moving forward using pre-walking methods (items 52 and 43 from the Bayley Scales of Infant Development motor subscale assessment 2nd Edition[21]).[17] However, the acquisition of all motor milestones was still delayed compared to those seen in typical development.

Treadmills and the associated training programs have been specifically designed for a single skill: walking. Thus, other technology and training are needed to address the range of other skills of infancy such as dynamic standing, pre-walking methods such as various scooting and crawling patterns, climbing, and walking over flat and inclined surfaces. Accordingly, Prosser and colleagues have questioned the application of regimented gait training focused only on stepping early on.[74] The authors argued that targeted stepping over treadmills may be useful in retraining stepping in individuals that had already learned how to walk but lost that ability, but it may not be the best for infants and toddlers learning to walk for the first time; since, it disregards developmental components such as the role of motor variability and error seen in typical motor development.[74]

To address this gap, the research team designed a novel mobility training to promote the emergence of various motor behaviors (e.g. crawling, knee walking, climbing, etc.) in a self-discovery playful environment tailored to each child's abilities. Five toddlers between 12-36 months of age with or at risk for CP visited a lab where they received the novel training three times per week for six weeks. During the training, children were using a commercially available dynamic body weight support system (BWSS) that provided support over a straight path and allowed for behaviors more than walking (e.g. crawling, knee walking, climbing, etc). These behaviors were encouraged by the therapists in the form of play. Toddlers' gross motor function was evaluated before, during, and after completion of the training. Four out of five toddlers demonstrated increased gross motor ability that was above the minimal clinical important difference as assessed by the Gross Motor Function Measure (GMFM-66).[74] In addition, this work showed that this paradigm was feasible and well tolerated by the toddlers, building the confidence to apply such programs in the future.

The technology in the Ulrich and Prosser's work determined, in part, the type and dosage of training used in their paradigms and the focus of their measurements. Ulrich and colleagues used small motorized treadmills that could be easily used by families in their homes. The type of training was specific to walking, the dosage was minutes per day, and the measures were largely to track the onset of infants' first steps. Prosser and colleagues on the other hand, focused on the initial study of a new commercial device called ZeroG™ (Aretech LLC, Ashburn, VA). ZeroG™ is a high-tech, non-portable, and expensive system that is usually seen in clinical settings. Although in the study the system supported movement in a straight path, it provided for a variety of motor behaviors and error experiences seen in typical development. Still, the high-tech element of the system that allows for application solely in clinical environments and use by therapists minimizes the dosage of training in natural environments.

1.5 Our Approach to Early Intervention

Our team has specifically focused on EI treatment programs for infants and toddlers that combine higher dosage training through the use of accessible technology and engagement in daily play activities in natural environments.[75–78] For the past decade, our team has developed and tested innovative devices that provide infants with opportunities to explore and learn from their environment, and thus potentially advancing their motor, cognitive, and social development.[75–77] This research project aims to use features from the aforementioned research study designs in an effort to combine and maximize their results in advancing the development of infants with DS.

This dissertation project is built upon the principles of dynamical systems approach and environmental enrichment, and extends the work of Ulrich and Prosser as well as our work by Galloway and colleagues. We combined all the above in an effort to advance the *type* and *dosage* of training, as well as the *technology* currently used for infants with mobility delays. Table 1 summarizes how these principles and study components were addressed with the current paradigm.

First, we designed an EE (type) that imposes various constraints for TD and DS infants to explore, gain experiences, and shape different behaviors, thus targeting a more holistic type of training. Our environment, similar to the animal EE, involved objects like an inclined platform, a staircase, and toys. Some objects required infants to display new behaviors to completely explore them (i.e. ascending of an inclined platform) since infants had no previous experience with these objects. Other objects required the adaptation of familiar behaviors (i.e. manipulating a chest-high table toy while standing).

Second, to maximize the time and area of exploration of the EE (dosage) we added a novel assistive device in the environment (technology). Our EE involves objects that require non-walkers to act in ways that may be beyond their typical capabilities. This characteristic, although critical for the formation of new behaviors, may in part discourage infants from exploration, especially those with DS. In an effort to overcome this potential effect, assistance by an open-area BWSS was added in the paradigm. The portable BWSS is a patented, FDA registered, commercial device (Enliten, LLC) that was co-designed by our lab. It provides mechanical support of the infant's body while allowing vertical and horizontal movement throughout the system footprint of about $8m^2$ (device described in detail in the Methods section of Chapter 2). This addition aimed to provide a low-tech, portable, and accessible solution for specifically addressing a higher-dosage application of EI by the family within the home.

The goal of this study was to assess the change in behavior of TD and infants with DS while exploring the objects of the EE with and without the assistance from the BWSS (Aims 1, 2, and 3). In addition, because this was a new system design not tested before, we also examined its feasibility as an in-home assistive/rehabilitative device (Aim 4). The latter information is important for incorporating the BWSS in longitudinal high-dosage intervention studies within the home EE in the future.

1.6 Summary of Innovation of the Proposed Study

The National Institutes of Health (NIH) defines Innovation as an application that "challenges and seeks to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions".[79] This research study was innovative in three ways. *First*, this project was the first study to examine the effect of an EE on the emergence of motor behaviors in very young infants (<1 year). *Second*, this project was the first study that examined the addition of a low-tech, accessible device (BWSS) in the paradigm as a way to potentially maximize infants' multiple activities in an open area. The design of the BWSS specifically allowed for participation in various tasks throughout an open area (e.g. climbing over inclined surfaces, etc.) that required a range of motor behaviors. *Third*, this project was the first study to examine the feasibility of the BWSS in real-world environments, like the families' homes, to gain insight into the planning for long-term interventions. The feedback from the families and users gathered from this initial study was critical for ensuring that the portable BWSS was easy to setup and use.

1.7 Summary of Significance of the Proposed Study

The NIH defines Significance as a project that "addresses an important problem or a critical barrier to progress in the field".[79] This research study was significant in three ways. *First*, results improved our understanding of the effects of an EE on very young infants' motor behaviors, both TD and those with DS. *Second*, results support this novel BWSS as an assistive technology that has the potential to provide opportunities for high dose exploration. *Third*, results suggest that BWSS and EEs can be combined as a form of EI in the families' homes. The results of this study, even with low numbers of patients, will trigger a more focused, national discussion of the importance, design and inclusion of EEs and EE principles into standard pediatrics care, and even more broadly into the adult rehabilitation models.

1.8 Specific Aims

This dissertation study involved four sessions over the period of two weeks (

Table **2**). Each session contained the three following conditions:

1) *Pre*, the infants were offered the opportunity to move in the EE *<u>without the assistance from the BWSS</u>*
2) *In*, the infants were offered the opportunity to move in the EE *<u>with the assistance from the BWSS</u>*
3) *Post*, the infants were again offered the opportunity to explore the EE *<u>without the assistance from the BWSS</u>*

These conditions are similar to the "baseline", "acquisition", and "baseline-II", terms seen in traditional learning designs. Accordingly, the specific aims of the study were the following:

Aim 1: To evaluate the instant change in performance of TD infants in the lab EE in *In* compared to *Pre*.

Aim 2: To evaluate the change in performance of TD infants in the lab EE in *Post* compared to *Pre*.

Aim 3: To explore the change in overall performance (across all conditions) of infants with DS in the lab EE and compare to that of TD infants.

Aim 4: To assess the feasibility of the novel open-area BWSS within the home EE.

The rationale for and the hypotheses for each specific aim are unfolded in the next Chapters.

Table 1. Main components of the study, principles critical in early intervention, and their integration into a single paradigm. Adapted from Prosser et al. (2012).

Component	Principle	Integration into the current paradigm
Type of Training	Early	Training was applied at very young age; in the beginning stages of upright posture and before upright mobility skills are developed
	Variable	The EE involved stations that required exploration of objects using various motor actions
	Challenging	Some of these objects have not been explored by the infants before in their lives and required great levels of stability and strength (i.e. inclined platform, staircase)
	Relevant	Activities involved were age-appropriate, tailored to the infants' need for daily play and self-exploration
	Error experiencing	Infants were 'allowed' to lose balance and fall (always within safety limits) to enhance learning of their limits
	Socially engaging	All activities took place in a social environment where parents encouraged their infants to follow their signals while moving and playing
Dosage of Training	Intensive	Sessions lasted for about 1.5-2 hours and occurred twice a week
Technology Used	Accessible	Device used was low-tech, portable, and easily handled by caregivers and users. It is currently available for commercial use

Table 2. Study Design.

	Week 1						Week 2					
	Priming Session (Lab)			Data Collection 1 (Lab)			Data Collection 2 (Lab)			Home Session (Home)		
Conditions	Pre	In	Post	Pre	In	Post	Pre	In	Post	Pre	In	Post
Assistance from the BWSS	x	√	x	x	√	x	x	√	x	x	√	x
EE Object Placement	Standardized, defined by Researcher									Arbitrary, defined by Parents		

Chapter 2

BEHAVIOR OF INFANTS WITH AND WITHOUT DOWN SYNDROME WITHIN AN ENRICHED ENVIRONMENT USING AN OPEN AREA BODY WEIGHT SUPPORT SYSTEM

2.1 Abstract

Background. Enriched environments (EE) are promising for inducing plastic changes in the brain and behavior early in life. The change in motor behavior while in EEs depends on the type of EE (selection of objects of various levels of complexity, familiarity and novelty), and the dosage of exposure within the EE. Typically developing infants (TD) have access to EEs daily through play at their homes and playgrounds. Infants with motor delays, such as with Down syndrome (DS), do not have the same access due to their immobility. Available technology for assisting movement in such environments is lacking, thus affecting both the type and dosage of exposure. **Objective.** To assess the effects of an EE paradigm combined with novel assistive technology on the behavior of TD and DS infants. **Methods**. Eleven TD infants and five infants with DS participated in two 2-hour data collections that occurred within a week. In each data collection, infants were offered the opportunity to move in and explore various objects of the EE with and without the assistance from a portable, novel, open-area body-weight support system (BWSS). We assessed their performance in and out of the BWSS within session and across time in various tasks: 1) open-area spontaneous activity, 2) ascending of an inclined platform and a staircase, and 3) standing supported by a chest-high multi-activity table toy. Our variables involved the Movement Path Length while spontaneously moving in the open area, the Success Rate of Ascending Completion, Distance covered and Speed of Ascending, Frequency of Leg Movements during standing, and Visual Attention while ascending. Wilcoxon Singed-Ranks tests were performed to identify significant changes within session and across time with and without the assistance from the BWSS. **Results**. Both populations performed the tasks of the EE and showed changes within session and across time. TD infants travelled longer distances and moved more both in and out of the BWSS. The changes were more evident in the open-area spontaneous activity and standing tasks; tasks they were more familiar doing in their daily lives. In the novel tasks of platform and staircase ascending their responses varied. They travelled more distance on the platform but their speed of ascending on the platform and the staircase was not different within session and across time. Visual attention to the end goal while ascending was not different within session and across time. Infants with DS had lower success rates of ascending completion and more variability in their responses in all tasks within session and across time. However, by the end of the second session their performance was improved. Some infants with DS performed behaviors for the first time. **Discussion.** Overall, infants showed rapid changes in our paradigm. Their previous experiences and level of complexity of the tasks affected their responses. In most cases, infants took advantage of the BWS and performed better in familiar tasks, like in spontaneous activity and standing. In the novel tasks, like platform and staircase

ascending, and especially DS infants, were not able to use the new information from the BWS instantly. However, in just two sessions DS infants' change showed positive trends. **Conclusions.** Our paradigm lays the foundation for future work on EE and harnesses. This study adds information on infants' capabilities of acting on certain objects as part of an EE, and on the interaction with BWS.

2.2 Introduction

Infants' continuous exposure to the various biomechanical, environmental and task constraints, such as during 'play', is thought to provide the active experiences that are critical for the emergence and progression of their behaviors.[18,29–33] An enriched environment (EE) is specifically structured to provide opportunities for exploration through the placement of objects of various levels of complexity, familiarity and novelty. In both animal[1–4] and human work,[5,6] EE exposure enhances activity-dependent plasticity, memory function, and behavior.

Changes in brain and behavior while in an EE appear to rely on the *type* of *EE* (objects of various levels of complexity, familiarity and novelty) and the *dosage* (frequency and duration) of exploration within the EE.[40,44,52] For infants who cannot fully explore an EE due to immobility or impaired ability, *technology* could play an *assistive* role and/or *rehabilitative* role in elevating the type and dosage of their exploration. The *assistive* role refers to the instant change in performance that is observed during the use of technology (i.e. substitutes for functional ability) whereas the *rehabilitative* refers to the change in performance that is observed without the technology (i.e. leads to positive changes in functional ability). We address the *type*, *dosage*, and *technology* used in our paradigm in the next section.

2.2.1 Description of Our Paradigm

Type of EE

One of the key initial steps of this dissertation project was to create the EE. Interestingly, a literature review paper of human research on EEs noted that most studies did not clearly define the enrichment features.[63] Specifically, the description of the selection and reason of selection of the objects were typically either missing or minimally described.[63] For example, Prosser et al. provided pictures showing children exploring foam padded uneven surfaces and climbing stairs but with no other description or rationale of the environment setup.[74] Nevertheless, taking the literature as a whole, there was information to build upon and create an EE that could be expected to provide for high levels of exploration.

A variety of objects such as platforms, tunnels and toys are common elements in both animal work on EE exposure and human development work within play environments. The latter is highly illustrated in Adolph's experiments with typically developing (TD) infants which take place in playrooms that contain similar objects.[64,80–84] These objects provide various levels of complexity, familiarity and novelty, for inducing a variety of behavioral responses. For example, exploration of inclined platforms and stairs may be considered novel tasks that require more advanced or a combination of behaviors, since these are objects that infants do not typically explore in daily life and especially not before they have acquired a certain level of ability.

Accordingly, Adolph has shown that when infants are exposed to such objects, they explore and move about them using newly-emerging behaviors based on their current level of ability and their previous experiences.[82–84] For example, 14-month-old toddlers used different strategies to ascend and descend an inclined platform compared to 8.5-month-old crawlers that did not have any walking experience.[85] The toddlers, when challenged with a steep slope for descend, were capable of switching their initial strategy (i.e. walking) to a safer one (i.e. sliding), thus re-evaluating the situation mid-way and adjusting accordingly for safety. On the contrary, the younger crawlers chose to go headfirst, and in many times they fell, thus not 'successfully' evaluating the interaction between their bodies and the newly-imposed changes in the task and the environment. This knowledge (i.e. error experiencing) is important for evaluating the situation the next time infants are exposed in a similar situation,[74,86] and this is one of the principles that this dissertation work was built on (see Table 1). Adolph's early work has been solely focused on TD infants, similar examination of responses of atypical populations to novel and familiar situations have not been examined.

The current study aimed to test the feasibility of an EE created to provide various levels of complexity, familiarity and novelty that was suitable for non-walking TD infants (<1 year of age) and infants diagnosed with Down syndrome (DS) (<2 years of age). Consequently, our paradigm included of a custom built inclined platform and a foam staircase for ascending, a chest-high multi-activity table toy for exploration while standing and cruising, and adequate free area for spontaneous physical activity (Figure 1).

Dosage of EE exposure

Providing the most suitable dosage of exposure in EE is still unclear. Since this was the first study that assessed the feasibility of our novel paradigm, we focused on the short-term effects of our EE on behavior. However, a key question was what would be the adequate *minimum dosage* to induce these changes? Animal work generally suggests that three weeks are necessary to detect enrichment effects.[38,44] However, rapid changes on motor tasks may emerge in brain and behavior even within 24 hours of motor training.[87–89] For example, in the rotarod task, improvement that lasts for a short period maybe seen within one session (20-30 minutes) of training.[87] Long-term effects on the same task develop over 4-6 days of training.[87] Similarly, infant work on short-term training for specific skills (i.e. not traditional EE exploration) also supports the notion that behavioral changes can emerge rapidly. For example, two days of reaching training resulted in increased frequency of object contacts, shorter and smoother reaching movements, and improved hand positioning when approaching for the object.[90] Even a single training session can result in changes in both the frequency of reaching and the grasping strategies.[91] Rapid changes were also seen in walking behaviors involving stepping over obstacles. Specifically, training involving trip-inducing stimuli produced steps that involved higher lifting of the leg immediately after the removal of the stimulus and within a session.[92] It is important to note that studies of rapid changes are not attempting to determine whether these changes are truly learning vs. performance. This limited work on short-term effects suggests that even a few sessions might provide enough opportunities for infants to alter their behaviors.[35]

Despite the general suggestions about the impact of EEs with infants and the specific data suggesting the potential for BWS and short-term training to have positive effects on pediatric rehabilitation populations, many basic questions remain in the interrelated areas of EE and short-term training. Moreover, our use of a novel technology requires an initial study of short-term effects and feasibility in order to gain initial data to support the larger work on EE and BWSS. Thus, this study was an initial attempt to provide basic information on the changes in behaviors of TD infants and those with DS when short-term training in EE was introduced.

Technology to assist activities in the EE

As previously stated, our EE involves objects that require non-walkers to act in ways that are beyond their capabilities. This characteristic, although critical for the formation of new behaviors, may in part discourage infants from exploration, especially those with DS. In an effort to overcome this potential effect, BWS was added in our paradigm through the use of a novel BWSS.

In this dissertation work, we introduce the Portable Mobility Aid for Children (PUMA®, Figure 1). This device provides mechanical support of the infant's body while allowing vertical and horizontal movement throughout the system footprint of about $8m^2$. The amount of BWS was manipulated through a counterweight system (device described in detail in the Methods section).

The 'right' amount of BWS by the PUMA® is an open question. Gait studies on older children (3-7 years old) with special needs that used BWS over treadmill based the selection of support on the judgment of the clinicians, and BWS varied or in some cases it was not even reported.[66,93] In toddlers, Prosser and colleagues used BWS that ranged from 10% to 40% of the total body weight of the toddlers. In infants, Ulrich required parents to hold them on the trunk completely in order to generate stepping behavior over treadmill and over ground but there was no formal assessment of support.[15,17,33,94] In addition, when Thelen placed infants in water, the amount of weight that the limb muscles had to overcome for the stepping behavior to emerge was almost negligible.[36]

So, is a large amount of BWS best for the emergence and practice of new behaviors such as stepping in infancy? Further work is needed to examine the optimal amount of BWS, which was beyond the scope of this initial study.

In this study, we combined low and high levels of BWS. Following a general method similar to the one used by Prosser[74] for determining the BWS, we found the least and most amount of BWS that allowed for behaviors such as standing, crawling, and stepping, and we combined those with the task characteristics and goals at each time (more detail on the tasks follows on section 2.2.2). For example, in the open-area spontaneous activity task, we found that a BWS of 20% was more appropriate for increasing general mobility, since the low vertical force 'stimulated' transitions out of stationary behaviors (i.e. getting out of sitting position) and at the same time allowed for movement in the horizontal (i.e. crawling). If the amount of the BWS was larger, then the greater vertical force may have favored the emergence and maintenance of more stationary behaviors throughout the trial which was not the goal for this task. On the contrary, in the multi-activity table toy exploration task, where the goal was to maintain upright posture and stepping, we found that 40-60% was more appropriate for allowing infants to keep themselves in standing for the longest duration, and even 'stimulate' for cruising as they explored the surface. Overall, the BWS used in our study ranged from 20-60% of the infants' body weight, a little more than the 10-40% used in Prosser's work with toddlers.[74]

A great advantage of our device is that the amount of the BWS can be modified easily by any individual with minimal training. The low-tech nature of the BWSS only requires steel rods or sand bags that can be placed inside the bucket of the counterweight system (Figure 1). This feature along with the portability of the device, make the BWSS a promising tool for use in settings outside of the clinic and/or lab.

2.2.2 Variables of Interest and Rationale

The self-organization abilities of the infants and their exploration of the dynamic relationship between their bodies and the environment was assessed through a series of tasks for each of the three conditions (Pre, In, Post). The “tasks” in this study refer to the actions that infants performed on and around the large objects placed in the EE (inclined platform, staircase, multi-activity table toy). It is through these tasks that infants gathered information, gained experience, and learned.

We tested infants on four tasks: 1) Open-area spontaneous activity, 2) Ascending of the inclined platform, 3) Ascending of the staircase, and 4) Standing close to the multi-activity table toy (to allow for both supported and unsupported standing). Based on the age and ability of the infants, the tasks can be categorized into “novel” and “familiar”. Tasks performed on the inclined platform and the staircase (ascending) to be ‘novel’ as infants had minimal if any experience with these objects based on parents’ reports. We considered the tasks related to the standing toy (standing) and the free space (open-area spontaneous activity) to be “familiar” tasks as infants had experience with these. To be clear, TD and DS infants in the study were not independently standing but parents confirmed that they had experience in the standing posture while being held by them or supported by themselves on the furniture. Variables for each task used to chart behavioral changes are introduced next (see also Table **3**).

2.2.2.1 Open-area Spontaneous Activity

Most spontaneous locomotor activity occurs while infants explore the environment and interact with caregivers.[64] Therefore, for the familiar task of spontaneous activity, we looked at the *movement path* infants covered while exploring the open area of our EE. We selected this variable based on Adolph and colleagues that quantified spontaneous activity using the amount of natural locomotion of crawlers and walkers in a lab playroom.[64] Researchers initially coded for duration of time of crawling and walking from the video recordings that lasted from 15-30 minutes. Then, they estimated the overall distance travelled by multiplying total step number by the average step length calculated during walking straight trials on a gait carpet. In our paradigm, we wished to capture the whole 3-minute continuous activity rather than just crawling and walking bouts, in an effort to get a snapshot of all forms of dynamic behaviors, even those that do not necessarily involve steps (e.g. rocking back and forth on all fours, transitions, etc.). Therefore, we adapted this measure and we assessed the overall distance travelled in the open area by using a tracking digitization method (see more detail in the Methods section 2.4.4).

The results of the Adolph's study supported that, with time and as older infants gain in experience, their locomotion improves dramatically, as reflected by the increase in the number of steps and the distance travelled. Similarly, in our EE paradigm, infants explored the open space multiple times in and out of the BWSS. Therefore, our prediction was that infants would take advantage of the multiple conditions, and of the BWS, and would explore more of the open area, as reflected by an increase in spontaneous activity within and across sessions.

2.2.2.2 Platform and Staircase Ascending

The task of ascending performed on the inclined platform and the staircase were considered novel since infants had minimal if any experience with these objects, as confirmed by parents. For example, in typical motor development, the onset of successful staircase ascending comes relatively late, at about 11 months,[84] at a time when infants have more motor abilities and experiences. However, if infants are exposed to this situation at an earlier age, they have the capability to adapt and act on this object, as shown by the earlier onset of ascending by infants that have a staircase at their homes.[84] This example emphasizes even more the role of experience on the task onset. In our paradigm, infants are exploring the staircase multiple times, and under altered biomechanical constraints (the assistance from the BWSS alters the way they need to control their body on this task – possibly making movement easier), they are gaining multiple experiences with the object, and thus we expect their rate of completion success to increase with time.

In these two novel tasks of our EE, we quantified three aspects of the behavior: 1) *Success rate of task completion*, 2) *Distance covered*, only for infants with incomplete ascends (platform only), and 3) *Speed of ascending*, only for infants with completed ascends. These variables were selected based on initial observations specifically to capture the change in behavior of all infants, knowing that each would have uniquely different capabilities. For example, some infants had incomplete ascends throughout the study or had incomplete ascends initially but were able to fully complete the task by the end. For these infants, the change in distance covered on the platform would most describe their ability to adapt to this novel task. For the infants who had completed ascends throughout the study, speed of ascending was quantified. Speed is thought to reflect both cognitive processing and motor ability, and/or adaptation to various environmental and task demands.[64,95,96] For example, movement speed often increases over a period of time after the emergence of a skill in infancy such as with reaching and walking.[64] In a novel task, such as the platform and the staircase ascending, speed provides a potential indication of how fast infants adapt to the different constraints the objects impose.[96] We expected infants to travel more and become faster with time.

Lastly, we examined infants' *visual attention* to a goal set at the end of the platform and the staircase. Visual attention has been used as measure of cognitive ability[97,98] and is thought to be the primary perceptual system for guiding locomotion.[99,100] It has also been linked to the development of a variety of behaviors early on such as reaching[101] and sitting.[102,103] This is a great example of involving a variable to examine the multi-factorial effect of our paradigm. We hypothesized that with time the visual attention would be more on the goal, which was the toy and the parent at the end of the platform and staircase.

2.2.2.3 Standing

In the task of standing while manipulating the chest-high multi-activity table toy, we assessed the *frequency of leg movements*. A leg movement was defined as a movement each limb performed after being stationary and/or changed position.[104]

Various types of leg movements including kicks, curls, and small side steps were all considered.[104] We chose this variable as this was a spontaneous and self-initiated behavior that was observed during the sessions and seemed to be more frequent when the BWS was present.

Leg movements are considered by some to be an early precursors to walking,[32] and therefore inducing more frequent and longer duration leg movements may serve our long-term purpose of reducing walking delays. For example, a link has been found between newborn stepping and walking. Specifically training stepping increases stepping frequency and is related to an earlier walking onset.[37] In addition, the occurrence of stepping and kicking is influenced by environmental and biomechanical constraints, such as rapid fat gain and postural orientation with respect to gravity.[33,36,37] The latter phenomenon is well documented in Thelen's work where she placed infants in water or added extra weights on the infants' limbs (described previously in section 1.2 of Chapter 1). Similarly, in our study, we altered these constraints by manipulating the BWS, which alters the weight the lower limbs must support in order to balance. Thus, BWS was predicted to result in more leg movements.

2.3 Hypotheses

This Chapter focused on the immediate, short-term effects of our EE-BWS paradigm on the motor behavior of TD and DS infants when **performing** the four tasks outlined above. The Aims and Hypotheses described below refer to Data Collection 1 and Data Collection 2 only.

Aim 1: To evaluate the instant change in performance of TD infants in the lab EE while using the BWSS **(In vs. Pre - within session)**. TD infants will demonstrate the following **while using the BWSS:**

Primary

H1.1: *Larger movement path during open-area spontaneous activity*

H1.2: *Faster adaptations in platform ascending (higher ascending completion success rate, more distance travelled on the platform, faster platform ascending)*

H1.3: *Faster adaptations in staircase ascending (higher ascending completion success rate, faster staircase ascending)*

Secondary

H1.4: *Increased visual attention to the end goal during platform ascending*

H1.5: *Increased visual attention to the end goal during staircase ascending*

H1.6: *Increased frequency of lower limb movements while standing*

Aim 2: To evaluate the change in performance of TD infants in the lab EE while not using the BWSS with time **(Post of Data Collection 2 vs. Pre of Data Collection 1 - across sessions)**. TD infants will demonstrate the following **while not using BWSS** in Data Collection 2:

Primary

H2.1: *Larger movement path during open-area spontaneous activity*

H2.2: *Faster adaptations in platform ascending (higher ascending completion success rate, more distance travelled on the platform, faster platform ascending)*

H2.3: *Faster adaptations in staircase ascending (higher ascending completion success rate, faster staircase ascending)*

Secondary

H2.4: *Increased visual attention to the end goal during platform ascending*

H2.5: *Increased visual attention to the end goal during staircase ascending*

H2.6: *Increased frequency of lower limb movements while standing*

Aim 3: To explore the change in overall performance of infants with DS in the lab EE while and while not using the BWSS, and compare to that of TD infants. Infants with DS will demonstrate:

H3.1: *Decreased performance on the platform ascending task compared to the TD infants as shown by the lower success rate of ascending completion across all conditions* **(DS vs. TD across conditions)**

H3.2: *Decreased performance on the staircase ascending task compared to the TD infants as shown by the lower success rate of ascending completion across all conditions* **(DS vs. TD across conditions)**

H3.3: *Increased frequency of lower limb movements while standing and using the BWSS* (**In vs. Pre – within session)**

2.4 Methods

2.4.1 Subjects

Eleven TD infants (six male) between the age of 8.2 and 11.8 months (M=9.9 ±1.2 months), five DS infants (two male) between the age of 12.4 and 19.7 months (M=17±3 months), and their parents participated in the study. Infants were included if they had acquired the ability to independently maintain their head in midline while placed at different postural positions (prone & sitting) and had body weight less than 22 kg. We also preferred if infants were able to crawl or scoot for a distance at least twice their body length[14] in order to achieve homogeneity in the ability among infants of the same and among groups. Infants were excluded from participation if their body weight was more than 22 kg, had a history of seizure disorder, a presence of non-correctable vision problems, and/or other severe motor impairments or conditions that would make their participation difficult. For the DS group, a physician clearance was provided before participation. Recruitment for the TD infants was largely via word of mouth and through media announcements at the University of Delaware campus area, and for the DS group through family support groups and associations in Delaware and Pennsylvania. This study was approved by the University of Delaware's institutional review board and all parents signed the consent form prior to participation (see Appendix C for the most recently approved Informed Consent).

2.4.2 Apparatus

The data collections for this study were conducted at the University of Delaware's STAR Campus. Participating families visited the Pediatric Mobility Lab and Design

Studio, which contained a data collection area purposefully designed to simulate a playroom for infant activity. The floor of the area (Figure 1) was foam-padded for safety (Imaginarium Alphabet & Numbers Foam Puzzle Mat, Toys R Us, Inc., Paramus, NJ) and was equipped on top with a standardized set of large objects for enrichment and the portable BWSS. Outside the play area, three video cameras and two screen displays were placed in fixed positions.

The objects of the EE involved an inclined platform, a staircase, a chest-high multi-activity table toy for standing and cruising, and a standardized set of small toys for play and stimulation. The platform was a custom built 152-cm-long wooden walkway, covered with a frictionless yoga mat, that could be adjusted to various inclinations (11.1°, 21.3°, 30.4° from the horizontal). Similar inclined platforms have been used to challenge infants' locomotor abilities in Adolph's work.[82,85,105,106] Infants were tested only on the most challenging inclination defined as the inclination that they didn't ascend or successfully complete in the Priming Session out of the BWSS (see next section 2.4.3). The staircase was a commercially purchased 54cm-high foam object (Foamnasium, Indianapolis, IN, USA) with four steps (step height = 12cm) down to the floor. The multi-activity table toy was a 38-cm-high plastic toy (3-in-1 Around We Go™ Activity Center, Bright Starts, Kids II Inc., Atlanta, GA, USA) that had a round surface (diameter=53cm) on top with different features (buttons with lights and sounds) for hand manipulation. The placement of the objects of the EE was standardized across infants and conditions.

The portable BWSS is a patented, recently FDA registered, commercial device (PUMA®, Enliten LLC, Newark, DE, USA) that provides support for movement in all three planes (2.75 m x 2.75 m x 2 m). The device contains a counterweight system for manipulation of the BWS. Infants wore a commercially available cloth harness (My Early Steps™, Little Dundi, LLC) that provided support and allowed for limb movements.

Data collections were video-recorded (full HD quality 1920x1080 pixels at 30 frames per second) using three color cameras (GoPro Hero3 White edition, GoPro Inc., San Mateo, CA, USA). The high resolution of the videos allowed for better distance estimation during the digitization analysis (see section 2.4.4 Data Analysis). The cameras were positioned at fixed distances from the center of the area to ensure front (d=3.3m), side (d=3.1m), and top (d=3.6m) views of the whole space (Figure 2). Cameras were controlled by the researcher via a hand remote controller (GoPro Smart Remote, GoPro Inc., San Mateo, CA, USA). The two screen displays provided live feedback of the front and side views to the parents and the researchers to assist in occlusion avoidance during the data collection. The screen displays were positioned about a meter off the ground to avoid distraction of the infants.

2.4.3 Experimental Protocol

All infants participated in two 2-hour data collections (Data Collection 1 and Data Collection 2) that occurred on different days within a week with at least two days apart from each other. Before the data collections, infants participated in a 2-hour session (Priming Session) where the researcher confirmed that infants met the inclusion criteria, collected anthropometric measurements (height and weight), and allowed infants time to become familiar with the BWSS and objects of the environment. Infants were allowed time to explore the platform, staircase, and standing toy while and while not being supported by the BWSS. This gave an insight on the selection of the %BWS (between 20-60%) that would allow walking, squatting, and more movements based on the task characteristics. We selected high % of BWS for standing to allow for more time in that position, low % of BWS in the spontaneous activity in the open area to allow for a variety of behaviors, and medium support for the platform and staircase ascending. In addition, we also selected the degree of slope of the platform. The slope that the infants did not successfully complete in this session was selected for the data collections later in order to see if the infants would be able to successfully complete it by the end of the study.

During the Data Collections 1 and 2, infants were offered the opportunity to explore the objects of the EE in a more controlled way. All infants went through the tasks (see sections 2.4.3.1 - 2.4.3.3 for detailed description of each task) three times (each time reflected a separate condition thus three conditions in total). The order of the tasks and the time with the objects of the EE were standardized. The first condition was the first time the infants explored the objects in the station without the assistance from the BWSS (*Pre*), the second condition was the second time they did the same with the assistance from the BWSS (*In*), and the third condition was the third time they again explored the objects without the assistance from the BWSS (*Post*). Each condition lasted for about 25-30 minutes. Both TD and infants DS went through the same protocol.

Throughout the Priming Visit and both Data Collections, the researcher kept the infants in a calm and alert state, and within arm's length to ensure protection while falling. Infants were physically touched as little as possible. The parent was also present and active in the play area and offered encouragement. Any time the infant became fussy, the session was paused for comforting/feeding, and then resumed when the infant was calm/alert.

2.4.3.1 Open-area Spontaneous Activity

The open-area exploration was always the first in the order of tasks at each condition. Infants were given the opportunity to move around and explore the free space and the stations of the enrichment setup for three minutes. The task, and consequently the video recordings, formally started after the researcher placed the infant in a sitting position at the center of the play area and ended at three minutes.

The overall goal for the researcher and the instructions to the parent were to motivate the infant to move throughout the area, and thus they both placed toys at the different stations and called for the infant, especially whenever the infant remained stationary for more than 10 seconds. At instances where the infant became fussy from being ‘stuck’ in a position, (e.g. at the top of the platform or staircase), the researcher and/or the parent would place the infant in the open space-ground level nearby. Any movement of the infant induced by an adult (e.g. carrying the infant) was excluded from analyses.

2.4.3.2 Platform and Staircase Ascending

The platform and staircase ascending tasks always followed the task of spontaneous activity in the open area. In between the two tasks, the standing task (see 2.3.3.3) was performed to eliminate an order effect that would be transferred from one ascending to the other. Each ascending, and consequently the video recordings, formally started with the researcher placing the infant in sitting position in close proximity to, and facing, the staircase and/or platform. Then, infants were allowed 90 seconds to initiate the ascending. Throughout that time, the parent remained at the other end of the staircase and/or platform presenting toys and calling for their infants to move towards them. The task duration would last until the infant completed the ascending (i.e. reach the top of the staircase and/or platform) or would be terminated if the infant: i) did not initiate ascending within the 90-second timeframe, ii) remained in the same stationary position for more than 90 seconds, iii) lost interest in moving further and/or was fussy.

2.4.3.3 Standing

This task was performed between the platform and staircase ascending tasks. The infant was placed by the researcher in a standing position with arms touching the toy for assistance. If/when the infant was able to independently maintain their standing posture the researcher stopped supporting them. The infant was allowed 90 seconds to explore the toy in the standing position and/or cruise if needed. The parent and the researcher also manipulated the toy and kept the infant motivated in maintaining the standing posture. Because this task required the infant to maintain in the that posture for some time and independent standing was a milestone not yet acquired by the infants, the researcher was within arm's length at all times to ensure safety while falling back to sitting position. When the infant fell, and did not immediately re-stand, the researcher and/or caregiver would place them again in standing position. This period of sitting and re-standing was excluded from the analyses.

2.4.4 Data Analysis

Measures were obtained though offline frame-by-frame behavioral coding and digitization kinematic analysis of the video recordings. Video coding analysis has been the gold standard for assessing behavioral measures. Coding was performed using Datavyu (datavyu.org), an open source software developed by developmental scientists and supported by NIH and NSF. Kinematic analysis was performed using Kinovea (version 0.8.15, Bordeaux, France), an open source digitization software that has been shown to be a valid and reliable tool for 2D motion analysis in physical activity and sports science, which often requires measurements in an open environment.[107–109] Kinovea has also been used in an infant study to track hand motion from videorecordings as part of a longitudinal home study.[110] Kinovea allows for distance measurement by converting pixels to centimeters through the calibration of a known distance in a video image. The variables of interest for each task are summarized in Table **3** and are described in the following sections.

2.4.4.1 Open-area Spontaneous Activity

The measure of the infants' performance while spontaneously moving in the open area was the <u>Movement Path Length</u>, defined as the total length of the path travelled during the trial (see previous section 2.2.2.1). To measure the distance, offline digitization kinematic analysis of the body in the 2D area was performed in Kinovea using one view of the video recordings (Figure 3A). Due to occlusions in the front and side views for multiple frames from the object placement and people moving within the environment, the video recording from the top view was selected for this analysis. The infant’s head was considered as a point of reference for tracking the body since it was visible at most of the times. At instances where the infant was frustrated from being ‘stuck’ in a position, (e.g. at the top of the platform or staircase), the researcher and/or the caregiver would intervene by placing the infant in a position where they could move and explore again (i.e. in the open space-ground level nearby). During this timeframe, the tracking was interrupted and it resumed when the infant was placed again in the free activity position. To allow comparisons across different observation times due to the above timeframes, the accumulated distance was expressed as a proportion of 1-minute rates.

2.4.4.2 Platform and Staircase Ascending

Infants’ performance on the platform and staircase ascending tasks was assessed though offline video coding and digitization analysis of the video recordings. Some infants completed the entire length of both tasks, and some did not. Therefore, the first thing we looked at was the Success Rate of Task Completion. Next, we selected different measures for each of these subgroups. Distance travelled on the platform was the measure for infants that had incomplete ascends. Speed of ascending was the measure for infants that had completed ascends. Visual Attention during ascending was assessed for both subgroups.

Success Rate of Task Completion was assessed from the video observations. It is depicted as the fraction of the number of infants that successfully ascended the platform or staircase over the total number of infants. Distance was computed in Kinovea using the front view. Kinovea contains the tool ‘Perspective Grid’ which allows for segmentation of an area of the video image (in this case the platform surface) to better estimate the position of a segment of interest (in this case the point of infant's contact on the platform). The frame in which the infant travelled the longest distance on the platform was chosen for this analysis (Figure 3B). Speed was computed also in Kinovea using the side view. It was calculated by dividing the total length of the platform (total distance d=152cm) or staircase (d=83.4cm diagonally) by the duration to complete the task ascending. Duration was computed as the difference in seconds from the frame where the lower limb left the floor to touch the platform or staircase (and an ascend would follow) to the last frame where the last lower limb would reach the top. Visual Attention during ascending was coded in Datavyu for the infants' looking at the end goal, the environment, or the platform and/or staircase.

2.4.4.3 Standing

For this task, behavioral coding in Datavyu was performed to identify the periods of independent standing and the Frequency of Leg Movements while standing. A leg movement was defined as a movement after the limb was stationary or changed position.[104] Various types of leg movements including kicks, curls, and small side steps were all considered.

2.4.5 Statistical Analysis

Statistical analyses were performed using the SPSS 24 software package (IBM, Armonk, NY). Power analyses were conducted using G Power 3.1. The overall threshold for significance was set to $p = 0.05$. Wilcoxon Signed-Rank tests were performed to identify differences between two conditions on the two separate data collections. The latter would give an insight on potential trends in the change of behavior that may be different among the two days. In addition, we reported for each variable, the direction of change for each infant across the conditions (if an increase or decrease was observed). Spearman correlation tests were performed to identify a relationship among two variables.

2.5 Results – Aim 1

Given that this was the first study of young infants in this type of BWSS, we initially did not even know if infants would participate or if major changes would need to be made to the device or research design. We were very pleased that all infants participated in all tasks without any problem that caused withdrawal of participation. The ability of the TD infants involved in the study was hands-and-knees crawling locomotion for ten out of the eleven infants and belly-crawling for one infant.

2.5.1 Open-area Spontaneous Activity

Wilcoxon Signed-Ranks test showed that the 2D Movement Path Length was significantly larger in *In* compared to *Pre* in Data Collection 2 (z=-2.134, p=0.033) but not in Data Collection 1 (z=-0.889, p=0.374) (Figure 4). In Data Collection 1, six out of eleven infants had longer movement paths in *In* compared to *Pre,* whereas in Data Collection 2, nine out of eleven infants had longer movement paths in *In* compared to *Pre*.

2.5.2 Platform and Staircase Ascending

Platform Ascending: Based on infants' performance, two subgroups were identified in the platform ascending task. Infants in the first subgroup (N=6) had only complete ascends (reached a ceiling effect), and infants in the second subgroup (N=5) had at least one incomplete ascend. More specifically, the six out of eleven infants (54.5%) successfully completed the task by reaching the top of the platform (d = 152cm) across all conditions and both data collections. In the second subgroup, out of the five infants (45.5%) that had at least one incomplete ascend, three had completed ascends only in the *In* condition of both data collections, one infant had incomplete ascends in both conditions of Data Collection 1 only, and the last remaining infant was the only infant that had completed ascends in the *Pre* condition of both data collections (Figure 5A).

For the five infants in the second subgroup, Distance on the platform was assessed. In both data collections, four out of the five infants increased the Distance covered in *In* compared to *Pre* (Figure 5A). More specifically, in Data Collection 1, three out of the four infants not just increased their Distance but they fully completed the ascend, whereas the fourth infant doubled the distance previously covered in *Pre*. In Data Collection 2, the same three out of the four infants were able to complete the ascend in *In* again, whereas the fourth infant was able to complete ascends in both conditions compared to Data Collection 1 that had incomplete ascends in both conditions. In addition, for these four infants, we observed an increase in Distance from *Pre* of Data Collection 1 to *Pre* of Data Collection 2, showing some retention in their performance.

However, the above observed increases were not enough to show a statistical significant difference between *Pre* and *In*, neither in Data Collection 1 (z=-0.813, p=0.416) nor in Data Collection 2 (z=-0.368, p=0.713), according to the Wilcoxon Signed-Ranks test. Finally, an overall picture of the changes in Distance for the whole group (N=11) is also depicted in Figure 5B.

For the six infants in the first subgroup, Speed of completion was assessed. The majority of infants increased their Speed in *In* compared to *Pre* in both data collections (Figure 5C), but no significant difference was found neither in Data Collection 1 (z=-0.943, p=0.345) nor in Data Collection 2 (z=-1.153, p=0.249).

Staircase Ascending: In the staircase ascending task, infants presented higher success rates of completion compared to the platform ascending task. This was true for both 1) the total number of infants that had only complete ascends across all conditions and data collections, and 2) the total number of infants that completed the ascend at each condition separately. In the first case (across all conditions and both data collections), eight out of eleven infants (72.7%) successfully completed the task by reaching the top of the staircase compared to the six out of eleven infants (54.5%) that successfully completed the task by reaching the top of the platform. In the second case (at each condition separately), the total number of infants that completed the ascend on the staircase always exceeded the number of infants that completed the ascend on the platform, except for the *In* of Data Collection 2 that was equal (Figure 6). Half-way ascends, seen in the platform ascending task, were not observed on the staircase ascending task. Thus, infants either ascended all the way up to the top of the staircase or they didn't initiate the ascending at all.

Similar to the performance on the platform ascending task, two subgroups were identified in the staircase ascending task. Infants in the first subgroup (previously mentioned, N=8) had only completed ascends, and infants in the second subgroup (N=3) had at least one incomplete ascend. The three infants (27.3%) that had at least one incomplete ascend were also in the same group of the five infants that had at least one incomplete ascend in the platform task. Out of the three infants of the second subgroup, one completed the ascend in the *In* condition of both data collections, one infant had an incomplete ascend in *In* of Data Collection 1, and the last infant had two incomplete ascends, one ascend in *Pre* of Data Collection 1 and one in *In* of Data Collection 2.

For the eight infants in the first subgroup, Speed of ascending was assessed (Figure 7). The Wilcoxon Signed-Ranks test showed that the speed of staircase ascending was not different between *Pre* and *In* conditions neither in Data Collection 1 (z=-1.820, p=0.069) nor in Data Collection 2 (z=-0.98, p=0.327). In addition, in Data Collection 1, there was a trend towards significance to the opposite direction to the proposed hypothesis, since the majority of infants had decreased speed in the *In* condition. However, this changed in Data Collection 2 where the majority of infants increased their speed in the *In* condition, although no significance was found.

Visual attention was assessed for the infants with only complete ascends in both platform and staircase ascending tasks. In the platform ascending task, the Wilcoxon Signed-Ranks test showed that visual attention to the end goal was not different between

Pre and *In* conditions neither in Data Collection 1 (z=-1.153, p=0.249) nor in Data Collection 2 (z=-1.483, p=0.138). In the staircase ascending task, in Data Collection 1, the Wilcoxon Signed-Ranks test showed that visual attention to the end goal in *In* was not different from the *Pre* condition (z=-0.420, p=0.674). However, in Data Collection 2, the Wilcoxon Signed-Ranks test indicated that visual attention to the end goal in *In* was significantly higher than the *Pre* condition (z=-1.96, p=0.05).

2.5.3 Standing

All eleven infants demonstrated an increased Frequency of Leg Movements in *In* compared to *Pre* in both data collections (Figure 8). The results were significantly different in both Data Collection 1 (z=-2.934, p=0.003) and Data Collection 2 (z=-2.934, p=0.003), according to the Wilcoxon Signed-Ranks tests.

2.6 Summary of Results – Aim 1

In this Specific Aim, we evaluated the instant change in performance of TD infants in the lab EE while using the BWSS (In vs. Pre - within session). With the assistance from the BWSS, TD infants demonstrated higher success rates of task completion and moved more. Specifically, they travelled longer paths while spontaneously moving in an open-area, covered more distance on the platform ascending, and moved their legs more during standing. The speed of platform and staircase ascending was not different between the two conditions. Visual attention to the end goal was greater on the staircase ascending task in the second data collection.

Figure 1. Play Area

Table 3. Variables of interest for each task.

Spontaneous Activity	Platform Ascending	Standing	Staircase Ascending
1. Movement Path Length	1. Success Rate of Task Completion 2. Distance covered (for infants with at least one incomplete ascend) 3. Speed of Ascending (for infants with complete ascends only) 4. Visual Attention	1. Frequency of Lower Limb Movements	1. Success Rate of Task Completion 2. Speed of Ascending (for infants with complete ascends only) 3. Visual Attention

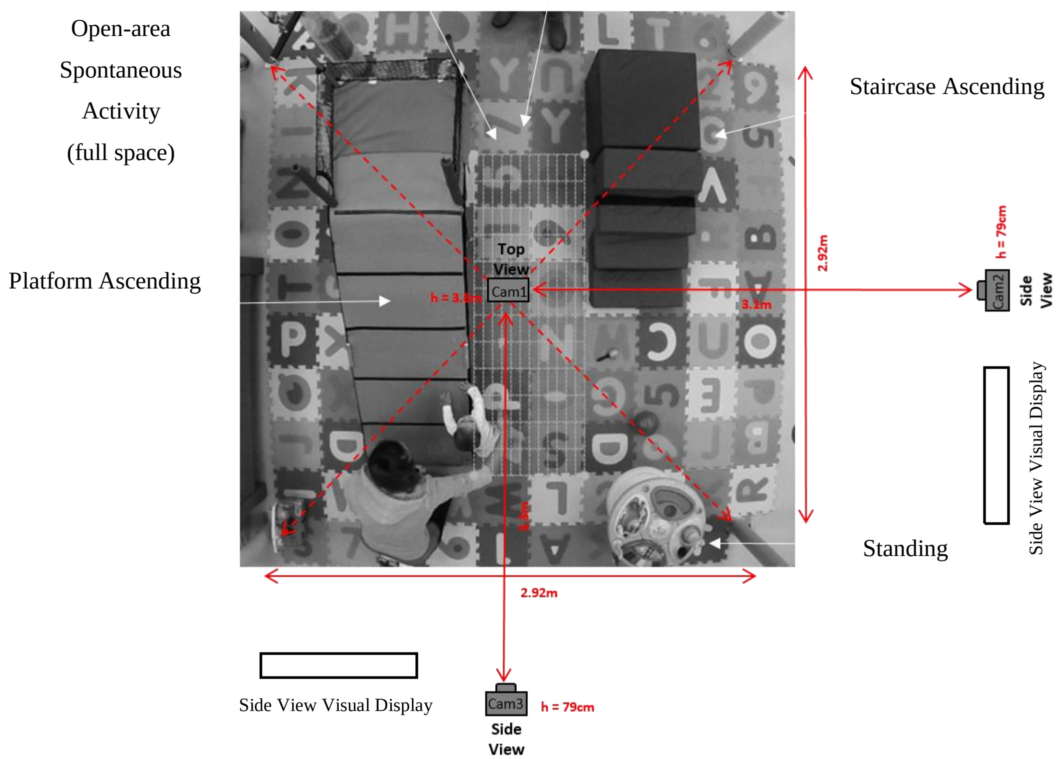


Figure 2. Equipment setup and the corresponding tasks in the play area.

Figure 3. **A.** Movement Path Length measurement in the Open-area Spontaneous Activity task. The top view video was imported in Kinovea software in order to track the head of the infant while moving. A known distance (d=2.75m) was used for calibration. **B.** Distance measurement in the Platform Ascending task. The front view video was imported in Kinovea for analysis. The tool 'Perspective Grid' was virtually attached on the platform surface to provide segmentation of the platform into 20 horizontal strips. Each strip equals to 7.6cm (Total Platform Length 152cm divided by 20). The strip that contains the feet's contact with the platform (or the knees if infant was crawling) in the video frame in which the infant covered the most distance was chosen. For example, in the figure, the infant covered 53.2cm which was the furthest point travelled on the platform.

Table 4. TD Infants' characteristics (N=11).

Age (months)	Gender	Height (cm)	Weight (kg)	Locomotor Ability
8.4	M	72	7.7	Crawling
10.8	F	71	8.2	Crawling
10.5	F	62	6.8	Crawling
10.5	F	64	6.9	Crawling
8.2	M	76	12.2	Belly-crawling
8.3	F	69	7.6	Crawling
10.8	M	76	9.3	Crawling
11.8	M	80	11.0	Crawling
9.8	M	75	9.5	Crawling
10.1	M	78	11.5	Crawling
9.5	M	75	10.0	Crawling

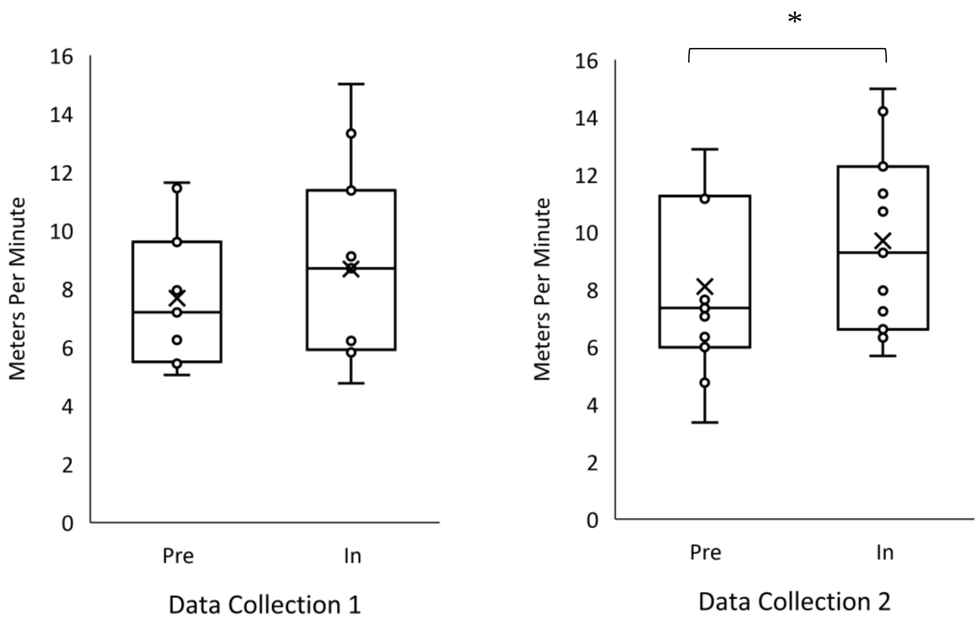


Figure 4. Movement Path Length during Spontaneous Activity in the open area. *Pre* is the condition in which the infants performed without the BWSS assistance and *In* is with the BWSS assistance. Wilcoxon Signed-Ranks test showed that the 2D Movement Path Length was significantly larger in *In* compared to *Pre* in Data Collection 2 (z=-2.134, p=0.033) but not in Data Collection 1 (z=-0.889, p=0.374). In Data Collection 2, nine out of eleven subjects moved more in *In* compared to *Pre,* whereas in Data Collection 1 six out of eleven infants moved more in the 2D space.

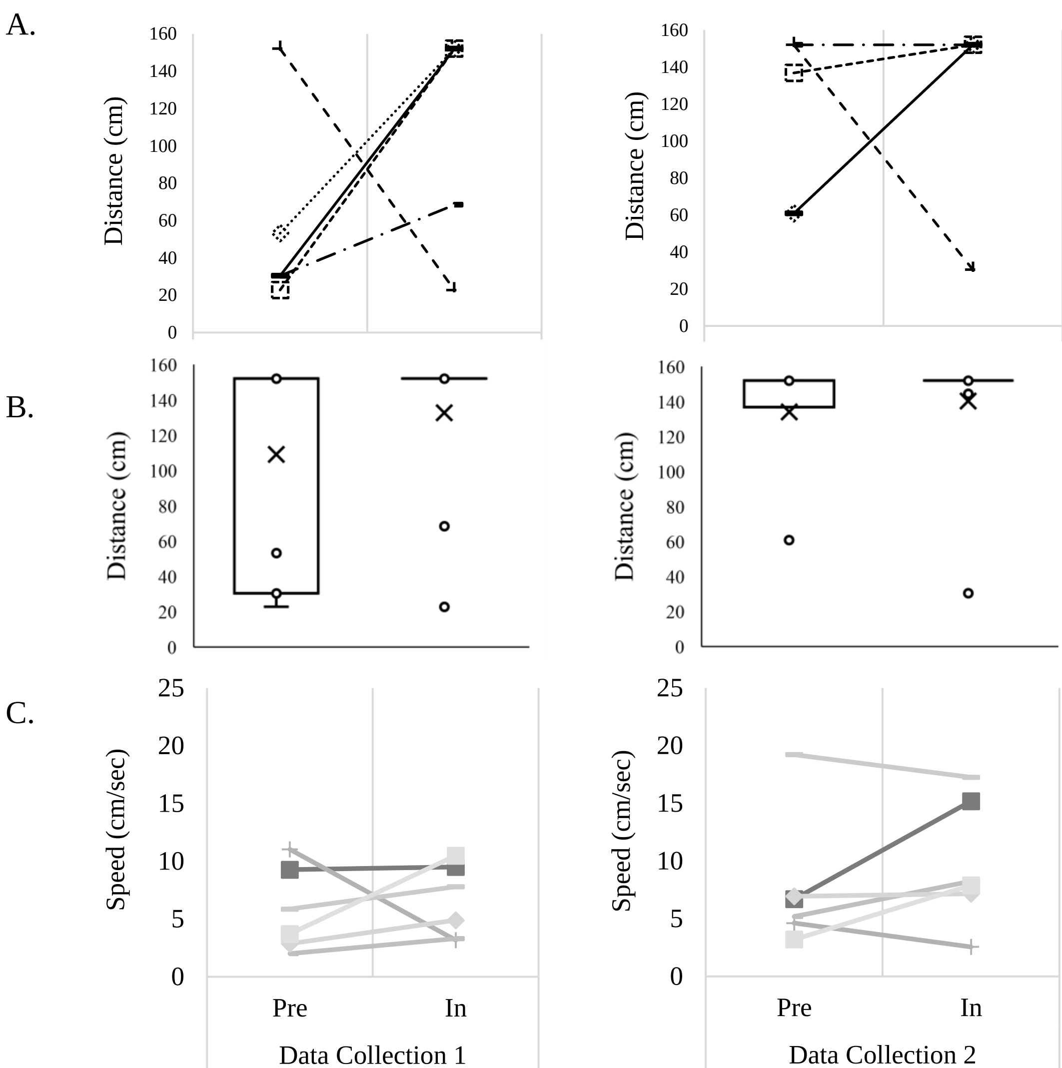


Figure 5. Distance covered and Speed of Platform Ascending. *Pre* is the condition in which the infants performed without the BWSS assistance and *In* is with the BWSS assistance. **A.** Distance covered for the infants that had at least one incomplete trial (N=5). All infants but one increased their distance in *In*, but the difference was not statistically significant neither in Data Collection 1(z=-0.943, p=0.345) nor in Data Collection 2 (z=-1.153, p=0.249). **B.** Box Plots depict the change in distance covered combined for all infants (N=11) in both data collections. **C.** Speed of ascending for the infants that had only complete ascends across all conditions and both data collections (N=6) was not statistically significantly different between *Pre* and *In* neither in Data Collection 1 (z=-0.943, p=0.345) nor in Data Collection 2 (z=-1.153, p=0.249).

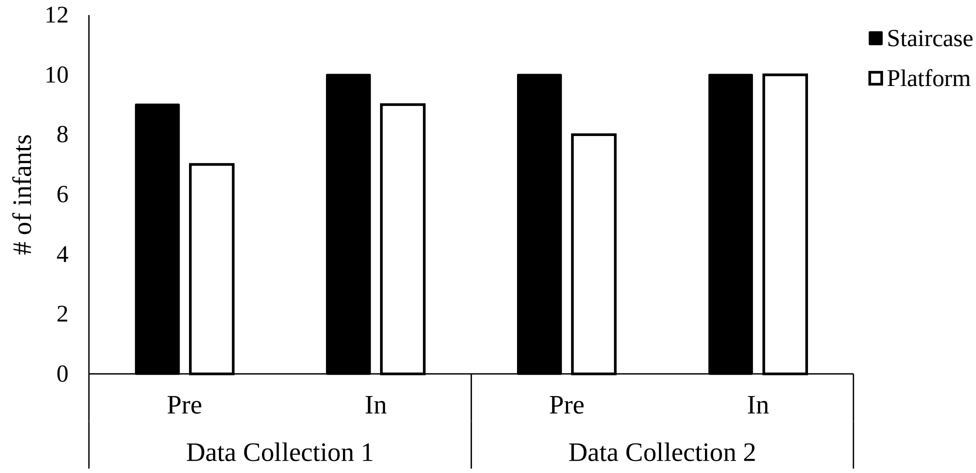


Figure 6. Success Rate of Task Completion across conditions in both data collections as defined by the number of infants reaching the top of the staircase and the platform. *Pre* are the trials that the infants performed the task without the assistance from the BWSS and *In* are the trials where BWSS assistance was introduced. The number of infants that successfully completed the task was bigger on the staircase compared to the infants' performance on the platform. However, the number of infants that successfully completed the ascending on the platform was bigger while assisted by the BWSS in both data collections.

A.

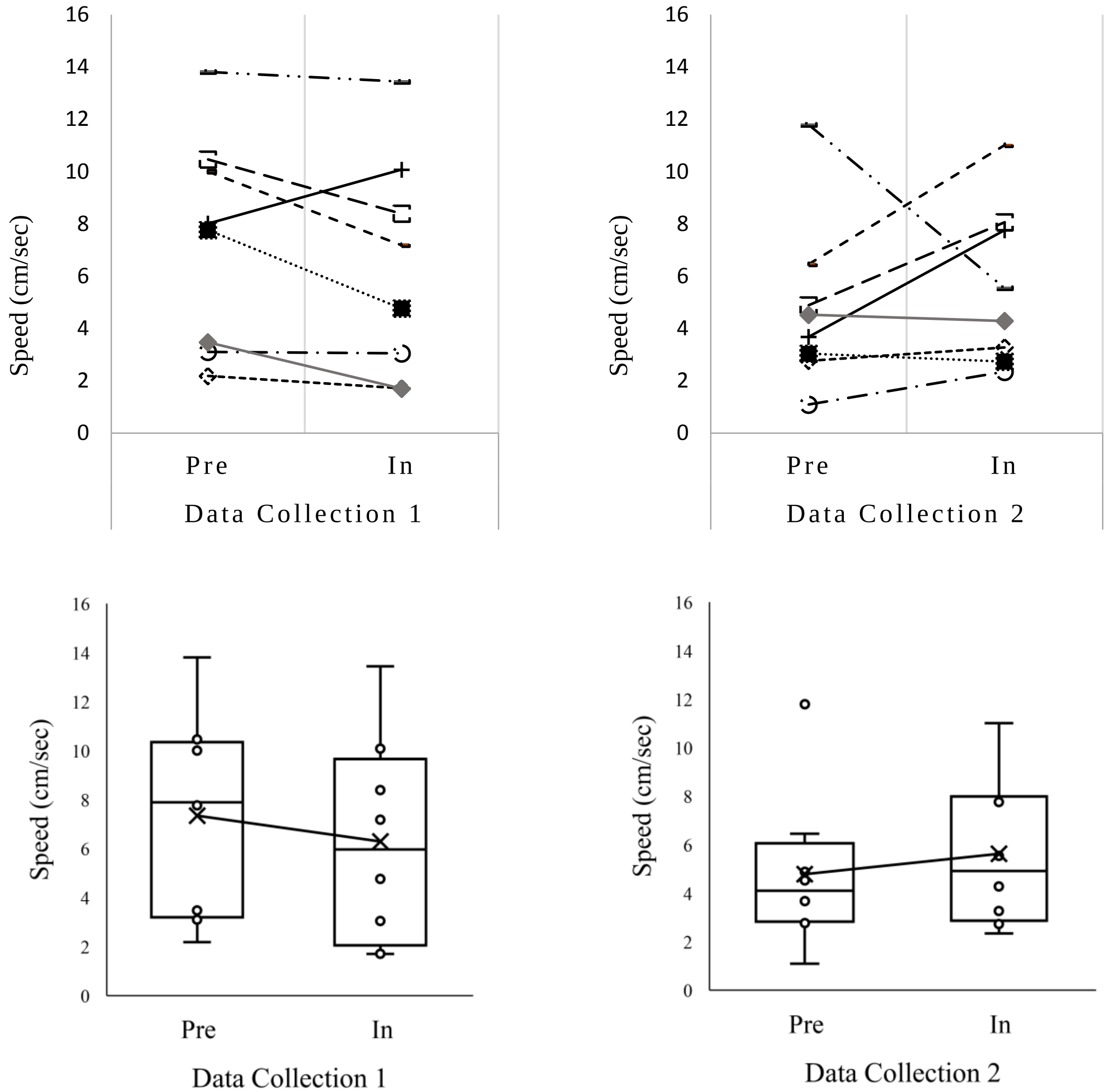


Figure 7. A. Direction of ascending Speed on the staircase for each infant that completed all trials (N=8). *Pre* are the trials that the infants performed the task without the assistance from the BWSS and *In* are the trials where BWSS assistance was introduced. In Data Collection 1, the direction of ascending speed is variable however in Data Collection 2, more subjects demonstrated an increase in speed while assisted from the BWSS. **B.** Box Plots that show the variance in the data. Despite the observed change in direction, there are no statistically significant differences between the two conditions in either data collection.

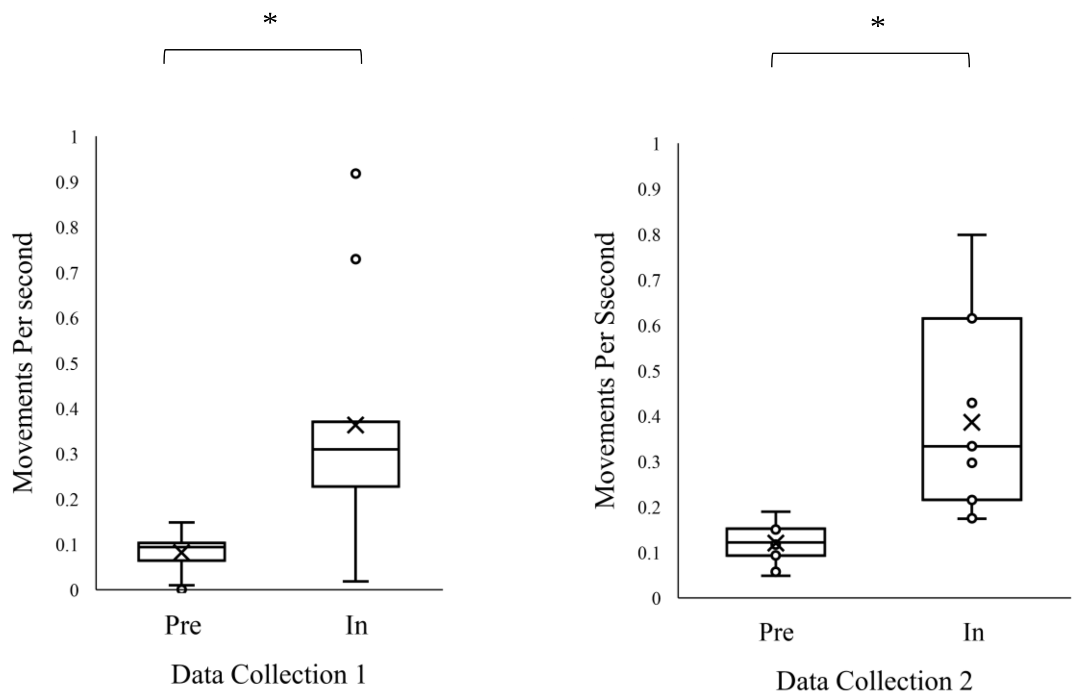


Figure 8. Frequency of Leg Movements during standing. Infants significantly ($p<0.05$) moved their legs more in *In* compared to *Pre* in both data collections.

2.7 Results – Aim 2

The results that follow focus on the change in performance of TD infants in the lab EE *while not using the BWSS*. Specifically, *Pre* of Data Collection 1 and *Post* of Data Collection 2 were compared. In both conditions, infants performed the tasks without the assistance from the BWSS.

2.7.1 Open-area Spontaneous Activity

Ten out of eleven subjects moved more in the 2D space in Data Collection 2 compared to Data Collection 1 (Figure 9). Wilcoxon Signed-Ranks test showed that the 2D Movement Path Length was significantly larger in *Post* in Data Collection 2 compared to *Pre* in Data Collection 1 (z=-2.223, p=0.026).

2.7.2 Platform and Staircase Ascending

Based on infants' performance in *Pre* of Data Collection 1 and *Post* of Data Collection 2, two subgroups were identified in the platform ascending task. Infants in the first subgroup (N=7) had only complete ascends (reached a ceiling effect), and infants in the second subgroup (N=4) had at least one incomplete ascend. More specifically, the seven out of eleven subjects (63.6%) successfully completed the task by reaching the top of the platform (*d* = 152cm) in both conditions. In the second subgroup (36.4%), three out of four subjects successfully completed the ascend in *Post* of Data Collection 2, and the last remaining subject had incomplete ascends in both conditions.

For the four infants in the second subgroup, distance on the platform was assessed (Figure 10). The three out of four infants that successfully completed the trial in *Post* of Data Collection 2 had to cover about five times the distance covered in *Pre* of

Data Collection 1. The remaining infant increased the distance in *Post* of Data Collection 2 compared to *Pre* of Data Collection 1 (Figure 10B). An overall picture of the changes in Distance for the whole group (N=11) is also depicted in Figure 10A. Wilcoxon Signed-Ranks test showed a trend towards significance (z=-1.841, p=0.066).

For the seven infants in the first subgroup, speed was considered. Six out of the seven subjects increased their speed in *Post* of Data Collection 2 compared to *Pre* of Data Collection 1 (Figure 10C). Wilcoxon Signed-Ranks test showed a trend towards significance (z=-1.859, p=0.063).

A higher success rate of task completion in the staircase task compared to the platform task was observed only in *Pre* of Data Collection 1, mentioned also in Aim 1 (Figure 11). Nine out of eleven subjects (81.8%) successfully completed the task by reaching the top of the staircase compared to the seven subjects (63.4%) that completed the task in the platform ascending. However, in the last condition of the study, the *Post* of Data Collection 2, infants had already managed to balance their performance success, which was high (ten out of eleven infants, 90.1%), among the two tasks. Again, half-way ascends trials on the staircase were not observed.

Similar to the performance on the platform ascending task, two subgroups were identified in the staircase ascending task. Infants in the first subgroup (previously mentioned, N=9) had only completed ascends, and infants in the second subgroup (N=2) had at least one incomplete ascend. The two subjects (18.2%) that had at least one incomplete ascend were also in the same group of the four subjects that had at least one incomplete ascend in the platform task. Both subjects had an incomplete ascend in *Pre* of

Data Collection 1, and only one of the two successfully completed the ascending in *Post* of Data Collection 2. For the nine subjects in the first subgroup, speed was assessed. The Wilcoxon Signed-Ranks test showed that the speed of staircase ascending was not different between *Pre* of Data Collection 1 and *Post* of Data Collection 2 (z=-0.533, p=0.594).

Visual attention was assessed for the infants with only complete ascends in both platform and staircase ascending tasks. Wilcoxon Signed-Ranks test showed that visual attention to the end goal was not different between *Pre* of Data Collection 1 and *Post* of Data Collection 2 neither in the platform ascending task (z=-0.734, p=0.463) nor in the staircase ascending task (z=-0.280, p=0.779). A Spearman's correlation was performed to assess a potential relationship between the visual attention and speed of ascending (Figure 12). There was a strong relationship only between the visual attention to the end goal and speed of staircase ascending in *Post* of Data Collection 2 (r_s =0.800, p=0.010) but not in *Pre* of Data Collection 1 (r_s =0.259, p=0.500).

2.7.3 Standing

Eight out of the eleven subjects demonstrated an increased Frequency of Leg Movements in *Post* of Data Collection 2 compared to *Pre* of Data Collection 1 (Figure 13) however this difference was not statistically significant according to the Wilcoxon Signed-Ranks test (z=-1.245, p=0.213).

2.8 Summary of Results – Aim 2

In this Specific Aim, we evaluated the change in performance of TD infants in the lab EE while not using the BWSS with time (Post of Data Collection 2 vs. Pre of Data

Collection 1 - across sessions). At the end of the second session and without the assistance from the BWSS, TD infants demonstrated higher success rates of task completion and moved more. Specifically, they travelled longer paths while spontaneously moving in an open-area, covered more distance and moved faster on the platform ascending, and moved their legs more during standing. These results are not all statistically significant but a trend toward significance is found. The speed of platform on the staircase ascending was not different between the two conditions. Visual attention to the end goal was not different between the two conditions but a strong relationship between visual attention and speed of staircase ascending was found in Post of the second data collection.

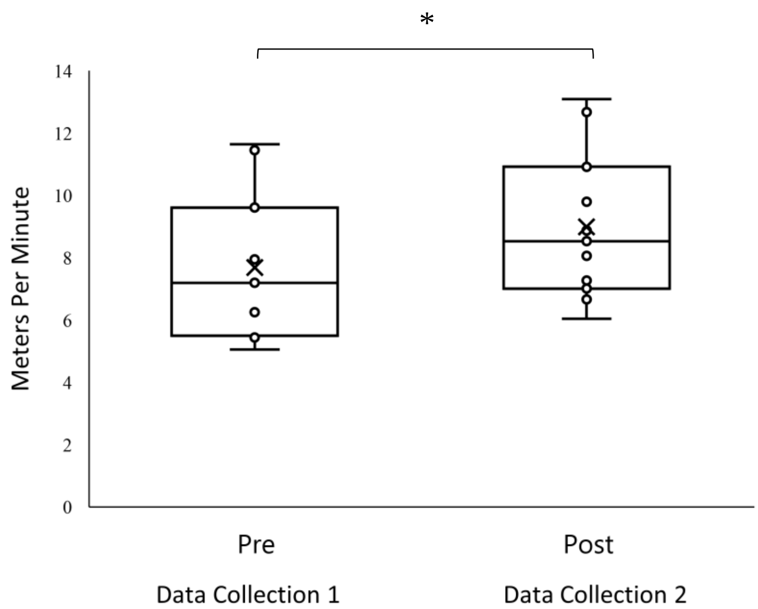


Figure 9. Movement Path Length during Spontaneous Activity in the open area. *Pre* and *Post* are both conditions in which the infants performed the task without the assistance from the BWSS in Data Collection 1 and Data Collection 2 respectively. Ten out of eleven infants moved more in the 2D space in *Post* of Data Collection 2 compared to *Pre* of Data Collection 1. Accordingly, the Wilcoxon Signed-Ranks test showed that the 2D Movement Path Length was significantly larger in *Post* in Data Collection 2 compared to *Pre* in Data Collection 1 (z=-2.223, p=0.026).

A.

B.

C.

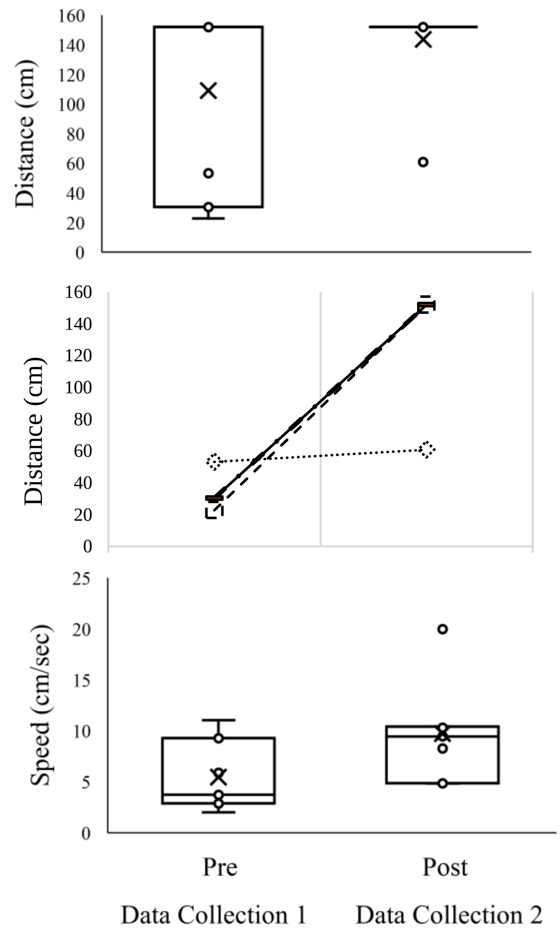


Figure 10. Performance in platform ascending. *Pre* and *Post* are the trials that the infants performed the task without the assistance from the BWSS in Data Collection 1 and Data Collection 2 respectively. **A.** Box Plots present the distance covered for all infants (N=11). A trend towards significance was noted according to the Wilcoxon Signed-Ranks test (z=-1.841, p=0.066). The great variability in *Pre* led to a secondary analysis, the visual inspection of individual data, and the presence of two subgroups in the sample: one subgroup that had only successfully completed trials (N=7), and one that had at least one incomplete trial (N=4). **B.** Distance covered for the second subgroup (N=4). All four infants increased their distance covered in *Post*, and for three of them the increase was marked by a successful completion of the ascending (*d*=152cm). **C.** Speed for the first subgroup was greater in *Post* of Data Collection 2 which led to a trend towards significance according to the Wilcoxon Signed-Ranks test (=-1.859, p=0.063).

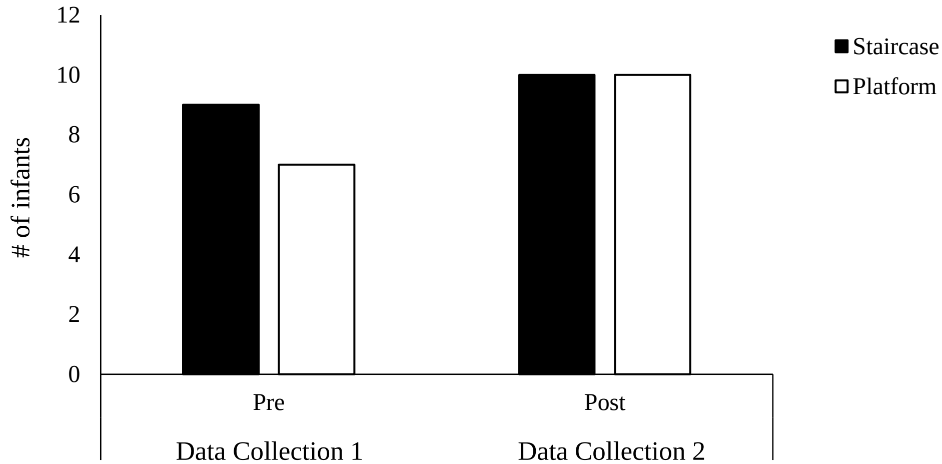


Figure 11. Success Rate of Task Completion on the staircase and platform ascending tasks.

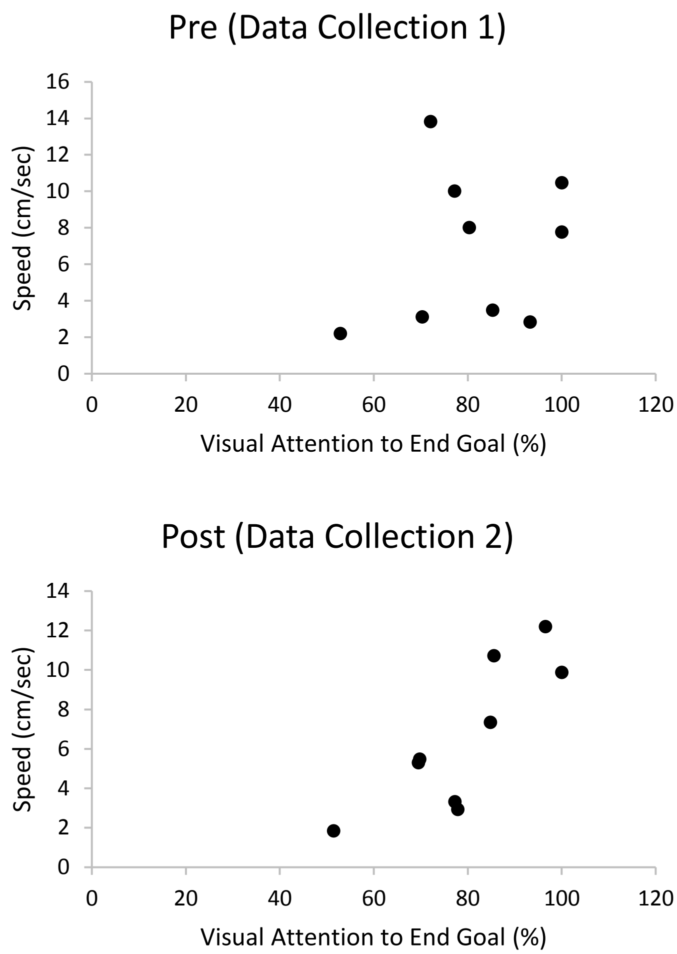


Figure 12. Scatterplots depict the relationship between visual attention and speed staircase ascending. *Pre* and *Post* are the trials that the infants performed the task without the assistance from the BWSS in Data Collection 1 and Data Collection 2 respectively. A statistically significant strong relationship was also found between the visual attention to the end goal and speed of ascending in *Post* of Data Collection 2 (r_s=0.800, p=0.010) but not in *Pre* of Data Collection 1 (r_s=0.259, p=0.500) according to Spearman's correlation analysis.

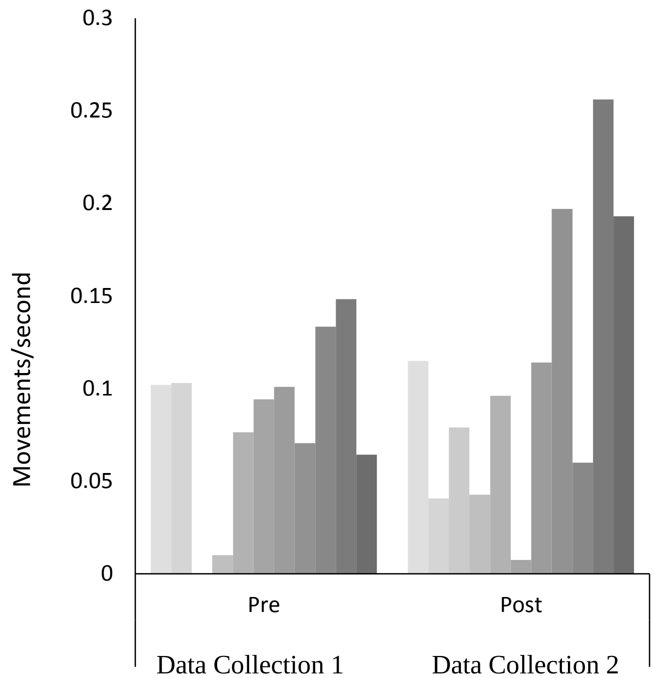


Figure 13. Frequency of Leg Movements during standing for all eleven infants. *Pre* and *Post* are the conditions in which the infants performed the task without the assistance from the BWSS in Data Collection 1 and Data Collection 2 respectively. Eight out of the eleven infants demonstrated an increased Frequency of Leg Movements in *Post* of Data Collection 2 compared to *Pre* of Data Collection 1, however this difference was not statistically significant (z=-1.245, p=0.213).

2.9 Results – Aim 3

The results that follow focus on the change in performance of DS infants across conditions and both data collections. The performance of DS infants is shown in relation to TD infants to provide a general overview of the two populations, and on the individual level when appropriate. To be clear, this is not a formal comparison of the two populations given the small sample size and widely varying range of ability in the infants with DS. This comparison proved to be very useful as it allowed us to identify the gap in the performance we need to fill with a larger study, and if and how much our paradigm might be expected to reduce that gap.

In this exploratory Aim, we slightly broadened our inclusion criteria for the DS population to include infants with various levels of locomotor experience (Table 5). Therefore, our sample consisted of three infants with hands-and-knees crawling experience, one infant with belly-crawling ability, and one infant with no prior locomotor ability (no crawling or scooting). The age of all DS infants however was within the typical age range of walking ability of a TD infant (> 1 year of age). We decided to include the infants with lower levels of ability for the special population to examine the potential to apply our paradigm at a younger age in the future. In that case, special needs infants may have not acquired locomotor ability yet. However, if we start early enough we maximize the potential to advance their development later.

Our paradigm was feasible for application in the DS population, as all infants with DS participated in all tasks without being fussy or without any problem that caused withdrawal of participation. Performance in the tasks of Platform and Staircase

Ascending, and Standing, in both Data Collection 1 and Data Collection 2 were considered for analysis. Statistical analysis was not performed for this exploratory Aim.

2.9.1 Platform and Staircase Ascending

Platform Ascending: In the Platform Ascending task, our results showed that 1) in the individual level, each infant with DS demonstrated a unique response across conditions and data collections which was matched for the majority of infants by an increase by the end of Data Collection 2, 2) as a group, infants with DS had reduced Success Rates of Task Completion and covered less Distance in the incomplete ascends compared to TD infants, and 3) again in the group level, visual inspection of the data revealed different patterns across time among the two populations.

Our first findings on the individual level are depicted in Figure 14. Out of the five infants with DS, only one infant completed the ascending (d = 152cm) across all conditions in both data collections. One infant was not able to ascend in *Pre* and *In* of Data Collection 1 but successfully completed all ascends after that. One infant, the youngest and less experienced, did not ascend in any of the conditions and data collections. And lastly, the two remaining infants had various responses with no clear patterns across time. Although, each infant performed differently across time, the majority of them were able to either complete the ascend or cover more Distance in *Post* of Data Collection 2, an increase in their performance compared to *Pre* of Data Collection 1.

On the group level, the performance of infants with DS in relation to the TD infants' performance is depicted in Figure 15. In general, the number of infants with complete ascends was always higher for the TD group throughout the conditions and data collections. As mentioned in the previous paragraph, only one DS infant out of five (20%) successfully completed the task across all conditions and data collections compared to the higher ratio of six out of eleven TD infants (54.5%), and there was one DS infant that did not ascend the platform at all (20%) but none in the TD group. Looking at the incomplete ascends, there is more variability on the Distance covered by the DS group compared to TD group (Figure 15). Infants with DS covered various Distances across time whereas TD infants either ascended the first half or fully ascended the platform (with one exception).

Visual inspection of the data also revealed different patterns across conditions among the two populations. At both data collections, the number of TD infants that successfully completed the ascending increased in a linear fashion across conditions. However, infants with DS showed a U-shaped pattern in their performance. This was caused by the difference in the response among the two populations in the *In* conditions. The number of TD infants that completed the task increased in *In* of both data collections compared to the number of infants with DS that decreased in the same condition. However, when we look at the comparison between *Pre* of Data Collection 1 and *Post* of Data Collection 2 (similar to our Aim 2) the pattern is similar; both populations showed an increase in the success rate of task completion. Lastly, there was one DS infant that did not ascend the platform at all whereas there was no similar case in the TD group.

Staircase Ascending: In the Staircase Ascending task, our results showed that1) in the individual level, infants with DS showed higher success rates of task completion compared to their performance in the platform ascending task, 2) as a group, infants with DS had reduced Success Rates of Task Completion compared to TD infants, and 3) again in the individual level, speed on the staircase ascending task in general increased in the *In* conditions.

In general, the performance of infants with DS in the staircase ascending task was better compared to their performance in the platform ascending task, as they showed greater success of completion throughout the study. However, their success rate of task completion was lower than that of TD infants throughout the study (Figure 16). In the group of TD infants, eight out of eleven infants (72.7%) successfully completed the task by reaching the top of the staircase across conditions and data collections compared to the three out of the five infants with DS (60%). Interestingly, we see a smaller difference (gap) between the two populations in the success rate of task completion in the staircase ascending task compared to the difference seen in the platform ascending task. Out of the two infants with DS that had at least one incomplete ascend, one infant with DS did not ascend at all (the same infant that did not ascend the platform), and one infant was not able to ascend the staircase at all until the last condition of the study, the Post of Data Collection 2, where the infant completed the ascending for the first time in life. Half-way ascends on the staircase were not observed in the group of TD infants but the infant with DS before ascending in *Post* for the first time, climbed the first step in *Pre* and *In* of Data Collection 2 (*Pre*, *In*, and *Post* of Data Collection 1 was a no ascend).

In the individual level, we examined the speed of staircase ascending in *In* compared to *Pre* for the three infants with DS that had only completed ascends. Two out of the three increased their speed in Data Collection 1, and all three infants increased their speed of ascending in Data Collection 2 (Figure 17).

2.9.2 Standing

In both data collections, four out of five infants with DS demonstrated increased Frequency of Leg Movements in the *In* conditions (Figure 18). Wilcoxon Signed-Ranks tests did not show significant difference in Data Collection 1 (z=-0.944, p=0.345), but showed a trend toward significance in Data Collection 2 (z=-1.753, p=0.08).

2.10 Summary of Results – Aim 3

In this Specific Aim, we explored the change in overall performance of infants with DS in the lab EE while and while not using the BWSS. We looked at changes in relation to the TD group and within the group of infants with DS. Overall infants with DS had lower success rates of task completion and more variability in their response compared to the TD group. Although the response pattern across conditions was not linearly improving as in the TD group, by the end of the second data collection the majority of infants with DS demonstrated gains even without the assistance from the BWSS.

Table 5. Characteristics of infants with DS (N=5).

Subject #	Age (months)	Gender	Height (cm)	Weight (kg)	Locomotor Ability
Infant 1	17.7	F	76	10.0	Crawling
Infant 2	16.7	M	72	9.5	Belly-crawling
Infant 3	12.4	F	75	10.2	-
Infant 4	19.7	F	77	9.5	Crawling
Infant 5	18.6	M	80	9.8	Crawling

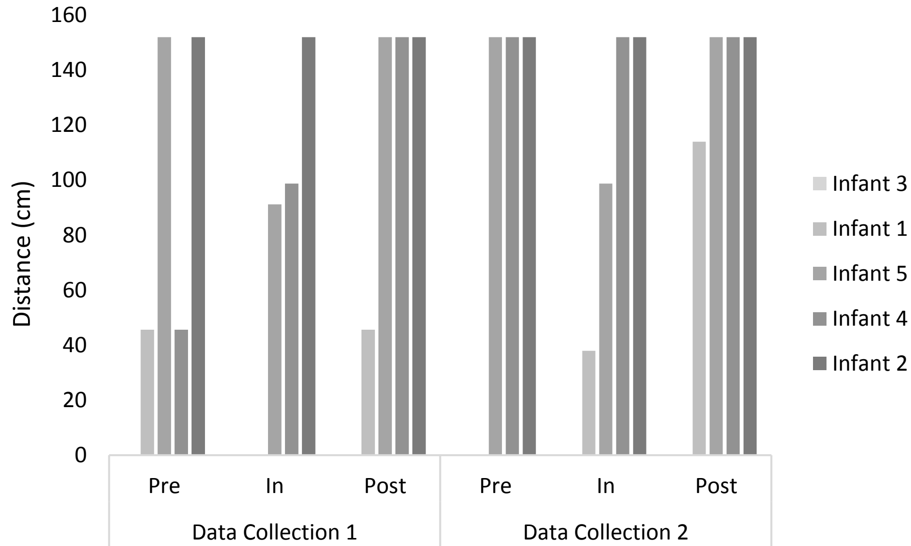
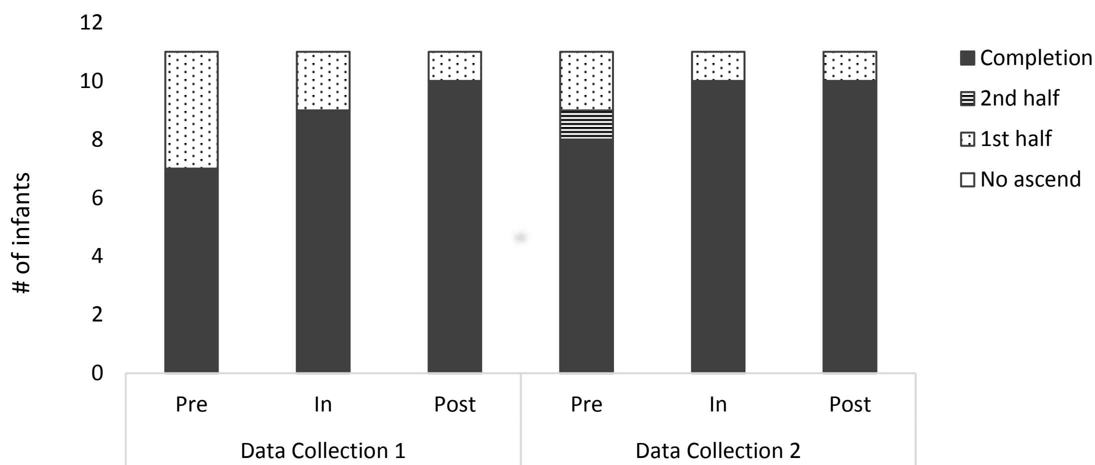


Figure 14. Distance covered in the Platform Ascending Task for the infants with DS. Each infant had a unique response across conditions and data collections. However, by the end of the Data Collection 2 (*Post*), the majority of infants covered more Distance compared to that in *Pre* of Data Collection 1.

A.



B.

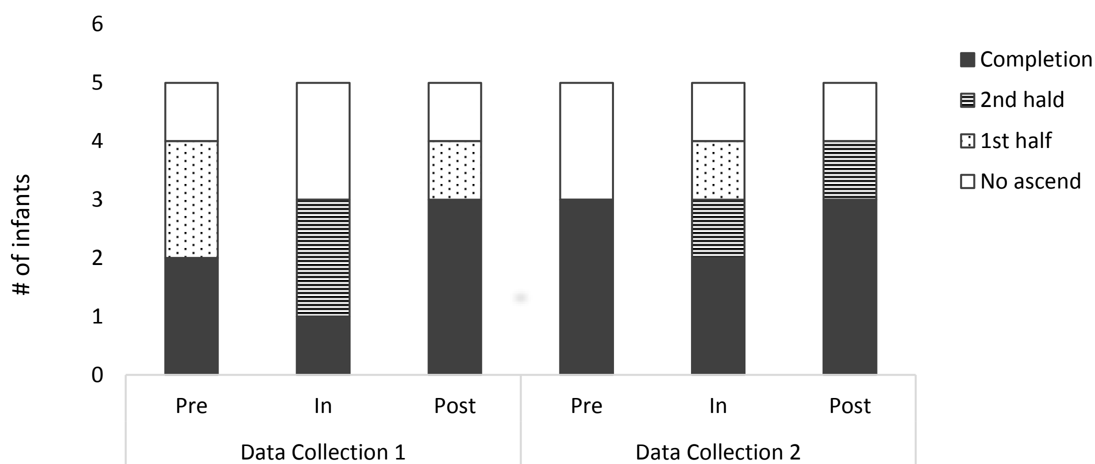
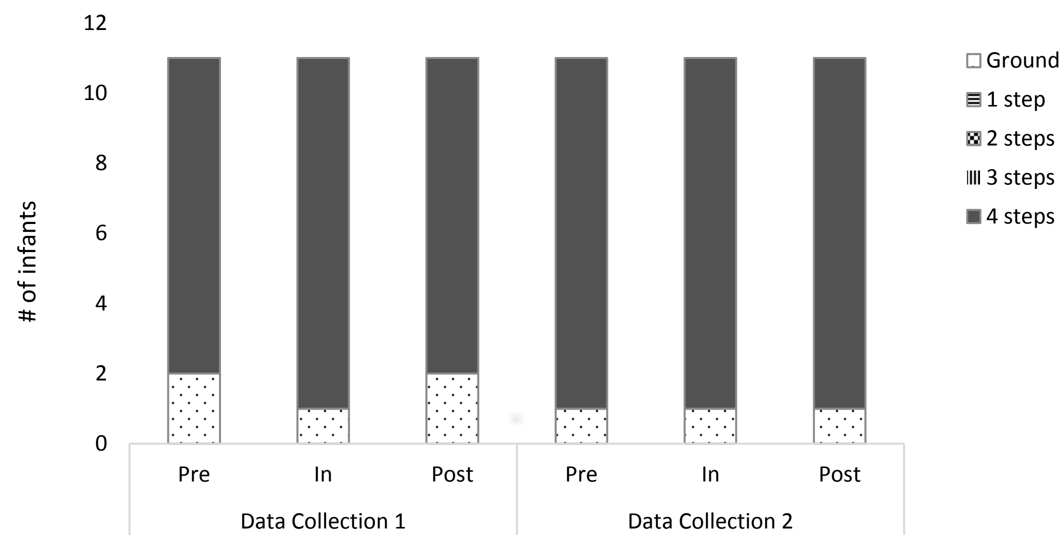


Figure 15. Overall performance of TD infants (**A**) and DS infants (**B**) in the Platform Ascending task. The 'No ascend' corresponds to 0cm distance covered, the '1st half' to distance covered between 0-76cm, the '2nd half' to distance between 76-152cm, and the 'Completion' to 152cm.

A.



B.

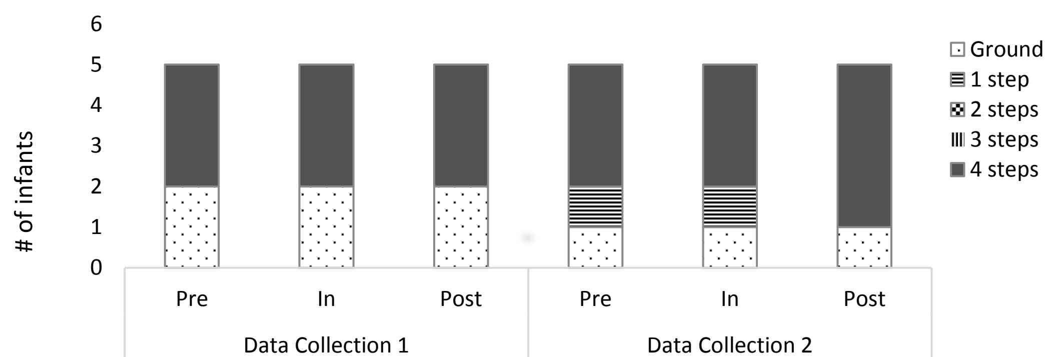


Figure 16. Performance of TD infants **(A)** and DS infants **(B)** in the staircase ascending task.

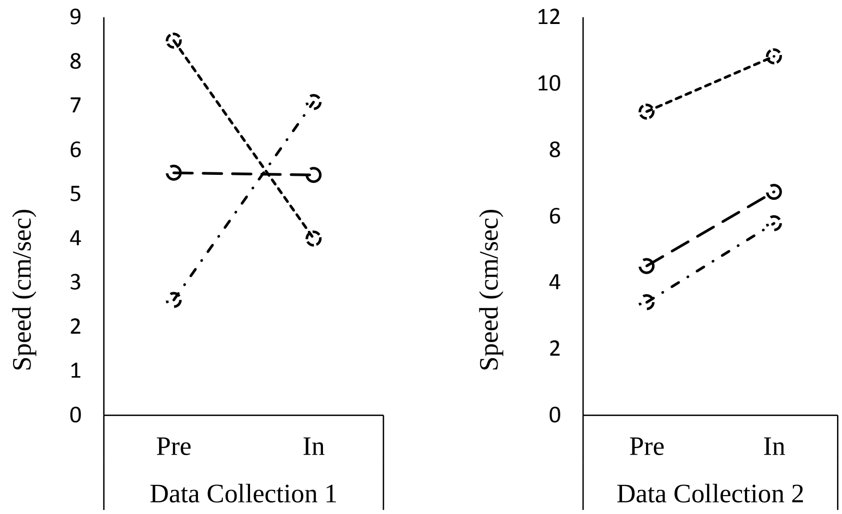


Figure 17. Speed on the staircase ascending of the three DS infants in both data collections. The first time the infants performed the task was without the assistance from the BWSS (*Pre*) and the second time they did the same while being supported by the BWSS (*In*). In Data Collection 1, infants' responses varied, but in Data Collection 2, infants showed similar trends across the three conditions with increased speed of ascending while being supported by the BWSS. A similar pattern was also observed in the performance of TD infants described in the Results – Aim 1 section of this dissertation work (**Figure 7**).

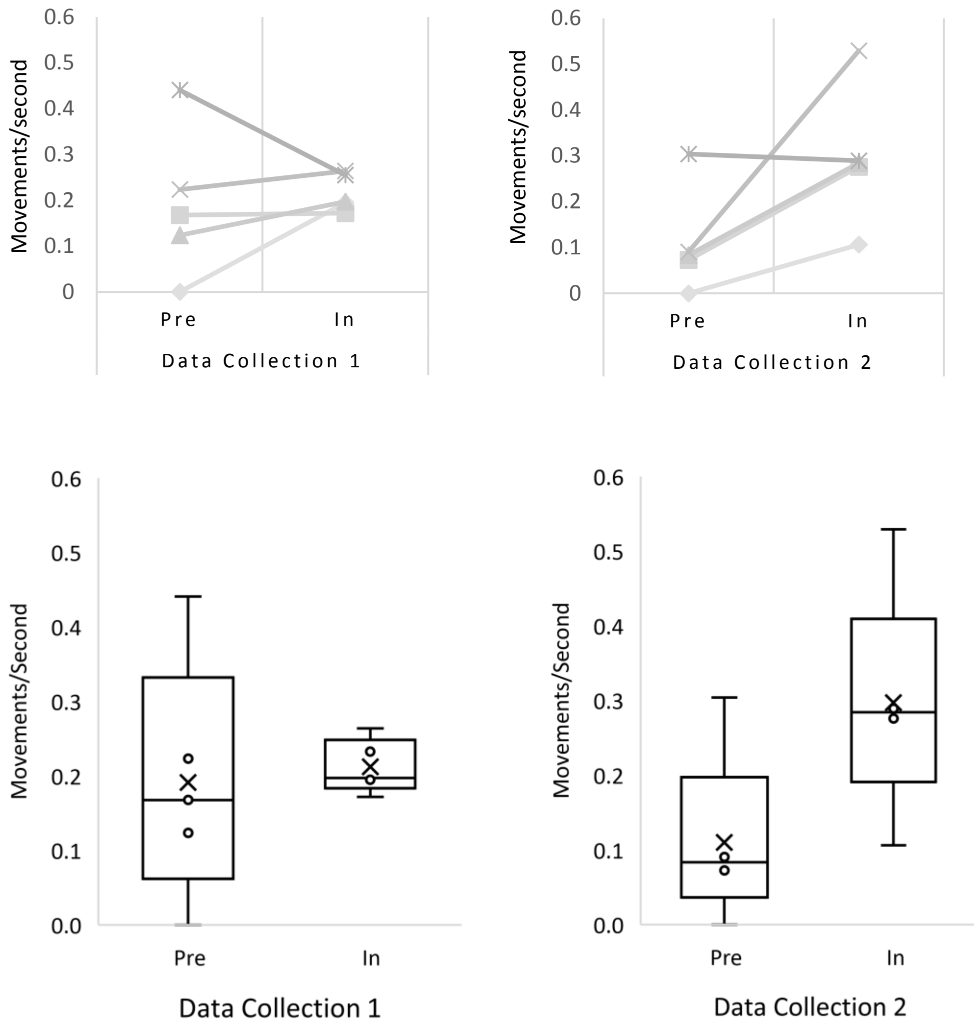


Figure 18. Lower limb movement in the standing task. In both data collections, four out of five DS infants demonstrated increased limb movement while assisted by the BWSS. Although Wilcoxon Signed-Ranks tests did not show significant difference in either data collection, in Data Collection 2, there was a trend toward significance (z=-1.753, p=0.08).

2.11 Discussion

The present study examined the change in behavior of eleven TD and five DS infants while exploring an EE that combined novel and familiar tasks with and without the assistance from a novel open-area BWSS. Given that this was the first study of young infants in this type of BWSS, we initially did not even know if infants would participate or if major changes would need to be made to the device or research design. We were very pleased that both populations participated in all tasks without any problem that caused withdrawal of participation. In addition, both populations showed changes in their behavior while performing the tasks across the BWS conditions, within session and across sessions.

<u>Positive Change in Behavior of TD Infants While Being Supported by the BWSS Within Session</u>

Non-walking TD infants "attacked" the objects in our paradigm and even within session they changed their behavior. Specifically, when assisted by the BWSS, the majority of TD infants instantly travelled and moved their legs more. Due to the low sample size, some of the observed changes were not significant, but indicate the reasoning to explore this tasks more in the future. In general, these observed behavioral changes reflect the infants' capacity to adapt to biomechanical, environmental, and task-related factors when these are altered.[18,32,35] The fact that the adaptation took place within one and/or two sessions suggests that TD infants have also the capacity to change rapidly. The above results suggest that the BWSS can be used as an assistive effect and substitute for functional ability to advance training.

Most infants covered a greater distance with the assistance from the BWSS in two different tasks; when spontaneously moving in the open-area, and while ascending the platform. It is important to note that in the platform ascending task, the majority of infants that could not go up initially managed to complete the ascend within the session for the first time in their life – which it was particularly noticeable to parents.

In general, covering more distance over ground with time is a phenomenon typically seen in development as infants get older (i.e. walkers travel more than crawlers) and move from one place to another to interact with objects and toys.[64] However, the fact that the change in distance emerged across contexts, in both over ground and over an inclined surface, and fast, suggests that there are other factors to behavioral change than just maturation. These changes show the infants' ability to adapt to biomechanical, environmental, and task-related factors.[18,32,35]

The adaptation to the different factors was also seen in supported standing. Change in postural orientation with respect to gravity and addition of BWS instantly gave TD infants the opportunity to move their legs more and thus explore the surrounding area with their feet more. A similar effect was seen in Thelen's series of experiments.[34,36,111] For example, in one of the experiments the team altered postural orientation by placing the infants in an inclined position. The emergence of reaching was with the feet first rather than the hands that it was widely thought.[34] In another experiment, she altered the BWS on the limbs by placing infants in water, and noticed the instant increase in stepping.[36] Our results supported by the above examples suggest that these behaviors are not evident initially because they are masked by the continuous changes in body dimension and strength; but when some factors change (e.g. BWS), these behaviors re-emerge.[32,35] The ability to induce behaviors in such ways is extremely important, as it may facilitate the repetition of the behaviors (aka training). For example, training on facilitation leg movements such as kicking patterns and stepping are related to walking and may contribute to an earlier walking onset.[37]

Although TD infants travelled and moved their legs more, in ascending, they showed various responses for the direction of speed in both the platform and the staircase. This was shown for both data collections. Thus, there was no clear pattern of increase of speed when assisted by the BWSS. This result contradicts the pattern of increased speed that comes with better control on the various soft constraints from experience; typically seen during the development of tasks like reaching and walking.[64,95,96] Visual attention while ascending did not show a consistent pattern either. In the first data collection, infants did not show more visual attention to the end goal, however, in the second data collection, visual attention to the end goal was more when assisted by the BWSS. This variable may be combined with the fact that no changes in speed were found between conditions as hypothesized.

Positive Change in Behavior of TD Infants While Not Supported by the BWSS After Exposure

Non-walking TD infants transferred some of the changes observed when inside the BWSS to outside of the BWSS. Similar to the within session changes previously described, TD infants travelled longer distances and moved their legs more when they got outside of the BWSS compared to the initial outside of the BWSS condition (before exposure). In addition, in some cases they moved faster (i.e. in platform ascending but not in staircase ascending). These results suggest the possibility of transferring some information from one condition to the other within just a couple of sessions. The above results suggest that the BWSS can be used as a rehabilitative tool and lead to positive changes in functional ability if used for longer periods of time.

The above changes in distance and leg movement emerged only after two sessions. This suggests that TD infants have the capacity to change rapidly. Rapid changes due to training during development have also been observed in other behaviors. For example, two days of reaching training resulted in increased frequency of object contacts, shorter and smoother reaching movements, and improved hand positioning when approaching for an object.[90] Even a single training session can result in changes in both the frequency of reaching and the grasping strategies.[91] Another behavior where rapid changes are also seen is stepping over obstacles. Specifically, training involving trip-inducing stimuli produced steps that involved higher lifting of the leg immediately after the removal of the stimulus and within a session.[92]

We cannot be certain if these changes are learning or performance. Both are very important in development as more permanent changes in behavior initial emerge from the minute to minute changes in performance. Our results suggest a retention in some behaviors such as the platform ascending. For example, the distance that infants covered in the platform ascending in *Pre* of Data Collection 2 was greater than that of *Pre* in Data Collection 1, thus showing an improvement with time and exposure. More studies need to be conducted and over longer periods in order to quantify a learning effect. Nevertheless, this work suggests that even a few sessions might provide enough opportunities for infants to alter their behaviors.

Adaptation in speed of ascending across time also shows a different pattern compared to the other variables. More specifically, speed of ascending was different between the two tasks. In staircase ascending, there was not a clear direction among infants, but in the platform, six out of seven infants ascended faster by the end of the second data collection (statistical trend). Two theories may explain the above result: 1) either that that adaptations in speed take longer to show up, 2) the infants in the staircase ascending task reached a ceiling effect by going too fast and thus subtle changes were not enough to induce significant differences. If the second is true, then infants with less ability level (e.g. younger, with less experiences) may show changes in speed. Further studies need to explore this question.

An interesting finding in the staircase ascending was that visual attention matched the speed of ascend by the end of the second data collection. Visual attention to the end goal for the nine infants that had only completed ascends on the staircase was not different between the two conditions. However, a strong relationship between visual attention to the end goal and direction of speed was found only at the *Post* of the second data collection. This means that infants that ascended slower on the staircase were looking less to the end goal whereas infants that ascended faster looked more to the end goal. This relationship was not shown in the initial condition. Initially, infants explored more the surroundings of the novel task including the staircase.

A similar effect was seen when infants were exposed to the novelty of crossing narrow bridges.[112] With experience, infants were able to look at the risky bridge and adjust accordingly their walking by going slower and doing smaller cautious steps to cross it. Our results suggest that changes in the interaction between the motor behavior and other skills, such as perception, may be achieved in our paradigm; since visual attention is thought to be the primary perceptual system for guiding locomotion.[99,100] This is a great example of a multi-factorial effect seen in our results, and is in agreement to the recurring motor and non-motor changes seen in development.[24]

Overall Change in Behavior of Infants With DS Across and Within Sessions

This study examined if similar changes seen in TD infants' behavior were also observed in DS infants. In general, although DS infants had almost double the age of TD infants, showed decreased performance in the tasks. In some tasks, DS infants took advantage of the BWS and in others they did not.

The success rate of task completion in platform and staircase ascending was different between the two populations. However, when we look at the pattern of change within the same population, they shared some common characteristics. First, both TD and DS infants showed the same pattern; a higher chance of completion of the staircase ascending compared to the platform ascending. However, by the end of the second data collection, the number of infants that completed the ascends increased and was more similar for the two tasks for each population.

We also examined specific within session changes in DS infants for this exploratory Aim. Although we only had five DS infants, we got some information about how and when these infants change with the support from the BWS.

Speed of the three DS infants that fully completed the staircase in all conditions was evaluated. All three ascended faster in the second data collection whereas in the first data collection the direction of speed varied among the three. This result suggests that in a novel task, DS infants have the capacity to take into advantage the BWS and adjust fast to the different constraints.

In addition, four out of five DS infants showed increased limb movement when supported by the BWSS in both data collections. Similarly, the increase was greater in the second data collection. This effect is important, since more time in practicing these early precursors may lead to the mature behavior of walking later.[32] Further studies need to be carried out to examine if the relationship between leg movements and earlier attainment of walking is possible to reduce the motor delays for this population. [9–11,23]

Does Novelty Play a Role in the Way Infants use the BWS?

Our findings suggest a common pattern in the change of infants' behavior. It seems that: 1) infants' previous experiences and the low level of complexity of the familiar tasks (open-area exploration, standing) allowed for rapid, positive behavioral change when supported by the BWSS – BWS seen as an mediator, 2) infants' unfamiliarity and high level of complexity of the novel tasks (platform and staircase ascending) along with the assistance from the BWSS led to a variability in performance – BWS became an extra constraint, and 3) infants within only two sessions were able to turn the BWS from a constraint into an mediator, as it was seen by their increased (although not significant) performance while assisted from the BWSS in the second data collection.

We need to be cautious with these interpretations as the low sample size due to the formation of subgroups, may have affected the non-significant results in the novel tasks. The notion that the BWS was seen as a constraint in the novel tasks, was more evident in the DS population, suggesting that this population may need more than two sessions in order to ‘figure out’ the softening of the biomechanical constraints from reducing weight from the limbs.

2.12 Conclusions

Our paradigm lays the foundation for future work on EE and harnesses. We examined non-walker TD and DS infants’ performance in a combination of different tasks of an enriched environment, both novel and familiar, and assessed the effects of BWS in on shaping their behavior while exploring these tasks. This pilot study was feasible, proving our paradigm may be used for longitudinal studies later. Results showed that infants’ previous experiences and level of complexity of the tasks are important toward the BWS role; in most cases, infants took advantage of the BWS and explored familiar tasks, like in spontaneous activity and standing. In the novel tasks, like platform and staircase ascending, and especially DS infants, were not able to use the new information from the BWS instantly. However, in just two sessions infants’ change showed positive trends. It seems also that there was a connection between the performance in the tasks while assisted by the BWSS and the increase after the exposure. However, more studies are needed to define this connection.

2.13 Limitations

This study is a pilot study and therefore the sample size is small. Due to the nature of the study design, which involved novel tasks, infants were not able to perform all tasks, and therefore the sample size was not enough for the subgroups that were formed (i.e. six vs. five infants in the platform ascending task) and thus identify statistically significant differences among the conditions. Further studies are needed in order to better describe the role of the BWSS assistance in novel tasks of an enriched environment for non-walkers.

Furthermore, the study design cannot describe if the aforementioned effects described in Aim 2 were due to the exposure in the tasks for multiple times or solely because of the addition of the BWS. In order to examine this question, further studies are needed that include multiple groups with a combination of BWS and tasks.

Chapter 3

A USER-CENTERED RESEARCH APPROACH TO ASSESS THE FEASIBILITY OF THE NOVEL OPEN AREA BODY WEIGHT SUPPORT SYSTEM WITHIN THE HOME ENRICHED ENVIRONMENT

3.1 Abstract

Background. Interventions that take place in real-world environments are critical for the enhancement of child development. For infants and toddlers, the home environment offers a variability of high-dosage activities in a natural social setting. Current rehabilitation technology lacks in-home mobility devices for maximizing those activities. The present work describes the development and application of novel technology for use in real-world environments and assessed its feasibility. The users, aka the family participated at all stages of the study. **Objective.** To assess the feasibility of the first in-home body weight support system (BWSS) for supporting activity in an open-area from the family's point of view. **Methods**. TD infants (n=11), infants with DS (n=5), and their parents (n=20, both parents of four infants participated and provided feedback), participated in a home session that involved the setup and use of the BWSS. Parents engaged their infants in play activities in and out of the BWSS. Next, parents completed a questionnaire to quantify: 1) parents' perception of the infant's behavioral change, if any, b) parents' and their infant's level of enjoyment, c) parent satisfaction of the BWSS, their need and hypothetical use of the BWSS, and d) parent recommendations for future modifications. **Results**. Our paradigm was feasible for application in the home by the family. The BWSS was successfully setup and used by the parents in all 16 homes. Both infants and parents happily participated in the play session without being fussy or without any problem that caused withdrawal of participation. All parents encouraged play activities and noted positive changes in their infants' performance while using the BWSS. Some parents reported that their infant initiated certain behaviors for the first time while using the BWSS. Furthermore, parents were satisfied with the current structure of the device and recommended future modifications specifically for the wearable harness to increase comfort and convenience for the infants. In general, infants and family members expressed behavioral improvement and overall satisfaction with the system. Parents and their infants actively participated in all sessions. **Conclusions.** This work contributes to the development of intervention programs that merge the advantages of body-weight supported activity with their application in real-world environments like that of the infants' homes in an effort to develop long-lasting effects and advance overall development.

3.2 Introduction

In Chapter 2, we described the effects of our paradigm that combines body-weight-supported activity in an enriched environment (EE). We reported the immediate positive changes on the infants' behavior while being assisted by the body weight support system (BWSS) as well as the transfer of some changes even when they get out of the BWSS in the lab EE. The latter observation is critical, since it indicates that the BWSS may go beyond acting solely as an assistive device to also provide a possible rehabilitative effect.

One important key to achieving a level of rehabilitative effect is high dosage use outside of the lab. In order to assess this potential, we went outside the lab and tested the application of the BWSS at the infants' homes. The addition of this extra step was not straight-forward. As discussed later, comprehensive feasibility studies of devices often involve multiple factors that need to be assessed. Similarly, in our study, we progressed systematically through stages to address key factors. These stages included:

1) *research and development* of a new device for use with young infants,

2) *testing of the newly-developed device* in real-world EEs (lab and homes),

3) *assessment of the novel paradigm* through the preliminary evaluation of infants and their families' responses.

But first, let's review the factors of feasibility studies, and why we needed to conduct one to move further with this work.

What is a feasibility study? One definition originates from the United Kingdom's National Institute for Health Research which defines those as "pieces of research done before a main study in order to answer the question 'Can this study be done?' and are used to estimate important parameters that are needed to design the main study".[113]

Feasibility studies are common in the medical field. Most commonly these focus on drug trials in which a single chemical ingredient is being tested and viewed as the causal effect of intervention outcomes.[114] However, the assumption that a single factor can cause the intervention outcomes does not apply in the rehabilitation research. Feasibility studies in rehabilitation contain a variety of factors that may affect the outcomes. Thus, they should be designed and evaluated considering all factors; the participant, their daily activity and/or occupation, and the environment they live in.[113–115]

Guidelines exist for designing feasibility studies in rehabilitation that focus on multiple factors.[114–117] For example, Bowen et al., (2009) have pointed out eight general areas to address when designing feasibility studies:

1) Acceptability (recipients' reaction to the intervention),

2) Demand (estimated use of the intervention),

3) Implementation (intervention may be implemented as planned),

4) Practicality (can the intervention be delivered when resources are constrained?),

5) Adaptation (modifications on procedures to accommodate the intervention in a new situation),

6) Integration (level of system change needed to integrate the intervention into an existing infrastructure and/or program),

7) Expansion (can the successful intervention have the same success with a different population or setting?),

8) Limited-efficacy testing (testing an intervention in a limited way, i.e. within shorter follow-up periods).[116]

Another group has focused on five objectives that involve the evaluation of:

1) recruitment capability and resulting sample characteristics,

2) data collection procedures and outcome measures,

3) acceptability and suitability of intervention and study procedures,

4) resources and ability to manage and implement the study and intervention,

5) small sample of participant responses to intervention.[115]

The above methodological components may vary from feasibility study to another; thus, they are flexible.[117] This flexibility was important to us as we designed the methodology of our study specifically to address our problem. However, the main key questions every feasibility study should answer are: '*Can it work*?', '*Does it work*?', and '*Will it work*?'.[116] Therefore, as we designed and applied our feasibility study we always kept these three important questions in mind.

Our paradigm involves several areas of innovation for rehabilitative technology. The areas of innovation include the: a) application of technology not being tested before with a very young population, and b) the application in an 'uncontrolled' environments like the families' homes. A feasibility study was needed to address both areas of innovation properly, and answer the questions '*Can it work*?', '*Does it work*?', and '*Will it work*?'. In order to address both areas of innovation properly, we had to go through different stages. Weightman et al. (2010) describe three stages in their study that involved older children's and family's involvement in the design and evaluation of devices for upper limb rehabilitation: 1) the preliminary rehabilitation device development, 2) the evaluation of the device in a semi-controlled environment, the school, and 3) the feedback after a period of using the equipment in an 'uncontrolled' environment, the home.[118] Accordingly, in our study, we adapted these three stages by focusing on the 1) *research and development* of a new device appropriate for use with a very young population, 2) *testing of the newly-developed device* in real-world EEs (lab and infants' homes), 3) *assessment of the novel paradigm* through the preliminary evaluation of participant responses (of infants and their families). The rest of this Chapter is structured around these three stages where we describe how we addressed the questions '*Can it work*?', '*Does it work*?', and '*Will it work*?' at each stage respectively.

3.2.1 Research and Development of the Device

In the initial phase of our feasibility study we focused on the 'Can it work' question.[116] More specifically, in our case, it was important to assess if we 'can develop technology to be used with infants in real-world environments that will work as part of effective early interventions (aka support increased dosage and duration)'. In that stage of the preliminary rehabilitation device development, research was needed to gather information and better describe the problem, which in turn will define the design requirements and the building of an initial protoype.[118] Thus, our research focused on the commercially available technology, the identification of the unmet need for assistive technology early on, and the technology being used in the research world. The above information would contribute to the identification of the specific features our technology should have in order to address the problem, and lastly it would lead to its development.

If this phase brings a successful design, we respond to the 'Innovation' that federal programs like NIH are looking for when they review studies to fund.

3.2.1.1 Technology Research

As previously mentioned, our technology research focused on the commercially available technology, the identification of the unmet need for assistive technology early on, and the technology being used in the research world. We summarize these research components, which have also been described in detail in Chapters 1 and 2, below.

A review of the commercially available technology to assist movement in very young children revealed a major gap. Low-tech orthoses and assistive devices that move with the user, such as walkers, canes, positioning devices, and crutches have been used literally for 1000s of years to assist ambulation in adults and older children. Using these devices leads to some level of improvement of functional mobility for 3 out of 4 children.[65] This improvement though probably does not reach the level of a fully functioning individual.

In addition, children that require technology with more support simply do not community-ambulate until their motor ability improves adequately as a result of development and/or training.[66] Thus, infants and toddlers that do not have the ability to walk yet, fall under this underrepresented category of patients waiting for a mobility device. In addition, the unmet need for mobility aids for this young population keeps increasing per the National Survey of Children with Special Health Care Needs. The 4.7% of children with unmet need for mobility aids reported in 2004 has increased to

7.7% as reported in 2016.[67,68] These reports reflect the need for devices that target immobility in infants and toddlers. Research studies focused in addressing that gap.

Two most commonly studied types of technology to address immobility in infants and toddlers involve treadmills and body weight support systems. Treadmills have been extensively used to enhance locomotor ability in infants with Down Syndrome (DS). More specifically, the goal of early interventions that incorporated such devices was to reduce the delay of the independent walking onset and/or to maximize walking performance for that population.[15–17,72,73] Great results came out from these early intervention studies. For example, a groundbreaking finding at the time by Ulrich et al. (2001) was that just minutes of daily training led to a reduction in the walking onset delay for these infants.[15] Another important aspect of these studies was that the intervention was performed at the families' homes by the parents; aspects that we were also looking for with our rehabilitation design. The problem however, is that motorized treadmills and these associated training programs, were specifically designed and applied for walking. Thus, sitting, standing, crawling, jumping and all the various transitions between these are not addressed by treadmills.

BWS devices can be used to target the emergence and training of various behaviors. In general, high technology BWS devices, like the ZeroG™, have been used in interventions with older children in combination with treadmills. That is BWS placed over a treadmill. Prosser's work is an important exception in the she used BWS over ground with obstacles for infants to explore.[74] The team showed the beneficial effects of such a paradigm on the gross motor function of young children with cerebral palsy

(CP).[74] The disadvantage is that this device is a high-tech, expensive, and non-portable technology that has only been applied to date in a clinical setting or lab, thus minimizing the chances for a longer term, high-dosage intervention and socialization with family.

From the above, a specific need for commercially available technology for very young infants was evident. However, pediatric rehabilitation research is currently more focused on the training rather than technology development. Our work aimed to develop accessible technology and examined the potential to enhance early intervention outcomes.

3.2.1.2 Development

The positive outcomes from Ulrich's and Prosser's work encouraged our lab's design of technology that combines BWS and training of various behaviors. To proceed with the development of a technology that combined all the above we had to bring child development experts and engineers together. Thus, our lab partnered with a local engineering company (Enliten LLC, Newark, DE, USA) that would assist in the design and manufacturing of the device. The formation of the interdisciplinary team was key to the successful development of a device that by the end of this study became several commercially available systems.

One of Enliten's devices designed specifically to address the above gap is the Portable Mobility Aid for Children (PUMA®), which is now a patented and FDA-registered BWSS (Figure 1). This is the device used in this dissertation work. The PUMA® provides mechanical support of the infant's body while allowing vertical and horizontal movement throughout the system footprint of about $8m^2$. The amount of BWS is manipulated through a counterweight system.

Figure 19 shows the development of the design. The first proof of concept prototype is a combination of a small foldable canopy structure, a wearable commercially available infant harness, and springs (Figure 19A). The instability of this structure led to a more robust canopy structure design that can hold infants up to 22 kg (Figure 19B). This device was tested for safety (see Appendix D for the device safety documentation) by the engineers of Enliten and it was combined with objects for enriching the area underneath (inclined platform, staircase, toys) by the researchers. The complete design was tested with a pilot family.

The pilot testing revealed that the use of the springs had three limiting factors in such a paradigm: 1) the % of BWS was not constant, since changes in vertical movement altered the amount of pulling force, 2) we couldn't accurately document the % of BWS especially when big changes in the vertical plane occurred (e.g. when climbing the inclined surfaces), and 3) it was difficult to manipulate the amount of % of BWS (i.e. we had to get the infant of the harness and attach another spring of a different stiffness). To overcome the above issues, a counterweight system was incorporated into the design. Thus, a small round bucket and a system of pulleys was added (Figure 19C). The % of BWS was now easily manipulated by adding or subtracting rod steels and sand bags into and out from the bucket. After that last component was added, the device was ready for the next phase, testing with a young population.

3.2.2 Testing of the Newly-developed Device

The next question to answer after the development of the BWSS was *'Does it work?' and 'Will it work?'*.[116] More specifically, 'Does it work with a very young population?' and 'Will it work in uncontrolled environments such that of the home?'. This information was extremely important as it provides the foundation for incorporating the BWSS into the families' dynamic, and initial suggestions that the BWSS could potentially be a part of a high dosage and long term early intervention.

The testing consisted of two phases, as did Weightman et al. (2010), which tested their devices first in schools and then in homes.[118] In our case, the first phase involved testing with a very young population in the lab EE (aka Priming Session, Data Collections 1&2) that led to the promising results of Chapter 2. The second phase, involved testing those same families in their home (aka Home Session). Before we outline the testing methodology and Aims from the second phase (described in detail in next section 3.2.3), we first emphasize below the importance of including that second phase, aka the Home Session.

Interventions applied in the home provide infants with more opportunities for social and physical interactions with the family. These interactions have been linked to the development of natural locomotion in infancy.[64] The importance of social interactions was emphasized a long time ago. For example, a study in 1971 examined the role of the home on the development of typically developing (TD) and infants with Down syndrome (DS).[45] TD and DS infants raised in institutions demonstrated differences from their peers raised in typical homes. The social development of both populations was significantly impacted from the under-enriched environment. Both populations had significantly less social interactions as well as more motor deficits. DS infants had minimal access to toys and were physically restrained by being left in a cot, playpen, or chair for extensive amounts of time. This had an effect on their motivation for moving and exploring around.[45] Forty-five years later, we see that motor delays are also observed in TD infants raised in orphanages.[119] For example, their Alberta Infant Motor Scale scores are low throughout their first year of life and they first walked five months later on average compared to their peers raised at home.[119] The above studies suggest that infants growing in environments away from home and family present delayed development. In addition to the importance of the family in the daily life of their infant, families of infants with special needs should also be engaged in the design and use of technology when this is incorporated in a home intervention.

When designing, and applying assistive and rehabilitative technology, feedback, both perceptions and actions from users and caregivers is thought to be important to ensure new technology addresses their key needs.[118,120–123] According to Briar-Lawson et al. (2009), an important feature of family-centered policies and practices is the belief that "Families are considered experts in what helps and hurts them".[124] However, studies that test the feasibility of assistive device use at home through feedback of the involved individuals is rarely considered.[123] Only a few recent feasibility studies have examined the application of the assistive technology at the families' homes. These studies focus mostly on upper extremity function and powered mobility.[76,77,118,125,126] Some of this work comes from our lab. For example, the feasibility of a novel arm exoskeleton for an infant with upper extremity dysfunction was assessed longitudinally at home. During the study, the family provided feedback on the use and limitations of the device.[125] Another study assessed the use of modified ride-on cars for exploration and enjoyment by children with complex medical needs.[77] To our knowledge, no support system has been evaluated for ground mobility yet.

3.2.3 Assessment of Our Paradigm

In some cases, feasibility studies, may include the development of a suitable outcome measure tailored to the specific study.[113,117] In our case, we developed our outcome measure, the questionnaire that was used to assess users' satisfaction of our paradigm at the Home Session. We developed this questionnaire to receive more information specific to our device and paradigm, since more questionnaires are developed for older children and do not involve certain variables, such as level of enjoyment by the user which is thought to be important for device use.

There are different ways to assess user satisfaction with questionnaires: a) the direct approach, which involves placing users in a situation that involves their participation and then asking them to describe their actual experience, and b) the indirect approach, which involves asking users to envision themselves in a situation and then describe their thoughts. In our study, we combined the two and developed a 18-item questionnaire to measure a) the families' satisfaction of their experience with the BWSS and the overall paradigm, and b) need and use in a hypothetical long-term situation. In order for the families to gain experience, the researcher brought the BWSS to their home and asked the parents to assist with its setup and to use it during play with their infant. The families then filled out our questionnaire immediately after.

The questionnaire focused on the following topics: the parents' *perception of the behavioral change*, if any, theirs and their infant's *level of enjoyment,* their *satisfaction of the BWSS*, their *need and hypothetical use of the BWSS*, and their *recommendations for future modifications* (see Appendix A for the Questionnaire). These topics were selected to capture all aspects; users (infant and the family), their activities, and the environment.[114] The questionnaire contained multiple-answer and open-ended questions. Certain questions were adapted from existing questionnaires commonly used with device satisfaction. Other questions were selected based on the literature that has shown these questions to be important for evaluation. For example, a valid and reliable tool to measure users' satisfaction with assistive devices is the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST).[127] It is a 12-item questionnaire that consists of two sections: satisfaction with 1) devices and 2) services. Questions from the section on devices were used in our questionnaire. An example of question that emerged from the literature review was about the level of enjoyment by the infant and the parents. Level of enjoyment is thought to be related to the usability of a device.[118,128] Our questionnaire, although not formally validated, would help us gather the general types of information we needed to move further with our work. If the information from this initial small sample proved useful, larger sample studies can build on this work to provide a formal validation.

3.3 Hypotheses

This Chapter focuses on three stages in our feasibility study: 1) *research and development* of a new device appropriate for use with a very young population, 2) *testing of the newly-developed device* in real-world EEs (lab and infants' homes), and 3) *assessment of the novel paradigm* through the preliminary evaluation of participant responses (of infants and their families). So far, we have described stages 1 and 2, and outlined our methodology of setting up the assessment involved in stage 3. Stages 1 and 2 did not involve any Hypotheses. Aim 4 and Hypotheses described below, refer to the goal for the assessment in stage 3 and the expected results from the questionnaire.

Aim 4: To assess the feasibility of the novel open area BWSS within the home EE. We anticipate that the majority of the parents will report:

H4.1: *A positive change in their infant's behavior due to short term BWSS use*

H4.2: *Increased levels of enjoyment for their infant and themselves while using the BWSS over the short term*

H4.3: *that the BWSS is safe, easy to set up and use over the short term*

3.4 Methods

3.4.1 Subjects

Twenty parents and their 16 infants with and without DS participated in the study. Both parents of four infants volunteered to participate in the sessions, and both responses were considered. The same infants whose characteristics have been described in Chapter 2 participated in this study: eleven TD infants (six male) between the age of 8.2 and 11.8 months (M=9.9 ±1.2 months), five DS infants (two male) between the age of 12.4 and 19.7 months (M=17±3 months).

Infants were included if they had acquired the ability to independently maintain their head in midline while placed at different postural positions (prone & sitting), were able to crawl or scoot for a distance at least twice their body length,[14] and had body weight less than 22 kg. Infants were excluded from participation if their body weight was more than 22 kg, had a history of seizure disorder, non-correctable vision problems, and/or other severe motor impairments or conditions that would make their participation difficult. For the DS group, a physician clearance was provided to the researcher before participation. Recruitment for the TD infants was largely via word of mouth and through media announcements at the University of Delaware campus area and for the DS group through family support groups and associations in the Delaware and Pennsylvania, over a 2-year period. This study was approved by the University of Delaware's institutional review board and all parents signed the consent form prior to participation.

3.4.2 Experimental Protocol

The session for this study was conducted at the participants' homes and lasted for about 1.5 hours. During this time, parents were asked to assist in the setup and taking down of the BWSS, engage their infant in a play session, and complete the questionnaire.

Before the Home Session, and within a 2-week period, the participating families had visited the Pediatric Mobility Lab and Design Studio three times. During these lab sessions, they became familiar with the BWSS and its function through their participation in play sessions with their infant. The BWSS used was the same for both lab and home sessions (PUMA, Enliten LLC, Newark, DE, USA) and it provided support for movement in all three planes (2.75 m x 2.75 m x 2 m). In the lab play sessions, the infant went through some novel tasks (e.g. climbing a platform, etc.) through placement of a standardized set of objects (e.g. platform, staircase, etc.) by the researcher (see detailed methodology for lab sessions in Chapter 2). In the Home Session, the selection and placement of objects, as well as the selection of the room for the BWSS setup (usually the living room), were defined by the parents. Infants spontaneously explored the environment that their parents set up with and without the assistance from the BWSS for five minutes each.

In the beginning of every session, infants were allowed time to adjust before moving on with the experiment. During the lab sessions, the researcher ensured the infants remained in a calm, alert state by allowing them breaks. In addition, the researcher kept the infants within arm's length by being in one side to ensure protection while falling. The parent was also present and active in the play area by offering motivation and words of encouragement for their infants to successfully complete the tasks. However, in the home session, the parent took care of everything whereas the researcher observed the session and intervened only if needed.

3.4.3 Variables of interest and Data Analysis

As previously described in section 3.2.3, measures included a) the parent *perception of the behavioral change*, if any, b) parents' and their infant's *level of enjoyment, c)* parent *satisfaction of the BWSS*, their *need and hypothetical use of the BWSS,* and d) parent *recommendations for future modifications*. These were evaluated from the 18-point questionnaire that we developed. Results for this Aim are descriptive.

3.5 Results

In summary, our paradigm was feasible for application in the home EE. The BWSS was successfully setup and used by the parents in all 16 homes. Both infants and parents happily participated in the play session without being fussy or without any problem that caused withdrawal of participation. All parents encouraged play activities and noted positive changes in their infants' performance while using the BWSS. Furthermore, parents were satisfied with the current structure of the device and recommended future modifications specifically for the wearable harness to increase comfort and convenience for the infants. In general, infants and family members expressed behavioral improvement and overall satisfaction with the system.

To better describe the data on the infants' *overall positive change in behavior* and potentially capture any differences attributed to the diagnosis, the responses from the two groups of parents (parents of TD and DS infants) were considered separately (Figure

20A). Out of the fourteen parents of TD infants, eight (57.1%) reported the two most positive items on the 5-point Likert scale. Out of the six parents of DS infants, five (83.3%) reported the two most positive items on the 5-point Likert scale. No parents reported a no change on their infant's behavior.

Parents' responses on theirs and their infant's *level of enjoyment* are reported altogether (Figure 20B). The majority of parents observed and reported that their infant was happy while using the BWSS. More specifically, 79% of parents scored the three most positive items on the 10-point Likert scale ("Strongly Disagree" – "Strongly Agree"), with 47.4% of parents reporting the highest level ("Strongly Agree"). In addition, parents reported that they also found this experience enjoyable. Specifically, 84.2% of parents scored the three most positive items on the 10-point Likert scale ("Strongly Disagree" – "Strongly Agree"), with 52.6% of parents reporting the highest level ("Strongly Agree").

Parents' *satisfaction of the BWSS* from both groups were combined as visual inspection of separate data did not show clearly different patterns. First, most parents perceived the BWSS to be safe, as 19 out of the 20 parents (95%) reported the two most positive items on the 5-point Likert scale (Figure 21A). In addition, 79% of parents scored the three most positive items on the 10-point Likert scale ("Strongly Disagree" – "Strongly Agree") for the easiness of the BWSS use and 66.5% for the easiness of the BWSS setup (Figure 21B). Furthermore, 62.2% of parents scored the three most positive items on the 10-point Likert scale ("Strongly Disagree" – "Strongly Agree") indicating that the infant was comfortable while using the BWSS, and 73% of parents scored the same items indicating that their infant using the harness was convenient to them (Figure 21B).

Parents' responses to their *need and hypothetical use of the BWSS* were again considered separately for those of TD and with DS. On the importance of having the BWSS at home, no parents of TD infants reported a strong need for having the device at home, as none scored any of the two most positive items on the 5-point Likert scale (Figure 22A). On the contrary, five out of the 14 (35.7%) reported the mid-item ("Moderately") on the 5-point Likert scale, and nine (64.3%) reported the last two items (including the last item-no need at all). The case was different with the parents of infants with DS where the majority (60%) reported the second most positive item on the 5-point Likert scale (Figure 22A). The rest of the parents (40%) reported "Moderately" and "Slightly". No parent of infant with DS reported the last item, that is there is no need. Lastly, in the hypothetical question of use time if they had it already at home, the majority of parents in both groups (57.1% of parents of TD infants and 50% of parents of DS infants) reported 1-2 hours per day (Figure 22B).

In addition to the multiple answer questions, feedback on the device and paradigm using open-ended questions was received. The feedback of parents of TD infants and infants with DS is listed in Table 6 and Table 7 respectively. Although, in general, the parents were satisfied with the BWSS, a common suggestion was the need for modifications of the wearable harness. The fact that the harness is one size is a potential limitation to consider, especially any follow-up home-intervention long-term study, where the infants' bodies will consistently keep changing.

3.6 Discussion

This Chapter focused on the three stages in our feasibility study that involved the 1) *research and development* of a new device appropriate for use with a very young population, 2) *testing of the newly-developed device* in real-world EEs (lab and infants' homes), 3) *assessment of the novel paradigm* through the preliminary evaluation of participant responses (of infants and their families). From this study, we successfully developed a novel device, tested it, and assessed its initial feasibility in the home EE over short term use. Users of this technology, infants and parents, were highly involved throughout each of these stages.

Our preliminary findings supported that: 1) parents and infants enjoyed using the device, 2) parents noted positive changes in their infant's behavior, and 3) parents perceived the device to be safe and were able to set it up and use it. These results confirm our hypotheses for this Specific Aim. In addition to that, we went a step further and received feedback for modifications that will maximize users' experience in the future.

The above preliminary results are important as they provide general support for a future longitudinal home intervention that incorporates our BWSS. For example, the level of enjoyment during the device use is sometimes hard to achieve, but is also crucial for keeping up with the intervention. Interestingly, only a few studies have examined 'fun' as a variable of interest and pointed out the necessity of including this measure.[76,118,128] In our paradigm, both infants and their parents, happily participated in all sessions and socially interacted, possibly leading to the BWSS use in the future.

Another key factor for keeping up with the intervention is the perceived effect. This is especially important as parents often contribute important input into continuing or discontinuing the use of a device or training program.[129] Our paradigm was simple but powerful enough to induce short-term changes in behavior that could be observed by both researchers and families. Researchers' conclusions on the immediate effects (outlined in Chapter 2) agreed with parent reports of positive changes while their infants while using the BWSS (e.g. faster transitions, attempts to make steps, etc.). Some parents observed positive changes on their infant's behavior even when the infant was outside of BWSS at home. For example, they reported that their infant started performing a behavior for the first time (i.e. climbing stairs) or more often (e.g. more supported stepping). This finding is encouraging as rapid, clear observations of meaningful changes in behavior with technology may contribute to the continued use of the technology.

The users' satisfaction with the actual technology is another important factor that for the continued use of an intervention that involves assistive and/or rehabilitative technology.[118,129,130] Interestingly, only a few studies have examined families' satisfaction of their children's use of technology. In our study, the BWSS was perceived as extremely safe, easy to setup and use, convenient for the caregiver to use, and comfortable for the infant. However, we noticed that the question about the infant's comfort while using the BWSS induced slightly less positive response compared to the other items on the BWSS satisfaction. This response combined with the responses to the open-ended question on what they would change, may be attributed to the limitations of the wearable harness. Some parents reported that the one size was too large for the little body of their infant, and others reported that the straps of the harness were distracting and in some cases annoying to the infant. This feedback leads to the next step, which will be the development of a wearable harness that can be customized to the size of the infant.

An interesting question was that of the actual need and hypothetical use of the BWSS, if it was available. Note that for most of the parents, when this question was addressed, the BWSS was not commercially available at the time. Previous studies have also assessed the perceived need for mobility devices.[67] However, 'user' responses in these studies were purely hypothetical. In our study, we gave the opportunity to the users, to try our device, assess it, and then report their need for longitudinal use. To no surprise, the responses of both groups of parents about the need was different but they were similar about the use time. Parents of infants with DS expressed a high need for having the BWSS at home which shows the wide acceptance of our technology. In addition, the majority of parents reported that they would use the system for 1-2 hours daily which indicates the potential for a high-dosage training in our next study. If just 8min/day of body-weight-supported training on the treadmill for five days can reduce the delay of walking onset,[15] what can 1-2 hours of body-weight-supported activity in an open area do for the infants' development? Our future work will address this question.

3.7 Limitations

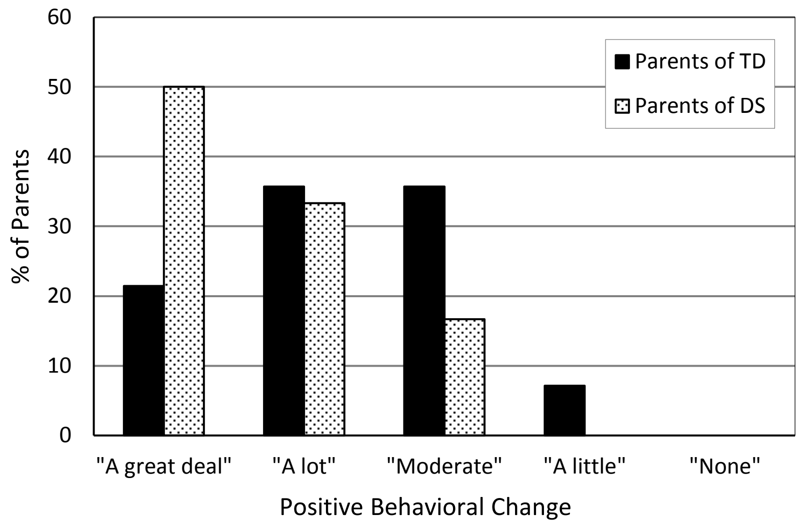
This feasibility study involved a small sample size, therefore larger group studies are needed to establish the use of the BWSS in the home, and potentially lead to a better device design in the future. In addition, our outcome measure was not formally validated; however, we were able to capture the users' initial reaction to such a novel paradigm.

3.8 Conclusions and Future Directions

The preliminary results from this study contribute to the development of intervention programs that merge the advantages of body-weight supported activity with their application in real-world environments like that of the infants' homes in an effort to develop long-lasting effects and advance overall development. The preliminary results from this study have already led to the successful implementation of the first in-home long-term mobility case study (aka Harness House). The ongoing study involves the setup of the portable BWSS in the playroom of a family's home with an infant with DS. We are currently monitoring the BWSS use and the infant's development. Next steps involve 1) a group longitudinal home-intervention study, and 2) the feasibility of testing and applying our BWSS to other real world EEs like playgrounds and recreational spaces. Our research further explores the maximization of intervention outcomes by encouraging family members to be more active in the individual's therapy[131–133] and by maximizing the dosage in complex environments.[134]

Figure 19. Development of the BWSS. **A.** First prototype, **B.** Portable design with springs, **C.** Final design with the counterweight system.

A.



B.

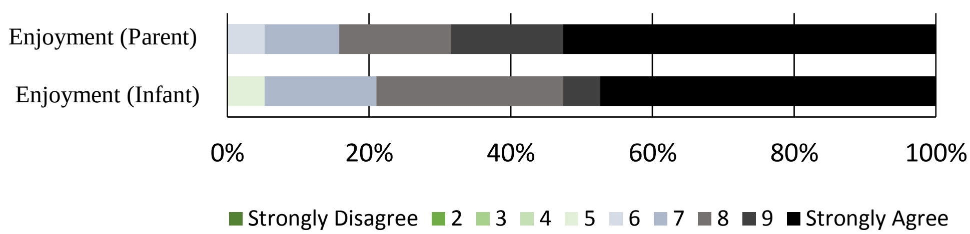
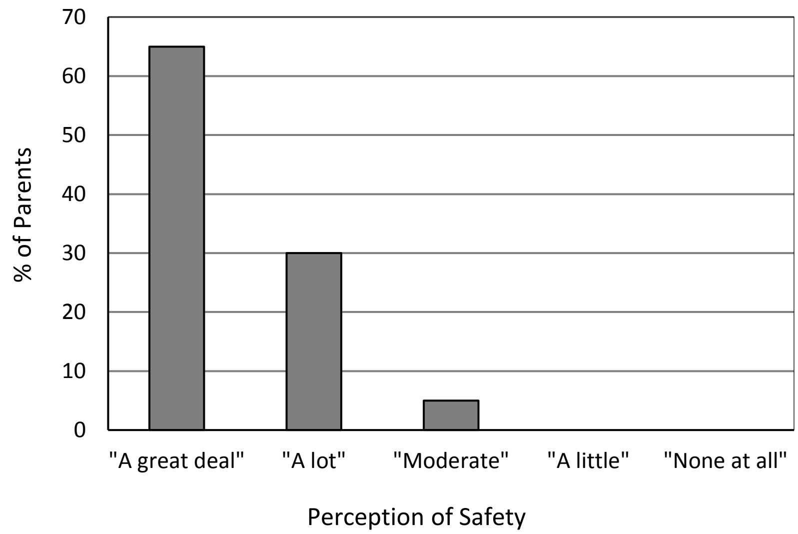


Figure 20. Parents' responses on the behavioral change of their infant while using the BWSS. **A.** Parents’ observations of the general behavioral change. **B.** Parents’ responses on theirs and their infant’s level of enjoyment.

A.



B.

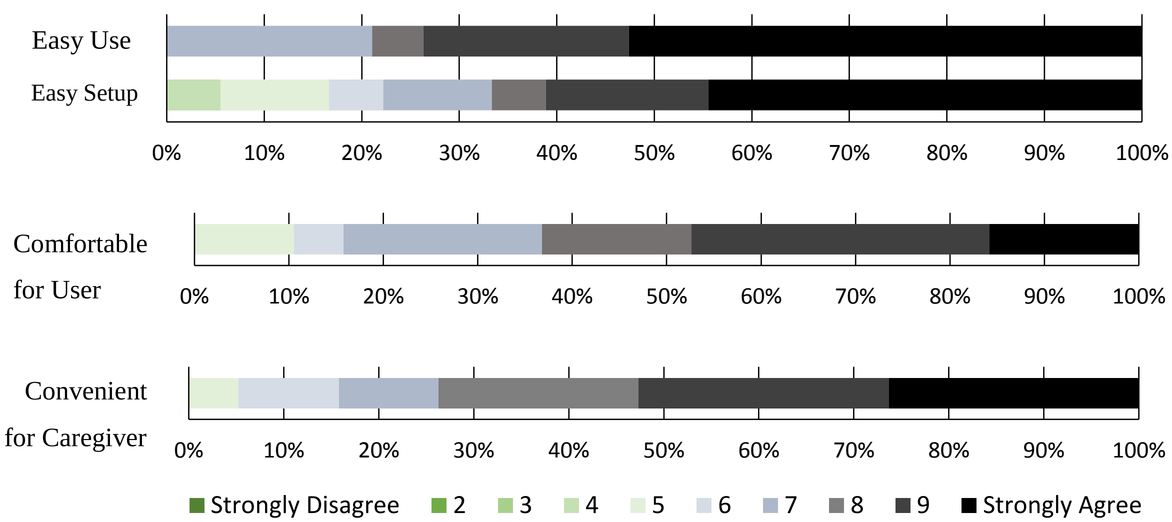


Figure 21. Parents' responses on BWSS satisfaction. **A.** Parents' perception of the safety of the system. **B.** Parents' responses on the use and setup of the BWSS, as well as the user's comfort and parent's convenience.

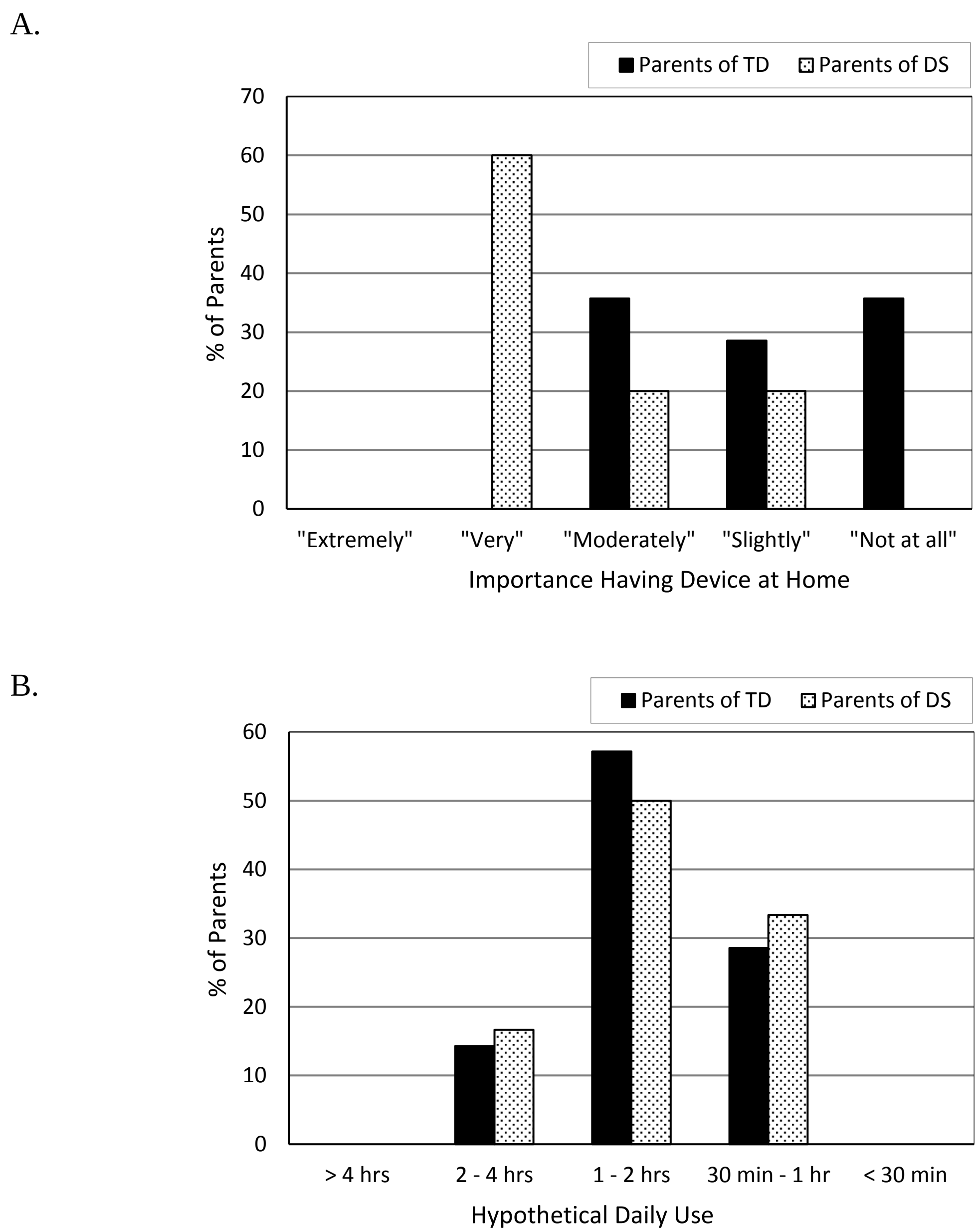


Figure 22. Parents' responses on the need and hypothetical use of the BWSS.

Table 6. Feedback of parents of TD infants on the open-ended questions. Symbols denote the responses from both parents of the same infant.

Changes Observed While Using the Device	Parent Liked Most About Device	Changes that Would Most Improve Device	What Would Make Using the Device More Likely
In harness: pulled to stand faster, began bouncing and taking first independent steps w/o UE assist, seemed able to figure out lateral base of support/limits. At home: attempting to stand beside the couch (crib, a box that slides when he stands, kitchen cabinets, walks with hand support).	Try new things, like stairs/ walking. Didn't inhibit UE use or head movement.	Toys that hang from center to play with to encourage standing/going upright, all black weight bag to prevent getting child's attention, non-colorful corners, padding that's non-skid to protect wood floors and device from slipping.	Space, how much space is needed for device. If actually needed for infant.
Much more adventurous, willing to walk unassisted, jump off low objects.	Able to move about freely without assistance.	Multiple harness sizes. Infant was small for age.	Cover larger area to explore. Infant likes to explore.
Confidence that harness provides was a big help. Seemed to improve with standing.	Fun to see how babies reacted to it.	N/a	Smaller. It filled the entire living room.
Did better with exploring, talking steps, and standing.	Helped get weight bearing and let explore better.	A thinner harness; Infant seemed distracted by the harness.	Smaller version for the home.
Felt more confident and courageous moving around.	Easy to set up and use.	"Mount" it to the ceiling to use the space easier.	N/a
Stood longer/more independently at toys with less support. Able to climb ramp and stairs more independently while in harness. Needed less support for mobility, but crawling seemed more difficult.	Fun to see more independently moving around.	Not much; minor thing was arm strap rubbing on cheeks/ears.	The set-up. Requires assistance in home and is large.
Demonstrated great confidence while trying to climb the stairs, able to stand more and took more risks (like going down the stairs and ramp). *	The ability to move more in the area they chose to play at.	Nothing, felt very safe.	If it came with some soft obstacles to challenge his gross motor skills.
Stood up more quickly from a seated position, went on feet more to attempt walking. *	Ability to go up a steeper ramp and learn from it. The harness integrated well with our play room.	Maybe having the harness hold upright from the front and back. It seemed to pull the infant posteriorly at times. In standing it seemed to pull him from side to side sometimes and had to be held to avoid lateral shifting. Would be nice if it promoted more safety going down stairs and ramps as it seemed to give him false safety, making him go down head first!	If he had a disability and needed the support of it I would consider using it for him to explore his environment.
Right after harness use: pulled to stand more often. At home afterwards: started trying to climb the stairs and wanted to walk with me more than usual.	The fact that it is simple and economical. It does not require a specialist to calculate % of weight.	N/a	If there was a way to make it take up less space. Nice if able to take it outdoors.
Confident to make first step.	Easy to put on.	Clear purpose.	More purpose.
Easy to pull up on things, interest and attempt in climbing up stairs. ǂ	Helping to shift body weight and being able to attempt doing new things on their own while wearing it.	Making the harness a little more comfortable around the head/finding a way to remove the straps being at head level for easier head movement.	Less bulky and more comfortable harness.
Confidence did increase while using the harness. ǂ	The devise developed confidence to try new activities and the confidence transferred to daily life.	The weight of the device is too heavy.	Make it modular and light.
Took steps, played in a squat, crawled up stairs. All of which were later observed out of the harness. †	So easy to use and set up.	I cannot think of any changes. I did not carry it personally but it looked heavy/awkward.	If my child needed mobility assistance I would want it!
Trying to take steps after the first session without assistance. †	The simplicity and ability to be placed anywhere.	Color code connecters or specific shapes for connecters. Plastic bearings, so it's quieter.	Making setup as easy as possible.

Table 7. Feedback of parents of DS infants on the open-ended questions. Symbols denote the responses from both parents of the same infant.

Changes Observed While Using Device	Parent Liked Most About Device	Changes That Would Most Improve Device	What Would Make Device Use More Likely
Seemed to be able to pull herself up on objects easier after the study. ‡	The ability to move freely in the playarea with limited obstructions.	Multiple harnesses or a different way to attach the harness. At first it seemed a little awkward to the infant. Maybe free play with harness on but not attached to the weights.	Multiple sizes.
She stood on her feet by herself (supported) for the 1st time. She climbed stairs on her own. ‡	After using the harness, she has made significant improvements in gross motor movement, standing from kneeling.	The noise from harness sliding seemed to bother infant and all of the straps were very close to her head.	If it were smaller or easier to setup. I would feel comfortable using it in a clinical office.
He is more secure with the arms and legs trying to crawl and walk.	I like the general idea of the device to gain the movement without or less weight.	It could have a better harness to support the baby. I think it is good as of now but it could be better.	N/a
Moved from belly to sitting up; had forward crawling movement - both for the first time.	The opportunity for movement it gives.	Elongate the hole for the counter weight so it can be adjusted while she is sitting in harness	N/a
Although he put more weight on his feet, he was distracted by the harness itself.	I like the opportunity it provided for moving around.	The device was great. It had lots of functions. Limitations include the child being uncomfortable at times from harness and size (i.e. crawling outside dimensions)	Using it daily to initiate standing and taking steps.

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Appendix A

FEASIBILITY QUESTIONNAIRE

General Survey Form

ID (Participant):______________________________

Overall, how satisfied are you with your experience using this device in the study?

7 - Extremely satisfied
6 - Moderately satisfied
5 - Slightly satisfied
4 - Neither satisfied nor dissatisfied
3 - Slightly dissatisfied
2 - Moderately dissatisfied
1 - Extremely dissatisfied

How much do you think your infant's behavior was positively changed while using the device?

5 - A great deal
4 - A lot
3 - A moderate amount
2 - A little
1 - None at all

What changes did you observe while your infant was using the device? Please specify.

____
____
____
____

How safe do you think the device is for your infant?

5 - A great deal
4 - A lot
3 - A moderate amount
2 - A little
1 - None at all

1

What did you like most about the device?

____
____
____
____

In your opinion, what changes would most improve the device?

____
____
____
____

What would make you more likely to use this device?

____
____
____
____

If this device were available today, how important is for you to have this device in your home?

5 - Extremely important
4 - Very important
3 - Moderately important
2 - Slightly important
1 - Not at all important

If this device were available today and you had it at home, how much time per day would you spend using it in average?

___ More than 4 hours
___ 2 to 4 hours
___ 1 to 2 hours
___ 30 minutes to 1 hour
___ Less than 30 minutes

If this device were available today, how likely would you be to recommend it to other parents?

5 - Extremely likely
4 - Very likely
3 - Moderately likely
2 - Slightly likely
1 - Not at all likely

The device was easy to set up.

1 2 3 4 5 6 7 8 9 10
Disagree Agree

The device was easy to use.

1 2 3 4 5 6 7 8 9 10
Disagree Agree

You would feel comfortable to use the device at home without the investigator present.

1 2 3 4 5 6 7 8 9 10
Disagree Agree

You would feel comfortable for your infant to use the device unattended.

1 2 3 4 5 6 7 8 9 10
Disagree Agree

The use of the device had a positive impact on your infant.

1 2 3 4 5 6 7 8 9 10
Disagree Agree

Using the device was fun for your infant.

1 2 3 4 5 6 7 8 9 10
Disagree Agree

Using the device was fun for you.

1 2 3 4 5 6 7 8 9 10
Disagree Agree

Using the device was comfortable for your infant.

1 2 3 4 5 6 7 8 9 10
Disagree Agree

Using the device was convenient to you.

1 2 3 4 5 6 7 8 9 10
Disagree Agree

Appendix B

IRB APPROVAL LETTERS

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE: December 6, 2013

TO: Elena Kokkoni, MSc
FROM: University of Delaware IRB

STUDY TITLE: [547646-1] The Immediate Effects of using a Body Weight Support System on the Behavior of Infants With Down Syndrome.

SUBMISSION TYPE: New Project

ACTION: ACKNOWLEDGED

Thank you for submitting the New Project materials for the above research study. The University of Delaware IRB has ACKNOWLEDGED your submission. A final determination letter will be issued following review of your project.

The following items are acknowledged in this submission:

- Consent Form - Immediate_Effects_BWSS_Consent Form.docx (UPDATED: 12/6/2013)
- Letter - Immediate_Effects_BWSS_Design_and_Proof_Load_Statement.pdf (UPDATED: 12/6/2013)
- Other - Immediate_Effects_BWSS_Verbal_Script.docx (UPDATED: 12/6/2013)
- Other - Immediate_Effects_BWSS_Withdrawal_Form.doc (UPDATED: 12/6/2013)
- Protocol - Immediate_Effects_BWSS_Project_Protocol.docx (UPDATED: 12/6/2013)
- Questionnaire/Survey - Immediate_Effects_BWSS_Personal_Information_Form.docx (UPDATED: 12/6/2013)
- Questionnaire/Survey - Immediate_Effects_BWSS_Survey.docx (UPDATED: 12/6/2013)
- Training/Certification - Immediate_Effects_BWSS_Inspection_Checklist.docx (UPDATED: 12/6/2013)
- Training/Certification - Supervising_Adult_Training_Manual.docx (UPDATED: 12/6/2013)

If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.

UNIVERSITY OF DELAWARE

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	June 2, 2014
TO:	Elena Kokkoni, MSc
FROM:	University of Delaware IRB
STUDY TITLE:	[547646-1] The Immediate Effects of using a Body Weight Support System on the Behavior of Infants With Down Syndrome.
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	June 2, 2014
EXPIRATION DATE:	April 15, 2015
REVIEW TYPE:	Full Committee Review

Thank you for your submission of New Project materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Full Committee Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

UNIVERSITY OF DELAWARE

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	March 31, 2015
TO:	Elena Kokkoni, MSc
FROM:	University of Delaware IRB
STUDY TITLE:	[547646-2] The Immediate Effects of using a Body Weight Support System on the Behavior of Infants With Down Syndrome.
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	March 31, 2015
EXPIRATION DATE:	April 15, 2016
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # *(9)*

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

UNIVERSITY OF DELAWARE

RESEARCH OFFICE

210 Hullihen Hall
University of Delaware
Newark, Delaware 19716-1551
Ph: 302/831-2136
Fax: 302/831-2828

DATE:	March 23, 2016
TO:	Elena Kokkoni, MSc
FROM:	University of Delaware IRB
STUDY TITLE:	[547646-3] The Immediate Effects of using a Body Weight Support System on the Behavior of Infants With Down Syndrome.
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	March 23, 2016
EXPIRATION DATE:	April 15, 2017
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # 9

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Appendix C

INFORMED CONSENT

UD IRB Approval from 03/23/2016 to 04/15/2017

University of Delaware
Informed Consent Form

Title of Project: The Immediate Effects of Using a Body Weight Support System on the Behavior of Infants With and Without Down Syndrome.

Principal Investigator (s): Elena Kokkoni
Other Investigators: Dr. James Cole Galloway, Dr. Sam Logan

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will do if you decide to take part, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything that you do not understand before you decide whether or not you want to participate. Your participation is voluntary and you can decide not to participate or withdraw (stop participating) at any time. You will not be penalized or lose any benefits. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?
Typically developing infants are constantly exploring their environment by moving around and interacting with toys and/or peers during daily play. Infants with Down syndrome lack that opportunity due to their later onset of walking. The goal of this study is to examine the immediate effect of using an open-area body-weight support system (BWSS) on the behavior of typically developing infants and those with Down syndrome. The BWSS is an investigational device designed by a local engineering company (Enliten, LLC). The use of the BWSS will provide infants with the potential to increase their mobility and exploration of their environment. The knowledge learned from this study is a potential benefit to other families and children with special needs and may provide the basis for other interventions that promote development.

You are being asked to participate in this study because your infant is between 4 and 24 months of age and may or may not be diagnosed with Down syndrome. Your infant may not be able to participate if he/she weighs more than 50 lbs, has any other diagnoses/conditions besides DS, or your family is not able to make the time commitment required for participation. 12 infants diagnosed with Down syndrome and 12 infants of typical development are expected to participate in this study.

WHAT WILL YOU BE ASKED TO DO?
This study will last for two weeks. During the study, you will be asked to participate in four play sessions that will be split into two sessions per week. Three of the sessions will take place in the Pediatric Mobility and Design Studio Lab and/or the Neuromotor Behavior Lab located in STAR campus (540 South College Ave., Newark, DE 19713), and one session will take place at your home. Each play session will take about 2 hours and you will be with your infant the whole time. During each session, you will be asked to interact with your infant in a safe play environment (figure 1) that involves toys and objects (i.e. foam padded slides and steps). Your infant's behavior will be evaluated while being

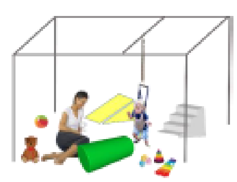
Figure 1. Play environment

Parent's Initials ______

outside and *inside* the BWSS. The BWSS is an investigational device manufactured by Enliten that provides body-weight support while moving around. It consists of a metal structure that looks like a four-legged square tent with a flat top with no cover (figure 2). Your infant will be wearing a light-weight, cloth harness (figure 3) that is connected to a moveable beam at the top of the metal structure. The BWSS will provide support up to 50lbs and will allow for movement anywhere beneath the structure. The BWSS is portable, foldable, light and easy to transfer and set up. The following measures will be collected:

Figure 2. BWSS

Figure 3. Harness

Developmental measure (Lab & Home - 15 minutes): The Alberta Infant Motor Scale (AIMS) will provide information about your infant's movement ability while placed in different body positions (i.e. lying in the back, sitting, etc.)

Height/Weight measure (Lab & Home - 5 minutes): Length and weight will be measured using a standard length board and an infant electronic scale. Your infant will be lying on their back during measurements.

Motion measure (Lab only - 60 minutes): High-speed cameras and equipment will be used to better understand how your infant uses his/her body and limbs to move around and explore. The cameras will capture your infant's movement through small shiny balls (called 'motion capture markers') attached on the body with hypoallergenic tape.

Walking/Crawling assessment (Lab only - 15 minutes): A portable electronic walkway mat will be used to describe the way your infant is walking and/or crawling. The mat has sensors that detect pressure every time the infant touches the ground while walking and/or crawling on the mat.

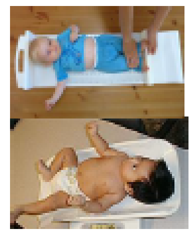

Figure 4. Weight and height measurement

Video Recording (Lab & Home - 60 minutes): We will video record three 20-minute play sessions: one outside of the BWSS, one inside the BWSS then another outside of the BWSS. During each play session you will be asked to present toys and interacting with your infant during play. Video recordings will be collected using video cameras and the KINECT™. The videos will provide important information about your infant's key behaviors during the play session (i.e. how long your infant was sitting or standing for, how many times your infant interacted with you, etc.).

Parent Perception Measure: You will also be asked to assist with the setup of the BWSS and fill out a survey upon completion of the study (see attached form), asking for your general perception of the BWSS setup, use and potential benefit to your infant.

Physician clearance: If your infant is diagnosed with Down syndrome, you will be asked to hand a form to your physician in order to get his/her clearance. Either you or your physician can deliver the completed/signed form to the investigator (via fax or hand the hard copy) prior to the first session.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are no psychological, social, financial or legal risks to your infant or family. Physical risks include your infant becoming tired, fussy or getting a bump during play session with family. Other physical risks include an accidental injury or entanglement due to BWSS malfunction and misuse, and a choking hazard of the motion capture markers. To reduce the above risks, your infant will be supervised by you and the researchers at all times and typically within arm's length of family. In addition, your infant will be given

Parent's Initials ______

breaks whenever you would like by easily removing him/her out of the harness. To further ensure safe participation in the play activities, we require for all infants to weigh less than 50lbs, have adequate neck control, and have no other medical conditions that would make the participation difficult (see attached form). We also require a physician's clearance for infants with Down syndrome to participate (see attached form). To further reduce risks: a) we require documentation on BWSS quality and safety control tests from Enliten, b) our researchers/staff will be experienced with infants and trained on how to safely setup and use the BWSS, c) our researchers/staff will administer safety procedures to ensure a secured play environment in each session, including inspection of the BWSS and the surrounding area prior to each use.

WHAT ARE THE POTENTIAL BENEFITS?

There are no direct benefits to your infant except for the opportunity to potentially experience new ways of moving and interacting with others. Infants with special needs may benefit in the future if this study results in positive changes after short-term use of the BWSS. Specifically, future studies will assess the use of the BWSS for longer periods, which may provide new ways of designing intervention protocols.

HOW WILL CONFIDENTIALITY BE MAINTAINED? WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

Confidentiality will be protected by assigning your infant an identification number for further analysis of the data. Only the investigators listed above will have access to personal information. Also personal information will be encrypted and kept in a locked and/or password protected storage separate from research data and video recordings, both of which will also be kept in locked and/or password protected storage in the Pediatric Mobility and Design Studio lab. The keys of those cabinets will be located in a password protected keybox.

After the home session, data will be secured and returned to campus right after collection as is practical. All electronic data records and video recordings/photographs will be stored after data collection on external password protected hard drives and password protected lap-tops and will be erased from the cameras. The hard-drives and lap-tops along with paper records identifying research participants including consent forms will be kept under the personal control of the investigator listed above until he/she returns and stores everything in the locked cabinets in the lab.

From this study, data and video/photographs may be published in scientific journals and/or presented at scientific meetings and reported using the subject's identification number. None of the published/presented video/photographs will have subjects identities obscured. All identifying information and data from this project will be destroyed when the data is no longer to be used or 5 years after the beginning of the study, whichever is sooner. Paper records will be shredded and electronic media used to store data and video/photographs will be scrubbed after the files are deleted.

The research team working on your infant's data consists of the investigators listed above and personnel of the Pediatric Mobility and Design Studio laboratory involved in this study. All members of the research team have completed the Human Subjects Research training and are aware of the processes involved in research.

Parent's Initials ______

Statement of obligation to report suspected child abuse

In accordance with Delaware state law (16 Del. C. 1953, § 1002), any person, agency, organization, or entity who knows or in good faith suspects child abuse or neglect must file a report. Researchers will comply with this state law.

WILL THERE BE ANY COSTS TO YOU FOR PARTICIPATING IN THIS RESEARCH?
There is no cost to you for your infant to participate in this research study.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATION?
There is no monetary compensation for participation in the study. The research team is grateful to you for your and your infant's participation in the study as well as for your time.

WHAT IF YOUR INFANT IS INJURED DURING PARTICIPATION IN THE STUDY?
If your infant is injured or has a medical problem as a result of this research, you should immediately contact one of the people listed at this consent form. If your infant is injured during research procedures in the lab, you will be offered first aid at no cost to you. If additional medical treatment is needed, the cost of this treatment will be your responsibility or that of your third-party payer (i.e. your health insurance). By signing this document you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?
Participation in this study is voluntary and you are free to withdraw at any time without penalty and without loss of benefits to which you or your infant are otherwise entitled. If you decide to withdraw your infant from the study and/or have your and your infant's data destroyed, you may simply stop participation and inform the investigator via phone or email.

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator,

______________Elena Kokkoni_____ at ___302.831.7422 (office), x3214 (lab)______

Or

______________Dr. James Cole Galloway____ at ___302.831.3697(office), x4234 (fax)___

If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at hsrb-research@udel.edu or 302-831-2137.

Parent's Initials ______

Your signature on this form means that:
• you are at least 18 years old
• you understand the information given in this form
• you have asked any questions you have about the research and the questions have been answered
• you accept the provisions in the form and voluntarily agree to join the study
You will be given a copy of this form to keep. You are not giving up any legal rights you have by signing this consent form.

____

(Signature of Parent/Guardian) (Date)

____

(Printed Name of Parent/Guardian)

Your signature below means that you allow your infant's participation in the study:

I, ____________________, the parent or legal guardian of ____________________, voluntarily give permission for my infant to participate in all aspects of the study described above. I have read and understand all of the above and have had all of my questions regarding the study and the procedures fully and satisfactorily answered. I understand that I can stop the study at any time without penalty. I have received a copy of this document for my records.

____

(Signature of Parent/Guardian) (Date)

____

(Printed Name of Parent/Guardian)

Your signature below means that you agree with your participation in the study:

I, ____________________, the parent or legal guardian of ____________________, voluntarily agree to participate in the study which involves my active engagement in play sessions, and in tasks related to the parent perception measure described above. I have read and understand all of the above and have had all of my questions regarding the study and the procedures fully and satisfactorily answered. I understand that I can stop the study at any time without penalty. I have received a copy of this document for my records.

____

(Signature of Parent/Guardian) (Date)

____

(Printed Name of Parent/Guardian)

Parent's Initials _____

Your signature below means that you allow yours and your infant's videos and photographs to be used:

I, _______________________, the parent or legal guardian of _______________________, voluntarily give permission for my infant's videos and photographs to be used for publications and presentations. I understand that my facial features and/or of the siblings may also be captured in my infant's videos and photographs. I understand that no identifying information beyond that contained in the video recordings/photos will be provided in to educational/scientific audiences; however the facial features of my infant, myself and/or of siblings may be seen. I understand that my permission of using the video recordings/photos for publications and presentations is voluntary and not required for my infant and myself to participate in this study. I have received a copy of this document for my records.

____

(Signature of Parent/Guardian) (Date)

____

(Printed Name of Parent/Guardian)

Investigator's signature:

My signature below certifies that all elements of informed consent described on this consent form have been explained fully to the parent(s)/legally authorized guardian(s). In my judgment, the parent(s)/legally authorized guardian(s) is/are voluntarily and knowingly giving informed consent and possess(es) the legal capacity to give informed consent to participate in this research.

____

(Signature of Person Obtaining Consent) (Date)

____

(Printed Name of Person Obtaining Consent)

Parent's Initials ______

Appendix D

DEVICE SAFETY DOCUMENTATION

ENLITEN

Enliten LLC
210 Executive Drive
Suite 5
Newark, DE 19702
Phone: 302-368-4540
Fax: 302-368-8498

March 26, 2014

Enliten, LLC has developed several body weight support systems to assist people with mobility limitations to move throughout a three dimensional space while maintaining full or partial body weight support. These systems have all been designed to withstand loads of at least five times the rated patient weight without failure, and all systems have been proof tested to at least 1.5 times the rated patient weight. The portable unit, which is based on an industrial canopy frame and can be collapsed for transportation in a car, is rated for a child up to 50 pounds.

Steven A. Cope, PE