

**RIDE-ON TOY CARS TO ADVANCE  
MOBILITY AND DEVELOPMENT  
IN INFANTS WITH CEREBRAL PALSY  
IN THE HOME SETTING: A PILOT STUDY**

by

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A thesis submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Honors Bachelor of Arts in Biological Sciences with Distinction

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## **ABSTRACT**

The purpose of this study was to examine the broad impacts of providing a ride-on car as a mobility device to promote self-produced locomotion and socialization in infants with Cerebral Palsy (CP). The research model was based on the interaction between the individual child, ride-on car device, environment and task. Two children with varying degrees of CP were given ride-on car devices for a three-month home intervention period: Brenden and Maya. The primary goals of the study were to test the feasibility of the device for the children by increasing independent locomotion and increasing interaction with the environment. Secondary goals included an improvement in measured developmental levels, positive perceptions from the child and family, as well as other improving other measures of socialization. There was a development of quantitative metric system of coding variables to assess mobility and interaction with the environment. Results from weekly home observations and parental questionnaires were coded using quantifiable metrics and it was found that the ride-on car device positively impacted both Brenden and Maya. They both exhibited an increase in independent mobility and increase in interaction/socialization with the environment. There were only marginal increases of developmental criterion for Maya, and no change for Brenden. The two different children provided important differences in results and highlighted the potential breadth of the ride-on car device applications. The ride-on car device could be used to increase mobility in a wide range of children with mobility impairments.

## **Chapter 1**

### **INTRODUCTON**

#### **1.1 Background**

The field of intervention for children birth through 3 yrs. of age with mobility disorders such as Cerebral Palsy (CP) and spina bifida is a dynamic field. Cerebral Palsy is a general term for a group of disorders that can involve brain and nervous system injury prior to, during or immediately after birth.<sup>10</sup> Symptoms range from mild to severe, involve one side or both sides of the body and can be more or less pronounced in arms and legs. Common symptoms include spasticity and tightening of the muscles, joint contractures, and various levels of incoordination. These result in a range of functional levels with some children being able to move and walk similar to typically developing children while others are not able to crawl, sit or walk. Some affected children have problems with cognition, speech, hearing and vision in addition to movement and posture issues.<sup>15</sup>

Many children with CP have issues with their mobility primarily through their poor ability or inability to walk. Mobility impairments limit the interaction with the social and physical environment. Thus, immobility in turn can negatively impact a range of developmental milestones outside of motor development including cognitive, psychological, social and emotional development. *The purpose of this study was to*

*examine the broad impacts of providing a ride-on car as a mobility device to promote self-produced locomotion and socialization in children with CP.*

### **1.1.1 Impact of Independent Mobility on Development of Infants With Special Needs**

Several studies support the link between mobility and development in infants. Early infancy is characterized by rapid and widespread increases in a child's ability to explore and interact with the environment through reaching and locomotion (i.e. crawling and walking). Infants with CP are unable to explore via self-produced independent locomotion. Studies done by Campos and Berenthal (1987) established the necessity of self-produced locomotion for infants with mobility disorders.<sup>4</sup> There was a focus on the various theories behind early experience and the "sensitive period". There was evidence that there were specific age ranges where certain experiences and outcomes were especially affected and could not be changed later. This phenomenon was known as pre-determined epigenesis. However Campos and Berenthal (1987) showed evidence that there can be more effect from interaction with experiences rather than a pre-determined neurophysiological mechanism. They suggested powered mobility devices as a medium to provide infants with mobility disorders the 'locomotor experience' that they could not independently produce.

Campos (2000) reviewed the effects of locomotor experience as a crucial agent of developmental change. For example, infant's locomotor experience has effects on the social and emotional development, the perception of self-movement and consequences, distance perception, the infant's manual search for hidden objects and spatial coding strategies.<sup>9</sup> Social interaction is defined as the reciprocal process of

initiating and responding to social stimuli presented by others.<sup>22</sup> For the current study, one important clinical implication is that without intervention to advance independent mobility, there may be lasting effects on a child's exploration and socialization. For example, without intervention an infant's ability to typically socialize as they grow older and are put into formal classrooms may be affected.

### **1.1.2 Use of Power Mobility Devices (PMD)**

The first systematic studies of powered mobility devices (PMD) for very young children with mobility impairments was conducted by Butler and Okamoto in the early 1980s. Specifically, the study "Motorized wheelchair driving by disabled children" from 1984 attempted to establish criteria for using PMD. Thirteen children with physical disabilities from 20-37 months used a pediatric power wheelchair for 7 weeks. 'Competent drivers' were those children that achieved seven specific driving skills, including the ability to stop and go when called, stopping without being prompted to avoid bumping something and attempting some simple turns. Results found that 12 of the children learned to drive in an average of 16 days.<sup>8</sup> In 1986, the same authors examined if self-initiated behaviors such as physical interaction and communication increased with the provision of a pediatric power wheelchair. Results suggested that there was an increase in independence and access to the environment.<sup>7</sup> The power wheelchairs allowed for children to expand their environment and see the world from a new perspective. Butler and Okamoto suggested that wheelchairs would allow for greater access to the environment, but restricted the child's ability to reach past the chair and freely interact with other children. However, the positive impacts on the children were noted in regards to psychosocial and locomotor behaviors.

### **1.1.3 Age of Children Given PMD**

A number of factors are evaluated when clinicians determine a child's readiness for a PMD, e.g. a power wheelchair. Current clinical standards of practice is such that power mobility is rarely used by children younger than 3 years.<sup>13</sup> The primary reasons cited as for waiting 36 months was cognitive difficulties, physical inability to control a wheelchair and behavioral issues.

Waiting for a child to turn three yrs. has consequences. The first years of life are critical for shaping both children and their various caregivers including family and teachers. The caregivers' perceptions towards both locomotion and the development of the children are affected in the early years. In 1983, Butler & Okamoto were critical of rehabilitation and education professionals' commitment to maximizing the movement of children with mobility impairments. They charged that the typical medical rehabilitation was based on management of symptoms with an over-focus on preparing for the 'eventual ambulation'.<sup>6</sup> Specifically, rehabilitation often emphasized 'normal' movement with the use of casting, bracing and surgery even for children with only a marginal chance of functional ambulation. The authors stressed the importance of the rapid development of locomotion in 2-3 year olds as a primary vehicle for learning, socialization and functional independence. Thus an over focus on 'normal locomotion' limits rehabilitation's focus on maximizing mobility and exploration by any means including PMDs.

Work by Butler and Okamoto prompted studies that tested driving skills in children with a range of disabilities and severities. Most studies focused on the child establishing independent control of the device. Taken together, these studies provided supporting evidence that children could become safe drivers as young as 18-24 months

of age.<sup>6-8, 17</sup> A study by Anderson and Campos (2001) developed the link between acquisition of prone locomotion to development. It stressed the importance of the development of postural control on the interaction of multiple systems with evidence that pre-locomotor infants are adept at controlling forward motion in power mobility devices from the age of 7 months.<sup>2</sup> This showed that infants who were given the opportunity to use PMDs could positively impact their postural development in addition to successfully using a device at a young age.

#### **1.1.4 Previous Studies of Early Power Mobility**

Previous studies from the Infant Behavior Lab at the University of Delaware have focused on determining the effects of early power mobility training with specialized power mobility devices designed for infants as young as 7 months of age. Initial studies focused on the importance of self-generated mobility in young infants including the effect on their advancement in cognitive, perceptual and motor abilities.<sup>11</sup> More recently, projects have delved into the interaction between mobility and socialization in the school setting and how powered mobility devices can be used for children with CP to foster interactions with peers and teachers.<sup>20, 21</sup>

#### **1.2 Gaps in Previous Literature & Research Question**

The current study addresses specific limitations of previous studies in the field of early intervention for infants with mobility impairments. The question that acts as the basis for this research project is “Why do we need a new device for use in early intervention for children with CP in the natural environments, e.g., home setting?”

### **1.2.1 Limitations of Pediatric Power Wheel Chair**

PMD in past experiments include the use of the pediatric power chair and others such as robotic devices. One of the key problems with the use of these PMD is the size. The dimensions of a standard pediatric power chair for infants range from 34-38 inches with a height of almost three feet above the ground. Elevated among their peers, the power chair does not allow for effective peer-to-peer interactions, e.g., eye-to-eye level communication.

Typical PMDs are not used for improving motor skills but focus more on simply providing functional mobility to improve participation. It is not a device that promotes other peripheral effects such as socialization, and interaction. Furthermore, typical powered wheelchairs are not seen as tools to improve body structure (leg strength, head control, trunk control). They are not seen as a rehabilitation device that can later lead one to use a walker, or standing device. Mobility intervention for infants with mobility impairments is three-fold. It involves three levels, with the first two levels being the participation and activity level and another level focusing on the function or body structure. The body structure aspect focuses on using the device to address the functional needs of the child based on their individual motor capabilities and fine and gross motor skills. The International Classification of Functioning, Disability and Health (ICF) classifies health through body, individual and societal perspectives.<sup>16</sup> The ICF classifies the power wheelchair as a “device designed to facilitate moving” with no further mention to the effects on body structure as it is simply seen as assistive technology that is used with more severe mobile-impairments that cannot use a walker.<sup>23</sup> Our study promotes the use of the ride-on car device as

having a positive impact on the body structure of the infant and influencing further locomotion.

Another limitation of the pediatric power wheel chair is the cost of the device. Ranging from \$1000 to \$4000 there is a stark contrast compared to other PMD, e.g., a ride-on toy car, which is conveniently available at toy stores for under \$150. It is easily replaceable if a child outgrows it without placing significant financial burden on the family. This is an important factor because most children with mobility impairments attend many other therapies ranging from physical therapy and occupational therapy to speech therapy in addition to frequent visits to various doctors, which can easily put financial strain on a family. Additionally, the clinical standard of using the power wheel chair for children with disabilities is from a starting age of three to five. A ride-on toy car device may be considered as a transition device to improve independent mobility at an early development stage of children with mobility impairments. The simple modifications of a toy car can be further used to address the body structure and impairment level, which is the lacking component of using the typical PMD for children with mobility impairments.

### **1.2.2 Home-based Intervention**

Previous studies of intervention using power mobility training have been implemented in school-environments in open, controlled spaces and in clinics and laboratories. There is limited history of early home-based intervention where children are able to integrate the device into their daily routines. The natural environment of the home is often where a child acts differently and interacts with people more closely. It is more realistic as it is a variable environment as opposed to a more controlled setting

of the school.<sup>18</sup> This study attempts to focus on the ‘fun index’ of mobility and using the ride-on car to promote powered mobility for children with CP as an enjoyable experience as opposed to a purely therapeutic method of intervention.

### **1.3 Research Model**

Based on the previous discussion, the research model for this study was the integration of four different variables that could be manipulated to affect the primary and secondary outcomes (Figure 1).

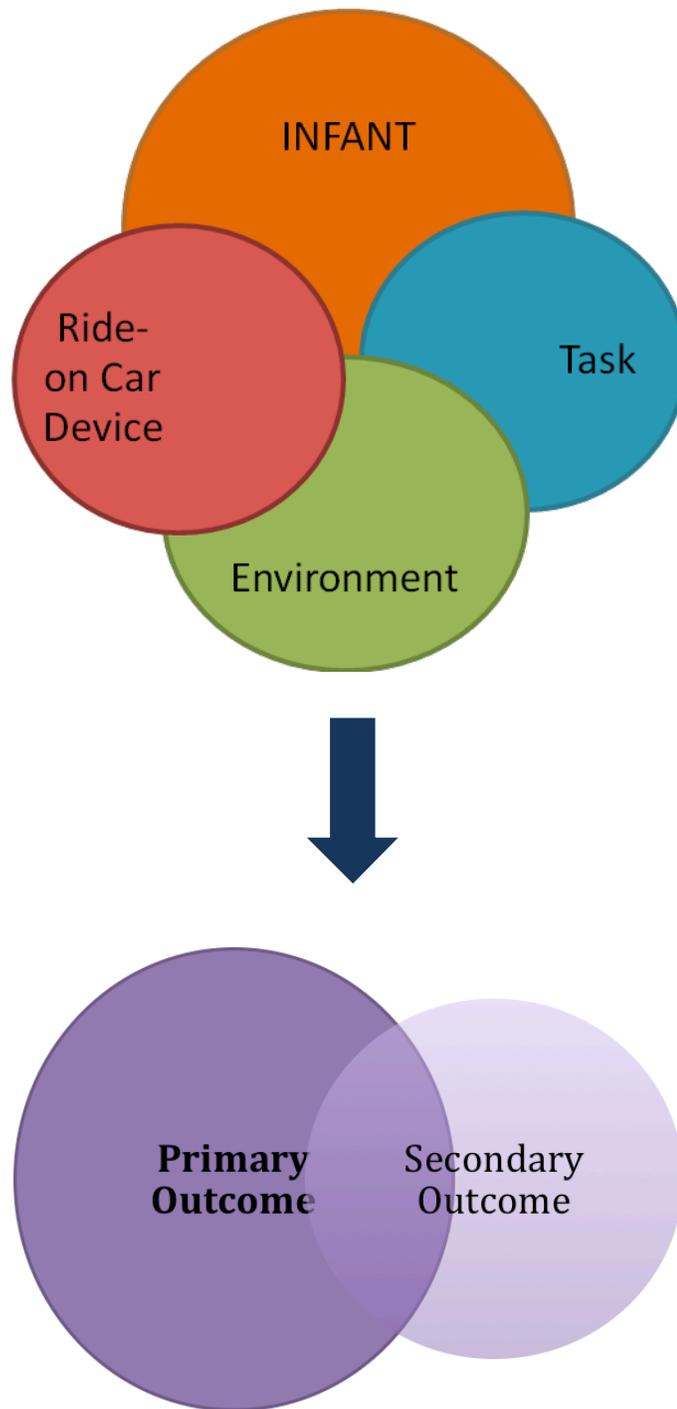
The critical variable of the research model is the individual infant who is the basis for all of the external factors that are being changed in this study. The infant consists of the child, who can be identified by his/her diagnosis, age, motivation, body growth and capabilities. Additionally, it includes their level of mobility and socialization functioning that is being influenced by the change in the other variables: the environment, ride-on car device, task.

Another component of the research model includes the modified ride-on car device. The ride-on car device is a powered mobility device that is sold in toy stores and is provided to the infant (Figures 2 and 3). It ranges from \$100 to \$200 as opposed to typical PMD and is a child-friendly character from a popular children’s movie. It is different from a typical pediatric power wheelchair and is specifically modified for each individual infant. The simple modifications can be done at home with limited tools and instead focus is directed towards addressing the child’s strengths and weaknesses in terms of posture, head and trunk control and other fine and gross motor skills. The effect of the ride-on car on the mobility comes at two interacting points and is highly relevant to the infant himself/herself. There are the initial participation

and activity levels that cater to the idea of locomotion and it's 'fun quotient' for the child as well as the more functional impacts on the body structure of the infant, such as posture, endurance, head and trunk control...etc. The 'fun quotient' can be defined as the positive psychosocial behaviors that the child associates with the driving the car.

Another element of the research model is the overall environment. The environment can be defined by the lifestyle of the infant, which consists of the family, friends, teachers, peers and general interaction with the surroundings. The natural environment or home setting as well as other settings that infant interacts with on a regular basis are termed the environment.

The fourth interacting variable is the task or intervention. The task/intervention is the vital attempt of this study, to introduce a change in the infant's life and induce an effect on the actions and interactions between the environment and the infant as well as the development of the infant who is using the ride-on car device. During the intervention each child is expected to focus on specific tasks such as goal-directed activity, but the means by which different children achieve this will focus on their individual capabilities, i.e., the child variable.



**Figure 1: Diagram of research model**

#### **1.4 Primary and Secondary Goals of Study**

The purpose of this study was to test the effects of the ride-on toy car on the mobility and social development when given to an infant with CP in the home setting during a prolonged intervention time. The criteria established for determining this was the amount of independent movement, interaction with the environment when in the car as well as in a ‘natural play’ setting, i.e., supportive sitting on the floor and play. These observational outcomes of mobility and social interaction were the primary goal. Secondary goals in this study were the tracking of social measures through standardized developmental assessments before and after intervention, as well as the family perceptions about the child, family dynamics and about using a mobility device, and more specifically the modified ride-on toy car. These were accomplished by implementing a home-based intervention protocol, weekly assessments assisted by video footage and supplemented by standardized developmental assessments and questionnaires. The research model was tested through the standardized protocol with two infants that both were formally diagnosed with quadriplegic CP but were known to be at varying developmental and motor conditions to investigate the feasibility of expanding the use of the ride-on toy car to a broader range of motor and social function.

#### **1.5 Hypothesis**

Based on the previous literature as well as previous data from the Infant Behavior Lab at the University of Delaware, I hypothesized that the use of the ride-on toy car in the home setting would be feasible as a means to exhibit an increase in independent mobility, increases in interaction with the environment and a favorable

improvement in the development of the infant. Additionally, there would be a positive interaction between the environment, tasks and ride-on car device with an overall positive impact on the infant.

## **Chapter 2**

### **METHODS**

#### **2.1 Participants**

Data were collected from two participants. The participant sample was two children ranging from age 20 months to 30 months with varying degrees of motor impairments. Both were previous participants in powered mobility projects through the Infant Behavior Lab and had experience driving pediatric powered wheelchairs.

Initial standards of development were assessed using the Gross Motor Function Classification System (GMFCS), where a higher number correlates to a more severe level of motor impairments. The GMFCS is based on self-initiated movement with an emphasis on sitting, transfers and mobility and results in a score that represents a child's abilities and limitations in gross motor function.<sup>17</sup> Another assessment used was the Manual Ability Classification System (MACS), which focuses on fine motor skills of an infant.<sup>11</sup> Lastly, the Modified Ashworth Scale (MAS) for grading spasticity in muscles was measured for both upper and lower extremities.<sup>5</sup>

The first subject, Brenden, was 21 months at the start of the study. He was formally diagnosed with quadriplegic CP. His GMFCS level was V reflecting his inability to walk and no ability to produce his own mobility. His MACS score was a level IV reflecting his ability to handle only a limited selection of easily managed

objects in adapted situations. His MAS score was 1+ in both upper and lower extremities.

The second subject, Maya, was 28 months at the start of the study and was formally diagnosed with quadriplegic CP. She had a GMFCS level of IV reflecting her ability to produce self-mobility with limitations and her use of a PMD. Her MACS score was a level III reflecting her ability to handle objects with difficulty as well as the need for help to prepare and/or modify activities. Her MAS score was 1+ in both upper and lower extremities.

## **2.2 Environment**

Brenden was the only child in the family and attended preschool at the Early Learning Center (ELC) in Newark, DE full-time. He interacted with his mother, father as well as maternal and paternal grandparents. He also interacted with peers as well as teachers in the school setting. Outside of school he spent time at his house as well as those of his maternal and paternal grandparents. During the time of the study he continued 7-8 hours per week of physical therapy, occupational therapy, water therapy, equine therapy, and speech therapy. Maya had one sister who was seven years old. Maya was not enrolled in preschool. At home she interacted with her mother, father and sister. During the time of the study she continued 5-6 hours per week of physical therapy, occupational therapy, water therapy, and equine therapy.

## **2.3 Apparatus- Ride-on Car**

Each participant was provided with a modified ride on toy car (Power Wheels Fisher-Price Ride On – Disney Pixar Cars 2 – Lil Mater). The toy car was purchased

from local toy stores and was modified by lab personnel in a workshop on the UD campus. Each ride-on toy car was mechanically and electrically modified to meet the child's capabilities using readily available, low cost materials. General mechanical modifications could include a roll cage, seating/harness and adapted steering apparatus. General electrical modifications could include a basic (large, round switch) or more advanced switch. An integral part of the research model was the specific, individual modifications for each car that differed between the infants.

Brenden's 'Lil-Mater' car was fitted with the roll cage, seating/harness and a large yellow switch (Figure 2). Due to his lack of trunk control, additional foam pipes were used to stabilize his posture as well as a T-bar made from PVC pipe to provide support so he would not fall forward. A foam backboard provided back support and various towels and pillows were used to assist with head control. The large, yellow switch was used, as it was touch-sensitive and easily activated by his limited reaching movements.



**Figure 2: Brenden's modified ride-on toy car**

Maya's 'Lil-Mater' ride-on car was fitted with a roll cage and seating/harness (Figure 3). Due to her lack of trunk control, additional foam pipes were used to stabilize her posture as well as a T-bar made from PVC pipe was provided as support so she would not fall forward. Modifications for Maya's car included a more advanced bicycle handle apparatus with a small, switch on the left handle because of her reaching and grasping abilities, and better upper extremity control of left hand than the right hand as she was left-hand dominant.



**Figure 3: Maya’s modified ride-on toy car**

## **2.4 Experimental Procedure**

### **2.4.1 Baseline Phase**

During the first week of Baseline, a home assessment was completed to determine the appropriate areas at home for each child to drive in for at least 20 minutes. All the rooms of the house and the yard were physically inspected to determine safe driving locations. Caregivers were required to sign a home assessment agreement and liability form regarding the use of the toy car. The child was only allowed to drive the car in the agreed upon areas, e.g., basement, living room, or

community space. Inappropriate use of the toy car such as driving on unallowable areas or other children using the car could have resulted in exclusion from further participation.

During the Baseline phase general development was determined from two separate standardized developmental assessments completed by a licensed clinical therapist. The Bayley Scales of Infant and Toddler Development III is a set of general development measures of the infant's language, motor, cognition and social behaviors.<sup>3</sup> The Pediatric Evaluation of Disability Inventory (PEDI) is a measurement of self-care, mobility and social functions and acts as a test of function in daily life.<sup>14</sup> Both standardized assessments were used to determine the baseline developmental level of each child prior to intervention with the ride-on toy car and were normalized to their age. The reliability and validity of both the Bayley and PEDI have been established.<sup>1</sup>

The baseline phase was a different length of time for each child. Each Baseline phase home visit consisted of a 10-15 minute 'Natural Play' session where the child was sitting on the floor with full support of a family member. The child's interactions with their surroundings during this play were videotaped. This session represented the interactions with the child in their natural setting *without the PMD*. The second session of the home visit involved a driving test. Driving a customized toy car tested the child's driving ability and interactions. Each child drove for 10 minutes, which was videotaped for later coding to record mobility and interaction measures. Parents also completed an interview including a questionnaire on their perception of powered

mobility device such as ride on toy cars and power wheelchairs (see Appendix B.1 for sample questionnaire).

#### **2.4.2 Intervention (Training) Phase**

During the Intervention phase, the ride-on toy car was provided for the child to use daily in the home for 10-12 weeks. The caregiver received an educational booklet and personal training on the toy car's use and safety (see Appendix A for copy of training booklet). Caregivers maintained a journal of the daily training time, location and general activities (10 minutes) (see Appendix C for daily log sheet). They were responsible for playing with their child in the toy car for a minimum of 20 minutes per day, 5 days per week. This might include 10 minutes for any play activity involving the car and 10 minutes for driving to specific location therefore providing goal-oriented training. .

##### **2.4.2.1 Task**

Similar to the Baseline phase, the Intervention phase included weekly home visits by researchers and clinical therapists. During the visit there was a 10-15 minute 'natural play' session followed by a 40 minute 'driving' session. The initial 10-minute part of the driving session in which researchers engaged the child in play tasks involving driving. Next a clinical therapist provided driving training with the child and caregivers and the group established the next week's driving goals.

For Brenden, he had a task-based goal focused on attaining the skill of 'stop and go'. He was engaged to drive a certain distance to an object and stop (release hand from switch). This progressed to more goal-directed activity and the implementation

of games into his driving. He would drive to his father to play catch with a ball. He would either catch or push the ball when he drove in a forward direction. Brenden interacted with toys that were matched to his cognitive ability and primarily included a ball, or larger object.

Maya had a more complex task-based assessment involving multiple steps and required driving up to five different goals. Her task, like Brenden's, promoted goal-oriented driving. The minimum driving length per task was five feet. Examples of tasks were collecting toy stars, cookies and returning them to a specified area. There was more vocal communication including asking her about where the next toy was during a scavenger hunt activity. The toys matched her cognitive abilities. Based on her motor capabilities, there was an attempt to implement some steering into her driving protocol as well.

During the Intervention phase the parents were asked to complete another questionnaire on their perception of using the ride-on toy car in the home environment (see Appendix B.2 for questionnaire). Following the Intervention phase the standardized developmental assessments (Bayley and PEDI) were re-evaluated by the clinical therapist.

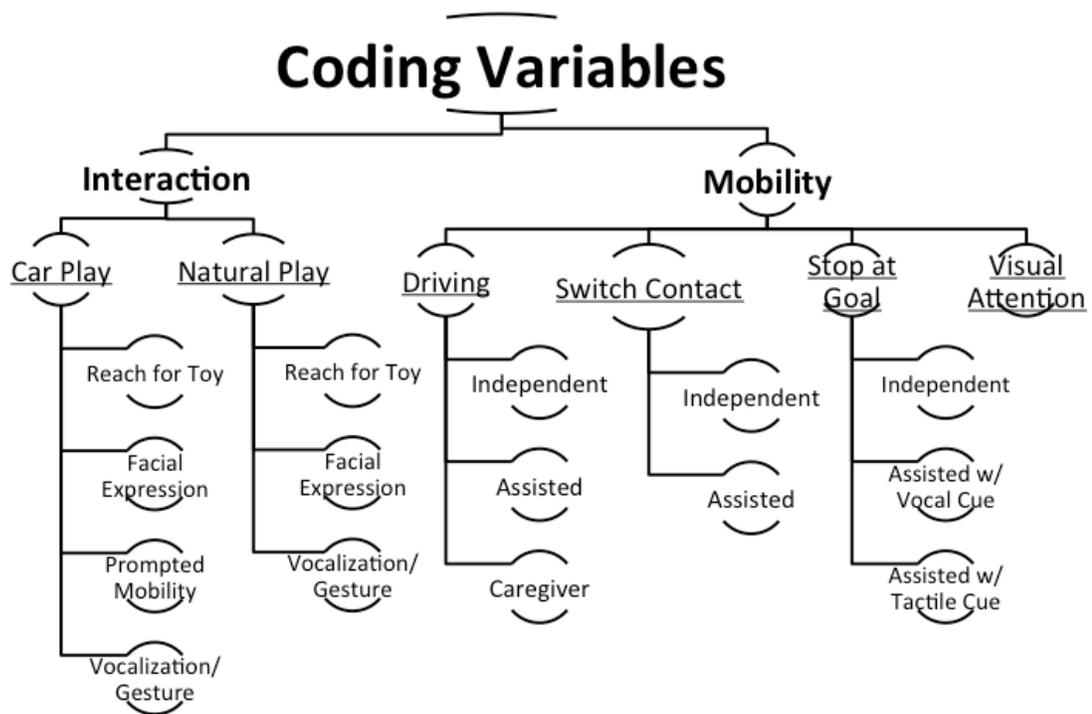
### **2.4.3 Retention Phase**

At the end of the Intervention period, the toy car was removed from the home. After 2 weeks the same set of observational tests completed during the Baseline and Intervention phases were repeated (Natural Play and Car Play) to assess the child's driving ability. Parents were asked to complete another questionnaire on their perception of using the ride-on toy car in the home environment for the extended

intervention period and the impact on their children (see Appendix B.3 for questionnaire).

## **2.5 Coding of Video Footage**

Coding of the video footage was done at the lab using computers and basic video watching programs (i.e. Quicktime). Coders' interrater reliability was at least 90% at all times. Coding measures were established for all driving and interaction measures. The results were based on a standard twenty minutes of video (1200 seconds) from each weekly home visit. The first ten minutes (600 seconds) of video footage from the 'natural play' session was coded for interaction. The first ten minutes of the 'driving' segment was coded for both mobility and interaction measures.



**Figure 4: Chart of all coding variables (Mobility and Interaction)**

### 2.5.1 Mobility Measures

During the Baseline, Intervention and Retention phases the following measures were obtained via coding video footage of driving for both children.

#### Interactions With Switch (Frequency)

- *Independent Switch Contacts*: The frequency (number of times) that the child puts his/her hand on the switch without caregiver intervention
- *Assisted Switch Contacts*: The frequency that an adult puts the child's hand on the switch

#### Driving (Time in seconds)

- *Independent Mobility*: When a child independently drives the device. Always preceded by an independent switch contact.
- *Caregiver Mobility*: When the child drives with an adult's hand directly on top (hand on hand).
- *Assisted Mobility*: When an adult puts the child's hand on the switch but the child independently pushes the switch to begin driving.

Visual Attention to Switch: The number of times that the child looks at switch.

Stopping At Goal: A "successful" stop at a pre-determined goal (ex. a toy, a person) was when child stopped within one car radius of the goal location.

- *Independent*: the child stops at the goal without assistance
- *Assisted with vocal cue*: the child is prompted by a researcher, caregiver or therapist to "let go" or "stop" the switch and reacts in response
- *Assisted with tactile cue*: the child's hand is physically moved from the switch to stop the car by a trainer, caregiver or therapist (can have additional vocal prompting)

## **2.5.2 Interaction Measures**

### **2.5.2.1 Natural Play**

During the Baseline and Intervention phases the following measures were obtained via coding video footage for both children.

- *Reaching for toy*: the frequency that the child initially extends arms to the play toy.
- *Facial Expression*: the frequency of both positive and negative facial expressions. Positive expressions include smiling and laughing. Negative expressions include discomfort and crying.
- *Vocalization/Gesture*: the frequency that the child vocalizes or gestures (ex. point or nod) to a play toy or person.

### 2.5.2.2 Car Play

During the Baseline and Intervention phases the following measures were obtained via coding video footage for both children.

- *Prompted Mobility*: The number of successful trials during the following driving test trials. Adult gestures or vocalizes to request that the child drive to a goal location. A successful trial was when the child independently interacts with the switch to move the ride-on toy car toward the goal location.
- *Reaching for toy*: the frequency that the child extends arms to the play toy.
- *Facial Expression*: the frequency of both positive and negative facial expressions. Positive expressions include smiling and laughing. Negative expressions include discomfort and crying.
- *Vocalization/Gesture*: the frequency that the child vocalizes or gestures (ex. point or nod) to a play toy or person.

## **Chapter 3**

### **RESULTS**

The results are organized based on the different categories measured: Mobility, Interaction/Socialization and Developmental measures. There are comparisons of Brenden and Maya in each section.

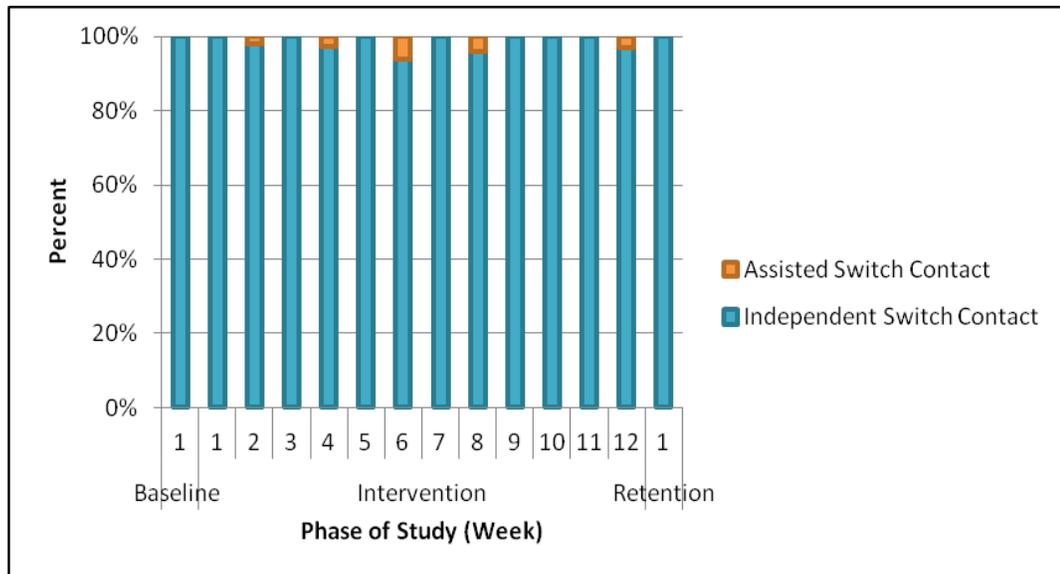
#### **3.1 Mobility Outcomes**

Interpretations of data were based on relative change from beginning to end of study. The variability that was seen could be attributed human subjects in their natural environment that was not completely controlled. Results are organized into those based on mobility and those based on interaction or socialization with the environment. The level of mobility was determined by the coded measures of interaction with the switch as well as a comparison of the different types of driving, including independent, assisted and caregiver ones.

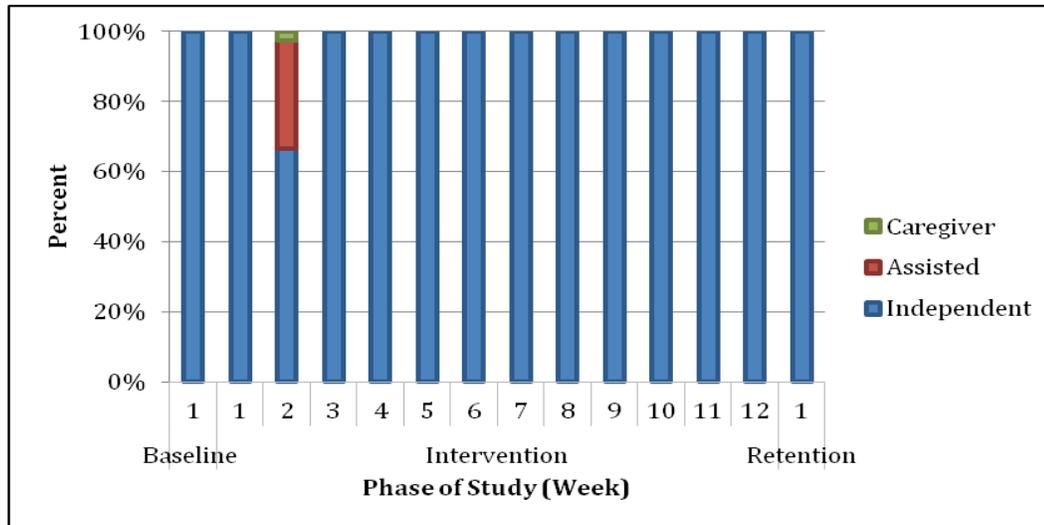
##### **3.1.1 Brenden**

Brenden displayed independent switch contacts close to 100% of the time. Through all phases, he consistently had a higher percent of independent switch contacts compared to assisted contacts in the ride-on toy car (Figure 5). His total driving time involved all three categories of driving, including caregiver, assisted and independent however the vast majority of time was independent (Figure 6). Thus,

despite his significant head and trunk control and poor arm and hand coordination, Brenden independently activated the switch from the start of the intervention period with minimal assistance from an adult.

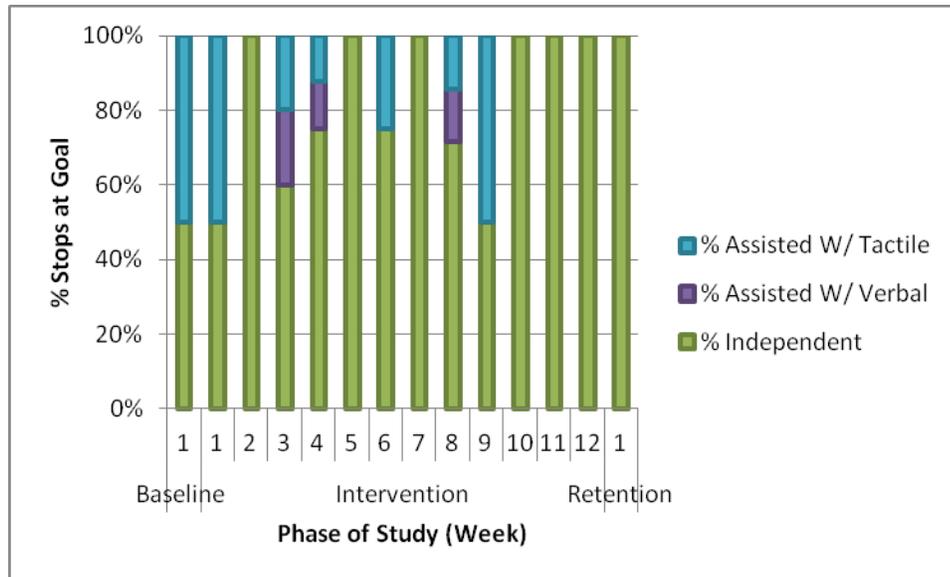


**Figure 5: Comparison of percent assisted vs. independent contact with switch for Brenden on ride-on toy car. There were two different types of possible interactions with the switch, either assisted (caregiver, therapist, or researcher) or independent (infant)**

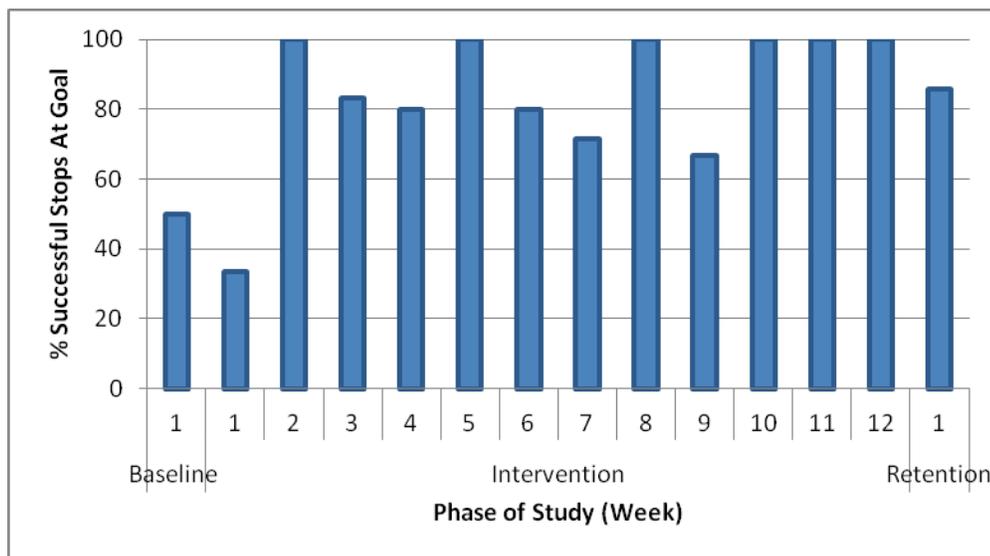


**Figure 6: Comparison of types of Brenden’s total driving time (Caregiver, Assisted vs. Independent)**

After initially activating the switch, Brenden was often able to display goal-oriented driving and the ability to stop at a pre-established goal. There were three different methods possible for Brenden to successfully stop at the goal: independently, assisted with verbal cues and assisted with tactile cues. Throughout the study, at least 50% of all stops were independent starting from the first day. During the last three days of the intervention phase (10-12) and the day of retention he stopped at the goal independently without assistance 100% of the time, while during days 1-9 there was a combination of methods used to stop the car (Figure 7). There was also observation of the percent of times Brenden successfully stopped at the goal, regardless of level of assistance. After day one of intervention, he stopped successfully at the goal, 88.93% of the time (Figure 8).



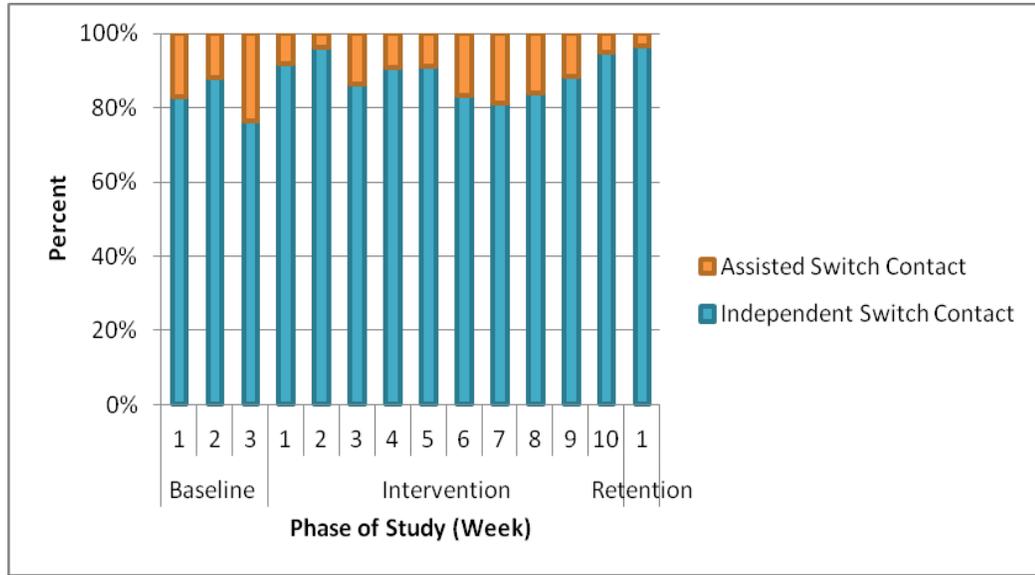
**Figure 7: Comparison of different methods of Brenden stopping at the goal**



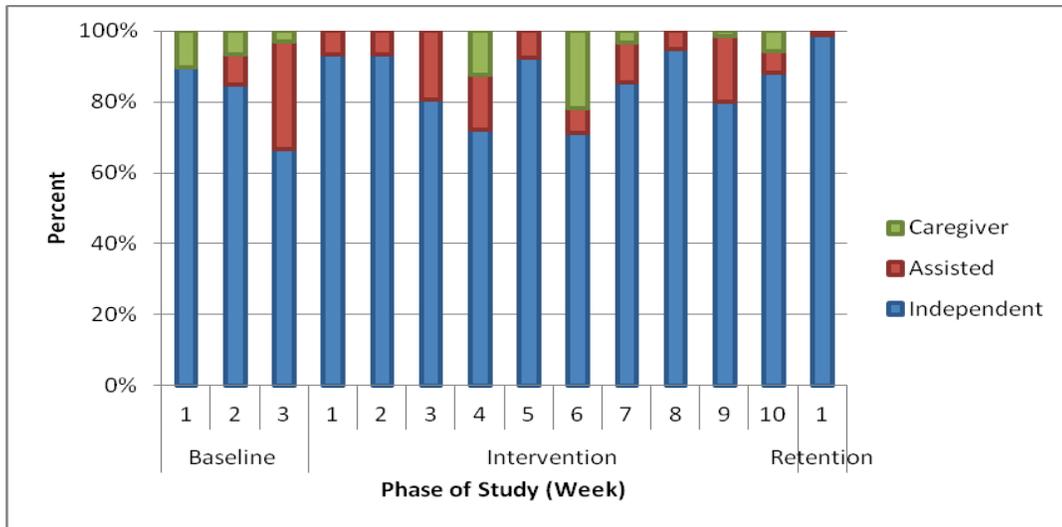
**Figure 8: Percent of successful stops at the goal for Brenden. A “successful” stop at the goal was when the Brenden was in within one car radius of the pre-established goal (toy, person, etc.) The successful stop could be: independent, assisted with verbal cue or assisted with tactile cue.**

### **3.1.2 Maya**

Maya's interaction with the switch (i.e., mobility measure) was also primarily independent. From the baseline phase through the intervention and retention, she consistently had a higher percent of independent switch contacts compared to assisted contacts in the ride-on toy car (Figure 9). When looking at her style of driving, she drove independently at least 65% of time throughout the study and by the retention phase, drove 96% of time independently (Figure 10). Thus, despite her lack of full arm and hand coordination, Maya independently activated the switch from the start of the intervention period with minimal assistance from an adult. Once given initial caregiver assistance with activating the switch she was able to drive herself as seen by more assisted driving as opposed to caregiver.

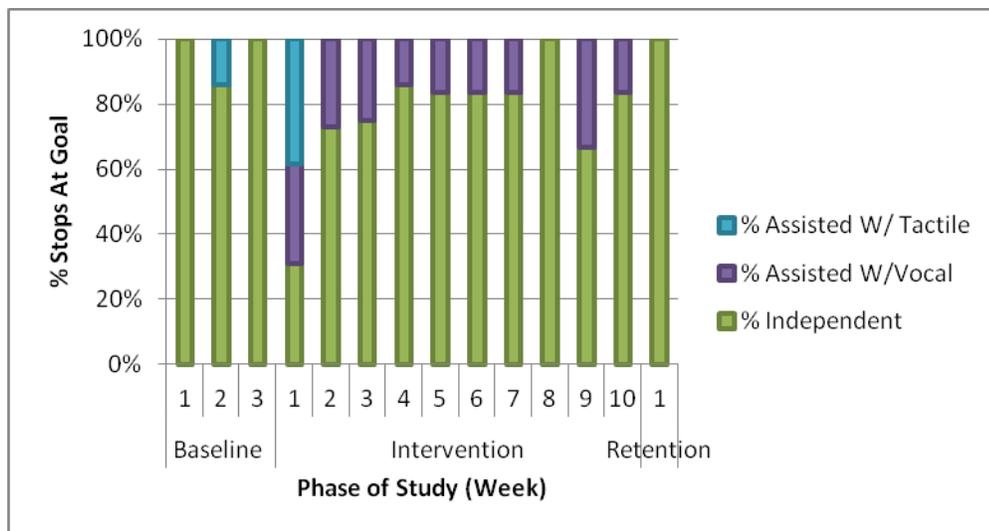


**Figure 9: Comparison of percent assisted vs. independent contact with switch for Maya on ride-on toy car. There were two different types of possible interactions with the switch, either assisted (caregiver, therapist, or researcher) or independent (infant)**

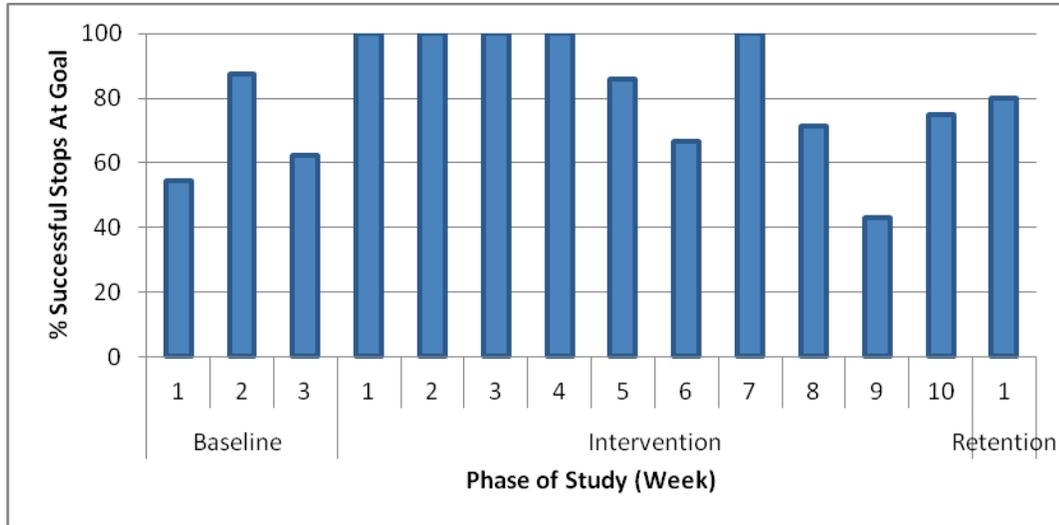


**Figure 10: Comparison of types of Maya's total driving time (Caregiver, Assisted vs. Independent)**

In terms of stopping at the goal, throughout the study, at least 65% of all stops were independent. One exception was the first day of intervention when her car had been modified with a new switch (Figure 11). There were few instances of assistance with tactile cues, but rather she would stop at the goal independently or with vocal cues. After day one of intervention, she stopped successfully at the goal the vast majority of the time (Figure 12).



**Figure 11: Comparison of different methods of Maya stopping at the goal**



**Figure 12: Percent of successful stops at the goal for Maya. A “successful” stop at the goal was when the Maya was in within one car radius of the pre-established goal (toy, person, etc.) The successful stop could be: independent, assisted with verbal cue or assisted with tactile cue.**

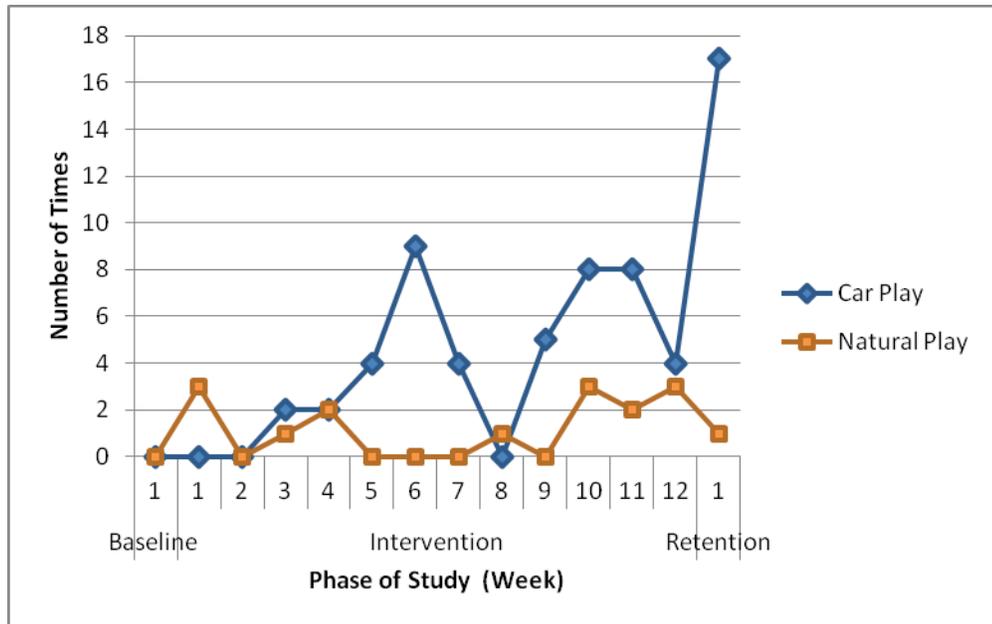
### 3.2 Interaction/Socialization Outcomes:

Interpretations of data were based on relative change from beginning to end of study. The variability that was seen could be attributed human subjects in their natural environment that was not completely controlled.

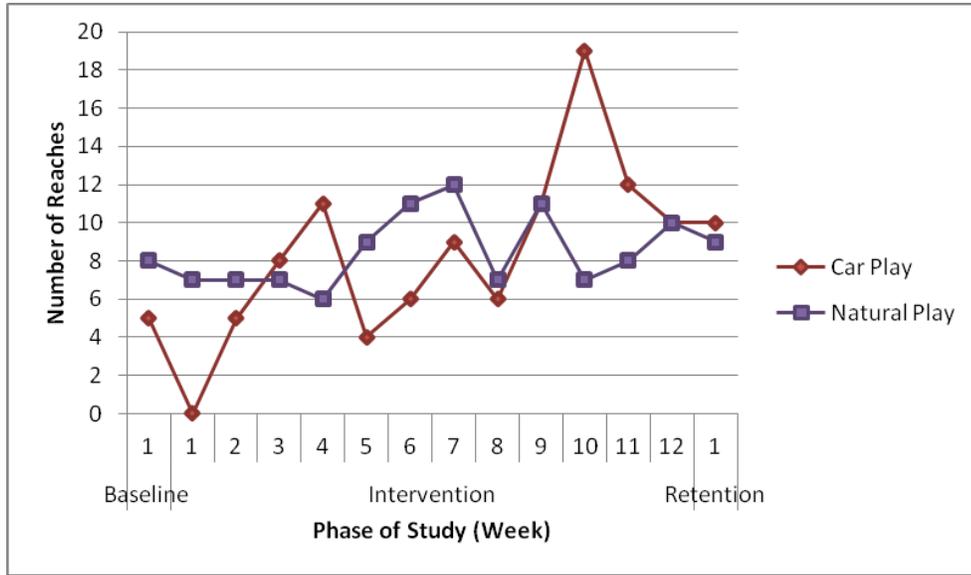
#### 3.2.1 Brenden

Another aspect of the study was the focus on interactions with the environment using the ride-on toy car. Brenden increased his vocalizations and gestures over the weeks of intervention during his time in the car (car play) as well as play outside of the car (natural play). He had the most vocalizations and gestures during the retention

phase when he was re-introduced to the ride-on toy car (Figure 13). During interactions with the environment, Brenden increased his reaches for toys when in the ride-on car during the intervention phase. During natural play, he maintained an average of 9 reaches per week (Figure 14).

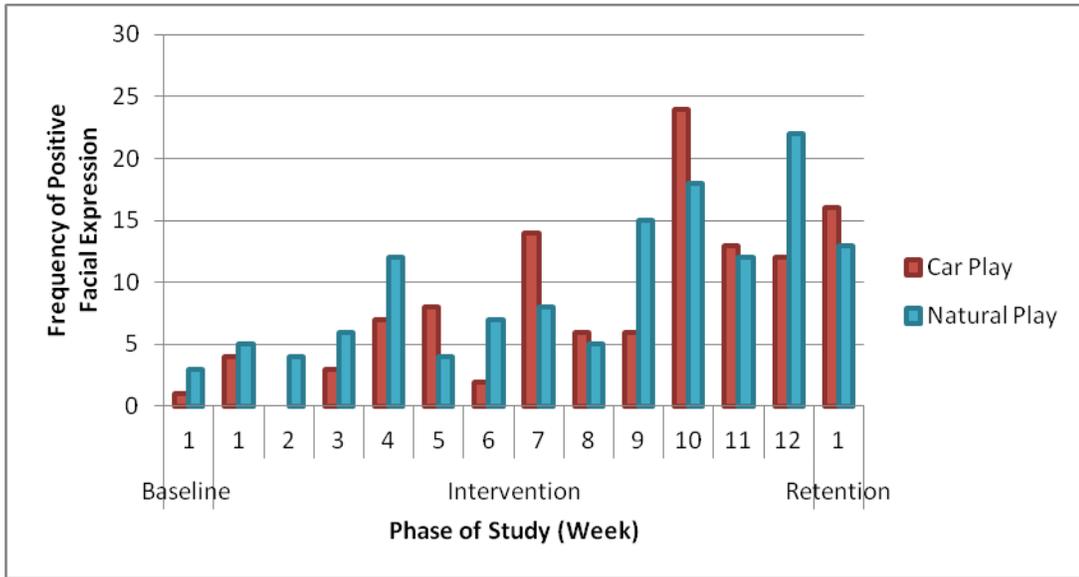


**Figure 13: Comparison of frequency of vocalizations and gestures between Car Play vs. Natural Play for Brenden**

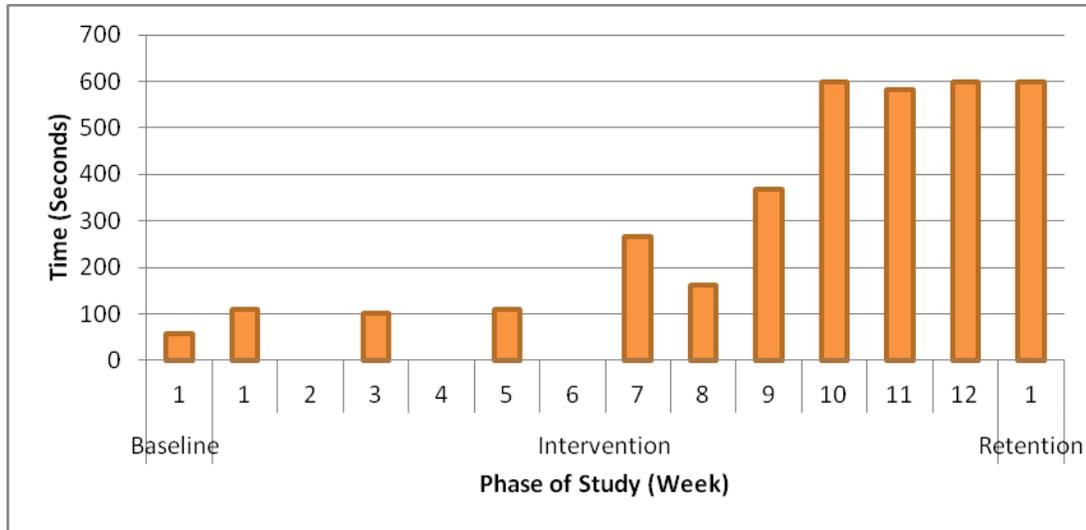


**Figure 14: Comparison of frequency of reaching for toys in Car Play vs. Natural Play for Brenden**

Brenden increased his positive facial expressions throughout the study both in the car as well as during the natural play setting (Figure 15). There might be a correlation of his positive facial expressions while in the ride-on toy car with the amount of caregiver-initiated interaction time. Specifically, the days when a parent spent more time interacting with him when he was in the car yielded higher frequencies of positive facial expressions (Figure 16).



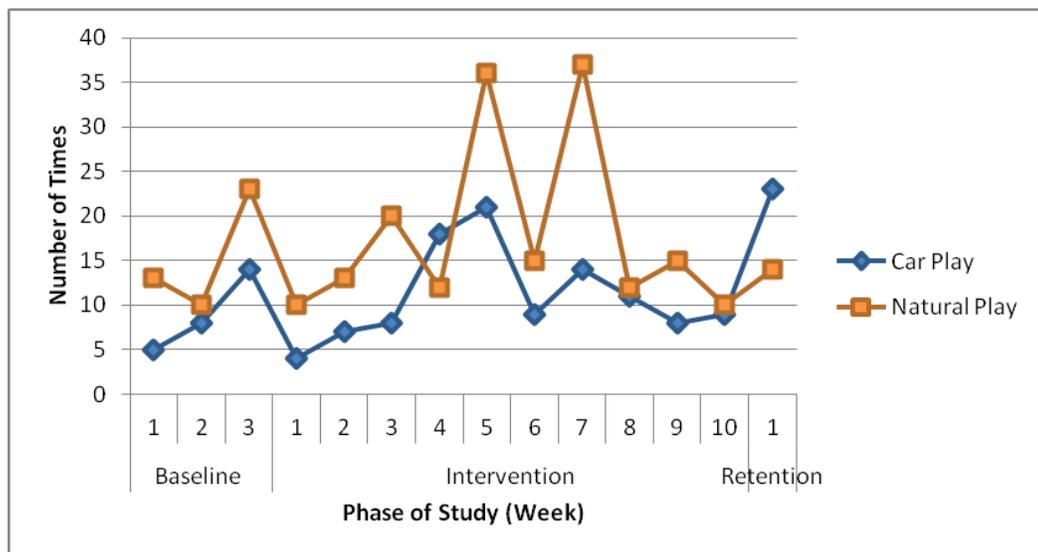
**Figure 15: Comparison of frequency of positive facial expression in Car Play vs. Natural Play for Brenden**



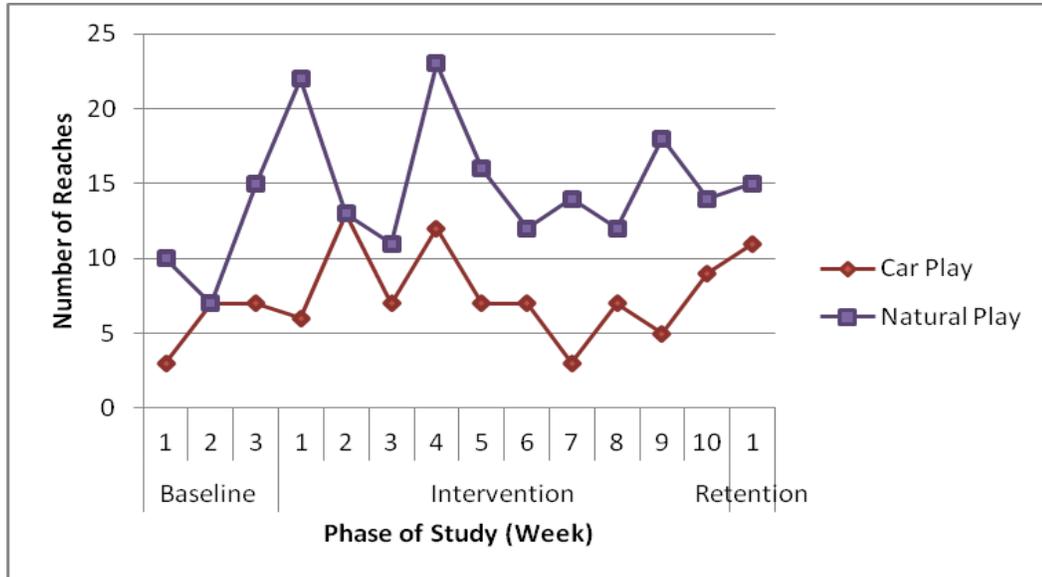
**Figure 16: Caregiver-Initiated Interaction Time for Brenden. The amount of time during 10 minutes of home assessment that Brenden spent in the ride-on toy car and was interacting with caregivers.**

### 3.2.2 Maya

Maya increased her vocalizations and gestures over the 10 weeks of intervention during her time in the car (car play). During natural play she displayed similar levels during the beginning and end of the study with an increase during the middle of the intervention phase. She had the most vocalizations and gestures in the retention phase when she was re-introduced to the ride-on toy car two weeks after intervention (Figure 17). When looking at interaction with the environment, Maya appeared increase her reaches for toys during natural play as opposed to when she was in the car. By the retention phase she was reaching more for toys in the car compared to the baseline period and there was less of a difference with the number of reaches during car play and natural play (Figure 18).

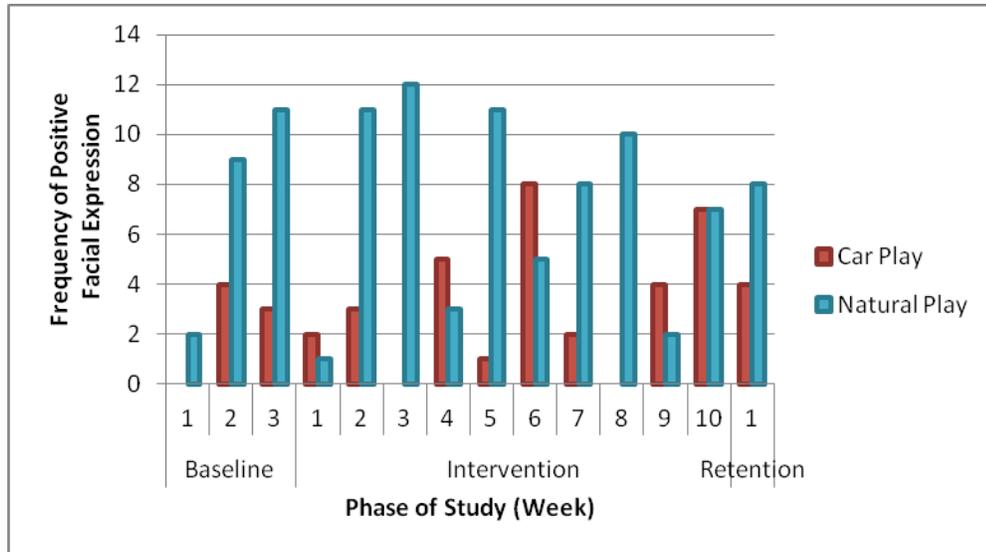


**Figure 17: Comparison of frequency of vocalizations and gestures between Car Play vs. Natural Play for Maya**



**Figure 18: Comparison of frequency of reaching for toys in Car Play vs. Natural Play for Maya**

Maya appeared to have more positive facial expressions during natural play compared to car play (Figure 19). She enjoyed her time when she was playing with toys during natural play and there was an overall increase in positive facial expressions through the study. There was a more constant frequency of positive facial expressions in car play during the study.



**Figure 19: Comparison of frequency of positive facial expression in Car Play vs. Natural Play for Maya**

### 3.3 Developmental Measures

#### 3.3.1 Brenden

The scores from the PEDI and BAYLEY were normalized to Brenden’s age. The results from the PEDI assessment included both the functional skill as well as the caregiver assistance for three different categories: self-care, mobility and social function. Positive results would include an increase in functional skill and a decrease in caregiver assistance. There was no change in Brenden’s scaled scores for caregiver assistance before and after the intervention. The Caregiver assistance portion assesses 20 complex functional activities and how much assistance a child needs in performing these and rates them on a scale between 0 (total assistance) and 5 (independent).<sup>14</sup> Brenden scored, 0, 20.3 and 20.4 on self-care, mobility and social function,

respectively. In terms of the functional skills section it was scored zero (limited or incapable of performing the skill) to 1 (capable of performing the skill) and focused on 197 various skills.<sup>14</sup> The scores were converted to scale scores that were age-normalized. His functional skill varied slightly between the two assessments in some categories. There was an increase in mobility functional skill from 29.0 to 37.1 and minimal change in social function from 35.1 to 36.1. These stable scores were not surprising given Brenden's overall low level of functional movement, mobility and communication.

The Bayley standardized assessment was performed when Brenden was 21 months and 24 months after the ride-on car intervention. During the three months there was no change in his scores. The Bayley scored cognitive levels, language receptiveness as well as expressiveness; fine motor skills, and gross motor skills. These were scaled scores that were age-adjusted. When converted they could range from 1-19 with the higher number being more equivalent to that developmental age.<sup>3</sup> He scored a 1 on cognitive level as well as fine and gross motor skills. He scored a 2 on language expressiveness and a 4 on language receptiveness. These stable scores were also not surprising given Brenden's overall low level of functional movement, mobility and communication.

From the weekly activity journal, Brenden's total driving time during the intervention period totaled 1150 minutes (19.2 hrs.) for the 12 weeks. This time was a total of all driving that Brenden had done during the week with his family in between the weekly assessments.

### **3.3.2 Maya**

The scores from the PEDI and BAYLEY were normalized to Maya's age. Maya's PEDI scores were also assessed before and after the three-month intervention with the ride-on toy car. During this three-month period, her self-care and mobility in the caregiver assistance categories did not change. However, there was an increase of social function from the initial assessment. Her scaled scores for self-care, mobility and social function in terms of functional skill level all increased. Her self-care increased from 43.6 to 46.7, mobility from 32 to 34.7 and social function from 46.2 to 49.7.

The Bayley standardized assessment was also performed for Maya when she was 28 months and 31 months after the ride-on car intervention. There were improvements between the first and second time of assessment in all categories except for gross motor skills, which remained the same. These were scaled scores that were age-adjusted. When converted they could range from 1-19 with the higher number being more equivalent to that developmental age. However, the Bayley scaled scores of cognitive level increased from 4 to 11, language receptiveness from 12 to 17, language expressiveness from 10 to 16, and fine motor skills from 1 to 5.

From the weekly activity logs, Maya's total driving time during the intervention period could be totaled to 585 minutes (9.8 hrs.) for the 9 weeks.

## **Chapter 4**

### **DISCUSSION**

#### **4.1 Brenden**

These findings suggest that relatively short-term power mobility training using a modified toy ride-on car device positively impacted Brenden's mobility and socialization. Specifically, he continued independent activation and self-initiated movement as well as an increase in the measured social measures of vocalizations as well as extending his arm for toys to interact with his environment. In my proposed model, there are four variables that affect outcomes: child, ride-on toy car, environment and task. One or more of these variables may have contributed to Brenden's positive changes, including the modifications of device, practice environment, and the overall task during the intervention phase. These variables likely interacted to influence his individual results.

##### **4.1.1 Individual Development Level**

Through the study, Brenden increased his vocalizations and gestures and increased expressivity of facial expressions (Figure 13). From this I speculate that he gained an increase comfort and independent expression of his thought through vocalization and gesture. Brenden's developmental level as reflected by his Bayley and PEDF scores, changed very little. A higher dosage of intervention and a more rigorous study to determine the magnitude of the effects on developmental aspects

may be required for children with such a low level of initial function and communication.

#### **4.1.2 Device**

The ride-on car device was modified to Brenden's specificities and developmental capabilities. His ride-on toy car had one large, colorful, touch sensitive switch for easy activation even on the first day (Figure 5). The results showed that the toy car is effective for stimulating a young child to attempt self-initiated mobility. There was a positive impact of the design of device on his acquisition of self-initiated independent mobility.

#### **4.1.3 Environment**

Brenden's environment was composed of his family, school and the places he drove. These likely contributed to driving success and his perception of the car. Brenden drove the ride-on car in various settings during the intervention period ranging from home driveway, street, sidewalk, gym at the Early Learning Center (ELC), family room and even an open karate studio. The family chose to vary the locations they allowed Brenden to drive and it showed the dedication they had to integrating the device into their lives. The "fun index", was a measure on the daily activity logs that focused on the parent's perception of the child's enjoyment level in the car. The scale for the fun index was 1-10. Despite Brenden's low functional and communication level, his fun index was very high with most days scoring 9 to 10 out of 10 during the intervention period. His parents chose to use the car in public places

and initiate peer-interaction including having his birthday party at an open karate studio specifically so he could drive around during this party.

His perceptions of the car were reflected in part through our facial expression coding and in the later weeks of the study he consistently had more positive facial expressions in the car as opposed to natural play. The ride-on toy car was Brenden's one available device; therefore his parents and family chose to integrate it in their daily activities to allow him a way of exploring the world. The environment likely positively impacted his level of independent mobility as he spent extended periods of time in the device per day (Figure 6).

In addition to start the car's motion, Brenden learned stop. Results suggest that he was able to stop at the goal successfully more over time and with less assistance. With a focus on teaching him the language of "let go" and providing stimulation with specific goals of toys, which were interest to him, we were able to influence his ability to use the car in goal-oriented driving situations. There was a positive growth of increasingly stopping at a goal independently as apposed to with vocal or tactile assistance (Figure 7). His interaction with the people and things around him was also influenced by his time in the car. Over the study, Brenden had a higher frequency of vocalizations and gestures while in the car as opposed to the natural play (Figure 13).

## **4.2 Maya**

Results suggest that short-term power mobility training using this ride-on car device positively impacted Maya's mobility as well as her socialization. This was supported by her continued independent activation and self-initiated mobility. Additionally, there were small increases in her vocalizations and gestures as well as

extending her arm for toys (goal) to positively interact with his environment (Figure 17). As with Brenden, I speculate that there was an interaction of the four critical variables in my proposed model contributed to the changes observed in the study, including the modifications of device, practice environment, and the tasks chosen during the intervention phase. Her individual developmental level during this three-month period was positively influenced by a combination of the device, environment and intervention.

#### **4.2.1 Individual Developmental Level**

Maya's cognitive levels as measured by her Bayley and PEDI scores showed a large improvement over the course of the study. Increases in developmental measures could be attributed to her interaction with therapists and researchers but may require higher dosage of intervention and a more rigorous study to determine the magnitude of the effects on developmental aspects. Her vocalizations and gestures also increased in frequency.

#### **4.2.2 Device**

Her ride-on car device was modified to match her current developmental level and abilities. During the intervention period Maya's ride on toy car was re-modified several times during the study in an attempt to produce an optimal steering mechanism. Additionally, her switch was altered after the baseline phase to be more accessible and easily activated (Figure 9). The various modifications maintained her ability to be mobile and have fun, which in part had positive results.

### **4.2.3 Environment**

The environment was a critical aspect of the study and a key factor in the interaction of the Maya and the ride-on car. Her perceptions toward the device were noted through the 'fun index', and her scaled scores ranged from 5 to 6. Interestingly, her fun level was markedly lower than the fun level of Brenden. Additionally, daily activity journal entries showed that her driving environments were more limited as compared to Brenden. For example, Maya was mobile only in the family room and kitchen of the house, and not outside of the house. This lack of multiple places to drive coupled with her access to a walker-device that she typically used across multiple places may have been factors that limited her enjoyment and the variety of use of the car. The ride-on car device did not allow her to get as close to her toys as her other device, however for outside use the ride-on car was a more feasible option.

She only interacted with her parents and sister and had no preschool or peer interaction while in the ride-on car. Positive facial expressions were much more frequent in the natural play setting as opposed to in the car. Additionally, she had higher vocalizations and gestures as well as interaction through reaching for toys in the natural play setting as well. The car was also not integrated as consistently into her daily routine because she would communicate vocally that she would often rather be in her walker as she could maneuver that easily. There was a positive effect of her environment on her socialization and interaction with the environment as she vocalized about her surroundings as well as attempted to reach out for toys and drive to particular goals (Figure 17). In goal-oriented driving she was able to effectively stop at the goal independently as opposed to with tactile or vocal assistance (Figure

11). Her parents' perception of the car was positive as following the study they purchased one for outside use in the summer months.

#### **4.2.4 Task Completion**

Similar to Brenden, her initial goal was to achieve sustained independent mobility by driving the ride-on toy car. Though there were multiple switches as well as steering handles during the first few weeks of the study, she exhibited clear ability to independently activate the switch (Figure 9). The next step was to teach the concept of steering. Bimanual coordination with disassociated movement, where one hand was to push forward while the other pull backward to move the 'bike handle', was difficult for Maya. However with steering modifications and training, Maya would participate in 'scavenger hunts', where she needed to find all the objects (ex. cookie toy) in various locations (ex. cookie jar). Her ability to stop was traced she consistently was able to with minimal assistance. Her initial task had a positive impact on stimulating independent mobility as she had particular goals to achieve (Figure 10). Additionally, her ability to successfully reach her goal during repeated instances of prompted mobility demonstrated her increasing interaction with the environment.

#### **4.3 Comparison of Brenden and Maya**

The same goal of providing a means of independent mobility was set for both Brenden and Maya during this study. Though clearly at varying developmental levels, they both managed to effectively gain independent mobility through the use of the ride-on toy car. Through different focuses, they began to move more into the functional use of the car with a focus on using mobility for the purpose of socialization

and an increase in interaction with the environment. For both Brenden and Maya there was an interaction of the device, environment and task on their ability to achieve self-initiated mobility as well as improve their interaction with the environment as evidenced by the observational outcomes of the intervention (Table 1).

	<b><u>Brenden</u></b>	<b><u>Maya</u></b>
<b>Individual Levels</b>	Same levels in BAYLEY & PEDI during study	Improvement in BAYLEY & PEDI scores during study
<b>Modified Ride-on Car Device</b>	Large, yellow switch that was easily activated	'Bike-handle' apparatus to provide easy accessibility and easy activation
<b>Environment</b>	Public locations, variety of locations in house, dove with friends and family	Limited locations of driving in house, only drove with immediate family
<b>Task</b>	Concept of 'stop & go', goal oriented driving	Goal-oriented driving, 'scavenger hunt', steering
<b>Completion of Primary Goals</b>	Independent mobility, increased interaction with environment, no change in BAYLEY & PEDI	Independent mobility, increased interaction with environment, change in BAYLEY & PEDI
<b>Completion of Secondary Goals</b>	Positive family and child perception and integration into daily activities	Positive perception but she liked to use variety of devices

Table 1: Comparison of results for Brenden and Maya

## **Chapter 5**

### **CONCLUSION**

This pilot study is continuing in the form of a larger group study involving 10-15 children with CP as well as other diagnoses such as Downs syndrome. This study focused on the feasibility of using ride-on cars for increasing mobility. Like other PMDs, such as powered wheel chairs, ride on cars meet the mobility criteria of providing increased levels of participation or activity. For example, Maya was able to participate in ‘scavenger hunt-like’ activities that promoted goal-oriented driving and could maneuver the device within reaching distance of the goal. Ride on cars can be further modified to enhance leg strength, head control and the use of fine and gross motor skills. The design of the device also effectively caters to young children as it is a well-known cartoon character and brings with it the socialization and the ability to interact with the environment.

The two different children provided important differences in results and highlighted the potential breadth of the ride-on car device applications. One important experience that was gained by the research team was the range of modifications that are required for children with varying cognitive and developmental levels. There was only one criterion that was pre-determined for a child to use the device, which was the inability to be independently mobile prior to the use of this device.

The use of this device in the home setting for an extended intervention phase requires the cooperation and participation from the family and friends of the infant. It depends on an attempt to integrate the ride-on toy car into the child's daily activities.

### **5.1 Limitations of Study**

As a pilot study, there are limitations of the study that need to be addressed in future work. The simple goal of activation was easy for both children, however further progress toward the ability to functionally steer was much more difficult. There is a gap between the two goals that was difficult to find a solution for with this particular device. Modifications to prompt directional driving involve the steering mechanism. Another limitation of the device was the relatively large turning radius for indoor home and classroom use.

### **5.2 Future Studies**

This study was used to evaluate a proposed protocol to modify a ride-on toy car and provide it as a PMD in lieu of a power wheelchair for infants with Cerebral Palsy who were immobile. In addition to testing the feasibility of the device in terms of providing independent mobility for infants, there was also an attempt to use it as a means for the child to interact and socialize with his/her environment. Currently, the Infant Behavior Lab at the University of Delaware is attempting to modify this protocol and test the feasibility of this device in a group study with 10-15 children with motor impairments.

## REFERENCES

1. Albers, C.A., and Grieve, A.J. "Review of Bayley Scales of Infant and Toddler Development--Third Edition." *Journal of Psychoeducational Assessment*. 25 (2007), 180-190.
2. Anderson, David I., et al. "The Flip Side of perception–action Coupling: Locomotor Experience and the Ontogeny of visual–postural Coupling." *Human Movement Science* 20.4-5 (2001): 461-87. Print.
3. "Bayley Scales Of Infant And Toddler Development, Third Edition (BAYLEY-III)." *Us department of health and human services*. Administration for Children and Families, 2005. Web. <[http://www.acf.hhs.gov/programs/opre/ehs/perf\\_measures/reports/resources\\_measuring/res\\_meas\\_cdif.html](http://www.acf.hhs.gov/programs/opre/ehs/perf_measures/reports/resources_measuring/res_meas_cdif.html)>.
4. Bertenthal, B. I., and Campos, J.J. "New Directions in the Study of Early Experience." *Child development* 58.3 (1987): 560-7. Print.
5. Bohannon, R.W., and Smith, M.B., "Interrater Reliability of a Modified Ashworth Scale of Muscle Spasticity." *Phys Ther*. 67 (1987): 206-207
6. Butler, C., G. A. Okamoto, and T. M. McKay. "Powered Mobility for very Young Disabled Children." *Dev Med Child Neurol* 25.4 (1983): 472–474. Print.
7. Butler, C. "Effects of Powered Mobility on Self-Initiated Behaviors of very Young Children with Locomotor Disability." *Dev Med Child Neurol* 28.3 (1986): 325-32. Print.
8. Butler, C., G. A. Okamoto, and T. M. McKay. "Motorized Wheelchair Driving by Disabled Children." *Archives of Physical Medicine and Rehabilitation* 65.2 (1984): 95-7. Print.
9. Campos, J. J., et al. "Travel Broadens the Mind." *Infancy* 1.2 (2000): 149-219. Print.
10. "Cerebral Palsy (CP)." *CDC*. Centers for Disease Control and Prevention, 2011. Web. <<http://www.cdc.gov/ncbddd/cp/index.html>>.

11. Eliasson, A., et al. "The Manual Ability Classification System (MACS) for children with cerebral palsy: scale development and evidence of validity and reliability." *Dev Med Child Neurol* 48 (2006): 549-554. Print.
12. Galloway, J. C., J. C. Ryu, and S. K. Agrawal. "Babies Driving Robots: Self-Generated Mobility in very Young Infants." *Intelligent Service Robotics* 1.2 (2008): 123-34. Print.
13. Guerette, P., D. Refft, and J. Furumasu. "Pediatric Powered Wheelchairs: Results of a National Survey of Providers." *Assistive Technology: The Official Journal of RESNA* 17 (2005): 144-58. Print.
14. Haley S, Coster, W, Ludlow L, Haltiwanger J, Andrellos J. "Pediatric Evaluation of Disability Inventory (PEDI)". Boston: Trustees of Boston Univeristy, 1998.
15. Hoch, D., N. Kaneshiro, and N. Kaneshiro, eds. "Cerebral Palsy." *Pubmed health. A.D.A.M. Medical Encyclopedia*, 2009. Web.  
<<http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001734/>>.
16. . "International classification of functioning, disability and health (icf)." *World Health Organization*. N.p., 2011. Web.  
<<http://www.who.int/classifications/icf/en/>>.
17. Jones, M. A., I. R. McEwen, and L. Hansen. "Use of Power Mobility for a Young Child with Spinal Muscular Atrophy." *Physical Therapy* 83.3 (2003): 253. Print.
18. Kangas KM. *Clinical Assessment and Training Strategies for the Child's Mastery of Independent Powered Mobility*. Arlington, VA: RESNA/Rehabilitation Engineering and Assistive Technology Society of North America; 1997:33-47.
19. Palisano, R., P. Rosenbaum, D. Bartlett, and M. Livingston. "Gross Motor function classification system." *CanChild Centre for Childhood Disability Research Institute for Applied Health Sciences*. N.p., 2007. Web.  
<<http://motorgrowth.canchild.ca/en/GMFCS/resources/GMFCS-ER.pdf>>.
20. Ragonesi, C. B., et al. "Power Mobility and Socialization in Preschool: Follow-Up Case Study of a Child with Cerebral Palsy." *Pediatric Physical Therapy* 23.4 (2011): 399-406. Print.
21. Ragonesi, C. B., et al. "Power Mobility and Socialization in Preschool: A Case Study of a Child with Cerebral Palsy." *Pediatric Physical Therapy* 22.3 (2010): 322. Print.

22. Shores, R.E. "Overview of Research on Social Interaction: A Historical and Personal Perspective." Behavioral Disorders 12.4 (1987): 233-241.
23. "The Industry Profile on Wheeled Mobility." Ed. Stephen Bauer and Ed. Mary Ellen Buning. Buffalo: State University of New York at Buffalo, 2009. Print. <[http://t2rerc.buffalo.edu/pubs/ip/MT/2009 IP on Wheeled Mobility v2.0.pdf](http://t2rerc.buffalo.edu/pubs/ip/MT/2009_IP_on_Wheeled_Mobility_v2.0.pdf)>.

## Appendix A

### Educational Brochure

#### Training Manual-Overall Guidelines

##### Suggestions for Training a Child to Use a Ride-on Car

- Encourage your child to explore 1. Switch 2. Movement (e.g., reaching, grasping, pressing) 3. Toy 4. Moving spaces at home
- Learn by doing.
- Give your child time to learn and react.
- Provide positive feedback (e.g., “You found the \_\_\_\_\_ [object your child ran into]” rather than “Oops, you crashed”).
- If your child looks distressed (e.g., crying, losing attention), then intervene immediately.
- Help your child by using words such as “come closer”, ”turn”, or “go back” rather than “push the switch and come here.

Young children in ride-on cars *must* be supervised at all times. Adults should be close by to monitor all activities and to ensure safety.

## **Training Manual Phase I-Car Exploration (start)**

### **Suggestions for Training a Child to Use a Ride-on Car**

#### **Do**

1. Encourage your child to explore the car first. Introduce the car to your child briefly before sitting in. For example, let him/her look at the car and say “Here is Mater. We will play with him now”.
2. After sitting into the car, you can touch the switch once and see how your child reacts. Give your child time to react. If there is no reaction, demonstrate it again.
3. If your child does not react after three times of demonstration from you, guide his/her hand to touch the switch directly. Once his/her hand touches the switch, lift your hand off the switch and see if your child will drive independently.
4. If your child can not independently drive the car after you place his/her hand on the switch, place your hand on top of his/her hand and drive the car with him/her for a while.
5. Provide positive feedback every time when the car moves.

#### **Do Not**

1. Expect your child will know how to control the car within few days. It may require some time for him/her to get familiar with this new device.
2. Directly guide your child’s movement through your own movement from beginning. Unless he/she does not have any exploratory behaviors (e.g., touch or look at different parts of the car), you can guide some of his/her movements by placing your hand on his/hers.
3. Provide direct physical guidance all the time. Try to encourage your child explore the driving possibilities (e.g., hit the switch and go) by himself/herself.
4. Intervene your child’s exploration of car and body movements all the time. Give him/her time to figure it out.
5. Give the positive feedback only when your child purposefully hits the switch. Every time when he/she hits the switch, you should give positive feedback whether the

movement occurs purposefully or accidentally.

## **Training Manual Phase II-Car Exploration (stop)**

### **Suggestions for Training a Child to Use a Ride-on Car**

#### **Do**

1. Encourage your child to drive around in the appropriate areas at home. Direct physical guidance could be provided depending on your child's responses. For example, hand over hand driving (i.e., directly physical guidance) can be provided when your child does not press the switch after you place his/her hand on the switch.
2. Tell your child "let go" (i.e., hands off) when he/she drives to you or the car hits some things (e.g., wall or sofa). If he/she cannot lift his/her hands off the switch, provide manual guidance.
3. Provide positive feedback when he/she hits the switch and moves the hands away from it.

#### **Do Not**

1. Expect your child will start the movements immediately. Give him/her time to initiate the movements.
2. Expect your child will understand "let go" (i.e., hands off) and connect it to the car motion within a few days or a week. It is a gradual learning process.
3. Give the positive feedback only when your child purposefully hits the switch. Every time when he/she hits the switch, you should give positive feedback whether the movement occurs purposefully or accidentally.

**Training Manual Phase III-Prompted Driving (no specific direction/distance)**  
**Suggestions for Training a Child to Use a Ride-on Car**

**Do**

1. Encourage your child to drive to you for the rewards (e.g., toy). Stand in front of the child with some distances and tell him/her to drive to you for the rewards.
2. Give your child time to drive to you even it takes a long time.
3. Make sure your child has eye contact with you and the rewards.

**Do Not**

1. Expect your child will start the movements immediately. Give him/her time to initiate the movements.
2. Intervene your child's driving movements immediately when he/she does not move immediately after your verbal or gestural prompt.
3. Provide the rewards directly to your child without any eye contact. Give him/her time to actively move toward the rewards and have eye contact on the target (i.e., you or reward).

## **Training Manual Phase IV-Prompted Driving**

### **(straight direction and a specific distance)**

#### **Suggestions for Training a Child to Use a Ride-on Car**

##### **Do**

1. Encourage your child to drive straight for 5 feet distances for the rewards (e.g., toy).
2. Provide different rewards if your child has multiple interests and short attention span. Take a break if he/she is tired.
3. Provide positive feedback even he/she does not drive continuously for 5 feet distances.
4. Make sure your child has eye contact with you and the rewards.

##### **Do Not**

1. Expect your child will complete the goal immediately. Give him/her time to initiate the movements.
2. Expect your child to play with one activity in a continuously 20-30 minutes of training time.
3. Give the positive feedback only when your child drive directly for 5 feet distances. If he/she stops in the middle, give him/her time to initiate the movements again. Encourage him/her to keep going.
4. Provide the rewards directly to your child without eye contact. Give him/her time to actively move toward the rewards and have eye contact on the target (i.e., you or reward).

**Training Manual Phase V-Prompted Driving**  
**(different directions and a specific distance)**

**Suggestions for Training a Child to Use a Ride-on Car**

**Do**

1. Encourage your child to drive to you at different directions for 5 feet distances for the rewards (e.g., toy).
2. Provide different rewards if your child has multiple interests and short attention span. Take a break if he/she is tired.
3. Provide positive feedback even he/she does not drive continuously for different locations for 5 feet distances.
4. Make sure your child has eye contact with you and the rewards.

**Do Not**

1. Expect your child will complete the goal immediately. Give him/her time to initiate the movements.
2. Expect your child to play with one activity in a continuously 20-30 minutes of training time.
3. Give the positive feedback only when your child drive directly for different locations for 5 feet distances. If he/she stops in the middle, give him/her time to initiate the movements again. Encourage him/her to keep going.
4. Provide the rewards directly to your child without eye contact. Give him/her time to actively move toward the rewards and have eye contact on the target (i.e., you or reward).

## **Training Manual Phase VI-Driving and Socialization**

**(different directions/distances)**

### **Suggestions for Training a Child to Use a Ride-on Car**

#### **Do**

1. Encourage your child to drive to you, other adults, or other children for the rewards (e.g., toy).
2. Make sure your child has eye contact with you and the target.
3. Provide positive feedback and eye contact when your child has the rewards.

#### **Do Not**

1. Expect your child will complete the goal immediately. Give him/her time to initiate the movements.
2. Expect your child to complete the goal when he/she does not pay attention on it.
3. Give positive feedback without any eye contact. Let your child see your facial expression while providing feedback.

## Training Manual-Flowchart

### *Car Exploration (phase I)*

Let your child understand: 1) the car can move 2) if he/she hits the switch, the car will move



### *Car Exploration (phase II)*

Let your child understand: 1) the car can stop 2) if he/she lifts the hand off the switch, the car will stop



### *Prompted Driving (phase III)*

Let your child drive the car: 1) within the home environments independently 2) without any manual guidance for forward



### *Prompted Driving-straight with a specific distance (phase IV)*

Let your child drive the car: 1) forward for 5 feet to reach the target (e.g., you or toy) without any manual guidance



*Prompted Driving-different directions with a specific distance (phase V)*

Let your child drive the car: 1) to different directions for 5 feet to reach the target (e.g., you or toy) without any manual guidance



*Prompted Driving-different directions and distances (phase VI)*

Let your child drive the car: 1) to different directions for different directions to reach the target (e.g., you or toy) without any manual guidance 2) to reach the target with different people (with eye contact)

## Appendix B

### Sample Interview Questionnaires

#### B.1 Baseline-Parents' Perceptions of Using Ride-on Car Interview Questions

Participant's Initials: \_\_\_\_\_

Date: \_\_\_\_\_

1. Does your child move at home *without* your assistance? Yes No
  - a. If yes, explain how your child moves at home without your assistance.
2. Does your child move at home *with* your assistance? Yes No
  - a. If yes, explain how your child moves at home with your assistance.
3. Are there situations in which your child experiences difficulty moving around at home? Yes No
  - a. If yes, explain one situation:
4. Before hearing about this study, has your child used a wheelchair, walker or ride-on toy car to move around the home? Yes No
5. If no on #3, before hearing about this study, would you have considered having your child use one or more of the following to move around the home:
  - a. power (also known as electric) wheelchair: yes no
  - b. manual (also known as push) wheelchair: yes no
  - c. walker: yes no
  - d. ride-on toy car: yes no
6. If no to 4a: why would you not consider a power wheelchair?
7. If no to 4b: why would you not consider a manual wheelchair?

8. If no to 4c: why would you not consider a walker?
9. Why do you volunteer to participate in this study?
10. Have you, your children or other children in your extended family (example: cousins) had a ride on toy car? Yes No
  - a. If yes, list who has/had a ride on toy car:
11. How will your child respond to consistent play in his/her ride-on car?
12. How much supervision do you believe you will need to provide your child during his/her time driving the car?
13. If you were to purchase one of the following for your child, how much would you personally (not with insurance assistance) be willing to pay for it? (please provide a number)
  - a. power (also known as electric) wheelchair: \$ \_\_\_\_\_
  - b. manual (also known as push) wheelchair: \$ \_\_\_\_\_
  - c. walker: \$ \_\_\_\_\_
  - d. ride-on toy car: \$ \_\_\_\_\_

## B.2 Intervention-Parents' Perceptions of Using Ride-on Car Interview Questions

Participant's Initials: \_\_\_\_\_

Date: \_\_\_\_\_

1. Does your child move at home *without* your assistance? Yes No
  - a. If yes, explain how your child moves at home without your assistance.
2. Does your child move at home *with* your assistance? Yes No  
If yes, explain how your child moves at home with your assistance
3. Describe a situation in which your child experienced difficulty moving around at home?
4. After participating in the training period of this study, has your child used one or more of the following to move around the home:
  - a. power (also known as electric) wheelchair: yes no
  - b. manual (also known as push) wheelchair: yes no
  - c. walker: yes no
5. If no on #3, now after participating in the training period of this study, would you *consider* having your child use one or more of the following to move around the home:
  - a. power (also known as electric) wheelchair: yes no
  - b. manual (also known as push) wheelchair: yes no
  - c. walker: yes no
  - d. ride-on toy car: yes no
6. If no to 4a: why would you not consider a power wheelchair?
7. If no to 4b: why would you not consider a manual wheelchair?
8. If no to 4c: why would you not consider a walker?
9. How much supervision did you or other adult family members provide your child during his/her time driving the car?

These next questions are related to your experiences having the ride-on toy car in your home:

10. Did the ride-on car increase, decrease or not change your concerns about your child's movement issues?    Increase    Decrease    Not change

Please explain:

11. Is there a particular experience with the ride-on car that you would like to share?

12. Describe a positive experience with the ride-on car.

13. Describe a negative experience with the ride-on car.

14. Did the ride-on car impact *your child's* life?    Yes    No

Please explain:

15. Did the ride-on car impact *your* life?    Yes    No

Please explain:

16. Did the ride-on car impact your relationship with your child?    Yes    No

Please explain:

17. If you were to purchase one of the following for your child, how much would you personally (not with insurance assistance) be willing to pay for it? (please provide a number)

a. power (also known as electric) wheelchair: \$\_\_\_\_\_

b. manual (also known as push) wheelchair: \$\_\_\_\_\_

c. walker:    \$\_\_\_\_\_

d. ride-on toy car: \$\_\_\_\_\_

18. Have your expectations of your child changed since participating in the training period of this study?    Yes    No

Please explain:

### B.3 Retention-Parents' Perceptions of Using Ride-on Car Interview Questions

Participant's Initials: \_\_\_\_\_

Date: \_\_\_\_\_

1. Does your child move at home *without* your assistance? Yes No
  - a. If yes, explain how your child moves at home without your assistance.
2. Does your child move at home *with* your assistance? Yes No
  - a. If yes, explain how your child moves at home with your assistance
3. Are there situations in which your child experiences difficulty moving around at home? Yes No
  - a. If yes, explain one situation:
4. After completing the training period of this study, has your child used one or more of the following to move around the home:
  - a. power (also known as electric) wheelchair: yes no
  - b. manual (also known as push) wheelchair: yes no
  - c. walker: yes no
  - d. ride-on toy car: yes no
5. If no on #4, now after completing the training period of this study, would you *consider* having your child use one or more of the following to move around the home:
  - a. power (also known as electric) wheelchair: yes no
  - b. manual (also known as push) wheelchair: yes no
  - c. walker: yes no
  - d. ride-on toy car: yes no
6. If no to 5a: why would you not consider a power wheelchair?
7. If no to 5b: why would you not consider a manual wheelchair?
8. If no to 5c: why would you not consider a walker?

These next questions ask you to compare your experiences during the training period (with the ride-on car) to the retention period (without the ride-on car):

9. Did your concerns about your child's movement issues increase, decrease or stay the same during the time without a ride-on car, compared to when you had the ride-on car in your home?

Increase    Decrease    Not change

Please explain:

10. Did it impact *your child's* life without the ride-on car in your home anymore?

Yes    No

Please explain:

11. Did it impact *your* life without the ride-on car in your home anymore?

Yes    No

Please explain:

12. Did it impact your relationship with your child without the ride-on car in your home anymore?    Yes    No

Please explain:

13. If you were to purchase one of the following for your child, how much would you personally (not with insurance assistance) be willing to pay for it? (please provide a number)

a. power (also known as electric) wheelchair: \$\_\_\_\_\_

b. manual (also known as push) wheelchair: \$\_\_\_\_\_

c. walker:        \$\_\_\_\_\_

d. ride-on toy car: \$\_\_\_\_\_

14. Did your expectations of your child increase, decrease or stay the same during the time without a ride-on car, compared to when you had the ride-on car in your home?    Yes    No

Please explain:

15. Which would you prefer for your child (circle all that apply):

Ride-on car

Power wheelchair

Walker

Please explain your choice(s):

16. Did participating in this study help you know more about your child?

Yes no

Please explain:

17. Did participating in this study help you know more about yourself?

Yes no

Please explain:

18. Did participating in this study alter your expectations for your child? Yes no

Please explain.

## Appendix C

### Sample Weekly Activity Log

Participant's Initials \_\_\_\_\_ Week \_\_\_\_\_  
Date \_\_\_\_\_

Please choose the item(s) that apply:

1. How much time do you play with your child? (with the ride-on car)

Duration: \_\_\_\_\_ minutes

2. Where do you play with your child?

\_\_\_\_\_ Basement \_\_\_\_\_ Living Room \_\_\_\_\_ Kitchen \_\_\_\_\_ Bed Rooms

\_\_\_\_\_ Community Space : \_\_\_\_\_ (please specify where, e.g.,  
playground)

\_\_\_\_\_ Others : \_\_\_\_\_ (please specify where)

3. From 1 (the least fun) to 10 (the most fun), how fun did you/your child have?

1      2      3      4      5      6      7      8      9  
10

4. Assistance and Type of activity

How much and what type of assistance did you provide your child?

\_\_\_\_\_ Drive without your assistances

\_\_\_\_\_ Drive around the house with your assistances, assisting in:

\_\_\_\_\_ pressing the switch, the percentages of time you helped:

100%    75%    50%    25%    less than 10%    None

\_\_\_\_\_ lifting the hand off the switch, the percentages of time you helped:

100%    75%    50%    25%    less than 10%    None

\_\_\_\_\_ steering the wheel, the percentages of time you helped:

100%    75%    50%    25%    less than 10%    None

\_\_\_\_\_ others: \_\_\_\_\_ (please specify)

Specific Activity:

Drive anywhere and play:

\_\_\_\_\_ Drive any direction and touch: furniture    others \_\_\_\_\_

\_\_\_\_\_ Drive any direction and play: toy(s) \_\_\_\_\_ others \_\_\_\_\_

Drive to a specific person or place and play:

\_\_\_\_\_ Drive to you

\_\_\_\_\_ Drive to you/others and touch/get toys \_\_\_\_\_

\_\_\_\_\_ Drive to you/others and do \_\_\_\_\_

The percentages of driving to each direction was:

\_\_\_\_\_ Drive straight    100%    75%    50%    25%    less than 10%    None

\_\_\_\_\_ Drive right    100%    75%    50%    25%    less than 10%    None

\_\_\_\_\_ Drive left    100%    75%    50%    25%    less than 10%    None

5. Is there any special note (e.g., something new: first time to press the switch by himself/herself or first time to turn the wheel) you would like to take regarding your child's performance and play activity today?    Yes    No

a. If yes, what is it?

## Appendix D

### IRB Approval Form



RESEARCH OFFICE

210 Hallihen Hall  
University of Delaware  
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DATE: September 28, 2011

TO: Hsiang-han Huang, ScD  
FROM: University of Delaware IRB

STUDY TITLE: [269717-1] Ride-on Cars to Advance Mobility and Development

SUBMISSION TYPE: New Project

ACTION: APPROVED  
APPROVAL DATE: September 28, 2011  
EXPIRATION DATE: September 20, 2012  
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.