The impact of an early and intense prone positioning program in infants with and without Down syndrome

by

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List of Abbreviations

AAP American Academy of Pediatrics

Bayley-III Motor Scales

BMI Body Mass Index

CI Confidence Interval

CNS Central Nervous System

DS Down syndrome

DV Dependent Variable

FMQ Fine Motor Quotient

GMQ Gross Motor Quotient

ICF International Classification of Functioning

LMM Linear Mixed Model

MVPA Moderate to Vigorous Physical Activity

PA Physical Activity

PDMS-II Peabody Developmental Motor Scales-II

PI Ponderal Index

SES Socio-economic Status

SIDS Sudden Infant Death Syndrome

SPSS Statistical Package for Social Science

TD Typically Developing

TMQ Total Motor Quotient

TOF Tetralogy of Fallot

WHO World Health Organization

Abstract

Introduction and Purpose: Early motor development influences global development and physical activity. The likelihood of delayed motor development, decreased physical activity (PA), increased obesity and decreased participation in persons with Down syndrome (DS) is recognized, yet little is known about methods for reducing these delays. This dissertation aimed to explore the differences in motor development, body composition and PA, in infants with and without DS, as a result of 'tummy time' participation.

Methods: Thirty-two infants, 13 infants with typical development (TD), 19 with DS, participated in 90 minutes of deliberate 'tummy time' daily until they could independently transition in and out of sitting. Motor development, ponderal index (PI), and PA were assessed regularly from study entry (0 to 20 weeks of age) through age 18 months. Historical data from 34 infants, 25 TD, 9 with DS, that did not engage in formal 'tummy time' were available. Motor development, PI and PA were compared between the intervention and non-intervention groups for infants with and without DS.

Results: Families progressed to a mean of up to 100 minutes of daily 'tummy time' before their infant skilled out of the intervention. Linear mixed modeling, survival analyses and effect size computation supported benefits of 'tummy time' in infants with and without DS. 'Tummy time' positively impacted the motor development of TD infants (p = .002) and infants with DS (p = .031) and PI in TD infants (p = .030). TD infants engaging in 'tummy time' achieved unilateral reaching (p < .001), pincer grasp (p < .001), block stacking (p < .001), sitting to play with toys (p = .004), four point crawling (p < .001), standing alone (p < .001) and walking alone (p < .001)

=.001) significantly earlier than TD infants not engaging in 'tummy time.' Infants with DS engaging in 'tummy time' achieved unilateral reaching (p =.001), pincer grasp (p =.018), block stacking (p =.046), rolling supine to prone (p =.043), and sitting to play with toys (p <.001) significantly earlier than infants with DS not engaging in 'tummy time.' A large effect (d >.8) of 'tummy time' was noted for motor development and PI in infants with and without DS.

Conclusion: 'Tummy time' is foundational to development and health status and should be actively promoted by infant practitioners.

Chapter 1

Introduction

Improved participation, defined as the ability to engage in meaningful life events (WHO, 2001), is the ultimate goal of any intervention. In infants and young children, the ability to participate in play activities is crucial as play encourages interactions with the environment which are essential for overall development and learning (Ashiabi, 2007; Case-Smith, 2005; Ginsburg, 2007). Mobility is a key factor in development and in participation. The more an infant is able to move, the greater the potential for infant-environmental interactions and exploration. These interactions and explorations are critical for learning (Ashiabi, 2007; Case-Smith, 2005; Ginsburg, 2007). Additionally, movement is requisite for physical activity, and habitual physical activity level has implications for body composition. Research indicates that activity level and weight status in infancy may be predictive of activity level and weight status in childhood (Perrin et al., 2014) as well as in adult life (Franks et al., 2010; Han et al., 2010). The health benefits of an active lifestyle are widely accepted in the general population, but the ability to participate in play activities, interact with the environment and be physically active is especially important for infants with Down syndrome (DS). A gap in motor development between typically developing (TD) infants and infants with DS appears by approximately four months of age (Angulo-Barroso et al., 2008). Children with DS are less physically active and at greater risk for obesity than their same age TD peers (Whitt-Glover et al., 2006; Rimmer et al., 2010). Ultimately, persons of all ages with DS have a more difficult time than their same age

peers participating in meaningful life events (King et al., 2010; Engel-Yeger et al., 2009; Law et al., 2011; Brown & Gordon, 1987).

While research identifies the risk for delayed motor development, decreased physical activity, increased obesity and decreased participation in persons with DS, little research has been done on interventions that can effectively mitigate these risks. It is hypothesized that enhancing motor development in infants with and without DS will positively impact physical activity level and body composition. In addition, because early mobility is critical for overall development and learning; and, because activity level and weight status in infancy have implications later in life, it is paramount to begin intervening as early as possible in an effort to prevent negative outcomes. The purpose of this dissertation was to examine differences in motor development, body composition and physical activity in infants with and without Down syndrome as a result of engaging in an early and aggressive prone positioning ('tummy time') program. This was accomplished through three studies. The first study investigated the feasibility of families of infants with and without DS participating in an early and aggressive 'tummy time' program. The second study examined the impact of 'tummy time' participation in TD infants on motor development, body composition and physical activity level. The third study explored the impact of 'tummy time' on the same three outcomes in infants with DS. Study one is detailed in chapter two of this dissertation and studies two and three are presented in chapter three. Studies such as these afford insight into what interventions can not only be implemented early in life, but can also be done with sufficient frequency, intensity and duration to positively impact motor development, physical activity and body composition. This knowledge will ultimately allow interventionists to facilitate improved development, participation and health in all infants.

Down syndrome

Down syndrome (DS) results from the triplication of genes on human chromosome 21 and is the most commonly occurring chromosomal condition, with one in every 691 babies in the United States born with the disorder (NDSS, 2015). An important feature of DS that can influence skill acquisition is the aberrant structure of the central nervous system (CNS) (Pereira at al., 2013). Differences in brain structure emerge in the earliest stage of brain development in infants with DS including reduced volumes of the frontal cortex, superior temporal gyrus, brainstem, cerebellum and hippocampus (Nadel, 1999; Underwood, 2014). Synaptic dysfunction occurs early in DS, preceding the development of significant motor and cognitive symptoms (Battaglia et al., 2008). There is deficient dendritic proliferation and myelination of cortical and subcortical brain structures (Abraham et al., 2012; Battaglia et al., 2008; Pinter et al., 2001). As a result of these neurological differences, the more complex the skill, the greater the difference in age of acquisition between TD infants and infants with DS (Palisano et al., 2001; Tudella et al., 2011; Pereira et al., 2013). Figure 1.1 illustrates the difference in motor development observed during the first 18 months of life between a cohort of infants with DS and a cohort of TD infants, neither cohort receiving intervention (Hauck, 2012; Ulrich & Hauck, 2013).

Challenges within the CNS translate into learning struggles for the infant and child with DS. From a very early age, children with DS may avoid opportunities for learning new skills, make poor use of skills that are acquired, and fail to consolidate skills into their repertoires (Wishart, 1993). This means that it will take longer and considerably more practice for the infant with DS to learn a new skill, and acquired skills will not be retained if not practiced.

Additionally, it will be difficult for the infant with DS to generalize learned skills to different

settings and situations (Orelove et al., 2004). For maximum effectiveness, interventions for infants with DS should consider these inherent learning difficulties.

In spite of the implicit CNS abnormalities in infants with DS, appropriately timed, planned and executed interventions can positively impact CNS function because of synaptic plasticity (Blauw-Hospers & Hadders-Algra, 2005). Synaptic plasticity refers to the dynamic nature of synapses, the sites of communication between the neurons, in which the structure, composition, or function of the synapse changes in response to network activity (Cramer & Galdzicki, 2012). Network activity is increased in response to expanded infant-environmental and infant-object interactions (Cramer & Galdzicki, 2012). Furthermore, the CNS is highly plastic, or responsive to sensory-motor stimuli, during the first year of life (Blauw-Hospers & Hadders-Algra, 2005). This substantiates the need for early interventions that enhance infant-environment and infant-object interactions, leading to more synaptic changes, maximizing outcomes in infants with DS.

Motor Development is Critical for Overall Development

The acquisition of motor behaviors in infancy is critical because it supports infant-environmental and infant-object interactions as well as cognitive, social, physical, language and adaptive behavior development (Ashiabi, 2007; Case-Smith, 2005; Ginsburg, 2007). Because of the dynamic inter-play amongst systems, delays in early motor behaviors can negatively impact an infant's global development (Lobo et al., 2013). Behaviors such as the ability to reach, sit, interact with objects, and locomote afford environmental exploration and knowledge acquisition (Gibson, 1988). These abilities promote understanding of the interrelationships between infants' own bodies, objects and people (Campos et al., 2000; Needham et al., 2002). Once they can reach, infants learn to share their attention between people and objects and to involve objects in

their social interactions (Fogel et al., 1999). The ability to sit impacts cognition by providing infants with an improved ability to process visual information (Harbourne & Stergiou, 2009; Lefevre, 2002). The coordination of improved gaze stabilization and manual skills during sitting further increases the opportunities for object interaction and learning (Rochat & Goubet, 1995). Sitting is associated with a larger number of utterances per breath, a decrease in simple vowel production, and a greater variability of consonant-vowel utterances which all serve to enhance expressive language development (Yingling, 1981). As infants gain experience through four point crawling, they use more gestures to communicate, and they initiate more interactions with others thus advancing their social skills (Campos et al., 2000; Whitney & Green, 2011). Walking infants use even more gestures and vocalizations than crawling infants (Clearfield, 2011). Infants with superior locomotor skills are more successful at spatial problem solving and memory tasks (Berger, 2010; Clearfield, 2004). For these reasons, delays in motor skill development are troublesome as they may lead to delays in the development of other systems. Alternately, interventions that attenuate delays in motor development could improve outcomes for infants with and without DS.

'Tummy Time'

Prone positioning or 'tummy time' is the deliberate placement of an infant on his or her belly for tolerable amounts of time for play during the day when the baby is awake. 'Tummy time' is crucial during infancy. Not only does 'tummy time' help develop the necessary strength in an infant's trunk needed for control in sitting and standing, it also provides a view point that promotes object and environmental exploration stimulating a baby's desire to move.

The practice of 'tummy time' became less prevalent starting in 1992 when the American Academy of Pediatrics (AAP) urged parents to put infants to sleep on their backs to decrease the

incidence of Sudden Infant Death Syndrome (SIDS). The incidence of SIDS has dramatically decreased as a result of the back to sleep program (Moon, 2011). However, the change in sleep positioning has influenced awake positioning practices as infants come to prefer the supine position when awake and because parents avoid the prone position as a routine (Monson et al., 2003). The AAP (2011) recommends that babies "spend some time on their tummies each day for developmental reasons" as supervised play time on the tummy is not a risk for SIDS. Yet, infants who sleep on their backs are less likely to be placed on their tummies during awake hours (Monson et al., 2003; Mildred et al., 1995). Lack of exposure to 'tummy time' limits an infant's opportunities to learn and practice motor skills requiring antigravity extension (Majnemer & Barr, 2006). To acquire skills in the sitting and standing positions, infants must first experiment in the prone position with skills that demand progressively more active muscle control (Tudella et al., 2011; Pereira et al., 2012). Motor control against the force of gravity is requisite for timely attainment of early motor milestones.

Evidence supports the relationship between 'tummy time' and early motor skill acquisition in TD infants. Infants who spend very little time in prone demonstrate a decrease in the ability to hold their heads up to 45 degrees and to sit (supported) with their head steady at two months of age (Salls et al., 2002). Infants who spend more awake time on their tummies achieve motor milestones (e.g. rolling supine to prone, prop sitting, belly-crawling) earlier (Kuo et al., 2008; Majnemer & Barr, 2006; Davis et al., 1998). Whereas minimal research exists to substantiate the precise amount of 'tummy time' infants should engage in, one study postulated that 81 minutes of deliberate daily 'tummy time' was necessary to achieve early motor milestones without delay (Dudek-Schriber & Zelazny, 2007). Given this finding, the indication is that many TD infants are not engaging in sufficient 'tummy time' to achieve timely motor development (Kuo et al.,

2008; Majnemer & Barr, 2006; Dudek-Schriber & Zelazny, 2007; Davis et al., 1998) which in turn places their overall development at risk.

While the benefits of 'tummy time' in TD infants are apparent, the impact of deliberate, daily 'tummy time' in infants with DS has not been studied. The overall trend of less wakeful time in prone, coupled with a diagnosis of DS, seemingly makes these infants highly susceptible to escalating motor delays. As previously mentioned, a gap in motor development between TD infants and infants with DS appears by about four months of age and widens as the complexity of motor demands increases (Tudella et al., 2011). Figure 1.1 illustrates this disparity in motor development between infants with TD and infants with DS (Hauck, 2012; Ulrich & Hauck, 2013). Beyond promoting anti-gravity strength of the trunk and providing a vantage point that promotes environmental exploration, early 'tummy time' done on the chest of a parent invokes the sense of touch, encouraging bonding and a sense of well-being that helps set the stage for a positive developmental course (Stack, 2008). This is another benefit of 'tummy time' for parents with infants with DS that might be unsure of how to interact with their young infant. 'Tummy time' is an important motor intervention for infants with DS because it can be started early, addressing a skill that is primary to overall development.

Parent Implemented Interventions

The premise of 'tummy time' is that parents and caregivers of infants with and without DS can easily participate, increasing the potential for intervention success. Interventions that support early learning experiences in children's homes with their usual caregivers have been shown to yield significant improvements in developmental skills for children with a range of abilities, environmental risk factors and diagnoses (M'Lisa and Rush, 2001). A systematic review of the early intervention literature found that interventions that focus on advancing motor

development and enhancing caregiver-child interactions positively impact overall development (Blauw-Hospers & Hadders-Algra, 2005). These findings support the relevance of parent involvement in interventions aimed at improving infant development.

Parents and caregivers are those best suited to provide sufficient frequency, intensity and duration of practice in their infant's natural environment for optimal learning of desired motor skills. Weekly interactions with an interventionist for an hour will not meet the repetition requirement for motor skill acquisition in infants (Adolph, 2012), especially infants with DS. Given the need for high amounts of practice and specificity for learning to occur in infants with DS, parent administered interventions are a vital component in the effort to minimize motor delays. The role of the interventionist, therefore, is to maximize natural learning environments and empower caregivers as the primary teacher for their infant as early in life as possible to insure the best possible developmental outcomes (Kuhn & Marvin, 2015). 'Tummy time' is a motor intervention that can be started immediately in life by parents and caregivers, potentially improving developmental outcomes in infants with and without DS.

The Risk for Obesity and the Adoption of Sedentary Behaviors Begins in Infancy

Lack of 'tummy time' in early infancy may have further health implications. Obesity and physical inactivity among children and adolescents in society have been increasing at a dangerous rate (De Onis et al., 2010). Still unknown are the underlying mechanisms that are causal predictors of obesity and inactivity (Stodden et al., 2008). In a large, multi-site sample of geographically, racially and ethnically diverse, low income parents caring for two month old infants, insufficient 'tummy time' was associated with "obesogenic" behaviors in early infancy contributing to a higher risk of obesity related disease later in life (Perrin et al., 2014). Sixty-six percent of the 863 parents studied did not accumulate 30 minutes per day of deliberate 'tummy

time' with their infant. Because many overweight children will become obese adults (Franks et al., 2010; Han et al., 2010), prevention is paramount. Once obesity develops it is more difficult to treat (Zwiauer, 2000). Rates of delayed motor skill development were found to be significantly higher in overweight infants (Shibli et al., 2008; Slining et al., 2010), suggesting a reciprocal relationship between these variables. To control the rising incidence of childhood obesity, interventions designed to prevent obesity from emerging must be developed (Ulrich & Hauck, 2013).

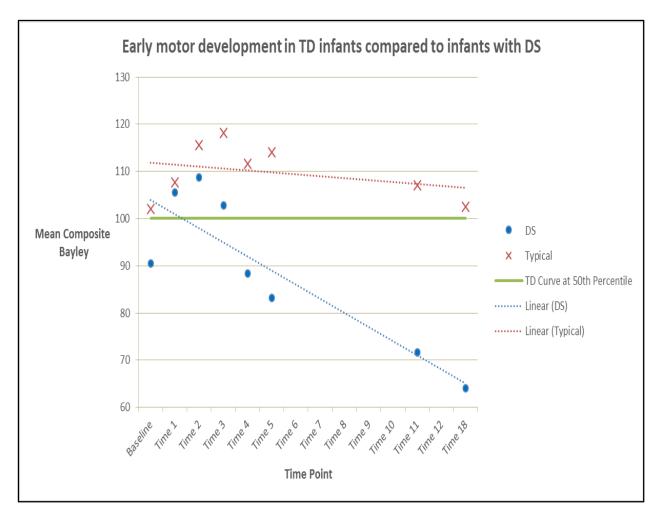
Learning to move is a necessary skill underlying physical activity. Children that cannot proficiently run, jump, catch, and throw will not have the prerequisite skills to be physically active (Wrotniak et al., 2006; Stodden et al., 2008). Motor proficiency has been found to be positively associated with physical activity and negatively associated with the percentage of time in sedentary activity in children (Wrotniak et al., 2006). Accordingly, infant interventions such as 'tummy time' that precipitate motor development are important for promoting physical activity earlier in life which may serve to mitigate the incidence of obesity in early childhood.

Summary

This dissertation aimed to explore the differences in several important participation and health related outcomes, specifically motor development, body composition and physical activity, in infants with and without Down syndrome as a result of engaging in a rigorous 'tummy time' program. Although the AAP states that "supervised, awake tummy time is recommended daily to facilitate development and minimize the occurrence of positional plagiocephaly (flat heads) (AAP, 2011)," parents are still not engaging in sufficient daily 'tummy time' for optimal development and adaptation of healthy activity levels in infancy (Kuo et al., 2008; Majnemer & Barr, 2006; Davis et al., 1998). Perhaps the AAP recommendations are

not emphasized or specific enough for families to commit to sufficient, deliberate daily 'tummy time,' especially when infants seem to prefer being positioned on their backs. The literature supports the relationship between 'tummy time' and motor development in TD infants (Kuo et al., 2008; Majnemer & Barr, 2006; Davis et al., 1998; Salls et al., 2002; Dudek-Schriber & Zelazny, 2007), but not in infants with DS. Early motor development is essential as it influences the development of the other systems and is necessary for early physical activity levels. A reciprocal relationship between motor skill acquisition and obesity has been established. Childhood obesity prevalence is dangerously high (De Onis et al., 2010), necessitating a paradigm shift from remediation to prevention. Since the possibility of obesity is established in infancy, prevention programs must also begin in infancy. The likelihood of delayed motor development, decreased physical activity, increased obesity and decreased participation in persons with DS is recognized, yet little is known about what interventionists can do to effectively reduce these odds. This study sought to provide the evidence needed to support the feasibility of families engaging in an early and aggressive 'tummy time' program, as well as to document differences in motor development, body composition and physical activity levels as a result of this deliberate, daily engagement in infants with and without Down syndrome. This evidence will serve to guide parents, educators and the medical community as to how to best intervene in infancy for optimal developmental, health and quality of life outcomes.

Figure 1.1 Early Motor Development in TD Infants Compared to Infants with DS (Hauck, 2012; Ulrich & Hauck, 2013)



Reference List

American Academy of Pediatrics (2011). Sleep Guidelines. Retrieved from http://www.aap.org/en-us/about-the-aap/aap-press-room/pages/aap-expands-guidelines-for-infant-sleep-safety-and-sids-risk-reduction.aspx#sthash.YpP2ETzw.dpuf.

Ábrahám, H., Vincze, A., Veszprémi, B., Kravják, A., Gömöri, É., Kovács, G. G., & Seress, L. (2012). Impaired myelination of the human hippocampal formation in Down syndrome. *International Journal of Developmental Neuroscience*, 30(2), 147-158.

Adolph, K. E., Cole, W. G., Komati, M., Garciaguirre, J. S., Badaly, D., Lingeman, J. M., . . . Sotsky, R. B. (2012). How do you learn to walk? Thousands of steps and dozens of falls per day. *Psychological Science*, 23(11), 1387-1394.

Angulo-Barroso, R., Burghardt, A. R., Lloyd, M. and Ulrich, D. (2008). Physical activity in infants with Down syndrome receiving a treadmill intervention. *Infant Behavior and Development*, 31, 255-269.

Ashiabi, G. S. (2007). Play in the preschool classroom: Its socioemotional significance and the teacher's role in play. *Early Childhood Education Journal*, 35(2), 199-207.

Battaglia, F., Quartarone, A., Rizzo, V., Ghilardi, M. F., Di Rocco, A., Tortorella, G., & Girlanda, P. (2008). Early impairment of synaptic plasticity in patients with Down's syndrome. *Neurobiology of Aging*, 29(8), 1272-1275.

Berger, S. E. (2010). Locomotor expertise predicts infants' perseverative errors. *Developmental Psychology*, 46(2), 326.

Blauw-Hospers, C. H., & Hadders-Algra, M. (2005). A systematic review of the effects of early intervention on motor development. *Developmental Medicine & Child Neurology*, 47(06), 421-432.

Brown, M., & Gordon, W. (1987). Impact of impairment on activity patterns of children. *Archives of Physical Medicine and Rehabilitation*, 68(12), 828-832.

Campos, J. J., Anderson, D. I., Barbu-Roth, M. A., Hubbard, E. M., Hertenstein, M. J., & Witherington, D. (2000). Travel broadens the mind. *Infancy*, 1(2), 149-219.

Case-Smith, J. Occupational therapy for children. 5th ed. St. Louis: Elsevier Mosby; 2005.

Clearfield, M. W. (2004). The role of crawling and walking experience in infant spatial memory. *Journal of Experimental Child Psychology*, 89(3), 214-241.

Clearfield, M. W. (2011). Learning to walk changes infants' social interactions. *Infant Behavior and Development*, 34(1), 15-25.

Cramer, N., & Galdzicki, Z. (2012). From abnormal hippocampal synaptic plasticity in Down syndrome mouse models to cognitive disability in Down syndrome. *Neural Plasticity*, 2012.

Davis, B. E., Moon, R. Y., Sachs, H. C., & Ottolini, M. C. (1998). Effects of sleep position on infant motor development. *Pediatrics*, 102(5), 1135-1140.

De Onis, M., Blössner, M., & Borghi, E. (2010). Global prevalence and trends of overweight and obesity among preschool children. *The American Journal of Clinical Nutrition*, 92(5), 1257-1264.

Down syndrome Facts. (n.d.). Retrieved from http://www.ndss.org/Down-Syndrome/Down-Syndrome-Facts/.

Dudek-Shriber, L., & Zelazny, S. (2007). The effects of prone positioning on the quality and acquisition of developmental milestones in four-month-old infants. *Pediatric Physical Therapy*, 19(1), 48-55.

Engel-Yeger, B., Jarus, T., Anaby, D., & Law, M. (2009). Differences in patterns of participation between youths with cerebral palsy and typically developing peers. *American Journal of Occupational Therapy*, 63(1), 96-104.

Fogel, A., Messinger, D. S., Dickson, K. L., & Hsu, H. C. (1999). Posture and gaze in early mother—infant communication: Synchronization of developmental trajectories. *Developmental Science*, 2(3), 325-332.

Franks, P. W., Hanson, R. L., Knowler, W. C., Sievers, M. L., Bennett, P. H., & Looker, H. C. (2010). Childhood obesity, other cardiovascular risk factors, and premature death. *New England Journal of Medicine*, 362(6), 485-493.

Gibson, E. J. (1988). Exploratory behavior in the development of perceiving, acting, and the acquiring of knowledge. *Annual Review of Psychology*, 39(1), 1-42.

Ginsburg, K. R. (2007). The importance of play in promoting healthy child development and maintaining strong parent-child bonds. *Pediatrics*, 119(1), 182-191.

Han, J. C., Lawlor, D. A., & Kimm, S. Y. (2010). Childhood obesity. *The Lancet*, 375(9727), 1737-1748.

Harbourne, R. T., & Stergiou, N. (2009). Movement variability and the use of nonlinear tools: principles to guide physical therapist practice. *Physical Therapy*, 89(3), 267-282.

Hauck, J. L. (2012). Developmental trajectory of physical activity and its relationship to rate of gain in weight, subcutaneous fat, and motor skill development during the first six months of life (Doctoral dissertation, The University of Michigan).

- King, G., Law, M., Hurley, P., Petrenchik, T., & Schwellnus, H. (2010). A developmental comparison of the out-of-school recreation and leisure activity participation of boys and girls with and without physical disabilities. *International Journal of Disability, Development and Education*, 57(1), 77-107.
- Kuo, Y. L., Liao, H. F., Chen, P. C., Hsieh, W. S., & Hwang, A. W. (2008). The influence of wakeful prone positioning on motor development during the early life. *Journal of Developmental & Behavioral Pediatrics*, 29(5), 367-376.
- Kuhn, M., & Marvin, C. A. (2015). "Dosage" Decisions for Early Intervention Services. *Young Exceptional Children*, 1096250615576807.
- Law, M., Anaby, D., DeMatteo, C., & Hanna, S. (2011). Participation patterns of children with acquired brain injury. *Brain Injury*, 25(6), 587-595.
- Lefèvre, C. (2002). Posture, muscular tone and visual attention in 5 month-old infants. *Infant and Child Development*, 11(4), 335-346.
- Lobo, M. A., Harbourne, R. T., Dusing, S. C., & McCoy, S. W. (2013). Grounding early intervention: physical therapy cannot just be about motor skills anymore. *Physical Therapy*, 93(1), 94-103.
- Majnemer, A., & Barr, R. G. (2006). Association between sleep position and early motor development. *The Journal of Pediatrics*, 149(5), 623-629. e621.
- Mildred, J., Beard, K., Dallwitz, A., & Unwin, J. (1995). Play position is influenced by knowledge of SIDS sleep position recommendations. *Journal of Paediatrics and Child Health*, 31(6), 499-502.
- M'Lisa, L. S., & Rush, D. D. (2001). The Ten Myths about Providing Early Intervention Services in Natural Environments. *Infants & Young Children*, 14(1), 1-13.
- Monson, R. M., Deitz, J., & Kartin, D. (2003). The relationship between awake positioning and motor performance among infants who slept supine. *Pediatric Physical Therapy*, 15(4), 196-203.
- Moon, R. Y. (2011). SIDS and other sleep-related infant deaths: expansion of recommendations for a safe infant sleeping environment. *Pediatrics*, 128(5), e1341-e1367.
- Nadel, L. (1999). Down syndrome in cognitive neuroscience perspective. *Neurodevelopmental Disorders*, 197-221.
- Needham, A., Barrett, T., & Peterman, K. (2002). A pick-me-up for infants' exploratory skills: Early simulated experiences reaching for objects using 'sticky mittens' enhances young infants' object exploration skills. *Infant Behavior and Development*, 25(3), 279-295.

- Orelove, F. P., Sobsey, D., & Silberman, R. K. (2004). Educating children with multiple disabilities: A collaborative approach. Baltimore, MD: Brookes Publishing Company.
- Palisano, R. J., Walter, S. D., Russell, D. J., Rosenbaum, P. L., Gémus, M., Galuppi, B. E., & Cunningham, L. (2001). Gross motor function of children with Down syndrome: creation of motor growth curves. *Archives of Physical Medicine and Rehabilitation*, 82(4), 494-500.
- Pereira, K., Basso, R. P., Lindquist, A. R. R., da Silva, L. G. P., & Tudella, E. (2013). Infants with Down syndrome: percentage and age for acquisition of gross motor skills. *Research in Developmental Disabilities*, 34(3), 894-901.
- Perrin, E. M., Rothman, R. L., Sanders, L. M., Skinner, A. C., Eden, S. K., Shintani, A., ... & Yin, H. S. (2014). Racial and ethnic differences associated with feeding-and activity-related behaviors in infants. *Pediatrics*, 133(4), e857-e867.
- Pinter, J. D., Eliez, S., Schmitt, J. E., Capone, G. T., & Reiss, A. L. (2001). Neuroanatomy of Down's syndrome: a high-resolution MRI study. *Neuroanatomy*, 158(10).
- Rimmer, J. H., Yamaki, K., Lowry, B. M., Wang, E., & Vogel, L. C. (2010). Obesity and obesity-related secondary conditions in adolescents with intellectual/developmental disabilities. *Journal of Intellectual Disability Research*, 54(9), 787-794.
- Rochat, P., & Goubet, N. (1995). Development of sitting and reaching in 5-to 6-month-old infants. *Infant Behavior and Development*, 18(1), 53-68.
- Salls, J. S., Silverman, L. N., & Gatty, C. M. (2002). The relationship of infant sleep and play positioning to motor milestone achievement. *American Journal of Occupational Therapy*, 56(5), 577-580.
- Shibli, R., Rubin, L., Akons, H., & Shaoul, R. (2008). Morbidity of overweight (≥ 85th percentile) in the first 2 years of life. *Pediatrics*, 122(2), 267-272.
- Slining, M., Adair, L. S., Goldman, B. D., Borja, J. B., & Bentley, M. (2010). Infant overweight is associated with delayed motor development. *The Journal of Pediatrics*, 157(1), 20-25.
- Stack, D. M. (2008). Chapter Thirteen The Salience of Touch and Physical Contact During Infancy: Unraveling Some of the Mysteries of the Somesthetic Sense. *Blackwell Handbook of Infant Development*, 351.
- Stodden, D. F., Goodway, J. D., Langendorfer, S. J., Roberton, M. A., Rudisill, M. E., Garcia, C., & Garcia, L. E. (2008). A developmental perspective on the role of motor skill competence in physical activity: An emergent relationship. *Quest*, 60(2), 290-306.
- Tudella, E., Pereira, K., Pedrolongo Basso, R., & Savelsbergh, G. J. (2011). Description of the motor development of 3 12 month old infants with Down syndrome: The influence of the postural body position. *Research in Developmental Disabilities*, 32, 1514-1520.

Ulrich, D. A., & Hauck, J. L. (2013, June). Developmental trajectory of physical activity, weight, skinfolds, and motor development in 1-6 month old infants with Down syndrome. In *Journal of Sport & Exercise Psychology (Vol. 35, pp. S73-S73)*. Champaign, IL: Human Kinetics Publishing Inc.

Underwood, E. (2014). Can Down syndrome be treated? Science, 343(6174), 964-96.

Whitney, P. G., & Green, J. A. (2011). Changes in infants' affect related to the onset of independent locomotion. *Infant Behavior and Development*, 34(3), 459-466.

Whitt-Glover, M. C., O'Neill, K. L., & Stettler, N. (2006). Physical activity patterns in children with and without Down syndrome. *Pediatric Rehabilitation*, 9(2), 158-164.

Wishart, J. G. (1993). The development of learning difficulties in children with Down's syndrome. *Journal of Intellectual Disability Research*, 37(4), 389-403.

Wrotniak, B. H., Epstein, L. H., Dorn, J. M., Jones, K. E., & Kondilis, V. A. (2006). The relationship between motor proficiency and physical activity in children. *Pediatrics*, 118(6), e1758-e1765.

World Health Organization. (2001). *International classification of functioning, disability and health: ICF*. World Health Organization.

Yingling, J. M. (1981). Temporal features of infant speech: A description of babbling patterns circumscribed by postural achievement.

Zwiauer, K. F. (2000). Prevention and treatment of overweight and obesity in children and adolescents. *European Journal of Pediatrics*, 159(1), S56-S68.

Chapter 2

The Feasibility of Families with Infants with and without Down syndrome Participating in 90 minutes of Deliberate, Daily 'Tummy Time'

Introduction

Research has shown that insufficient 'tummy time' negatively impacts motor development in TD infants (Kuo et al., 2008; Majnemer & Barr, 2006; Davis et al., 1998; Salls et al., 2002; Dudek-Schriber & Zelazny, 2007), but minimal attention has been devoted to determining how much daily 'tummy time' parents should strive to achieve. One study of four month old infants found that 81 minutes of 'tummy time' per day is necessary to achieve specific motor milestones on time (Dudek-Shriber & Zelazny, 2007). Another study reported that while most babies had prone experience by three to four months of age, only 5% of these babies were on their tummies for more than 60 minutes per day. Forty-two percent of the babies in this study reported doing 20 minutes or less of daily 'tummy time' (Kuo et al., 2008). Notably, for milestones such as rolling supine to prone, belly-crawling and 4-point crawling, babies that did more 'tummy time' achieved these skills significantly earlier (Kuo et al., 2008). There is little published research on the daily dose of 'tummy time' TD infants should engage and no research could be found on how much 'tummy time' infants with DS should do. Based on the paucity of available evidence, the families participating in this study were asked to accumulate 90 minutes of deliberate 'tummy time' with their infants, with and without DS, over the course of each day, until the time at which the infant could independently transition in and out of the sitting position.

Evidence supports the use of parent driven interventions in maximizing outcomes for children with and at risk for developmental delays. In spite of the evidence associating parent participation with positive intervention effects, some families participate to a higher degree than others (Ramey et al., 1992). Encouraging optimal parent participation in intervention is an ongoing challenge as the precise determinants of individual differences in family participation are not well established (Ramey et al., 1992). Appreciating these familial differences is necessary to improve intervention adherence. A qualitative approach to determining feasibility of 'tummy time' participation was utilized to better understand each family's unique 'tummy time' experience.

The purpose of this study was to examine the feasibility, in families with TD infants and in families with infants with DS, of accumulating 90 minutes of deliberate 'tummy time' daily from study entry until the time at which the infant could independently transition in and out of the sitting position. The study was the first part of a broader longitudinal intervention study investigating outcomes related to participation and health resulting from the 'tummy time' intervention. The hypothesis was that families with TD infants and families with infants with DS would be able to implement the 'tummy time' intervention as recommended. Additionally, study one hoped to gain a better understanding of factors that facilitate or act as barriers to parent participation in intervention programs such as 'tummy time' so that future programs might demonstrate improved adherence.

Methods

All methods and procedures were approved by the Medical School Institutional Review Board (IRBMED) of the University of Michigan, and all parents signed written informed consent prior to beginning the study.

Participants

Nineteen infants with DS and 13 TD infants between 0 and 20 weeks of age were recruited to participate in the study from southeast Michigan (Ann Arbor, Milan, Grosse Pointe Woods), Grand Rapids, Lansing, multiple cities in Ohio (Toledo, Cleveland, Cincinnati), Nashville, the metro Atlanta area and the New York City-Philadelphia metropolitan areas. Recruitment exceeded the goal of 12 infants per intervention group which was based on prior recruitment results in similar infant studies done at the University of Michigan. Participants were recruited from local support groups and agencies working with families with DS, from word of mouth of families that had participated in previous studies at the University of Michigan, from pediatricians and pediatric physician specialists working closely with persons with DS, and from connections with families with TD babies or babies with DS. Exclusion criteria were infants that were placed in the prone position for sleeping or infants that had or developed serious medical conditions such as infantile spasms, extensive cardiac complications or leukemia. Infants who attended daycare, that otherwise met the inclusion/exclusion criteria, were eligible to participate in the study if their daycare staff was willing to monitor prone time during the time spent at the daycare center or if the family was committed to performing the 'tummy time' at home daily, outside of hours spent in daycare. One additional infant with DS was recruited but had to drop out of the study after developing infantile spasms by time 3 (i.e. three months after study entry); this child's data were not included in the analyses. Another infant with DS dropped out after time 7 (i.e. seven months after study entry) because mom became overwhelmed with the additional demands of study participation on their daily schedule. Because more than half of the data points were collected, this participant's data were included in the analyses. Finally, one infant with DS had a more serious heart complication, Tetralogy of Fallot (TOF), requiring open

heart surgery in the first half of her 'tummy time' program. She missed only one data collection, time point 3, recovering from surgery. Since she was willing and able to participate as recommended in the 'tummy time' program in spite of her heart condition and surgery, her data were included in the analyses.

Demographic information was collected on all infants participating in the 'tummy time' intervention including gender, age in days at baseline, location (where the family lived), daycare outside of the home attendance, number of siblings, number of pre/peri/post natal complications, maternal education, annual family income and physical therapy received outside of this study. Age in days was calculated by multiplying the infant's age in months by thirty and adding any remaining days. A corrected age was used for infants born at or before 37 weeks gestation, calculated by subtracting the number of weeks/days the infant was premature from the calculated age in days. Premature infants in the study were between three and six weeks premature. An age at study entry of 0.00 (zero) reflected an infant who started the study on or before the time he or she should have been born. Pre/peri/post natal complications included prematurity (<= 37 weeks gestation), a stay in the neonatal intensive care unit (NICU), cardiac defects requiring surgical correction in the first year of life, Hirschsprung's disease and bilateral club feet. See Table 2.1 for details on the demographics of the 'tummy time' participants.

Procedures

'Tummy time' instruction and logging

The 'tummy time' intervention took place in the participant's home or daycare. The initial baseline visit occurred when the infant was between the ages of zero and 20 weeks (corrected age) with the parent or a primary caregiver in attendance. The family and/or primary caregiver was instructed to engage in a supervised, prone positioning

program with the goal of accumulating 90 minutes each day. Written guidelines and strategies to improve success and adherence were provided, but families could ultimately chose any activity that worked for their infant to comprise their 90 minutes. See Figure 2.1 for a sample of 'tummy time' activities that were provided to families.

Following the baseline visit, infants were visited in their home or daycare monthly for 12 months, with an optional follow up visit requested at 18 months of age. Besides 'tummy time' instruction, these visits also included assessments of motor development and body composition as well as the provision of equipment to measure physical activity. Participating families were provided written feedback after each monthly visit that included mean daily 'tummy time' minutes as well as information on motor, body composition and physical activity progress. More detail on home visits and parent feedback forms will be provided in Chapter 3.

A log (see appendix 2.1) was provided to record daily 'tummy time' and was turned in on each subsequent visit until the time at which the infant could independently transition in and out of the sitting position. Once an infant could transition in and out sitting, he or she could effectively put him or herself in 'tummy time,' so imposed prone positioning was obsolete. At this point, families were no longer required to engage in or to log deliberate 'tummy time,' but monthly monitoring of progress continued. Families were encouraged to be truthful about 'tummy time' minutes performed when logging.

The explanation provided was that part of the purpose of the study was to discern if 90 minutes a day was a reasonable expectation for families, so honesty in recording was essential. Families understood that while there was evidence to support the recommended 90 minutes as being ideal for their baby, they would not be penalized in

any way or excluded from further study participation if they failed to meet the recommendations. Two families chose not to utilize the log provided for recording of daily 'tummy time' minutes. Any method of record keeping that worked for the family was acceptable. Mean daily 'tummy time' minutes were computed for every month in which each participant was actively engaged in the intervention. Using this data, an aggregate mean number of 'tummy time' minutes could be computed monthly for each intervention cohort.

Feasibility Questionnaire

After at least six months in the program, parent reaction to the prescribed 90 minutes of 'tummy time' per day with the program was assessed by questionnaire in order to ascertain the feasibility of being able to complete the recommended 'tummy time' protocol. Families in both the TD and DS cohorts were asked to share their experience in writing. Response rate was high with 18/19 (94.7%) of the families with infants with DS and 12/13 (92.3%) of the families with TD infants returning completed questionnaires.

The questions posed to each participating family were:

- 1. What was/were your primary reason(s) for wanting to participate in the 'Tummy Time' intervention study?
- 2. What is/are the most positive aspect(s) of participating in the 'Tummy Time' intervention thus far?
- 3. What is/are the most negative aspect(s) of participating in the 'Tummy Time' intervention thus far?

4. Please indicate how committed you are at this time to completing 90 minutes per day of deliberate, wakeful 'Tummy Time.' Circle one.

Very committed Committed Somewhat committed Not committed

- 5. Please list any factors that help you achieve the recommendation of 90 minutes per day deliberate, wakeful 'Tummy Time.'
- 6. Please list any barriers that work to prevent you from achieving the recommendation of 90 minutes per day deliberate, wakeful 'Tummy Time.'
- 7. Would you recommend participation in this study to other infants with Down syndrome? Why or why not?

Qualitative Analysis

Qualitative analysis was utilized in an attempt to understand the families' experience of participating in the 'tummy time' intervention. Completed questionnaires were systematically analyzed using the constant comparative method (Glauser & Strauss, 2009), an analytic approach in which the researcher reads each document, carefully noting possible themes, and compares the themes with those already identified in prior documents. As each document is read, the researcher considers whether it contained already identified themes, or if a new theme has emerged. The researcher typically begins by generating a large number of themes, but ultimately some are discarded as infrequent or less coherent and others are merged if they are determined to overlap significantly. Completed questionnaires were reviewed by four research assistants that were upper level undergraduate or graduate students at the University of Michigan, in the School of Kinesiology. Each research assistant independently read all completed questionnaires with the goal of identifying common themes among respondents. Themes were categorized by group, TD or DS, and for participants collectively. Once individual themes were identified, each research assistant then read the themes identified by all research assistants and further

summarized results into common themes identified by all readers. In this process, highly concordant themes across researchers were identified. The objective of this process was to develop a structural explanation of the findings regarding feasibility of 'tummy time' as described from the participants' point of view. This information is relevant because it aides in the understanding of facilitators and barriers to participating in parent driven interventions, such as the 'tummy time,' so that future interventions might demonstrate improved parent participation.

Results

Neither intervention cohort was able to achieve the recommended 90 minutes per day of deliberate 'tummy time' in the first months after study entry. The TD cohort achieved a mean of 54.74 minutes per day and the cohort with DS achieved a mean of 54.01 minutes per day in the first month after study entry. All participating families increased their mean 'tummy time' minutes each month following study entry, but the families with infants with DS increased their 'tummy time' minutes more rapidly and peaked at a higher mean number of minutes. The cohort with DS achieved the recommended 90 minutes per day by month seven, reached a maximum of 100.05 minutes at month eight and remained at or above 90 minutes through time 10. The TD cohort never reached the recommended 90 minutes per day, hitting a ceiling of 73 minutes at time point six and dropping off rapidly after that because the majority of participants were transitioning independently in and out of sitting by this time. See Figure 2.2 'Tummy Time' for a graphic representation of the amount of 'tummy time' minutes achieved by each cohort.

Several important themes emerged from the questionnaires completed by participating families. Families with infants with DS chose to get involved in the study because they wanted to improve the quality of life for their child and to gain knowledge about DS. The families with

TD infants participated in 'tummy time' because they believed they were helping to further developmental science and because they wanted to track their child's development. The most positive aspect of 'tummy time' for families with infants with DS was seeing developmental progress better than what they expected for their child given his or her diagnosis. Similarly, for families with TD infants, the best part of 'tummy time' was seeing their child progress more quickly than older siblings or friends and getting regular updates on their baby's development. For the families in both cohorts, the hardest part of the study was completing the recommended 90 minutes per day given an already busy schedule. In spite of the challenge of accumulating 90 minutes per day, 67% of the families with infants with DS described themselves as "very committed" to the program. Families with TD infants were less enthusiastic, with only 22% describing themselves as "very committed" and 44% characterizing themselves as "committed." Both cohorts agreed that being a stay at home parent as well as support from the entire family made it easier to achieve the recommended amount of 'tummy time' each day. Decreased tolerance for prone positioning, especially when the infant was young, as well as a busy schedule and the demands of siblings were barriers to adherence of 'tummy time' recommendations reported by both intervention cohorts. Families with TD infants also reported gastroesophageal reflux as an additional barrier to 'tummy time.' Finally, 100% of participating families in both cohorts said they would recommend participating in 'tummy time' to other families with an infant with DS as they felt participation held them accountable to a program that positively impacted their child's development.

Specific examples of family reflections on the 'tummy time' experience supporting the above themes are provided below.

Primary reason for wanting to participate:

"When our son was diagnosed with Down syndrome at his birth, we knew we would do absolutely anything we could to help improve his quality of life. The purpose of the study and the goal of the research was made very clear- to get our son more mobile at an earlier age. The parameters of the study were in the best interest of our son and there was no danger to his health, so we decided to do it. It was another opportunity for our baby to receive physical therapy. All visits were at home. There was never any inconvenience." (Mother of participant 100, with DS)

"To make sure I was doing everything I could to promote positive overall development and in particular motor development." (Mother of participant 301, TD)

Most positive aspect(s) of participating:

"The positive aspect of this study is seeing the growth of my baby. Knowing where she's at and where she needs to be." (Mother of participant 305, TD)

"Seeing the progress in my baby that I believe is directly related to her concentrated tummy/floor time." (Mother of participant 108, with DS)

Most negative aspect(s) of participating:

"It is hard to get daycare to log." (Mother of participant 112, with DS)

"Recording "tummy time" was tedious. 90 minutes was an intimidating goal." (Mother of participant 303, TD)

Facilitators to 'tummy time' adherence:

"I am a stay at home mom so I can devote the time and full attention towards tummy time and striving to hit the 90 minutes each day." (Mother of participant 310, TD)

"We have an excellent nanny who works with our son all day. She pushes for as much tummy time as possible. My husband and I work with him from the time we get home until the time he goes to bed." (Mother of participant 111, with DS)

Barriers to 'tummy time' adherence:

"Convenience. We are a very active family and it is hard to get ...on his tummy when we are out. Plus he is so sweet and cuddly, I want to spend my time holding him whenever I can." (Mother of participant 103, with DS)

"Keeping up with three older siblings meant he spent a lot of time in a car seat or stroller. Then he would be sleeping or eating for most of the rest of the day, especially when he was younger." (Mother of participant 307, TD)

Would you recommend 'tummy time?'

"I would recommend participation because I think the intervention helped my son to be more on track developmentally and I appreciate the resources provided to me by the researcher." (Mother of participant 107, with DS)

"Without hesitation. It is hard work but I believe this would drastically help the child's development and help them meet their milestones earlier. Plus it isn't a complex home exercise program. Very, very simple!" (Mother of participant 302, TD)

Discussion

Participation in 'tummy time' proved to be a valuable experience for families with and without DS, one that they would all recommend other families get involved in. The consensus among participating families was that 'tummy time' did hasten their baby's motor development, making it worth the effort to implement. As anticipated, adherence to the recommended 90 minutes per day of deliberate 'tummy time' varied, with some families readily achieving 90 or more minutes of 'tummy time' daily and some struggling to do 20 minutes. The qualitative approach was successful in providing insight into factors that both positively and negatively impacted program adherence, factors that may be extrapolated to improve adherence in future parent driven interventions.

Ninety minutes per day of deliberate 'tummy time' was a formidable goal for families with and without DS. Both cohorts started off equally motivated, with an identical mean number of 'tummy time' minutes (54) achieved in the first month of participation (see Figure 2.2). Both cohorts increased their daily 'tummy time' minutes each month. The TD cohort never achieved a mean of 90 minutes, peaking instead at 73 minutes of daily 'tummy time' before the majority of babies in this group started transitioning independently in and out of the sitting position. It is not surprising that the mean number of 'tummy time' minutes in the cohort of infants with DS rose more quickly. The universal theme for families with infants with DS wanting to participate

in this study was to improve the quality of life for their child. Understanding the risk for developmental delay associated with a diagnosis of DS likely was a motivating factor in program adherence for these families. On the other hand, while families with TD infants consistently expressed a desire to prompt their baby's development, they ultimately knew their infant would achieve its milestones with or without 'tummy time.' The desire to mitigate the challenges their baby might encounter could also explain why the cohort of infants with DS was able to achieve and even surpass the recommended number of 'tummy time' minutes, peaking at 100 minutes by month eight. The sharp decline in 'tummy time' minutes observed in the TD cohort at month six can be explained by the fact that most infants in this group were no longer participating in deliberate 'tummy time.' By time six, the preponderance of TD infants were independently transitioning in and out sitting, effectively skilling out of the intervention. The few TD babies still participating in 'tummy time' after time six were not doing as many minutes, thus the sharp decline revealed on the graph. Given the evidence supporting earlier motor development with more daily minutes of 'tummy time' (Kuo et al., 2008; Majnemer & Barr, 2006; Davis et al., 1998; Salls et al., 2002; Dudek-Schriber & Zelazny, 2007), these babies might not have skilled out of 'tummy time' as quickly because they were not as adherent to the intervention. The number of 'tummy time' minutes in the cohort of infants with DS declined more gradually after time nine, probably because infants with DS were slower to master independent transitions in and out of sitting. There was also more variability in achievement age, with some infants with DS accomplishing this skill by month nine and others taking until month 12 after beginning the intervention. In summary, families with infants with and without DS were not able to immediately engage in 90 minutes per day of deliberate 'tummy time.' Participating families required several months to increase their 'tummy time' minutes, with families with TD infants

building to a mean of 73 daily minutes and families with infants with DS building to 100 daily minutes of 'tummy time.'

A pivotal aspect of qualitative processes is understanding what it was like for families in both cohorts to participate in 'tummy time.' It is probable that families were not able to immediately achieve the recommended 90 minutes per day because in early life most of the infant's day is spent sleeping. For participants in this study, the young infant's minimal awake time was spent eating, being transported to sibling activities, being held or placed in a positioner, apportioning little time for 'tummy time' activities. Young infants also struggled with and complained about engaging in 'tummy time' for more than a few minutes at a time making it difficult for parents or caregivers to persevere. Additionally, four of the TD infants suffered from reflux early in their lives causing them to spit up when placed in prone. As participating infants gained strength and their reflux subsided, their tolerance for 'tummy time' gradually increased. Families in both groups using daycare reported push back from daycare providers both in putting the infant on his or her tummy more during the day and in logging 'tummy time' minutes done in the daycare setting. It was more difficult for families using daycare to get in the recommended dosage of 'tummy time' outside of the hours spent in daycare.

While using daycare outside the home proved to be a barrier to 'tummy time' adherence, having a sitter in the home, as well as whole family involvement in providing 'tummy time,' increased the number of minutes families were able to achieve. Families with a stay at home parent also found it easier to engage in the recommended number of 'tummy time' minutes.

These findings have adherence implications for single parent families or families in lower socioeconomic statuses (SES) that can't manage in-home daycare, having a parent stay at home, or adequate manpower for intervention implementation due to financial or logistical constraints.

Therefore, the facilitating factors identified may not be applicable for families in lower SES or families outside the demographics of this study (see Table 2.1).

Families in both intervention groups valued the monthly visits and developmental feedback from the researcher, stating that this was the most positive aspect of participating. Seeing their baby develop faster than expected given his or her diagnosis or than siblings or friends made their implementation struggles worthwhile. Given the high retention rate, only one out of 32 total enrolled families dropped out for a non-medical reason, the parent feedback feature of the study appears integral. Regular parent feedback and instruction from a qualified interventionist, offered in a convenient location such as the home, could be a valuable resource for families with and without an infant with DS, especially in lower SES where resources to improve development, health and quality of life are scarce.

In spite of the challenges encountered in adhering to the 'tummy time' intervention, 100% of participating families stated that they would recommend the intervention to other families, particularly families with an infant with DS. In general, families purported that involvement in the 'tummy time' study made them more aware and accountable not only of how much time their infant spent on his or her tummy, but also of his or her developmental progress and how it was positively impacted by their investment in the project.

Study Limitations

The demographics of both intervention groups in this study were one limitation. The participants in both groups were primarily Caucasian, two parent households, with more than 90% of the parents holding at least a college degree, and 60% of the families reporting an annual household income of \$80,000 or more. This demographic may not be representative of the

general population of families with infants with and without DS so study findings might not be generalizable to families that don't identify with this demographic.

Another study limitation is that the questionnaires were distributed by and returned to the researcher. Because family responses to the questionnaires were not anonymous or de-identified, bias could have been introduced into the results. A response bias results when families deviate from the truth to varying degrees and present instead what they feel the researcher would want to see in order to create a positive impression. A similar bias could have resulted in parent logging of 'tummy time' minutes. In spite of assurances that truth in recording was of upmost importance to the feasibility results, families still could have diverged from actual 'tummy time' minutes in their logging efforts to present themselves as being more adherent. This bias introduces error into the results and again limits the generalizability of study findings.

Implications for Practice and Future Research

The results of this study have several implications for practice and future research. Parents of infants with and without DS benefit from information that will enhance the quality of their interactions with their infant. This study demonstrated that parents can and will participate in interventions they believe will positively impact their child's development, especially if their child has special healthcare needs, such as a diagnosis of DS. To protect anonymity and decrease response bias, future qualitative studies should consider having questionnaires returned to a neutral third party, instead of to the principal investigator, so families can feel comfortable being completely honest about their experiences in the intervention. To keep parent motivation and adherence to the intervention high, regular parent feedback on their child's progress is integral. Families want to see that their efforts are paying off. This feedback should be specific: "Jane is now performing locomotion skills at the 8 month old level and last month she was

performing them at the 6 month old level. Keep doing 60 minutes of the intervention every day because your work is paying off!" General statements, such as "Jane is doing great! Keep up the good work," may be less effective in keeping adherence high. Interventionists need to thoughtfully involve all caregivers as well as siblings in intervention implementation to share the responsibility and to increase the opportunity for practice. Logging of intervention efforts, such as daily 'tummy time' minutes, is helpful to some families in increasing accountability but burdensome to other families. Interventionists should consider a variety of methods of helping families stay accountable and implement the method that best fits the personality of the family. Because push back from daycare providers was a barrier to intervention adherence in the 'tummy time' study, education and instruction on why 'tummy time' is critical to development and how to successfully implement 'tummy time' in a daycare setting is needed for daycare providers. Future studies might include a similar feasibility measurement in daycare settings to identify facilitating factors and barriers that are unique to this environment. Finally, because resources, such as in-home childcare and a stay at home parent, were found to be facilitators to intervention adherence, future studies should also include families in lower SES that don't have the support and/or resources available to families in this study to gain awareness of the adherence factors distinctive to this lower SES demographic.

Conclusion

Families with infants with and without DS were able to achieve 54 minutes of daily 'tummy time' in the first month following study entry. The amount of 'tummy time' minutes achieved by participating families increased every month but the number of daily minutes increased more rapidly in the group with infants with DS. Families with infants with DS were able to achieve and surpass the 'tummy time' dosage recommendation, but families with TD

infants were only able to build up to 73 daily 'tummy time' minutes before the majority of infants in this group skilled out of the intervention. Resources, such as a stay at home parent, in home childcare and total family involvement, were identified as an important adherence facilitator which has implications for infants that attend daycare and for families in lower SES.

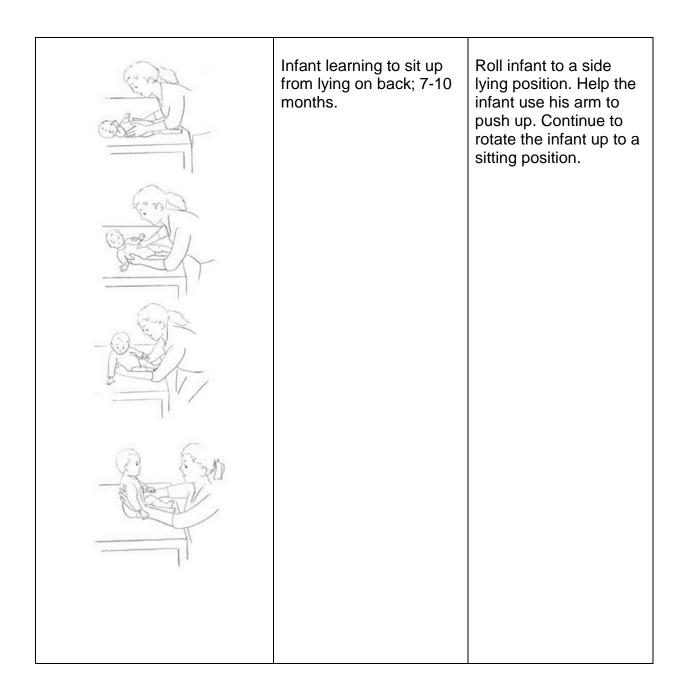
Table 2.1 Characteristics of 'Tummy Time' Study Participants (Intervention Groups)

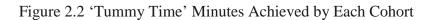
Study ID	Gender	Age at Baseline	Location	Daycare Outside	#of Siblings	# of Pre/Peri/Post-	Maternal Education	Family	Received Additional PT2	Notes
100	Male	35.00	Fact Lancing MI	No	21111152		Graduate Degree	70 000	٨	
101	Female	103.00	Toledo, OH	Yes	9	1	College Graduate	10,000		Left study after T5(v6) due to infantile spasms.
102	Female	81.00	Brooks, GA	No	1	1	Some College	70,000	Yes	
103	Male	87.00	Grosse Pointe Woods, MI	No	2	0	College Graduate	100,000 Yes	Yes	
104	Male	61.00	New York, NY	No	1	0	Graduate Degree	>150,000	Yes	Left study after 17(v8) because overwhelmed.
105	Female	113.00	Willow Grove, PA	No	3	1	College Graduate	30,000	Yes	
106	Male	79.00	Holland, OH	No	2	1	College Graduate	20,000 Yes	Yes	
107	Male	77.00	Milan, MI	No	2	0	College Graduate	60,000 Yes	Yes	
108	Female	86.00	Whitehouse, OH	No	2	7	College Graduate	80,000 Yes	Yes	
109	Female	136.00	Waterville, OH	No	2	3	College Graduate	100,000 No	No	
110	Male	0.00	Toledo, OH	No	0	7	College Graduate	80,000 Yes	Yes	
111	Male	43.00	Pepper Pike, OH	No	0	0	College Graduate	>150,000	Yes	
112	Female	0.00	Cincinnati, OH	Yes	1	.2	College Graduate	>150,000	Yes	
113	Male	29.00	Williamstown, KY	No	4	1	Some College	70,000 No	No	
114	Female	95.00	Mayfield Heights, OH	Yes	2	1	College Graduate	40,000 Yes	Yes	
115	Female	101.00	Fort Thomas, KY	No	1	0	Graduate Degree	90,000 Yes	Yes	
116	Male	71.00	Loveland, OH	No	0	3	College Graduate	>150,000	Yes	
117	Female	34.00	East Lansing, MI	No	2	0	College Graduate	>150,000	Yes	
118	Female	57.00	Ada, MI	No	1	2	Graduate Degree	>150,000	Yes	
119	Female	49.00	Williamston, MI	No	1	0	College Graduate	70,000 Yes	Yes	
300	Female	00.09	Mableton, GA	Yes	2	0	Graduate Degree	>\$150,000 No	No	
301	Female	38.00	Ann Arbor, MI	No	0	0	Graduate Degree	>\$150,000	No	
302	Male	42.00	Milton, GA	No	1	0	Graduate Degree	100000.00 No	No	
303	Female	46.00	Atlanta, GA	Yes	0	0	Graduate Degree	100000.00 No	No	
304	Female	79.00	Marietta, GA	No	0	0	Graduate Degree	100000.00 No	No	
	Female	25.00	Macon, GA	No	1	0	College Graduate	90000.00 No	No	
306	Male	38.00	McDonough, GA	No	1	0	College Graduate	50000.00 No	No	
	Male	134.00	Ann Arbor, Mi	No	3	0	College Graduate	40000.00 No	No	
	Male	27.00	Atlanta, GA	Yes-2 days/wk	0	0	Graduate Degree	20000.00 No	No	
	Male	28.00	Ann Arbor, MI	No	1	0	College Graduate	100000.00 No	No	
	Female	20.00	Franklin, TN	No	0	0	College Graduate	100000.00 No	No	
	Male	38.00	Dunwoody, GA	No	1	0	Graduate Degree	>\$150,000 No	No	
312	Male	22.00	Woodstock, GA	No	2	0	Graduate Degree	80000.00 No	No	

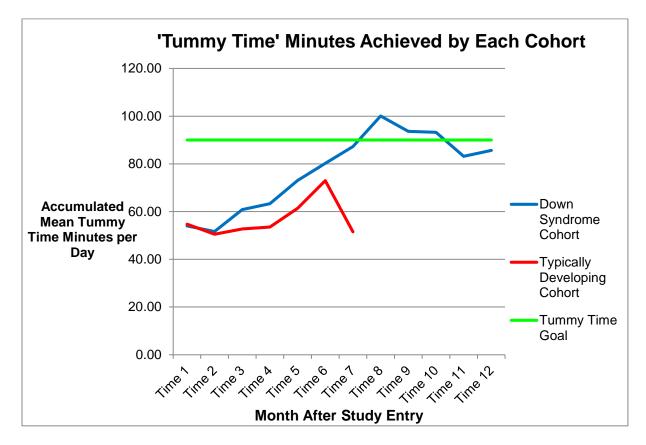
Figure 2.1 Sample Progression of 'Tummy Time' Exercises

Illustration	Exercise	Description
	Infant lying on parent's chest; Parent semi-reclined; 0 to 4 months	Parent seated in semi- reclined position with back supported. Infant's upper body supported by parent as needed. Encourage head up and eye contact.
	Tummy lying towel roll support; 2 to 5 months	Medium sized towel under infant's chest for support. Infant's elbows forward of shoulders. Weight bearing through forearms. Encourage head up, visual attention and interaction with toys.
	Infant lying on parent's shins; parent flat on back with knees to chest; 2-5 months.	Parent lies flat on back, bringing knees to chest. Place infant face down on shins and hold hands. Incorporate motion (e.g. gentle bouncing or rocking) as tolerated. Encourage eye contact and head control.

Infant lying across parent's legs, arms straight; 3 to 6 months	Parent sits with back supported. Infant lies face down across lap. Infant's arms forward with hands on the floor. Weight bearing through extended arms. Encourage interactions with toys. If infant's arms do not reach floor, can use book or other flat object to bring level of floor to meet arms.
Tummy lying reaching for toys. Supporting arm is bent; 3 to 6 months.	Parent lies on floor next to infant. Infant's arms are forward. Encourage infant to weight shift onto the bent arm and then reach for toy.
Infant on hands and knees propped on a couch cushion; 4 to 7 months	Place couch cushion on floor. Position infant's knees on floor next to the cushion with upper body on cushion. Encourage infant to push up on arms and interact with toys.
Infant on hands and knees, supported by parent's leg; 5 to 9 months.	Parent on floor with legs outstretched or bent comfortably. Place infant over lower part of leg. Bend infant's knees so they are under his hips. Place infant's hands on floor so he can push up.







References

Davis, B. E., Moon, R. Y., Sachs, H. C., & Ottolini, M. C. (1998). Effects of sleep position on infant motor development. *Pediatrics*, 102(5), 1135-1140.

Dudek-Shriber, L., & Zelazny, S. (2007). The effects of prone positioning on the quality and acquisition of developmental milestones in four-month-old infants. *Pediatric Physical Therapy*, 19(1), 48-55.

Glaser, B. G., & Strauss, A. L. (2009). *The discovery of grounded theory: Strategies for qualitative research.* Transaction Publishers.

Kuo, Y. L., Liao, H. F., Chen, P. C., Hsieh, W. S., & Hwang, A. W. (2008). The influence of wakeful prone positioning on motor development during the early life. *Journal of Developmental & Behavioral Pediatrics*, 29(5), 367-376.

Majnemer, A., & Barr, R. G. (2006). Association between sleep position and early motor development. *The Journal of Pediatrics*, 149(5), 623-629. e621.

Ramey, C. T., Bryant, D. M., Wasik, B. H., Sparling, J. J., Fendt, K. H., & La Vange, L. M. (1992). Infant Health and Development Program for low birth weight, premature infants: Program elements, family participation, and child intelligence. *Pediatrics*, 89(3), 454-465.

Salls, J. S., Silverman, L. N., & Gatty, C. M. (2002). The relationship of infant sleep and play positioning to motor milestone achievement. *American Journal of Occupational Therapy*, 56(5), 577-580.

Chapter 3

Differences in Motor Development, Ponderal Index, and Physical Activity Level in Infants with and without Down syndrome as a Result of 'Tummy Time' Participation

Introduction

Parents of infants with and without DS strive to foster the best developmental pathway for their baby in order to maximize his or her health and quality of life across the lifespan. Motor milestones have long been used by pediatricians as an outward indicator of development during infancy (Capute & Accardo, 1991). Ergo, parents are sensitive to the ages at which their child achieves certain motor skills and are eager to compare their child to what other same aged children are accomplishing. As motor development was established as a key determinant in overall development, the impact of 'tummy time' on motor development was chosen as a primary outcome measure of this research. Body composition and physical activity level need to be monitored in infancy as habits are adopted early and are likely to be perpetuated into childhood, adolescence and adulthood (Perrin et al., 2014; Franks et al., 2010; Han et al., 2010). Furthermore, persons with DS are more likely to be obese and to embrace sedentary behaviors (Whitt-Glover et al., 2006; Rimmer et al., 2010). Interventions that preclude sedentary living and obesity in infancy are imperative for public welfare. For these reasons, the impact of 'tummy time' on body composition, as measured by ponderal index (PI), and physical activity (PA) were also key outcome measures of this work. 'Tummy time,' a parent delivered initiative, has the potential to hasten development, movement and fitness, thereby bettering health and quality of life outcomes, in infants with and without DS.

Enabling participation in meaningful everyday activities is a mission shared by parents of children with and without DS and as well as by interventionists. Participation occurs as a result of the intrinsic and extrinsic factors surrounding the child that act as facilitators and barriers (Oates et al., 2011). Examples of intrinsic factors are the infant's temperament, curiosity, or perseverance. Extrinsic factors may include how stimulating the infants' environment is, how aggressive an infant's parents are in prompting skill attainment, or the climate (physical and/or emotional) in which the infant lives. These determinants operate at the personal, contextual and environmental levels of the International Classification of Functioning (ICF) model (see Figure 3.1). According to the ICF model, interventions can be directed toward remediating impairment, reducing activity limitations, and/or improving participation (WHO, 2001). This dissertation did not specifically examine changes in participation precipitated by the 'tummy time' intervention. Instead, the impact of 'tummy time' on pertinent impairments in body structure and function (i.e. body composition) and activity limitations (i.e. motor development and physical activity) were examined as these variables hinder participation if not allayed.

This chapter encapsulates studies two and three of the overall dissertation project. They are grouped together in this chapter because they had similar aims, methods, and analytical procedures. The principal difference was that study two involved TD infants, and study three involved infants with DS. The purpose of these studies was to investigate the impact of engaging in a deliberate 'tummy time' intervention, recommended as an accumulation of 90 minutes per day, beginning at study entry (corrected age of 0 to 20 weeks) and ending at the time at which the infant independently transitioned in and out of the sitting position, on motor development, PI and PA in infants with and without DS. The hypothesis was that active engagement in the parent administered 'tummy time' program would have a positive impact on motor development, PI and

PA in both groups of infants. These augmentations were desirable as they may have broader developmental, health and participation related implications.

Specific Aims/Hypotheses

The specific aims and hypotheses of these studies were as follows:

- Determine the impact of the prescribed 'tummy time' intervention on *motor development* in infants with and without DS.
 - H1. Infants with and without DS that engage in active 'tummy time' as recommended will demonstrate higher motor skill development than infants with and without DS not engaging in the formal 'tummy time' program.
- Determine the impact of the prescribed 'tummy time' intervention on *ponderal index* in infants with and without DS.
 - H2. Infants with and without DS that engage in active 'tummy time' as recommended will demonstrate lower *ponderal indices* than infants with and without DS not engaging in the formal 'tummy time' program.
- 3) Determine the impact of the prescribed 'tummy time' intervention on *physical activity* in infants with and without DS.
 - H3. Infants with and without DS that engage in active 'tummy time' as recommended will demonstrate higher levels of physical activity than infants with and without DS not engaging in the formal 'tummy time' program.

Methods

All methods and procedures were approved by the Medical School Institutional Review Board (IRBMED) of the University of Michigan, and all parents signed written informed consent prior to beginning the study.

Participants

Participants in the intervention groups of these studies were the same 19 infants with DS and 13 TD infants that engaged in the 'tummy time' feasibility study, described in Chapter two, Methods, Participants. See Table 2.1 for a review of the demographics of the two experimental groups.

Historical comparison groups

The historical comparative data came from studies done by Hauck and Ulrich (2012; 2013) at the University of Michigan. In these studies, observational data on motor development, PI and PA were collected from nine infants with DS and 25 TD infants once monthly for six consecutive months, and then again at 12 and 18 months of age. All historical data were collected in the home of the infant, with the exception of initial recruitment information. The mother was present at all times during data collection. The first home visit occurred when the infant was aged approximately one month (+/- one week). It was not assumed that infants in the historical comparative groups failed to engage in any 'tummy time' because pediatricians routinely recommend that all babies be put on their bellies for developmental reasons. Rather, it was assumed that the infants in the historical groups did not complete the deliberate or systematic 'tummy time' minutes performed by the intervention groups.

Motor development, PI, and PA of each infant in the historical cohorts were monitored as described above. At the first home visit, demographic information was collected.

During each home visit, infant weight, length, and PI were measured. Infant weight (kg) using a Tanita digital baby scale and infant recumbent crown-heel length (cm) using an infant length board were measured. The length board had a static headboard and moveable footboard. The infant's ankle was dorsiflexed to 90 degrees while the body was aligned. Weight and length were used to determine PI. PA was measured once monthly during a 24-hour period using an Actical accelerometer (Mini-Mitter Inc., Bend, OR) in the TD infant cohort and using an Actical accelerometer and/or a Actigraph GT3X+ (Pensacola, FL) triaxial accelerometers in the cohort of infants with DS. Infants in both cohorts were the monitor on their right ankle and right wrist attached with an elastic band covered by a cloth sleeve. These monitors were easily removed for clothing change and bathing. During the monitoring period, each mother completed a monitoring log in order to corroborate data received from the monitor. The log required the mother to classify the type of activity her infant engaged in as either sleeping, feeding, quiet play, active play, or being mechanically or adult handled in 30 minute intervals. This information was helpful in providing a template to accurately remove data that reflected mechanical or adult handling rather than infant produced movement. Motor development was measured during each home visit using the Bayley-III Motor Scales (Bayley-III) (Bayley, 2006). Gross and fine motor raw scores were used to create the overall motor composite.

Attention was given in the design of this project to create as many similarities as possible with the studies done by Hauck (2012) and Hauck and Ulrich (2013) to maximize comparability. The original baseline data in the historical, non-intervention, groups was taken from parent report of birth height and weight and did not include measurements of motor development, PI or PA. Additionally, the original first time point after birth for the non-intervention groups had some missing data for motor development, PI and PA, perhaps due to the infants' young age. In

an effort to match the intervention ('tummy time') and non-intervention groups as closely as possible by age at baseline, the second time point after birth was used as baseline data for both historical (non-intervention) cohorts. By doing this, the mean age in days at baseline for the 'tummy time' TD cohort was 48.23 and for the historical TD cohort was 61.65. The mean age in days at baseline for the 'tummy time' cohort with DS was 66.53 and for the historical cohort with DS was 64.00. In the case of the TD cohorts, it was deemed best to match the time points such that the intervention cohort was slightly younger rather than slightly older than the historical TD cohort at baseline. Age impacts development even in the absence of an intervention. In the event differences between the groups were discovered, closely age matched groups would be more indicative of an intervention effect as opposed to an age or maturation effect. The matching of groups in this manner did not produce a statistically significant difference in age at baseline (see Table 3.1). The way the groups were matched afforded seven common time points at which the intervention and non-intervention groups were aligned by age such that differences in motor development, PI and PA could be compared: baseline, time point one, time point two, time point three, time point four, time point 11, and time point 18.

Procedures

With the ultimate goal of maximizing participation in meaningful life events in persons with and without DS, interventionists need to know if their treatment plan is serving to minimize related body structure and function limitations (e.g. obesity), while maximizing activity performance (e.g. motor development and physical activity), within the context of personal and environmental factors (see Figure 3.1, ICF Model). The procedures outlined below provide the rationale for and the descriptions of strategies used to measure each of the dependent variables, motor development, PI, and PA in the experimental groups.

Motor assessments

Motor progress assessed by norm referenced tools are salient for many families as they are sensitive to the age at which their child is achieving certain key milestones. Two norm referenced assessments, the Bayley-III (Bayley, 2006) and the Peabody Developmental Motor Scales-II (PDMS-II) (Folio & Fewell, 2000) were used to determine the motor development of the experimental cohorts. Parents of TD infants want to see how their baby is performing compared to the majority of other same aged babies. Rather than employing dedicated DS motor development curves (that compare performance in children with DS to other children with DS), typically developing curves, such as provided by the PDMS-II and the Bayley-III, were also used as the measure of intervention effectiveness in the cohort of infants with DS. These results provided information as to whether the 'tummy time' intervention was successful in narrowing the gap in motor development between TD infants and infants with DS (see Figure 1.1), as well as provided information on how 'tummy time' affected the motor development of TD infants compared to their peers not engaging in the intervention.

The Bayley-III (Bayley, 2006) was administered to the (historical) comparison groups, so the motor development of the 'tummy time' groups was also assessed using the Bayley-III in order to facilitate direct comparison between groups. The Bayley-III is a valid discriminative measure that is recommended for identification of motor delay or determination of eligibility for early intervention services (Tieman et al., 2005). There is thought that the Bayley-III can be used for the evaluation of changes in neuromotor function, thus capturing the effect of intervention (Heineman & Hadders-Algra, 2008). In addition, reliability information for special populations supports the generalizability of

the instrument (Bayley, 2006). Limitations of the Bayley-III include the inability to differentiate gross and fine motor development (raw scores on gross and fine motor items lead only to an overall motor composite), a decreased number of items perhaps not providing for a comprehensive measure of motor development, and items being scored as present (score of 1) or not present (score of 0) without accounting for emerging ability (Tieman et al., 2005). Data presented in the Bayley-III Technical Manual (Bayley, 2006) shows moderate correlations between the Motor Composite (Bayley-III) and the Total Motor Quotient (PDMS-II) (r=.55).

The PDMS-II is a norm referenced motor assessment tool with excellent reliability and validity as a discriminative measure (Folio & Fewell, 2000; Tieman et al., 2005). It is a valid measure for determining a child's eligibility of services in early intervention or preschool programs as it is intended to determine whether children six years of age and younger have delayed motor development based on a large normative sample (n = 2003). The PDMS-II was also found to have internal consistency in children with physical disabilities (Folio & Fewell, 2000). While Folio and Fewell (2000) indicate that the PDMS-II can be used for both discriminative and evaluative purposes, there is minimal evidence of responsiveness to change in children with disabilities (Tieman et al., 2005). Although it is primarily a discriminative measure, it was chosen as one of the motor assessments for this study because of the hypothesis that the intervention, if adhered to, would mitigate motor delays in infants with and without DS. The intention was to look at how study participants performed compared to the large, normative sample. In addition, the PDMS-II is comprised of five subtests, three gross motor subtests and two fine motor subtests, that led to the establishment of not only a

total motor quotient (TMQ), but also a gross motor quotient (GMQ) and a fine motor quotient (FMQ) allowing differentiation of intervention effects. The PDMS-II includes more test items and items are scored more precisely than the Bayley-III, as present per criteria (score of 2), not present per criteria (score of 0), or emerging per criteria (score of 1), making it advantageous to perform and include results of both tools for the intervention cohorts.

Ponderal index

A simple measure of infant body composition that could be easily determined in the home with transportable equipment was necessary for the purpose of this study. A body proportionality index provides an assessment of body mass relative to length or height (Olsen et al., 2009). Body mass index (BMI), the most commonly used body proportionality index, in children and adults is known to be correlated with body fat and with risk of obesity related diseases (Wells et al., 2007). When examining body proportionality in infants, ponderal index (PI), which is computed by dividing the infant's weight in kilograms by his or her height in meters cubed, is a common pediatric measure of leanness and is the preferred index because, unlike BMI, it is not highly correlated with length (Ekelund et al., 2006). A study performed by Cole et al. (1997) confirmed that the most appropriate index for infants, if gestation is ignored, is PI. In infants with gestations over 40 weeks, PI over-adjusts for length such that long babies appear thin and short babies appear fat; and, using BMI (weight in kilograms divided by height in meters squared) as an alternative over adjusts in the other direction (Cole et al., 1997). De Cunto et al. (2014) found that BMI z-score predicted adiposity better than PI in newborns, but that both BMI z-score and PI were poor predictors of adiposity at birth. Cole et al.

(2005) found that while BMI *z*-score is optimal for assessing adiposity on a single occasion, it is not the best scale for measuring change in adiposity inasmuch as the within-child variability over time depends on the child's level of adiposity. For monitoring adiposity over time, BMI, not BMI *z*-score, is the better determinant, or in the case of infants, PI (Cole et al., 2005). Given this evidence, PI was the proportionality index chosen as the indicator of adiposity for this study as monitoring of body composition took place over time, from 0 to 20 weeks (study onset) through 12 or 18 months of age, a period that extended well beyond birth and the newborn period of life.

Physical activity

While the rationale for measuring physical activity (PA) in infancy is well established in the literature, valid and reliable procedures for doing so have not yet been established. PA can be defined as any bodily movement generated by skeletal muscles that raises energy expenditure above resting values (Caspersen et al., 1985). To measure PA in infants, their body movements must somehow be quantified. Activity or movement during the first six months of life primarily consists of movement of the legs and arms when the infant is lying on its back or stomach, reaching and grasping objects, and turning of the head towards a stimulus. From six to 12 months of age, infant movement is characterized by the learning of rudimentary skills such as belly crawling, four point crawling, pulling to stand and finally walking (Cliff et al., 2009). One common characteristic regarding movement in children zero to five years is that it is mainly sporadic and intermittent in nature (Cliff et al., 2009) making it difficult to accurately quantify using indirect measures such as a parent diary.

Objective measurement of PA using accelerometry is becoming more common in pediatric populations where indirect methods such as parent report tend to overestimate activity levels (Cliff et al., 2009). Cliff et al. (2009) explained the premise of capturing PA using accelerometry. "Accelerometers are instruments designed to measure timevarying differences in force or acceleration. When applied to the measurement of PA, an accelerometer can assess the magnitude and total volume of movement as a function of The devices are band limited in order to filter out vibration forces outside the range of normal human motion. The generated electric charge is filtered and converted by the accelerometer in samples taken multiple times every second. These samples are summed over a user-specified cycling period called an epoch and are recorded in the accelerometer's internal memory. After recording the magnitude of the accelerations over a given epoch in activity "counts," the numerical indicator is reset and the process is repeated." Describing the largely unstructured and intermittent PA behaviors in very young children is challenging, but accelerometers are considered well suited for this task (Cliff et al., 2009).

The Actigraph (Pensacola, FL) is an accelerometer that has evidence of validity and reliability in children (Trost et al., 2005). However, minimal methodological studies in children less than three years of age have been performed, thereby necessitating extrapolation from studies in older children for feasible accelerometer-based PA assessments in infants (Cliff et al., 2009). Ott et al. (2000) found that the Actigraph provided valid information over a range of free-living activities about children's PA; and, Kelly et al. (2004) used an observational system to compute reliability (r=.72) using the Actigraph in 78 free-living children ages three to four years. Actigraphic processes have

been found to be valid in infants less than one year of age for assessing sleep-wake patterns (Sadeh et al., 1995). In terms of how long to monitor PA using an Actigraph, studies done in older children indicate that the reliability of estimates of total PA (counts per minute) are maximized when monitoring occurs for seven days with a minimum of ten hours per day of continuous monitoring, but that three days of monitoring with a minimum of three hours per day of continuous monitoring is sufficient (Penpraze et al., 2006). Tulve et al. (2007) found consistency across four days of monitoring in nine participants under the age of 24 months according to parent diary and accelerometer output. Monitoring PA using actigraphy for a 24 hour period has been previously used in research in infants with DS (Lloyd et al., 2010; Hauck, 2012; Ulrich & Hauck, 2013) and found to be useful in correlating PA level with motor development.

The procedures employed in this study were derived from the above findings on PA measurement done with older children and from methods used in similar work with infants with DS. Because of the logging demands associated with PA monitoring, in addition to logging 'tummy time,' and to avoid overburdening participating families with very young infants, one day or 24 hours was chosen as the monitoring period for the experimental groups. Additionally, the infants in the historical comparison groups wore accelerometers on their right wrist and ankle for 24 hours with parent logging so it was important for the procedures for PA measurement to match in the intervention and non-intervention groups. Placement of the accelerometers at the wrist and ankle was appropriate because during infancy much of volitional movement is happening at the extremities. Therefore, families in the 'tummy time' groups were provided with two Actigraph GT3X+ (Pensacola, FL) triaxial accelerometers and instructed to place one on

the infant's right wrist and one on the infant's right ankle for a 24 hour monitoring period after each home visit in order to quantify their infant's PA level. Actigraph monitors were worn by participating infants when they were awake as well as when they were asleep for the 24 hour period. During the monitoring period, parents kept a written log of their infant's activity in 30 minute intervals. Activity by 30 minute intervals was coded as "x" meaning not worn, "0" movement occurring under the power of others, "1" sleeping, "2" feeding, "3" quiet play or "4" active play. "Quiet play" was defined as awake but with minimal movement of the arms and legs and "active play" was defined as a great deal of movement in the arms and legs. See appendix 3.1 for a sample of the Infant Physical Activity Monitoring Directions and Infant Physical Activity Log provided to families. Families were instructed to choose a day close to the day of the home visit that represented a "typical" day for their infant at that point in time. If the infant was sick (i.e. fever > 100 degrees Fahrenheit, vomiting or diarrhea) the family was instructed not to use sick time as representative of a "typical" day.

PA data were collected in raw counts, at a sampling frequency of 30 Hz, with a 15 second epoch to capture the intermittent nature of movement typical in infants. Raw accelerometer counts are unit-less and dimensionless. In order to translate raw counts into time spent at different activity intensities, count information must be calibrated using proven algorithms for children of similar ages (Cliff et al., 2009). Reliable and valid algorithms have not yet been established for infants so reporting of individual PA data as well as group comparisons of PA data were made on the basis of raw counts only for data collected prior to 18 months of age. Each accelerometry file was manually cleaned to include only data generated by the infant, based on the information provided by the

parent on the log. That is, all counts generated by mechanical handling, outside of the infant's volitional control, were removed from the data. Monthly comparisons of PA, in counts per minute for the ankle and for the wrist, between the groups were thus made on data attributable only to actual infant movement. Mean counts per minute for the wrist and for the ankle were used as the comparative parameter because this measure evaluates the raw data provided by the accelerometer without imposition of any external criteria other than determination of wear and non-wear time (Troiano et al., 2008). Mean counts per minute were calculated by dividing the sum of activity counts for the day by the number of minutes of wear time in that day. This parameter was thought to be the most analogous between groups as it accounted for differences in wear procedures between participants. During logging, parents were also asked to subjectively distinguish between "quiet" and "active" play for their child. Because of the variation inherent in parent reporting, comparisons between participating infants on "quiet and "active" play could not be made. Parents were given a monthly summary of the amount of counts for their infant for both quiet and active play, per their interpretation, so within infant comparisons could be made over the course of the study.

These procedures for PA monitoring and reporting were used by all four groups for all visits that occurred prior to 18 months of age. In ambulatory children, monitoring at the hip is considered to be most accurate when using accelerometry (McIver et al., 2005). Therefore, for the final visit at 18 months of age, participating infants in the experimental and comparison groups completed the same 24 hour monitoring using an Actigraph on the right ankle (with logging) and a one week (seven day) monitoring using an Actigraph at the hip (no logging). No wrist accelerometer was worn by any of the

infants at the 18 month time point. Because it was challenging for many families to wear the waist accelerometer for a full seven days, the minimum wear time was set at three days, with a minimum wear time of 180 minutes per day, for data to be included in the analyses. The three days chosen for analysis (if more than three days of activity was recorded) were the three days with the lowest amount of time spent in sedentary activity. Using the analytical capabilities of the Actilife software and the preschool algorithms established by Pate et al. (2006), raw accelerometer counts were translated into time spent at differing activity intensities such as average sedentary minutes per day, average light activity minutes per day, and average minutes per day of MVPA which provided supplemental information on the quality and type of movement being engaged in by older infants in the intervention and non-intervention groups.

A challenge was encountered in the comparison of PA data between the intervention and non-intervention TD infants due to advances in accelerometer technology that occurred between studies. Physical activity was measured monthly during a 24-hour period using an Actical accelerometer in the historical TD infant cohort. At the time of the present study, the Actical software at the University of Michigan was outdated and incompatible with existing technology so Actigraph was the only accelerometer option for PA measurement in the experimental groups. Raw counts from Actical and Actigraph are not equivalent making it impossible to directly compare PA results between the two TD cohorts. Indirect comparison was made possible because some of the infants with DS in the non-intervention group wore both an Actical and an Actigraph accelerometer at several time points. Since data was obtained simultaneously on both devices, a calibration formula could be created using a linear regression model.

The model constructed allowed raw counts on the Actigraph to be predicted based on raw counts on the Actical. The R², or the proportion of the variance of one variable (Actigraph) that is predictable from the other variable (Actical), was .374. This meant only 37.4% of the total variation in Actigraph measures could be explained by the linear relationship between Actical and Actigraph. The other 62.6% of the total variation in Actigraph remained unexplained. This percentage of unexplained variance was less than ideal and reflected the considerable number of outliers that fell outside the model. These outliers were likely consequence of the high degree of variability within and between infants in terms of daily PA as well as of imperfections in the methodology utilized for measuring PA in infants. See Figure 3.2 for a scatterplot illustrating the regression model used to predict Actigraph from Actical data. Nonetheless, in order to facilitate some type of indirect comparison of PA data between the TD infants in the intervention and non-intervention groups, Actical raw counts were converted to Actigraph raw counts using the following calibration formula:

Actigraph counts = 360.35 + 5.128(Actical counts)

Home Visits

Home visits were structured to mimic home visits done with the historical groups, in their respective studies, as closely as possible, the exception being the inclusion of 'tummy time' instruction in the experimental group visits. Home visits were the same for 'tummy time' groups with and without DS. A background history and family demographic questionnaire was completed at study entry to examine any differences between the intervention and non-intervention comparison groups present at baseline, not related to the intervention itself. All intervention visits took place in the participant's

home or daycare, with the parent or a primary caregiver in attendance. The baseline visit occurred when the infant was between zero and 20 weeks corrected age. The infant's height and weight was measured for computation of PI. Infant weight (kg) was measured using a Tanita digital baby scale and infant recumbent crown-heel length (cm) was measured using an infant length board. The length board had a static headboard and moveable footboard. The infant's ankles were dorsiflexed to ninety degrees while the body was aligned. The PDMS-II and Bayley-III were administered to determine motor skill development. To measure PA level, the family was provided with two Actigraph activity monitors to be worn as previously described in Chapter 3, Method, Physical Activity. These monitors were attached with an elastic band covered by a cloth sleeve making them easily removable as needed for clothing change and bathing. After the 24 hour monitoring period, the family returned the Actigraphs and the activity log in the self-addressed, stamped envelope provided. The family and/or primary caregiver were instructed in the 'tummy time' program as previously described in Chapter 2, Method, Procedures, 'Tummy Time' Procedures and Logging. Following the baseline visit, infants were similarly monitored and assessed each month for another 12 months, with an optional follow up visit requested at 18 months of age. The formal intervention, i.e. structured daily prone positioning, stopped when the infant could independently transition in and out of the sitting position. If the infant "skilled out" of the intervention before the end of the 12 month intervention period, families were no longer required to engage in deliberate 'tummy time' or logging activities, but monthly visits continued in order to examine intervention effects through the 12 month post baseline visit time frame (through 18 months for those families that opted for an 18 month visit).

It should be noted that despite one participant with DS dropping out of the study after time seven, one participant with DS requiring surgery for a serious cardiac defect (TOF), and five participants (one TD infant and four infants with DS) not able to take part in time 18 visits because the study ended prior to them turning 18 months of age, commitment to the fulfillment of prescribed home visits was very high. Every participant that was offered the optional visit at 18 months of age chose to partake. Out of a maximum of 448 total visits (32 participants with a possible 14 visits each), 436 home visits were carried out for a 97% rate of completion.

Health and Therapy Questionnaire

In addition, the families in the intervention groups completed a brief monthly questionnaire regarding their child's health and hospitalizations as well as the amount of outside therapies received during the previous month because these potential covariates could impact 'tummy time' as well as the outcome variables of interest in this study. Health and hospitalization information collected each visit for the infants in the non-intervention (historical) groups revealed similar health patterns in all four groups. Neither of the TD groups, 'tummy time' or historical, received external physical therapy at any time during the course of their respective studies. On the other hand, infants with DS in both the 'tummy time' and the non-intervention group received concurrent external physical therapy. While the families in the 'tummy time' group were questioned about concomitant physical therapy each visit, families in the historical group were questioned after study completion. Because of the suspected amount of recall error in families attempting to remember the frequency of physical therapy their infant received perhaps up to a year previously, valid comparisons in concurrent therapies received between the

two cohorts with DS could not be made or controlled for. Granting the inability to directly compare the amount of external therapies received by the groups with DS, it could be presupposed that because the groups with DS were represented by very similar demographics (see Table 2.1), that the amount of external physical therapy received was also similar. See Appendix 3.2 for the amount of concurrent therapy participants in the 'tummy time' group with DS received over the course of the study.

Parent Feedback Forms

After each monthly visit, parents in the intervention groups were provided with an electronic parent feedback form that detailed their infant's progress. Each monthly report gave information about the infant's age, height, weight and PI; average number of 'tummy time' minutes performed daily (for the months that the infant was still performing imposed 'tummy time'); results of the PDMS-II (raw scores for 5 subtests, age equivalents for 5 subtests, standard scores for 5 subtests, total motor quotient, gross motor quotient, fine motor quotient and percentiles); results of the Bayley III (raw scores for fine and gross motor skills, age equivalents for fine and gross motor skills, scaled scores, motor composite score and percentile rank); physical activity counts (Total as measured by the Actigraph; Light Activity and Vigorous Activity counts as measured by the Actigraph but distinction as determined by parent report on the log); special circumstances surrounding the visit or the days prior to the visit, milestones met that month; and graphs depicting motor skill progress on both the Bayley-III and the PDMS-II (compared to the 50th percentile for TD infants and to the corresponding non-intervention group), PI over time (compared to the corresponding non-intervention group), as well as PA at the wrist and the ankle over the course of the study (compared to the corresponding

non-intervention group) and detailed waist information at time 18. Each month's results were added onto the previous month's report such that by study completion the parent had a complete record of their infant's progress as a result of participation in the study.

See appendix 3.3 for a sample of a parent feedback form disseminated in this study.

Data Analysis

The design of these studies was quasi-experimental, longitudinal, and prospective. The Statistical Package for Social Science (SPSS) 22.0 was used for data analysis. Statistical significance was set at .05 (5%). Demographic data at study entry were compared between the cohorts to identify any confounders that might need to be controlled for in the analysis. Linear Mixed Model (LMM) procedures and the determination of effect size (Cohen's d) were employed in the exploration of the impact of 'tummy time' on the outcome variables of motor development, ponderal index (PI), and physical activity (PA) in infants with and without DS. Independent t-tests were performed to compare waist PA data at time point 18 in infants with and without DS. A series of survival analyses were utilized to investigate the effect of 'tummy time' on the achievement of certain hallmark motor milestones in both TD infants and in infants with DS. An additional analysis was completed to probe further into the correlation between 'tummy time' minutes and motor development in infants with and without DS. Finally, in an attempt to discern if 'tummy time' was more impactful in infants with or without DS, the data from all four groups was compiled, and an LMM was created to test the interaction between 'tummy time' and group (DS vs TD). The following subsections provide explanation and rationale for each of the analytic procedures, as well as a description of procedures for missing data, error management, possible correlations between DV's, and spaghetti plots, used in these studies.

Comparison of Baseline Measures and Demographic Data

Descriptive statistics were used to summarize the demographic data in all four groups. Chi-squared or independent t-tests examined the differences of the demographic variables as well as the baseline measures of the dependent variables (outcome measures) between the intervention and non-intervention comparison groups, both for the TD cohort and for the cohort with DS. Using SPSS, Q-Q plots were used to check for normal distribution of each variable and Levene's Test of Equality of Variances determined homogeneity of variance between the groups. Any potential confounders identified in this process were controlled for in the subsequent analyses such that results could be attributed to the impact of intervention, not to other group differences.

Linear Mixed Models: Impact of 'Tummy Time' on the Outcome Variables in Infants with and without DS

Based on the study design and the hypotheses related to the research questions of these two studies, linear mixed models (LMM) were constructed to investigate the interaction between group and time in TD infants and in infants with DS for each outcome variable. An LMM is a parametric, linear model for longitudinal or repeated-measures data that quantifies the relationships between a continuous dependent variable and various predictor variables (West et al., 2014). The distinctive feature of an LMM is that the mean response is modelled as a combination of fixed effects, characteristics assumed to be shared by all participants that are constant, and random effects, unobserved characteristics unique to each participant (Fitzmaurice et al., 2012). This type of model is valuable in infant research because although the literature can provide known sources of variability in infant response, there are many factors, intrinsic and extrinsic to the infant, that impact behavior and performance that are difficult to measure

and control for. Examples might be how much time the infant is placed in positioners during the day, how much time a family devotes to activities such as reading or infant massage, the infant's own motivation to moving and exploring, or how inviting the home environment is for interactions of all types. Thus the random effects of the model allowed each infant participant their own unique intercept (i.e. the expected value of the outcome for that participant when all predictors were zero) to account for undefined variability between participants. The choice of fixed effects for the model, maternal education and number of siblings, was based on evidence suggesting that infants from lower SES are at increased risk for developmental delays, obesity and sedentary behaviors (Perrin et al., 2014) and older information implying that infants with siblings are likely to be more active (Sharay & Bowman, 1992; Samuels, 1980). Maternal education was used as the indirect indicator of SES since data on annual family income was not collected for the historical comparison groups. Additionally, participant's PI at baseline (p = .062) and participant's Bayley motor composite at baseline (p = .072)emerged as potential confounders based on the results of independent t-tests performed on baseline data in the groups with DS and were also included in the fixed effects for analyses in these groups. Raw ankle counts/min at baseline (p = .076) likewise appeared as a potential confounder and was controlled for in the analyses between the TD cohorts. The purpose of formulating these LMM's was to ascertain the impact of 'tummy time' on each of the dependent variables, motor development, ponderal index and physical activity, given variability within and between participants, in infants with and without DS.

Independent t-Tests for Comparison of 18 Month Waist Data in Infants with and without DS

Considering that at 18 months of age the most accurate method of measuring PA is at the waist (see Method, Procedures, Physical Activity), data collected in this manner, at this time point was not comparable, and therefore, could not be included in the LMM's created for PA measured at the wrist or the ankle. Instead, independent *t*-tests were performed between intervention and non-intervention groups for both TD infants and infants with DS to compare results at the waist for time point 18.

Effect Size of 'Tummy Time' on Outcome Variables in Infants with and without DS

Linear mixed modeling generated trajectories of each of the DV's over the course of the studies, and these trajectories were compared, applying a test of significance, for the 'tummy time' and non-'tummy time groups. Because a test of significance does not readily indicate the magnitude of difference between two measures and because it is difficult to compare a test of significance across studies, a measure of effect size lends additional information to the results of a study (APA, 2001). In this study, the trajectories produced for the historical groups did not reflect as many data points as those created for the intervention groups (seven vs 14), so computation of effect size provided an alternate means of quantifying intervention impact at each common time point. Cohen's *d* is a standard measure of intervention effect that can be calculated from statistical outputs and is independent of sample size (Neill, 2008). Cohen's d was calculated by subtracting the mean of the non-intervention group from the mean of the intervention group and dividing this result by the pooled standard deviation. Cohen (1988) interprets an effect size of greater than or equal to .8 as large, an effect size of .5 to .79 as moderate, and an effect size of .2 to .49 as small. For certain outcome variables

at certain time points, the non-intervention groups demonstrated superior results to the intervention groups. Admitting Cohen's *d* represents an absolute value and thus does not typically appear with a negative value, in the results of this study, time points in which the non-intervention group results surpassed the intervention group results were illustrated using a negative effect size. In this manner, the effect size of the 'tummy time' intervention was reported between the intervention and non-intervention TD groups and between the intervention and non-intervention groups with DS for the common time points, for motor development, PI and PA (wrist and ankle).

Survival Analysis: The Impact of 'Tummy Time' on Eight Motor Milestones in Infants with and without DS

A survival analysis was performed to investigate the effect of 'tummy time' on the achievement of eight hallmark milestones in infants with and without DS. As described by Hosmer et al. (2008), a survival analysis is a set of methods for analyzing data where the outcome variable is the time until the occurrence of an event of interest. In studies two and three, the events of interest were the time to achievement of three fine and five gross motor items on the Bayley-III, determined *a priori*, that are typically attained in the first year of life. The skills of interest were: reaching unilaterally (in sitting), thumb to finger-tip (pincer) grasp, stacking two 1-inch blocks, rolling supine to prone, sitting alone and holding an object, four-point crawling, standing from the floor without support, and walking alone. Observations were considered "censored" when information about their survival time was incomplete. A participant that did not experience the event of interest for the duration of the study, or that dropped out before the end of the study, was considered to be (right) censored. The DV was composed of two parts: one was the time to event and the other was the event status, i.e. did the event

of interest occur or not. The Kaplan-Meier method was used to estimate and graph survival probabilities as a function of time for each of the skills of interest in infants with and without DS. A Mantel-Cox log rank test was used to assess the equality of the two survival curves generated which then allowed for inferences to be made regarding the influence of 'tummy time' on that skill. The hazard function provided information on first achieving the skill as a function of time, which was subsequently referred to as the chance of achieving the skill. The Cox regression model was used to test the chance of achieving the skill (i.e. the hazard function) between the two groups of infants (with DS or TD). In many cases, this exercise served to produce supplemental information on the impact of 'tummy time' on motor development.

Correlation between 'Tummy Time' Minutes and Motor Development in Infants with and without DS

Although the methods of studies two and three did not specifically account for an analysis of 'tummy time' dosage on the dependent variable of motor development, it was hypothesized that those participants that were more adherent to 'tummy time' recommendations would attain higher motor skill development. To assess this premise, a bivariate correlation coefficient between average number of 'tummy time' minutes and Bayley Motor Composite was calculated for each time point for each intervention group (i.e. TD infants and infants with DS). A similar correlation coefficient was also calculated between average number of 'tummy time' minutes and PDMS-II Total Motor Quotient to gauge congruency between the motor instruments. Each correlation coefficient was tested for significance using a one tailed test because, based on the literature, it was presumed that 'tummy time' would not negatively impact a participant's motor development (Kuo et al., 2008; Majnemer & Barr, 2006; Davis et al., 1998; Salls et

al., 2002; Dudek-Schriber & Zelazny, 2007). A one tailed test increased the statistical power of the analysis which was important given the relatively small size of each group. This exercise allowed for general assumptions as to whether engaging in more 'tummy time' yielded superior motor results to be made.

Combined Linear Mixed Model: Was 'Tummy Time' More Impactful in Infants with or without DS?

A large focus of the data analysis process was on the construction of several LMM's to assay the effect of 'tummy time' on each of the outcome variables, in each cohort of infants (i.e. in TD infants and in infants with DS). While these analyses afforded a parsing of 'tummy time' results, they did not provide a means of judging whether the 'tummy time' intervention was more compelling in infants with or without DS. To answer this question, the data were merged into a single data set that included all four groups of infants. An LMM was then generated for each of the outcome variables, controlling for maternal education, siblings, PI at study entry, Bayley Total Motor Composite at study entry, and Raw Ankle Counts/Minute at study entry, that tested the interaction between 'tummy time' and group (DS vs TD). This permitted comparisons of motor development, PI and PA (wrist and ankle) results over the 18 months study period between all four groups under the same contextual parameters.

Missing Data

With 97% of all possible home visits completed, there was not a large amount of missing data for variables measured on site by the author. Missing data were an issue for the physical activity (PA) variable as the collection of this information involved a process that took place after the home visit ended. Problems with missing PA data emerged in both 'tummy time' groups as well as in both historical groups. For example, several

families reported putting the monitors aside after the home visit to put on their infant later and then forgetting to put them on their infant all together. Four monitors fell out in the return process when the mailing envelope was ripped. Four monitors were misplaced by families and not recovered. Parents became frustrated when their infant developed the ability to remove the monitors and had to repeatedly replace them on their infant once discovering they were off. One family requested not to be involved in the PA collection process once her infant could remove the monitors as it became too stressful. In several situations, monitors were returned with little or no wear time recorded in spite of the parent log reflecting 24 hours of wear time. In 16 instances, cleaned and processed PA data were identified as outliers, rechecked for accuracy in reduction, but ultimately removed as not being representative of plausible activity for that infant (see Error Checking below). Missing PA values could have emerged from the wrist or the ankle of any participant at any time point. In sum, there were 63/832 (7.6%) PA values missing from the intervention groups and 79/408 (19.4%) missing from the historical groups. Because of the number of missing values, representative data could not be reasonably imputed using a method based on a parametric model such as regression imputation (Andridge & Little; 2010). Instead, a hot deck imputation method was used which involved manually replacing missing values with values obtained by similar participants.

The hot deck imputation method consists of replacing missing values of a variable with observed values from a donor participant that is similar to the participant with missing data with respect to characteristics observed by both cases (Andridge & Little; 2010). Potential donors were considered a match if similar in gender, siblings (none or one or more) and race (Caucasian or other). Donors were identified separately for the

cohorts with DS and the TD cohorts. The donor was randomly selected from a donor pool of at least five similar participants. If a participant did not have five matches on all three criteria, he or she was matched on gender and siblings. If a participant did not have five matches on those two criteria, he or she was matched on gender alone. This process of randomly selecting donors for missing data was performed five times yielding five distinct data sets. These five data sets were then analyzed using the multiple imputation technique. In this technique, each of the five data sets were analyzed individually and then results were combined, using existing rules for combination (Little & Rubin, 2014), to yield an overall estimate of the PA comparisons between groups. By imputing the missing values multiple times, analyzing individually and then combining results, the uncertainty inherent in the imputed values is more accurately reflected. The results of the multiple imputation analysis of PA data was then compared to the analysis of PA data from complete cases to reveal any bias introduced as a result of certain participants not providing data.

Error Management

A great deal of data was generated in the process of analyzing results related to motor development, body composition and PA in 32 infants for 13 or 14 visits each. Data manipulations included computations (e.g. age in days, PI), scoring of motor assessments, reductions of wrist and ankle PA information, as well as the process of manually entering data into various spreadsheets. The potential for introducing human error into these processes was ever present. In an effort to minimize errors, each step of the data manipulation, entry and presentation process was re-checked, corrected or confirmed by an independent person (author or research assistant). An accountability

record of all reviews performed was maintained. Additionally, because of the arduous nature of the PA reduction process, 10% or 90 cases were randomly selected (using a random number generator) to be re-cleaned, with results either being corrected or confirmed. Finally, PA values that were exceedingly unusual (i.e. outliers) for any given participant at any time point were identified and re-reduced. In this practice, reduction errors were identified and corrected, unusual values were situationally re-evaluated (e.g. participant was sick or sleeping more than usual) and retained, or truly deviant results were removed thereby creating missing data. If data were removed as unfounded, the hot deck imputation method described above was used to replace missing values.

Correlations between the Dependent Variables

In order to appreciate potential interrelationships between the three outcome measures (motor development, PI and PA) a correlation analysis was conducted for each combination of dependent variables (DV), at each time point, for each of the experimental groups. Twenty-eight analyses were performed exploring the relationship between motor development (Bayley-III composite) and PI. Of these 28, only two (7%) were found to have a significant correlation signifying little association between motor development and PI. Of the 26 analyses completed between motor development (Bayley-III composite) and PA (Wrist + Ankle PA act/min), two (8%) were significantly correlated, also indicating minimal connection between these DV's. Five, or 19%, of the 26 analyses between PI and PA (Wrist + Ankle PA act/min) produced significant results. In summary, only nine of a possible 80 (11%) correlation analyses reached statistical significance inferring relative independence amongst the outcome measures.

Spaghetti Plots

Spaghetti plots were constructed using data from five randomly chosen infants in each cohort. This type of graph plots a participant's values for the repeated outcome measure on the vertical axis and time on the horizontal axis. The spaghetti plots depicted intervention compared to non-intervention data for both infants with DS and for TD infants for each of the three dependent variables. The purpose of spaghetti plots was to reveal trends in the data (e.g. groups of infants responding similarly), and to insure reasonable values and sensible collection patterns of repeated-measures data (Swihart et al., 2010). See Figure 3.3 for an example of a spaghetti plot created to illustrate the Bayley Motor Composite over time in infants with DS, comparing intervention to nonintervention groups. The graph emphasizes the high degree of between subject variability. Similar graphs were created for the Bayley Motor Composite in TD infants, as well as for PI and PA in both TD infants and in infants with DS. All six plots exhibited substantial between subject variability affording solid rationale for the decision to utilize linear mixed modelling, which accounts for between and within participant variability, in the analytical approach.

Results

The results of the data analyses broadly supported 'tummy time' as a positive intervention in both TD infants and in infants with DS. The response to 'tummy time' on the outcome variables of motor development and ponderal index (PI) was more compelling than the response on the physical activity (PA) outcome variable in both cohorts of infants. The following subsections detail the findings from each of the analyses performed.

Comparison of Baseline Measures and Demographic Data

Minimal group differences were identified in this comparative process. In fact, maternal education in the TD cohort was the only truly significantly demographic variable difference (p =.011), but maternal education (as an indirect indicator of SES) was already a suspected covariate based on the literature and was controlled for in the analysis in both cohorts. There were no differences in number of siblings between the intervention and non-intervention groups, either with DS or TD. However, this demographic was also a suspected covariate based on the literature and was controlled for in the analysis in both cohorts. Additionally, participant's PI at baseline (p =.062) and participant's Bayley motor composite at baseline (p=.072) emerged as potential confounders based on the results of independent t-tests performed on baseline data in the groups with DS and were also included in the fixed effects for analyses in these groups. Raw ankle counts/min at baseline (p = .076) likewise appeared as a potential confounder and was controlled for in the analyses between the TD cohorts. See table 3.1 for a summary comparison of the demographics of the intervention ('tummy time') groups and the historical (non-intervention) groups at study entry (baseline).

LMM: Influence of 'Tummy Time' on Motor Development in TD Infants

While both cohorts of TD infants demonstrated motor development well above the 50^{th} percentile (i.e. a Bayley motor composite of 100) at study onset, the course of motor development after baseline in the non-intervention group of TD infants was negative, with a slope of -.612 (p = .001). Conversely, the cohort of TD infants participating in 'tummy time' maintained their above average start, and even trended upward albeit not significantly, exhibiting a trajectory with a slope of .409 (p = .111). See Figure 3.4 for a graphical representation of the course of motor development in each group of TD Infants over the 18 month study period.

The difference in slopes between the two motor trajectories was -1.022, and this difference was significant at the 5% level (p = .002). The estimated variance of the random infant intercepts was 50.09 (p = .002), and the estimate of the residual (within-infant) variance was 88.83 (p < .001) suggesting a significant amount of unexplained between and within-infant variability for motor development. These results indicate that in spite of variation among participants, 'tummy time' did have a statistically significant positive impact on the motor development of TD infants.

LMM: Influence of 'Tummy Time' on Motor Development in Infants with DS

The course of motor development in both cohorts of infants with DS became increasingly delayed over time. That being said, the downward slope of motor development in the first 18 months of life in the infants with DS participating in 'tummy time' was significantly less steep than the downward slope for infants not participating in 'tummy time.' See Figure 3.5 for a graphical representation of the course of motor development in each group of infants with DS. The slope of the line depicting 18 months of motor development in infants with DS not engaging in 'tummy time' was -1.76 (p <.001) and the slope for infants with DS engaging in 'tummy time' was -.90 (p < .001). The difference in slopes between these two motor trajectories was -.86, and this difference was significant at the 5% level (p =.031). The estimated variance of the random infant intercepts was 52.77 (p = .008) and the estimate of the residual (within-infant variance) was 87.83 (p <.001), suggesting a significant amount of unexplained between and within-infant variability for motor development in infants with DS. These results indicate that variation among participants notwithstanding, 'tummy time' did have a statistically significant positive impact, by reducing the degree of decline over time, on the motor development of infants with DS.

LMM: Influence of 'Tummy Time' on Ponderal Index in TD Infants

For ponderal index (PI), lower values indicate lower body fatness and a lower risk of obesity related disease (Wells et al., 2007). It was therefore positive to see trajectories with a downward slope for this outcome variable. See Figure 3.6 for an illustration of how PI changed over the first 18 months of life in each of the TD cohorts. The slope for the non-intervention cohort of TD infants was -.247 (p <.001) and the slope for the TD infants participating in the 'tummy time' intervention was -.398 (p <.001). The difference between the two PI trajectories was .151, and this difference in slopes was significant at the 5% level (p =.030). The estimated variance of the random infant intercepts was 2.10 (p =.001) and the estimate of the residual (within-infant variance) was 3.39 (p <.001) suggesting a significant amount of unexplained between and within-infant variability for PI in TD infants. These results indicate that in spite of the variation among participants, 'tummy time' did have a statistically significant positive influence on PI in TD infants in the first 18 months of life.

LMM: Influence of 'Tummy Time' on Ponderal index in Infants with DS

Both groups of infants with DS, those participating in 'tummy time' and those not, demonstrated the desirable downward trend in PI over the course of study. The slope of the trajectory for infants with DS participating in 'tummy time' was -.212 (p <.001) and the slope for the non-intervention group with DS was -.300 (p <.001). See Figure 3.7 for a representation of the changes in PI over the first 18 months of life in both groups with DS. Interestingly, the infants with DS in the non-intervention group demonstrated a slightly greater decrease in PI than the infants with DS in the 'tummy time' group (-.088, p =.154), although this difference was not statistically significant. The estimated variance of the random infant intercepts was 2.34 (p =.003) and the estimate of the residual (within-infant variance) was 1.79 (p <.001) suggesting the

same significant amount of unexplained between and within-infant variability among participants for infants with DS in terms of their PI. Although both groups of infants exhibited significant positive change in PI over time, these results do not support a significant positive influence of 'tummy time' for this outcome variable in infants with DS in the first 18 months of life.

LMM: Influence of 'Tummy Time' on Physical Activity in TD Infants

Physical activity (PA), as measured by actigraphy at the wrist and ankle in raw counts per minute, increased over the 18 month (12 months for wrist) period after baseline in TD infants in the intervention and non-intervention groups. The slope of the line for wrist raw counts per minute versus time in TD infants participating in 'tummy time' was 37.94 (p < .001) and the slope for the non- 'tummy time' TD group was 34.38 (p = .028). The slope of the line for ankle raw counts per minute versus time in TD infants participating in 'tummy time' was 47.13 (p <.001) and was 48.86 (p <.001) for TD infants not participating in 'tummy time.' See Figure 3.8 for an illustration of the changes in PA over the 18 month study period in both TD groups. The difference in trajectories between the intervention and non-intervention groups was not significant at the wrist (3.56, p = .841) or at the ankle (-1.73, p = .850). The estimated variance of the random infant intercepts was 30,419.03 (p = .056) at the wrist and 21,623.79 (p = .010) at the ankle. The estimate of the residual (within-infant variance) was 119,815.62 (p < .001) at the wrist and 71,305.15 (p < .001) at the ankle suggesting the same significant amount of unexplained between and within-infant variability for PA as in motor development and PI. Although both groups of infants exhibited increased PA over time, these results do not support a significant positive influence of 'tummy time' for this outcome variable in TD infants during the first 18 months.

Due to the relatively large amount of missing PA data in both groups of TD infants, the previously described hot deck imputation of missing values and analysis using the multiple imputation technique (Method, Data Analysis, Missing Values) was conducted as an additional sensitivity analysis. This analysis provided a means of monitoring if bias had been introduced by certain participants not providing PA data. An analogous LMM was fitted to each of the imputed PA data sets, for PA as measured at the wrist and for PA as measured at the ankle, and results for each of these five models were combined to form a final overall set. The results from the hot deck imputation of missing values and multiple imputation analysis were very similar to the results generated using only the complete data sets for this variable, indicating that bias was not introduced into the analysis by discarding the missing data. See Table 3.2 (Comparison of Complete Data Set Results with Results from Multiple Imputation Procedures for PA Data at the Wrist and Ankle in Infants with and without DS) for a summary of the similarities in PA results obtained using only complete data and results obtained with missing PA data imputed.

LMM: Influence of 'Tummy Time' on Physical Activity in Infants with DS

Physical activity (PA), as measured by actigraphy at the wrist and ankle in raw counts per minute, increased significantly over the 18 month (12 months for wrist) period after baseline in infants with DS in both the 'tummy time' and non- 'tummy time' groups. The slope of the line for wrist raw counts per minute versus time in infants with DS participating in 'tummy time' was $30.11 \ (p = .001)$ and the slope for the non- 'tummy time' group with DS was $33.56 \ (p = .050)$. The slope of the line for ankle raw counts per minute versus time in infants with DS participating in 'tummy time' was $14.00 \ (p = .027)$ and was $29.77 \ (p = .001)$ for infants with DS not participating in 'tummy time.' See Figure 3.9 for an illustration of the changes in PA for 18 months in both groups with DS.

The difference in PA trajectory between the intervention and non-intervention groups was not significant at the wrist (-3.44, p =.856) or at the ankle (-15.77, p =.145). The estimated variance of the random infant intercepts was 43,553.22 (p =.007) at the wrist and 34, 416.14 (p =.006) at the ankle. The estimate of the residual (within-infant variance) was 83,653.42 (p <.001) at the wrist and 82,622.69 (p <.001) at the ankle suggesting a similar significant amount of unexplained between and within-infant variability for PA as in motor development and PI in infants with DS. Although both groups of infants exhibited increased PA over time, these results do not support a significant positive influence of 'tummy time' for this outcome variable in infants with DS in the first 18 months.

A follow up sensitivity analysis was similarly conducted for the PA variable in the cohorts of infants with DS, also because of the relatively large amount of missing data in these groups. Missing PA values for the wrist and ankle were imputed using the hot deck technique previously described. Comparing the results for the LMM constructed from the complete PA data sets with the results from the imputed data sets revealed minimal bias in the analysis results due to certain babies failing to contribute data. There was a discrepancy in one out of seven parameters compared in the wrist PA data, and in none of the seven parameters compared in the ankle PA data, where the results from the complete PA data set differed from the results of the imputed data set (see Table 3.2).

Independent *t*-Tests for Comparison of 18 Month Waist PA Data in Infants with and without DS

PA data collected at the waist at time point 18 in infants in all four groups also failed to corroborate benefits of 'tummy time' on PA. Results of the independent *t*-tests done to compare waist data in infants with and without DS at Time 18 can be found in Table 3.3.

When comparing the percentage of time spent in moderate to vigorous physical activity (MVPA) at 18 months of age, there was no significant effect of 'tummy time' in TD infants (p =.727) or in infants with DS (p =.678). Furthermore, there was no significant influence of 'tummy time' on percentage of time spent in sedentary activity at 18 months of age in TD infants (p =.067) or in infants with DS (p =.436). Of particular concern was the high percentage of time spent in sedentary activity and the low percentage of time spent in MVPA by all four groups, regardless of intervention status or diagnosis. Curiously, when comparing participants by condition (i.e. TD vs DS) instead of by intervention status, the infants with DS had a two percent higher percentage of time spent in MVPA than TD infants (p =.137) and a similar percentage of time spent in sedentary activity as TD infants (p =.534). Based on the methods used to determine PA in this project, this suggested that there was no significant consequence of having a diagnosis of DS on PA at 18 months of age.

Effect Size (d) of 'Tummy Time' on Motor Development, PI and PA in TD Infants

The effect size was computed to explore the difference between the 'tummy time' and non-'tummy time' TD groups at each of the common time points (i.e. baseline, time one, time two, time three, time four, time 11 and time 18) for the motor development, PI and PA outcome variables. 'Tummy time' generated a very large effect in TD infants for both motor development and ponderal index (PI), but was less impactful for physical activity (PA). See Figure 3.10 for a graphical representation of effect size (Cohen's *d*) on each outcome variable at time points common to both the intervention and the non-intervention TD groups.

A large effect of 'tummy time' participation on motor development (Bayley motor composite) was realized by month three (d = .94) after study entry for TD infants. Cohen's d remained large through time 18 when it had increased to 2.07. 'Tummy time' was similarly

impactful on PI, producing a large effect size by month two (d = .92). Cohen's d for PI continued to increase over the remainder of the study, reaching 3.15 at time 11 and declining only slightly to 2.51 at time 18.

The effect of 'tummy time' on PA did not appear to be as meaningful. The effect size as measured at the wrist (counts/minute) did not follow a clear pattern as it decreased from baseline through time two, peaked at .81 at time three, and then decreased again through time 11 (no time 18 data was generated at the wrist). For PA as measured at the ankle (counts/minute), the intervention group started off with less raw counts at baseline (d = -.61); and, the effect size became increasingly negative over the course of the study, measuring -1.42 at time 11 and at time 18.

Effect Size (d) of 'Tummy Time' on Motor Development, PI and PA in Infants with DS

In general, 'tummy time' elicited a positive effect in infants with DS for each of the outcomes variables. See Figure 3.11 for a graphical representation of effect size (Cohen's *d*) on each outcome variable at time points common to both groups (i.e. baseline, time one, time two, time three, time four, time 11 and time 18).

'Tummy time' generated the largest effect on motor development in infants with DS. Infants in the intervention group actually entered the study with slightly lower motor skills (d = .76) than the infants with DS in the non-intervention group, but a moderate effect (.71) was observed by month three after study entry and a large effect (d = .80) was produced by month four. The effect size (d) on motor development continued to increase over the course of the study, reaching almost two by time 18 (d = 1.92).

The effect of 'tummy time' in infants with DS was less pronounced for PI. Infants with DS in the 'tummy time' group exhibited a better PI (d = .74) at study entry. None the less, the

effect size for 'tummy time' on PI increased over time until time 18, with large effect sizes observed at time two (d = .93), three (d = .99), four (d = 1.17) and 11 (d = .95). By time 18, the effect size for 'tummy time' on PI had decreased to .43.

'Tummy time' precipitated a positive effect on PA, as measured at both the wrist and the ankle, in the months immediately following study entry, and then its impact lessened over the remainder of the study. The effect size of 'tummy time' peaked at time two (d = .79) for PA measured at the wrist and then diminished to .12 by time 12 (no PA at the wrist was measured for time 18). The effect of 'tummy time' as measured at the ankle also peaked at time two (d = .99), remained large at time three (d = .83), declined to zero (d = .07) by time four and remained as such through time 18.

Survival Analysis: Unilateral Reaching in Infants with and without DS

'Tummy time' significantly affected the time to achieve unilateral reaching in both TD infants and in infants with DS. This analysis created and considered survival curves depicting the time in days it took participants in each of the four groups to achieve reaching for an object using a single hand more often than using both hands when in a seated position (Bayley, 2006). See Figure 3.12 for illustrations of the survival curves in both cohorts of infants.

The Mantel-Cox chi-square value testing the equality of the survival curves in the intervention and non-intervention TD infants was 16.21 (p < .001) implying that 'tummy time' did significantly impact the ability to reach with one hand. Additionally, based on the fitted Cox models, the likelihood of TD infants engaging in 'tummy time' achieving unilateral reaching was 4.01 (p < .001) times greater (95% Confidence Intervals (CI) 1.95, 8.57) at any time point than TD infants not engaging in 'tummy time'.

In infants with DS, the Mantel-Cox chi-square value was 10.25 (p = .001), also suggesting that 'tummy time' significantly influenced the ability to preferentially reach with one hand while seated. The likelihood, as determined by Cox Regression, of infants with DS participating in 'tummy time' achieving unilateral reaching was 6.38 (p = .004) times greater (95% CI 1.79, 22.73) at any time point than infants with DS not engaging in 'tummy time.'

Survival Analysis: Pincer Grasp in Infants with and without DS

'Tummy time' significantly affected the time to achieve a pincer grasp in both TD infants and in infants with DS. This analysis created and considered survival curves depicting the time in days it took participants in each of the four groups to achieve a thumb to finger-tip grasp to pick up a cheerio when in a seated position (Bayley, 2006). See Figure 3.13 for illustrations of the survival curves in both cohorts of infants.

The Mantel-Cox chi-square value testing the equality of the survival curves in the intervention and non-intervention TD infants was $54.28 \ (p < .001)$ inferring that 'tummy time' did significantly impact the ability to use a thumb-fingertip grasp. While the survival curves for the 'tummy time' and non- 'tummy time' groups were significantly different, there was not enough variation of age in days for skill achievement in either group to compute a reasonable hazard (likelihood) function. The lack of variation is illustrated by the curves for both groups having a similar shape. The difference was that most TD babies in 'tummy time' group achieved a pincer grasp at approximately 300 days, and the majority of TD babies in the non- 'tummy time' group achieved a pincer grasp at roughly 385 days.

In infants with DS, the Mantel-Cox chi-square value was 5.56 (p = .018) also intimating that 'tummy time' significantly influenced the ability to use a thumb-fingertip grasp to pick up small objects. The likelihood, as determined by Cox Regression, of infants with DS participating

in 'tummy time' achieving a pincer grasp was 4.11 (p = .030) times greater (95% CI 1.15, 14.68) at any time point than infants with DS not engaging in 'tummy time.'

Survival Analysis: Stacking two 1-inch Blocks in Infants with and without DS

'Tummy time' significantly affected the time to achieve stacking two 1-inch blocks in both TD infants and in infants with DS. This analysis created and considered survival curves depicting the time in days it took participants in each of the four groups to build a stable stack of two or more 1-inch blocks while in a seated position (Bayley, 2006). See Figure 3.14 for illustrations of the survival curves in both cohorts of infants.

The Mantel-Cox chi-square value testing the equality of the survival curves in the intervention and non-intervention TD infants was 22.85 (p <.001) implying that 'tummy time' significantly altered the time to achieve the ability to build a stable stack of two 1-inch blocks. Likewise, the likelihood of TD infants engaging in 'tummy time' building a stable stack of two 1-inch blocks was 7.34 (p<.001) times greater (95% CI 2.91, 18.54) at any time point than TD infants not engaging in 'tummy time'.

In infants with DS, the Mantel-Cox chi-square value was 3.97 (p = .046) asserting that 'tummy time' significantly influenced the ability to stack two 1-inch blocks in this cohort as well. Although the survival curves between the intervention and non-intervention groups were significantly different, the hazard function, as determined by Cox Regression, was only marginally significant (p = .082) for the skill of stacking of two 1-inch blocks. So for stacking two 1-inch blocks, there was only weak evidence in favor of the 'tummy time' intervention.

Survival Analysis: Rolling from Supine to Prone in Infants with and without DS

'Tummy time' significantly affected the time to achieve rolling from supine to prone in infants with DS but not in TD infants. This analysis created and considered survival curves

depicting the time in days it took participants in each of the four groups to roll from back to stomach (Bayley, 2006). See Figure 3.15 for illustrations of the survival curves in both cohorts of infants.

The Mantel-Cox chi-square value testing the equality of the survival curves in the intervention and non-intervention TD infants was $1.50 \ (p = .221)$ indicating that the curves were not significantly different for the two groups. Participation in 'tummy time' did not impact the time to achieve rolling from supine to prone in TD infants.

However, for infants with DS, the Mantel-Cox chi-square value was $4.10 \ (p = .043)$ indicating a significant result from 'tummy time' participation on the ability to roll from back to front. The likelihood, as determined by Cox Regression, of infants with DS participating in 'tummy time' rolling back to stomach was $2.75 \ (p = .052)$ times greater (95% CI .993, 7.620) at any time point than infants with DS not engaging in 'tummy time.'

Survival Analysis: Sitting and Holding an Object in Infants with and without DS

'Tummy time' significantly affected the time to achieve independent sitting while holding an object in both TD infants and in infants with DS. This analysis created and considered survival curves depicting the time in days it took participants in each of the four groups to sit independently for at least 60 seconds while manipulating an object (Bayley, 2006). See Figure 3.16 for illustrations of the survival curves in both cohorts of infants.

The Mantel-Cox chi-square value testing the equality of the survival curves in the intervention and non-intervention TD infants was $8.44 \ (p = .004)$ suggesting a positive influence of 'tummy time' on the ability to sit. Additionally, the likelihood of TD infants engaging in 'tummy time' sitting independently for at least 60 seconds while manipulating an object was

2.92 (p = .006) times greater (95% CI 1.36, 6.26) at any time point than TD infants not engaging in 'tummy time'.

In infants with DS, the Mantel-Cox chi-square value was $23.27 \ (p < .001)$ creating a similar argument for 'tummy time' positively contributing to the ability to sit independently in this group. While the survival curves for the 'tummy time' and non- 'tummy time' groups were significantly different, there was not enough variation in the age in days of skill achievement in either group to compute a reasonable hazard function. The lack of variation is illustrated by the curves for both groups having a similar shape. The difference was that most babies with DS in the 'tummy time' group achieved independent sitting and holding an object at approximately 310 days, while the majority of babies with DS in the non- 'tummy time' group achieved the same skill at roughly 385 days.

Survival Analysis: 4-point Crawling in Infants with and without DS

'Tummy time' significantly affected the time to achieve 4-point crawling in TD infants but not in infants with DS. This analysis created and considered survival curves depicting the time in days it took participants in each of the four groups to make at least five feet of forward progress by crawling on hands and knees (Bayley, 2006). See Figure 3.17 for illustrations of the survival curves in both cohorts of infants.

The Mantel-Cox chi-square value testing the equality of the survival curves in the intervention and non-intervention TD infants was 36.44~(p < .001) illustrating again the positive influence of 'tummy time' on this skill. Additionally, the likelihood of TD infants engaging in 'tummy time' achieving the ability to 4-point crawl at least five feet forward was 30.46~(p < .001) times greater (95% CI 6.39, 145.21) at any time point than TD infants not engaging in 'tummy time'.

In infants with DS, the Mantel-Cox chi-square value was 1.38 (p =.239). This indicates that the curves for achievement of 4-point crawling were not significantly different in infants with DS as a result of participating in 'tummy time.'

Survival Analysis: Stands Up from the Floor in Infants with and without DS

'Tummy time' significantly affected the time to achieve the ability to stand from the floor independently in TD infants but not in infants with DS. This analysis created and considered survival curves depicting the time in days it took participants in each of the four groups to come to a standing position, from back lying (supine), without using support (Bayley, 2006). See Figure 3.18 for illustrations of the survival curves in both cohorts of infants.

The Mantel-Cox chi-square value testing the equality of the survival curves in the intervention and non-intervention TD infants was 20.48~(p < .001) implying that 'tummy time' significantly impacted the ability to stand from the floor unsupported. The likelihood of TD infants engaging in 'tummy time' achieving the ability to stand from the floor independently was 5.19~(p < .001) times greater (95% CI 2.36, 11.41) at any time point than TD infants not engaging in 'tummy time'.

In infants with DS, the Mantel-Cox chi-square value was .451 (p =.502). This indicates that the curves for achievement of standing from the floor independently were not significantly different in infants with DS as a result of participating in 'tummy time.'

Survival Analysis: Walks Alone in Infants with and without DS

'Tummy time' significantly affected the time to achieve the ability to walk alone in TD infants but not in infants with DS. This analysis created and considered survival curves depicting the time in days it took participants in each of the four groups to take at least three

steps without support, once placed in a standing position (Bayley, 2006). See Figure 3.19 for illustrations of the survival curves in both cohorts of infants.

The Mantel-Cox chi-square value testing the equality of the survival curves in the intervention and non-intervention TD infants was $12.09 \ (p = .001)$ lending further support for 'tummy time' as a positive influence on motor development in this cohort. Likewise, the probability of TD infants engaging in 'tummy time' achieving the ability to take at least three independent steps was $3.42 \ (p = .001)$ times greater (95% CI 1.62, 7.18) at any time point than TD infants not engaging in 'tummy time'.

In infants with DS, the Mantel-Cox chi-square value was .356 (p =.551). This indicates that the curves for achievement of taking at least three steps independently were not significantly different in infants with DS as a result of participating in 'tummy time.'

Correlation between 'Tummy Time' Minutes and Motor Development in TD Infants

'Tummy time' minutes performed were significantly correlated with motor development as measured by the total motor composite/total motor quotient on the Bayley- III and the PDMS- II in TD infants during the first six months of intervention. See Figure 3.20 for a graphical representation of how 'tummy time' minutes correlated with motor development on both instruments over the nine months of active 'tummy time' participation in TD infants.

The correlation between 'tummy time' and motor development was statistically significant (one-tailed p) for time points two, four, five and six after baseline, for motor development determined by one or both motor assessments.

Correlation between 'Tummy Time' Minutes and Motor Development in Infants with DS

The correlation between 'tummy time' minutes and motor development was not as discernable in infants with DS as it was in TD infants. 'Tummy time' minutes were only

correlated with motor development in the early months of the intervention for infants with DS. See Figure 3.21 for an illustration of how 'tummy time' minutes correlated with motor development on both the PDMS-II and the Bayley-III over 12 months of active 'tummy time' participation in infants with DS.

The correlation between 'tummy time' and motor development was statistically significant (one-tailed p) for time points two, three and four after baseline, for motor development as determined by one or both assessments. Remarkably, the correlation between 'tummy time' minutes and motor development decreased dramatically in infants with DS, and even became negative, after six months of participation in the intervention.

Combined Linear Mixed Model: Was 'Tummy Time' More Impactful in Infants with or without DS?

The combined LMM examined the impact of 'tummy time' in all four groups on motor development, PI and PA (wrist and ankle) using a unified model that included the same fixed effects for all participants. The TD, non-intervention group was used as the reference group in the model. The results allowed quantification of 'tummy time' benefits, if any, for each outcome between the TD groups compared to the groups with DS.

For motor development, the reference group experienced a decrease of .66 (p =.001), in Bayley motor composite score every month after study entry. The TD intervention group, however, experienced a .36 increase in Bayley motor composite score every month after baseline. This represented a positive difference of 1.02 (p=.003) in the expected increase in monthly Bayley motor composite score in the 'tummy time' TD group. Both groups with DS displayed decreases in Bayley motor composite over the course of the study. The non-intervention group with DS decreased 2.19 in Bayley motor composite score each month after baseline, a difference of -1.53 (p <.001) from the reference group. The 'tummy time' group with

DS experienced a decrease of 1.24 in Bayley motor composite each month, a difference of -.58 (p = .054) from the reference group. Accordingly, 'tummy time' improved the Bayley motor composite by 1.02 in TD infants and by .95 in infants with DS each month after study entry.

All groups decreased in PI, over the course of the 18 month study. Recall that this is a desired outcome for this variable. The reference group decreased .27 (p <.001) in PI each month. In this model that included all possible covariates including PI at baseline, the TD infants engaging in 'tummy time' decreased .28 in PI each month, just .01 (p =.813) more than the reference group. Infants with DS in the non-intervention group decreased .33 in PI each month, .06 (p =.371) more than the reference group. Infants with DS in the 'tummy time' group decreased .24 in PI each month, .03 (p =.597) less than the reference group and .09 less than the infants with DS not doing 'tummy time.' Although all four groups displayed similar decreases in PI in this combined model, the TD group participating in 'tummy time' improved marginally more than the non-intervention TD group, while the infants with DS engaging in 'tummy time' did not improve in PI compared to infants with DS not engaging in 'tummy time.'

All groups increased in wrist raw counts per minute over the first 12 months of the study. Recall that no data was collected at time 18 at the wrist. The reference group increased 30.15 counts per minute at the wrist every month (p = .035). TD infants engaging in 'tummy time' increased 42.08 counts per minute every month, 11.94 counts per minute more (p = .509) more than the reference group. Infants with DS in the non-intervention group increased 33.54 counts per minute per month, just 3.4 counts per minute more (p = .869) than the reference group. Infants with DS participating in 'tummy time' increased 34.32 counts per minute each month, 4.2 counts per minute more (p = .804) than the reference group. While all four groups increased analogously in wrist raw counts per minute each month, TD infants engaging in 'tummy time'

increased by 12 counts per minute and infants with DS engaging in 'tummy time' increased by 1.2 counts per minute more than their non-intervention counter-parts.

All groups increased in ankle raw counts per minute over the 18 month study period, but the participants in the reference group increased their ankle raw counts per minute the most each month. The reference group increased 49.29 (p <.001) counts per minute at the ankle every month. TD infants doing 'tummy time' only increased 36.63 counts per minute each month, 12.66 counts per minute less (p=.211) than the reference group. Infants with DS in the 'tummy time' group increased their ankle counts by 12.36 per minute each month, 36.93 counts per minute less (p <.001) than the reference group. Infants with DS in the non-intervention group increased their ankle counts per minute by 23.50 each month, 25.79 less per minute than the reference group (p=.034). Because both intervention groups failed to increase ankle counts per minute as much as their non-intervention analogue, it can only be established in this comparison that 'tummy time' was not impactful at all on this variable in this model.

Based solely on the sizes of positive slope difference between TD infants and infants with DS and their comparable non-intervention group, 'tummy time' appeared to be marginally more impactful in TD infants than in infants with DS for motor development, PI and PA as measured at the wrist. 'Tummy time' was not impactful for either TD infants or infants with DS for PA as measured at the ankle.

Discussion

The purpose of studies two and three was to explore the influence of a structured, daily 'tummy time' intervention on motor development, ponderal index (PI) and physical activity (PA) in infants with and without DS. The applied analytical procedures provided for an inspection of the impact of 'tummy time' on each of the outcome variables, as well as for a more detailed

examination of motor development in each cohort of infants. Several of the hypotheses were supported. It has been established, by LMM, by effect size (*d*) at given time points, or by both, that engaging in 'tummy time' stimulates motor development and PI in infants with and without DS. Survival analysis affirmed the advantage of 'tummy time' on certain key motor milestones for infants in both intervention groups. A significant benevolent consequence of the 'tummy time' intervention on PA, however, could not be confirmed in either group of infants in the first 18 months of life. An advantage of 'tummy time' participation on the outcome variables, in one cohort over (i.e. in TD infants vs. infants with DS) the other was not readily apparent from the results of the collective LMM, but these results considered in concert with other findings from the project allowed for conclusions to be drawn.

The high degree of within group variability as well as the pathophysiology of DS were two possible reasons it was difficult to determine if 'tummy time' impacted PA levels in either cohort of infants, and if 'tummy time' was more compelling in TD infants or in infants with DS. As confirmed by the estimated variance of the random intercepts in each of the constructed LMM's, infant participants in the study, both with and without DS, presented with a significant degree of between baby differences for all outcome measures. By virtue of the many intrinsic and extrinsic determinants of infant achievement, this level of inter-baby variation was anticipated. Such determinants might include how clean and safe the floor is for 'tummy time,' family perceptions on the importance of being physically active, how much weight the baby has to move around given his or her strength, or how curious he or she is about exploring the surrounding environment. For infants with DS, these same factors contribute to infant variability, but there are complications associated with a diagnosis of DS that augment fluctuation in skill presentation and performance. Systemic difficulties common in infants with

DS include congenital heart disease, hearing and/or vision deficits, obesity and low fitness, hypothyroidism (Roizen & Patterson, 2003), as well as reduced strength (Vicari, 2006), problems with postural control and balance (Shumway-Cook & Woollacott, 1985), increased time required to learn complex skills (Palisano et al., 2001), perceptual motor deficits (Meegan et al., 2006), slow reaction times during movement (Harris & Shea, 1991), intellectual disability (Vicari, 2006), and low motivation (Vicari, 2006). This study was interested in the impact of the 'tummy time' intervention under real world circumstances. In the real world, infant achievement is multi-faceted so creating homogeneous groups for ideal comparative purposes was neither practical nor possible. Infants in the DS groups were not excluded because they required corrective heart surgery during the first year of life, if they had club feet, if they had hearing and/or vision impairments, or if they were premature. For an intervention to be deemed effective in infants with or without DS, it must be effective in spite of the heterogeneity in infant presentation. The subsections that follow deliberate study findings in greater detail as they had pervasive implications not only for the stated outcome variables, but also for infant and child development, health and participation.

'Tummy Time' and Motor Development in Infants with and without DS

Motor development was the most influential variable of the 'tummy time' study and hence received the most attention in the analysis. The ability to move, as established in the introduction of this work, has widespread developmental implications. The impact of self-produced locomotion on infant competencies such as spatial cognitive performance (Yan et al., 1998), social communicative behaviors (Gustafson, 1984), and brain development (Kolb et al., 1998; Chugani, 1998) have been endorsed in the literature for many years. Correspondingly, the

provocative influence of 'tummy time' on motor development was very important for infants with and without DS.

'Tummy time' significantly impacted the motor developmental trajectory in TD infants. The LMM for motor development illustrated that while both TD groups entered the study well above the average motor composite, infants in the 'tummy time' group maintained their above average trajectory while TD infants not engaging in 'tummy time' demonstrated a downward course back towards the 50th percentile over the 18 month study period (see Figure 3.4). The above average results in both groups at baseline, month 1 and month 2 likely reflected the simplicity of motor skills to be achieved early in life. Additionally, families in both groups were highly educated, upwardly mobile, resourced and motivated which probably contributed to above average achievement initially. Over and above performance in the early months, the core finding of the LMM for motor development in TD infants was that participation in 'tummy time' significantly enhanced the trajectory for this outcome variable.

A comparison of effect size (d) at the time points common to the intervention and non-intervention group corroborated the importance of engaging in 'tummy time' for motor development in TD infants. An effect of 'tummy time' was not observed at baseline, time 1 or time 2 when both groups were demonstrating above average motor skills. By time 3, continuing through time 4, time 11 and time 18, a large effect $(d \ge 8)$ on motor development in TD infants was exhibited, validating the importance of 'tummy time' participation (see Figure 3.10).

The interpretations of the eight survival analyses added substantiation to the positive influence of 'tummy time' on motor development in TD infants. For all three of the fine motor and for four out of five of the gross motor milestones tested, TD infants engaging in 'tummy time' achieved the milestones significantly earlier than their non-intervention complements (see

Figures 3.12 through 3.19). TD infants engaging in 'tummy time' achieved reaching unilaterally, a pincer grasp to pick up small objects, stacking two 1-inch blocks, sitting alone and holding an object, four point crawling, standing from the floor without support and walking alone significantly earlier than TD infants not participating in 'tummy time.' The only milestone not impacted by 'tummy time' in TD infants was rolling supine to prone, a skill expected to occur earlier in the intervention period. This was a skill expected to be impacted by 'tummy time' participation because of the congruence of the two tasks. It was conceivable, however, that the complexity of rolling from back to tummy was not sufficient for differentiation in time of attainment to be noted between the TD groups.

Determination of optimal 'tummy time' dosage was not an objective of this project. That being said, by computing the bivariate correlation coefficient between average number of 'tummy time' minutes performed and motor composite, as determined by the Bayley-III and the PDMS-II, for each time point in which the TD infants were actively engaged in 'tummy time' (see Figure 3.20), it could be established that TD infants doing more 'tummy time' exhibited higher motor scores on one or both instruments. This correlation held true for time points two, four, five and six in TD infants. After time six, most of the infants in the TD cohort were able to transition in and out of the sitting position independently and had thus skilled out of the caregiver imposed intervention. Infants still engaging in 'tummy time' after time six were behind the rest of the group in their motor development. Thus, it was not remarkable that a positive correlation between 'tummy time' minutes and motor development was not observed after time six.

Moreover, it could have been that infants still engaging in 'tummy time' after time six were doing less minutes and consequently had not yet skilled out of the intervention. The relevant finding from this analysis was that during months two through six, doing more 'tummy time'

was associated with higher motor skill development, confirming earlier work done by Kuo et al. (2008). A specific 'tummy time' dosage requirement could not be determined for meeting motor milestones on time given the methods of this study. Be that as it may, TD infants averaged 51 to 73 minutes of deliberate 'tummy time' daily in months two through six after study entry, suggesting that future recommendations in this realm are both realistic for families and productive for motor development.

'Tummy time' also significantly impacted motor development in infants with DS. The LMM for motor development illustrated that while both groups with DS exhibited downward trends in motor development over the 18 month study period, the slope of the line representing motor development in the 'tummy time' group was significantly less steep than the slope for the non-intervention group. In other words, 'tummy time' participation kept infants with DS from declining as rapidly in their motor development over the study period (see Figure 3.5). Recall that the scores for motor development, both on the Bayley-III and on the PDMS-II, were norm referenced from a large sample of TD infants. It was of interest to note, that like both groups of TD infants, both groups of infants with DS entered the study at approximately the 50th percentile for TD babies and demonstrated above average motor performance in months one and two after study entry. Again, this finding could be a reflection of the relatively low complexity level of early motor skills, as well as of the high education, level of resources and motivation of those that volunteer to take part in research studies. Infants with DS engaging in 'tummy time' began to distinguish themselves from their non-intervention peers at month three after baseline. The LMM depicted a significantly widening gap in motor development between the groups from time three through time 18 for infants with DS.

A comparison of effect size (d) at the time points common to the intervention and non-intervention group corroborated the importance of engaging in 'tummy time' for motor development in infants with DS. Infants with DS in the intervention group entered the study with slightly lower motor skill development than the non-intervention group and both groups were relatively high performing early, thus an effect of 'tummy time' was not observed at baseline, time one or time two (see Figure 3.11). This was similar to effect size findings for motor development in the TD groups. By three months after study entry, 'tummy time' was generating a moderate effect (d=.71) on motor development for infants with DS. A large intervention effect (d>=.8) was noted at time four, 11, and 18, substantiating the importance of 'tummy time' participation on motor development in infants with DS.

The findings from the motor milestone survival analyses were not as obvious for infants with DS as they were for TD infants. Infants with DS in the intervention group achieved all three fine motor skills (unilateral reaching, pincer grasp and stacking blocks) significantly earlier than infants with DS in the non-intervention groups (see Figures 3.12 through 3.14). Likewise, 'tummy time' had a significant influence on the time to achieve rolling from supine to prone and the time to achieve sitting without support while holding an object (see Figures 3.15 and 3.16). While the LMM delineated a widening gap in motor development in infants with DS not participating in 'tummy time' (see Figure 3.5) and the effect (*d*) of 'tummy time' at time 11 and 18 for motor development was large (see Figure 3.11), the survival analyses for four point crawling, standing from the floor without support, and walking alone do not support a significant influence of 'tummy time' on these specific skills (see Figures 3.17-3.19). One reason for this could have been the fact that the LMM's and computed effect sizes (d) reflected all the skills measured on the motor assessment instrument while the survival analysis tested time to

achievement for the skill in question only. Another reason for the analytical differences in motor findings could have been that the survival curves included babies that had dropped out (one in the 'tummy time' group) as well as babies that were excluded from the final 18 month visit because they were not yet 18 months of age when the study ended (four in the 'tummy time' group). The comparison group with DS only had nine infants in it at any time point. Larger groups, especially at the 18 months, would have yielded more robust survival curves. Survival curves aside, 13/14 infants with DS still active in the 'tummy time' group were able to 4-point crawl at 18 months of age compared to five out of nine infants with DS in the comparison group. Five out of 14 infants with DS in the 'tummy time' group were able to stand independently from the floor at 18 months of age compared to two out of nine in the comparison group. Five out of 14 infants with DS in the 'tummy time' group were able to walk independently at 18 months of age compared to three out of nine in the historical group. Furthermore, four point crawling, standing from the floor without support and walking alone are complex skills that require higher levels of motor control and coordination than what is developed through 'tummy time' participation alone. Infants with DS surely had trouble generalizing skills gained through 'tummy time' to skills such as four-point crawling, standing alone and walking due to their inherent learning struggles. Finally, by the time infants with DS in both groups were pursuing success in these more complex skills, many of the infants in the intervention group had already skilled out of imposed 'tummy time' leading to more congruity in motor development efforts between the groups later in the study period. In other words, at this point in the study the motor guidance being received by the intervention and non-intervention groups was similar.

The correlation between 'tummy time' minutes and motor development over time was also more complicated in infants with DS. A statistically significant (one-tailed *p*) correlation

was only observed for time points two, three and four after baseline, as determined by one or both motor assessments (see Figure 3.21). Of initial concern was the dramatic decrease in the correlation between 'tummy time' minutes and motor development in infants with DS beginning at six months of participation in the intervention. The correlation assumed a negative value as determined by one or both of the motor assessments for time six, eight, nine, 10, 11 and 12, seemingly indicating a detrimental consequence of 'tummy time' in later months. Adverse effects of 'tummy time' were not supported in the literature for TD infants and were improbable for infants with DS. More likely, the incongruous results beginning at six months after baseline reflected the large degree of variation in higher level motor skill attainment in infants with DS receiving the intervention. For infants achieving motor milestones later due to a myriad of reasons common to DS (e.g. heart surgery, prematurity, cognitive delays), but not related to the intervention, 'tummy time' minutes appeared to be negatively correlated to motor development. The rest of the analytical findings advocating the benefits of 'tummy time' on motor development in infants with DS over the first 18 months of life, together with the fact that 'tummy time' minutes were positively correlated with motor development early in the study when the group was more homogenous in its motor performance, lends perspective to the low and even negative correlational findings at six months. Infants with DS in the intervention group engaged in a mean of 52 to 63 structured minutes of 'tummy time' daily during the months of highest correlation with motor development. Although this group was able to achieve a higher mean number of daily intervention minutes than the TD group in this study, overall results supported a similar future recommendation of 60 to 75 minutes of daily, deliberate 'tummy time' minutes as being both feasible and advantageous for motor development in infants with DS.

Despite the fact that the combined LMM facilitated a comparison of motor development in all four groups under unified contextual parameters, it was difficult to make a determination about whether TD infants or infants with DS benefitted more from 'tummy time' participation. "Tummy time" produced significant differences in the motor developmental trajectory in TD infants and in infants with DS over the 18 month study period. Notwithstanding, it was ambitious to claim with certainty whether the 1.02 slope differential in TD infants was more meaningful than the .95 slope differential in infants with DS. A more impressive finding from the collaborative model was the comparison it afforded between the intervention group with DS and the reference group, the TD group not receiving any intervention. In chapter one, the expanding gap in motor development between TD infants and infants with DS was identified as an overarching contributor to participation barriers for persons with DS. Additionally, the procedures for measuring motor development described earlier in this chapter provided rationale for using norm referenced assessments so that it could be determined if the 'tummy time' intervention was successful in narrowing the gap between TD infants and infants with DS. The results of the joint LMM showed that the difference in slope of the motor trajectory between TD infants in the reference group and infants with DS in the intervention group was just -.58 (p =.054), a difference not quite meeting statistical significance. On the other hand, the nonintervention group with DS displayed a difference in slope of -1.53 (p <.001) from the reference group. This difference was quite significant, but more importantly it indicated that the 'tummy time' intervention was successful in diminishing the disparity in motor development between TD infants and infants with DS. Delayed motor development is one of the activity limitations that must be confronted as interventionists endeavor to eliminate the barriers to participation (in meaningful life events) for persons with DS.

'Tummy Time' and Ponderal Index in Infants with and without DS

As established in chapter one, the prevalence of childhood obesity and obesity related health concerns have become widespread. Children with DS are at even greater risk for obesity and associated poor health outcomes (Rimmer et al., 2010). Recent research has proposed that in order to control the rising incidence of childhood obesity, interventions designed to prevent obesity from emerging must be developed (Ulrich & Hauck, 2013). This study hypothesized that by increasing the amount of 'tummy time' performed in early infancy, obesity, as implied by PI, would be diminished. In fact, a mitigating influence of 'tummy time' on PI was confirmed in TD infants and to a lesser degree in infants with DS.

Whereas both groups of TD infants significantly decreased their PI over the 18 month study period (see Figure 3.6), TD infants participating in 'tummy time' decreased their PI significantly more (p = .030). These results coupled with the results of effect size (d) at common time points (see Figure 3.10) supported the advocacy of early 'tummy time' in TD infants. 'Tummy time' had a large effect on PI beginning two months after study entry (d = .92) and this effect continued to increase through time 11 (d = 3.15). A large effect of 'tummy time' on PI was still present at time 18 (d = 2.51), although it had decreased slightly.

PI in both groups of infants with DS also decreased significantly over the 18 month study period (see Figure 3.7). The difference between the trajectories established via LMM did not similarly endorse 'tummy time' as a positive influence on PI in infants with DS. The intervention group with DS did enter the study with a lower PI. The difference in PI at baseline did not quite reach statistical significance (p = .062), but it was controlled for in the formation of the LMM. Even so, the LMM might not have fully appreciated the influence of 'tummy time.' While the effect size (d) at baseline and time 1 was moderate, a large effect of 'tummy time' on

PI in infants with DS was noted at time two (d = .93), three (d = .99), four (d = 1.17) and 11 (d = .95) (see Figure 3.11). By time 18, the impact of 'tummy time' on PI had decreased to a small effect (d = .43). These results were conceivably indicative of the large number of 'tummy time' minutes being performed by infants with DS in the intervention group during the first 11 months. By 12 months after study entry, all infants with DS had stopped doing deliberate 'tummy time' furnishing a reasonable explanation as to why there was not a noted effect on PI at 18 months of age. Ostensibly, 'tummy time' did have a positive impact on PI in infants with DS, lending further evidence in support of daily 'tummy time.'

The consolidated LMM failed to expose significant group differences in PI from the reference group over the course of the study. Contributing to this finding were the unified confounders that were controlled for in the comprehensive model. Specifically, baseline PI was an identified confounder for infants with DS but not for TD infants. In the comparison under similar parameters, the improvements in PI made by TD infants doing 'tummy time' were not significant (p = .813). Infants with DS doing 'tummy time' did not improve in PI more than infants with DS not doing 'tummy time.' Based on these narrow results, it could not be comfortably stated that 'tummy time' was more impactful in TD infants than in infants with DS. Instead, it would be better to use the amalgamation of data generated on PI to reinforce the importance of engaging in 60 to 75 minutes of daily 'tummy time' in infancy. This endorsement has developmental and health implications, as 'tummy time' is impactful not only on motor development, but also on body composition, in infants with and without DS.

'Tummy Time' and Physical Activity in Infants with and without DS

Along with endeavors to curtail obesity in early childhood are equally well placed efforts to prompt higher levels of habitual physical activity (PA) in infancy. Recall that obesity and

sedentary behaviors established early in life tend to perpetuate into childhood, adolescence and adulthood (Perrin et al., 2014; Franks et al., 2010; Han et al., 2010); and, that persons with DS are more likely to adopt sedentary practices (Whitt-Glover et al., 2006). For these reasons, interventions that promote PA in the beginning of life are necessary. Although it was hypothesized that the 'tummy time' intervention would encourage higher levels of PA in infants with and without DS, this finding was not actualized given the design of these studies.

As previously mentioned, the high degree of within group and within baby variability was a possible explanation as to why it was difficult to ascertain if 'tummy time' impacted PA levels in either cohort of infants. As confirmed by the estimated variance of the random intercepts and by the estimates of the residuals in all of the constructed LMM's, infant participants in the studies, both with and without DS, presented with a significant degree of between and within baby differences for all outcome measures. Accordingly, the standard deviations for the mean PA in raw counts per minute at the wrist and at the ankle were exceedingly high at every time point in both cohorts. Additionally, it was not uncommon for an infant in any of the groups to demonstrate fluctuating raw counts of PA at the wrist and/or the ankle from month to month. Although this variability was anticipated, it did befuddle the quantification of 'tummy time' impact on the PA outcome measure.

All four groups of infants studied demonstrated an increase in mean PA, as measured at the wrist and ankle in raw counts per minute, over the course of the study. An impact of 'tummy time' participation on PA could not be determined by LMM, either in direct comparison within the cohort or in the combined model, in infants with or without DS. The effect (*d*) of 'tummy time' on PA was large (>=.8) at only one time point (time two) for the wrist in TD infants, and for just three time points in infants with DS (time two at the wrist; time two and three for the

ankle). Given this paucity of evidence, 'tummy time' could not be purported as influential on PA in infants with or without DS.

Despite of the lack of substantiation derived from the methods employed in these studies, 'tummy time' should be given further consideration as an intervention that boosts PA levels in infancy. First and foremost, it could not be verified that measuring only raw counts of activity at the wrist and the ankle were altogether representative of maturing infant activity in the first 18 months of life. Although movements were decidedly random early, as babies became more skillful and as their movements became more goal directed, it could be argued that raw counts, both at the wrist and ankle, decreased. If this were the case, then infants demonstrating greater skill development might have actually generated less raw counts for a given competency. For example, more raw counts would be generated in repeated unsuccessful attempts to reach for a desired object than in one successful attempt made by a more skilled infant. However, in order to translate raw counts into more meaningful measures such as time spent at different activity intensities, count information must be calibrated using proven algorithms for children of similar ages (Cliff et al., 2009). In the absence of reliable and/or valid algorithms for infants, accelerometer based PA comparisons could only be made on the basis of raw count data.

Preschool algorithms established by Pate et al. (2006) were used to translate raw counts generated at the waist into time spent in both sedentary activity and moderate to vigorous physical activity (MVPA) at the 18 month time point. These translated counts also did not demonstrate significant differences in time spent in sedentary activity or in MVPA between the four groups (see Table 3.3). In fact, the PA findings at 18 months not only failed to establish an influence of 'tummy time,' but also declined to expose an effect of having DS on PA levels. The lack of group differences at time point 18 could have been because the preschool algorithms

utilized were not generalizable to toddlers. It could be contended that there is appreciable dissimilarity in the motor behaviors of an 18 month old compared to those of a three or four year old, rendering preschool algorithms inappropriate for use at this age. In terms of the lack of differences in MVPA between infants with DS and TD infants, perhaps differences were not apparent at 18 months as measured at the waist because most infants with DS were not walking or not walking well at this age. Thereby, many infants with DS were probably still being carried or strolled (i.e. mechanically handled) a great deal of the time. The 18 month waist procedures did not include methods for removing activity generated by mechanical handling (i.e. no log was completed for waist data) so this could have accounted for infants with DS appearing to engage in as much, or slightly more, MVPA as TD infants.

Many parents in the intervention groups, with and without DS, struggled with the PA measurement process. As discussed in the section on Missing Data earlier in this chapter, unknowing parents found that their infant removed the accelerometer(s), accelerometers fell off during play or sleep, or well-intended siblings removed the accelerometers, time and again during the 24 hour wear period. This, coupled with challenges in meticulously recording activity levels in 30 minute increments for 24 hours, increased measurement error for this outcome variable.

In the TD cohort, the difference in accelerometers used to capture PA amplified the challenge of accurately comparing PA between the intervention and non-intervention groups. Even though a model was created to predict Actigraph counts from Actical counts for the TD non-intervention group, the model only accounted for 37.4% of the total variation in Actigraph measures. Without the model, however, no comparisons could have been made between the TD groups for the PA outcome measure. That being said, the 62.6% of total variation in Actigraph

left unexplained introduced a great deal of ambiguity in the translation of Actical counts and the subsequent comparative efforts of PA results between the TD groups.

Additionally, group differences in PA could have been more subtle than in the other outcome variables, requiring not only more precise methods of detection, but also a larger sample to realize. The relatively small sample size of each of the groups undoubtedly compromised the power to detect group differences for this outcome measure. A post hoc analysis of statistical power and sample size calculation was completed for the cohort of infants with DS (see Table 3.4), as both the 'tummy time' and the comparison group employed the Actigraph to measure PA. Only time point two was adequately powered with an appropriate sample size in infants with DS. In fact, time point two was the only time point to demonstrate a large effect of 'tummy time' on PA in infants with DS.

Although the LMM's did not demonstrate an impact of 'tummy time' on PA during the first 12 months, perhaps because of the methodological concerns described above, the absence of a direct 'tummy time' effect at time 18 was likely reinforced by the fact that no babies were actively engaged in 'tummy time' at this point in the study. The indirect consequences of 'tummy time' on PA as a result of improved motor development or more desirable body composition might not be immediately apparent and may have taken longer than the 18 month study period to recognize. Given the many methodological concerns expressed, the potential positive influence of 'tummy time' on PA should not be discounted. Instead, alternative means of more accurately capturing infant PA should be explored and implemented in future comparative endeavors.

Study Limitations

There were several underlying limitations to this project. The previous section on 'Tummy Time' and Physical Activity in Infants with and without DS detailed the methodological concerns encountered in these studies when measuring and comparing PA including the appropriateness of using raw counts as measured at the wrist and ankle as being representative of infant activity, the suitability of using preschool algorithms for translating waist counts into activity intensity levels at 18 months of age, a lack of process for removing mechanical handling data from waist data in the absence of a log, parent induced inconsistencies in wearing the accelerometers and logging activity, and a less than ideal model for transforming Actical counts into Actigraph counts in the TD non-intervention group. The high degree of between and within infant variability inevitably impacted the comparisons of all three outcome variables, but was particularly problematic for PA data. Similarly, the relatively small samples sizes of each of the four groups was a limitation for the entire project, but was also magnified in the analysis of PA information.

The study design was quasi-experimental with two experimental groups, one TD and one with DS, and two historical non-intervention groups, one TD and one with DS. There was no randomization process for group designation. Furthermore, the primary investigator was not blind to group membership as all participants monitored were in the 'tummy time' groups. In spite of efforts to measure all outcome variables accurately, bias could have been introduced into the results due to the lack of blinding.

While it was fortuitous to have had historical data from which to make relevant analogies between the intervention and non-intervention groups with and without DS, there was obviously no way of controlling the methods utilized in the comparative work. The current and historical

projects were completed by two different researchers, without a viable means of establishing inter-rater reliability for the different measurements employed. There was some information not gathered for the historical groups. For example, annual family income data were not collected in the historical groups so, as a substitute, maternal education was the indicator of SES.

Information on the amount of concurrent external physical therapy was not collected for the non-intervention group with DS. Whereas significant differences in external physical therapy received over the course of each study may not have existed, there was no manner of corroborating or controlling for this. There were also gaps in the historical data collection time points, affording just seven common points where direct comparisons could be made.

Additionally, having only seven time points, in contrast to 13 or 14 in the experimental groups, made trajectories generated relatively less robust. Finally, the reduced number of time points in the historical groups undoubtedly influenced the rigor of the survival analysis process.

Implications for Future Research

Perhaps the most important void exposed by this project was the call for a valid and reliable process for measuring and comparing PA data in infants. The justification for quantifying and enhancing PA levels in infancy is grounded in current literature, but procedures for accurately representing baseline values or response to intervention do not exist. Without this process in place, it is impractical to consider intervention effects on the PA outcome variable.

Future work should strive to utilize assessors blind to group assignment and study purpose. One way that motor development could be blindly determined going forward is to have the principal investigator video the in home assessments and then have a third party or parties, unaware of study purpose as well as group assignment, score the assessments from the videos.

Having assessors blind to study purpose as well as group assignment increases the strength of the findings.

'Tummy time' had decisive effects on motor development in infants with and without DS, but 'tummy time' was only ubiquitous for the first six months after study entry in TD infants and for approximately the first nine months in infants with DS. After these times, infants in each group began to skill out of the intervention. Future research should consider subsequent parent implemented interventions, especially for infants with DS. Infants with DS have learning challenges that limit their ability to attain more complex skills and their ability to generalize success in one skill to a novel skill. This study indicated that 'tummy time' participation alone was not sufficient for success in the ability to four-point crawl or walk independently. Success in attaining these skills requires an activity-specific intervention such as crawling up stairs or treadmill training. The next step would be to consider the impact of a developmentally, as well as diagnostically, appropriate series of parent implemented motor interventions on the same outcome variables.

Infants with and without DS engaging in 'tummy time' averaged 55 to 70 minutes per day during the period of time that 'tummy time' minutes were most highly correlated with motor development. This finding was the basis of future recommendations of 60 to 75 daily minutes of 'tummy time' from birth to the time at which the infant can independently transition in and out of sitting. That being said, future studies should manipulate the dosage of 'tummy time,' not only to corroborate the recommendations from this work, but also to ascertain precisely how much 'tummy time' is necessary for timely and/or accelerated motor development.

This study considered the impact of the 'tummy time' program over a 12 to 18 month period. While benefits were actualized during this time frame, it is not known if the advantages

gained from 'tummy time' had a chronic effect that would still be present later in the early childhood period, for example at preschool entry. It would useful to examine the impact of 'tummy time,' and/or other similar motor interventions, over a longer period of time to determine if the intervention impact is finite or truly trajectory altering.

The literature supports the influence of motor development on global development. Forthcoming studies should explore the impact of a motor intervention, or series of motor interventions, on the other infant domains. For example, in addition to motor assessments, measures of cognitive, language and/or social development should be periodically administered during the study period to objectively appraise the influence of motor development on the other systems.

The ultimate goal of any intervention is an enhanced ability to actively engage in meaningful life events for that client or participant. The relationship between impairments in body structure and function such as obesity and activity limitations such as delayed motor development or decreased activity level on participation was discussed and illustrated using the ICF model (WHO, 2001). In conjunction with enhanced participation, benefits to global health and quality of life were proposed effects of 'tummy time' participation. In the absence of participation, health and quality of life measures, these broader intervention implications were only theoretical. Future investigations should consider including objective measures of participation, health and quality of life to produce evidence of pervasive intervention effects.

Conclusion

'Tummy time' was established as a meaningful motor intervention for infants with and without DS because of its positive influence on motor development and body composition as measured by ponderal index (PI). Even though the benefit of 'tummy time' on physical activity

(PA) could not be demonstrated, largely because of methodological problems, a yet undetermined benefit is predicted. 'Tummy time' minutes were most predictive of motor development during the first six months after study entry. Based on the compilation of findings from these studies, interventionists should recommend that infants with and without DS engage in an accumulation of 60 to 75 minutes of daily structured 'tummy time' until the time at which the infant can independently transition in and out of the sitting position.

Table 3.1 Demographics of Intervention Compared with Historical Groups at Baseline

De	mographic comparison be	tween TD co	horts		
		N	Mean	Std. Deviation	Sig.(2 tailed)
Participant's gender	TD Intervention	13	.46	.519	
	TD Non Intervention	26	.62	.496	.374
Participant's mother's highest level of	TD Intervention	13	1.00	0.000	
education	TD Non Intervention	26	.77	.430	.011
Particpant's race	TD Intervention	13	.31	.480	
	TD Non Intervention	26	.19	.402	.433
# of siblings Participant has	TD Intervention	13	.92	.954	
	TD Non Intervention	26	1.00	.938	.812
Participant's weight in kg at birth	TD Intervention	13	3.5000	.28604	
	TD Non Intervention	26	3.4936	.44464	.957
Participant's age in day at study entry	TD Intervention	13	48.23	30.125	
	TD Non Intervention	26	61.65	5.351	.136
Participant's ponderal index at study entry	TD Intervention	13	26.7638	4.06691	
	TD Non Intervention	26	27.5165	2.83742	.504
Participant's total motor composite on	TD Intervention	13	110.69	9.656	
Bayley at study entry	TD Non Intervention	25	107.72	13.406	.484
Transformed Raw Wrist Counts/min at	TD Intervention	12	1181.6865	543.37465	
baseline	TD Non Intervention	18	1011.9863	427.16687	.347
Transformed Raw Ankle counts/min at	TD Intervention	12	666.2177	272.02841	
baseline	TD Non Intervention	23	810.0325	189.98083	.076

Dem	ographic comparison bet	ween cohort	s with DS		
		N	Mean	Std. Deviation	Sig.(2 tailed)
Participant's gender	Tummy Time	19	.53	.513	
	Historical	9	.56	.527	.890
Participant's mother's highest level of	Tummy Time	19	.89	.315	
education	Historical	9	.56	.527	.102
Particpant's race	Tummy Time	19	.05	.229	
	Historical	9	.22	.441	.303
Participant's weight in kg at birth	Tummy Time	18	2.9211	.69632	
	Historical	9	2.9169	.39763	.987
# of siblings Participant has	Tummy Time	19	1.68	1.293	
	Historical	9	1.33	1.323	.511
Participant's age in day at study entry	Tummy Time	19	66.53	35.135	
	Historical	9	64.00	10.524	.776
Participant's ponderal index at study	Tummy Time	19	26.5468	2.82152	
entry	Historical	9	29.0651	3.89967	.062
Participant's total motor composite on Bayley at study entry	Tummy Time	19	97.47	10.595	
	Historical	9	105.56	10.713	.072
Wrist raw counts per min at baseline	Tummy Time	18	1101.4413	382.32117	
	Historical	8	1050.2913	402.15717	.759
Ankle raw counts per min at baseline	Tummy Time	18	777.3036	257.91665	
	Historical	8	647.1275	216.07038	.226

Table 3.2 Comparison of Complete Data Set Results with Results from Multiple Imputation Procedures for PA Data at the Wrist and Ankle in Infants with and without DS

Comparison	of Complete	e PA [Data Set Re	sults	vs Multiple Imp	utation Res	ults		
TD PAwrist	complete		MIHotDed	k	TD PAankle	complete		MIHotDed	k
Intercept	486.76	sig	612.28	sig	Intercept	562.31	sig	589.19	sig
group	298.8	sig	198.53	sig	group	-147.61	sig	-165.46	sig
months	34.38	sig	28.49	sig	months	48.86	sig	49.91	sig
sibs	1.49	NS	9.16	NS	sibs	21.27	NS	12.49	NS
grp*months	3.56	NS	14.37	NS	grp*months	-1.73	NS	-3.86	NS
resid	119815.6	sig	143515.5	sig	resid	71305.15	sig	72615.49	sig
Intercept	30419.03	NS	10193.03	NS	Intercept	21623.79	sig	17447.21	sig
DS PAwrist	complete		MIHotDed	k	DS PAankle	complete		MIHotDec	k
Intercept	663.82	NS	967.64	sig	Intercept	1009.93	sig	875.21	sig
group	219.23	NS	161.12	NS	group	158.75	NS	163.68	NS
months	33.56	sig	35.18	sig	months	29.77	sig	28.86	sig
sibs	-24.69	NS	-20.49	NS	sibs	0.37	NS	4.79	NS
grp*months	-3.44	NS	-2.31	NS	grp*months	-15.77	NS	-14.33	NS
resid	83653.42	sig	89142.86	sig	resid	82622.69	sig	80347.45	sig
Intercept	43553.22	sig	34934.23	sig	Intercept	34416.14	sig	33013.58	sig

Table 3.3 Time 18 Comparison of Waist Data in Infants with and without DS

	Time 18 Wais						
Group	% Time MVPA	Ind t-Test	% Time Sedentary	Ind t-Test			
Tummy Time	9.93%		79.55%				
Historical	9.42%	t=.352 (p=.727)	67.59%	t=1.95 (=.067)			
Group	Time 18 Wais	Time 18 Waist Comparison in Infants with DS					
Tummy Time	11.29%		78.51%				
Historical	12.41%	t=422 (p =.678)	70.43%	t=.825 (p=.436)			

Table 3.4 Statistical Power Analysis for PA Data in Infants with DS

	Statistical Power Analysis PA Data-Infants with DS							
	Baseline	Time 1	Time 2	Time 3	Time 4	Time 11	Time 18	
Statistical Power								
wrist act/min	6.1%	9.5%	57.3%	28.2%	15.8%	6.0%	na	
Statistical Power	24.7%	28.6%	69.0%	45.1%	5.2%	5.6%	6.8%	
ankle act/min								
Sample Size Needed								
(alpha=%5; beta=50%)								
Wrist	318	59	9	23	30	348	na	
Ankle	20	13	5	8	1189	587	133	

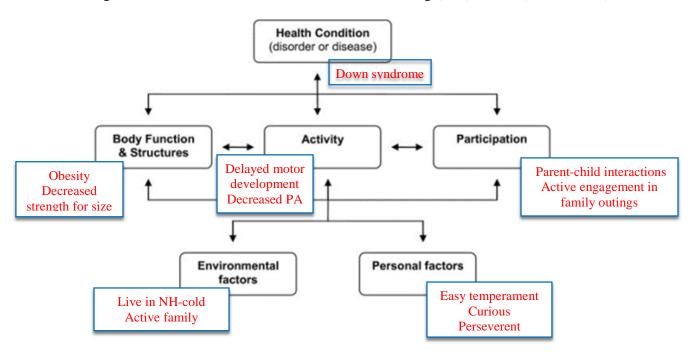
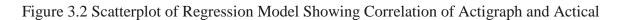
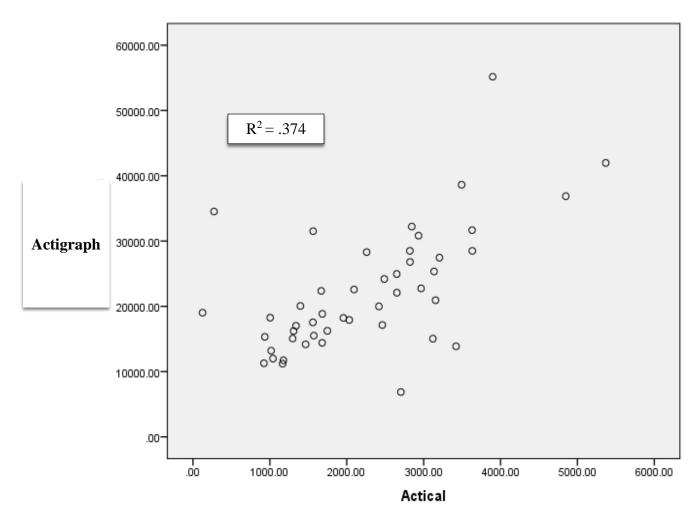
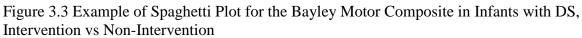
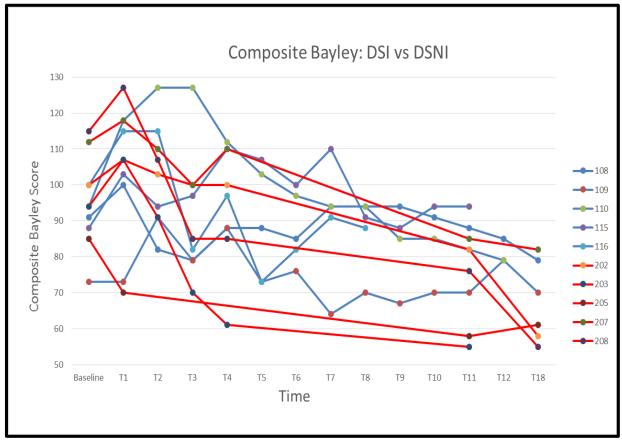


Figure 3.1 International Classification of Functioning (ICF) Model (WHO, 2001)

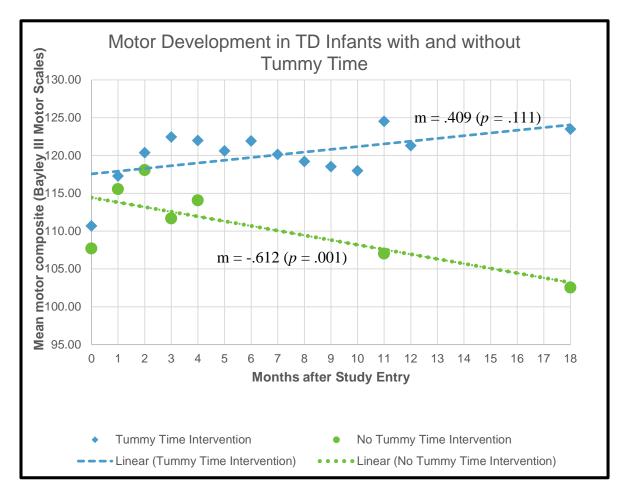


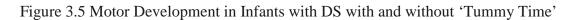


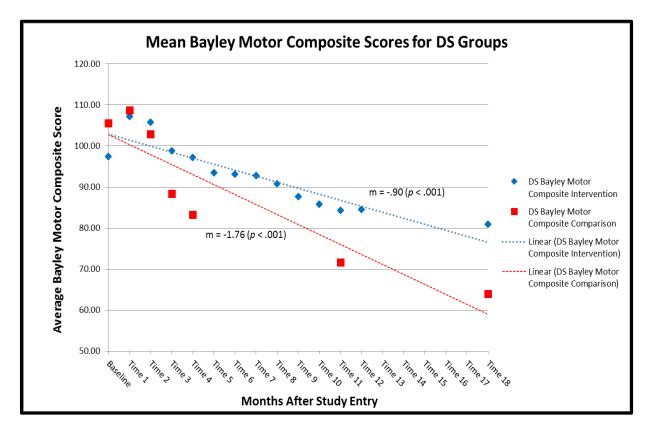


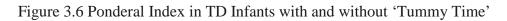


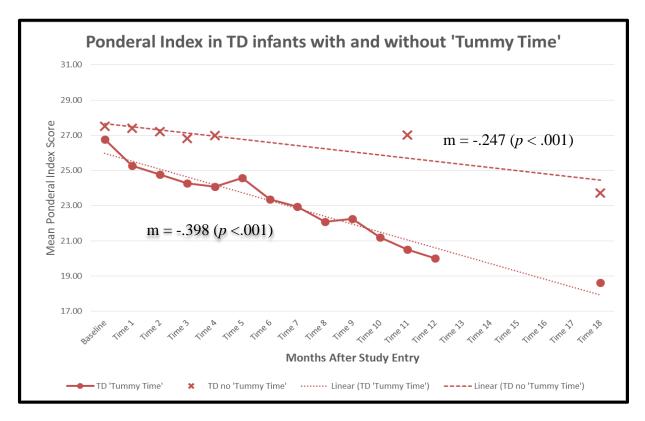


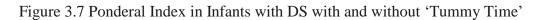


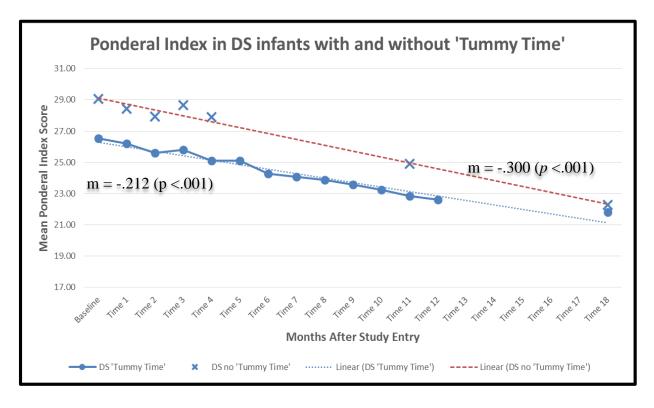


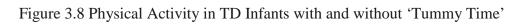


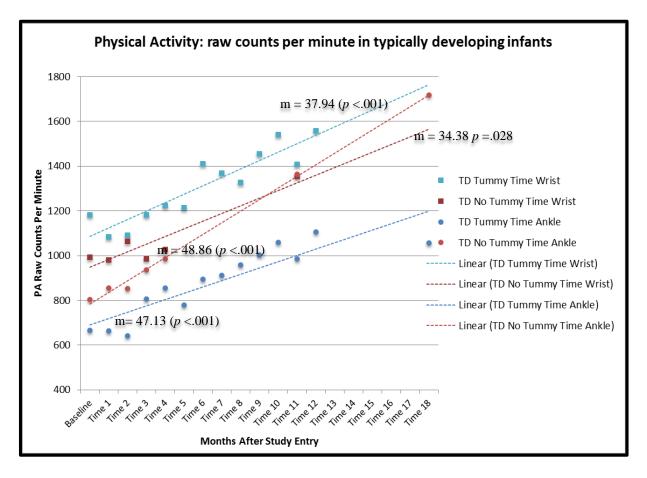


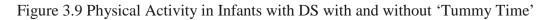


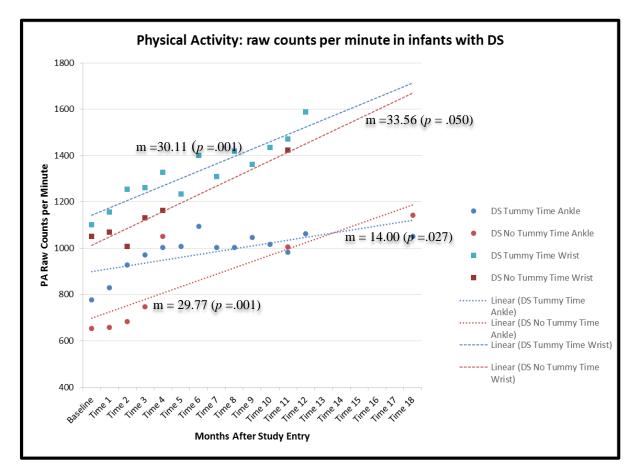




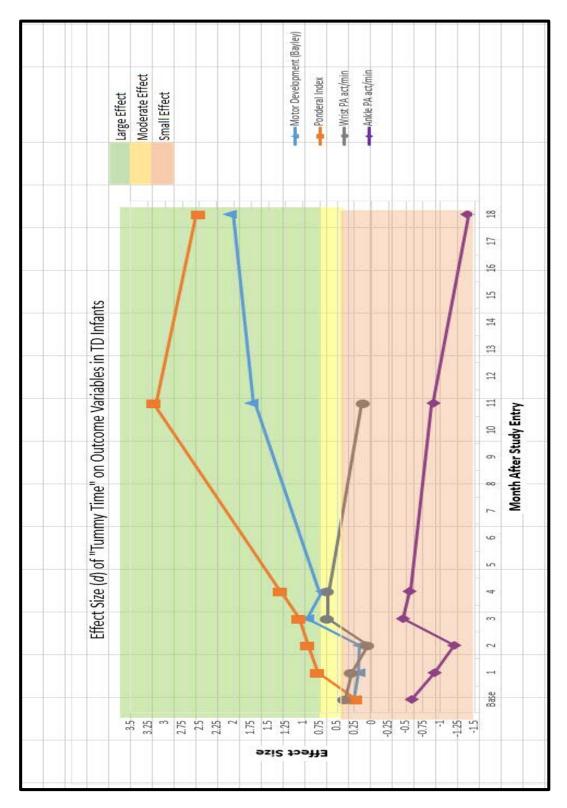


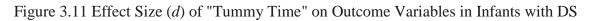












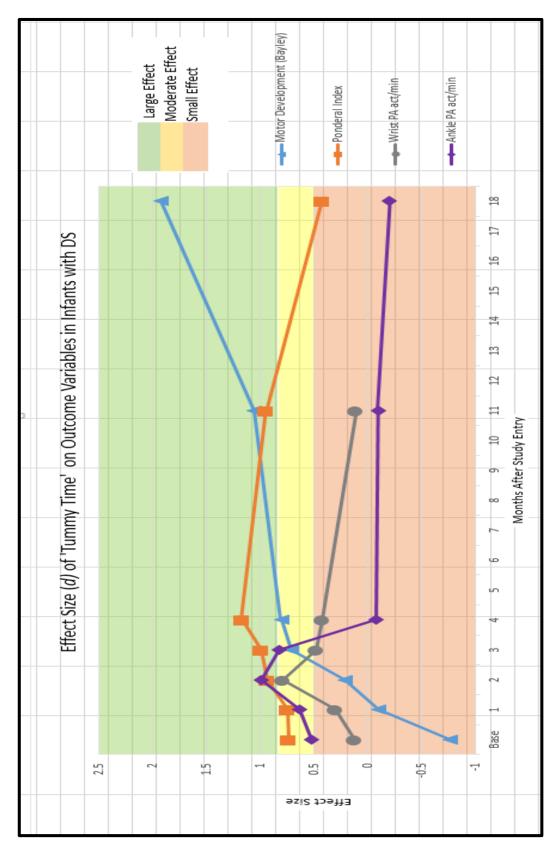


Figure 3.12 Survival Curves for Unilateral Reaching in TD Infants and in Infants with DS

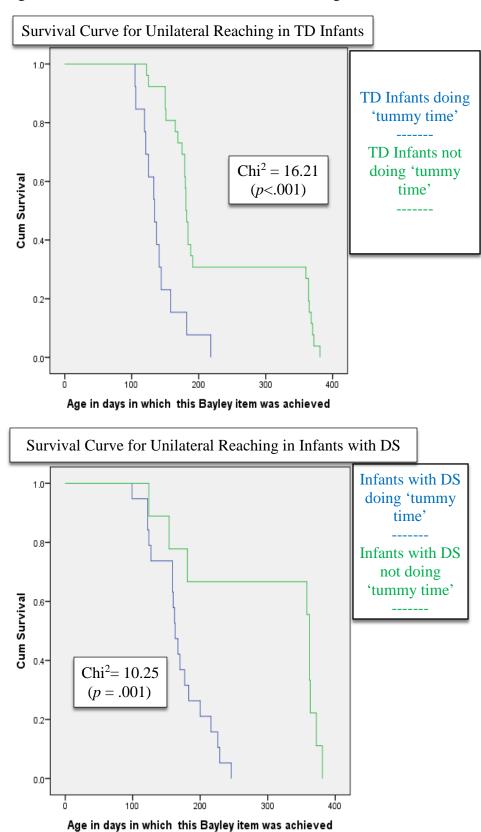
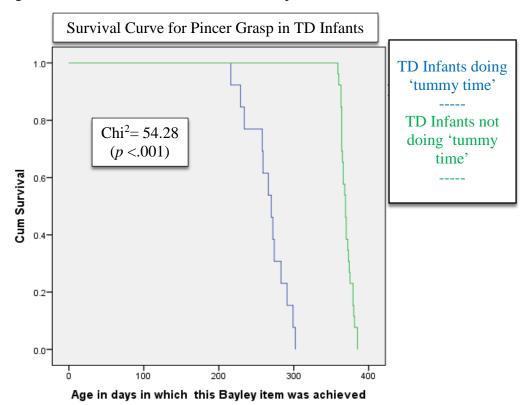


Figure 3.13 Survival Curves for Pincer Grasp in TD Infants and in Infants with DS



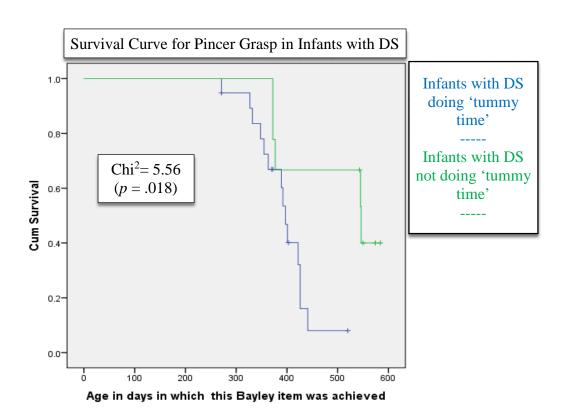
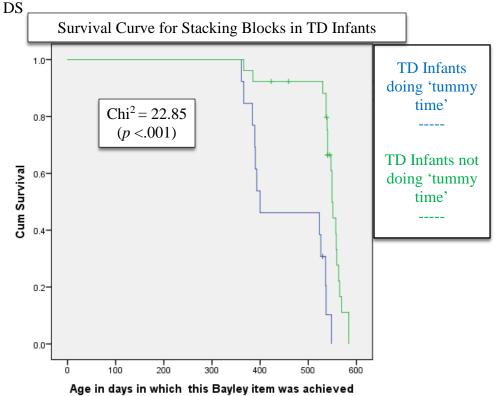


Figure 3.14 Survival Curves for Stacking Two 1-inch Blocks in TD Infants and in Infants with



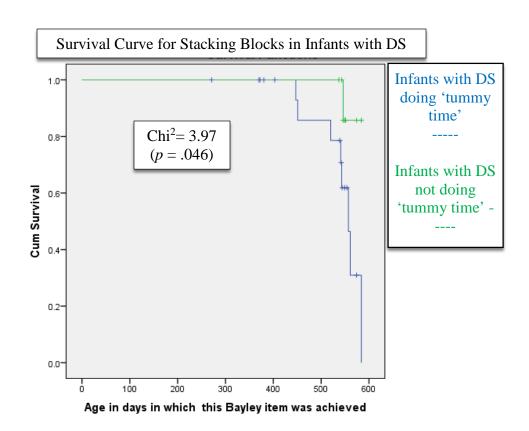
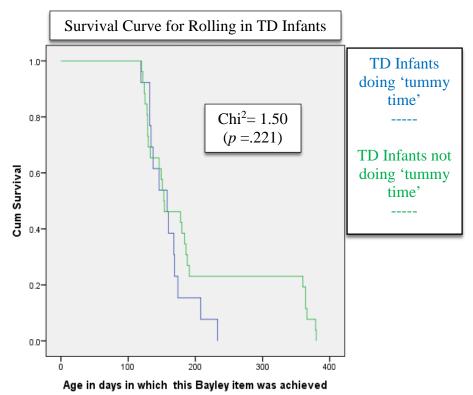


Figure 3.15 Survival Curves for Rolling Supine to Prone in TD Infants and in Infants with DS



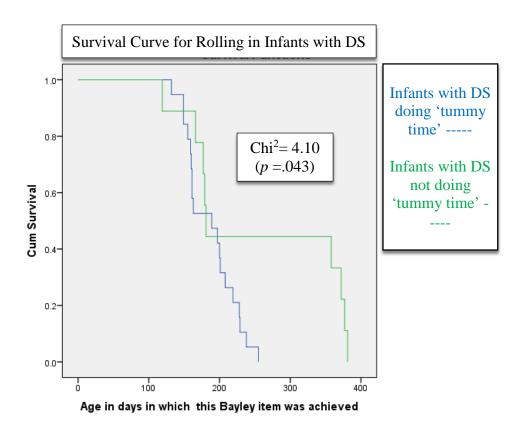
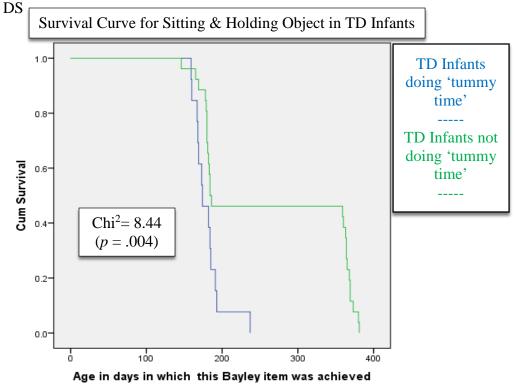


Figure 3.16 Survival Curves for Sitting and Holding an Object in TD Infants and in Infants with



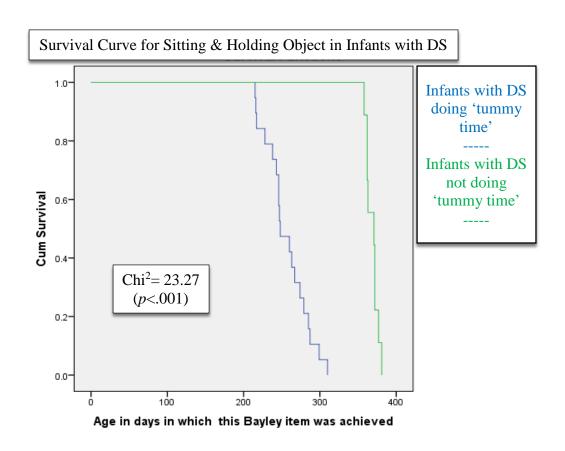
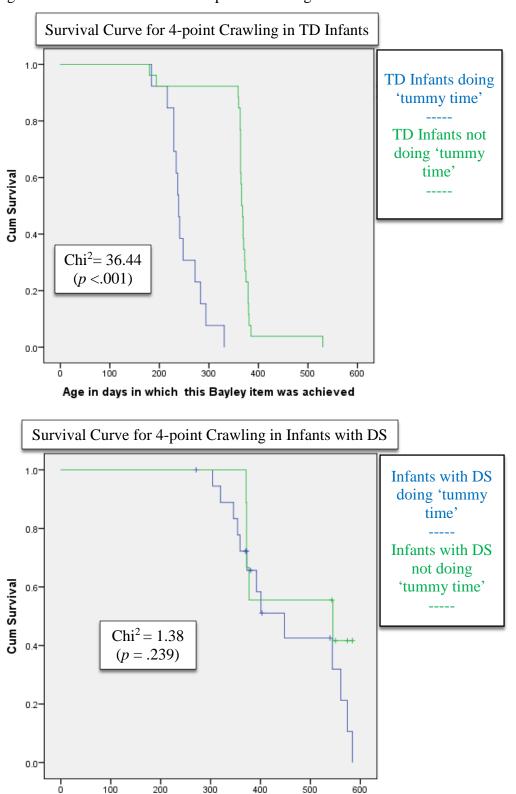
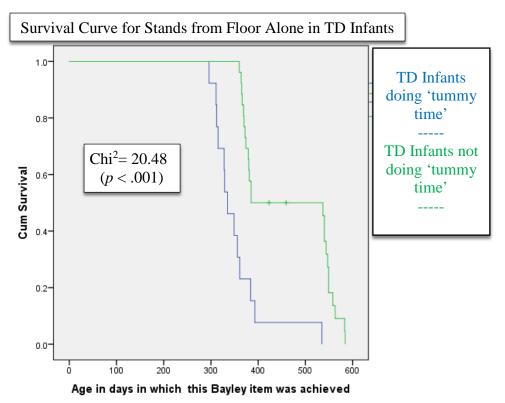


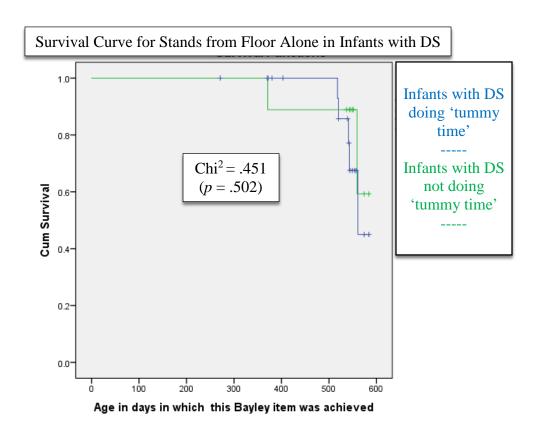
Figure 3.17 Survival Curves for 4-point Crawling in TD Infants and in Infants with DS



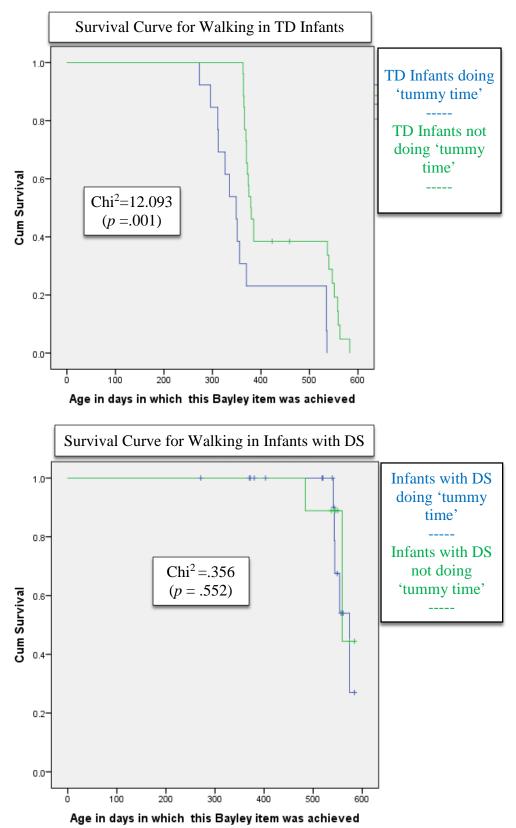
Age in days in which this Bayley item was achieved

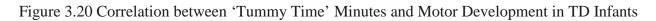
Figure 3.18 Survival Curves for Stands from Floor Alone in TD Infants and in Infants with DS











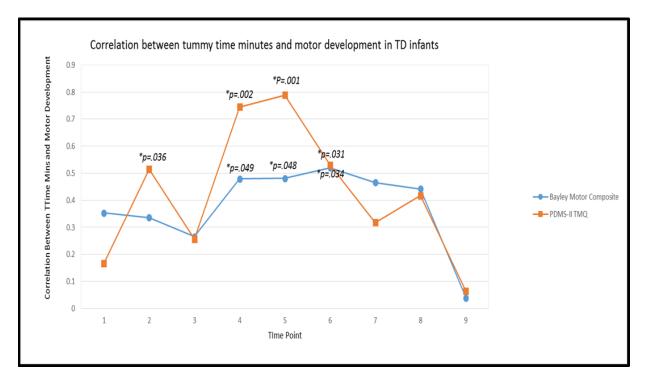
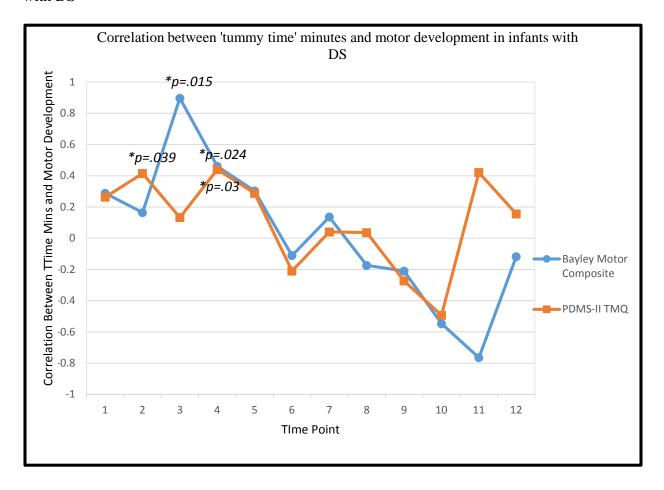


Figure 3.21 Correlation between 'Tummy Time' Minutes and Motor Development in Infants with $\ensuremath{\mathsf{DS}}$



References

Andridge, R. R., & Little, R. J. (2010). A review of hot deck imputation for survey non-response. *International Statistical Review*, 78(1), 40-64.

Bayley, N. (2006). *Bayley Scales of Infant and Toddler Development, 3rd edition, Technical Manual.* San Antonio, TX: NCS Pearson, Inc.

Capute, A. J., & Accardo, P. J. (1991). *Developmental disabilities in infancy and childhood*. Baltimore, MD: Paul H Brookes Pub Co.

Caspersen, C. J., Powell, K. E., & Christenson, G. M. (1985). Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. *Public Health Reports*, 100(2), 126.

Cliff, D. P., Reilly, J. J., & Okely, A. D. (2009). Methodological considerations in using accelerometers to assess habitual physical activity in children aged 0–5 years. *Journal of Science and Medicine in Sport*, 12(5), 557-567.

Cohen, J. (1988). Statistical power analysis for the behavioral sciences. 2nd edn. Hillsdale, New Jersey: Lawrence.

Cole, T. J. (1997). Growth monitoring with the British 1990 growth reference. *Archives of Disease in Childhood*, 76(1), 47-49.

Cole, T. J., Faith, M. S., Pietrobelli, A., & Heo, M. (2005). What is the best measure of adiposity change in growing children: BMI, BMI%, BMI z-score or BMI centile? *European Journal of Clinical Nutrition*, 59(3), 419-425.

Chugani, H. T. (1998). A critical period of brain development: studies of cerebral glucose utilization with PET. *Preventive Medicine*, 27(2), 184-188.

Davis, B. E., Moon, R. Y., Sachs, H. C., & Ottolini, M. C. (1998). Effects of sleep position on infant motor development. *Pediatrics*, 102(5), 1135-1140.

De Cunto, A., Paviotti, G., Ronfani, L., Travan, L., Bua, J., Cont, G., & Demarini, S. (2014). Can body mass index accurately predict adiposity in newborns? *Archives of Disease in Childhood-Fetal and Neonatal Edition*, 99(3), F238-F239.

Dudek-Shriber, L., & Zelazny, S. (2007). The effects of prone positioning on the quality and acquisition of developmental milestones in four-month-old infants. *Pediatric Physical Therapy*, 19(1), 48-55.

Ekelund, U., Ong, K., Linné, Y., Neovius, M., Brage, S., Dunger, D. B., . . . & Rössner, S. (2006). Upward weight percentile crossing in infancy and early childhood independently predicts

fat mass in young adults: the Stockholm Weight Development Study (SWEDES). *The American Journal of Clinical Nutrition*, 83(2), 324-330.

Fitzmaurice, G. M., Laird, N. M., & Ware, J. H. (2012). *Applied longitudinal analysis (Vol. 998)*. Hoboken, NJ: John Wiley & Sons.

Folio, M. R. & Fewell, R. R. (2000). Examiners Manual PDMS-2. Austin, TX: Pro-Ed, Inc.

Franks, P. W., Hanson, R. L., Knowler, W. C., Sievers, M. L., Bennett, P. H., & Looker, H. C. (2010). Childhood obesity, other cardiovascular risk factors, and premature death. *New England Journal of Medicine*, *362*(6), 485-493.

Gustafson, G. E. (1984). Effects of the ability to locomote on infants' social and exploratory behaviors: An experimental study. *Developmental Psychology*, 20(3), 397.

Han, J. C., Lawlor, D. A., & Kimm, S. Y. (2010). Childhood obesity. *The Lancet*, *375*(9727), 1737-1748.

Harris, S. R., & Shea, A. M. (1991). Down syndrome. *Pediatric Neurologic Physical Therapy*, 131-168.

Hauck, J. L. (2012). Developmental trajectory of physical activity and its relationship to rate of gain in weight, subcutaneous fat, and motor skill development during the first six months of life (Doctoral dissertation, The University of Michigan).

Heineman, K. R., & Hadders-Algra, M. (2008). Evaluation of neuromotor function in infancy—a systematic review of available methods. *Journal of Developmental & Behavioral Pediatrics*, 29(4), 315-323.

Hosmer, D.W., Lemeshow, S., & May, S. (2008). *Applied survival analysis: Regression modeling of time-to-event data*. Hoboken, NJ: John Wiley & Sons.

Kelly, L. A., Reilly, J. J., Fairweather, S. C., Barrie, S., Grant, S., & Paton, J. Y. (2004). Comparison of two accelerometers for assessment of physical activity in preschool children. *Pediatric Exercise Science*, *16*(4), 324-333.

Kolb, B., Forgie, M., Gibb, R., Gorny, G., & Rowntree, S. (1998). Age, experience and the changing brain. *Neuroscience & Biobehavioral Reviews*, 22(2), 143-159.

Kuo, Y. L., Liao, H. F., Chen, P. C., Hsieh, W. S., & Hwang, A. W. (2008). The influence of wakeful prone positioning on motor development during the early life. *Journal of Developmental & Behavioral Pediatrics*, 29(5), 367-376.

Law, M., Anaby, D., DeMatteo, C., & Hanna, S. (2011). Participation patterns of children with acquired brain injury. *Brain Injury*, 25(6), 587-595.

- Little, R. J., & Rubin, D. B. (2014). *Statistical analysis with missing data*. Hoboken, NJ: John Wiley & Sons.
- Lloyd, M., Burghardt, A., Ulrich D. A., & Angulo-Barroso, R. (2010). Physical activity and walking onset in infants with Down syndrome. *Adapted Physical Activity Quarterly*, 27, 1-16.
- Majnemer, A., & Barr, R. G. (2006). Association between sleep position and early motor development. *The Journal of Pediatrics*, 149(5), 623-629. e621.
- McIver, K., Pfeiffer, K., Almeida, J., Dowda, M., Pate, R., & Columbia, S. C. (2004). Validity of the ActiGraph and Actical accelerometers in 3–5 year-old children. *North American Society for Pediatric Exercise Medicine*.
- Meegan, S., Maraj, B., Weeks, D., & Chua, R. (2006). Gross motor skill acquisition in adolescents with Down syndrome. *Down Syndrome Research and Practice*, *9*(*3*), 75-80.
- Neill, J. (2008). Effect size. Retrieved from http://wilderdom.com/research/effectsizes.html
- Pate, R. R., Almeida, M. J., McIver, K. L., Pfeiffer, K. A., & Dowda, M. (2006). Validation and calibration of an accelerometer in preschool children. *Obesity*, *14*(11), 2000-2006.
- Penpraze, V., Reilly, J. J., MacLean, C. M., Montgomery, C., Kelly, L. A., Paton, J. Y., ... & Grant, S. (2006). Monitoring of physical activity in young children: how much is enough? *Pediatric Exercise Science*, 18(4), 483.
- Perrin, E. M., Rothman, R. L., Sanders, L. M., Skinner, A. C., Eden, S. K., Shintani, A., ... & Yin, H. S. (2014). Racial and ethnic differences associated with feeding-and activity-related behaviors in infants. *Pediatrics*, *133*(4), e857-e867.
- Oates, A., Bebbington, A., Bourke, J., Girdler, S., & Leonard, H. (2011). Leisure participation for school-aged children with Down syndrome. *Disability and Rehabilitation*, *33*(19-20), 1880-1889.
- Olsen, I. E., Lawson, M. L., Meinzen-Derr, J., Sapsford, A. L., Schibler, K. R., Donovan, E. F., & Morrow, A. L. (2009). Use of a body proportionality index for growth assessment of preterm infants. *The Journal of Pediatrics*, 154(4), 486-491.
- Ott, A. E., Pate, R. R., Trost, S. G., Ward, D. S., & Saunders, R. P. (2000). The use of uniaxial and triaxial accelerometers to measure children's" free-play" physical activity. *Pediatric Exercise Science*, 12(4), 360.
- Palisano, R. J., Walter, S. D., Russell, D. J., Rosenbaum, P. L., Gémus, M., Galuppi, B. E., & Cunningham, L. (2001). Gross motor function of children with Down syndrome: creation of motor growth curves. *Archives of Physical Medicine and Rehabilitation*, 82(4), 494-500.

- Publication manual of the American psychological association. Washington, DC: American Psychological Association, 2001.
- Rimmer, J. H., Yamaki, K., Lowry, B. M., Wang, E., & Vogel, L. C. (2010). Obesity and obesity-related secondary conditions in adolescents with intellectual/developmental disabilities. *Journal of Intellectual Disability Research*, 54(9), 787-794.
- Roizen, N. J., & Patterson, D. (2003). Down's syndrome. The Lancet, 361(9365), 1281-1289.
- Sadeh, A., Acebo, C., Seifer, R., Aytur, S., & Carskadon, M. A. (1995). Activity-based assessment of sleep-wake patterns during the 1st year of life. *Infant Behavior and Development*, 18(3), 329-337.
- Salls, J. S., Silverman, L. N., & Gatty, C. M. (2002). The relationship of infant sleep and play positioning to motor milestone achievement. *American Journal of Occupational Therapy*, 56(5), 577-580.
- Samuels, H. R. (1980). The effect of an older sibling on infant locomotor exploration of a new environment. *Child Development*, 607-609.
- Sharav, T., & Bowman, T. (1992). Dietary practices, physical activity, and body-mass index in a selected population of Down syndrome children and their siblings. *Clinical Pediatrics*, *31*(6), 341-344.
- Shumway-Cook, A., & Woollacott, M. H. (1985). Dynamics of postural control in the child with Down syndrome. *Physical Therapy*, 65(9), 1315-1322.
- Swihart, B. J., Caffo, B., James, B. D., Strand, M., Schwartz, B. S., & Punjabi, N. M. (2010). Lasagna plots: a saucy alternative to spaghetti plots. *Epidemiology (Cambridge, Mass.)*, 21(5), 621.
- Tieman, B. L., Palisano, R. J., & Sutlive, A. C. (2005). Assessment of motor development and function in preschool children. *Mental Retardation and Developmental Disabilities Research Reviews*, 11(3), 189-196.
- Troiano, R. P., Berrigan, D., Dodd, K. W., Masse, L. C., Tilert, T., & McDowell, M. (2008). Physical activity in the United States measured by accelerometer. *Medicine and Science in Sports and Exercise*, 40(1), 181.
- Trost, S. G., Way, R., & Okely, A. D. (2006). Predictive validity of three ActiGraph energy expenditure equations for children. *Medicine and Science in Sports and Exercise*, 38(2), 380.
- Tulve, N. S., Jones, P. A., McCurdy, T., & Croghan, C. W. (2007). A pilot study using an accelerometer to evaluate a caregiver's interpretation of an infant or toddler's activity level as recorded in a time activity diary. *Research Quarterly for Exercise and Sport*, 78(4), 375-383.

Ulrich, D. A., & Hauck, J. L. (2013, June). Developmental trajectory of physical activity, weight, skinfolds, and motor development in 1-6 month old infants with Down syndrome. In *Journal of Sport & Exercise Psychology* (Vol. 35, pp. S73-S73). Champaign, IL: Human Kinetics Publ Inc.

Vicari, S. (2006). Motor development and neuropsychological patterns in persons with Down syndrome. *Behavior Genetics*, *36*(*3*), 355-364.

Wells, J. C., Chomtho, S., & Fewtrell, M. S. (2007). Programming of body composition by early growth and nutrition. *Proceedings of the Nutrition Society*, 66(03), 423-434.

West, B. T., Welch, K. B., & Galecki, A. T. (2014). *Linear mixed models: a practical guide using statistical software*. Boca Raton, FL: CRC Press.

Whitt-Glover, M. C., O'Neill, K. L., & Stettler, N. (2006). Physical activity patterns in children with and without Down syndrome. *Pediatric Rehabilitation*, *9*(2), 158-164.

World Health Organization (2001). *International classification of functioning, disability and health*. Geneva: World Health Organization.

Yan, J. H., Thomas, J. R., & Downing, J. H. (1998). Locomotion improves children's spatial search: a meta-analytic review. *Perceptual and Motor Skills*, 87(1), 67-82.

Chapter 4

Putting Research into Practice

The methods employed in this research are pertinent to current intervention practices because they demonstrated the effectiveness of 'tummy time,' they were appropriate for implementation early in life, and they were highly translational.

This study was not a randomized control study which would have generated the strongest intervention-effect causal relationship. A randomized control design provides evidence of intervention efficacy. Efficacious interventions produce the expected results under ideal conditions, often minimizing or controlling for differences, for example, among participants or in intervention implementation. Adhering to this level of rigor would have meant that the intervention may have been delivered under circumstances that were not representative of typical pediatric practice. If administration of the intervention was not easily replicable in typical practice, its results would have minimal clinical relevance, limiting widespread application.

Instead the 'tummy time' intervention was effective. That is, 'tummy time' produced the expected results under real world circumstances. Intervention success, especially in infants, involves the interplay of multiple parameters, both implicit and explicit to the client and his or her family. These parameters represent the status quo for that individual. Each 'tummy time' participant was unique; analysis confirmed a high degree of between participant variability.

Each family implemented 'tummy time' in a way that worked given its unique circumstances. In

spite of these differences, 'tummy time' had significant positive results in infants with and without DS, affirming it as an effective intervention.

As reviewed in this work, habits developed in infancy tend to persist into childhood, adolescence, and adulthood (Perrin et al., 2014; Franks et al., 2010; Han et al., 2010). Interventions that focus on the development of healthy behaviors and ideal health status early in life are therefore optimal. Furthermore, the brain and nervous system is especially responsive to neuromotor stimulation early in life making infancy a time where facilitating change through intervention is more potent (Blauw-Hospers & Hadders-Algra, 2005). 'Tummy time' was a neuromotor intervention that could feasibly be implemented at birth or earliest medical stability. It has been shown to be influential on motor development and body composition in infants with and without DS, confirming its role in the cultivation of early health behaviors.

Translational research involves moving knowledge and discovery from scientific inquiry to application in clinical and community settings (Khoury, 2007). To facilitate translation into practice, research methods should be easily replicated by other researchers, practitioners as well as by the client and/or family members. 'Tummy time' was a parent implemented intervention. In fact, its favorable outcome was contingent on parent involvement. The rationale behind and the implementation of 'tummy time' was uncomplicated, simplifying adoption on a larger scale. The highly translational nature of the 'tummy time' intervention enhances the likelihood of it becoming the standard recommendation for all infants.

Overall Conclusions for the Project

The ten conclusions that can be drawn from the 'tummy time' research include:

Families with an infant with or without DS were willing to engage in 'tummy time'
 as they believed it would augment their baby's development

- Ninety minutes per day of recommended 'tummy time' was intimidating for most families and required several months to progress towards
- Families with a TD infant were able to build up to an average of 73 minutes of deliberate 'tummy time' daily before the majority of participants skilled out of the intervention, but averaged 51 to 73 minutes during the months that 'tummy time' was most highly correlated with motor development
- Families with an infant with DS were able to build up to an average of 100 minutes of deliberate 'tummy time' daily before the majority of participants skilled out of the intervention, but averaged 52 to 63 minutes during the months that 'tummy time' was most highly correlated with motor development in this cohort
- Single parent involvement, daycare outside the home, multiple time constraints were barriers to 'tummy time' participation
- Having a stay at home parent or in home nanny, having both parents and siblings
 involved were facilitators to 'tummy time' participation
- The component that families most appreciated about participating in the 'tummy time' research was the monthly developmental progress reports they received
- A high degree of between and within baby variability in presentation was confirmed in all four groups of infants participating in this research
- In spite of this level of variability, 'tummy time' emerged as an effective early intervention for improving motor development and body composition in infants with and without DS

 The impact of 'tummy time' on physical activity is not yet known because reliable and valid methods for measuring and comparing infant physical activity are not well established

Recommendations to Practitioners and Parents

'Tummy time' is essential to development and health status and thus should be actively promoted by all infant practitioners. 'Tummy time' is an effective intervention that is easily implemented by parents, potentially decreasing their need for direct medical services and increasing their sense of self-efficacy, their belief in their ability control their circumstances. Recommending that families merely engage in daily 'tummy time' for developmental reasons, the current AAP guideline (2011), is not sufficient. Based on the results of this research, specific recommendations should be made to accumulate 60 to 75 minutes of 'tummy time' daily until the time at which their baby can independently transition in and out of the sitting position. This recommendation is appropriate and feasible for infants with and without DS. Parents should be advised by pediatric interventionists to begin 'tummy time' at birth or earliest medical stability, and should be synchronously educated on strategies for success that are appropriate for their family's status and circumstances. Regular feedback on developmental outcomes impacted by 'tummy time' participation is integral in maintaining adherence.

Reference List

American Academy of Pediatrics (2011). Sleep Guidelines. Retrieved from http://www.aap.org/en-us/about-the-aap/aap-press-room/pages/aap-expands-guidelines-for-infant-sleep-safety-and-sids-risk-reduction.aspx#sthash.YpP2ETzw.dpuf.

Blauw-Hospers, C. H., & Hadders-Algra, M. (2005). A systematic review of the effects of early intervention on motor development. *Developmental Medicine & Child Neurology*, 47(06), 421-432.

Franks, P. W., Hanson, R. L., Knowler, W. C., Sievers, M. L., Bennett, P. H., & Looker, H. C. (2010). Childhood obesity, other cardiovascular risk factors, and premature death. *New England Journal of Medicine*, *362*(6), 485-493.

Han, J. C., Lawlor, D. A., & Kimm, S. Y. (2010). Childhood obesity. *The Lancet*, *375*(9727), 1737-1748.

Khoury, M. J., Gwinn, M., Yoon, P. W., Dowling, N., Moore, C. A., & Bradley, L. (2007). The continuum of translation research in genomic medicine: how can we accelerate the appropriate integration of human genome discoveries into health care and disease prevention?. *Genetics in Medicine*, *9*(10), 665-674.

Perrin, E. M., Rothman, R. L., Sanders, L. M., Skinner, A. C., Eden, S. K., Shintani, A., ... & Yin, H. S. (2014). Racial and ethnic differences associated with feeding-and activity-related behaviors in infants. *Pediatrics*, 133(4), e857-e867.

Appendices

Appendix 2.1 'Tummy Time' Log

	Daily Tummy Time Log							
Infant (number)							
Month/	Year							
Record	the number o	of minutes	(min) spen	t in tummy	time durin	g each exp	perience (Ex	cp)
during t	he day and t	hen record	the total r	ninutes at	the end of	each day.		
	nay not be ar							
Day	Exp 1 (min)	Exp 2 (min)	Exp 3 (min)	Exp 4 (min)	Exp 5 (min)		TOTAL (min)	
1								
2								
3								
4								
5								
6								
7								
8	_							
9								
10								
11	_							
12								
13								
14	_							
15								
16								
17								
18								
19								
20	_							
21	_							
22	_							
23	_							
24								
25	_							
26	_							
27	_							
28								
29								
30								
31								
_								
Comme	nts:							

Appendix 3.1 Infant Physical Activity Monitoring Directions and Infant Physical Activity Log

Infant Physical Activity Monitoring Directions
The leg is to be completed during the 24 hour monitoring period when your infant is wearing the
The log is to be completed during the 24 hour monitoring period when your infant is wearing the
activity monitor on the right ankle and wrist. Please try to complete the 24 hour monitoring peri
as close to the monthly visit by the research physical therapist as possible.
The log is best completed by a parent.
For each 30 minute time block, please use the KEY to indicate the type of activity occuring.
During the 24 hour monitoring period, please try to fill the log out throughout the day,
rather than in just one sitting. Filling it out as each time block passes or once per hour will
ensure that the information is accurate. This of course only applies to waking hours.
The monitoring period is suppose to occur for 24 hours straight,
this is for us to gauge when your child is awaking during the night.
Please feel free to wait until morning to fill out the log however.
At times, you may want to record more than one KEY code for a 30 minute time block,
instead, we ask that you record the KEY code that reflects the majority of your infant's
movement during that time block. Just one code is plenty.
Although we'd like the activity monitor to be worn during sleep, we please ask that you
remove the monitor for bathing.
Please feel free to leave comments or explanations where you see fit in either the comments
section or anywhere on this sheet.
Section of anywhere of this sheet.
How to interpret the I/EV.
How to interpret the KEY:
Mark X if: Your infant is not wearing the monitor anytime during the 24 hour monitoring period
Mark 0 if: Your infant's movement occurs under the power of others including being carried,
riding in a car, sitting in a swing or in a stroller, or being rocked.
Mark 1 if: Your infant is sleeping, whether in their crib or another location. But not in a swing.
Mark 2 if: Your infant is feeding, whether in a high chair or being held.
Mark 3 if: Your infant is engaged in quiet play, awake but with minimal movement
in their arms/legs.
Mark 4 if: Your infant is engaged in active play, a lot of movem ent in the arms/legs.

								Date:			
								Start Time:		AM o	r PM
Infant Phy	sical A	ctivity	Log					Name:			
		_						Infant age in	months:		
АМ						-					
	Activity	Position	# min	0.00.0.00	Activity	Position	# min	4.00.4.00	Activity	Position	# min
12:00-12:29				8:00-8:29				4:00-4:29			
12:30-12:59				8:30-8:59				4:30-4:59			
1:00-1:29				9:00-9:29				5:00-5:29			
1:30-1:59				9:30-9:59				5:30-5:59			
				0.00				0.00			
2:00-2:29				10:00-10:29				6:00-6:29			
2:30-2:59				10:30-10:59				6:30-6:59			
3:00-3:29				11:00-11:29				7:00-7:29			
3:30-3:59				11:30-11:59				7:30-7:59			
0.00				PM				1100 1100			
4:00-4:29				12:00-12:29				8:00-8:29			
4:00-4:29				12:30-12:29				8:30-8:59			
4.30-4.33				12.30-12.33				0.30-0.33			
5:00-5:29				1:00-1:29				9:00-9:29			
5:30-5:59				1:30-1:59				9:30-9:59			
J.JU-J.JJ				1,30-1,33				3.30-3.33			
6:00-6:29				2:00-2:29				10:00-10:29			
6:29-6:59				2:30-2:59				10:30-10:59			
0.20 0.00				Zioo Zioo				10100 10100			
7:00-7:29				3:00-3:29				11:00-11:29			
7:30-7:59				3:30-3:59				11:30-11:59			
KEY:											
Activity Type											
	Not worr	1									
0			s under	power of other	ers						
1		g (not in									
	Feeding										
3	Quiet pla										
4	Active pl										
C											
Comments											

Appendix 3.2 External Therapy Received by Intervention Group with DS

Mean Number of PT Minutes Received Outside of 'Tummy Time' Monthly						
	N	Minimum	Maximum	Mean	Std. Deviation	
# minutes of physical therapy receieved btwn study entry and visit 1	19	0	180	42.63	49.226	
# minutes of physical therapy receieved btwntimepoints 1 and 2	19	0	480	49.74	110.773	
# minutes of physical therapy receieved btwn timepoints 2 and 3	18	0	480	74.44	120.500	
# minutes of physical therapy receieved btwn btwn timepoints 3 and 4	19	0	360	106.32	92.148	
# minutes of physical therapy receieved btwn timepoints 4 and 5	19	0	420	118.95	115.657	
# minutes of physical therapy receieved btwn timepoints 5 and 6	19	0	480	125.79	123.303	
# minutes of physical therapy receieved btwn timepoints 6 and 7	19	0	360	120.53	111.379	
# minutes of physical therapy receieved btwn timepoints 7 and 8	18	0	330	114.44	104.599	
# minutes of physical therapy receieved btwn timepoints 8 and 9	15	0	240	97.00	82.523	
# minutes of physical therapy receieved btwn timepoints 9 and 10	18	0	240	93.33	85.869	
# minutes of physical therapy receieved btwn timepoints 10 and 11	18	0	240	104.72	83.498	
# minutes of physical therapy receieved btwn timepoints 11 and 12	18	0	240	89.17	69.181	
# minutes of physical therapy receieved btwn timepoints 12 and 18	13	0	240	120.00	90.830	
Valid N (listwise)	11					

Appendix 3.3 Sample Parent Feedback Form

Parent Feedback Form

Tummy Time Intervention

Study ID#: 100

Age at entry into study: adjusted 1 month 5 days

Baseline Information

Weight/Height/PI:	4.62 kg/56 cm/26.31
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PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	4	4 mos	84%	13
Stationary	9	1 mos	37%	9
Locomotion	9	2 mos	63%	11
Grasping	8	1 mos	50%	10
Visual Motor Integration	0	<1 mos	5%	5
Gross Motor Quotient (%-ile)		106 (65%)		
Fine Motor Quotient ((%-ile)	85 (16%)		
Total Motor Quotient	(%-ile)	97 (42%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled
Fine Motor	2	< 16 days	8	
Gross Motor	6	1 mos	10	18
Composite Se	core (%-ile)	94 (34%)		

Physical Activity:

	Total	Light Activity	Vigorous Activity
Wrist	2,131,948	814,270.5	831,725.7
Ankle	1,296,491	460,319.1	548,859.8

Special circumstances

Born 3 weeks early. Spent 8 days in NICU.

Month 1

Age: adjusted 2 mos 3 days

Weight/Height/PI: 5.16 kg/60.3 cm/23.6

Average # of minutes of Tummy Time/Day: 71.2 min/day

% at or above average: 48% (13/27)

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	5	5 mos	75%	12
Stationary	18	3 mos	63%	11
Locomotion	12	3 mos	63%	11
Grasping	11	2 mos	50%	10
Visual Motor Integration	17	4 mos	75%	12
Gross Motor Quotient (%-ile)		109 (73%)		
Fine Motor Quotient (%-ile)		106 (65%)		
Total Motor Quotient ((%-ile)	108 (70%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	9	3 mos 10 days	14	
Gross Motor	15	4 mos	15	29
Composite S	core (%-ile)	127 (90	5%)	

Physical Activity:

	Total	Light Activity	Vigorous Activity
Wrist	1,832,871	851,532.3	448,603
Ankle	1,793,503	739,119.5	356,031.6

Notes/Special circumstances

Sick for 2 days this month. 1.5 hours of home based PT & OT received. Ponderal index decreased. All scores on PDMS-II increased. All scores on the Bayley increased.

Age: Adjusted 3 months 4 days

Weight/Height/PI: 5.55 kg/61 cm/24.44

Average # of minutes of Tummy Time/Day: 62.31 min/day

% at or above average: 46.2%

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	5	5 mos	63%	11
Stationary	19	4 mos	63%	11
Locomotion	20	4 mos	63%	11
Grasping	13	3 mos	50%	10
Visual Motor Integration	22	5 mos	75%	12
Gross Motor Quotien	t (%-ile)	106 (65%)		
Fine Motor Quotient	(%-ile)	106 (65%)		
Total Motor Quotient	(%-ile)	107 (68%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	11	4 mos	14	
Gross Motor	16	4 mos	14	28
Composite	Score (%-ile)	124 (95%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	2,419,136	1,237,012	277,699.8
Ankle	1,838,102	847,214	186,109.1

Notes/Special circumstances

Month 3

Age: Adjusted 4 months 3 days

Weight/Height/PI: 6.15 kg/62.9 cm/24.71

Average # of minutes of Tummy Time/Day: 64 min/day

% at or above average: 53.3%

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	6	5 mos	63%	11
Stationary	20	4 mos	50%	10
Locomotion	24	5 mos	63%	11
Grasping	18	4 mos	50%	10
Visual Motor Integration	24	6 mos	75%	12
Gross Motor Quotien	nt (%-ile)	104 (61%)		
Fine Motor Quotient	(%-ile)	106 (65%)		
Total Motor Quotien	t (%-ile)	105 (63%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	15	4 mos 20 days	14	
Gross Motor	17	4 mos 10 days	11	25
Composite	Score (%-ile)	115 (84	4%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	2,515,227	1,447,465	484,072.3
Ankle	2,307,855	1,186,421	437,068.5

Notes/Special circumstances

120 minutes of home based PT and OT this month. All scores advanced on PDMS-II increased. All scores on the Bayley increased.

⁴⁵ minutes of home based PT and OT this month. Ponderal index increased. All scores on PDMS-II increased. All scores on the Bayley increased.

Age: Adjusted 5 months 5 days

Weight/Height/PI: 6.41 kg/64.4 cm/23.98

Average # of minutes of Tummy Time/Day: 69 min/day

% at or above average: 50%

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	8	6 mos	63%	11
Stationary	23	5 mos	50%	10
Locomotion	27	5 mos	50%	10
Grasping	19	4 mos	37%	9
Visual Motor Integration	24	6 mos	63%	11
Gross Motor Quotien	t (%-ile)	102 (55%)		
Fine Motor Quotient	(%-ile)	100 (50%)		
Total Motor Quotient	(%-ile)	101 (53%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	19	6 mos	13	
Gross Motor	21	5 mos 10 days	11	24
Composite	Score (%-ile)	112 (79	9%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	2,313,752	1,224,764	554,779.7
Ankle	2,212,420	1,057,386	724,396.8

Notes/Special circumstances

Stuffy and congested 10 days this month. 135 minutes of home based PT and 90 minutes of home based OT this month. Ponderal index decreased. All scores advanced on PDMS-II increased. All scores on the Bayley increased. Milestones achieved: rolling back to tummy

Month 5

Age: Adjusted 6 months 4 days

Weight/Height/PI: 6.98 kg/66.7 cm/23.49

Average # of minutes of Tummy Time/Day: 84.5 min/day

% at or above average: 63.3%

Raw Score	Age Equiv	%ile Rank	Std Score
11	7 mos	63%	11
25	6 mos	50%	10
33	6 mos	50%	10
23	5 mos	37%	9
27	6 mos	50%	10
t (%-ile)	102 (55%)		
(%-ile)	97 (42%)		
t (%-ile)	100 (50%)		
	11 25 33 23 27 at (%-ile) (%-ile)	11 7 mos 25 6 mos 33 6 mos 23 5 mos 27 6 mos at (%-ile) 102 (55%) (%-ile) 97 (42%)	11 7 mos 63% 25 6 mos 50% 33 6 mos 50% 23 5 mos 37% 27 6 mos 50% at (%-ile) 102 (55%) (%-ile) 97 (42%)

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	19	6 mos	10	
Gross Motor	24	6 mos	10	20
Composite	Score (%-ile)	100 ((50%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	1,773,139	1,095,376	371,181.2
Ankle	1,496,244	1,012,329	275,398

Notes/Special circumstances

80 minutes each of home based PT and OT this month. Ponderal index decreased. All scores increased on PDMS-II. Bayley gross motor scores increased.

Milestones achieved: Rolling back to tummy; prop sitting >10 seconds

Age: Adjusted 7 months 4 days

Weight/Height/PI: 7.75 kg/69.5 cm/23.1

Average # of minutes of Tummy Time/Day: 85.2 min/day

% at or above average: 53.6%

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	11	7 mos	50%	10
Stationary	26	6 mos	37%	9
Locomotion	37	7 mos	50%	10
Grasping	34	9 mos	75%	12
Visual Motor Integration	36	8 mos	63%	11
Gross Motor Quotient	t (%-ile)	98 (45%)		
Fine Motor Quotient	(%-ile)	109 (73%)		
Total Motor Quotient	(%-ile)	103 (58%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	21	7 mos	9	
Gross Motor	28	7 mos	10	19
Composite	Score (%-ile)	97 (4.	2%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	2,568,585	545,799.3	1,307,112
Ankle	2,313,510	419,184.1	1,209,293

Notes/Special circumstances

120 minutes each of home based OT and 60 min of home based PT this month. Ponderal index decreased. All scores increased on PDMS-II and Bayley increased. Fine motor skills had big increase this month. Milestones achieved: belly crawling >3 feet. Up on hands/knees and rocking for first time day before this visit.

Month 7

Age: Adjusted 8 months 5 days

Weight/Height/PI: 7.75 kg/70 cm/23.1

Average # of minutes of Tummy Time/Day: 107.6 min/day

% at or above average: 51.6% (16/31)

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	12	7 mos	37%	9
Stationary	26	6 mos	25%	8
Locomotion	38	7 mos	37%	9
Grasping	32	8 mos	50%	10
Visual Motor Integration	33	7 mos	37%	9
Gross Motor Quotien	t (%-ile)	91 (27%)		
Fine Motor Quotient	(%-ile)	97 (42%)		
Total Motor Quotient	(%-ile)	93 (32%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	25	9 mos	12	
Gross Motor	31	8 mos	9	21
Composite	Score (%-ile)	103 (58%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	2,217,356	711,368	1,002,822
Ankle	2495330.63	672,359.7	860,759.1

Notes/Special circumstances

60 minutes of home based OT and 60 min of home based PT this month. Fussy during assessment on/off. Bayley scores increased. Reflex and locomotion scores on PDMS-II increased.

Milestones achieved: Sitting upright x 30 seconds

Age: Adjusted 9 months 4 days

Weight/Height/PI: 7.95 kg/72 cm/21.3

Average # of minutes of Tummy Time/Day: 140.7 min/day

% at or above average: 43.3% (13/30)

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	14	9 mos	50%	10
Stationary	36	11 mos	75%	12
Locomotion	48	9 mos	50%	10
Grasping	33	8 mos	37%	9
Visual Motor Integration	45	9 mos	50%	10
Gross Motor Quotien	t (%-ile)	104 (61%)		
Fine Motor Quotient	(%-ile)	97 (42%)		
Total Motor Quotient	(%-ile)	101 (53%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	25	9 mos	10	
Gross Motor	35	9 mos	10	20
Composite	Score (%-ile)	100 (.	50%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	2,688,206	1,493,273	678,707.8
Ankle	1,870,219	951,402.4	480,210.7

Notes/Special circumstances

120 minutes of home based PT and 60 min of home based OT this month. Ponderal index decreased. Scores on both assessments continue to improve.

Milestones achieved: Independent sitting to play with toys; transitioning in/out of sitting; pulling to stand

Month 9

Age: Adjusted 10 months 4 days

Weight/Height/PI: 8.02 kg/73.5 cm/20.2 Average # of minutes of Tummy Time/Day: na

% at or above average: na

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	16	11 mos	63%	11
Stationary	36	11 mos	63%	11
Locomotion	46	8 mos	25%	8
Grasping	33	8 mos	25%	8
Visual Motor Integration	48	10 mos	50%	10
Gross Motor Quotient	(%-ile)	100 (50%)		
Fine Motor Quotient (%-ile)		94 (35%)		
Total Motor Quotient	(%-ile)	97 (42%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	27	10 mos	10	
Gross Motor	36	9 mos	9	19
Composite	Score (%-ile)	97 (4.	2%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	2,528,311	908,189.4	1,071,626
Ankle	1,679,603	565,663.7	6,934,480.2

Notes/Special circumstances

Ponderal index decreased. Scores on both assessments continue to improve.

Milestones achieved: 4 point crawling up to 5 ft

Age: Adjusted 11 months 6 days **Weight/Height/PI:** 8.16 kg/74 cm/20.1

Average # of minutes of Tummy Time/Day: na

% at or above average: na

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Reflexes	16	11 mos	50%	10
Stationary	36	11 mos	50%	10
Locomotion	59	10 mos	37%	9
Grasping	34	9 mos	25%	8
Visual Motor Integration	53	11 mos	50%	10
Gross Motor Quotient	(%-ile)	98 (45%)		
Fine Motor Quotient (%-ile)	94 (35%)		
Total Motor Quotient	(%-ile)	96 (39%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	28	11 mos	10	
Gross Motor	38	10 mos	9	19
Composite	Score (%-ile)	97 (4.	2%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	2,062,992	342,192.7	1,049,377
Ankle	1,583,054	248,003.7	834,091.2

Notes/Special circumstances

45 min of home PT and 60 min of home OT this month. Sick for 10 days. Scores on both assessments continue to improve.

Milestones achieved: 4 point crawling as primary means of household mobility. Cruising.

Month 11

Age: Adjusted 12 months 3days

Weight/Height/PI: 8.48 kg/74 cm/20.9

Average # of minutes of Tummy Time/Day: na

% at or above average: na

Raw Score	Age Equiv	%ile Rank	Std Score
36	11 mos	37%	9
63	11 mos	37%	9
2	12 mos	37%	9
42	20 mos	91%	14
66	13 mos	63%	11
nt (%-ile)	94 (35%)		
Fine Motor Quotient (%-ile)			
t (%-ile)	103 (58%)		
	36 63 2 42 66 at (%-ile) (%-ile)	36 11 mos 63 11 mos 2 12 mos 42 20 mos 66 13 mos nt (%-ile) 94 (35%) (%-ile) 115 (84%)	36 11 mos 37% 63 11 mos 37% 2 12 mos 37% 42 20 mos 91% 66 13 mos 63% nt (%-ile) 94 (35%) (%-ile) 115 (84%)

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	30	13 mos	11	
Gross Motor	39	11 mos	8	19
Composite	Score (%-ile)	97 (4.	2%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	3,025,630	1,408,380	970,930.2
Ankle	1,897,525	916,046.2	485,899

Notes/Special circumstances

120 min of home PT and 120 min of home OT this month. Sick for 2 days. Scores on both assessments continue to improve. Big fine motor increases this month.

Milestones achieved: Cruising between surfaces

Age: Adjusted 13 months 3 days **Weight/Height/PI:** 8.60 kg/75 cm/20.4

Average # of minutes of Tummy Time/Day: na

% at or above average: na

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Stationary	36	11 mos	37%	9
Locomotion	64	11 mos	25%	8
Object manipulation	4	12 mos	37%	9
Grasping	36	10 mos	25%	8
Visual Motor Integration	58	11 mos	25%	8
Gross Motor Quotie	nt (%-ile)	91 (27%)		
Fine Motor Quotien	t (%-ile)	88 (21%)		
Total Motor Quotien	nt (%-ile)	89 (23%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	29	12 mos	9	
Gross Motor	39	11 mos	7	16
Composite	Score (%-ile)	88 (2	1%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Wrist	2,546,833	979,271.5	987,460.3
Ankle	1,885,113	779,822.5	687,995.6

Notes/Special circumstances

60 min of home PT and 60 min of home OT this month.

Month 18

Age: Adjusted 18 months 3 days **Weight/Height/PI:** 9.25 kg/78 cm/19.5

Average # of minutes of Tummy Time/Day: na

% at or above average: na

PDMS-II	Raw Score	Age Equiv	%ile Rank	Std Score
Stationary	38	18 mos	50%	10
Locomotion	73	14 mos	9%	6
Object manipulation	6	13 mos	9%	6
Grasping	41	15 mos	37%	9
Visual Motor Integration	78	17 mos	37%	9
Gross Motor Quotient (%-ile)		83 (13%)		
Fine Motor Quotient (%-ile)		94 (35%)		
Total Motor Quotien	ıt (%-ile)	86 (18%)		

Bayley

	Raw Score	Age Equiv	Scaled Score	Sum of Scaled Scores
Fine Motor	35	20 mos	11	
Gross Motor	42	12 mos	5	16
Composite	Score (%-ile)	88 (2	1%)	

Physical Activity

	Total	Light Activity	Vigorous Activity
Waist	15.583	9.33	4
Ankle	1983378.74	820582.8	761112.2

Notes/Special circumstances

Milestones met: standing alone, floor to stand transitions, sit to stand transitions, two independent steps

