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TUMMY TIME IN INFANCY: REAL-WORLD ASSESSMENTS AND ASSOCIATIONS WITH DEVELOPMENTAL OUTCOMES IN EARLY CHILDHOOD

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TUMMY TIME IN INFANCY: REAL-WORLD ASSESSMENTS AND ASSOCIATIONS WITH DEVELOPMENTAL OUTCOMES IN EARLY CHILDHOOD

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

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Dedication

To my Ajji and Ajoba (Grandma & Grandpa): thank you for passing on your magical stories, passion for healthcare and teaching, and everlasting empathy

Wish you could read this! Miss you

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ABSTRACT

TUMMY TIME IN INFANCY: REAL-WORLD ASSESSMENTS AND ASSOCIATIONS WITH DEVELOPMENTAL OUTCOMES IN EARLY CHILDHOOD

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Tummy time or awake, supervised, prone play is an important developmental play position in infancy. Engaging in more than 15 minutes of tummy time per day is associated with a lower risk of plagiocephaly, lower body mass index, and achievement of higher motor scores in full-term and at-risk preterm infants. However, there are significant gaps in the measurement of tummy time in current literature. Conventionally used subjective parent reports have not been validated against gold standard direct observation and the feasibility and real-world validity of objective solutions such as wearable sensors has not been examined in full-term and at-risk preterm infants. The existing evidence for tummy time in infants also lacks a comprehensive evaluation of prone motor abilities and its impact on development, with only one study focusing on this topic in healthy full-term infants. Validation of sensitive measures and examination of additional tummy time parameters on health outcomes, especially in at-risk infants can assist in designing translational studies for tummy time.

This dissertation aimed at bridging the gap between assessment and practice for tummy time in the form of three research papers. The first two papers (Chapter 2 and 3) included a sample of 32 infants aged 3-6 months (19 full-term and 13 preterm), observed across 3 days in the home environment. The first paper (Chapter 2) focused on testing the feasibility and validity of two wearable sensors (GENEActiv and MonBaby) for tracking tummy time at home. Findings suggest that the GENEActiv sensor is feasible and highly accurate for tracking tummy time at home in term and preterm infants. The purpose of the second paper (Chapter 3) was to, a) validate conventionally used parent recall for measuring tummy time against gold standard direct observation, b) compare the results with the GENEActiv sensor, and c) to explore the impact of prematurity on parent reporting. Results showed that parent recall has a moderate correlation with direct observation and may be used in population-based studies for full-term infants. Parents of preterm infants overestimated tummy time by 22 minutes per day. Compared to parent recall, the GENEActiv sensor was highly accurate for tracking tummy time in both term and preterm infants. The third longitudinal study (Chapter 4) focused on assessing the impact of early prone motor abilities on concurrent and long-term motor and cognitive outcomes in 39 very preterm infants. Findings suggest that prone motor abilities at 3-months of age predict gross motor outcomes at both 6- and 12-months of age. Prone motor abilities at 6-months of age are associated with gross motor, fine motor, and cognitive outcomes at 6-months of age in very preterm infants. Taken together, these three studies provide crucial information for the selection of appropriate tummy time assessment measures in healthy and at-risk populations and highlight the importance of tummy time in at-risk preterm infants. We discuss the clinical implications of our findings for intervention design and implementation.

Chapter 1: Introduction

Participation, defined as "involvement in a life situation", is a core concept of the International Classification of Functioning, Disability and Health (ICF) model and is considered to be the ultimate goal of any rehabilitation (Rosenbaum & Gorter, 2012). Play is an important component of the participation domains in young children and infants (Mobbs et al., 2021). Maria Montessori, one of the last century's most brilliant educators, said that "play is the work of children." Movement experiences during play bolster the infant's ongoing motor, cognitive, and social development (Yogman et al., 2018). The American Academy of Pediatrics (AAP) prescribes at least 30 minutes of tummy time or awake and supervised prone play, distributed in 2-3 sessions per day as the primary play experience for infants who are not yet mobile (Ginsburg et al., 2007). In the sections below, I outline the: a) history of AAP's Back to Sleep Campaign, b) discuss the benefits of tummy time on multiple health outcomes in healthy full-term infants, c) briefly review the literature on tummy time in infants born preterm, and d) summarize the gaps in literature using a conceptual diagram.

The Back to Sleep Campaign

Starting in the 1960's, sudden infant death syndrome (SIDS), defined as the sudden, medically unexplained death of a child younger than one year of age, was identified as a significant health issue (Duncan & Byard, 2018). The AAP Task Force on Infant Sleep Position and SIDS was formed in 1991 to investigate the risk factors for SIDS. In 1992, the AAP Task Force conducted a meta-analysis to evaluate the effects of infant's sleeping position on SIDS and found that prone sleeping (or sleeping on tummy) was strongly correlated with the development of SIDS (AAP, 1992). Following up on these findings, the AAP in partnership with the National Institute of Child Health and Human Development, started the "Back to Sleep" campaign (now known as the Safe to Sleep campaign) in 1994 as a way to educate caregivers on reducing the risk of SIDS (Kattwinkel et al., 1996). This

public initiative was well-received and led to a 94% decrease in the incidence of SIDS (Pai-Jun M. Liao, 2005). However, the downside of this initiative was that infants who slept in supine also preferred to play in supine. In addition, parents avoided placing their infants on tummy even during awake play due to the fear of SIDS (Mildred et al., 1995). This was followed by a marked change in the gross-motor milestone attainment in young infants. At 4 months of age, infants who slept in supine were less likely to roll (Jantz et al., 1997) and exhibited poor anti-gravity extension (Majnemer & Barr, 2005) compared to infants who slept in the prone position. Similarly, at 6 months of age, supine sleeping infants were less likely to sit unsupported (Majnemer & Barr, 2006) and scored lower on developmental screening tools (Dewey et al., 1998) compared to age-matched prone sleeping peers. These differences were found to be short-term with all infants achieving similar motor milestones by 18 months of age (Dewey et al., 1998). In 1996, Davis et al., conducted a prospective study to determine the relationship between sleeping position and motor milestones in 351 infants. They found that the onset of rolling, prop sitting, creeping, crawling, and pull to stand motor milestones occurred at an earlier age in prone sleeping infants compared to supine sleeping infants. Thus, lack of prone sleeping not only impacted motor development but also delayed the attainment of future motor milestones.

In addition to the impact on motor development, researchers found that there was a significant increase in the incidence of positional head deformities such as plagiocephaly (asymmetrical skull development with flattening on one side) and brachycephaly (shortened anterior-posterior skull diameters with wide medial-lateral diameter) in infants who spent more time in supine position. Specifically, Graham et al., 2005, found that the prevalence of plagiocephaly increased from 1 in 300 births to 1 in 60 births after the onset of the Back of Sleep Campaign.

In response to the aforementioned findings, the AAP Task Force started prescribing a few minutes of active and awake tummy time positioning to support development and prevent plagiocephaly in infants (Kattwinkel et al., 2000). Finally, in 2012, the AAP published the "Back to Sleep, Tummy to Play" campaign to encourage tummy time in infants while maintaining the safe sleep precautions (U.S. Department of Health and Human Services. (n.d.)). Since then, these guidelines continue to be reflected in all of the AAP's proceedings (Moon et al., 2016). Apart from the AAP, tummy time is now included in multiple national (Benjamin-Neelon et al., 2018), and international movement guidelines for infants (Hesketh et al., 2017; Tremblay et al., 2017), including the World Health Organization's (WHO) 24-hour movement recommendations (Sommer et al., 2021).

Health benefits of tummy time in healthy full-term infants

While measuring the impact of movement experiences on health outcomes, it is important to measure both quantity and quality of the movement experience. Quantity ("how much") refers to the dosage of the movement experience, for example, number of steps taken, or number of hours spent in physical activity. Further, quality ("how well") represents the capacity portion of the movement experience, for example, skill-level of physical activity. Tummy time dosage and abilities (referred to as prone motor abilities in the following sections) can have distinct but significant influence on health outcomes in infants via specific mechanisms.

Evidence for tummy time dosage and health outcomes

This section outlines the evidence for tummy time dosage ("how much") and its influence of health outcomes in full-term infants.

Tummy time and deformational plagiocephaly

As described earlier, plagiocephaly is the asymmetry in skull development associated with flattening of the skull on one side. Infants who perform less than 15 minutes or less than three occasions of tummy time per day, are identified to be at a greater risk for the development of plagiocephaly (Hutchison et al., 2003; Van Vlimmeren et al., 2007). Rogers (2011) proposed the "Pumpkin Analogy" to describe the development of plagiocephaly in young infants. This analogy suggests that the flattening of skull seen in infants is similar to the flattening spots seen in pumpkins when they grow against hard surfaces. Performing intermittent bouts of tummy time aids in reducing the constant pressure that could occur if the infant stays in the supine position for a long time. In fact, performing more than five minutes of tummy time per day can act as a protective factor against the development of plagiocephaly in infants (Van Vlimmeren et al., 2007). Early prevention of plagiocephaly is important because plagiocephaly is not an isolated cosmetic condition. Speltz et al. (2010) compared developmental outcomes in 235 infants with and without plagiocephaly and found that infants with plagiocephaly scored lower on all scales of the Bayley Scales of Infant and Toddler Development, Third Edition (Bayley-III), compared to age-matched controls. Specifically, these infants scored approximately 10 points lower on the motor composite scales compared to the controls. In another study, Collett et al. (2019) found that 8-9 years aged children with a history of moderate to severe plagiocephaly, scored lower on cognitive and academic assessments compared to age-matched controls. In summary, these findings highlight the association of tummy time dosage and its influence on plagiocephaly prevention in young infants.

Tummy time and obesity

Although relatively new, evidence suggests that tummy time is an excellent form of physical activity for infants and can influence obesity related parameters by supporting environmental exploration in infants (Wentz et al., 2021). Tummy time is the first posture that allows infants to

perceive their environment vertically (Senju et al., 2018). This new-found viewpoint encourages infants to identify objects of interest in their environment. Tummy time further supports exploration of these objects by supporting early locomotion in the form of movement on belly (pivot and crawl), as well as movement to and from belly (rolling). These active movements constitute the young infant's physical activity and may aid in reduction of weight gain, and later obesity.

Typically developing infants who performed approximately 90 minutes of tummy per day starting at 1-5 months of age have a significantly lower ponderal index (effect size=0.92) at 18 months of age than typically developing infants who do not participate in tummy time (Wentz, 2017). Ponderal index is a measure of leanness in infants and is calculated by dividing the infant's weight in kilograms by their height in meters cubed. A higher ponderal index in infancy is associated with a higher body mass index (BMI) at 12 months of age (Lande et al., 2005). Perrin et al. (2014) examined 863 infants from minority populations at 2-months of age and found that infants who performed less than 30 minutes of tummy time per day were at an increased risk of obesity at 2 years of age. Finally, Koren et al. (2019) suggested that infants who performed greater than 12 minutes of tummy time per day at 2 months of age were found have a lower BMI at 4 months of age. In summary, this evidence suggests that it is important to initiate tummy time early (2 months or earlier) and a dosage of minimum 12 minutes of tummy time per day is required to observe a change in physical activity parameters in infants.

Tummy time and developmental milestones

Tummy time can support the acquisition of several developmental milestones, especially in the motor domain. One of the first studies to identify this association was conducted by Salls et al. (2002) and they found that infants who engaged in more than 15 minutes of tummy time per day demonstrated greater head control in prone and sitting, compared to age-matched infants who

performed <15 minutes of tummy time per day. Majnemer & Barr (2006) examined fifty 6-month-old typically developing infants and found that 22% of infants with limited exposure to tummy time and greater durations of supine sleeping time, exhibited gross motor delays as assessed by the Peabody Developmental Motor Scale (both gross and fine motor subscales). Dudek-Shriber & Zelazny (2007) assessed a similar relationship in 100 four-month-old infants and found that infants who performed tummy time above the threshold of 1 hour 21 minutes per day, achieved gross-motor milestones earlier than age-matched infants performing tummy time below the mentioned threshold. Finally, an experimental study by Wentz (2017), compared the effect of a tummy time intervention started at two time points (early- before 11 weeks of age, and late- after 11 weeks of age) on motor development in infants with Down syndrome. They found that infants in the early group had higher motor scores at 1, 2, and 3 months post-baseline compared to infants in the late and control groups. Similarly, an intervention study by Uzark et al. (2021) examined the effect of a tummy time intervention on motor skills in infants with congenital heart disease post-surgery. They found that infants who performed >15 minutes of tummy time per day had a greater improvement in motor scores compared to infants who performed <15 minutes of tummy time per day.

Evidence for prone motor abilities and health outcomes

Motor abilities can have far-reaching effects on non-motor developmental domains such as cognition or language. Theoretically, this is explained by the developmental cascades hypothesis which suggests that attainment and mastery of each motor milestone is associated with significant changes in multiple developmental areas (Masten & Cicchetti, 2010). For example, infants with independent sitting ability can access a larger visual environment and use the upper extremities to explore objects of interest and engage in communicative gestures (Harbourne & Kamm, 2015). This further leads to improved object permanence (An et al., 2022), focused attention (Surkar et al., 2015),

and later language development (Libertus & Violi, 2016; Iverson, 2010) in independently sitting infants. Similar evidence for prone motor abilities is available in only one study by Senju et al. (2018). This study assessed the relationship between prone motor abilities and developmental outcomes in 2,020 full-term infants aged 6-months. They classified infants as prone and non-prone, based on their ability to stay on extended arms in the prone position and assessed their development every 6-months up to 3 years of age. Results showed that the prone infants scored significantly higher on the gross motor domain than the non-prone infants and this difference persisted till 3 years of age (effect size=0.33). Similar differences between the two groups were noted for fine motor, problem solving, and personal-social domains and these differences persisted up to 1 year of age. This study provides preliminary evidence on the role of prone motor abilities as a prognostic indicator of later development in healthy full-term infants.

Prematurity and the impact of tummy time in preterm infants

A premature birth is defined as "birth before 37 weeks of gestation". Advances in obstetric and pediatric medicine have increased the survival rates in infants born preterm. The age of viability for infants born preterm in developed countries has now improved from 28 weeks of gestation to 22-25 weeks of gestation (Fanczal et al., 2020). Despite the reduction in mortality rates, preterm birth survivors are often have health consequences such as motor, visual, hearing, and learning disabilities. In fact, 7-20% of infants born extremely preterm (<28 weeks of gestation) are at a risk for developing cerebral palsy (Hafström et al., 2018). In preterm infants who do not develop cerebral palsy, motor dysfunction is the most commonly seen impairment (Valentini et. al., 2021). Emerging evidence in early detection shows that differences in motor control and learning can be observed as early as 3-4 months of age in infants born preterm (Dusing et al., 2009; Heathcock et al., 2004). Coincidentally,

this is also the time when infants engage most in tummy time. Tummy time can benefit preterm infants in multiple ways.

Health benefits of tummy time in preterm infants

A comprehensive literature review completed on 180 articles concluded that the prone position consistently improves respiratory gaseous exchange, decreases respiratory rate, and improves chest wall symmetry in infants born preterm. Preterm infants who are cared for in the prone position tend to have a lower energy expenditure compared to infants who are cared for in the supine position (Monterosso et al., 2002). Further, preterm infants with limited prone positioning in the Neonatal Intensive Care Unit (NICU) are at risk for postural abnormalities that impact their motor development such as retracted scapular position or "W-position" of the arms (Monterosso et al., 2002). This biomechanical position limits the infant's ability to use their upper extremities for support during prop sitting and crawling (Georgieff & Bernbaum, 1986), and reduces toy-contact behaviors during the onset of reaching (Heathcock et al., 2008).

Prematurity is also identified as risk factor for the development of head deformities. Preterm infants have a softer skull, higher head-weight ratio and spend more time sleeping in the supine position compared to full-term infants (Yang et al., 2019). Tummy time is a protective factor against plagiocephaly in term infants (Hutchison et al., 2003) and may benefit preterm infants as well, however, comparative research for preterm infants is limited. Similarly, the physical activity benefits of tummy time are crucial for preterm infants at risk for childhood obesity. A recent meta-analysis showed that preterm birth increases the risk of obesity by 1.2 times (Ou-Yang et al., 2020). Finally, 17-59% of preterm infants are at a risk of neurological impairments, 5-36% for intellectual disabilities, and 9-18% for cerebral palsy (Jarjour, 2015). Currently, there is only study by Bartlett & Fanning (2003) assessing the impact of tummy time dosage on developmental outcomes in preterm

infants. Bartlett & Fanning assessed the motor development of 60 very preterm infants (<32 weeks of gestation) at 8 months corrected age. In addition, parents were requested to report their infant's favorite play position and the average time spent in the position. They found that preterm infants who preferred the prone position for play and spent an average of 46 minutes on tummy time per day obtained higher scores on motor assessment compared to preterm infants who played in supine at 8 months corrected age. The long-term retention of this relationship has not yet been examined in preterm infants. Similarly, the impact of prone motor abilities on concurrent and long-term preterm infant development has not been assessed. Given the early emergence of developmental delays and risk for adverse health outcomes in preterm infants, it is important to identify early prognostic indicators of delays. Tummy time dosage and prone motor abilities may contribute to this gap and research focusing on these relationships in preterm infants is needed.

In summary, this literature review highlights several conspicuous gaps in the current tummy time literature (see **Figure 1**). Below, is a brief discussion of each gap and the role of this dissertation in bridging those gaps.

Gaps in tummy time literature and focus of this dissertation

As seen in **Figure 1**, the ultimate goal is to improve participation of infants in tummy time. Results from these studies would further inform the health benefits of tummy time (red dotted lines), making it an ongoing process.

Accurate and sensitive measurement of tummy time dosage would be the first step towards initiating this process. Subjective measures such as daily parent-reports or parent recall are commonly used to track tummy time durations in infants. In fact, 12 of 12 studies focused on tummy time

duration in our literature review used some variation of parent reports (see **Table 1** for a summary). Parent reports are straightforward and inexpensive, making them a popular choice for large-scale population studies (Adamo et al., 2009). Literature from older children shows that parents often overestimate their child's physical activity either due to a recall bias (Kippe et al., 2022) or due to social desirability (Klesges et al., 2004) when compared against a gold standard measure. Furthermore, none except one study (Perrin et al., 2014) in our literature review reported some information on the validity of parent report measures. This finding is important because many association studies in our literature review identified trends in the dose-response relationship between tummy time and health outcomes. Given the drawbacks of parent measures, objective measures such as wearable sensors are gaining popularity in movement assessment for infants (Rodgers et al., 2019). Wearable sensors can allow for uninterrupted movement assessment within natural settings (Dobkin, 2013), and are not impacted by biases seen with parent reports. However, studies examining the feasibility and real-world validity of wearable devices for measuring tummy time in infants have not yet been conducted. Importantly, the validity of tummy time dosage measures need to be tested in the at-risk preterm population.

Chapter 2 of this dissertation focuses on testing the feasibility and concurrent validity of two wearable sensors (GENEActiv and MonBaby) for objectively assessing tummy time in both term and preterm infants across days in the natural environment. We hypothesize that both the sensors will be feasible for tracking tummy time at home and the MonBaby sensor will be rated higher on feasibility. The GENEActiv will demonstrate stronger concurrent validity with the gold standard (direct observation), compared to the MonBaby for tracking tummy time in the natural environment. Finally, the concurrent validity of both the sensors will be higher in term infants compared to preterm infants.

Chapter 3 of this dissertation will describe the validation of parent recall compared to the gold standard (direct observation) for tracking tummy time in term and preterm infants. We will also compare the accuracy of parent recall with the accuracy of an accelerometer (GENEActiv) for tummy time tracking at home. We hypothesize that parent recall will have weak to moderate correlation with direct observation, and the GENEActiv sensor will demonstrate a strong concurrent validity with direct observation. The concurrent validity of parent recall and GENEActiv sensor will be stronger in term infants compared to preterm infants

The second measurement gap identified from the literature relates to the impact of prone motor abilities on development in term and preterm infants. Of the 14 studies we reviewed, 11 studies focused on a time-outcome i.e. duration and/or frequency (**Table 1**) and only one study measured the impact of prone motor abilities on development and is focused only on healthy full-term infants (Senju et al., 2018). Recent naturalistic research shows that motor abilities can determine the time an infant spends in that posture. For example, Franchak (2019) found that there was a 7.2% increase in the sitting duration of young infants as their ability to sit improved. Thus, it is likely that improved prone motor abilities may contribute to improvement in the prone play time duration. Importantly, current evidence in the field of pediatric physical therapy identifies quality of movement experience as a critical parameter for supporting development in infants (Lobo et al., 2013). How prone motor abilities may impact long-term developmental outcomes, especially in preterm infants, is currently not known.

Chapter 4 of this dissertation focuses on bridging this gap by examining the concurrent and longitudinal impact of early prone motor abilities on motor and cognitive development in at-risk very preterm infants. We hypothesize that prone motor abilities at both 3- and 6-months of age will be positively associated with motor and cognitive development in very preterm infants at the same time

point. Prone motor abilities at 3- and 6-months of age will predict motor and cognitive development at 12-months of age in very preterm infants.

Table 1: Description of tummy time outcomes in the synthesized literature

Study	Population	Tummy time parameter	Assessment method	Time points
(Van Vlimmeren et al., 2007)	380 healthy term infants aged 7 weeks	Frequency and duration of tummy time while awake	Parent recall	48 hours after birth and 7 weeks of age
(Hutchison et al., 2003)	194 term infants with or without plagiocephaly, aged 2-12 months	Daily duration of tummy time	Parent recall	At 6 weeks of age and at the time of interview
(Wentz, 2016)	13 term infants, 19 infants with Down syndrome	Daily duration of tummy time	Daily parent report	From 0-20 weeks of age to 18 months
(Perrin et al., 2014)	863 term infants from minority populations, aged 2 months	Tummy time duration dichotomized as >30 minutes and <30 minutes	Recall questionnaire*	At 2 months clinical visit

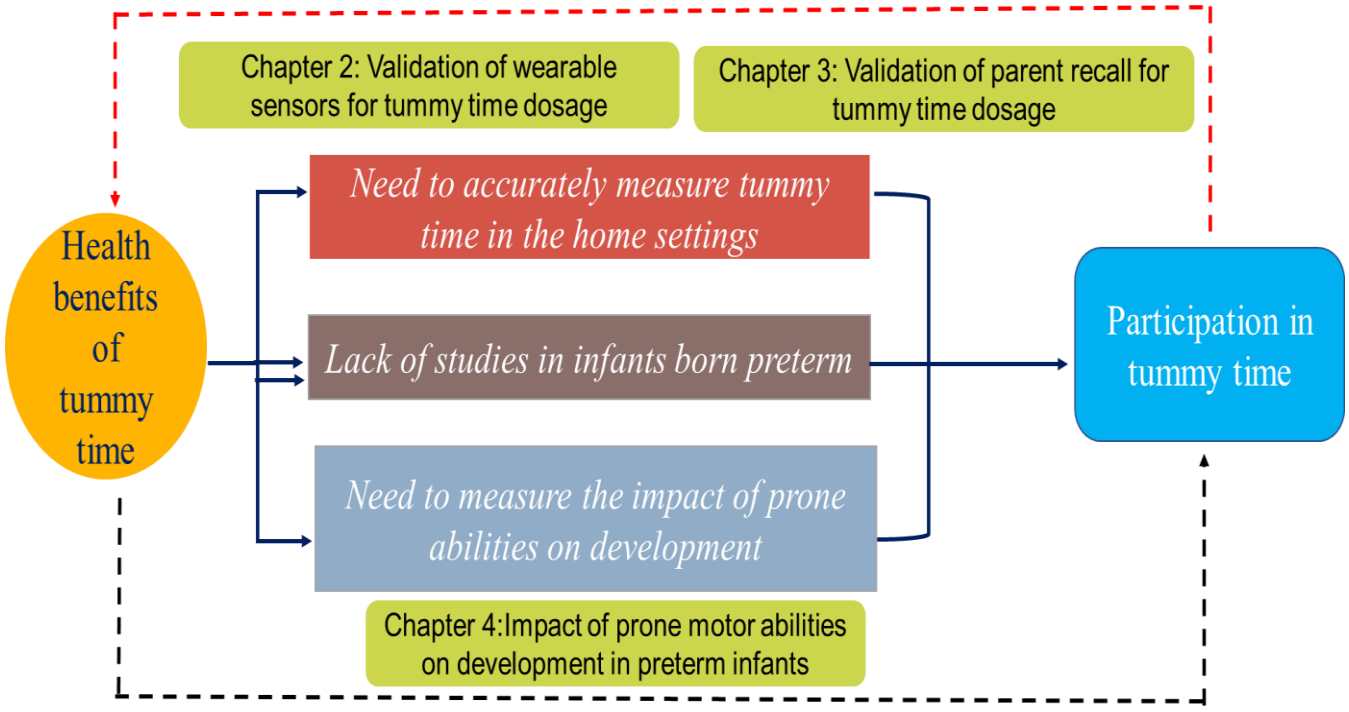
(Koren et al., 2019)	50 term infants aged 2, and 4 months	Time in tummy time (number of minutes per day x frequency per day) categorized as : -Lowest (0-6 minutes/day) -Medium (7-20 minutes/day) -High (>20 minutes/day)	Telephonic surveys	At 2 months and 4 months of age
(Salls et al., 2002)	66 term infants aged 2,4, and 6 months	Time spent on tummy per day (0, 1–15, 16–30, 31–60, 61–90, 91–120, > 120 min)	Parent recall	At 2, 4, and 6 months of age
(Majnemer & Barr, 2005)	71 term infants aged 4 months and	Time spent on tummy	Parent diary for 3 consecutive days	At 4 and 6 months

	50 term infants aged 6 months			
(Dudek-Shriber & Zelazny, 2007)	100 term infants aged 4 months	Time spent on tummy categorized as none, less than an hour, and increments an of hour	Parent Questionnaire	At 4 months
(Senju et al., 2018)	2,020 term infants aged 6 months	Prone motor abilities (prone on extended arms- yes or no)	Clinical assessment	From 6 months to 3 years of age (every 6 months)
(Monterosso et al., 2002)	180 studies were reviewed	Prone position exposure	Medical records	Neonatal period
(Fetters & Huang, 2007)	51 preterm infants (30 with white matter lesions) and 17 term infants aged 1,5, and 9	Infant's preferred play position	Parent interview	At 1, 5, and 9 months corrected age

	months corrected age			
(Bartlett & Fanning, 2003)	60 at-risk preterm infants aged 8 months (corrected)	Infant's favorite play position and time spent in it	Parent interview	At 8 months of age
(Wentz, 2017)†	19 infants with Down syndrome aged 0-20 weeks	No tummy time outcomes	Not applicable	Not applicable
(Uzark et al., 2021)†	64 infants with cardiac surgery aged <4 months	Duration of tummy time categorized as: <15 minutes, >15 minutes	Daily parent report	

*Questionnaire was designed based on previously validated position questionnaires in infants, †Intervention studies

Figure 1: Conceptual diagram for gaps in the tummy time literature



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Chapter 2: Real-world feasibility and validation of wearable sensors for tracking tummy time in term and preterm infants

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Abstract

Background: Tummy time is the primary recommended physical activity for children aged less than 1 year of age. However, objective measurement to quantify duration or intensity of tummy time in the natural environment is a challenge.

Purpose: To assess the feasibility and concurrent validity of the GENEActiv and MonBaby sensors when compared to direct observation for tracking tummy in the home environment.

Methods: Caregivers were taught to use the two sensors while recording their infant's play sessions for 3 consecutive days and report their perceived feasibility. Sensor prone and non-prone durations were compared with video to determine validity using correlation, mixed models, and Bland-Altman plots.

Results: The MonBaby sensor was preferred by the caregivers but had >45% data loss. Both the sensors were strongly correlated with video (r's>0.9). The GENEActiv sensor was more accurate in detecting prone position (mean difference=1.47 minutes, p=0.2) compared to the MonBaby (mean difference= -4.6 minutes, p=0.007). The accuracy of sensors did not differ based on birth status.

Conclusions: Our results suggest that the GENEActiv sensor is more accurate in precisely detecting tummy time in term and preterm infants at home but may require some modifications to improve its feasibility. The MonBaby sensor's connectivity needs to be improved before using it in home settings. Objective measurement of tummy time can aid in implementing health policies and capture change post intervention.

Introduction

The COVID-19 pandemic highlighted a conspicuous gap in the remote patient monitoring capabilities of our healthcare system (Pronovost et al., 2022; Watson et al., 2020). Wearable technologies show promise in addressing this gap and in opening up new avenues for remote healthcare assessment and delivery (Majumder et al., 2017). Wearable technology can be defined as technology solutions that can be worn by a person, as accessories, or embedded in clothing, to monitor well-being passively or actively (Patel et al., 2012). Wearable sensors are a type of wearable technology that incorporates accelerometers or inertial movement units (Lobo et al., 2019) and can be used to track various physiological (Patel et al., 2012) and movement parameters(Francisco-Martínez et al., 2021; Kristoffersson & Lindén, 2022) in typical and clinical populations. In particular, wearable sensors afford continuous, in-depth assessments within an individual's real-world environment, allowing clinicians to capture (Adams et al., 2021; De Quirós et al., 2022) and augment participation outcomes (Zhang et al., 2020). In the last decade, there has been significant progress in the development and application of wearable sensors to remotely monitor participation outcomes for adults and children older than 12 months of age in real-world settings (Abreo et al., 2015; Bianchim et al., 2020; Kippe et al., 2022; Porciuncula et al., 2018). However, similar evidence for children under the age of 12 months (infants), particularly in the natural environment, is still limited (Airaksinen et al., 2022; Greenspan et al., 2021; Trujillo-Priego et al., 2017).

Participation, as defined by the ICF model, for infants primarily comprises 'play'. Assessment of an infant's play abilities in their natural environment provides a window into their motor, cognitive, and social development (Yogman et al., 2018). The World Health Organization's (WHO) 24-hour movement guidelines strongly recommend 30 minutes of daily awake and supervised prone play also known as tummy time as the primary physical activity for young infants (Sommer et

al., 2021). The primary movement recommendation of tummy time is built on a well-established body of evidence related to its positive impact on health outcomes in infants (Hewitt et al., 2020). Tummy time is the first development position to afford anti-gravity movement control in infancy and provides several opportunities to strengthen the neck, trunk, and arm musculature (Jones, 2005). This foundational anti-gravity control is pivotal for later gross motor skill development. Term-born and preterm infants who spend more time on the tummy during play attain motor milestones earlier (Hewitt et al., 2020) and score higher on motor assessments compared to infants who spend less time on their tummy (Bartlett & Fanning, 2003; Fetters & Huang, 2007). Practicing motor skills during tummy time provides infants with opportunities to initiate social interactions with caregivers, practice vertical looking, and improve their upper extremity strength (Senju et al., 2018). A recent study found that 6-month old term infants who could push up on arms in the prone position scored higher on gross motor, fine motor, communication, problem-solving, and personal–social domains of the Ages and Stages Questionnaire till 3 years of age, compared to age-matched infants who could not push up in prone (Senju et al., 2018). Tummy time is also recognized as the primary modifiable factor to prevent positional plagiocephaly in infants (Hutchison et al., 2003; Van Vlimmeren et al., 2007) and can assist in the reduction of adiposity indicators in young infants if initiated early in life (Wentz, 2017).

Parent reports are the preferred method for tracking tummy time in infants but are often limited by subjectivity, recall bias, and lack of evidence about their psychometric properties (Kippe et al., 2022; Koning et al., 2018). Wearable sensors such as three-axis accelerometers or inertial movement units are a potential solution to this problem and can be utilized to track infant positioning in the real-world environment (Airaksinen et al., 2022; Franchak et al., 2021). A recent study developed and validated accelerometer algorithms to differentiate and track tummy time positioning bouts in term-born healthy infants using three accelerometers (GENEActiv, MonBaby, and

Actigraph) in controlled laboratory settings (Hewitt et al., 2019). They concluded that the GENEActiv sensor was the most accurate (95%) in detecting prone positioning and the MonBaby sensor was the most preferred by parents. While this study provided proof of concept for the use of accelerometers in tummy time tracking, these results cannot be directly generalized to the natural environment. Tummy time in the real world includes mobility on the belly (pivot/crawl) and is often associated with transitions from tummy to back and vice versa. Lab-based sensor algorithms may fail to capture these natural transitions and can lead to high misclassification rates. For example, the accuracy of lab-based validation models for physical activity tracking in preschool children was reduced by 11-15% when tested in outdoor settings (Ahmadi et al., 2020). Similarly, the accuracy of a lab-based validation model for infant position tracking was lowered by 13% in home settings (Franchak et al., 2021).

Along with testing in the natural environment, it is important to validate smart wearables in diverse samples, particularly in clinical populations at risk of developmental delays (Keadle et al., 2019). Infants born preterm with or at risk for delays often demonstrate movement patterns that are different from typically developing infants (Dusing et al., 2009). In a study by Örtqvist et al. (2021), 13% of preterm infants aged 3-4 months demonstrated atypical hyperextension of the trunk and neck compared to 2% of term-born infants of the same age. Since the prone position is an extension-biased posture, hyperextension patterns may be more commonly seen in preterm infants during tummy time. Prone position has also been identified as the least-favorite position in preterm infants and is frequently supported by the use of positioning devices (Bartlett & Fanning, 2003). How the use of positioning devices during tummy time can impact sensor accuracy is not known. Given the heterogeneity in positioning patterns and preferences between term-born and preterm infants, it is crucial to validate and compare the accuracy of wearable sensors in both these populations. Importantly, including at-risk samples in validation studies can support the use of wearable sensors

for early detection of atypical movement patterns and early referral to intervention (Abrishami et al., 2019).

Keadle et al. (2019) proposed a framework to achieve consistency and enable comparisons between validation methods for sensor-based physical behavior measurement. This framework divides sensor validation into four phases; Phase 0 and Phase I comprises mechanical testing of the sensor signal and lab-based algorithm development respectively. Phase II comprises of semi-structured evaluation of the lab algorithm, including natural transitions but with a high degree of researcher control. Phase III is a 'true', rigorous free-living validation in the participant's natural environment when compared to gold standard measures, and Phase IV involves the adoption of validated sensors and methods into applied studies. Based on this framework, Phase 0 and I for tummy time sensors have been completed (Hewitt et al., 2019). **Figure 2** depicts the timeline for tummy time sensor validation phases.

In the current study, we aim to evaluate the validity of two wearable sensors (GENEActiv and MonBaby) for tummy time measurement in real-world use through Phase II and Phase III testing. Our first objective is to assess the caregiver's perceived feasibility of using the tummy time sensors at home and examine the data quality of natural environment validation **(Aim 1).** Based on the results of the lab-validation study (Hewitt et al., 2019), we hypothesize that both the sensors will be feasible for tracking tummy time at home and the MonBaby sensor will be rated higher on feasibility. The second objective is to compare and examine the concurrent validity of the GENEActiv and MonBaby sensors for measuring tummy time in term and preterm infants in a semi-structured natural environment (Phase II, **Aim 2**). The third objective is to complete a similar concurrent validation in an unstructured true natural environment (Phase III, **Aim 3**). We hypothesize that the GENEActiv will demonstrate stronger concurrent validity with the gold standard (direct observation), compared to the

MonBaby for tracking tummy time in the natural environment. Finally, the concurrent validity of both sensors will be higher in term infants compared to preterm infants.

Methods

Participants

The study sample consisted of N=32 infant-parent dyads aged 3-6 months (19 term-born and 13 preterm). Convenience sampling was used to recruit eligible infants from the Virginia Commonwealth University Health systems and the surrounding community using flyers, social media advertisements, and mailed letters. Infants were eligible for the study if i) they were aged between 3-6 months of age (adjusted age or chronological age minus weeks preterm, was used for preterm infants), ii) the caregivers were at least 18 years of age, and spoke English, and iii) if the caregiver consented to video and audio recording. Infants were excluded from the study if, i) they were intolerant to tummy time as reported by the parent —operationally defined as crying for more than 30 seconds when placed on the tummy, ii) having a medical condition preventing them from lying on their tummy. Infants intolerant to tummy time were excluded from this study as we required infants to spend time on their tummy to validate the sensors. All infant-parent dyads were included in the study after obtaining written informed consent and were compensated $100 on the last day of participation. This study was approved by the Institutional Review Board at Virginia Commonwealth University (**IRB #HM20020592**).

Measures

Tummy time sensor feasibility questionnaire

The caregiver-perceived feasibility of the two tummy time sensors in the home settings was assessed using a 16-item Likert-type questionnaire on a 5-point scale (**Appendix A**). Six questions

focused on measuring the applicability of the sensors, defined in terms of ease of attachment to the infant's clothing, activation of sensors, and retention of wearables on the body. Six questions focused on the comfort, aesthetics, and usefulness of the sensors. One question asked the caregivers to choose a preferred sensor and three open-ended questions allowed caregivers to express their thoughts about the individual sensors. This survey was administered through REDCap (Harris et al., 2019) on Day 3 of this study.

Tummy time sensors

The GENEActiv sensor (Activinsights Ltd, Cambridgeshire, UK) is a lightweight (16 grams), triaxial accelerometer and a research-grade activity monitor. For this study, the GENEActiv was initialized with a sampling frequency of 30Hz using the GENEActiv PC software and allows for continuous recording for up to 21 days. The GENEActiv was initially set up for the caregivers to activate and deactivate it. This led to a loss of data in the first few participants due to the caregiver's forgetting to activate the sensor. Hence, we changed the setting of the GENEActiv sensor to 'continuous recording on button press', which allows uninterrupted recording. The axis orientation of the GENEActiv with the baby in the supine position is as follows: x-axis horizontally, side to side (right side as the reference), y-axis head to feet (pointing towards the feet), and z-axis front to back (pointing forward). For this study, the GENEActiv was placed on the infant's right (anterolateral) hip using a soft elastic velcro strap (**Figure 3**).

The MonBaby sensor (MonDevices Inc, New York, NY, USA) is a 14-bit, tri-axial accelerometer, and a commercial 'Smart breathing and rollover' monitor (https://monbabysleep.com/), with a sampling frequency of 6.25 Hz. It connects via Bluetooth and streams information related to the infant's breathing, body position (supine, prone, and side-lying), body temperature, and fall incidences to an app on a smartphone device (iOS and Android). The

MonBaby includes a smart button that can be secured to the infant's clothing using a snap-on ring. It was attached at the center of the infant's chest or slightly lateral to the chest (in infants with a middle zipper or button on clothing) (**Figure 3**). To activate the MonBaby, the caregivers were required to install the MonBaby app and complete a position calibration with the baby in the supine position. Calibration was successful when they saw a message saying "I am on my Back" on the app (see **Appendix B** for sensor activation protocols). The caregivers logged out of the app to deactivate the sensor after each play session and were requested to charge the smart button every night. The axis orientation of the MonBaby is the same as the GENEActiv.

Gold standard (Video observation)

Since this study was conducted across several days in the participant's homes, a video camera was used as a proxy to the gold standard 'direct observation'. The Panasonic HC-770 camcorder mounted on a tripod was used to complete the video recording at home. This camera was chosen as it allows for continuous recording while being charged and can be used for longer durations throughout the day. The resolution was set at 720 pixels to maximize recording and minimize data storage issues.

Study Procedure

This cross-sectional study was conducted in the participant's homes across 3 days. Since the data collection period occurred during the COVID-19 pandemic (April 2021-March 2022), we developed a minimal-contact validation protocol to accommodate the physical distancing and sanitation regulations. The concurrent validity of wearable sensors against video was tested in two phases: i) A researcher-guided semi-structured validation session (Phase II) and ii) a 3-day caregiver-driven natural environment validation (Phase III). To ensure participant safety and minimize personnel exposure during the pandemic, both phases took place in the participant's home. A pre-sanitized study package consisting of the GENEActiv and MonBaby sensors, attachment and

charging accessories, a camcorder on a tripod, and an illustrated study manual outlining the steps for sensor and camera placements was dropped off at the participant's doorstep on Day 1. The study package was mailed to participants' houses if they lived farther than 40 miles from the recruiting location **(**see **Figure 4** for methodology**)**

Semi-structured validation **(Aim 2)**

This session occurred on Day 0 or Day 1 after the participants received the study package and was offered in remote (via zoom conferencing) and in-person formats. The CDC sanitization protocols were adhered to if the session was conducted in person. The session took place in the area where the infant spent most of their playtime. The researcher first oriented the caregivers to the sensor and camera placements. The camera was placed on the tripod and recording was started at the beginning of each play session. Before attaching the sensors to their infant's clothing, the caregivers were instructed to complete a synchronization event by shaking the two sensors for 3-5 seconds on the camera. This event was repeated at the beginning and end of each play session for the following 3 days of data collection. Consistent with the protocol, the GENEActiv sensor was fastened snugly on the infant's right hip using an elastic strap and the MonBaby sensor was placed at the center of the infant's chest using a snap-on ring. The researcher completed the Alberta Motor Infant Scale (AIMS) assessment for semi-structured (Phase II) validation. The AIMS was selected because it is a performance-based observational tool and allowed the researcher to recreate natural infant play in four positions i.e. supine, prone, sitting, and standing without excessive handling of the infant (Piper, 1994). The entire session lasted 20-30 minutes and the researcher left the participant's home after the assessment was completed.

Natural environment validation **(Aim 3)**

Following the semi-structured validation, caregivers were requested to perform the synchronization event, reattach the sensors on the infant's clothing, and record their infant's play for the rest of Day 1 and two additional consecutive days (Day 2 and 3). There were no restrictions on the location and duration of the recording and the caregivers were instructed to mimic their daily play routines as closely as possible. The sensors and the video were turned off during clothing change, diaper change, bathing time, and sleeping time due to privacy concerns. To minimize attachment errors, caregivers were provided with an illustrated instruction manual **(Appendix B)**, and a printed checklist of steps to follow; sent text reminders two times a day. They were also given the option of troubleshooting through phone calls or zoom sessions any time of the day. The researcher completed a doorstep pick-up on Day 3 and the entire study package was sanitized.

Data coding and processing

Video data coding

Video data for each infant was accessed through the camcorder's local storage and downloaded for behavior labeling using the Datavyu software (www.datavyu.org). A customized coding manual was developed (**Appendix C**) and two variables (events and posture) were coded. Events included the sensor attachment, detachment, and synchronization procedures performed by the caregivers and were marked separately for the GENEActiv and MonBaby. The events data was used to identify the periods when the wearables were on and off the infant. Infant posture was divided into three broad categories: i) prone (prone with head down, prone on forearms, prone on hands, different forms of prone mobility, and quadruped), ii) prone supported (lying down on a parent's chest or on a positioning device), and iii) non-prone (supine, reclined in a swing, side-lying, supported/independent sitting, sitting in seating device, supported standing, caregiver holding). Quadruped was included in prone as we anticipated very few infants within our included age range to perform this skill. Times

when the sensors fell or were briefly removed and reattached or when the infant was out of view, were noted in the video coding and adjusted for in the sensor data. The behavior and event definitions are briefly described in **Table 2.** Two coders, who were trained previously with excellent inter-(ICC=0.91) and intra-rater (ICC=0.95) reliability completed the video coding. Inter-and intra-rater reliability was maintained throughout the study by assigning 20% of the videos for secondary coding. The reliability results for secondary coding are as follows: inter-rater reliability (ICC=0.93) and intra-rater reliability (ICC=0.97). The cumulative prone and non-prone positioning times per day were obtained using a customized position calculator in excel**.**

Sensor data processing

After data collection, accelerometers were downloaded for subsequent data reduction and analysis. The GENEActiv raw data was obtained using the GENEActiv PC software (Version 3.3). We planned on using the synchronization events to identify the sensor-wear times, however, 40% of our caregivers failed to complete the synchronization procedures. Thus, we identified the sensor wear-time instances using video stamps, and to ensure accuracy, we visually inspected the accelerometer signal magnitude. A similar method has been used to identify sensor wear time in a previous study (Van Cauwenberghe et al., 2011). **Figure 5** visually depicts the GENEActiv accelerometer signal with synchronization events in one participant. The total time GENEActiv prone and non-prone position times during each play session per day were calculated using a customized MATLAB script (**Appendix D**)**.** The per-day totals were summed to get a 3-day cumulative prone and non-prone durations.

The MonBaby data was extracted from a custom-built dashboard developed by the manufacturers (MonDevices Inc.). The MonBaby raw data is organized as 5-7 rows (epoch frequency) per second in excel and consists of timestamps (in UNIX time) and raw x,y, and z-axis

data. The .csv file was converted into an Excel file and the UNIX time was converted to excel time in 'dd/mm/yyyy hh:mm:ss' format to get the MonBaby timestamps. Using the lab-validated algorithm, a 360-degree angle was calculated, and all angles <134 degrees were classified as 'non-prone'. The prone and prone supported positions were differentiated using a z-axis cut point of <0.10 gravity. As with the GENEActiv, the MonBaby wear-time was identified using the video stamps and a customized MATLAB script (**Appendix E**) to calculate the time spent in prone and non-prone positions per day and summed to get a 3-day total.

Statistical Analyses

JMP® Pro (version 15.1.0) was used to perform the statistical analyses addressing each study aim. Statistical significance level was set at ≤ 0.05. Descriptive statistics were used to report participant characteristics (see **Table 3**). Mean and standard deviation (SD) or median and interquartile range were used to describe continuous variables, based on the data distribution. Frequency and percentages were used to describe categorical variables. To address **Aim 1** of sensor feasibility**,** the tummy time feasibility questionnaire responses were first collapsed as positive responses (scores ≥ 4), neutral responses (score of 3), and negative responses (score ≤ 2). The frequency and percentages of the responses were reported for both sensors. Caregiver's open-ended responses were summarized descriptively based on the feasibility domain. Additionally, the data quality results from the natural validation phase were reported descriptively. To address **Aim 2** and **Aim 3**, concerning the validation of the sensors, we first assessed the correlation between the GENEActiv and video, and the MonBaby and video using Spearman's correlation analyses. Scatter plots were created to visualize the associations between the tummy time tracking methods. The strength of the correlation was interpreted as follows: weak (0.1 to 0.4), moderate (0.4 to 0.7), and strong (0.7 to 1.0) (Akoglu,2018). This was followed by the linear mixed model (LMM) analyses to examine absolute differences between

GENEActiv and video and MonBaby and video accounting for the birth status. For each model, tummy time measurement method (sensor and video), birth status (term and preterm), and an interaction term of method x birth status were included as fixed effects, and subject ID was included as the random effect. The least-square mean estimates, standard error (SE), and 95% confidence intervals (CI) were reported for each model. In addition, the mean difference between the measurement methods with SE and 95% CI, and fixed effect results were reported for each model. Normality of residuals and variance of data were examined for each model. The sensor and video were operationally defined to be in good agreement if the mean absolute difference between them was ≤ 10 minutes. This value was chosen after considering the average expected change in tummy time with intervention (Palmer et al., 2019; Tripathi et al., 2020), previously observed margin of error (Hewitt et al., 2019; Lynch et al., 2019), and clinical judgement. Third, we used the Bland-Altman plots to visualize the mean differences (systematic bias), and 95% limits of agreement between the individual sensors and video for the natural validation phase (Bland & Altman, 1999). The bias from Bland Altman was also used to facilitate comparisons with the previously completed lab-validation study (Hewitt et al., 2019). Normality of the differences was assessed for the Bland Altman analyses.

Results

Participant characteristics

The final sample comprised a total of 32 infants (n=19 term-born; mean age=5.35, SD=1.17 months, and n=13 preterm; mean adjusted age=4.60, SD=1.02 months). Descriptive statistics for the infants and their caregivers are presented in **Table 3**.

For the semi-structured validation **(Aim 2)**, data for n=3 infants was missing (n=2 infants had poor video quality, and n=1 infant could not tolerate prone due to a recent vaccination). The total duration of videos for the semi-structured validation was 646.96 minutes, with 188.34 minutes of

prone time and 458.62 minutes of non-prone time. During the natural environment validation **(Aim 3)**, none of the infants in our study were placed in prone-supported positions (on caregivers' chest/lap or in positioning devices), and hence this position was merged into the prone category for analyses. Total 78% (n=25) of the infants engaged in tummy time on the floor, 15.6% (n=5) were in a prone play gym, and 6.25% (n=2) did tummy time in bed or in the crib. The total duration of recorded play sessions for the natural validation phase was 4361.24 minutes (mean=142.53, SD=82.19 minutes). The total prone duration was 1769.8 minutes (mean=57.76, SD=48.55 minutes) and the total non-prone duration was 2591.4 minutes (mean=84.76, SD=59.51 minutes). For the total 3-day tummy time, term infants had higher durations of tummy time (3-day mean tummy time=67.05, SD=43.43 minutes) compared to preterm infants (3-day mean tummy time=44.18, SD=54.1 minutes). For the per-day average tummy time, all the infants in our study completed less than the WHO recommended dosage of tummy time i.e. <30 minutes/day, with the durations being lower in preterm infants. However, there is a possibility that the infants completed more tummy time off-camera (see **Figure 6**, for per-day tummy time averages stratified by birth status).

All infants were engaged in active position changes/ transitions during the play sessions with per day average play transition frequencies for term infants as follows: Day 1= 46.7, Day 2=70.5, and Day 3=62.9. The average per day position transition frequencies during the play sessions for preterm infants were: Day 1=28.07, Day 2=32.92, and Day 3=51.76. Preterm infants engaged in fewer play transitions compared to term infants, with their frequency being almost 50% lower on Day 1 and Day 2.

Aim 1: Feasibility parameters

Tummy time sensor feasibility questionnaire

A total of 31 caregivers (96.8%) completed the sensor feasibility questionnaire. The frequency and percentages of positive responses to each question (score ≥ 4, on the 5-point scale) are reported and compared between the two tummy time sensors in **Table 4**.

Neutral (score of 3) and negative responses (score ≤ 2) are summarized in **Appendix F.** In terms of applicability, more than 90% of caregivers reported that the GENEActiv sensor was easier to attach, activate, and retained better on their infants compared to the MonBaby sensor. However, >60% of caregivers felt that the MonBaby sensor was more comfortable, had better aesthetics, and was more useful in monitoring tummy time compared to the GENEActiv. When asked to choose a tummy time sensor for their infant, 51.6% (n=16) of caregivers chose the MonBaby sensor, 6.5% (n=2) chose the GeneActiv, 29% (n=9) were flexible with either of the sensors, and 12.9% (n=4) preferred neither. The caregivers' open-ended responses provided critical insight into the problem areas in terms of sensor feasibility. They are summarized in **Table 5** (for the GENEActiv) and **Table 6** (for the MonBaby)**.**

Data quality during the natural validation testing

Both sensors had several instances of loss of data during the natural validation. For the GENEActiv sensor, there was complete loss (≥50% of recorded time) of sensor data for 6.25% of participants (n=2). One caregiver accidentally turned off the sensor and there was a sensor malfunction for another participant during the remote mailing process. Partial loss of data (<50% of recorded time) was seen in 9.4% of infants (n=3). The reasons were that two caregivers forgot to turn on the sensor on 1 out of 3 days and there was a sensor malfunction on 1 of the 3 days for one participant. Finally, there were positioning errors for 21.8% (n=7) infants. We further categorized the positioning errors into two types: correctable and not correctable. Correctable positioning errors were defined as those where we could apply an axis correction by modifying the algorithm and were seen

in 15.6% of participants (n=5). Corrections were applied in instances where two caregivers fastened the GENEActiv sensor to the left side instead of the right, or when three caregivers fastened it on the right side, but the orientation of the golden pins was reversed. Uncorrectable positioning errors were defined as those where axis corrections could not be applied as the sensor was tilted at different angles during the session and thus these could influence the accuracy of the sensors. Uncorrectable positioning errors were seen in 9.4% of (n=3) participants.

For the MonBaby, complete loss of data was seen in 9.3% (n=3) participants. This loss was due to the device error i.e. either the battery died or there was a disconnect in the Bluetooth connection during the play sessions. Partial loss of data was seen in 43.5% (n=14) participants due to a combination of reasons, the majority being continuous Bluetooth disconnection (>2 minutes), battery issues or data download errors. Uncorrectable positioning errors (sensor attached lower near stomach instead of the chest) were seen in 9.4% (n=3) participants. The MonBaby also had instances where the Bluetooth disconnected and reconnected intermittently (<2 minutes) mid-way through the play session, leading to a sensor reset.

In summary, none of the sensors provided 100% of the data, with higher loss and positioning errors seen with the MonBaby sensor compared to the GENEActiv. For the validation analyses, instances of partial data loss of both the sensors were deducted from the time-matched video sections. The reason for intermittent resets seen with MonBaby could not be deducted due to their random order. Since the MonBaby had an overall higher loss of data, the comparison video durations for the MonBaby were significantly shorter compared to the GENEActiv. Hence, separate comparisons were made between GENEActiv and time-matched GENEActiv video, and MonBaby and time-matched MonBaby video.

Aim 2: Semi-structured validation of the tummy time sensors

Correlations between the sensors and video

Scatter plots for GENEActiv and MonBaby comparisons are presented in **Figure 7 (a, b)** and **Figure 8 (a, b)** respectively. Spearman's correlation coefficients and p-values for the GENEActiv and MonBaby sensors against video observation are reported in **Table 7.** The GENEActiv sensor had a significant and strong (r's>0.9) positive correlation with video for measuring both prone and non-prone durations, and this relationship was similar in both term and preterm infants. The MonBaby sensor had a significant and strong (r's>0.8) positive correlation with video for measuring both prone and non-prone durations. Although strong, the magnitude of correlation for MonBaby prone duration versus video prone duration was lower for preterm infants (r=0.72) than term infants (r=0.96).

Absolute differences between GENEActiv sensor and video

Two LMM were fitted to examine the absolute differences between GENEActiv versus video-measured prone and non-prone duration. The method x birth status interaction was not significant, indicating that the magnitude of absolute differences did not vary between term and preterm infants. Results show that the difference between GENEActiv prone duration and video-measured prone duration was 0.03 minutes (SE=0.17, 95% CI= -0.31,0.39, F(1,28)=0.05, p=0.83), and the difference between GENEActiv non-prone duration and video-measured non-prone duration was -0.09 minutes (SE=0.17, 95% CI= -0.46,0.27, F(1,28)=0.29,p=0.59). Both these results were not statistically significant. The least-square mean estimates with 95% CI for the GENEActiv sensor are reported in **Table 8.**

Absolute differences between MonBaby sensor and video

Two LMM were fitted to examine the absolute differences between MonBaby versus video-measured prone and non-prone duration. As with the GENEActiv, the method x birth status

interaction was not significant. The mean absolute difference between MonBaby prone duration and video-measured prone duration was -0.39 minutes (SE=0.22, 95% CI= -0.85,0.05, F(1,25)=3.27,p=0.08), and the difference between MonBaby non-prone duration and video-measured non-prone duration was 0.35 minutes (SE=0.22, 95% CI= -0.11,0.82, F(1,25)=2.45,p=0.13). Both these results were not statistically significant. The least-square mean estimates with 95% CI for the MonBaby sensor are reported in **Table 8.**

In summary, these findings indicate that the GENEActiv and MonBaby prone and non-prone durations were similar to the video-measured prone and non-prone durations for term and preterm infants when assessed in a semi-structured researcher controlled environment.

Aim 3: Natural validation of the tummy time sensors

Correlations between the sensors and video

Scatter plots for GENEActiv and MonBaby comparisons are presented in **Figure 9 (a, b)** and **Figure 10 (a, b)** respectively**.** Spearman's correlation coefficients and p-values for the GENEActiv and MonBaby sensors against video observation are reported in **Table 9.** As seen with the semi-structured validation, the GENEActiv sensor had a significant and strong (r's>0.9) positive correlation with video for measuring both prone and non-prone durations, and this relationship was similar in both term and preterm infants. The MonBaby sensor also had a significant and strong (r's>0.9) positive correlation with video for measuring both prone and non-prone durations, with similar results for both term and preterm infants.

Absolute differences between GENEActiv sensor and video

We first examined whether the differences between both the sensors and video differed across the 3 days, stratified, and aggregated by birth status. LMM's were fit, including day, birth status, and

day x birth status interaction term. The results showed that the differences between sensor and video did not differ across the days for both GENEActiv prone, F(2,52.8)=0.49,p=0.61, and GENEActiv non-prone, F(2,52.9)=0.20,p=0.81. Likewise, the differences between sensor and video did not differ across the days for both MonBaby prone, F(2,56)=2.09,p=0.13, and MonBaby non-prone, F(2,58.9)=1.82,p=0.17. Hence, the 3-day durations were summed, and the totals were tested in the final models.

Two LMM were fit to examine the absolute differences between GENEActiv detected versus video detected total prone and non-prone durations. The mean absolute difference between the GENEActiv prone time and video measured prone time was 1.47 minutes (SE=1.47, 95% CI=-0.88,3.82) and this difference was not statistically significant, F(1,29)=1.62,p=0.21. The mean absolute difference between the GENEActiv non-prone time and video measured non-prone time was 1.65 minutes (SE=0.17, 95% CI=-0.46,0.27), and not statistically significant, F(1,29)=2.06,p=0.16. The least-square mean estimates with 95% CI for the GENEActiv sensor are reported in **Table 10.** The GENEActiv prone and non-prone accuracy did not vary between term and preterm infants.

Absolute differences between MonBaby sensor and video

Two LMM were fit to examine the absolute differences between MonBaby detected versus video detected prone and non-prone duration. The mean absolute difference between MonBaby prone duration and video measured prone duration was - 4.6 minutes (SE=0.22, 95% CI= -0.85,0.05), and this difference was statistically significant, F(1,31)=8.07,**p=0.007**. The mean absolute difference between MonBaby non-prone duration and video-measured non-prone duration was 3.9 minutes (SE=1.58, 95% CI= 0.66,7.13), and the difference was statistically significant, F(1,31)=6.04,**p=0.0019**. The MonBaby prone and non-prone accuracy did not vary between term and

preterm infants. The least-square mean estimates with 95% CI for the MonBaby sensor are reported in **Table 10.**

Taken together, these findings indicate that the GENEActiv mean prone and non-prone durations are similar to the video-measured mean prone and non-prone durations. However, the MonBaby measured mean prone and non-prone durations differ significantly from the video-measured durations in the natural environment. Both the sensors performed similarly in term and preterm infants.

Bland-Altman analysis for systematic bias between the sensors and video

The differences between sensor and video were normally distributed as examined through histogram plots. The Bland-Altman plot for the GENEActiv versus video measured prone duration **(Figure 11a)** showed a mean bias of 1.47 minutes (SE=1.15, 95% CI= -0.8, 3.8) and 95% limits of agreement (-10.8, 13.8), and a total of three observations were outside the limits of agreement. The mean bias in our study is 1.61 minutes higher than that of the lab-validation study (lab-validation GENEActiv prone bias= -0.14 minutes). The Bland-Altman plot for the MonBaby versus video measured prone duration **(Figure 11b)** shows that MonBaby underestimated prone duration by 4.6 minutes (SE=1.6, 95% CI= -7.9, -1.3), and 95% limits of agreement (-22.57, 13.36). One observation was outside the limits of agreement. The magnitude of differences between the MonBaby and video was higher for prone durations >15 minutes. The mean prone bias for MonBaby increased by 4 minutes compared to the lab study (lab-validation MonBaby prone bias= 0.63 minutes).

The Bland-Altman plot for the GENEActiv versus video measured non-prone duration **(Figure 12a)** reported a mean bias of -1.65 minutes (SE=1.14, 95% CI= 0.07, -4.0) and 95% limits of agreement (-13.9, 10.68). Three observations were outside the limits of agreement and there was an increase in non-prone bias by 1.13 minutes (lab-validation GENEActiv non-prone bias= -0.52

minutes). Last, the Bland-Altman plot for the MonBaby versus video measured non-prone duration **(Figure 12b)** shows that MonBaby overestimates non-prone durations by 3.8 minutes (SE=1.5, 95% CI= 0.66, 7.13) and 95% limits of agreement (-13.6, 21.48). Total of three observations were outside the limits of agreement. The mean prone bias for MonBaby increased by 1.8 minutes compared to the lab study (lab-validation MonBaby prone bias= 0.63 minutes).

Discussion

Wearable sensors such as accelerometers are emerging as promising assessment tools to objectively capture developmental behaviors and health practices of young children. Our findings show that >60% of caregivers responded positively to the feasibility parameters of the tummy time sensors and preferred using the MonBaby sensor. The natural validation results suggest that both the tummy time sensors are strongly correlated with video observation but the GENEActiv is more accurate in measuring prone durations in both term and preterm infants. In the following sections, we discuss our findings in more detail.

The Clinical Trials Transformation Initiative (CTTI), which is a partnership between Duke University and the FDA, is designed to provide recommendations for improving the applicability of mobile technology and quality in research. Their recent recommendation (https://ctti-clinicaltrials.org/topics/mobile/ctti-unveils-new-database-of-feasibility-studies-on-mobile-technologies-in-clinical-research/) states that researchers need to conduct small feasibility studies using wearable technology to identify data quality challenges and to gauge stakeholder experience. Convenience of sensor use and a pleasant end-user experience are identified as crucial elements for the implementation of wearable technologies in the real-world (Smuck et al., 2021). Caregivers constituted the primary stakeholders in our study. The caregivers had slightly higher positive responses for the GENEActiv than the MonBaby in terms of applicability (donning/doffing,

retention) of the sensors, both being > 80%. The MonBaby is a commercial-grade sensor and requires the caregivers to perform two additional steps — i) connect the sensor using an App, and ii) calibrate the sensor. On the contrary, the GENEActiv was pre-calibrated and switched on, reducing the number of steps the caregivers had to complete. Additionally, the MonBaby sensor's snap-on ring was not sturdy enough leading to multiple instances of sensor detachment due to the cracking of the ring.

In terms of comfort, all caregivers thought that the MonBaby was more comfortable than the GENEActiv. For the GENEActiv, one caregiver reported, "*It's bulky so could possibly be uncomfortable, The belt would often slide up my child's torso and needed readjustment, especially during tummy time or sitting up...*". Similarly, the caregivers preferred the aesthetics of the MonBaby sensor over the GENEActiv sensor and reported that the MonBaby seemed more useful. Many caregivers were particularly impressed by the MonBaby sensor's app design and visualization of the output. One caregiver said, *"The MonBaby device was a lot easier to control and I could tell by watching the activity in my child that it was capturing the movements appropriately in the app"*. Although no adverse events were reported in our study, few caregivers expressed anticipatory concerns about the size and location of the GENEActiv **(**see **Table 5)**. They felt the easy detachability of the GENEActiv was a safety concern and could be choking hazard if left unsupervised. Thus, not surprisingly, when asked to choose a single sensor, majority of the caregivers chose the MonBaby sensor over the GENEActiv. These findings are similar to the lab-validation study (Hewitt et al., 2019) and highlight the importance of designing sensors from the end-user perspective.

Although the MonBaby was more popular among the stakeholders, our results demonstrate that it has multiple issues with data quality. In summary, we found that 43% of participants had a partial data loss with the MonBaby compared to 10% loss seen with GENEActiv. Complete loss of

data was rare (<10%) for both the sensors. This data loss especially for the MonBaby sensor is higher than that seen in previous studies (Van Cauwenberghe et al., 2011; Verbestel et al., 2011). However, previous studies used a research-grade sensor that was specifically designed for the intended purpose. First, the MonBaby sensor is a commercial-grade sensor and is not intended for tummy time measurement. It works on the Bluetooth Low Energy (BLE) mechanism to wirelessly connect to a phone and is designed for distances up to 60 feet, which is a long enough range for an average-sized home. Despite this, we noticed instances of loss of data whenever the caregiver moved out of the room with their phone. The MonBaby also comes with a "connection alert" option to notify caregivers of a potential sensor disconnect. Caregivers were requested to keep this alarm switched-on, but it did not seem to handle the issue very well in this study. Second, the MonBaby battery drained mid-session for some participants leading to partial loss of data. Caregivers were sent two reminders per day to charge the MonBaby sensors. Hence, we can only assume that they either forgot to charge the sensor or failed to disconnect the sensor from the app between sessions, leading to faster battery discharge. Since the GENEActiv was constantly switched on, we did not encounter similar challenges. Several studies using wearables for natural data collection in young children utilize a continuously switched on sensor to reduce caregiver-handling errors (Deng et al., 2019; Franchak et al., 2021; Greenspan et al., 2021). Last, the MonBaby also experienced random disconnections and resetting of the sensor mid-sessions. Hewitt et al., 2019 reported experiencing similar disconnections due to either the infant or the caregiver blocking the signal of the device. Since our data collection was conducted at the home, the signal could have been blocked by anybody in the path of the device.

The GENEActiv presented a unique challenge for real-world use i.e. positioning errors. Despite providing an illustrated positioning manual, several caregivers mispositioned the GENEActiv sensor on the wrong side of the body. A potential solution to this problem could be using customized electronic onesies (Airaksinen et al., 2022) or jumpsuits (Greenspan et al., 2021) or leggings

(Franchak et al., 2021) with embedded accelerometers and labeling the garments to ensure the caregivers orient the sensor in the right direction. Franchak et al. (2021) found that this method is successful at reducing caregiver-positioning errors in the real-world. In summary, caregivers preferred the MonBaby sensor primarily due to its design and visual feedback. However, this sensor has a consistent connectivity issue reducing its feasibility for real-world dynamic data collection.

The concurrent validation of the two tummy time sensors was conducted in two phases (semi-structured and natural environment). The primary purpose of completing the semi-structured validation was to discern if the tummy time sensors were able to account for the play transitions in their calculations during controlled real-world testing. Our results showed that both the sensors were highly accurate (mean difference <1 min) in measuring tummy time durations while accounting for natural transitions during play in both term and preterm infants. Importantly, there was zero sensor data loss during the semi-structured testing. This finding highlights the importance of sensor placement and activation during real-world implementation. When comparing the accuracy for the three days during the natural environment testing phase, we found no differences, suggesting that both the sensors were consistent across the 3-days. Previous studies using sensors in the home environment for infants and preschoolers have found that 2-3 days of testing are usually reflective of the infant's natural behavior (Aadland & Johannessen, 2015; Cliff et al., 2009; Deng et al., 2019). Thus, we can assume that the reliability of the two sensors will stay consistent across an additional number of days.

During the natural environment validation, both the sensors demonstrated strong correlations with video observation ($r > 0.9$) for detecting tummy time in both term and preterm infants. Previous studies measuring infant positions using accelerometers report similar correlations for the prone position in age-matched infants (Franchak et al., 2021; Greenspan et al., 2021). Tummy time is a

well-defined gross-motor position and is easier to detect when compared to specific movement parameters (Deng et al., 2019) or generalized physical activity (Cliff et al., 2017). From an implementation perspective, the results from the correlation analysis are more reflective of relative concurrent validity (Chinapaw et al., 2010). This implies that both the sensors can be used to measure tummy time in studies where the precision of measurement is not a requirement. For example, population studies focusing on measuring the adherence to the Back to Sleep, Tummy to Play campaign usually do so by using parent recall in time intervals of 15 minutes (0-15 minutes, 16-30 minutes, and so forth) (Zachry & Kitzmann, 2011). Recent evidence shows that parent recall may not be accurate for tracking tummy time behaviors over longer durations of time (Inamdar et. al, in writing). Both the sensors tested in our study would be appropriate for objectively tracking tummy time adherence in such studies, provided, the connectivity issues of MonBaby are improved.

We also determined the absolute differences between the sensors and video and predefined accuracy as durations < 2 minutes. Based on this assumption, we found that the GENEActiv is more accurate for detecting tummy time in the home setting. The precision of accuracy was high (1.5 minutes), given the increased frequency of position transitions seen. In comparison, the MonBaby underestimated tummy time duration by approximately 5 minutes. The Bland-Altman analyses supplemented these findings by showing that the MonBaby had a consistent negative bias and the magnitude of differences between MonBaby, and video increased when the mean duration of tummy time was > 15 minutes. The primary reason for the increased discrepancy with the MonBaby sensor could be the repeated disconnection seen randomly mid-sessions. Additionally, the MonBaby is only designed to categorize prone versus non-prone positions. In comparison, the GENEActiv can identify individual non-prone positions such as side-lying, sitting, and standing. MonBaby algorithm cut-points were likely misclassifying weight shifts in prone position (commonly seen during transitions) as non-prone positions. We did not notice this trend during the semi-structured validation; however,

the frequency of movement transitions was much lower during the semi-structured validation compared to the natural environment validation. Both the sensors performed similarly in both term and preterm infants.

Mean differences are indicative of absolute concurrent validity (Chinapaw et al., 2010) and can inform the implementation of sensors in intervention-based studies, where the precise change in tummy time duration over time or pre- and post-intervention is the objective. Very few of the current studies focusing on tummy time interventions utilize "tummy time duration" as the outcome (Palmer et al., 2019; Tripathi et al., 2020). Majority of the studies focus on other qualitative outcomes such as head lift in prone (Ortega & Fienup, 2015) or reduced negative vocalizations (Mendres-Smith et al., 2020) in prone. The reason for this could be the lack of objective measures for tummy time for use in home settings. Tummy time duration is an important parameter and has specific dose-response relationship with important health outcomes in young infants (Hewitt et al., 2020). Our findings suggest that the GENEActiv sensor can be used to precisely measure changes in tummy time over long periods of time.

Limitations and Future Directions

There are a few limitations to this natural validation study. First, all the preterm infants in our study were prone-tolerant and no caregiver used positioning devices to support preterm infants during tummy time or place their infants on chest or lap. Our inclusion criteria were designed to include infants who would be willing to stay on their tummy for longer periods of time to assist with the validation. We also encouraged caregivers to mimic their daily routines as closely as possible. However, it is likely that caregivers chose to play on the floor without devices since they were aware of the study's focus and were being video-recorded. Thus, our study sample may not be completely representative of all preterm infants, especially those that are intolerant to prone and require

positioning devices. Future studies should compare the accuracy of the sensors in prone-tolerant versus intolerant infants, and with the use of tummy time positioning devices versus tummy time on floor.

Second, our recorded sessions were limited to sessions of active play. Thus, we may have failed to capture tummy time bouts occurring during caregiving activities such as a diaper change. This decision was made to ensure the participant's privacy as they were constantly being recorded. Future studies should include a 24-hour sensor recording to determine if the caregiving activities hamper tummy time accuracy. Recent studies have shown that caregiver handling constitutes approximately 15% of noise while measuring infant leg movements (Zhou et al., 2019). Since tummy time or prone positioning is a more generalized posture compared to leg movements, we anticipate lower percentage of noise. A wear versus non-wear time identification algorithm was recently published for the GENEActiv sensor (Hewitt et al., 2021) and can be utilized to minimize the data volume with 24-hour sensor recordings.

Third, the sample size of our study was limited, especially for preterm infants. Previous studies utilizing sensors for young infants report similar (Hewitt et al., 2019) or lower (Franchak et al., 2021; Greenspan et al., 2021) sample sizes. However, including a larger and a more variable preterm sample could help identify trends in sensor accuracy based on the tummy time abilities of the infants. For example, is the sensor accuracy similar in a preterm infant who is unable to lift their hand in prone versus a preterm infant who is consistently playing in an "prone on extended arms or hands" position.

Finally, future studies should consider the stakeholders (caregivers and infants) while designing wearables for the younger population. All the caregivers in the current study were

enthusiastic about monitoring their infant's positioning. Based on our feasibility results and caregiver feedback, we recommend wearable design with visual feedback to enhance caregiver participation.

Conclusion

A natural environment validation of tummy time sensors completed in 3-6 month old term and preterm suggests that the GENEActiv wearable sensor algorithm is accurate in measuring tummy time across multiple days in the home settings, in both term and preterm infants. The GENEActiv is more suitable for clinical studies requiring a precise tracking of tummy time but may require modifications in attachments to improve its feasibility. The MonBaby sensor is the caregivers' preferred choice but is associated with a high data loss percentage and lower accuracy compared to the GENEActiv sensor. Wearable sensors can be used to objectively track the adherence to public health recommendations for tummy time in infants. Early identification of lower tummy time durations, especially in at-risk preterm infants, can have long-term developmental implications.

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Table 2: Behavioral coding definitions for positions and events

Position	**Description**
Prone	Infant is lying on the floor on their tummy and the infant's weight has shifted onto the ventral side of the infant's body
Prone supported	Infant is lying on their tummy using some form of supportive device, or on parent's lap or chest
Supine	Infant is lying on the back, while the back is in contact with the floor/base, and the infant's weight is shifted onto the dorsal side of the infant's body
Side-lying	Infant is lying on their side (right or left), while their side is in contact with the floor.
Sitting	Infant is in a seated position while on the floor
Standing	Infant is in an upright position, where the feet/knees are supporting the infant
Sitting in a seat	Infant is in a seated or reclined seated position in a chair or supportive device
Out of view	Infant is currently not on the video screen
Events	**Description**
GENEActiv switch on	The parent presses the GeneActiv button, and you may/may not see a green flash
GENEActiv shake on	The parent shakes the sensor in front of the camera
MonBaby switch on	The parent opens the app on the phone—clicks on connect—and calibrates
MonBaby shake on	The parent shakes the sensor after attaching it to the baby's onesie

Table 3: Participant characteristics

	All infants (n=32)	Term infants (n=19)	Preterm infants (n=13)
INFANT DEMOGRAPHICS			
Age in months*	5.04 (1.16)	5.35 (1.17)	4.60 (1.02)
Birth weight in lbs.	5.78 (1.92)	6.9 (0.85)	3.96 (1.73)
Current weight in lbs.	13.81 (3.32)	14.5 (1.5)	14.5 (11.3, 16.13) †
Head circumference in cm.	41.43 (2.72)	40.8 (39.1,43.9)†	41.5 (2.8)
Body length in cm.	62.96 (3.62)	63.3 (3.6)	62.5 (3.9)
Gestational age in weeks			
>37 weeks	19 (59.4%)	19 (100%)	0 (0%)
32-37 weeks	6 (18.8%)	0 (0%)	6 (46.2%)
28-32 weeks	5 (15.6%)	0 (0%)	5 (38.5%)
<28 weeks	2 (6.3%)	0 (0%)	2 (15.4%)
Ethnicity			
Hispanic	0 (0%)	0 (0%)	0 (0%)
Not Hispanic	31 (97%)	19 (100%)	11 (84.62%)
Not reported	1 (3%)	0 (0%)	2 (15.38%)
Race			
White	20 (64.5%)	15 (78.9%)	4 (33.3%)
Black	4 (12.9%)	0 (0%)	4 (33.3%)
Asian	0 (0%)	0 (0%)	1 (8.3%)
Multi-racial	5 (16.1%)	4 (21.1%)	1 (8.3%)

Not reported	3 (9%)	0 (0%)	3 (23.1%)
PARENT DEMOGRAPHICS			
Age in years (yrs.)			
18-25 yrs.	4 (13.3%)	2 (11.1%)	2 (16.7%)
26-35 yrs.	21 (7%)	14 (7.8%)	7 (58.3%)
36-45 yrs.	4 (13.3%)	1 (5.5%)	3 (25%)
46-55 yrs.	0 (0%)	0 (0%)	0 (0%)
56+ yrs.	1 (3.3%)	1 (5.5%)	0 (0%)
Not reported	2 (6.25%)	1 (5.5%)	1 (8%)
Ethnicity			
Hispanic	0 (0%)	0 (0%)	11 (84.6%)
Not Hispanic	31 (97%)	19 (100%)	1 (8%)
Not reported	1 (3%)	0 (0%)	1 (8%)
Race			
White	22 (70.9%)	17 (89.5%)	5 (41.7%)
Black	4 (12.9%)	0 (0%)	4 (33.3%)
Asian	2 (6.4%)	1 (5.3%)	1 (8.3%)
Multi-racial	1 (3.2%)	1 (5.3%)	0 (0%)
Not reported	3 (9)	0 (0%)	3 (23.1%)

*adjusted age for preterm infants, Means (standard deviations) reported for normally distributed continuous variables, † Medians and interquartile range reported for not normally distributed continuous variables, Frequencies (percentages) reported for categorical variables

Table 4: Tummy time sensor feasibility questionnaire (positive responses, N=31)

Parameter	GeneActiv	MonBaby
Ease of attachment and detachment	29(93.5%)	27(87.1%)
Ease of activation and deactivation	29(93.5%)	26(83.8%)
Ease of retention	30(96.8%)	29(93.5%)
Comfort	22(71%)	24(77.4%)
Aesthetics	10(32.3%)	19(61.3%)
Usefulness during everyday play	15(48.38%)	21(67.7%)

Table 5: Caregiver's open-ended responses for the GENEActiv sensor on the feasibility questionnaire

Feasibility domain	Caregiver responses
Applicability and comfort	"I was surprised at how well this device stayed attached to the belt with rolling and side-lying positioning…"
	"The belt the sensor was on slid around during play…"
	"It's bulky so could possibly be uncomfortable…"
	"The belt would often slide up my child's torso and needed readjustment…"
Safety	" She managed to pull it off once…"
	"It was very easy to attach and detach but that also means it was extremely easy for toddler to remove…"
	"My baby has lots of tummy issues including reflux and at times I was worried that it was putting too much pressure on his belly. I loosened it a little when I was worried about that…"
Aesthetics	"The sensor itself is Slightly bulky but the belt was easy and comfortable…"
Usefulness	"Am not sure how useful it is as I did not see any of the data it was recording…"
	"The difficulty turning on/off was not knowing when the device was on or off…"

Table 6: Caregiver's open-ended responses for the MonBaby sensor on the feasibility questionnaire

Feasibility domain	Caregiver responses
Applicability and comfort	"The MonBaby did not attach well to clothes that had embellishments…"
	"Fell off a few times and also does not fit well if there is any sort of stitching on the chest of the child's outfit…"
	"More difficult setup, but once on, more comfortable…"
	"Mon baby sensor is fixed on chest/ sternal area. If child is not clearing neck and shoulders in tummy time it seems uncomfortable for the child…"
Safety	"The clip broke at some point making the attachment not secure and at times [insert baby's name] would find it and want to play with it in supine…"
Aesthetics	"The MonBaby device was a lot easier to control and I could tell by watching the activity in my child that it was capturing the movements appropriately in the app…"
	"Enjoyed the app and being able to see recorded data…"
Usefulness	"This sensor was the most convenient I think. Did not budge and didn't have to worry about attaching to belt on outside of clothing…"
	"The only thing I noticed is that the app on my phone did not really register if my child was sitting or standing. In those instances, it claimed my child was on their back…"

	“Monitor was not always accurate saying whether she was on her back or stomach. Sometimes when she pushed up, it would say she was on her back…”

Table 7: Correlations between the sensors and video for semi-structured validation

		Prone		Non-prone	
Method	**N**	**r**	**p-value**	**r**	**p-value**
GENEActiv vs Video					
All infants	29	0.97	<.0001	0.99	<.0001
Term infants	17	0.98	<.0001	0.99	<.0001
Preterm infants	12	0.99	<.0001	0.98	<.0001
MonBaby vs Video					
All infants	26	0.88	<.0001	0.96	<.0001
Term infants	15	0.96	<.0001	0.97	<.0001
Preterm infants	11	0.72	0.012	0.93	<.0001

N= sample size, r= correlation coefficient

Table 8: Least square mean estimates for sensor versus video comparisons during the semi-structured validation (in minutes)

SE=

	Prone		Non-prone	
Parameter	**Estimate (SE)**	**95% CI**	**Estimate (SE)**	**95% CI**
GENEActiv vs Video				
GeneActiv	6.53 (0.97)	(4.54,8.52)	15.71 (1.04)	(13.5,17.8)
Video	6.49 (0.97)	(4.50,8.48)	15.81 (1.04)	(13.6,17.9)
MonBaby vs Video				
MonBaby	4.06 (0.53)	(2.97,5.15)	12.73 (1.08)	(10.5,14.9)
Video	4.46 (0.53)	(3.36,5.55)	12.38 (1.08)	(10.2,14.6)

standard error, CI= confidence intervals

Table 9: Correlations between the sensors and video during the natural environment validation

		Prone		Non-prone	
Method	**N**	**r**	**p-value**	**r**	**p-value**
GENEActiv vs Video					
All infants	30	0.99	<.0001	0.99	<.0001
Term infants	17	0.98	<.0001	0.99	<.0001
Preterm infants	13	0.98	<.0001	0.97	<.0001
MonBaby vs Video					
All infants	32	0.97	<.0001	0.98	<.0001
Term infants	19	0.95	<.0001	0.98	<.0001
Preterm infants	13	0.99	<.0001	0.97	<.0001

N= sample size, r= correlation coefficient

Table 10: Least square mean estimates for the sensor versus video comparisons during the natural environment validation (in minutes)

	Prone		Non-prone	
Parameter	**Estimate (SE)**	**95% CI**	**Estimate (SE)**	**95% CI**
GENEActiv vs Video				
GeneActiv	58.65 (8.74)	(40.75,76.54)	81.35 (9.15)	(62.61,100.09)
Video	57.18 (8.74)	(39.28,75.07)	83.00 (9.15)	(64.24,101.75)
MonBaby vs Video				
MonBaby	41.76 (6.32)	(28.86,54.66)	73.30 (9.11)	(54.69,91.91)
Video	46.36 (6.32)	(33.46,59.26)	69.40 (9.11)	(50.79,88.01)

SE= standard error, CI= confidence intervals

Figure 2: Timeline of the tummy time sensor validation phases based on the Keadle et al., 2019 framework

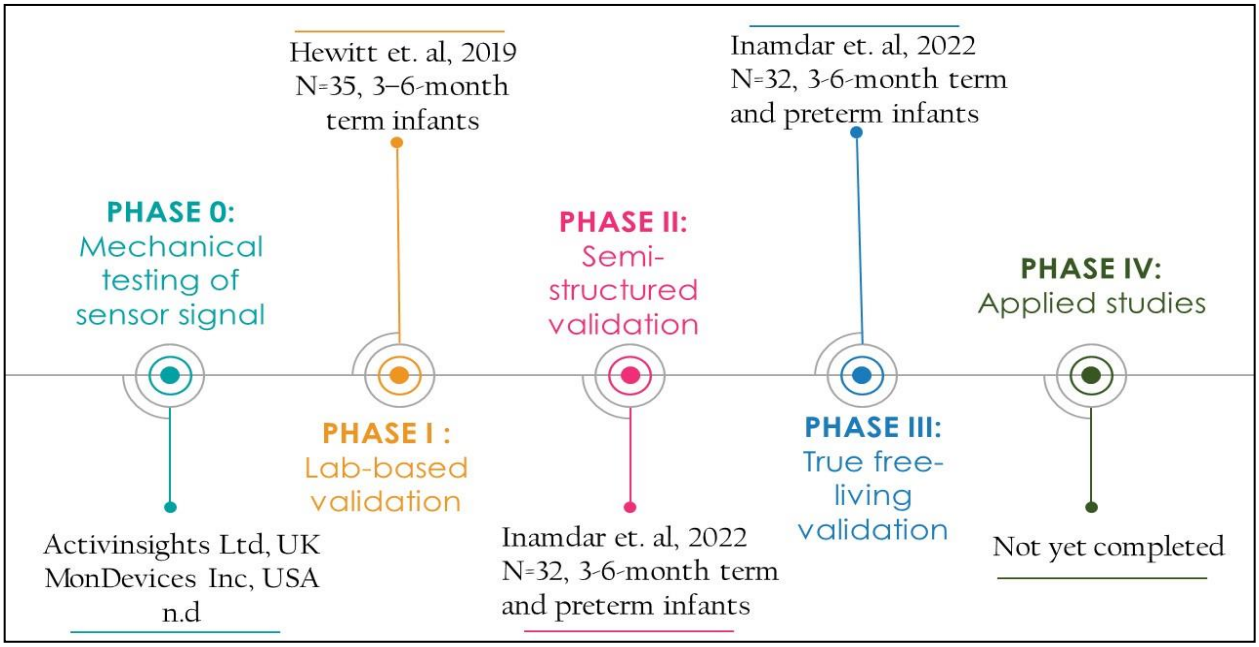


Figure 3: Placement and orientation of the tummy time sensors on the infant's clothing

MonBaby is attached to the center of the chest using a snap-on ring and *GENEActiv* is attached to the anterolateral right hip using an elastic strap

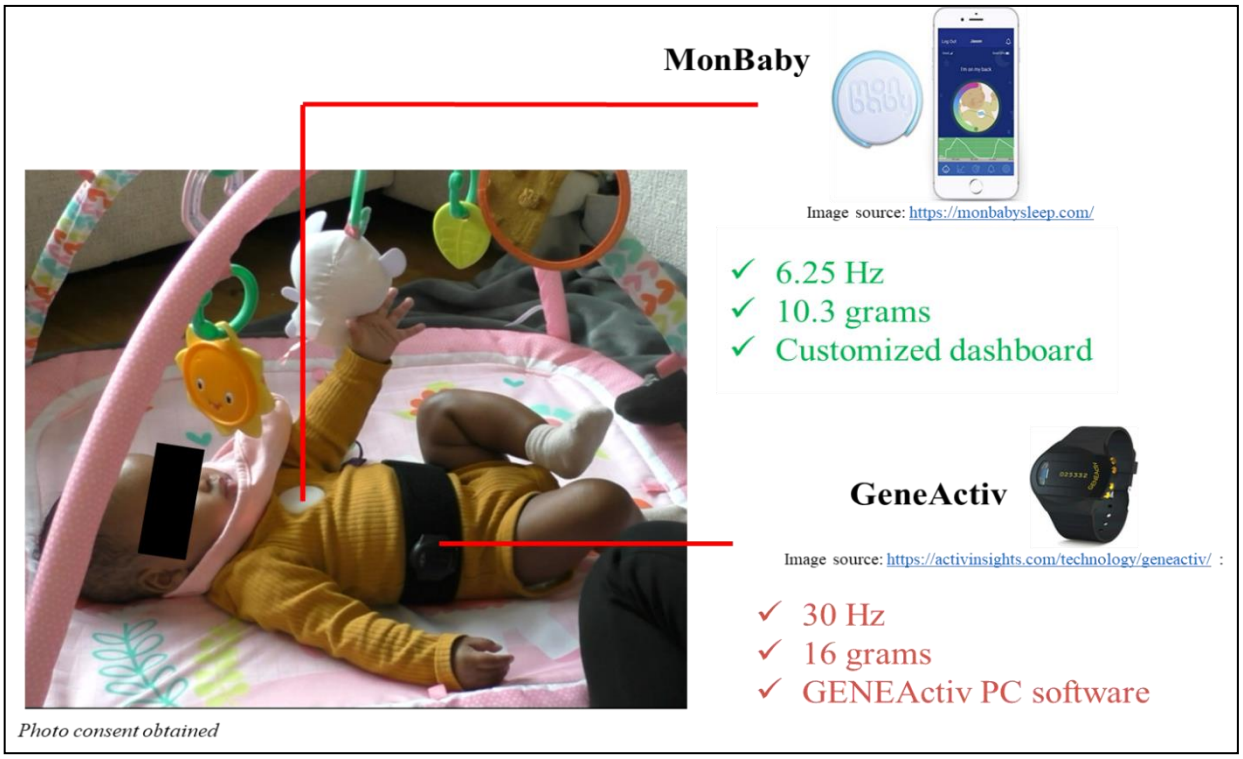
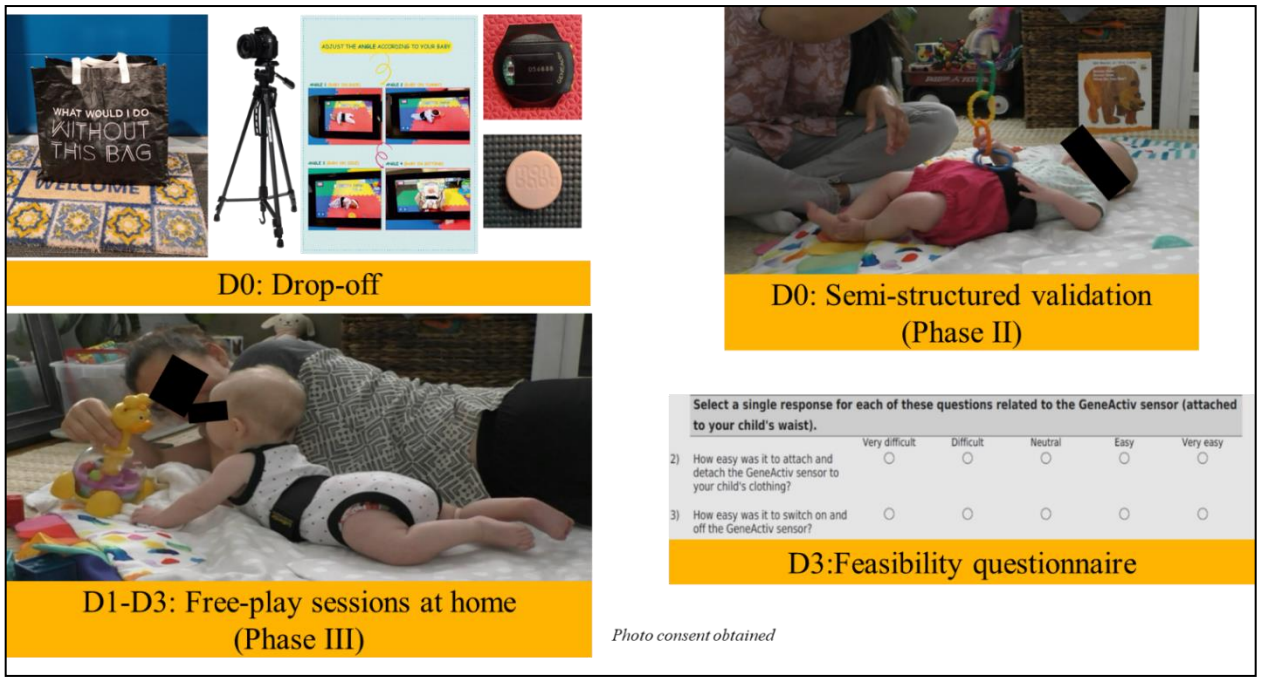


Figure 4: Methodology for the validation of sensors in the natural environment



*****D=Day (i.e. Day 0-Day 3)

Figure 5: Example timeline for a 3-month old infant's play session (3:45 PM to 4:40 PM)

Synchronization procedures are indicated using **red boxes** at the start and end of the play session Prone positions are indicated using **orange boxes** and text labels. Every other position was a non-prone position y-axis= GENEActiv y-axis data, x=timestamps in 15 minute intervals

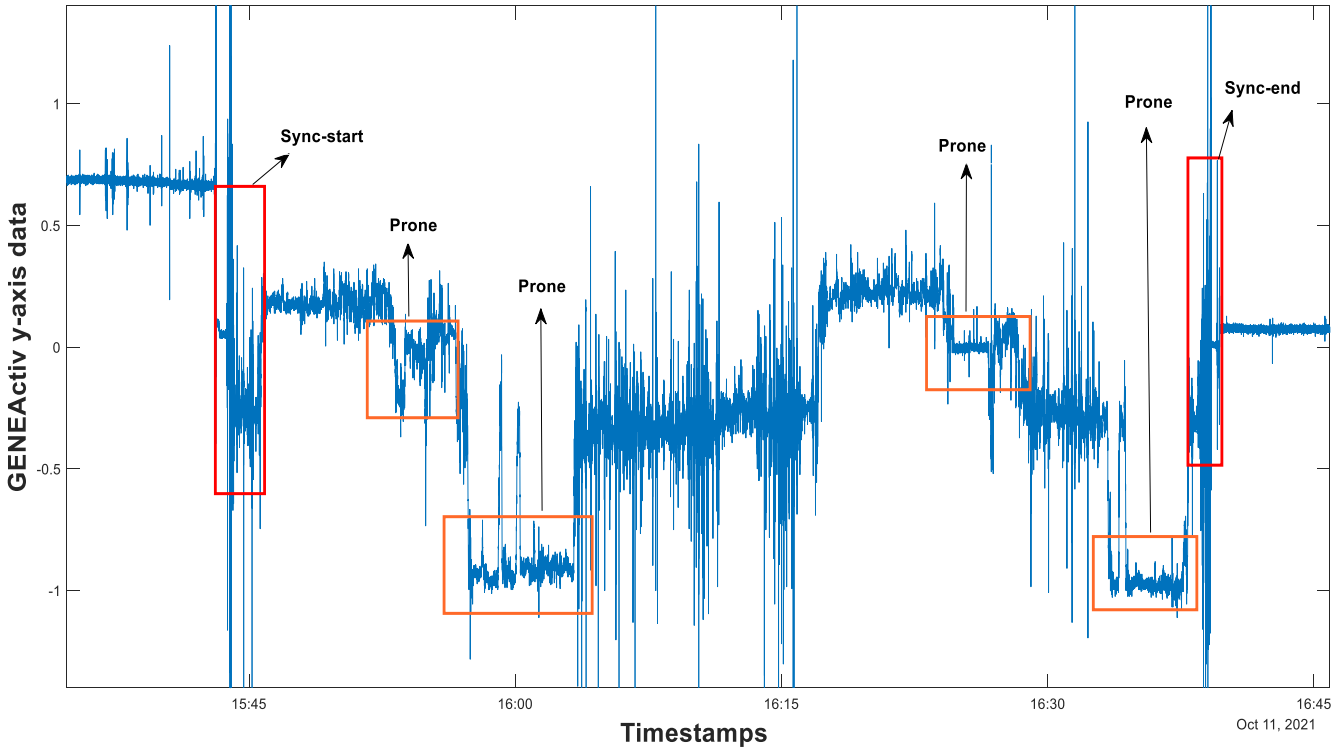


Figure 6: Average tummy time durations during the recorded play sessions for term (n=19) and preterm (n=13) infants

Tummy time in minutes on y-axis, days on x-axis,

Green bars represent full-term infants, blue bars represent preterm infants

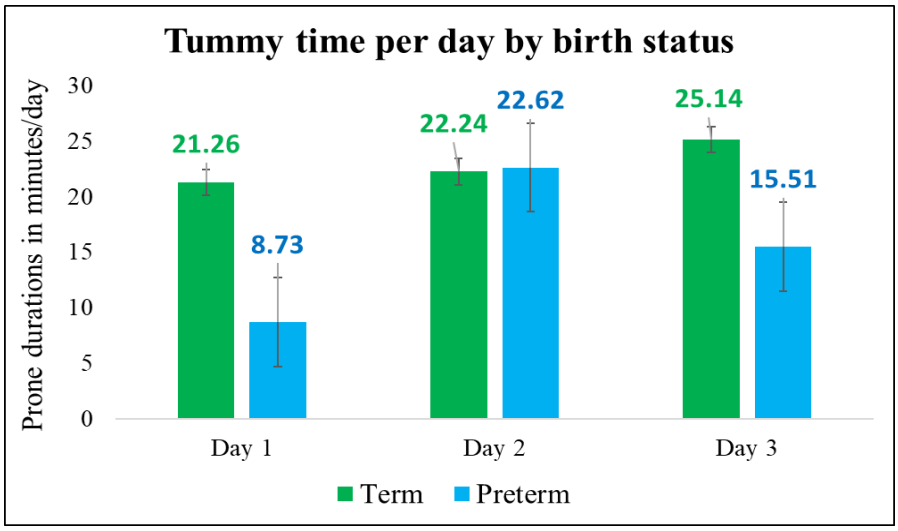
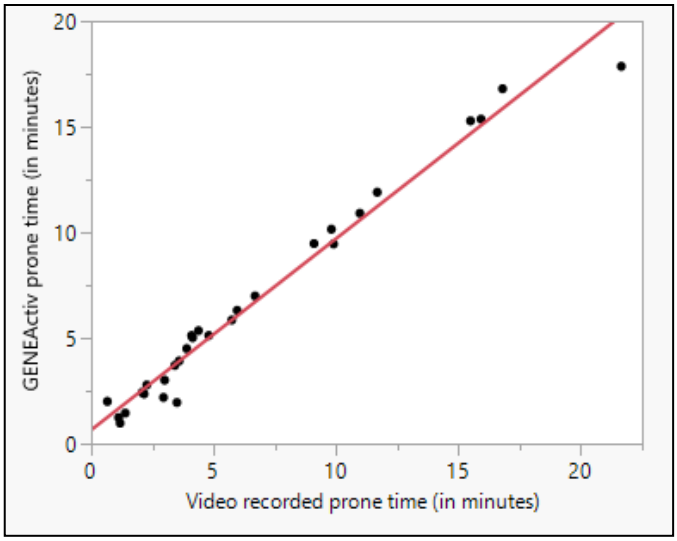


Figure 7: Scatter plots and identity lines (y = x) for the associations between GENEActiv sensor and video for prone and non-prone durations for the semi-structured validation (n=29)

a) <u>Prone durations (r>0.9)</u>



b) <u>Non-prone durations (r>0.9)</u>

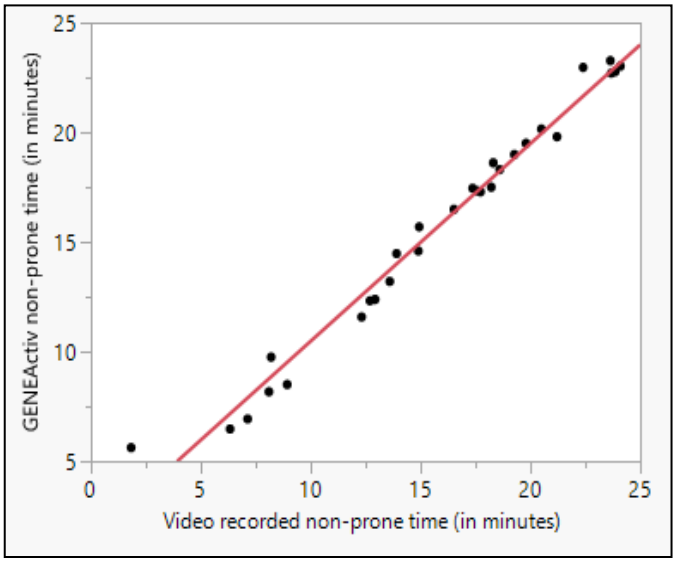
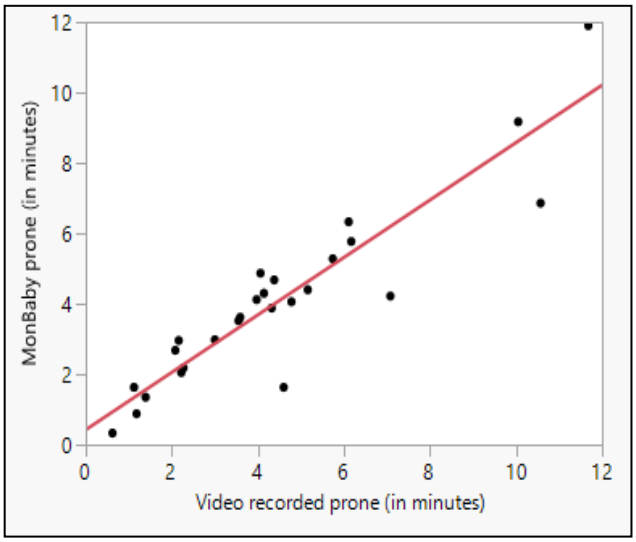


Figure 8: Scatter plots and identity lines (y = x) for the associations between MonBaby sensor and video for prone and non-prone durations for the semi-structured validation (n=26)

a) <u>Prone durations (r>0.8)</u>



b) <u>Non prone durations (r>0.8)</u>

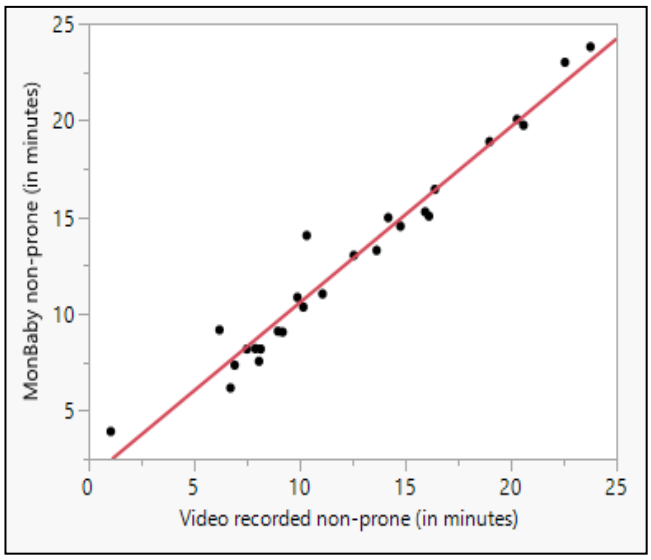
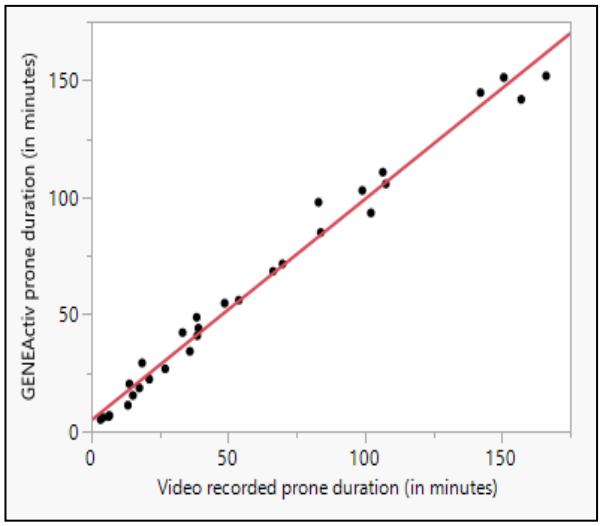


Figure 9: Scatter plots and identity lines (y = x) for the associations between GENEActiv sensor and video for prone and non-prone durations for the natural environment validation (n=30)

a) <u>Prone durations (r>0.9)</u>



b) <u>Non prone durations (r>0.9)</u>

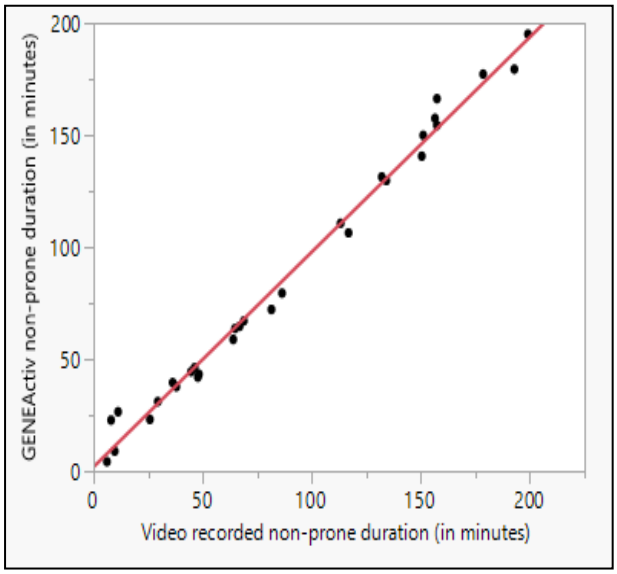
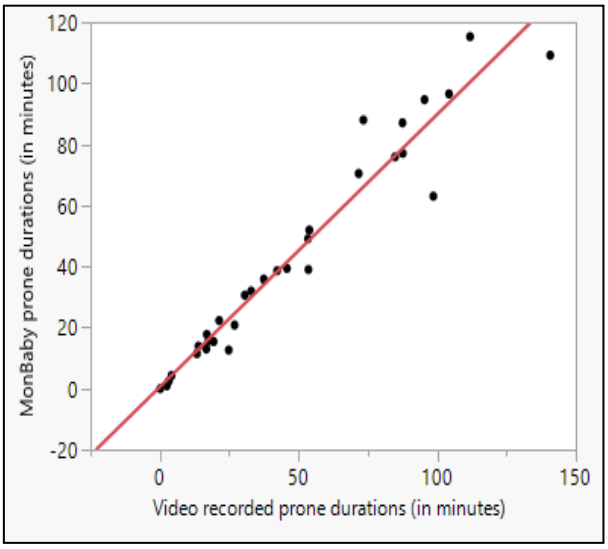
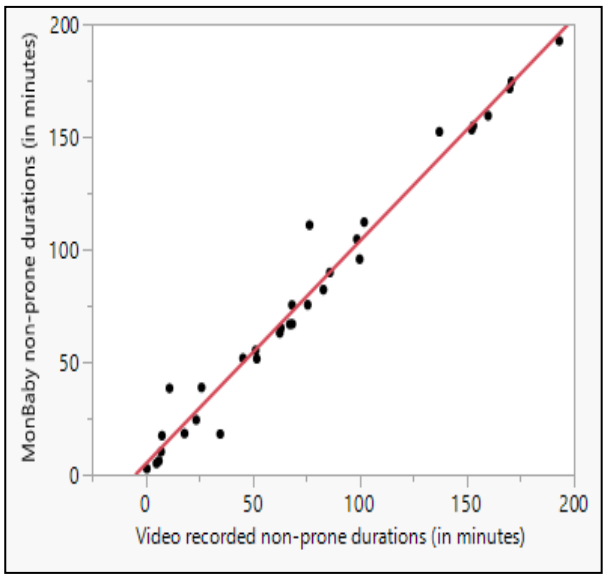


Figure 10: Scatter plots and identity lines (y = x) for the associations between MonBaby sensor and video for prone and non-prone durations for the natural environment validation (n=32)

a) <u>Prone durations (r>0.9)</u>



b) <u>Non-prone durations (r>0.9)</u>

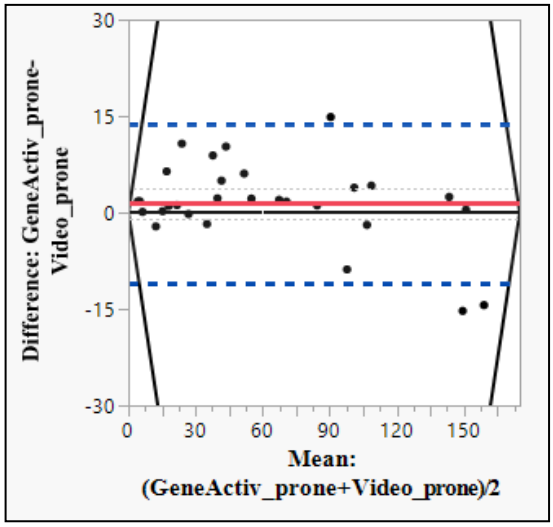


Figures 11-12 description

For all the Bland-Altman plots, the differences between the two approaches are plotted on the Y axis and the average of the two approaches are plotted on the X axis. The solid red line represents the average mean of differences between the two measurement approaches and is referred to as the bias. The solid black line represents the zero line or the point where the two measurement approaches have no differences. If the solid red line is located above the zero line, then we can conclude that the parents or the GENEActiv overestimate tummy time recall compared to direct observation. Likewise, if the solid red line is located below the zero line, the two measurement approaches underestimate compared to direct observation. The dashed blue lines show the upper (mean + 1.96 SD) and lower (mean - 1.96 SD) limits of 95% limits of agreement (LOA). Narrower the limits of agreement, stronger the agreement between approaches.

Figure 11: Bland–Altman plots with 95% limits of agreement between the sensors and video for prone durations (n = 30)

a) <u>GENEActiv versus video</u>



b) <u>MonBaby versus video</u>

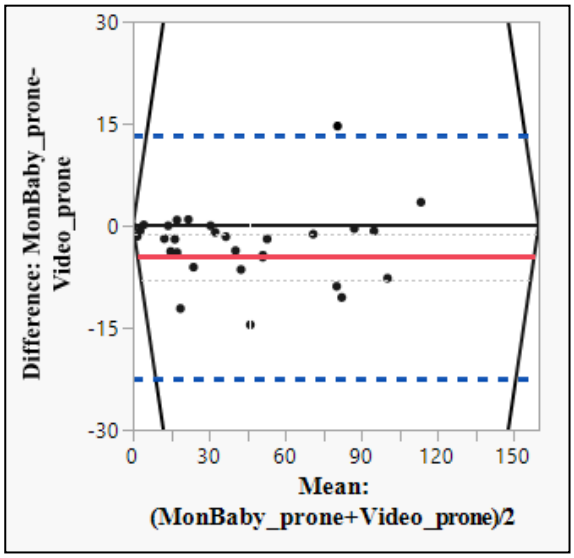
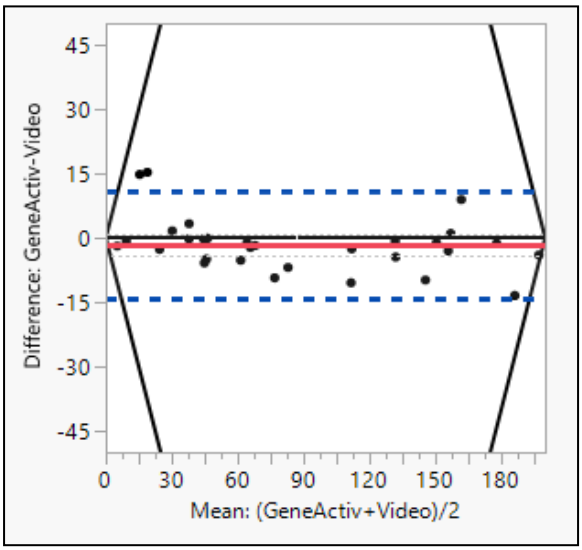
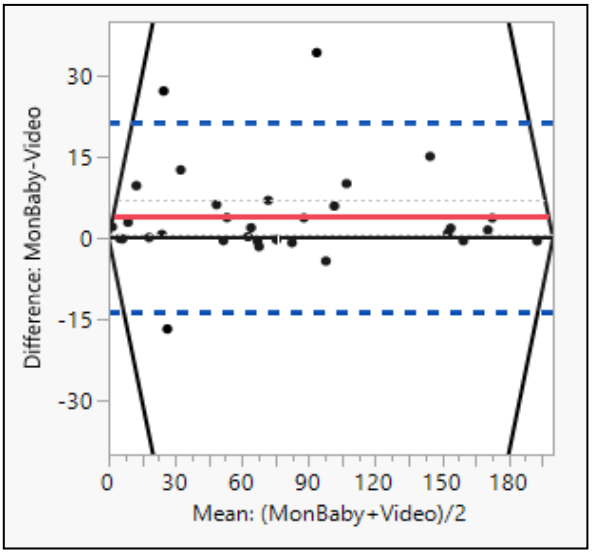


Figure 12: Bland–Altman plots with 95% limits of agreement between the sensors and video for non-prone durations (n = 32)

a) <u>GENEActiv vs video</u>



b) <u>MonBaby vs video</u>



Chapter 3: Validation of parent recall and accelerometer measure for tracking tummy time at home in term and preterm infants

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Abstract

Background: Parent recall is a commonly used subjective measure to track adherence to tummy time recommendations in young infants. Accelerometers may be an objective solution for the same. However, the concurrent validity of parent recall and accelerometers for measuring tummy time in the natural environment is not established.

Purpose: To compare the validity of parent recall and GENEActiv accelerometer against direct observation for measuring the duration of tummy time in term and preterm infants.

Methods: Nineteen term and thirteen preterm infants aged 3-6 months participated. Infants wore the GENEActiv sensor during video-recorded play sessions for three days and parents completed a tummy time recall survey at the end of Day 3. The validity of the two measures was compared against video data using correlation analysis, Bland Altman plots, and mixed model analysis.

Results: Parent recall had a significant moderate correlation ($r=0.54, p=0.002$) with direct observation for term infants. Parent recall was not correlated ($p=0.23$) with direct observation for preterm infants. On average, parents of preterm infants overestimated tummy time by 22 minutes. The GENEActiv sensor was strongly correlated with direct observation for both term and preterm infants ($r's>0.7$) and absolute differences between the two measures were <3 minutes.

Conclusions: Subjective recall measures of tummy time can be used with caution in term infants. The GENEActiv sensor is a more valid and accurate measure of tummy time recall in both term and preterm infants. The results of this study will aid researchers in selecting the appropriate tummy time measurement method based on their study objective and population.

Introduction

Movement experiences during the early years of development (0-4 years) are positively associated with the acquisition of developmental milestones, improvement in executive function and language, reduced adiposity, augmented bone health, and cardiometabolic health (Carson et al., 2016, 2017, 2022). Early movement experiences also influence long-term physical activity behaviors in childhood. Prioreschi & Micklesfield (2019) found that infants who spent fewer minutes in active play were three times more likely to have reduced physical activity as toddlers. Further, infants who spent less time restrained and more time engaged in floor play demonstrated higher levels of activity than their peers with fewer opportunities. The World Health Organization's 24-hour movement guidelines (Sommer et al., 2021), support caregivers and other stakeholders in implementing optimal movement experiences during everyday play. For young infants who are not yet mobile, these guidelines recommend at least 30 minutes of active prone play while being awake, also called as tummy time as the primary movement experience. This recommendation is consistent with the American Academy of Pediatrics', "Back to Sleep, Tummy to Play" campaign (AAP, 2016).

Tummy time is an important physical activity that is known to improve health outcomes in young infants (Hewitt et al., 2020). However, recent studies show that while it is important to perform tummy time, the dosage or how much tummy time the infant is spending on tummy is equally crucial in achieving positive health outcomes. For example, term infants who perform 30-90 minutes of tummy time per day attain head control, rolling, sitting with and without support, and prone motor milestones earlier than infants spending <30 minutes on their tummy (Dudek-Shriber & Zelazny, 2007; Russell et al., 2009). Preterm infants (born <37 weeks of gestation) are at an inherent risk of motor delays and may particularly benefit from practicing tummy time. Fetters & Huang (2007) found that in preterm infants with white matter disease, spending time on tummy at 5 months

corrected age was associated with higher gross-motor skills at the same age. Similarly, Bartlett & Fanning (2003) found that tummy time was the least favorite play position in preterm infants, given the motor challenges of this position. Despite this, infants who spent >40 minutes on their tummy at 8 months corrected age, had better gross motor skills compared to age-matched preterm infants who spent lesser time on tummy. Relatively new evidence demonstrates that tummy time performed for >12 minutes per day at 2 months of age can also lead to reduced adiposity indicators at 4 months of age in healthy full-term infants (Koren et al., 2019). Apart from developmental and physical activity outcomes, tummy time dosage is also identified as a protective factor for the prevention of plagiocephaly in infants. Infants with severe deformational plagiocephaly, who begin tummy time at 7 weeks of age and perform more than 5 minutes per day, show a 46% reduction in the severity of plagiocephaly at 6 months of age (Van Vlimmeren et al., 2008). Taken together, these findings suggest it is crucial to accurately measure tummy time dosage to study the health benefits of tummy time on targeted health outcomes.

The most frequently used method to track tummy time dosage is parent report, commonly in the form of a retrospective recall ranging from a 24-hour recall (Dudek-Shriber & Zelazny, 2007) to a month-long recall (Bartlett & Fanning, 2003). Parents are uniquely positioned to observe tummy time as it is a sporadic activity that is often performed in small intervals throughout the day. Thus, parent recall measures can capture tummy time in different contexts and over longer periods of time (Giraldo-Huertas & Schafer, 2021). Parent recall measures are also more cost-effective, less time-intensive, and can be administered and completed via online data collection methods, making them the preferred measurement choice for longitudinal and population-based studies (Bennetts et al., 2016; Feldman et al., 2000). Despite the advantages, concerns about the validity of parent recall measures have been raised, as dosages reported by caregivers often do not correspond to the gold-standard methods (direct observation). For example, Kippe et al. (2022), found that only 5% of

parents of children aged 4-6 years estimated physical activity levels correctly, with a majority of them overestimating their child's physical activity by three-fold. Similarly, a recent systematic review evaluated 37 proxy-report questionnaires for measuring 24-hour movement behaviors in children aged 0-5 years and found that none of the questionnaires were sufficiently valid or reliable (Arts et al., 2022). Parent recall measures are also susceptible to subjectivity burden (van Zyl et al., 2016), and are moderated by personal-social factors such as parental mental health (Harvey et al., 2013), maternal education (Reese & Read, 2000), ethnicity (Harvey et al., 2013), and socioeconomic status (Bornstein et al., 2020; De Reyes & Kazdin, 2005). A high bias in reporting is observed for parent recall especially when the social desirability for a favorable outcome is high. For example, a meta-analysis found that 50% of parents of overweight/obese children under-reported their children's weight (Lundahl et al., 2014). Existing studies for the psychometric properties of parent recall measures show that caregivers are reliable in tracking milestones (Bodnarchuk & Eaton, 2004) and the presence or absence of a developmental skill (Adolph, 2008) but similar information for time-based outcomes is limited.

Objective measures such as wearable sensors can offset the subjectivity and bias seen with parent recall measures. Advances in sensor research for infants in the last five years have made automated tracking of infant movement experiences in the real world a possibility. Given their precision, wearable sensors are particularly appealing options for measuring the change in movement outcomes in infant intervention studies (Hewitt et al., 2020; Rosales et al., 2022) or for the assessment of adherence to the 24-hour movement guidelines (Cliff et al., 2017). Wearable sensors for infants are lightweight, can be worn across multiple days, and primarily comprise three-axis accelerometers with (inertial movement units) or without gyroscopes. One or more individual sensors can be placed on an infant's wrist or ankle to measure specific movement parameters such as kicking frequency (Smith et al., 2015) or multiple wearable sensors can be embedded in a garment ('smart

garment') to obtain a more comprehensive assessment of infant movement and posture (Airaksinen et al., 2020; Greenspan et al., 2021). Wearable sensors can also be used to compare the differences in movement parameters between term and at-risk preterm infants and aid in early detection of developmental delays (Abrishami et al., 2019). Hewitt et al. (2019), found that a single 3-axis accelerometer (GENEActiv, Activinsights Ltd, Cambridgeshire, UK) placed on the infant's hip can measure tummy time duration with an accuracy of 95%. Some of the drawbacks associated with wearable sensors are that they can be relatively expensive and intrusive, require parent training to use in free-living situations, and can be associated with a high research burden due to the large volume of data for processing, specifically when used across days (Cliff et al., 2009; Lobo et al., 2019).

To summarize, both parent recall and wearable sensors have notable strengths and limitations for tracking movement in infants. To date, no study has directly compared these two methods against direct observation for tracking tummy time within the infant's natural environment. Furthermore, whether and how the agreement of these measures differs in term versus preterm infants is not known. Parents of preterm infants are also likely to exhibit the social desirability bias seen with other clinical populations (Lundahl et al., 2014). Thus, in the current study, we aim to complete a comprehensive comparison of tummy time measures in 3-6 month old term and preterm infants within their natural environment.

Our first objective is to examine the concurrent validity of a 3-day tummy time parent recall compared to the gold standard i.e. direct observation **(Aim 1).** Based on previous evidence (Zhang et al., 2022), we hypothesized that parent recall will have weak to moderate correlation with direct observation. Second, we will assess the concurrent validity of the GENEActiv wearable sensor for calculating 3-day tummy time when compared to direct observation **(Aim 2).** We hypothesized that the GENEActiv sensor will demonstrate a strong concurrent validity with direct observation (Hewitt

et al., 2019). Additionally, the concurrent validity of parent recall and GENEActiv sensor will be stronger in term infants compared to preterm infants

Materials and methods

Participants

The study sample consisted of N=32 infants between 3-6 months of age (19 term-born and 13 preterm). Convenience sampling was used to recruit eligible infants from the Virginia Commonwealth University Health systems and the surrounding community using flyers, social media advertisements, and mailed letters. Infants were eligible for the study if i) they were aged between 3-6 months of age (adjusted age was used for infants born preterm), ii) the caregivers were at least 18 years of age and spoke English, and iii) if the caregiver consented to video and audio recording for both themselves and their infant. Infants were excluded from the study if i) they were intolerant to tummy time as reported by the parent (operationally defined as crying for more than 30 seconds when placed on the tummy) or ii) if they had medical conditions preventing them from lying on their tummy. The infant-parent dyads were included in the study after obtaining written informed consent and were compensated $100 on Day 3 of the study. This study was approved by the Institutional Review Board at Virginia Commonwealth University (**IRB# HM20020592**).

Measures

Direct observation (gold standard)

A tripod-mounted camcorder (Panasonic HC-770) was used as a proxy for direct observation of tummy time at home. This camcorder model can be used while being charged, allowing for continuous recording over longer duration of time. Video data for each infant was coded frame-by-frame using the Datavyu software (www.datavyu.org) to identify the tummy time bouts throughout

the day for three days. The following positions were categorized as tummy time: prone with head in midline or turned to side, prone on forearms, prone on hands, and 4-point. All the tummy time positions were coded irrespective of when the infant was stationary or mobile when on their belly. Two coders, who were trained previously with excellent inter- (ICC=0.91) and intra-rater (ICC=0.95) reliability completed the video coding.

Parent recall for tummy time

A 12-item parent survey (**Appendix G**) was designed to document infant play positions and was administered on Day 3 of the study via a secured REDCap link. The first section of the survey included pictures of seven age-appropriate play positions (supine, side-lying, prone, sitting with or without support, sitting in a seat, standing with support, and being held or carried) and parents were requested to document the amount of time their infant spent in each position during their recorded play session. Given the age of our participants, 4-point variations were presented as initial attempts to push up on hands and knees, or immature quadruped (Piper, 1994) and were included in the tummy time category. In the second section, parents completed a 3-day tummy time recall for all the recorded play sessions, via the following question *"How many hours of total tummy time did your baby perform in the past 3 days while being recorded on the camera in your house (do not include the 'not on camera' minutes here)*". All the durations were reported in hours and minutes. Information about all the play positions was included in the survey to minimize the tummy time bias and only the tummy time information was used for the analysis.

Wearable sensor (GENEActiv)

The GENEActiv sensor (Activinsights Ltd, Cambridgeshire, UK) is a lightweight (16 grams), triaxial accelerometer and a research-grade activity monitor. This sensor has been previously validated to measure tummy time in controlled laboratory settings and has an accuracy of 95%

(Hewitt et al., 2019). The GENEActiv was initialized with a sampling frequency of 30Hz using the GENEActiv PC software. It was calibrated to continuously record data for the 3-days and to minimize caregiver errors in sensor activation. The GENEActiv was attached to the infant's right (anterolateral) hip using a soft elastic velcro strap and the 'golden pins towards feet' was used as the landmark for determining orientation (**Figure 13**).

Before attaching the sensors to their infant's clothing, the caregivers were instructed to complete a synchronization event by shaking the GENEActiv sensor for 3-5 seconds on the camera. This event was repeated at the beginning and end of each play session for the 3 days of data collection. The axis orientation of the GENEActiv with the baby in the supine position is as follows: x-axis horizontally, side to side (right side as the reference), y-axis head to feet (pointing towards the feet), and z-axis front to back (pointing forward).

Study Procedure

This cross-sectional study was conducted in the participant's homes across 3 days. Since the data collection period occurred during the COVID-19 pandemic (April 2021-March 2022), we developed a minimal-contact validation protocol to accommodate the physical distancing and sanitation regulations (see **Figure 14** for methodology). A similar protocol has been tested for free-living validation in infants and was found to be feasible (Franchak et al., 2021). A pre-sanitized study package consisting of the GENEActiv sensor and an attachment belt, a camcorder on a tripod, and an illustrated study manual outlining the steps for sensor and camera placement was dropped off at the participant's doorstep on Day 0 or Day 1. We mailed the study package to participants who lived farther than 40 miles from the recruiting location.

Parents were oriented to the placement of the video camera and the GENEActiv sensor, either through at-home visits or virtual video conferencing sessions, as preferred by the parent. The CDC

sanitization protocols were adhered to if the session was conducted in person. At the beginning of each play session, the parents' set-up the camera in the infant's play area, completed the sensor synchronization procedure and attached the GENEActiv sensor on their infant's right hip per protocol. Parents were instructed to mimic their daily play routines as closely as possible while wearing the GENEActiv sensor. The sensor and the video were turned off during clothing change, diaper change, bathing time, and sleeping time due to privacy concerns. At the end of Day 3, parents completed the parent-recall survey via REDCap (Harris et al., 2019). The researcher completed a doorstep pick-up on Day 3 and the entire study package was sanitized.

Video data for each infant was downloaded through the camcorder's local storage and behaviorally annotated for tummy time positions using the Datavyu software (www.datavyu.org). This was compared against the parent recall, to determine its concurrent validity (**Aim 1**).Twenty percent of all videos were secondarily coded with excellent inter-rater reliability (ICC=0.93) and intra-rater reliability (ICC=0.97). The GENEActiv raw data was obtained using the GENEActiv PC software (Version 3.3). We planned on using the synchronization events to identify the sensor-wear times, however, 40% of our caregivers failed to complete the synchronization procedures. Thus, we identified the sensor wear-time instances using video stamps, and to ensure accuracy, we visually inspected the accelerometer signal magnitude. A similar method has been used to identify sensor wear time in a previous study (Van Cauwenberghe et al., 2011). The total time GENEActiv tummy time duration during each play session per day was calculated using a customized MATLAB script (see **Appendix D**). The per-day totals were summed to get a 3-day cumulative tummy time duration. This 3-day total was compared to the direct observation to determine the concurrent validity (**Aim 2**).

Statistical Analyses

JMP® Pro (version 15.1.0) was used to perform the statistical analyses addressing each study aim. Statistical significance level was set at ≤ 0.05. Descriptive analyses were performed to report the demographic characteristics of the sample; aggregated and stratified by birth status (term and preterm). Mean and standard deviation (SD) or median and inter-quartile range were used to describe continuous variables, based on the data distribution. Frequency and percentages were used to describe categorical variables. The concurrent validity of the parent recall **(Aim 1)** and GENEActiv **(Aim 2)** was assessed in three steps. First, we evaluated the associations between each measurement approach i.e. parent recall versus direct observation, and GENEActiv versus direct observation using the Spearman's rank correlation analyses. Correlation coefficients (r) and p-values were reported for each measurement approach and the strength of correlation was interpreted as follows: weak (0.1 to 0.4), moderate (0.4 to 0.7), and strong (0.7 to 1.0) (Akoglu, 2018). Second, we visualized the systematic bias and agreement between the measurement approaches using the Bland-Altman plots (Bland & Altman, 1999). The mean bias and 95% limits of agreement were reported for each plot. Normality of the differences between approaches was assessed for the Bland Altman analyses. Last, we determined the absolute mean differences between the measurement approaches and evaluated whether birth status moderated the differences using the linear mixed model (LMM) analyses. One between-subject factor (birth status i.e. term and preterm), one within-subject factor (measurement approach i.e. parent recall, GENEActiv, and direct observation), and the interaction between birth status and measurement approaches, were added as fixed effects in the model. Participant ID was included as the random effect. The least-square mean estimates ($\hat{\beta}$), standard error (SE), and 95% confidence intervals (CI) were reported for each model. In addition, the mean difference between the measurement methods with SE and 95% CI, and fixed effect results were reported for each model. If the interaction term was significant, Student's-t all pairwise comparisons were reported. Normality of residuals and variance of data were examined for each model. Given that infants, usually perform 15-60 minutes of

tummy time per day (Dudek-Shriber & Zelazny, 2007; Zachry & Kitzmann, 2011), we operationally defined a mean absolute 3-day difference of ≥ 10 minutes as acceptable. Any difference above this value was indicative of poor agreement.

Results

Participant characteristics

The final sample consisted of a total of 32 infants (n=19 term-born; mean age=5.35, SD=1.17 months, and n=13 preterm; mean gestational age= 31.62, SD=3.66 weeks, mean adjusted age=4.60, SD=1.02 months). Descriptive statistics for the infants and their caregivers is presented in **Table 11.**

All infants were tolerant to tummy time and six parents (n=5 for term infants, n=1 for preterm infants) reported using a play gym, boppy pillow, or a wedge during tummy time. None of the infants used these devices during the study period. Total 78% (n=25) of the infants engaged in tummy time on the floor, 15.6% (n=5) were in a prone play gym, and 6.25% (n=2) did tummy time on bed or in the crib.

Of the 32 enrolled infants, parent recall data were missing for two participants (one parent forgot to complete the form and one parent could not recall the tummy time duration). The parent recall surveys were primarily completed by the infant's mother (n=27, 90%). One survey was completed by a grandparent (3.3%), and two were completed by the infant's father (n=2, 6.6%). The GENEActiv data was missing for three participants (two parents forgot to switch on the sensor on one or more days; and one infant's data had an extraction error). In addition n=5 parents mispositioned the sensor on their infant's clothing (left instead of the right, or on the right side, but the golden pins orientation was reversed). Axis corrections were completed for these five infants by modifying the

algorithm. For n=2 infants, the GENEActiv was variably tilted during the play sessions and axis corrections could not be completed

The total duration of recorded play sessions across three days was 4361.24 minutes (mean 3-day play time=142.53, SD=82.19 minutes) and within those sessions, infants engaged in tummy time for approximately 40% of the time (total 3-day tummy time= 1769.8 minutes, mean=57.76, SD=48.55 minutes). Segregated by birth status; for term infants, the total duration of recorded play sessions across three days was 3148.9 minutes (mean 3-day play time=165.73, SD=98.53 minutes) and 40% of time was dedicated to tummy time (total 3-day tummy time= 1195.36 minutes, mean=70.32, SD=44.59 minutes). For preterm infants, the total duration of recorded play sessions across three days was 1212.29 minutes (mean 3-day play time=93.25, SD=50.93 minutes) and 47% of time was spent playing on tummy (total 3-day tummy time= 574.44 minutes, mean=44.19, SD=54.08 minutes). The average per day tummy time durations for term and preterm infants are depicted in **Figure 15.**

Correlations between the tummy time measurement approaches

The data were assessed for normality and since departures from normality were observed, Spearman's rank correlation was used to report the correlations between, i) parent recall and direct observation (**Figure 16 a, b, c)**, and ii) GENEActiv and direct observation (**Figure 17 a, b, c**). The individual scatter plots revealed the presence of outliers (**seen in red**). The analysis was re-run excluding the outliers but no changes in the magnitude of the correlation coefficient were found; hence the original sample was retained.

Parent recall: For all infants (n=29), parent recall had a significant (**p=0.0024**) and moderate positive (r=0.54) correlation with direct observation. For term infants (n=18), parent recall had a significant (**p=0.012**) and moderate positive (r=0.58) correlation with direct observation. However, for preterm

infants (n=11), the correlation between parent recall and direct observation was non-significant (r=0.49, p=0.23).

GENEActiv: A significant and strong positive correlation was found between GENEActiv and direct observation for all infants aggregated and stratified by birth status. The results are as follows: all infants (n=31, r=0.81, **p=<0.001**), term infants (n=19, r=0.75, **p=0.002**), and preterm infants (n=12, r=0.98, **p<0.001**).

Bland Altman analysis for systematic bias between tummy time measurement approaches

For all the Bland-Altman plots, the differences between the two approaches are plotted on the Y axis and the average of the two approaches are plotted on the X axis. The solid red line represents the average mean of differences the two measurement approaches and is referred to as the bias. The solid black line represents the zero line or the point where the two measurement approaches have no differences. If the solid red line is located above the zero line, then we can conclude that the parents or the GENEActiv overestimate tummy time recall compared to direct observation. Likewise, if the solid red line is located below the zero line, the two measurement approaches underestimate compared to direct observation. The dashed blue lines show the upper (mean + 1.96 SD) and lower (mean - 1.96 SD) limits of 95% limits of agreement (LOA). Narrower the limits of agreement, stronger the agreement between approaches.

As seen in **Figure 18**, parent recall significantly overestimated the tummy time duration when compared to direct observation. The bias for parent recall for all infants was 10.40 minutes/day (95%CI= 0.74, 20.05; SD= 25.38 minutes, **p=0.03**) with 95% limits of agreement (-39.35, 60.15). The magnitude of differences increased as the duration of tummy time recall increased beyond 15 minutes/day.

Figure 19 depicts the Bland-Altman plot for GENEActiv compared to direct observation for all infants. The bias for GENEActiv for all infants was -2.10 minutes/day (95% CI= -4.94, 0.73, SD=7.74 minutes, p=0.14) with 95% limits of agreement (-17.28, 13.07). The bias was consistently low for varying magnitudes of tummy time durations and the limits of agreement were narrow, indicating a good agreement between measurement approaches.

Mean absolute differences between the tummy time measurement approaches

The LMM analysis was completed to examine the mean absolute differences between the measurement approaches, with the birth status as a moderator. The LMM permits the use of all available data (Walker et al., 2019) such that all infants with at least two of the three measures were included in the model (n=31).

In the final model, we examined the differences between the measurement approaches as moderated by the birth status (measurement approach x birth status interaction). The model confirmed a significant measurement approach x birth status interaction, $F(2,57.8)=3.29$, **p=0.04**, which suggests that the tummy time recall durations measured by each approach differs between the term and preterm infants. The main effect for the measurement approach was also significant, $F(2,57.8)=8.25$, **p=0.0007**. This indicates that the 3-day tummy time recall duration varies based on the type of measurement approach.

For all infants (n=31), the least square mean estimates for the measurement approaches were as follows: direct observation ($\hat{\beta}$= 21.1 SE=3.8, 95% CI=13.49,28.76), parent recall ($\hat{\beta}$= 31.7, SE=3.9, 95% CI=23.93,39.53), and GENEActiv ($\hat{\beta}$= 18.9, SE=3.8, 95% CI=11.40,26.48). The least square means of the tummy time recall duration stratified by birth status are reported in **Table 12**.

Pairwise comparisons were conducted to examine the differences between the measurement approaches (parent recall-direct observation, GENEActiv-direct observation). For all infants (n=31), compared to direct observation, parents overestimated tummy time recall by 10.60 minutes/day (SE=3.93, 95% CI=2.7,18.5,**p=0.009**). Sensor under reported tummy by 2.18 minutes/day (SE=3.83, 95% CI= -9.8, 5.5) but this difference was not statistically significant (p=0.57). The differences between approaches stratified by birth status are reported below. For term infants (n=19), compared to direct observation, parents overestimated tummy time recall by 3.56 minutes/day (SE=4.83, 95% CI= -6.11, 13.27,p=0.46). Sensor under reported tummy by 2.93 minutes/day (SE=4.74, 95% CI= -12.43, 6.55, p=0.54). Both of these differences were not statistically significant. For preterm infants (n=12), compared to direct observation, parents overestimated tummy time recall by 22.01 minutes/day (SE=6.15, 95% CI= 9.71, 34.33) and this difference was statistically significant (**p=0.0007**). Sensor under reported tummy by 0.82 minutes/day (SE=5.91, 95% CI= -12.66, 11.02), but this difference was not statistically significant (p=0.88). The least square means plot with the interaction term is presented in **Figure 20.** This plot depicts the stability of the two tummy time recall measurement approaches in term infants as compared to preterm infants.

Discussion

Quantifying the efficacy of intervention programs for young infants depends on accurate pre and post intervention measurement of the desired outcomes (Calder et al., 2018). Since most infants' physical activity takes place within the home environment, measurement approaches that are tested and allow for assessments within the same environment are considered to be more ecologically valid (Franchak, 2019). Our study is unique in using directly recorded play sessions across days in the home settings for validating parent recall for tummy time. Our findings demonstrate the concurrent

validity of parent report and sensor measures against the gold standard direct observation. We also provide preliminary evidence on the impact of prematurity on parent recall measures of tummy time.

A total of 76% (n=23) infants in our study completed <30 minutes of tummy time per day, and 11 of them were preterm infants. Parents were requested to video record all of their infant's play sessions, however, the amount of recording they completed was voluntary. It is possible that infants completed additional tummy time during caregiving activities or at times when the parent was not recording the child. A previous study that assessed whole day tummy time positioning in 205 term infants found that >50% of the infants completed >30 minutes (Zachry & Kitzmann, 2011). Our percentages were slightly higher given the restrictive recording time, but they are still in alignment with population-based results for tummy time positioning. Mothers were the primary informants for the parent recall. This finding is similar to other studies using parent reports for younger children (Kippe et al., 2022; Steenhoff et al., 2019). Moreover, the children in our study were 3-6 months old and were more likely to spend time with their mothers.

Our first primary finding shows that parent recall for tummy time is moderately correlated (r=0.54) with direct observation for term and not correlated with direct observation for preterm infants. There are limited studies validating parent recall measures in young infants (Zhang et al., 2022). However, when compared to physical activity studies in toddlers and young children, the correlations in our study are slightly higher (Arts et al., 2022; Chinapaw et al., 2010). This finding is not surprising as physical activity is more a generalized construct to measure compared to tummy time. Importantly, unlike physical activity, tummy time is usually confined to indoor settings and requires adult supervision (AAP, 2016). Our results were similar to another study that compared tummy time questionnaires with accelerometers in age-matched infants in the home settings and reported moderate correlations (r=60) (Zhang et al., 2022).

Recent papers on statistical approaches recommend against solely relying on correlation analysis to report validity of measures (Bennetts et al., 2016; Bland & Altman, 1999; Giavarina, 2015). Although the results from the correlation analysis describe the relationship between our measures, they are not reflective of the agreement between the measures (Giavarina, 2015). The Bland-Altman plots are a simple and accurate method for testing the agreement between measures and allow for visualization of the differences between measures across magnitudes (Bland & Altman, 1999). The results from our Bland-Altman plots showed that parents overestimate tummy time recall by an average of 10 minutes, with the highest overestimation being as high as 60 minutes. Examining the impact of prematurity on the parent reporting, we found that parents of preterm infants overestimated tummy time by approximately 22 minutes/day. This value was much higher than that seen in parents of term infants, who overestimated tummy time by only 4 minutes/day. Based on our pre-defined acceptable limit, parent recall measures for preterm infants demonstrate poor agreement with direct observation. The mean difference observed in our study is still lower than the study by Zhang et al. (2022), who found that parent recall questionnaires overestimated tummy time in term infants by 42 minutes on a 3-day recall. This difference can be explained by the fact that the above mentioned study used a 24-hour recall and included questions related to sedentary activities as well as play activities. The 3-day recall in our study was restricted to the recording sessions and only included questions on play positions (**Appendix G**). Previous studies have shown that the accuracy of proxy-reports reduces as the number of variables to report increases (Lapin et al., 2021; Skolarus et al., 2010)

Given the smaller sample of preterm infants in our study, it is possible that the data could be skewed by outliers. Hence, we descriptively discuss the individual-level variations in parent recall accuracy below and individual data is also reported in **Appendix H**. In n=11 infants, we found that eight infants (73%) performed less than 15 minutes of tummy time per day and overestimation of

recall by parents in these infants was ≤ 5 minutes. Three preterm infants performed ≥20 minutes of tummy time/day and the overestimation of recall by parents in these infants was ≥ 30 minutes. These findings have two important implications. First, >50% of the preterm infants in our study were performing less than 15 minutes of tummy time/day, at least as recorded during our play sessions. We expected infants in our study to perform more than usual durations of tummy time practice as parents were aware of the focus of our research questions. An increase in desired behavior is often observed in behavioral studies due to its inherent bias (Althubaiti, 2016). However, our findings suggest otherwise. This could either mean that the durations we observed are likely reflective of the infant's daily routine or that they are more than what the infant usually performs. In both cases, preterm infants were not receiving the desired tummy time dosage. Second, the magnitude of over-reporting seems to be directly related to the duration of tummy time performed in preterm infants. Preterm birth is known to significantly increase the family stressors, especially for the primary caregivers (Menon, 2012). Previous studies in clinical populations have shown that parent-report measures are strongly influenced by the caregiver-burden. For example, Corder et al. (2012) found that parents tend to overestimate physical activity durations when their involvement in their child's activity (for support or supervision) is high. Thus, it is possible that the parents of preterm infants in our study included their participation or supervision efforts during tummy time in reporting the tummy time duration, leading to overestimations.

Social desirability, defined as an individual's behavior or desire to obtain favorable outcomes is also a common source of proxy-report error, especially in at-risk children (Bornstein et al., 2015). Parent-report versus direct measure comparison studies in children with obesity frequently report that although parents are aware of the health risks of obesity, they tend to under-report their child's weight on recall questionnaires (Jain et al., 2001). A desire to see their child perform well in gross motor postures combined with the knowledge that they were required to report the outcome, could

have led parents of preterm infants in our study to over-report tummy time durations. In summary, we found that parent recall are moderately correlated with direct observation and may be used with caution in population studies for term infants. However, parent recall is not correlated with direct observation and significantly overestimates tummy time when assessed across three days in the home setting.

Our second analyses focused on observing the same relationship using wearable sensors. Wearable sensors such as accelerometers are routinely used as proxy for direct measures to assess physical activity in older children, both typically developing (Adamo et al., 2009; Carson et al., 2019) and at-risk children (Hulst et al., 2022; Nordstrøm et al., 2013). Physical activity in infants primarily comprises of play and involves the attainment and practice of series of developmental postures (Yogman et al., 2018). Physical activity accelerometer algorithms developed for older children need to be modified for younger infants and validated for use in natural environments, before utilizing them as gold standard comparisons for parent-recall studies (Lobo et al., 2019). We utilized a recently lab-tested accelerometer i.e. the GENEActiv (Hewitt et al., 2019) and validated it against direct observation for measuring tummy time recall in term and preterm infants. Our results show that the GENEActiv sensor is strongly correlated with direct observation irrespective of the birth status for measuring tummy time recall at home. The Bland-Altman analysis shows that the GENEActiv sensor has a minimal bias of approximately 2 minutes/day. The high accuracy of the wearable sensor seen in our study is similar to previous studies utilizing sensors for tracking infant positions. For example, Franchak et al. (2021), used three wearable sensors to track multiple infant positions during play and found correlations >0.9 for the prone or tummy time position, when compared to direct observation. Similarly, Airaksinen et al. (2020) utilized a sensor suit that demonstrated an accuracy of >85% for detecting prone position and mobility. Finally, Hewitt et al. (2019), validated the GENEActiv to

specifically measure tummy time durations and found that it was highly accurate (95%) compared to direct observation.

On looking at absolute differences, we found that not only was the sensor more accurate than parent recall (average differences for sensor <3 minutes versus differences for parent recall >3 minutes) , but the magnitude of differences was much lower in infants born preterm (0.8 minutes). Wearable sensors are objective measures not influenced by parameters such as parent burden, mental health (Harvey et al., 2013), or social desirability (Althubaiti, 2016). Thus, the bias seen with parent recall for preterm infants was not observed with wearable sensors. On the other hand, preterm infants in our study were also smaller in number and performed lower durations of tummy time compared to term infants. Hence, it is likely that this influenced the accuracy of the GENEActiv. On examining individual-level differences for preterm infants for the GENEActiv, we found that even in infants who performed >20 minutes of tummy time, the sensor versus direct observation differences consistently remained as low as ≤ 5 minutes. Based on pre-defined acceptable difference, the GENEActiv sensor is in good agreement with direct observation for measuring tummy time recall. Importantly, the precision in measurement with the GENEActiv, makes it a suitable choice for intervention-based research studies. Currently, there are limited studies focusing on tummy time interventions that use a duration measure as an outcome (Palmer et al., 2019; Tripathi et al., 2020). In these studies, a change of ≥ 10 minutes of tummy time from pre- to post-intervention is considered to be clinically significant. The GENEActiv sensor with a precision of differences <3 minutes may be able to capture this change effectively.

To recommend wearable sensors for use in the natural environment, it is also important to identify the challenges with natural data collection. There was complete loss of GENEActiv data in two infants due to a sensor malfunction. This type of technical errors are common in sensor studies

and the data loss observed in our study is lower compared to other studies (Ahmadi et al., 2020; Van Cauwenberghe et al., 2011). Five caregivers mispositioned the sensor on their infant's body, and the sensor was tilted or rotated in two infants during play. Since the GENEActiv sensor was not designed for infants, we modified the attachment using an elastic strap. However, to minimize positioning errors, future studies should consider using customized electronic onesies (Airaksinen et al., 2020), or jumpsuits (Greenspan et al., 2021) with embedded accelerometers.

Limitations and Future directions

This study had some limitations. First, our sample size is limited compared to previously completed validation studies (Bennetts et al., 2016; Miller et al., 2017). A small sample can lead to the overinflation of findings with greater individual-level variance (Hackshaw, 2008). However, a significant strength of our study compared to previous studies is the use of a rigorous gold standard comparison tool. We used direct observation followed by frame-by-frame behavioral coding of play positions across three days at home, increasing the ecological validity of our findings (Franchak, 2019). Additionally, we included a comparison of two measures (subjective and objective) against direct observation. Our sample for preterm infants was particularly small, however, this study is one of the first to include preterm infants for validating tummy time measures in the natural environment. Future studies should build on this preliminary evidence by assessing the accuracy of parent recalls for tummy time in preterm infants of varying gestational ages.

Although we used the Bland-Altman plots, the results should be interpreted with caution due to our sample size. It is suggested that a minimum of n=50 sample with at least 3 repeated measurements should be recruited to accurately describe the findings (Bland & Altman, 1999; Giavarina, 2015). The Bland-Altman plots in our study are primarily used as means of visualizing the

agreement between our select measurement approaches, and any conclusions on the absolute accuracy are based on the results of the linear mixed model analysis.

Second, parents in this study were aware that the focus of the study was tummy time and were informed about the parent recall at the beginning of the study. Having this information could have biased parents in being more aware of their infant's positioning than they would on a typical day. Parents also had access to the recording camera for the three days and could have checked the videos to get an accurate tummy time duration estimate. However, we do not anticipate a majority of parents doing it given the time requirements of such a task. Our parent recall survey was also set to be a 'one-attempt' only survey to prevent parents from constantly changing their responses.

Third, all infants in our study were prone-tolerant and did not use any positioning devices for support during tummy time. Using a positioning device can change the orientation of the infant's body with respect to the ground, while being on tummy. If and how these positioning devices alter the accuracy of the GENEActiv sensor remains to be determined. Future studies should perform comparisons on the accuracy of the GENEActiv in prone tolerant versus prone intolerant infants.

Fourth, we could not examine the impact of demographic variables on the accuracy of parent recall and sensor, as we were underpowered to do so. Demographic variables are known to influence the accuracy of parent reports and may influence the feasibility of wearable devices. Future studies should examine these variables for tummy time recall in a larger sample.

Finally, future studies should compare the accuracy of per-day tummy time parent reports versus parent recalls against direct observation in young infants. Studies on ecological momentary assessments (multiple assessments conducted in naturalistic environments) demonstrate dense reporting improves the accuracy of reporting in young infants (Franchak, 2019) compared to recall

reporting (Rosales et al., 2021). Thus, if per-day tummy time reports are found to be accurate, they can be a more economical substitute for wearable sensors.

Conclusion

A three-day parent recall for tracking tummy time in the natural environment has moderate validity with direct observation and may be used with caution in population studies for term infants. Parent recall measures for tummy time may be inaccurate in infants born preterm, however, these findings should be confirmed with a larger sample. In comparison, the GENEActiv wearable sensor demonstrates a strong concurrent validity and a high accuracy in tracking tummy time in prone-tolerant term and preterm infants. It can be used in both population-based studies as well as intervention studies assessing change over time in tummy time duration.

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Table 11: Participant characteristics

	All infants (n=32)	Term infants (n=19)	Preterm infants (n=13)
INFANT DEMOGRAPHICS			
Age in months*	5.04 (1.16)	5.35 (1.17)	4.60 (1.02)
Birth weight in lbs.	5.78 (1.92)	6.9 (0.85)	3.96 (1.73)
Current weight in lbs.	13.81 (3.32)	14.5 (1.5)	14.5 (11.3, 16.13) †
Head circumference in cm.	41.43 (2.72)	40.8 (39.1,43.9)†	41.5 (2.8)
Body length in cm.	62.96 (3.62)	63.3 (3.6)	62.5 (3.9)
Gestational age in weeks			
>37 weeks	19 (59.4%)	19 (100%)	0 (0%)
32-37 weeks	6 (18.8%)	0 (0%)	6 (46.2%)
28-32 weeks	5 (15.6%)	0 (0%)	5 (38.5%)
<28 weeks	2 (6.3%)	0 (0%)	2 (15.4%)
Ethnicity			
Hispanic	0 (0%)	0 (0%)	11 (84.6%)
Not Hispanic	31 (97%)	19 (100%)	1 (8%)
Not reported	1 (3%)	0 (0%)	1 (8%)
Race			
White	20 (64.5%)	15 (78.9%)	4 (33.3%)
Black	4 (12.9%)	0 (0%)	4 (33.3%)
Asian	0 (0%)	0 (0%)	1 (8.3%)
Multi-racial	5 (16.1%)	4 (21.1%)	1 (8.3%)

Not reported	3 (9%)	0 (0%)	3 (23.1%)
PARENT DEMOGRAPHICS			
Age in years (yrs.)			
18-25 yrs.	4 (13.3%)	2 (11.1%)	2 (16.7%)
26-35 yrs.	21 (7%)	14 (7.8%)	7 (58.3%)
36-45 yrs.	4 (13.3%)	1 (5.5%)	3 (25%)
46-55 yrs.	0 (0%)	0 (0%)	0 (0%)
56+ yrs.	1 (3.3%)	1 (5.5%)	0 (0%)
Not reported	2 (6.25%)	1 (5.5%)	1 (8%)
Ethnicity			
Hispanic	0 (0%)	0 (0%)	11 (84.6%)
Not Hispanic	31 (97%)	19 (100%)	1 (8%)
Not reported	1 (3%)	0 (0%)	1 (8%)
Race			
White	22 (70.9%)	17 (89.5%)	5 (41.7%)
Black	4 (12.9%)	0 (0%)	4 (33.3%)
Asian	2 (6.4%)	1 (5.3%)	1 (8.3%)
Multi-racial	1 (3.2%)	1 (5.3%)	0 (0%)
Not reported	3 (9)	0 (0%)	3 (23.1%)

*adjusted age for preterm infants, Means (standard deviations) reported for normally distributed continuous variables, † Medians and interquartile range reported for not normally distributed continuous variables, Frequencies (percentages) reported for categorical variables

Table 12: Least square mean estimates for tummy time recall by each measurement approach from linear mixed model analysis

	Term infants (n=19)		Preterm infants (n=12)	
Approach	**Estimate (SE)**	**95% CI**	**Estimate (SE)**	**95% CI**
Direct obs.	24.7 (4.9)	(14.95,34.44)	15.7 (6.1)	(3.52,27.78)
Parent recall	28.3 (4.9)	(18.35,38.17)	37.7 (6.2)	(25.19,50.14)
GA sensor	21.7 (4.9)	(12.01,31.50)	14.8 (5.8)	(3.04,26.61)

SE=Standard error, CI= confidence intervals

Figure 13: GENEActiv placement on the infant

This is a 4-month-old preterm infant wearing the GENEActiv device on the anterolateral right hip using an elastic strap. Parental consent for publishing this image has been obtained.

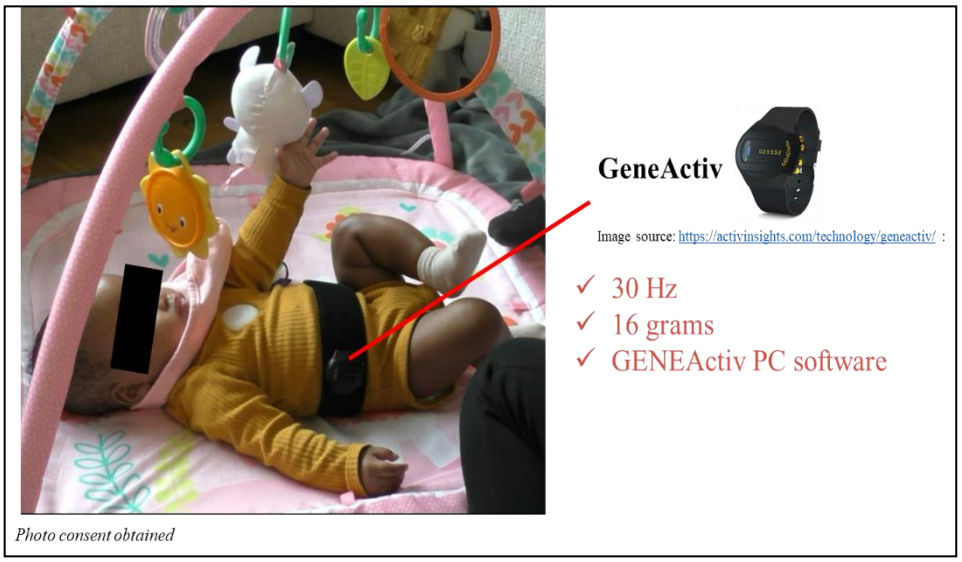


Figure 14: Minimal-contact validation methodology

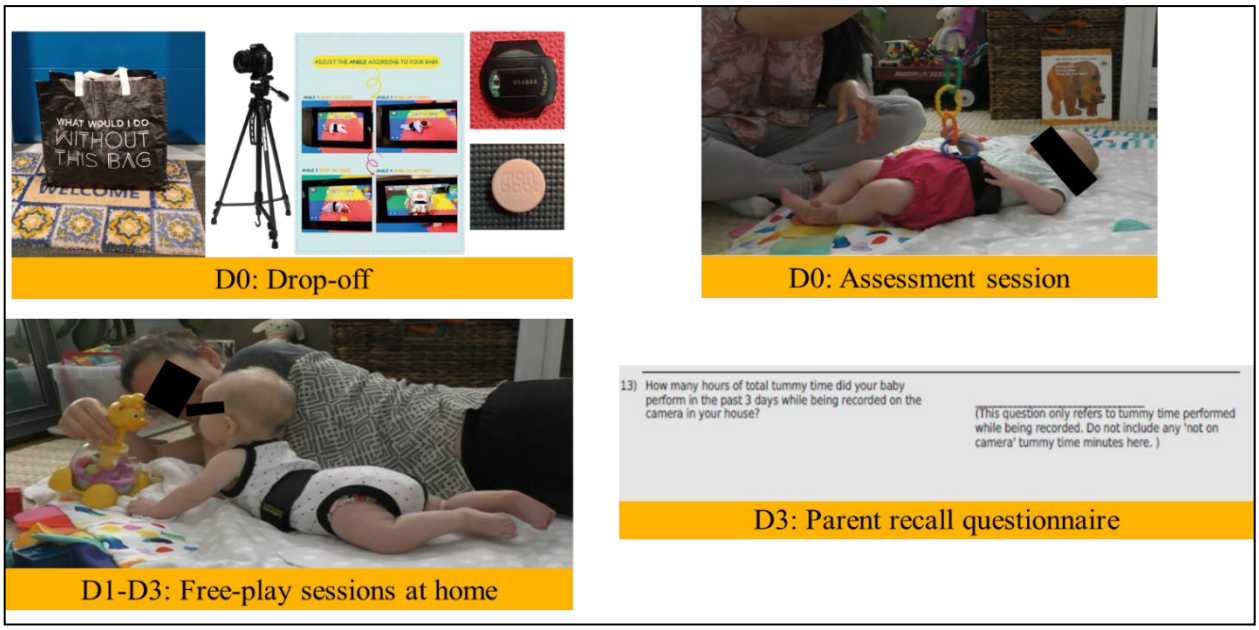


Figure 15: Average tummy time durations during the recorded play sessions for term (n=19) and preterm (n=13) infants

Tummy time in minutes on the y-axis, days on the x-axis

Green bars represent full-term infants, blue bars represent preterm infants

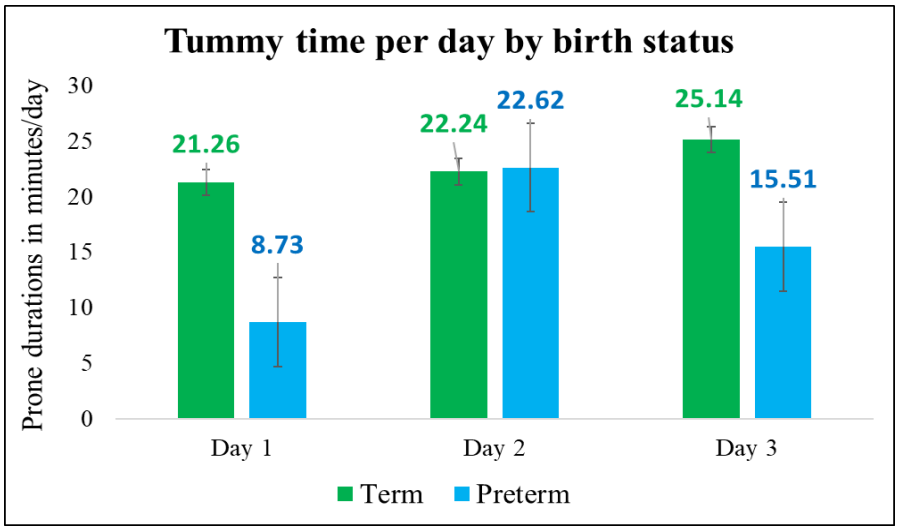
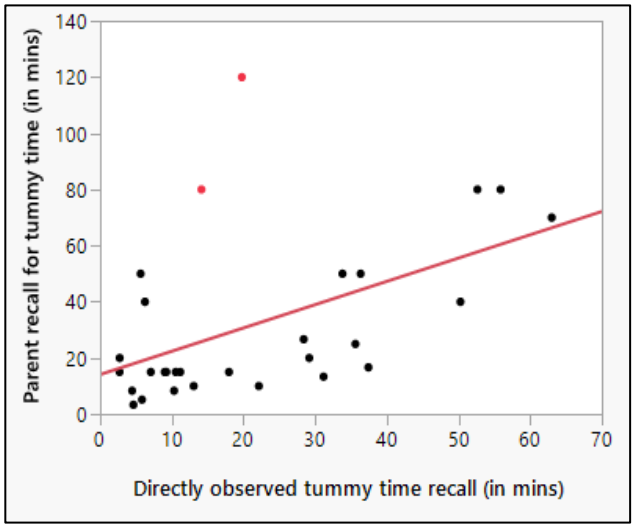
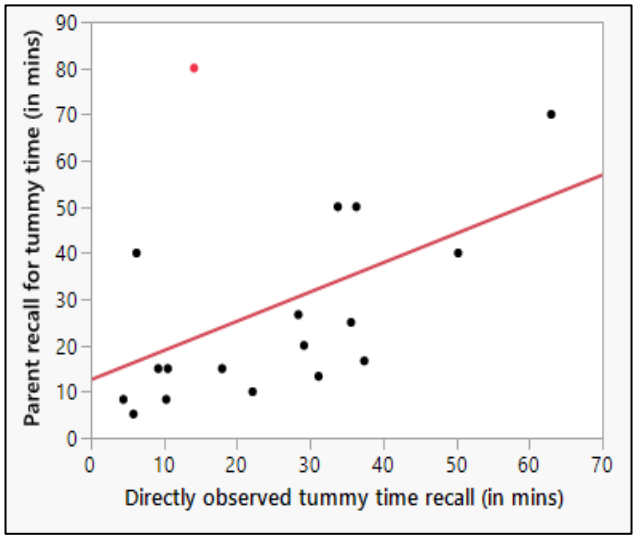


Figure 16: Scatter plots and identity lines (y = x) for the associations between parent recall and direct observation for tummy time

a) **All infants (n=29)**



b) **Term infants (n=18)**



c) **Preterm infants (n=11)**

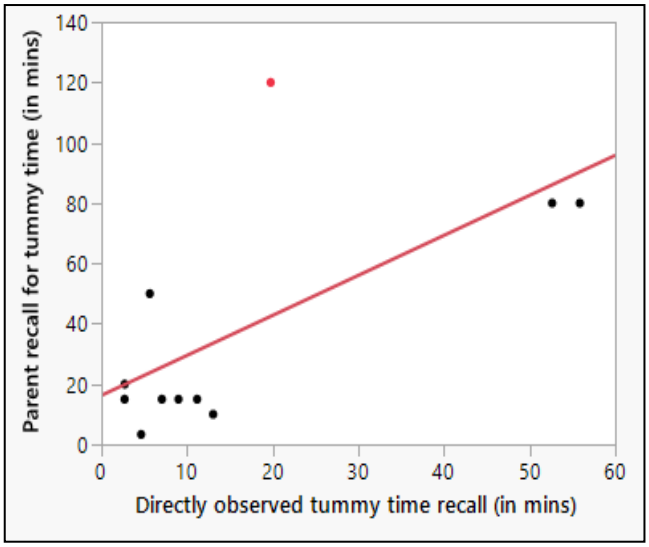
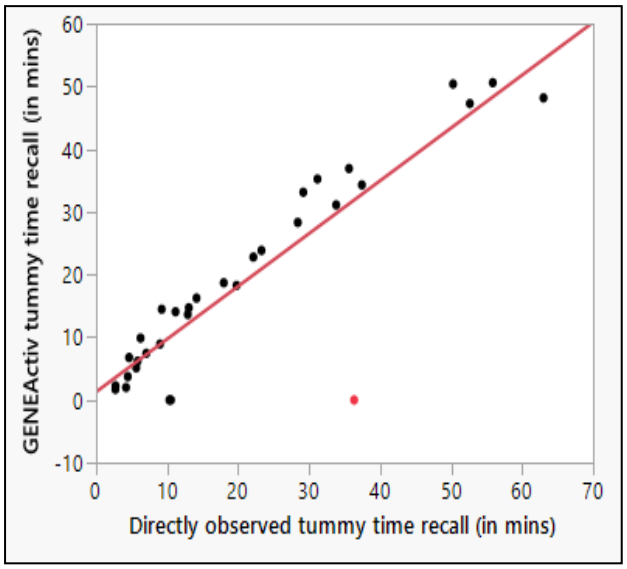
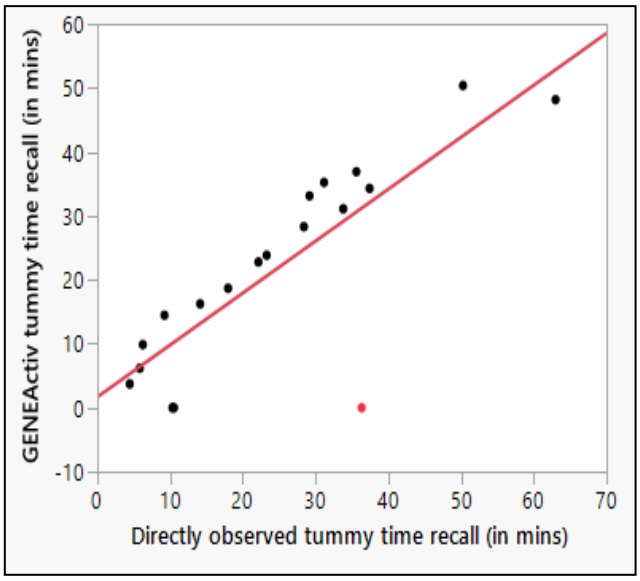


Figure 17: Scatter plots and identity lines (y = x) for the associations between GENEActiv sensor and direct observation for tummy time

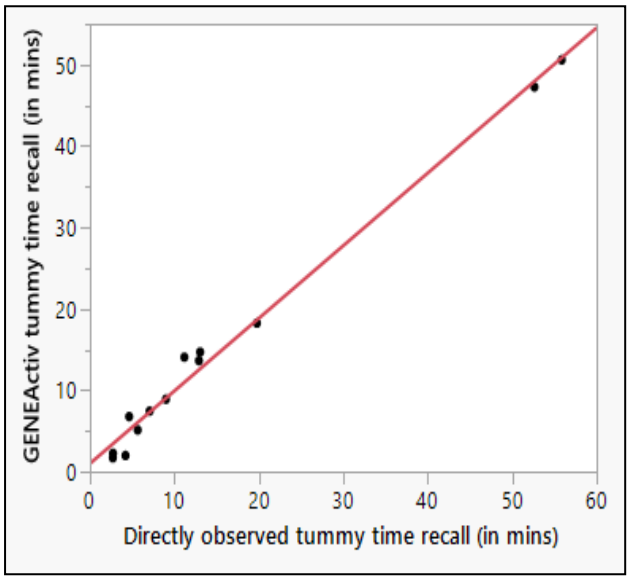
a) **All infants (n=32)**



b) **Term infants (n=19)**



c) **Preterm infants (n=11)**



Figures 18-19 description

For all the Bland-Altman plots, the differences between the two approaches are plotted on the Y axis and the average of the two approaches are plotted on the X axis. The solid red line represents the average mean of differences between the two measurement approaches and is referred to as the bias. The solid black line represents the zero line or the point where the two measurement approaches have no differences. If the solid red line is located above the zero line, then we can conclude that the parents or the GENEActiv overestimate tummy time recall compared to direct observation. Likewise, if the solid red line is located below the zero line, the two measurement approaches underestimate compared to direct observation. The dashed blue lines show the upper (mean + 1.96 SD) and lower (mean - 1.96 SD) limits of 95% limits of agreement (LOA). Narrower the limits of agreement, stronger the agreement between approaches.

Figure 18: Bland–Altman plots with 95% limits of agreement between parent recall and direct observation of tummy time (n = 29)

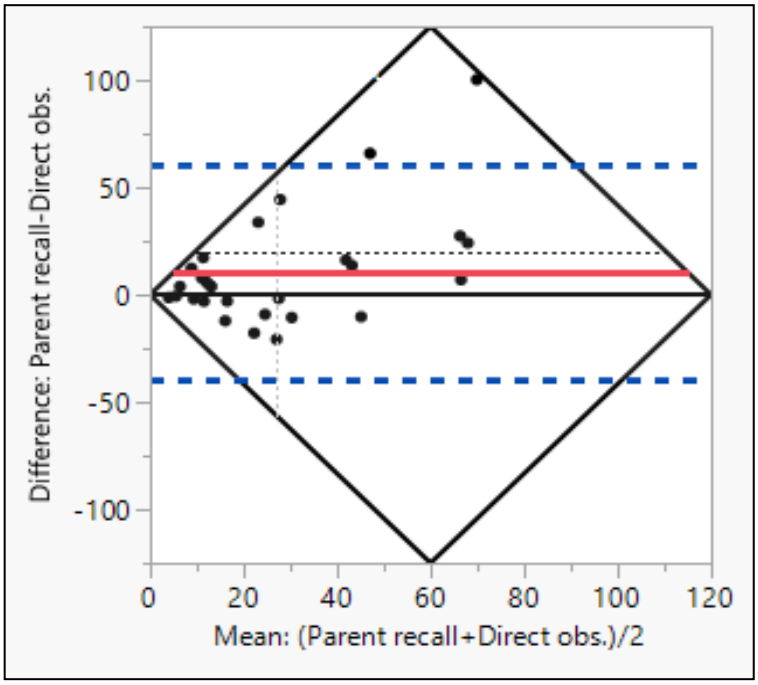


Figure 19: Bland–Altman plots with 95% limits of agreement between GENEActiv sensor and direct observation of tummy time (n=31)

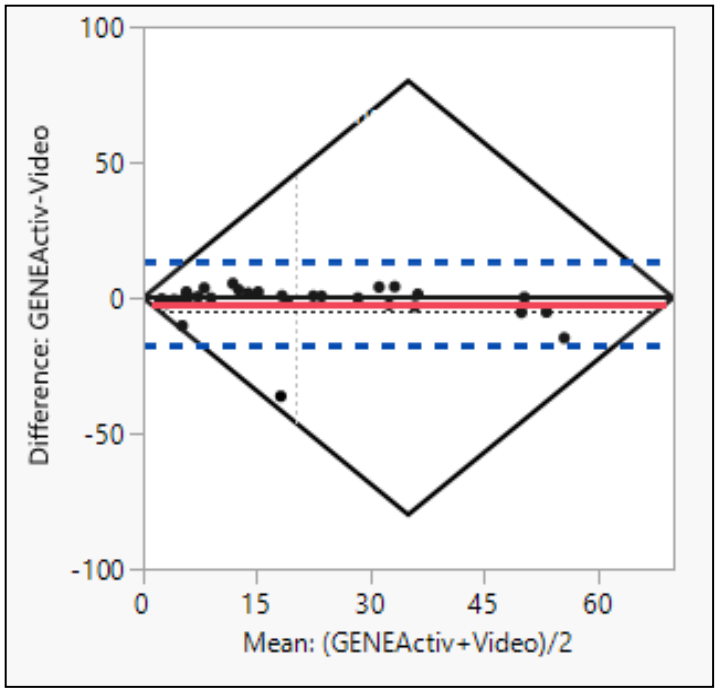
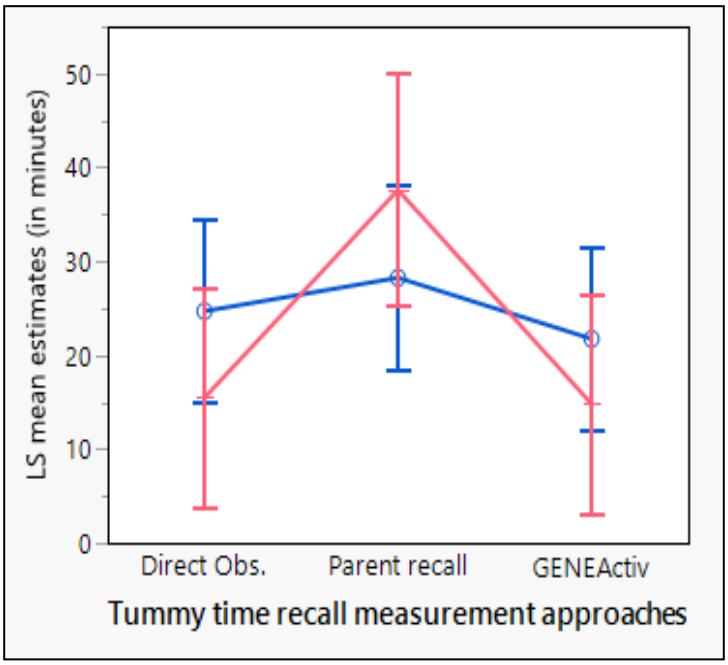


Figure 20: Least square mean plot with birth status x measurement approach interaction term
y-axis= least square (LS) mean estimates for tummy time recall reported in minutes/day

x-axis=measurement approaches i.e. direct observation (direct obs.), parent recall, and GENEActiv sensor



Chapter 4: Early prone motor abilities impact motor and cognitive development in extremely to very preterm infants

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Abstract

Background: Tummy time or wakeful prone positioning is an important developmental position for motor development in the first year of life. But how prone motor abilities influence long-term development, especially in infants born preterm is currently unknown.

Purpose: To quantify the concurrent and predictive association between early prone motor abilities and long-term motor and cognitive development in extremely to very preterm infants (<32 weeks of gestation).

Methods: Prone motor abilities (Alberta Infant Motor Scale-Prone subscale) and motor and cognitive skills (Bayley-III motor and cognitive subscales) of 39 extremely to very preterm, aged 3 months were assessed 3 times (3-,6- and 12-month) using Pearson's correlation analyses and Linear Mixed models.

Results: Prone motor abilities had a significant concurrent association (r's=0.34-0.73) with Bayley-III motor and cognitive skills at 6-months. However, 6-month prone motor abilities did not predict long-term development. Prone motor abilities at 3-months had a significant concurrent association (r=0.55) with Bayley-III gross motor skills and predicted gross motor development at 6- and 12-months ($\hat{\beta}$=0.75, p=0.02).

Conclusion: Early prone motor abilities are associated with concurrent motor and cognitive development and are predictive of future gross motor development in extremely to very preterm infants. These findings highlight the predictive value of prone position and provide suggestions for its inclusion in early detection and intervention implementation.

Introduction

Every year, about 15 million infants in the United States, are born preterm (<37 weeks of gestation) (Harrison & Goldenberg, 2016). Advances in perinatal care and preemptive strategies in the neonatal intensive care unit (NICU) have improved the survival rate of preterm infants (Bell et al., 2022). However, this comes at the cost of later neurodevelopmental concerns among preterm survivors, leading to a high medical and educational burden (De Kieviet et al., 2009; Johnson & Marlow, 2017; McGowan & Vohr, 2019). In the United States, the annual societal economic cost associated with preterm birth is an estimated $25.2 billion (Behrman et al., 2007; Waitzman et al., 2021).

Gestational age is a strong predictor of morbidity in preterm infants and is inversely related to neurodevelopmental delays (Hochstedler et al., 2021). Up to 24-52% of very preterm infants (born <32 weeks of gestation), referred to as VPT infants in this paper, present with impairments in one or more neurodevelopmental domains (Pascal et al., 2018). Among VPT infants without cerebral palsy, mild motor dysfunction is now identified as the most prevalent neurodevelopmental sequelae (Aylward, 2014; Serenius et al., 2013). A meta-analysis including 9653 very preterm children found that they lagged behind their term-born peers in motor development by an average of 0.57 to 0.88 SD, when assessed by the Bayley Scales of Infant Development version II, the Movement Assessment Battery for Children, and the Bruininks-Oseretsky Test of Motor Proficiency (De Kieviet et al., 2009). The motor impairments were widespread in areas of balance, bimanual skills, and manual dexterity, and not all children were able to ‘catch-up’ with increasing age.

Motor dysfunction in VPT infants not only impacts gross motor development but also hampers their ability to explore the environment and perceive the affordances that are required for learning and cognitive development (Hofsten, 2009). Strong theoretical evidence for this assumption

can be found in seminal work in the field of developmental science. In 1992, Thelen described development as a complex and dynamic interaction of sub-systems, such that activity in one developmental domain causes changes in the trajectories of others (Thelen, 1992). Similarly, in 1993, Bushnell & Boudreau, described motor development as a control parameter and a prerequisite for the attainment of perceptual or cognitive abilities. Finally, the recent empirical work on developmental cascades (Masten & Cicchetti, 2010) demonstrates the far-reaching and cumulative cross-domain effects of specific gross motor skills in young infants. For example, the emergence and development of walking are said to drastically alter infants' ability to explore their surroundings — walking infants have greater visual access compared to crawling infants (Kretch et al., 2014); they are more likely to initiate social interactions with caregivers and engage in more adult-directed vocalizations and gestures (Clearfield M.W, 2011). Similarly, when young infants begin to sit independently, they can free their hands to engage in visual, manual, and oral exploration of objects (Soska & Adolph, 2014) and are more likely to receive caregiver-provided cognitive opportunities for learning (Kretch et al., 2022). As a result, independent sitting is associated with the early achievement of object perception (Ross-Sheehy et al., 2016) and higher problem-solving ability (Marcinowski et al., 2019).

Motor dysfunction is not only associated with later development but can also predict delays in at-risk preterm infants. Zuccarini et al. (2020) showed that overall gross motor skills at 6-months of age can predict a delay in the gross motor domain at 12-months of age in VPT infants. Specifically, a one-unit increase in gross motor skills on the Griffiths Mental Development Scales at 6-months of age was found to decrease the 12-month gross motor delay by 0.27 units. Fallang et al. (2005) found that poor quality of reaching in VPT infants at 6-months was associated with the development of minor neurologic dysfunction and fine motor disability at 6 years of age. Similarly, a study by Kwong et al. (2022) found that higher motor scores in VPT infants at 3-4 months of age were associated with lower odds (odds ratio=0.94) of cognitive impairment at 2 years of age. In summary, these findings

highlight the impact of early motor behaviors on concurrent and long-term motor and cognitive functioning in VPT infants. Despite this evidence, studies examining the longitudinal associations of early motor assessment on later motor development in VPT infants are scarce and mostly focus on milestones at or after the onset of sitting. Only 56% of VPT infants achieve independent sitting by 8 months of age, compared to 90% of term infants (T. W. Pin et al., 2009). Thus, it is crucial to examine the influence of other motor milestones on later development in VPT infants. Identifying an earlier predictive motor milestone can aid in the early detection of developmental delays and improve referrals for early intervention.

Tummy time or active prone play is a commonly observed motor behavior between 3-6 months of age. Movement practice in prone position affords opportunities to develop motor control against gravity and achieve stability in later weight-bearing positions, such as sitting and prone on hands and knees (Carson et al., 2022; Wentz, 2017). Experience in tummy time may be even more beneficial for VPT infants as they often present with greater cervical hypotonia and less muscle mass, compared with full-term infants, and consequently, preterm infants are faced with more challenges in the performance of sustained postures against gravity (Valentini et al., 2019). Empirical evidence for the benefits of tummy time in preterm infants has been accrued in recent years with the majority of the studies focusing on tummy time dosage/duration. These studies confirm that preterm infants who perform more tummy time, attain motor milestones earlier (Bartlett & Fanning, 2003; Fetters & Huang, 2007; Hewitt et al., 2020), however similar evidence for the impact of tummy time duration on fine motor skills and cognition remains inconclusive (Hewitt et al., 2020). Currently, there is only one study assessing the impact of tummy time or prone motor abilities on developmental outcomes, and it was completed in full-term infants. This study found that infants who could stay prone on extended arms at 6 months had significantly higher communication, fine motor, problem-solving, personal-social, and total development scores up to 1-2 years of age compared to infants who could

not stay prone on extended arms (Senju et al., 2018). To the best of our knowledge, no study has examined a similar relationship in VPT infants.

In the current study, we aim to study the impact of early prone motor abilities on long-term motor and cognitive development in VPT infants using a longitudinal design. Our first objective is to examine the concurrent associations between prone motor abilities and motor and cognitive development at 3- and 6-months of age **(Aim 1)**. Based on the study by Senju et al. (2018) , our second objective was to examine the predictive associations between 6-month prone motor abilities and 12-month motor and cognitive development **(Aim 2)**. Valentini et al. (2021) found that red flags for motor delays in preterm infants could be detected before 6-months of age. Thus, in our third objective, we aimed to examine the predictive associations between 3-month prone motor abilities and 6- and 12-month motor and cognitive development **(Aim 3)**. We hypothesize that prone motor abilities at both 3- and 6-months of age will be positively associated with motor and cognitive development in VPT infants at the same time point as well as at a future time point.

Methods

Participants

The study sample comprised n=49 infants born extremely to very preterm (mean gestational age=26 weeks, SD=1.5; and mean birth weight=917 grams, SD=207) who participated in the intervention and control groups of a larger multisite longitudinal clinical trial (Dusing et al., 2020). This clinical trial met ethical guidelines for human subject protection and an institutional ethical review board approval was obtained (**IRB # HM20013026**). Written informed consent for participation, and data publication was obtained from caregivers of all participating infants.

Infants born very preterm (<29 weeks of gestation) and cared for in level IV neonatal intensive care units (NICUs) of three sites in Virginia were enrolled in the clinical trial if they were medically stable, off ventilator support by 42 weeks of gestation, and if they lived within 60 miles of a participating hospital. These infants were considered to be at a high risk of developmental disability and were eligible to receive early intervention services in Virginia. Exclusion criteria included a diagnosis of a genetic syndrome, an unstable medical condition, or ventilator dependency beyond 42 weeks of gestation. For this analysis, we included infants from both intervention and control groups to improve statistical power and controlled for the effects of intervention in our model.

Procedure

For the current study, assessment data from 3 time points (3-month, 6-month, and 12-month from baseline enrollment) for infants recruited between February 2019 to September 2022, were used to study the relationship between prone motor abilities and motor and cognitive development. The infant's corrected age (chronological age in weeks subtracted by weeks born preterm) was calculated at each assessment, to account for the impact of gestational age on outcomes (Sansavini et al., 2010). The mean corrected ages at each time-point are as follows: 3-month (mean age=3.25, SD=0.78 months); 6-month (mean age=6.87, SD=1.15 months); and 12-month (mean age=14.19, SD=1.89 months). All assessments took place in the participant's home setting or a dedicated play space in a research lab at Virginia Commonwealth University based on the family's preference. During the COVID-19 pandemic (March 2020 to March 2021), assessments were either conducted remotely through video conferencing or hybrid (part remote/part in-person) to adhere to the social-distancing guidelines. Details about the study's data collection methods during the COVID-19 pandemic are described in detail in Brown et. al, 2022 (under review). All assessments were either scored live or

from video. Assessors were physical therapists or occupational therapists who completed a training outcomes administration and were blinded to group assignment.

Measures

Assessment of prone motor abilities

Since none of the included assessment measures in the SPEEDI trial (Dusing et al., 2020) were designed to measure prone skills as a separate domain, the prone subscale of the Alberta Infant Motor Scale (AIMS) was secondarily scored from videos of other assessments on all infants to quantify the prone motor abilities at the 3- and 6-month time points. Researchers viewed SPEEDI gross motor assessment (specifically the Gross Motor Function Measure and Test of Infant Motor Performance) videos and scored independently observable prone skills. The AIMS is a norm-referenced, standardized assessment tool used to assess gross motor development from birth until the age of 18 months or well-controlled walking (Piper, 1994). It is an observational measure that requires minimal handling or facilitation of the infant and hence secondary scoring from observation was possible. The AIMS is comprised of 58 items distributed across 4 gross motor subscales (prone, supine, sitting, and standing) and within each subscale, commonly observed motor behaviors are organized according to their developmental sequence. For each subscale, the least matured and most matured observed motor item is identified and all items within these two motor items, constitute the "window" of motor repertoire. A score of 1 is credited for all the motor items observed within the window and a score of 0 is credited for items that are not observed. Each motor behavior is scored based on three criteria i.e. weight-bearing, postural alignment, and anti-gravity movements. A raw score for each subscale is obtained by summing all items below the least mature item plus all the observed items within the window. The sum of the subscale raw scores constitutes the total AIMS

score and can be converted into a percentile rank (Piper, 1994). The AIMS demonstrates strong psychometric properties in preterm infants with systematic review reporting excellent concurrent validity with the Bayley Scale of Infant Development (r=0.93) and excellent intra-rater (ICC=0.98), and inter-rater (ICC=0.97) reliability (Spittle et al., 2008). Individual prone subscale AIMS scores have been used in a previous study and were able to distinguish motor function between term and preterm infants (Syrengelas et al., 2022). Two assessors (physical therapists) who were trained on AIMS and blinded to group assignment completed the scoring. Twenty percent of the assessments were double-scored with excellent inter-rater reliability (ICC=0.93) and intra-rater reliability (ICC= 0.99).

Assessment of motor and cognitive skills

The Bayley Scales of Infant and Toddler Development- Third Edition (Bayley-III) were used to longitudinally assess motor and cognitive development at three-time points. The Bayley-III is a norm-referenced, standardized assessment tool for children aged 1-42 months of age and takes 45-60 minutes to administer. It provides three composite scores and five subscale raw scores: Cognitive, Language (expressive language and receptive language), and Motor (fine motor and gross motor). Each item is scored as 1 or 0 based on standardized instructions in the manual and the credited items are summed to obtain the total raw scores for each scale. For this analysis, the Cognitive (sensorimotor development, exploration and manipulation, object relatedness, concept formation, memory, and simple problem solving), Fine motor (grasping, perceptual-motor integration, motor planning, and speed), and Gross motor (sitting, standing, locomotion and balance) subscale raw scores were used. Raw scores were used as they are more accurate in capturing change over time (Zuccarini et al., 2020). The Bayley-III subscales have good internal consistency and strong test-retest reliability (≥ 0.87) (Bayley, 2006). Total of five physical therapists and one occupational

therapist, who were trained in Bayley-III and blinded to group assignment, scored the assessments. All assessors were monitored for adherence to assessment protocol throughout the study period. Twenty percent of all assessments were double-scored and the ICC values per Bayley subscale were excellent and are reported as follows: i) Inter-rater (cognitive=0.98, fine motor=0.98, and gross motor=0.99); ii) Intra-rater (cognitive=0.97, fine motor=0.96, and gross motor=0.98).

Statistical Analyses

JMP® Pro (version 15.1.0) was used to perform the statistical analyses and the significance level was set at ≤ 0.05. Descriptive statistics were used to report participant characteristics (see **Table 13**). The concurrent associations between 3- and 6-month prone motor abilities and Bayley-III cognitive, fine motor, and gross motor skills were examined using the Pearson correlation analyses **(Aim 1)**. The strength of the correlation was interpreted as follows: weak (0.1 to 0.4), moderate (0.4 to 0.7), and strong (0.7 to 1.0) (Akoglu, 2018).

Missing data points is a commonly reported challenge of longitudinal studies (Moeller et al., 2007). Since the data collection of this study was conducted during the COVID-19 pandemic, we experienced more than usual data loss (Brown et. al, 2022, under review). To account for this, linear mixed model (LMM) analyses were used to study the longitudinal associations. LMM analyses permit the use of all available data based on the assumption of *Missing at Random (MAR)* (Ibrahim & Molenberghs, 2009) and thus any participant with at least one future data point for the longitudinal analysis was included in the analyses. For ease of reading, all analyses looking at time points 3-months versus 6- and 12-months, are referred to as ***"3-month prediction"*** and all analyses looking at time points 6-months versus 12-months, are referred to as ***"6-month prediction"*** in the paper (see **Figure 21,** for graphical representation of the analyses).

Recent studies show that early motor and cognitive development explain additional variance in later motor and cognitive development, and hence need to be controlled for in longitudinal analyses (Zuccarini, 2020). To explore the intra-domain associations between Bayley-III subscales, we ran an additional Pearson's correlation analyses. Any intra-domain association that was significant ($p \leq 0.05$) was controlled for in the LMM models. LM Models 1-3 examined the 6-month predictive associations **(Aim 2)** and Models 4-6 examined 3-month predictive associations **(Aim 3)** for each Bayley-III subscale (see **Figure 21**). For each model, the prone motor ability scores as assessed by prone subscale, adjusted age, and time (only for predictive models) were included as fixed effects and subject ID was included as the random effect. Adjusted age at each time point was included in all models since we used the Bayley-III raw scores The effect of the intervention group, time, and group x time interactions were examined for each model. The Bayesian information criterion (BIC) was used to identify an appropriate statistical model and a lower BIC indicates a better model fit.

Results

Participant characteristics

Of the included n=49 participants, Bayley-III scores were missing at both 6- and 12-month time points for n=10 participants. These participants were excluded from the analyses, resulting in a final sample of n=39. Descriptive analyses for participant characteristics are presented in **Table 13**. Frequency and percentage are used to report categorical variables and mean and standard deviations are used to report continuous variables.

In the n=39 sample, available Bayley-III scores at each timepoint were as follows: 3-month (n=34), 6-month (n=35), and 12-month (n=26). Prone subscale scores were available for n=36

participants at 3-month and n=35 participants at the 6-month timepoint. The mean and standard deviations for AIMS and Bayley-III scores at each time point are reported in **Table 14.**

Aim 1: Concurrent associations between prone motor abilities and motor and cognitive development

Scatter plots for the concurrent associations are presented in **Figure 22** and **Figure 23**. At 6-month, prone motor abilities had a significant positive correlation (p's <0.05) with all Bayley-III subscales i.e. gross motor, fine motor, and cognition. The magnitude of the correlation was strong (r=0.73) for gross motor scores and weak (r=0.34) for fine motor and cognitive (r=0.35) scores.

At 3-month, prone motor abilities had a significant and moderate positive correlation (r=0.55, p<0.001) with Bayley-III gross motor scores and a weak positive correlation (r=0.30) with fine motor scores that was trending towards significance (p=0.07). Prone motor abilities at 3-month were not correlated with Bayley-III cognitive scores (r=0.16, p=0.36).

Bayley-III intradomain associations for the 3- and 6-month prediction time points

To explore intra-domain Bayley-III subscale associations, we ran a preliminary Pearson correlation analysis for the two predictive time points. For the 6-month prediction timepoint, both the gross motor and fine motor scores at 6-month were not significantly correlated with 12-month gross motor (r=-0.22, p=0.27) and fine motor scores (r=0.10, p=0.61). However, the 6-month cognitive scores were significantly correlated with the 12-month cognitive scores (r=0.61, p=0.003) and hence were controlled for in the 6-month prediction models.

Results for the 3-month prediction revealed that gross motor scores at 3-month were not significantly correlated with gross motor scores at 6-month (r=0.22, p=0.19) and 12-month (r=0.005, p=0.98). Fine

motor scores at 3-month were not significantly correlated with fine motor scores at 6-month (r=0.10, p=0.55) and 12-month (r= -0.07, p=0.71). However, cognitive scores at 3-month were significantly associated with cognitive scores at 6-month (r=0.33, p=0.05) but not at 12-month (r=0.18, p=0.41). Hence the 3-month Bayley-III cognitive scores were controlled for in the 3-month prediction models.

Aim 2: Predictive associations between prone motor abilities and motor and cognitive development (6-month longitudinal timepoint)

Three LMM were fitted to examine the association between 6-month prone motor abilities and 12-month cognitive, fine motor, and gross motor skills (**Table 15**). Model 1 showed that 6-month prone motor abilities (estimate $\hat{\beta}$=-0.70, F(1,14)=4.11) did not predict 12-month cognitive scores, but the results were trending towards significance (p=0.06). Results from Models 2 and 3, showed that 6-month prone motor abilities did not predict 12-month fine motor skills ($\hat{\beta}$=-0.17, F(1,19)=1.35, p=0.26) or 12-month gross motor skills ($\hat{\beta}$=-0.15, F(1,19)=0.82, p=0.37).

Aim 3: Predictive associations between prone motor abilities and motor and cognitive development (3-month longitudinal timepoint)

Three LMM were fit to examine the association between 3-month prone motor abilities and 6- and 12-month cognitive, fine motor, and gross motor skills (**Table 16**). Model 4 showed that 3-month prone motor abilities ($\hat{\beta}$=0.58, p=0.25) did not predict 6- and 12-month cognition, F(1,29.1)=1.35. When 3-month cognition scores were controlled for in the model, the results remained the same ($\hat{\beta}$=0.47, p=0.30, F(1,22)=1.09). Model 5 showed that 3-month prone motor abilities ($\hat{\beta}$=0.44, p=0.09) did not predict 6- and 12-month fine motor skills, F(1,23.2)=3.05, but the p-value was trending towards significance. Model 6 showed that 3-month prone motor abilities ($\hat{\beta}$=0.75, p=0.02) significantly predicted 6- and 12-month gross motor skills, F(1,20.3)=5.5.

Discussion

Our findings suggest that prone motor abilities contribute uniquely to motor and cognitive development in extremely to very preterm infants and highlight the influence of the 3-month and 6-month developmental time periods in this association. The following discussion is organized based on the individual developmental domains. The associations between prone abilities and gross-motor skills are referred to as intradomain associations, and the associations between prone abilities and fine-motor and cognitive skills are referred to as cross-domain associations.

Intradomain associations for prone motor skills and gross motor development in extremely to very preterm infants

Our results demonstrate that in general VPT infants having higher prone motor abilities at 6- and 3-months of corrected age also had higher scores on Bayley-III gross motor scales at the same time point. In addition, prone motor scores at 3-month time point predicted future gross motor performance at both 6- and 12-month time points. These findings are similar to other studies which show that prone motor skills contribute significantly to the development of early motor milestones such as head control, supported and unsupported sitting, and rolling in infants (Carmeli et al., 2009; Dudek-Shriber & Zelazny, 2007; Majnemer & Barr, 2006; Monson et al., 2003). There could be two possible hypotheses for this relationship. First, biomechanically, tummy time or prone positioning affords opportunities for developing strength in the cervical and thoracic musculature by challenging infants to work against gravity. Siddicky et al (2020) measured the activity of cervical and lumbar (erector spinae) paraspinal muscles, two muscle groups that are primarily responsible for cervical and spine extension, in different postural positions using surface electromyography in 2-6 month-old infants. They found that the mean muscle activity and percentage of active muscle time of the lumbar paraspinals was highest during the prone position, compared to other postural positions in infants.

This is the same muscle group that is found to be active during the development of sitting dynamic control (Harbourne R et al., 1993; Washington et al., 2004) as well as during crawling (Xiong et al., 2018) in both typically developing and at-risk infants. Thus, it can be hypothesized that early prone positioning experience allows infants to develop and practice muscular patterns that are responsible for the achievement of later gross motor milestones.

Second, the dynamical systems theory (DST) suggests that the development of upright postural control results from a constant reorganization of the neuromuscular systems within the infant's biomechanical and environmental constraints (Thelen, 1992). With maturing postural control, the constraints for achieving a higher motor skill are reduced. For example, progression in prone skills such as performing head control in prone and moving up to prone on elbows, allows young infants to shift their center of gravity towards their lower limbs, allowing them to move on their belly (pivoting, crawling) as well as moving in and out of the prone (rolling), thus reducing the constraints for gross motor development. Russell et al. (2009) qualitatively studied the motor abilities of 6-week-old infants who performed the recommended prone positioning (prone-infants) versus infants who did not perform the recommended prone positioning (non-prone infants). They found that 29% of prone-infants were able to displace their weight on the upper trunk compared to only 2% of non-prone infants. Likewise, 94% of prone-infants were able to achieve knee extension compared to 68% of non-prone infants. Thus, prone motor abilities may influence gross motor development in VPT infants via the biomechanical and dynamic systems mechanisms.

Interestingly, we found that that 6-month prone motor abilities did not predict the 12-month gross motor abilities in VPT infants. These findings are in contrast to that of Senju et al. (2018) who found that higher prone motor scores at 6-months of age were associated with higher gross-motor scores up to 3 years of age. There are several methodological and developmental reasons for this

discrepancy. First, the study by Senju et al., included term-born infants compared to our study which included extremely to very preterm infants. Full-term infants tend to have higher prone scores between 6-12 months of age compared to infants born preterm (Valentini et al., 2019). Thus, this discrepancy in scores could partially explain the difference in relationships with gross motor outcomes. Second, they measured prone motor abilities categorically (yes/no) using a single prone motor milestone i.e. prone on extended arms whereas we measured the entire prone motor repertoire of infants using the AIMS measure. Several studies have demonstrated that prone duration increases significantly up to 6-months of age and plateaus from 6-12 months of age in both typically developing (Franchak, 2019) and at-risk infants (Kretch et al., 2022). In contrast, infants tend to spend more time practicing upright and sitting postures from 6-month onwards. Thus, it is possible that more upright positions predict long-term development instead of prone position from the age of 6-months compared to earlier ages. Previous studies have reported a similar relationship in extremely to very preterm infants (Zuccarini et al., 2020).

Cross-domain relationships for prone motor skills and fine motor and cognitive development in extremely to very preterm infants

Our findings revealed that prone motor abilities at 6-months of age had a significant but weak positive correlation ($r \geq 0.3$) with fine motor and cognitive skills at the same time point. Studies from older adults with stroke (Hunter et al., 2008) or sports injuries (Myers & Lephart, 2002) and children with Cerebral Palsy (Pin et al., 2007) show that weight bearing on upper extremity provides proprioceptive input to the joints, mediates muscular control, and helps in improving prehension. When placed in prone at 6-months of age, infants typically perform skills such as “prone on forearm support”, “prone on extended arms”, “pivoting”, and “reaching from forearm support”. These skills are representative of improved proximal spinal and upper extremity control and may aid infants in

participating in more efficient reaching behaviors (Wang et al., 2011). From an embodied cognition perspective, reaching and prone motor abilities are hypothesized to develop concurrently. With the improvement of motor skills, infants are presented with increasing opportunities to act on the environment. For example, as preterm infants practice higher prone motor skills at 6-months of age, they are not only gaining gross-motor skills but are also improving their fine motor and cognitive skills as a result of increased active engagement with the immediate environment (Harbourne & Berger, 2019). This is in line with our current findings, where 6-month tummy time abilities were correlated with 6-month cognitive skills in VPT infants. As infants get better at prone skills, they can prop themselves up and experience verticality for the first time, contributing to the initial perceptual development (Senju et al., 2018). These early visual and perceptual experiences support cognitive development in infants. For example, typically developing infants with crawling experience demonstrated a spatial memory for hidden objects compared to infants with none or lesser crawling experience (Clearfield, 2004). In the same manner, infants with greater head and cervical control in prone can fixate their gaze on objects in the environment facilitating the development of early cognitive constructs such as focused attention (Surkar et al., 2015).

Despite significant concurrent associations, 6-month prone motor abilities did not predict fine motor and cognitive outcomes at 12-months of age. We hypothesize that the motor benefits of the prone position on developmental domains are overshadowed by other complex motor postures that occur between 6-12 months period. Below, we provide two explanations for our findings. First, the contributions of each motor skill are highly dynamic during infant development. For example, infants are relatively still in prone at earlier ages (<6 months), however, they start engaging in prone mobility, typically transitioning out of prone at 6-months of age (Bly & Ariz, 1995). Eye-tracker studies during dynamic play have shown that achieving mobility in each posture drastically shifts the infant's visual access to the environment. While in the prone position, infants are able to visually

access toys that are closer to them but are unable to access distant toys (Luo & Franchak, 2020). In comparison, as infants start crawling (around 9 months of age), they can travel distances to access more distant toys and this visual advantage keeps getting more complex and sophisticated as infants start achieving bipedal postures such as standing and walking (Kretch et al., 2014). This change in gross motor postures is reflected in the fine motor development trajectory in infants. Fine motor skills in infants show the largest and most variable growth in the first 6 months of life, with a 50% increase in object-holding ability from birth to 6-months (Lobo et al., 2014). From 6-months to 24-months of age, infants refine their fine motor skills by leveraging their new-found gross motor mobility and social-interaction abilities (Lobo et al., 2014). Second, it is likely that motor skills are weighted to determine their effect on cross-domains of development such as cognition. For example, recent research demonstrates a strong predictive association of cumulative gross-motor skills on long-term cognitive development in at-risk and specifically in VPT infants using the embodied-cognition approach (Oudgenoeg-Paz et al., 2017). However, similar predictions do not hold true while assessing a specific motor posture, especially in infants older than 6 months. A study by Molinini et al. (2021) assessed the relationship between sitting skills and problem-solving skills in typically developing infants and infants with motor delays. They found that sitting skills had a strong concurrent association with problem-solving skills but failed to predict long-term problem-solving abilities. In contrast, overall gross motor skills predicted both concurrent and long-term problem solving skills. Achievement of sophisticated motor skills drastically changes the infant's environment. While in the prone position, infants are able to visually access toys that are closer to them but are unable to access distant toys (Luo & Franchak, 2020). In comparison, as infants start crawling (around 9 months) and then walking (around 12-18 months), they can travel distances to access more distant toys (Kretch et al., 2014). Thus, attainment of upright postures after 6 months of

age is associated with a complex interaction between multiple developmental domains which may dilute the effects of individual motor postures.

Interestingly our results for the cross-domain relationship for the 3-month prediction are opposite to that of the 6-month prediction. We observed a non-significant concurrent as well as a non-significant predictive association between 3-month prone motor abilities and fine motor and cognitive skills. These findings are in alignment with the systematic review on tummy time by Hewitt et al. (2020) which found indeterminate associations between tummy time and cognitive skills; and no associations between tummy time and fine motor skills in 3-4 month-old infants. The prone repertoire at 3-months of age primarily comprises achieving head control in prone and initial attempts at weight-bearing on the elbow. Thus, with regard to fine motor development, infants may not be able to fully leverage the proprioceptive advantage of prone position at this age. In addition, studies have shown that prone skills at 3-4 months of age do not afford a lot of opportunities for direct object exploration due to the infants' inability to free their hands, as seen with a reduction in frequency and duration of hand-mouth behaviors in prone infants at 3 to 4 months of age (Soska & Adolph, 2014). Similarly, preterm infants may trade cognitive learning at 3-months for practicing the emerging prone motor skills at 3-months of age. This phenomenon is referred to as cognition-trade-off and is often seen in at-risk infants who are learning a new motor skill (Berger et al., 2018) . As per the cognition-action hypothesis, while learning an emerging motor skill, infants tend to allocate their attentional resources to learning that skill at the cost of their cognitive skills. This was observed in a study by Berger et al. (2018) where at-risk infants demonstrated a drop in cognitive performance during the development of independent sitting control. Similarly, Molinini et al. (2021) found that children with motor delays traded problem-solving abilities for learning new motor skills during specific developmental periods. In summary, 6-month prone motor abilities have a weak but significant association with 6-month fine-motor and cognitive skills. Measuring proprioception in young infants

is challenging, however, based on our findings we can hypothesize that the sensorimotor benefits of the prone position at 3-months of age do not directly transfer to improved fine-motor function in VPT at the same and future time points. Younger preterm infants aged < 6 months may trade fine motor and cognitive development during prone positioning to focus on the gross-motor challenges of the prone position.

Limitations and Future directions

The first limitation of this study is related to the use of outcome measures. We completed a secondary analysis of data from a larger clinical trial (Dusing et al., 2020) as the longitudinal design of the clinical trial helped us analyze the long-term impact of prone motor abilities across developmental periods. However, this question was not a part of the primary trial and we had to complete a secondary scoring of the Alberta Infant Motor Scale- prone subscale from pre-recorded Gross Motor Function Measure and Test of Infant Motor Performance assessment videos. Additionally, due to the impact of COVID-19, several assessments were conducted and recorded virtually (Brown et. al, under review). Although this is not the proposed method of completing this measure, the Alberta Infant Motor Scale has been previously validated to be scored from home-recorded videos (Boonzaaijer et al., 2019) and assessors in our study were trained to only score prone motor behaviors that were independently performed by the infants. We used the Bayley-III, which is a standardized test that is routinely used in clinics and research trials, to measure the fine motor and cognitive skills of the preterm infants in our study. However, the Bayley-III has a limited number of items for fine motor and cognitive testing at 3-months of age and may preclude a detailed assessment of the relationship with prone motor abilities. Future studies should consider using behavioral measures of fine motor function—for example, reaching frequency, hand-to-toy contacts (Inamdar et

al., 2022), as well as early measures of cognition (Molinini et. al, under review) to gain a deeper understanding between specific motor skills and cross-domain relationships.

The second limitation is concerning the study design. As described in our methodology, the age time points chosen in this study do not precisely coincide with the 3-,6- and 12-month ages. Hence, the preterm infants in our study at the 12-month time point were slightly older (mean age=14.2, SD=1.9 months). It is likely that the lack of association of prone motor abilities with the 12-month time point was influenced by the age variability, especially for fine motor and cognitive skills (Lipkin et al., 2020). Our sample size for the 12-month time point was also much lesser compared to the 3- and 6-month time points. There were two reasons for this discrepancy—first, assessments were being conducted in real-time as a part of the SPEEDI clinical trial. Hence many of the infants who were enrolled in the study had not reached the 12-month age range during the analysis of this study. Additionally, many infants who had reached the 12-month age range had scheduling delays or missed visits due to the COVID-19 pandemic (Brown et. al, under review). Missing data is a commonly reported drawback of all research studies conducted during the pandemic, especially in the pediatric population (Brown et. al, under review). Future studies should include sample size-matched subjects to examine longitudinal relationships.

The third limitation of this study is the lack of a term-born comparison group. The inclusion of an age-matched typically developing term-born sample can help discern the impact of prematurity on the relationship between prone abilities and development. A recent study including a comparison between term-born and VPT infants groups showed that neonatal status influences predictive relationships between gross-motor abilities and later developmental skills, especially in the cognitive domain (Zuccarini et al., 2020). Including a term-born comparison group in future studies would also

allow researchers to describe and compare the developmental trajectories of prone motor abilities across the first year of life.

The fourth limitation of this study was that more than half of the included participants received a developmental intervention starting in the NICU and continuing for 15 weeks or between the 3 and 6-month time point. The intervention group was included in the study to overcome the sample size limitations due to the COVID-19 pandemic and to improve the power of the study. Since this intervention was designed to empower caregivers to provide learning opportunities during different postural experiences (Dusing et al., 2020), it may have influenced the cross-domain relationships in our study. To control for the effect of intervention, we tested all the models using an intervention and intervention x time interaction term. None of our models reported significant interactions and hence all infants were aggregated in the study.

Finally, our analysis only included the assessment of prone motor abilities as examined from a single clinical assessment. Although the Alberta Infant Motor Scale is designed to capture the cumulative functional experience in each postural position (Piper, 1994), it may fail to capture the impact of prone experience or prone duration on developmental skills. Future studies should consider using a combination of prone duration/ experience variables with prone motor abilities to determine their unique influence on development. These studies can consider using validated tools such as wearable sensors (Inamdar et. al, in writing) to objectively assess the dose-response relationship of prone duration longitudinally.

Conclusion

Our study is the first to examine the long-term impact of early prone motor abilities in at-risk extremely to very preterm infants. Our findings underscore the relevance of prone motor abilities for gross-motor, fine-motor, and cognitive development of preterm infants and highlight the unique

influence of developmental time-periods on this relationship. Our results provide clinical implications for designing tummy time interventions based on the embodied-cognition perspective.

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Table 13: Participant characteristics (N=39)

Descriptive variable	All participants
Gestational age (weeks)	26 (1.5)
Birth weight (in grams)	916.69 (207.6)
Sex	
Male	18 (46.1%)
Female	21 (53.8%)
Race	
Asian	1 (2.5%)
Black	14 (35.8%)
White	22 (56.4%)
Not reported	2 (5.1%)
Ethnicity	
Hispanic or Latino	0 (0%)
Not Hispanic or Latino	35 (92.1%)
Not reported	4 (11.4%)
Maternal Education	
< HS Diploma/GED	7 (18.4%)
Some college degree	5 (13.1%)
Associate degree	5 (13.1%)
Bachelor's Degree	11 (28.9%)
Post-Bachelor's Degree	10 (26.31%)
Not reported	1 (2.3%)
Intervention group	
SPEEDI-Early	13 (33.3%)
SPEEDI-Late	16 (41.0%)
Control	10 (25.6%)

Means (standard deviations) reported for normally distributed continuous variables, Frequencies (percentages) reported for categorical variables

Table 14: Mean and standard deviations for prone motor abilities and Bayley-III scores at each time point (N=39)

Time	Adjusted age in months	Prone motor score		Bayley-Cognition		Bayley-Fine motor		Bayley-Gross motor	
	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
3-month	3.2 (0.8)	37	4 (1.6)	34	10.9 (4.9)	34	7.7 (3.6)	34	12.4 (4.4)
6-month	6.8 (1.2)	35	11.2 (3.6)	35	28.1 (4.4)	35	20.0 (3.2)	35	26 (5.3)
12-month	14.2 (1.9)	26	-	26	42.5 (5.5)	26	29.0 (3.1)	26	42.4 (3.4)

N=sample size, SD= standard deviations, Prone motor scores were not assessed at 12-month time point

Table 15: Linear mixed model with 6-month prone motor scores (Alberta Infant Motor Scale), adjusted age, and time as fixed effects and 12-month Bayley-III scores as the dependent variable

Model	Predictor (6-month)	Dependent variable (12-month)	Estimate (SE)	Test (df)	p-value	95% CI
1	Prone motor score	Cognition	-0.70 (0.34)	t=-2.03 (14)	0.06	(-14.16,35.78)
2		Fine motor	-0.17 (0.15)	t=-1.16 (19)	0.26	(-0.49,0.14)
3		Gross motor	-0.14 (0.16)	t=-0.9 (19)	0.37	(-0.49,0.19)

SE= standard error, df= degrees of freedom, CI= confidence intervals, level of significance $p \leq 0.05$

Table 16: Linear mixed model with 3-month prone motor scores (Alberta Infant Motor Scale), adjusted age, and time as fixed effects and 6- and 12-month Bayley-III scores as the dependent variables

Model	Predictor (3-month)	Dependent variable (6- and 12-month)	Estimate (SE)	Test (df)	p-value	95% CI
1	Prone motor score	Cognition	0.47 (0.45)	t=1.05 (22)	0.30	(-0.47,1.42)
2		Fine motor	0.44 (0.25)	t=1.75 (23.2)	0.09	(-0.08,0.95)
3		Gross motor	0.75 (0.32)	t=2.35 (20.3)	0.02	(0.08,1.42)

SE= standard error, df= degrees of freedom, CI= confidence intervals, level of significance $p \leq 0.05$

Figure 21: Analysis plan for examining the concurrent and predictive associations between early tummy time abilities and motor and cognitive development

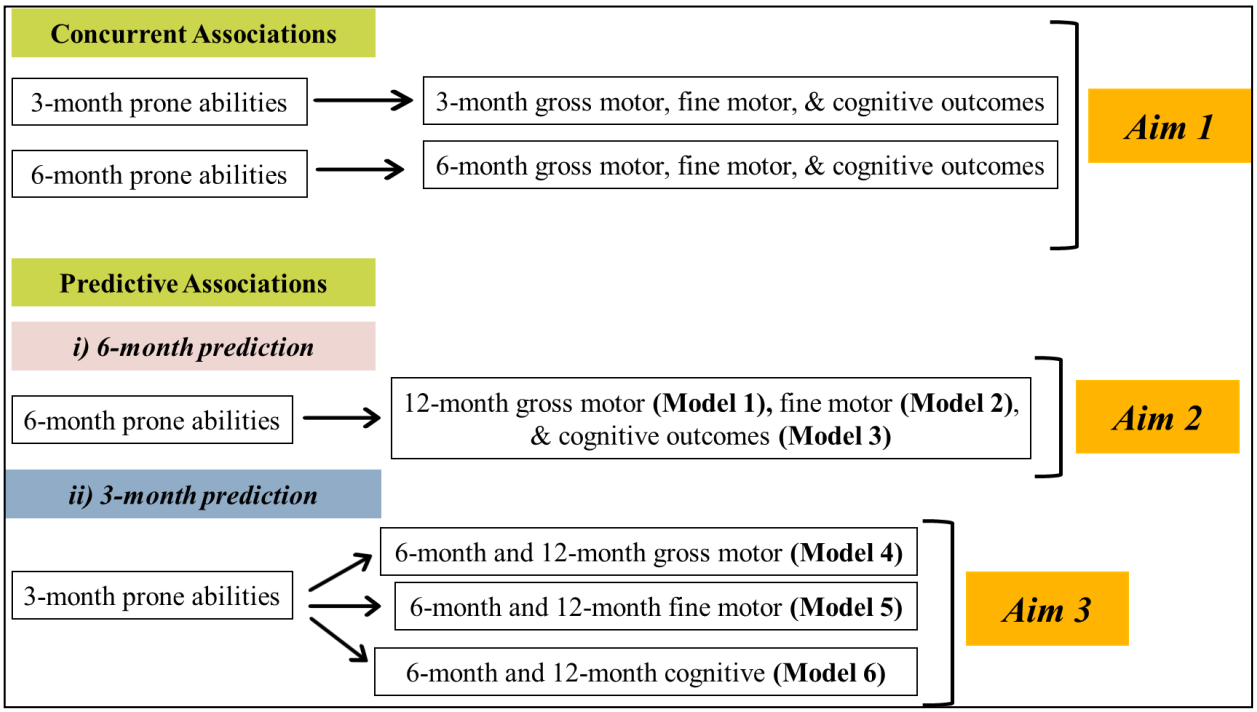
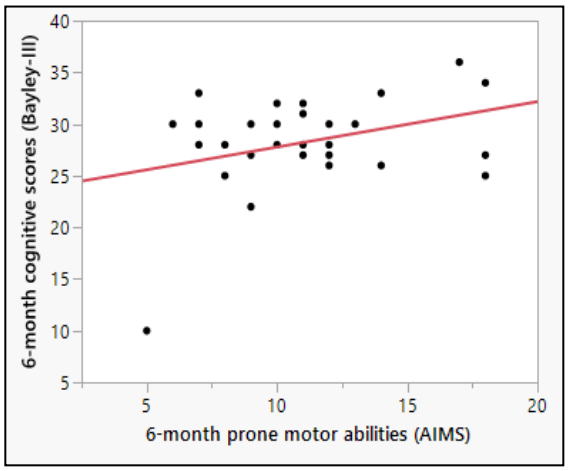
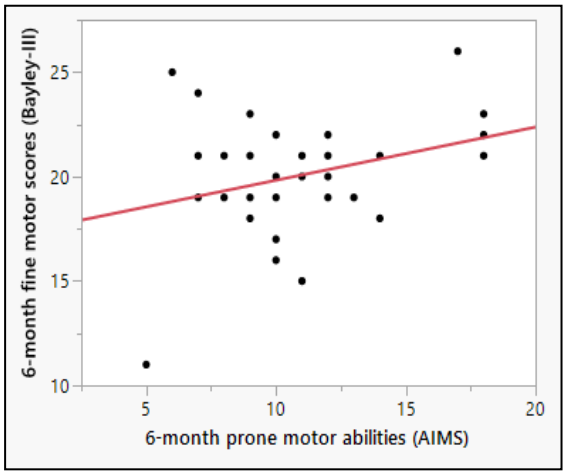


Figure 22: Scatter plots and identity lines (y = x) for the associations between 6-month prone motor scores (Alberta Infant Motor Scale/AIMS) and 6-month Bayley-III scores (n=32)

a) 6-month prone motor scores and 6-month cognitive scores



b) 6-month prone motor scores and 6-month fine motor scores



c) 6-month prone motor scores and 6-month gross motor scores

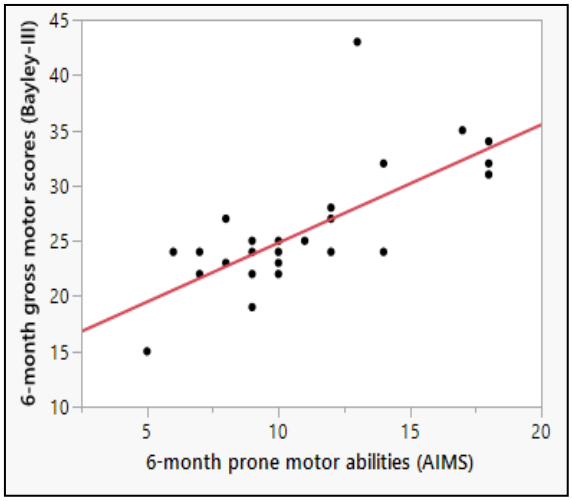
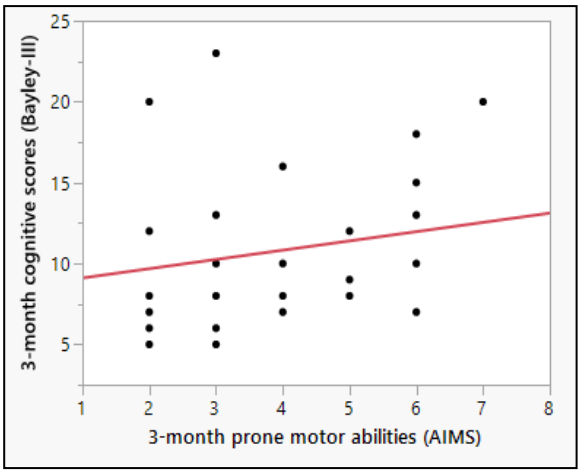
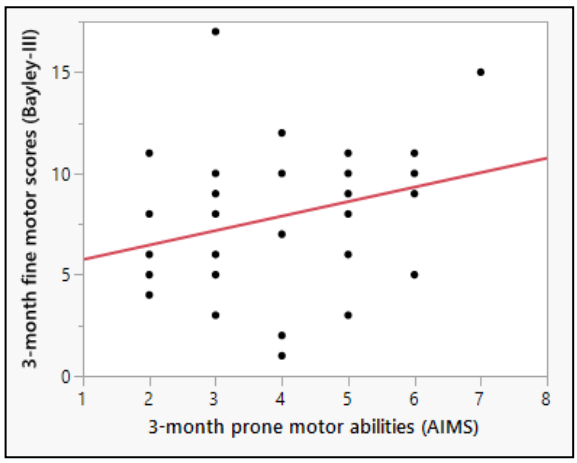


Figure 23: Scatter plots and identity lines (y = x) for the associations between 3-month prone motor scores (Alberta Infant Motor Scale/AIMS) and 3-month Bayley-III scores (n=33)

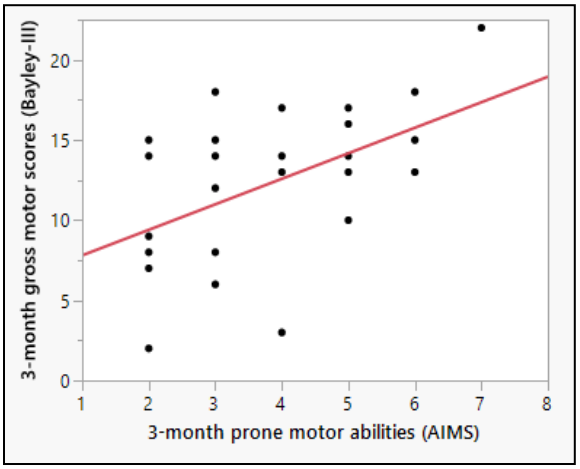
a) 3-month prone motor scores and 3-month cognitive scores



b) 3-month prone motor scores and 3-month fine motor scores



c) 3-month prone motor scores and 3-month gross motor scores



Chapter 5: Conclusions and Clinical Implications

The overall goal of this dissertation was to bridge the gaps in the tummy time literature in infancy by validating conventionally used subjective tummy time measures i.e. parent recall, examining the feasibility and concurrent validity of new objective measures for tracking tummy time in the natural environment i.e. GENEActiv and MonBaby sensors, and assessing the long-term impact of prone motor abilities on developmental outcomes in very preterm infants. Our findings suggest that: 1) Both GENEActiv and MonBaby sensors are perceived to be feasible for home-use by caregivers. However, the GENEActiv has significantly lower data loss issues than the MonBaby and is highly precise in measuring tummy time durations (differences <2 minutes) compared to direct observation, 2) Parent recall for tummy time has a moderate correlation and acceptable accuracy compared to direct observation in full-term infants. However, parents of preterm infants' overestimate tummy time by 22 minutes per day on a 3-day recall. Average parent reported tummy time was ~38 minutes/day compared to the directly observed tummy time of ~16 minutes/day. The GENEActiv sensor is more accurate for recall in both term and preterm infants, 3) Prone motor abilities at 6-months are positively associated with both motor and cognitive scores at the same age in very preterm infants. Moreover, prone motor abilities at 3-months predict gross motor development at 6- and 12-months of age. **Figure 24** illustrates the contributions of this dissertation to the tummy time literature in infancy.

In the following sections, I discuss the clinical implications of our findings using the **Figure 24** framework.

Measurement of tummy time dosage ("How much")

The results from **Chapter 2** and **Chapter 3** provide evidence to support the selection of measurement approaches for tracking tummy time in the natural environment. In summary, parent recall for tummy time may be used for large-scale population studies in term infants, where economic costs are high and the need for precision is lower. Comparing our results with those of Zhang et al. (2022) we found that parent recall surveys that include a limited number of questions are more strongly correlated with gold standard measures. For example, if the goal of the study is to track positioning patterns in infants, then surveys should only be focused on those specific items. Parent recall may not be a suitable for measuring tummy time in preterm infants. Previously used parent reports for preterm infants primarily focus on identifying the infant's preferred play position versus duration of tummy time (Bartlett & Fanning, 2003; Fetters & Huang, 2007). Future studies interested in utilizing parent reports for preterm infants may opt for denser sampling methods. Examples of such methods are the ecological momentary assessment (EMA) (Franchak, 2019), timed-use tummy time diaries (Zhang et al., 2022), or daily parent reports. Such reports require the parents to complete the requested prompts every few minutes or hours and are found to be feasible, have lower recall-bias, are and more accurate compared to recall reports (Rosales et al., 2021). Zhang et al., found that time-use tummy diaries were strongly correlated with the GENEActiv sensor for tracking tummy time at home in full-term infants.

The GENEActiv sensor is the preferred choice for more clinical data-driven studies which require precision in measurement. This sensor can be used to track tummy time in naturalistic settings with high accuracy in both term and preterm infants. However, our results from **Chapter 2** highlight

the challenges of real-world data collection and outlines caregiver's perspectives for the use of tummy time sensors in home settings. Majority of our caregivers were not satisfied with the modified application of the GENEActiv sensor using the elastic strap. Their concerns revolved around the activation of the sensor, discomfort to the infant while sitting, and the ability for a toddler or older sibling to easily access the sensor. Given its high accuracy, we provide three practical suggestions for researchers and clinicians interested in using the GENEActiv sensors for tummy time tracking:

1. Researchers utilizing the GENEActiv sensor for tracking tummy time should set it to continuous recording mode in order to avoid caregiver errors in activation. The recently published GENEActiv wear versus non-wear time algorithm (Hewitt et al., 2021) may be used to filter out periods of non-use to minimize data volume and assist with data processing. Three consecutive days of recording can provide sufficient data to capture real-world tummy time behavior in young infants.
2. The elastic strap method used in our study and the study by (Hewitt et al., 2019) can be replaced with a onesie or leggings with GENEActiv embedded (Airaksinen et al., 2022; Franchak et al., 2021). A more economical solution to this design could be stitching pockets on existing onesies or leggings to snugly place the GENEActiv. These pockets can be padded to reduce the pressure and discomfort of the GENEActiv, while the infant is rolling or playing in side-lying. This solution will also limit the infant or siblings from detaching the GENEActiv sensor, effectively managing the safety concerns expressed by some caregivers in our study.
3. Finally, the GENEActiv in its current form is not designed to provide any visual output to the caregivers and is not suitable for parent-feedback related studies. The GENEActiv is particularly suitable to use in tummy time or other early intervention studies focusing on improving prone positioning in infants, or to identify relations between tummy time dosage

and its impact on developmental milestones (dose-response studies). Examining these relationships, particularly in preterm infants, will help in early detection of lower tummy time duration patterns and aid in implementation of caregiver education and intervention strategies to improve tummy time.

Impact of tummy time or prone motor abilities ("How well")

Chapter 4 combined the gap in research on assessment of tummy time abilities and lack of tummy time research in preterm infants. Our findings bolster the American Academy of Pediatrics' recommendation of encouraging active prone play in young infants and carry several clinical implications for at-risk extremely to very preterm infants (Moon & Syndrome, 2011). Early motor skills are a strong prognostic indicator of later development in preterm infants(Chung et al., 2020) and specific milestones such as sitting (Marcinowski et al., 2019) and walking (Jeng et al., 2000) are known to predict specific developmental skills. Our findings suggest that the prone position is an important early milestone with predictive value, especially for gross motor domain, in very preterm infants.

The 3-month time point in our study was particularly fascinating as 3-month prone motor abilities predicted gross-motor performance up to one year of age in very preterm infants but were not associated with cognitive or fine-motor skills. In contrast, 6-month prone motor abilities were significantly associated with gross motor, fine-motor, and cognitive skills at the same time point but the long-term associations were not significant. These findings have several clinical implications.

From an early detection perspective, therapists completing gross motor assessments on young preterm infants should observe for delays or atypical patterns in the prone position. Our findings suggest that infants with lower prone motor scores at 6-months may also have lower gross motor, fine motor, and cognitive scores at the same age. Similarly, younger preterm infants (~3 months corrected

age) with lower prone motor scores should be intervened early and followed-up to assess gross motor performance across one year of age. From an early intervention perspective, we hypothesize that that the sensorimotor and strength-related gains from prone practice were not being directly translated to other domains in preterm infants at 3-months of age and that this population may need additional support to establish the connection between motor and fine-motor domains, especially at younger ages. Moreover, using the cognition-trade off hypothesis, it is possible that the 3-month old preterm infants were trading cognitive development to focus on the motor challenges of tummy time (Berger et al., 2018). Harbourne & Berger, (2019) examined the role of embodied cognition in designing motor interventions and found that interventions that solely focus on motor skills without consideration for active exploration and problem solving, often have a null or negative effect on cross-domain variables.

In line with these findings, it may be important to design tummy time interventions that support multiple developmental skills, especially in younger preterm infants. This can be accomplished by utilizing the two key components of effective motor interventions (Inamdar et al., 2021; Morgan et al., 2016) i.e. parent education and active, variable practice by the infant. Tummy time can be a challenging motor posture at 3-months of age. Parents can be trained to identify these motor challenges in their infants and provide the "just-right" challenge (Dusing et al., 2020). For example, parents could utilize supportive positioning devices such as the boppy pillow or tummy wedge to reduce the motor challenge of tummy time in young infants. In conjunction, desired toys can be placed at varying heights to encourage infants to raise their head or attempt reaching for the toys. Tripathi et al. (2020) used a similar intervention approach based on the contingency paradigm, where every active head lift of the infant (based on a threshold) was associated with the activation of the toy. Previous research shows that using such contingent toys not only improves the gross-motor skills but also supports the development of fine motor skills and early cognition in infants (Inamdar et

al., 2022). Fine motor skills can be further shaped in the prone position by varying the shape and size of objects or using different textured mats for weight-bearing (Heathcock et al., 2008). As infant's get better at tummy time, the supportive devices can be eliminated or reduced, and the infant can be challenged to reach for toys or actively move in different directions. The therapist or the parent's input can focus on assisting the infant with weight-shifts while the infant explores how to perform the movement. This trial and error is reflective of typical development and help preterm infants to learn how to adaptively overcome motor challenges.

Planned future studies

The findings from this dissertation open up interesting avenues for future research in tummy time for infants. First, we plan to complete a second-by-second analysis of the GENEActiv sensor data to identify specific non-prone positions that were misclassified as prone positions in infants with the highest inaccuracy. We are particularly interested in examining the individual-level variations in sensor accuracy based on the infant's characteristics such as body length and prone motor ability. This information could further improve the applicability of our findings as we could provide a specific age-range when the sensors are more appropriate for tummy time tracking. Using the validated and accurate GENEActiv algorithms, we will train and test machine-learning classifiers to automate the identifying of tummy time bouts across the days. This study will make data collection across multiple days easier and will allow researchers to identify the variability and challenges associated with tummy time positioning in the home settings.

Second, we aim to validate daily parent reports for tracking tummy time against direct observation in both term and preterm infants. We will also compare the differences in accuracy of daily tummy time reports and tummy time recall reports. This finding will add to our results and help clinicians and therapists choose a type of parent report based on the objective of their study.

Third, since prone motor abilities have a stronger influence on gross motor performance, we will further examine if prone motor abilities impact the attainment of mobility milestones such as rolling, crawling, and walking in very preterm infants.

Finally, we utilize the GENEActiv sensor with the suggested modifications in combination with longitudinal prone motor ability assessment to identify the dose-response relationship between tummy time and developmental outcomes in at-risk clinical population.

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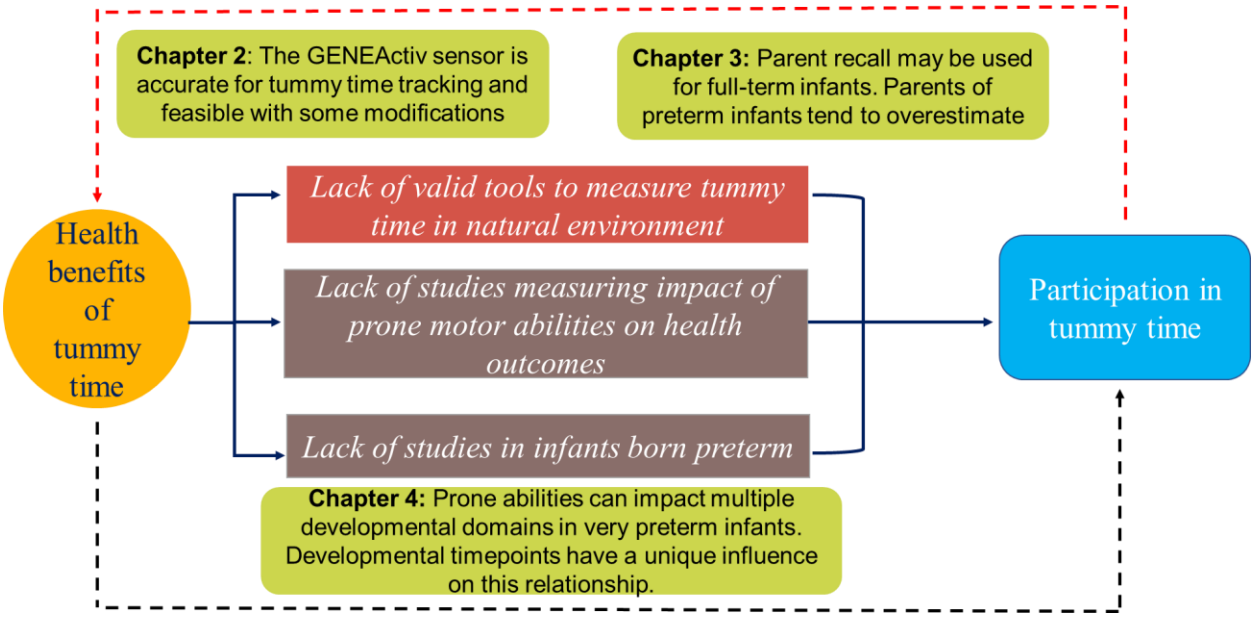
Figure 24: Contributions of this dissertation to the gaps in tummy time literature



Appendix A: Tummy time sensor feasibility questionnaire

Sensor feasibility form

This form is designed to collect information about your opinion on the use of the sensors.

1) Participant ID _____

Select a single response for each of these questions related to the GeneActiv sensor (attached to your child's waist).

		Very difficult	Difficult	Neutral	Easy	Very easy
2)	How easy was it to attach and detach the GeneActiv sensor to your child's clothing?	○	○	○	○	○
3)	How easy was it to switch on and off the GeneActiv sensor?	○	○	○	○	○
4)	How easy was it to ensure the GeneActiv sensor stayed on your child after attachment.	○	○	○	○	○

5) How comfortable was your child wearing the GeneActiv sensor during play?

Very uncomfortable — Neutral — Very comfortable

_____

(Place a mark on the scale above)

6) How would you rate the look and feel of the GeneActiv sensor?

Very unattractive — Neutral — Very attractive

_____

(Place a mark on the scale above)

7) How useful do you think the GeneActiv is to monitor your child's play in everyday life?

Not useful — Neutral — Very useful

_____

(Place a mark on the scale above)

8) Any other comments or suggestions for the GeneActiv sensor?

_____

(write "none" if you have no comments.)

Select a single response for each of these questions related to the MonBaby sensor (attached to your child's chest).

		Very difficult	Difficult	Neutral	Easy	Very easy
9)	How easy was it to attach and detach the MonBaby sensor to your child's clothing?	○	○	○	○	○
10)	How easy was it to switch on and off the MonBaby sensor?	○	○	○	○	○
11)	How easy was it to ensure the MonBaby sensor stayed on your child after attachment?	○	○	○	○	○

12) How comfortable was your child wearing the MonBaby sensor during play?

Very uncomfortable — Neutral — Very comfortable

(Place a mark on the scale above)

13) How would you rate the look and feel of the MonBaby sensor?

Very unattractive — Neutral — Very attractive

(Place a mark on the scale above)

14) How useful do you think the MonBaby is to monitor your child's play in everyday life?

Not useful — Neutral — Very useful

(Place a mark on the scale above)

15) Any other comments or suggestions for the MonBaby sensor?

_____

(write "none" if you have no comments.)

CHOICE OF SENSORS

16) Which of the two sensors would you prefer to use for your child?

- ◯ GeneActiv
- ◯ MonBaby
- ◯ Both
- ◯ Neither

17) Is there any other information you would like to share about your experience?

_____

(write 'none' if you have no comments.)

Appendix B: Illustrated study manual for caregivers

STEP 1: SET-UP THE CAMERA

- Open the camera
- Press the bottom most button (POWER BUTTON)
- Set -Up the camera using the TRIPOD

ADJUST THE **ANGLE** ACCORDING TO YOUR BABY

ANGLE 1 (BABY ON BACK)

ANGLE 2 (BABY ON TUMMY)

ANGLE 3 (BABY ON SIDE)

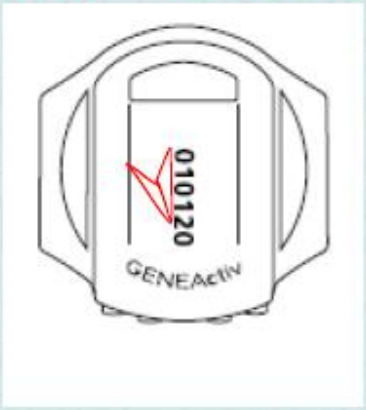
ANGLE 4 (BABY IN SITTING)

STEP 2: SET-UP THE GENE-ACTIV SENSOR

- Open the Bag labelled GeneActiv.
- Remove the belt and attach it to your ***Baby's Hip***

NOTE: The two white velcro strips need to be on the right side of your baby's hip

SWITCHING ON THE GENEACTIV SENSOR



You will have to press a button, which is hidden under the number (shown in red) on the sensor's body

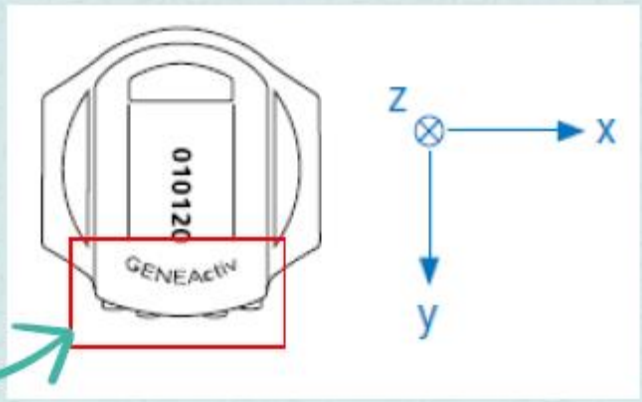
Long flash in 'Button Start' mode = recording started

NOTE: You may need to press the button firmly to start it. You will see a *long green light flash* when the sensor has started recording.

SHAKING THE SENSOR

- Once you see the green light, shake the sensor for 3-5 seconds.
- Repeat this step every time you turn the sensor on.

Now stick the sensor to the white velcro strips with the golden pins on the sensor pointing down (shown in red)



The final position of the sensor should look like this

STEP 3: SET-UP THE MONBABY SENSOR

- Open the Bag labelled MonBaby and get the sensor out

ATTACHING THE MONBABY SENSOR

Parts of the sensor

The button body

The button enclosure/bracket

HOLLOW SIDE

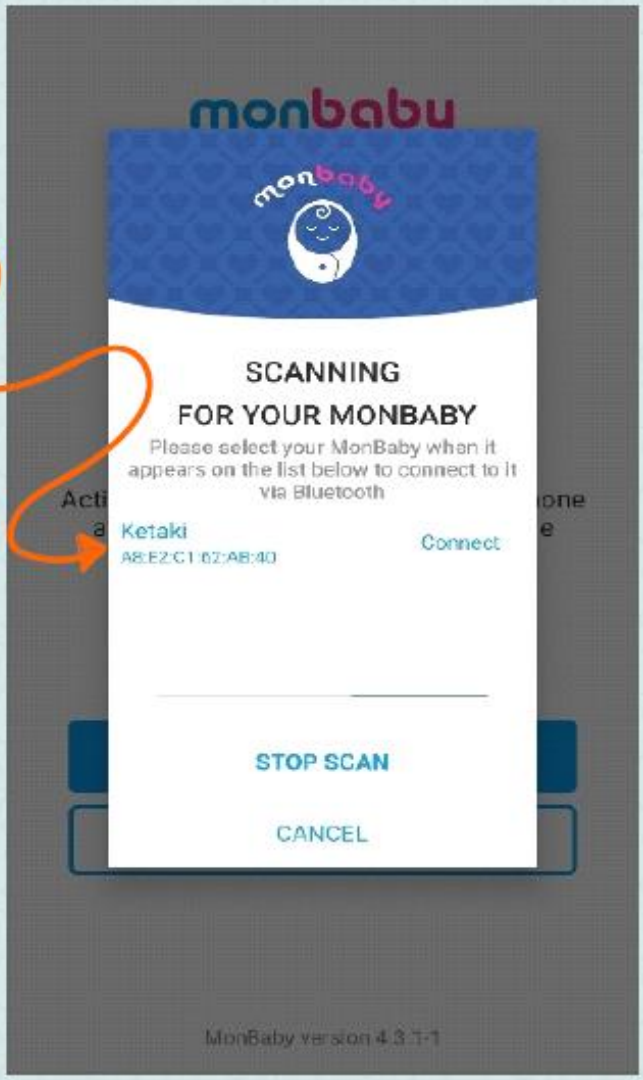
FLAT SIDE

- Place the bracket on the inside of the baby's onesie/ t-shirt, with the flat side touching the baby's chest.
- Insert the button from outside of your baby's t-shirt into this bracket.
- You will hear a click sound after its inserted.

The final position of the sensor should look like this

CONNECTING THE MONBABY SENSOR TO THE APP

- Enable Bluetooth on your device and click on the MonBaby App icon.
- When you first open the MonBaby app, you are taken to the Connection setup screen, which lets you connect the MonBaby Smart Button to the App.
- Tap the connect button at the bottom of the screen, and you should see a pop-up with the detected MonBaby devices listed.
- Tap on the connect button beside the device name *'Ketaki'* to complete the pairing process



CALIBRATION OF THE MONBABY SENSOR

- You will have to calibrate the sensor before use
- For calibration ensure that your baby is lying on their back tap on the calibration button
- You should get a message *'Calibration successful'*

IMAGE 1

IMAGE 2

YOU SHOULD SEE THE DASHBOARD WITH THE MESSAGE 'I'M ON MY BACK'

SHAKING THE MONBABY SENSOR

- Once you see the "I am on my back" message, shake the MonBaby sensor while it is attached to your baby's t-shirt for 3-5 seconds.

The device is now ready to record!

SWITCHING OF MONBABY SENSOR

- Log out of the MonBaby App, remove the sensor from your baby's clothing and place it in the bag.

NOTE : Repeat all the steps for collecting data next time

SET-UP FOR THE MONBABY IS COMPLETE

Appendix C: Tummy time study position coding manual

Purpose of the coding protocol and operational definitions

This protocol will be used to code the **duration of time** infants play or actively spend time in different postural positions **while wearing two sensors.**

"Postural positions" for the purpose of this study are broadly classified into: Prone and Non-Prone positions (see operational definitions below for details).

General Comments:

1. Start the coding after at least one sensor is calibrated. If the video does not have calibration, mention that in "comments" and start coding at the start of the video

2. Calibration for the GeneActiv sensor should look as follows: AT START: Parent pressing the GeneActiv button to switch it on and shaking it in front of the camera **OR** Parent just shaking the sensor in front of the camera; AT END: Parent pressing the GeneActiv button to switch it off **OR** Parent just shaking the sensor in front of the camera

3. Calibration for the MonBaby sensor should look as follows: AT START: Parent pressing the calibrate button on their mobile app and shaking the MonBaby sensor while it is attached to the infant's clothing; AT END: Parent shaking the sensor and logging out of the app *** If the parent shakes the sensor before calibration is completed mention that in "comments"***

4. Cease coding when both the sensors are disconnected or when the video is switched off.

5. There is no time restriction for position coding. However, only code a position change when the change is clearly visible. For example: An infant may perform tiny weight shifts while in a side-lying position without actually rolling into a prone position. Continue coding side-lying until you see the infant roll 45 degrees towards prone.

6. **Mobility does not matter for this coding pass**. Whether an infant is stationary or crawling in the 4-point position, the code would still be 4-point.

7. **Parent Transition (PT)** pass is coded when the parent changes the infant's position by lifting and placing the infant in a new position. For example: the parent lifts the infant from *supine* and places them in *sitting.*

8. The **PT** pass does not have a time restraint. End the PT pass only when the parent has finished transitioning and the infant is settled in a new position. For example, a parent might lift their child---place them sitting--- and continue adjusting the position until the child is well-settled in the sitting position. End the PT transition at this point and start a *sitting position.*

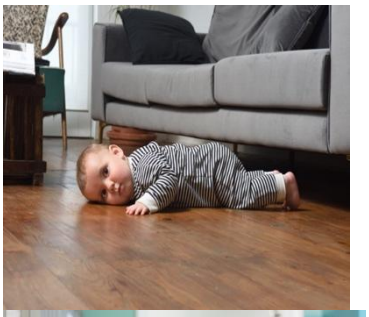
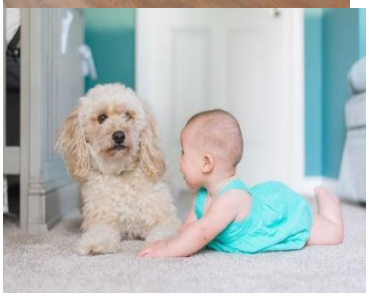
9. Although all the positions are clearly outlined in the operational definitions table (Pages 4-10), in case you have doubts, contact the PI.

10. Any problems with calibration, sensor falling off, camera failure etc. should be noted in the comments at the same time point.

11.

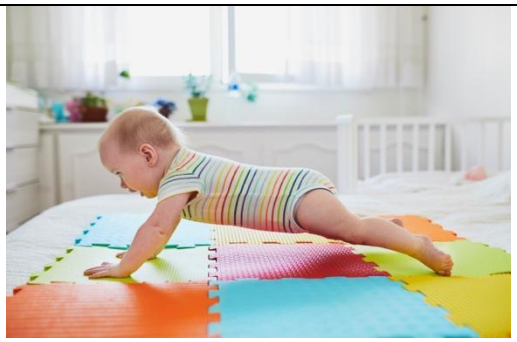
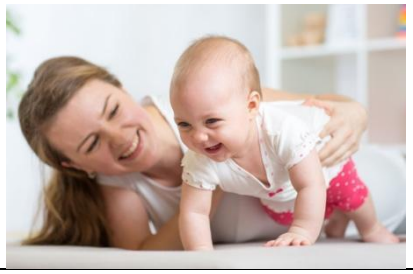
OPERATIONAL DEFINITIONS OF POSITIONS

-

Positions & Definition	Category	Pictorial definition
1. **Prone** Infant is lying on the floor on their tummy and the infant's weight has shifted onto the ventral side of the infant's body (e.g., tummy, front side of legs, etc.) Infant needs to be awake and supervised for safety. Can include the following variations: -Prone lying- tummy on floor w/head against mat, turned to either side -Prone prop or forearm support- tummy on floor, head lifted, chest elevated, weight bearing on forearm -Prone on extended arm support- tummy on floor, weight bearing on hands with elbows extended, head and chest lifted -Prone with lateral weight shifts- tummy on floor, shifting weight on one arm or hands, trunk shifting to that side (may reach out with one arm) -"Superman" – tummy on floor w/ arms/legs up -"Swimming" – tummy on floor and legs/arms moving	PRONE	  

-“Pivoting”- tummy on floor, shifts to a new position by moving arms and legs with lateral trunk flexion **Code: prn**		   

2. Prone supported -Infant is lying on the floor on their tummy using some form of supportive device like towel roll or boppy pillow. -Infant is lying on their tummy on the parent's lap or over parent's leg(s) -Infants lying on their tummy while resting on parent's chest. **Code: psup**	PRONE	  
3. **4-point (or "3pt" variations)** Infant is in the "hands and knees" position, where the belly is off the ground and 4 (or 3) points are bearing weight on limbs Can include the following variations: -Stationary or non-mobile rocking on hands/knees	PRONE	

-Creeping/Crawling on hands and knees, bear crawling on feet and hands -"Push-up/Plank" legs are extended so weight is on toes and arms are supporting body, but stomach is not on the surface -Held in 4-point with parents' support **Code: 4pt**		 
4. Supine Infant is lying on the back, while the back is in contact with the floor/base, and the infant's weight is shifted onto the dorsal side of the infant's body (e.g., back, back of the head, etc.) **Reclined <45 from flat and NOT reclined sitting** Can include the following variations: -Lying on back, hands at sides or in midline -Lying on back, infant is playing w/feet -Lying belly up across a parent's lap, could be facing the parent or away, must be reclined more than upright -Lying belly up on a boppy, pillow, or cushion	NON-PRONE	 

so long as they are closer to flat than upright. **Code: sup**		
5. **Side-lying** Infant is lying on their side (right or left), while their side is in contact with the floor. Both shoulder and hip should be lifted off ground on one side to consider it as side-lying. Can include the following variation: -Reclined lying on the side of a rolled up towel. -Play while lying on side w/head down -Lower body turned to side with shoulder off the ground **Code: sid**	NON-PRONE	  

6. **Sitting** Infant is in a seated position while on the floor. Can include following variations: -Prop sitting: Infant is in a seated position while using arms to steady/hold the body stable, independently or without another person or anything to lean on. -Side sitting: Infant is in sitting, w/sides of hip and thigh in contact with the floor and 1 or both hands used for balancing. -Independent arms free sitting: Infant is in an arms-free seated position while on the floor. Legs can be in a ring, W, straight or any variety of these -Supported sitting: Infant is in a seated position on the floor, on parent's lap, on parent's body and parent is supporting the infant continuously. Or the infant is sitting on floor with support against a stable surface. **Code: sit**	NON-PRONE	 

7. Standing (Supported and Unsupported) Infant is in an upright position, where the feet/knees are supporting the infant. Hand may be on a surface, holding someone's hands or hands free. Can include following variations: -Infant is in an upright position, while the knee (at least 1) and lower leg (at least 1) are supporting the infant on the floor. -Parent holding infant in standing by either holding both or one hand/ holding the infant at hips **Code: std**	NON-PRONE	 
8. **Sitting in a seat** Infant is in a seated or **reclined seated position** in a chair or supportive device **Reclined >45 degrees from flat and NOT elevated supine** Can include following variations: -Sitting in feeding or high-chair -Sitting in chair with buckles, bumbo	NON-PRONE	

-Sitting in bath seat, reclining bouncy seat -Sitting in a reclined car seat -Sitting in any device that allows the baby to be upright of at least 45 degrees **Code: seat**		  
9. **Holding** Parent is holding or hugging the infant to interact or support the infant, but there is not a clear sit, prone or supine position. Can include following variations: -Parent holds infant on the parent's hip and shows the baby toys -Parent holds the infant to their chest and pats the baby's back. -Parent holds and consoles a fussy baby -Parent holds and feeds the baby **Code: hld**	NON-PRONE	  
10. **Out of View**	OTHER	

Infant is currently not on the video screen. Can include following variations: a. Parent/Sibling/pet is in front of the infant covering most of the infant's body b. Parent took baby off screen to feed/change nappy/settle ** Do not code an out of view if parent temporarily blocked the camera and on return there is was no change in infant's position *** **Code: o**		
10. **Invalid code** Code an invalid code if both the sensors are not attached/ switched on/ or not calibrated	OTHER	

*** If you identify any position that is not present in this protocol, notify the PI's.

II. Position Coding in Datavyu

We will code the recorded video data using the Datavyu coding software. Datavyu is an open-source software package for visualizing and coding behavioral observations from video data sources. Due to ethical concerns, you will have to code the videos on Datavyu on the MDL Lab computers only.

For more information on Datavyu, refer to these tutorials:
https://datavyu.org/user-guide/guide/getting-started.html
https://datavyu.org/user-guide/guide/tutorials.html

I. Identifying videos for Coding

- Open the Tummy Time and sensors coding sheet (shared with you): look for which visits are assigned for you to code with your initials in the Coder column. Please use the color-coding system when you start coding as it helps track the coding progress.

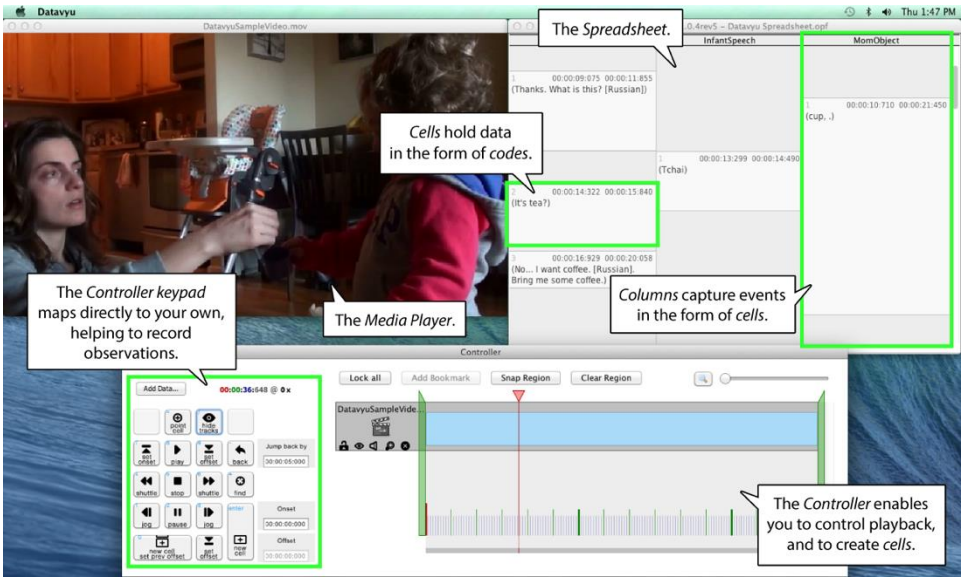
- Each participant will have 3 days of video data. Each day will have multiple videos based on the time of recording. The number of videos for each participant will be indicated in the coding sheet.

II. Accessing the Datavyu File templates

[redacted]

III. Opening Datavyu

- Click on the Datavyu files to open Datavyu. It has already been installed on your computer. You will see this screen:



IV. Adding video files to Datavyu

- Select "Add Data" option in the Datavyu Controller
- Follow this path: [redacted]

V. Adding Columns to Datavyu File (https://datavyu.org/user-guide/guide/tutorials/add-a-column.html)

Each Column in the Datavyu is referred to as "Pass". You will add the columns in the following order:

PASS 1 (column 1): SUBJECT INFORMATION **Double-check this information to make sure it is correct. If the data is missing alert PI**

- This Column is used for entering participant information and is labeled as: "infinfo".
- This column needs additional codes (https://datavyu.org/user-guide/guide/tutorials/configure-datavyu-codes.html)
- To add codes to this column, Select Spreadsheet—Code editor—Find the column labelled "infinfo" and add the following codes in the bracket following the column name by selecting "Add code". The codes are: <id>, <day>, <doa>, <toa>, <coder>. The final code should look like this: infinfo (<ID>, <day>, <doa>, <toa>, <coder>)

Definitions of each code:

- ID-Just type the infant's 3-digit ID number. Example: 100
- Day- Enter the day of assessment in Day X format. Example: Day 1
- DOA-Enter the date of the assessment. Enter in 00-00-00 format. Example: 051121
- TOA-Enter the time of assessment. Enter in hh-mm-ss format. Example: 101523. Each video is labeled based on time.
- Coder: Your initials. Example: Richard Parker is the coder, then enter "RP"

Enter the total duration of the video in the time section of this column. The start time would always be 00:00:00:00 and the end time would be the total video duration, for example 00:14:05:23.

PASS 2 (column 2): TRIAL DURATION

- This column is for entering the start of coding and end of coding time. This differs from the start and end of the video entered in Column 1.
- This column is labeled as "trial_duration (<trial>)"
- Coding starts when at least one sensor is calibrated (usually GeneActiv).
- Complete this column after you have finished position coding.
- Example: Start time would be 00:00:02:00 and end time would be the total video duration 00:13:06:13.

PASS 3 (column 3): COMMENTS

- This column is labeled "comments (<comments>)" and is used to indicate the sensor switch on and calibration times.
- Switch on for GeneActiv: The parent presses the GeneActiv button, and you may/may not see a green flash. Code: *"GeneActiv switch on"*
- Calibration for GeneActiv: The parent shakes the sensor in front of the camera. Start code at the start of the shake. Code: *"GeneActiv shake on"*
- Switch on for MonBaby: The parent opens the app on the phone—clicks on connect—and calibrates. Ideally, you should see a circle appear on the parent's phone. If you do not see the phone screen, code when the parent keeps the phone down. Code: "*MonBaby switch on*"

- Calibration for MonBaby: The parent shakes the sensor after attaching it to the baby's onesie. Start code at the start of the shake. Code: *"MonBaby shake on"*
- *For new videos you may need to code "GeneActiv shake off" and "MonBaby shake off"*
- *Parent shakes the GeneActiv sensor at the end of the video. Code: "GeneActiv shake off".*
- *Parent shakes MonBaby at the end of the video. Code: "MonBaby shake off"*
- Switch off for GeneActiv: The parent removes the belt and presses the GeneActiv button, and you may/may not see a red flash. Code: "*GeneActiv switch off" (Maybe missing in new videos)*
- Switch off for MonBaby: The parent logs out of the app. Code: "*MonBaby switch off*"

PASS 4 (column 4): POSITION

- This column is for the primary position coding and is labeled "position (<position>)". Begin this column when either of the sensors is switched on (usually GeneActiv).
- The start time of the position should match the start time of the "sensor switch on" code in the "*comments"* column.
- Code the type of position based on the operational definitions and code a transition between each new position.
- Stop coding when both the sensors are switched off.
- Add onset and offset durations to each cell. To do this—go to the second cell—click on start time of the cell—click "+" on your number pad—go to first cell--- click on end time—click "." On your number pad. Repeat this process for cells below.
- The end time of each cell should correspond to the start time of the cell below.
- Enter the trial duration in **PASS 2** based on the start time of the first cell and end time of the last cell in the position column.

*****A template Datavyu file is ready with all the columns added. You can copy this template for individual participant coding. Do not edit the template*****

Note: This is an ongoing project, so please keep an eye out for data collection issues and notify PI of any consistent problems.

SHORTCUTS FOR DATAVYU

Number 8	Play
Number 2	Pause
Number 1	Rewind
Number 3	Forward
+	Enter a new cell
Command + Back Slash	Delete a cell

Command + S	Save the file
Command + T	Temporal alignment

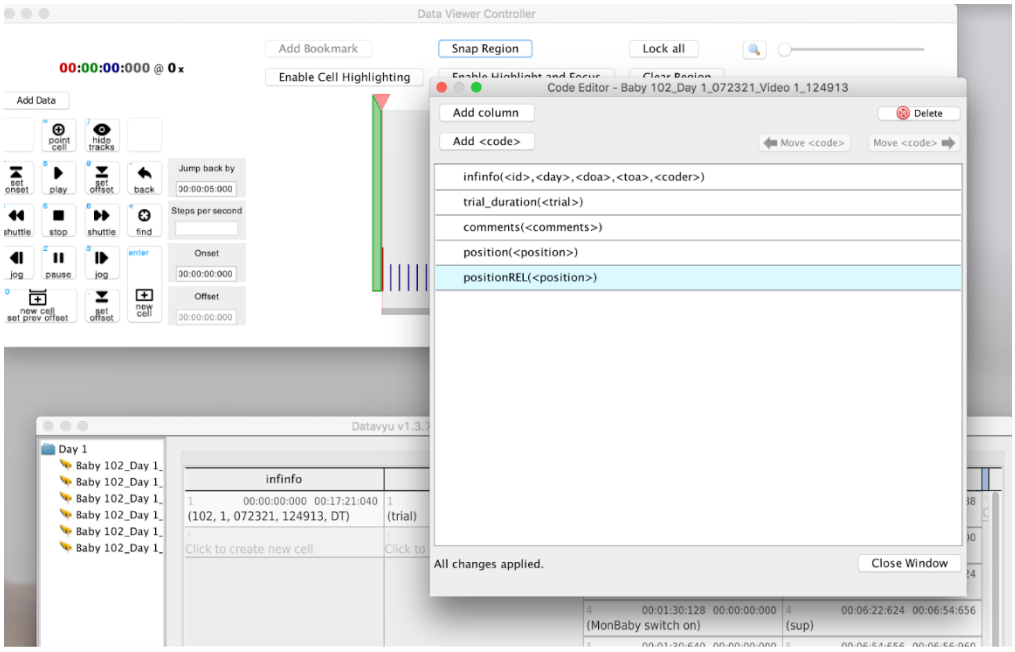
III. Reliability Coding for Position

For all videos, **we will conduct 20% inter-rater reliabilities.** Inter-rater reliability is when 2 different coders code the same videos 2x and compare the % overlap between the files.

- Inter-rater reliability is obtained as a percent agreement. The goal is to maintain inter-rater reliability **to ≥ 95%**.
- If the IR reliability is less than 95%, notify PI and she will code the video to reach an agreement.
- **Please conduct intra- and inter-rater reliabilities regularly**. A general rule of thumb is to conduct a reliability every 5 videos you code (i.e., 20%).

STEPS FOR RELIABILITY CODING:

1. Open the Tummy Time and sensors coding sheet (shared with you). In Sheet 2 titled "Reliability coding" identify the videos assigned to you.
1. Open the Datavyu file for the video----Click Spreadsheet-- Uncheck the box for "position" (This done to prevent bias while coding reliabilities)
2. Click Spreadsheet--Code editor--Add Column--Name it as follows "positionREL(<position>)

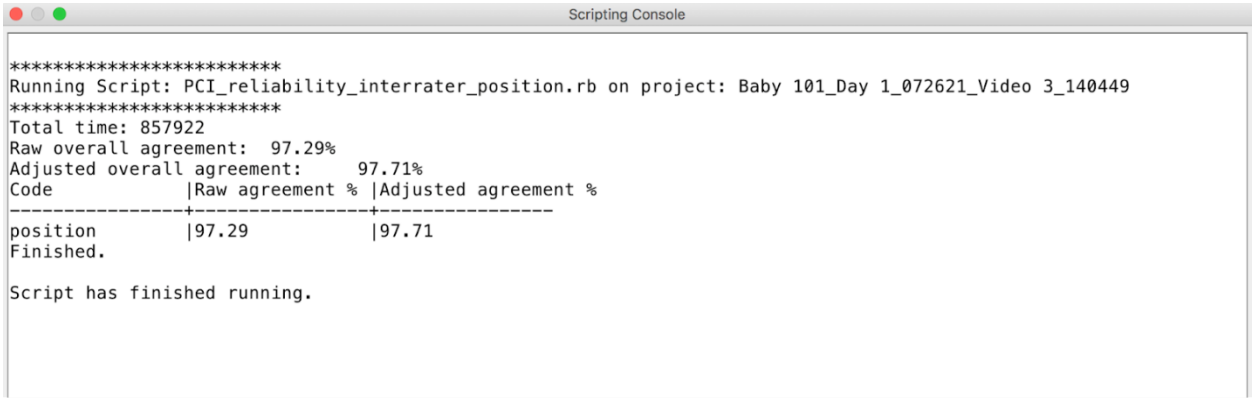


3. Continue coding positions when at least one sensor is calibrated as you normally would. You do not need to code the comments column and can rely on the original coder's comments section to determine the start point.

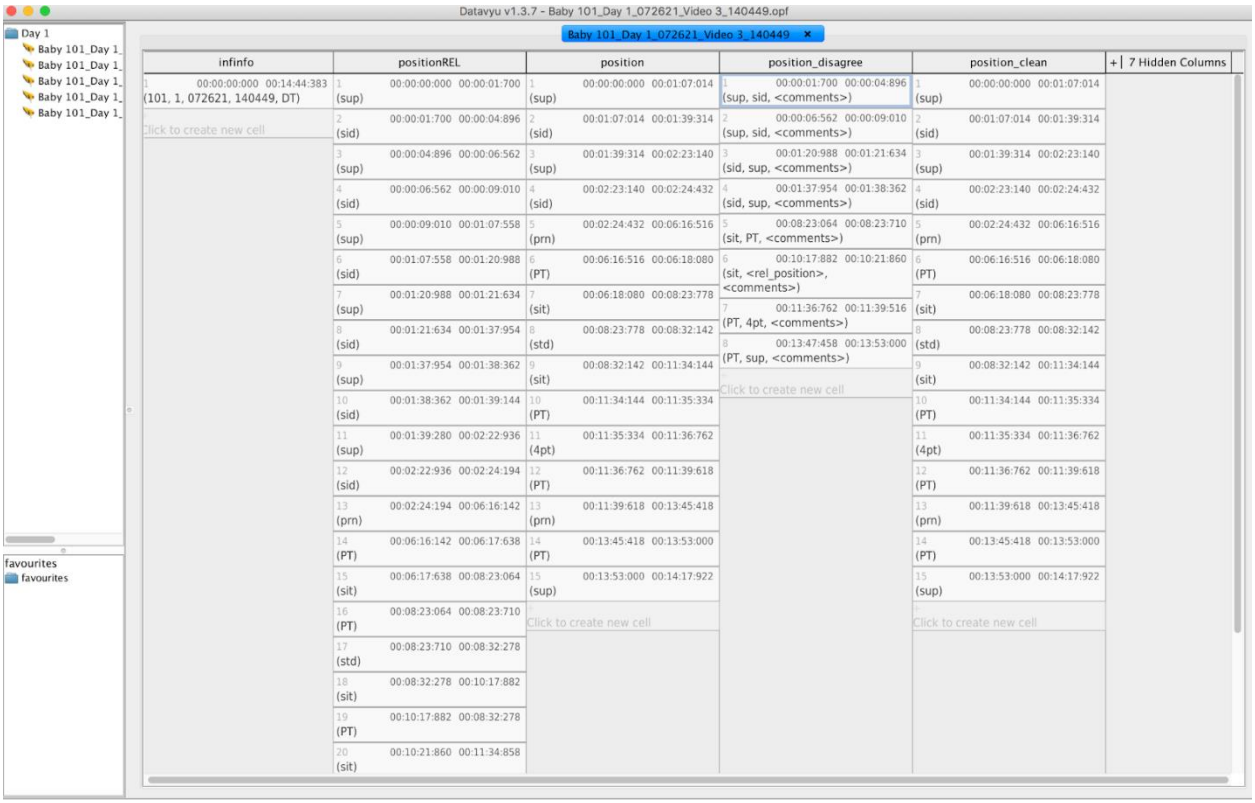
RUNNING SCRIPTS FOR RELIABILITY CODING

Datavyu scripts are .rb files that help automate the calculation of desired variables. A reliability script automatically identifies the percent agreement between the original coder and the reliability coder. After you finish reliability coding you will run a script to identify the agreement and document it.

1. Before running the script ensure that you have completed marking the durations (onset and offset for each position)
2. Ensure your columns are named as recommended because SCRIPTS ARE SUPER-SENSITIVE
3. Click Script in Datavyu---Run Script--Go to the location of the script i.e., [redacted]
4. The output should look like this:



5. You will document the raw agreement % (example 97.29) in the "Reliability %" column on the coding spreadsheet.
6. If you get an error on the script--first make sure you have labeled the columns right and try again. If error still persists--Contact PI
7. If your % agreement is <95% look closely at the "position_disagree" column to identify where you went wrong. This column shows the codes that do not match between the coders. For best results, look at the column in temporal view (Command+T or Ctrl+T)


Datavyu v1.3.7 - Baby 101_Day 1_072621_Video 3_140449.opf
Day 1
Baby 101_Day 1_
Baby 101_Day 1_
Baby 101_Day 1_
Baby 101_Day 1_
Baby 101_Day 1_
favourites
favourites
Baby 101_Day 1_072621_Video 3_140449
infinfo
positionREL
position
position_disagree
position_clean
+ | 7 Hidden Columns
1 00:00:00:000 00:14:44:383 (101, 1, 072621, 140449, DT)
Click to create new cell
1 00:00:00:000 00:00:01:700 (sup)
2 00:00:01:700 00:00:04:896 (sid)
3 00:00:04:896 00:00:06:562 (sup)
4 00:00:06:562 00:00:09:010 (sid)
5 00:00:09:010 00:01:07:558 (sup)
6 00:01:07:558 00:01:20:988 (sid)
7 00:01:20:988 00:01:21:634 (sup)
8 00:01:21:634 00:01:37:954 (sid)
9 00:01:37:954 00:01:38:362 (sup)
10 00:01:38:362 00:01:39:144 (sid)
11 00:01:39:280 00:02:22:936 (sup)
12 00:02:22:936 00:02:24:194 (sid)
13 00:02:24:194 00:06:16:142 (prn)
14 00:06:16:142 00:06:17:638 (PT)
15 00:06:17:638 00:08:23:064 (sit)
16 00:08:23:064 00:08:23:710 (PT)
17 00:08:23:710 00:08:32:278 (std)
18 00:08:32:278 00:10:17:882 (sit)
19 00:10:17:882 00:08:32:278 (PT)
20 00:10:21:860 00:11:34:858 (sit)
1 00:00:00:000 00:01:07:014 (sup)
2 00:01:07:014 00:01:39:314 (sid)
3 00:01:39:314 00:02:23:140 (sup)
4 00:02:23:140 00:02:24:432 (sid)
5 00:02:24:432 00:06:16:516 (prn)
6 00:06:16:516 00:06:18:080 (PT)
7 00:06:18:080 00:08:23:778 (sit)
8 00:08:23:778 00:08:32:142 (std)
9 00:08:32:142 00:11:34:144 (sit)
10 00:11:34:144 00:11:35:334 (PT)
11 00:11:35:334 00:11:36:762 (4pt)
12 00:11:36:762 00:11:39:618 (PT)
13 00:11:39:618 00:13:45:418 (prn)
14 00:13:45:418 00:13:53:000 (PT)
15 00:13:53:000 00:14:17:922 (sup)
Click to create new cell
1 00:00:01:700 00:00:04:896 (sup, sid, <comments>)
2 00:00:06:562 00:00:09:010 (sup, sid, <comments>)
3 00:01:20:988 00:01:21:634 (sid, sup, <comments>)
4 00:01:37:954 00:01:38:362 (sid, sup, <comments>)
5 00:08:23:064 00:08:23:710 (sit, PT, <comments>)
6 00:10:17:882 00:10:21:860 (sit, <rel_position>, <comments>)
7 00:11:36:762 00:11:39:516 (PT, 4pt, <comments>)
8 00:13:47:458 00:13:53:000 (PT, sup, <comments>)
Click to create new cell
1 00:00:00:000 00:01:07:014 (sup)
2 00:01:07:014 00:01:39:314 (sid)
3 00:01:39:314 00:02:23:140 (sup)
4 00:02:23:140 00:02:24:432 (sid)
5 00:02:24:432 00:06:16:516 (prn)
6 00:06:16:516 00:06:18:080 (PT)
7 00:06:18:080 00:08:23:778 (sit)
8 00:08:23:778 00:08:32:142 (std)
9 00:08:32:142 00:11:34:144 (sit)
10 00:11:34:144 00:11:35:334 (PT)
11 00:11:35:334 00:11:36:762 (4pt)
12 00:11:36:762 00:11:39:618 (PT)
13 00:11:39:618 00:13:45:418 (prn)
14 00:13:45:418 00:13:53:000 (PT)
15 00:13:53:000 00:14:17:922 (sup)
Click to create new cell

Appendix D: Customized MATLAB script for calculating position durations for the GENEActiv sensor

```
% filename = "E:\MATLAB\BabyID_Day#.mat";
% load(filename);

%% Define variables at the start- example of Infant 124's Day 3 data
VarX=B124_3_x;
VarY=B124_3_y;
VarZ=B124_3_z;
VarTime=B124_3_Timestamp;

%% Calculate 360 angle
ts_angle = (sign(VarX).*acos(-VarZ./sqrt(VarX.^2+VarZ)).*180./pi()+180);

%% Calculate updownangle
ud_angle = (asin(VarY./sqrt(VarX.^2+VarY.^2+VarZ.^2)).*180./3.14);

%% Calculate bodyrotation
threshold=140;
position_class = NaN(size(ts_angle)); %zeros(size(ts_angle));
x=length(ts_angle);
for a=1:x
  if (threshold < ts_angle(a)) && ((threshold+180) > ts_angle(a))
     position_class(a) = 1; %supine-recline class
  else
     position_class(a) = 2; %prone-sit class
  end
end

%% Calculate overall position

final_position = NaN(size(position_class));
y=length(position_class);
for d=1:y %prone-sit class
  if (position_class(d) == 2) && (ud_angle(d) > 0) && (isnan(final_position(d)))
     final_position(d) = 7; %prone
  elseif (position_class(d) == 2) && (ud_angle(d) > -23) && (isnan(final_position(d)))
     final_position(d) = 8; %prone_supported
  elseif (position_class(d) == 2) && (ud_angle(d) > -63) && (isnan(final_position(d)))
     final_position(d) = 5; %upright
  elseif (position_class(d) == 2) && (isnan(final_position(d)))
     final_position(d)= 6;%sitting
  end
end
```

```
for b=1:y %supine-recline class
   if (position_class(b) == 1) && (ud_angle(b) > 15) && (isnan(final_position(b)))
         final_position(b) = 0; %upsidedown
   elseif (position_class(b) == 1) && (ud_angle(b) < -36) && (isnan(final_position(b)))
      final_position(b) = 1; %reclined
   elseif (position_class(b) == 1) && (ts_angle(b) < (threshold + 69))&& (isnan(final_position(b)))
      final_position(b) = 2; %left-side
   elseif (position_class(b) == 1) && (ts_angle(b) > (threshold + 101)) && (isnan(final_position(b)))
      final_position(b) = 3; %right-side
   elseif (position_class(b) == 1) && isnan(final_position(b))
      final_position(b) = 4; %supine
   end
end

clear opts filename
clear opts threshold
clear opts a
clear opts b
clear opts x
clear opts y
clear opts d

%% Input date and video start time
t1=datetime(2021,12,25,19,36,43,033,'Format','yyyy-MM-dd HH:mm:ss:SSS')
t2= t1 + seconds(0) % GA start timestamp
t3= t1 + seconds(0) % sensor on baby 1 timestamp
t4= t1 + seconds(1285) % sensor off baby 1 timestamp
% t5= t1 + seconds(203) %sensor on baby 2 timestamp
% t6= t1 + seconds(429) %sensor off baby 2 timestamp
% t8= t1 + seconds(46) %Sync start on timestamp
% t9= t1 + seconds(51) %Sync start off timestamp
% t10= t1 + seconds(1405) %Sync end on timestamp
% t11= t1 + seconds(1411) %Sync end off timestamp
%can add additional timestamp calculations here

%% Create a position table
TT=timetable(VarTime, final_position);
t = datetime(t3, 'Format', 'yyyy-MM-dd HH:mm:ss:SSS');
p = datetime(t4, 'Format', 'yyyy-MM-dd HH:mm:ss:SSS');
S=timerange(t,p,'closed');
TT2 = TT(S,:);
a=timetable2table(TT2);
[C,ia,ic] = unique(a.final_position);
a_counts = accumarray(ic,1);
value_counts = [C, a_counts] %7 and 8 are considered "prone"
non_prone_time=(sum(value_counts(1:7,2)))/30 %check here before running! standard format is 1:7
```

```
prone_time=(sum(value_counts(8:9,2)))/30 %check here before running! standard format is 8:9
non_prone_time_int=seconds(non_prone_time)
prone_time_int=seconds(prone_time)

%% For use when there are two sensor on/off baby timestamps (when parent removes sensor
midway)
%
% TT3=timetable(B113_1_Timestamp, final_position);
% g = datetime(t5, 'Format', 'yyyy-MM-dd HH:mm:ss:SSS');
% w = datetime(t6, 'Format', 'yyyy-MM-dd HH:mm:ss:SSS');
% S=timerange(g,w,'closed');
% TT4 = TT3(S,:);
% a=timetable2table(TT4);
% [C,ia,ic] = unique(a.final_position);
% a_counts2 = accumarray(ic,1);
% value_counts2 = [C, a_counts2] %7 and 8 are considered "prone"
% non_prone_time2=(sum(value_counts2(1:3,2)))/30
% prone_time2=(sum(value_counts2(4:5,2)))/30
% non_prone_time_int2=seconds(non_prone_time2)
% prone_time_int2=seconds(prone_time2)
%
% finalprone=prone_time_int+prone_time_int2
% finalnonprone=non_prone_time_int+non_prone_time_int2

clear opts a
clear opts a_counts
clear opts C
clear opts ia
clear opts ic
clear opts p
clear opts S
clear opts t
%clear opts TT
%clear opts t1
%clear opts TT2
clear opts value_counts
clear opts w
clear opts g
```

Appendix E: Customized MATLAB script for calculating position durations for the MonBaby sensor

```
%% overall position - reduces the data to one row per second
final_position_MB = NaN(size(Difference));
y=length(Difference);
for z=1:y
   if (Position(z) == 'non-prone') & (Difference(z)~=0) & (isnan(final_position_MB(z)))
      final_position_MB(z) = 1; %non-prone
   elseif (Position(z) == 'prone') & (Difference(z)~=0) & (isnan(final_position_MB(z)))
      final_position_MB(z) = 2; %prone
   else
      final_position_MB(z) = 0; %multiple second calculations
   end
end

%% Input the session start and end time, input day of data collection

t1= datetime(2022,03,04,17,48,00,'Format','yyyy-MM-dd HH:mm:ss')
t2= datetime(2022,03,04,18,08,54,'Format','yyyy-MM-dd HH:mm:ss')
% t3= datetime(2022,03,05,10,50,48,'Format','yyyy-MM-dd HH:mm:ss')
% t4= datetime(2022,03,05,11,14,46,'Format','yyyy-MM-dd HH:mm:ss')

%% creates a position table

TT1=timetable(ExcelTimes1, final_position_MB, Difference);
M_1 = datetime(t1, 'Format','MM-dd-yy HH:mm:ss');
B_1 = datetime(t2, 'Format', 'MM-dd-yy HH:mm:ss');
S=timerange(M_1,B_1,'closed');
TT2 = TT1(S,:);
a_1=timetable2table(TT2);

[C,ia,ic] = unique(a_1.final_position_MB);
a_counts_1 = accumarray(ic,1);
value_counts_1 = [C, a_counts_1]
irrelevant_1=(sum(value_counts_1(1:1,2)))
non_prone_time_1=(sum(value_counts_1(2:2,2)))
prone_time_1=(sum(value_counts_1(3:3,2)))

non_prone_time_in_minutes_1 = non_prone_time_1/60
prone_time_in_minutes_1 = prone_time_1/60

%% if there is a second set of timestamps (sensor removal midway) use the following

% TT3=timetable(ExcelTime1, final_position_MB);
% M_2 = datetime(t3, 'Format','MM-dd-yy HH:mm:ss');
% B_2 = datetime(t4, 'Format', 'MM-dd-yy HH:mm:ss');
```

```
% S=timerange(M_2,B_2,'closed');
% TT4 = TT3(S,:);
% a_2=timetable2table(TT4);
% %
% [C,ia,ic] = unique(a_2.final_position_MB);
% a_counts_2 = accumarray(ic,1);
% value_counts_2 = [C, a_counts_2]
% irrelevant_2=(sum(value_counts_2(1:1,2)))
% non_prone_time_2=(sum(value_counts_2(2:2,2)))
% prone_time_2=(sum(value_counts_2(3:3,2)))
% %
% non_prone_time_in_minutes_2 = non_prone_time_2/60
% prone_time_in_minutes_2 = prone_time_2/60
% %
% non_prone_time_total = non_prone_time_in_minutes_1 + non_prone_time_in_minutes_2
% prone_time_total = prone_time_in_minutes_1 + prone_time_in_minutes_2

% clear opts a_1
% clear opts a_counts_1
% clear opts B_1
% clear opts C
% clear opts final_position_MB
% clear opts ia
% clear opts ic
% clear opts irrelevant_1
% clear opts M_1
% clear opts non_prone_time_1
% clear opts non_prone_time_in_minutes_1
% clear opts prone_time_in_minutes_1
% clear opts S
% clear opts TT1
% clear opts TT2
% clear opts t1
% clear opts t2
% clear opts t3
% clear opts y
% clear opts z
% clear opts prone_time_1
% clear opts value_counts_1
```

Appendix F: Tummy time sensor feasibility questionnaire (neutral and negative responses, N=31)

	Neutral		Negative	
	GeneActiv	**MonBaby**	**GeneActiv**	**MonBaby**
Ease of attachment and detachment	2 (6.5%)	2 (6.5%)	0 (0%)	2 (6.5%)
Ease of activation and deactivation	0 (0%)	2 (6.5%)	2 (6.5%)	2 (6.5%)
Ease of retention	1 (3.2%)	0 (0%)	0 (0%)	2 (6.5%)
Comfort	7 (22.6%)	5 (16.1%)	2 (6.5%)	2 (6.5%)
Aesthetics	14 (45.2%)	10 (32.3%)	7 (22.6%)	1 (3.2%)
Usefulness during everyday play	9 (29%)	6 (19.4%)	6 (19.4%)	4 (12.9%)

Appendix G: Tummy time recall survey

Parent Report_Day 3

This form is designed to collect information about your child's positioning at home. In this form, 'You' refers to the caregiver of the child.

1) Participant ID

_____

2) Today's date

_____

3) Day of Data Collection

- ◯ 1st Day
- ◯ 2nd Day
- ◯ 3rd Day

HOW MANY MINUTES DID YOUR CHILD SPEND IN THE FOLLOWING POSITIONS WHILE BEING RECORDED ON THE CAMERA IN YOUR HOUSE (TIME STARTS AFTER SENSORS ARE ATTACHED)? SEE PICTURES FOR REFERENCE

On their Back

4) Add Minutes your child spent on their back here

_____

(Type 999 if you do not remember)

On their tummy

5) Add minutes your child spent on their tummy here

_____
(Type 999 if you do not remember)

On their side

6) Add minutes your child spent on their side here

_____
(Type 999 if you do not remember)

Sitting on Lap or Floor

7) Add Minutes your child spent sitting on Floor or Lap here

_____
(Type 999 if you do not remember)

Standing with support

8) Add Minutes your child spent standing with support here

_____
(Type 999 if you do not remember)

Being held or carried

9) Add Minutes your child spent being carried or held here

_____
(Type 999 if you do not remember)

In a seating device (can include a high chair, stroller, car seat, reclined seat, or bouncer seat, bumbo-style seat, or a regular chair). It does not include sitting on lap or floor (refer to the previous question for that).

10) Add Minutes your child spent in seating device here

_____
(Type 999 if you do not remember)

TUMMY TIME PERFORMED THROUGHOUT THE DAY

11) How many minutes of tummy time did your baby perform throughout the day. This time is not restricted to the camera recording or sensors.
Include times on tummy during a diaper change, bathing, or any active activity. Do not include times on tummy during sleep.

_____

3-DAY TUMMY TIME MINUTES RECALL

12) How many hours of total tummy time did your baby perform in the past 3 days? Include times on tummy during a diaper change, bathing, or any active activity. Do not include times on tummy during sleep.

_____
(This time is not restricted to the camera recording. Include tummy time throughout the day for past 3 days.)

13) How many hours of total tummy time did your baby perform in the past 3 days while being recorded on the camera in your house?

_____
(This question only refers to tummy time performed while being recorded. Do not include any 'not on camera' tummy time minutes here.)

Appendix H: Individual-level data for preterm infants (n=12)

ID	Tummy time recall (minutes/day)		
	Direct Observation	Parent recall	GENEActiv sensor
1	11.17	15	14.07
2	13.04	10	14.7
3	4.2	Unable to recall	1.99
4	7.06	15	7.44
5	52.63	80	47.3
6	55.86	80	50.6
7	8.99	15	8.91
8	4.63	3.3	6.77
9	2.72	20	2.3
10	2.7	15	1.7
11	5.64	50	5.13
12	19.76	120	18.3
13	12.9	Forgot to complete	13.6

Appendix I: IRB approved study consent form

STUDY TITLE: Tracking tummy time development in infants using wearable sensors during the COVID19 pandemic

VCU INVESTIGATOR: Virginia W. Chu, PhD, OTR/L

Assistant Professor, Department of Occupational Therapy, Virginia Commonwealth University [redacted]

NOTE: In this consent form, "you" always refers to the research participant. If you are a parent or legal guardian, then "you" refers to the activities you will perform with the child study participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may read an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to monitor the development and time of children's tummy time play in home environment using wearable sensors. Wearable sensors are smart electronic devices such as the Fitbit, or an apple watch that are worn directly on the child's body or over their clothing. This study will provide us valuable information on if sensors are accurate in measuring a child's tummy time play in the home environment. The knowledge gained from this study will help parents monitor their child's play position and time at home. Researchers will be able to use the tummy time play information to develop remote monitoring devices for measuring child development over long periods of time. Your child is being asked to participate in this study because your child is 3-6 months old and tolerates playing on his/her tummy for at

least a few minutes.

What will happen if I participate?

If you decide your child can participate in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to your child. If you consent, you will be asked to do the following things:

1. The introductory session for this study will be conducted over 'Zoom' video platform and requires only 90 minutes of your time. The researcher will drop-off a small, well sanitized 'study package' containing sensors, a camera, and instructions at your doorstep. For families who stay more than 40 miles away, the study team can provide an option to receive the materials mailed.

2. *Steps for participants who are eligible for the mailing option* (SKIP TO STEP 3 if you are receiving a drop-off). If you select the mailing option, you will receive a study package delivered to your doorstep by the UPS. This package will contain the study materials and a pre-printed and pre-paid return label. You will also receive an "Acknowledgment of equipment return" form in your email. You will be required to consent and sign this form. The purpose of the form is to ensure the materials are safely delivered to you and returned back to us. At the end of this study (Day 3), you will be required to pack the study materials in the box and attach the return label to it. We will arrange for the UPS to collect the package from your house.

3. On Day 1, you will join a 90-minute zoom session with your child which will be recorded for analysis purpose. We will start the session by asking you to fill two forms online containing some demographic and well-being questions about you and your child. These forms will be sent to you through a private and secure link. We will then teach you how to calibrate and attach the two sensors to your child's clothing. Sensor #1 is like a watch and will be attached to your child's hip using a soft strap. Sensor #2 is a small button that will be snapped to your child's onesie over the chest. Sensor #2 works on Bluetooth and requires you to download a free mobile application on your phone for the time of data collection. There will written instructions on how to download and install this app in your study package. We will also explain the use of the video cameras and placement.

4. We will then perform a quick motor assessment of your child as they are engaged in free play. This assessment is just to document the starting point of play for your child and will take 10-15 minutes. At any time, if your child gets fussy, you are free to pick them up and soothe them. You are also allowed to end the data collection at any time point.

5. You can ask questions related to the data collection process at the end of the zoom session. You will be asked to retain both the sensors on your child during their active play time for the

rest of that day and during active play time for the 2 consecutive days after that. The Day 1 introductory session can also be completed at your home by our study team if you prefer that option. We will also provide troubleshooting assistance regarding the sensors or camera over zoom on Day 2 and 3 if preferred.

6. The video camera will be placed in the room where your child spends most of their play time, although this is not mandatory. You can choose the space you are comfortable with. The camera will be recording your child's play while they are wearing the sensors. This camera has a local storage, and the researcher will not have any direct access to the events occurring in your house. You can remove the sensors during a clothing change, bath time, travel time, and sleep time. You can stop the recording or cover the camera if you want to perform a diaper change or feed your baby. You can also move the camera to a new location if you are moving your child and are comfortable with being recorded in the new space. We will ask you to say "I am stopping/pausing the video" if and when you switch off the camera on your own. We do not need a reason for the switch off. This procedure is only done to ensure that you have voluntarily stopped the recording and it is not due to potential recorder malfunction. The goal will be to get at least 6-7 hours of your infant's play time recorded on the camera while they wear sensors each day, but this duration is not compulsory.

7. At the end of each day, you will receive another secure link for a survey asking you to report the total time your child spent playing in different play positions during the recording and on their tummy throughout the day. You will receive one last survey on Day 3 to get your opinion and suggestions of the use of sensors. This survey will also be sent using a secure link. You will also be allowed to review the day's recorded footage using an SD card reader that will be provided in the package. This SD reader has an USB port, and can be used with an PC, Mac, Laptop, or some TVs too. If you are uncomfortable if any of the footage recorded, you can delete it after contacting the researcher over phone or a video call. Contacting the researcher is voluntary and only needed if you need the researcher's help in either using the SD card reader or deleting the footage. The researcher does not need to know which footage was deleted and for what reason it was deleted. If you do not have any of the equipment for the SD card reader at home, the researcher would be willing to visit your home with their laptop. You can review and delete the footage using the researcher's laptop and ensure that it is completely deleted from the laptop as well. You can do this at the end of each day or at the end of the total 3 days. We will collect the sensors one day after the study ends through a pick-up. Families who were mailed the materials will be required to mail it back to us using the return shipping label provided.

Your participation in this study will need 3 days. Approximately 35 children along with their parents/caregivers will participate in this study.

What are the risks and benefits of participating?

There are risks and benefits of participating in research studies. We want you to know about a few minimal risks right now.

Risks and Discomforts	Benefits to You and Others
1. Children may become tired or a little fussy during or after the study visit. 2. Since we will deliver the equipment at home, there is a potential risk for equipment contamination due to external delivery. We do not anticipate this happening due to our stringent sanitization procedure, but it is a possibility. We will allow you to re-sanitize the sensors if needed. 3. There is a slight possibility that the position of the sensor placement could cause the child to be uncomfortable or irritated in certain positions. For instance, the sensor #1 is attached to the side of the hip. This sensor position could be uncomfortable for the child if they are in side-lying position. We do not anticipate this happen often as these sensors have been previously tested in young infants. 4. There is also a potential risk of breach in confidentiality as we will be video recording the assessment sessions and your child's face will be on the videos. The videos will not have your or your child's name, only an identification number. The only place where your or your child's name will be linked to the identification number is in the VCU lab computer which is password protected. The presence of a video camera at your home also has the risk of recording sensitive family situations, non-consenting members, or any activities (if present) that are against the law. For families opting for the mail back option, we are using mailing services that ensure tracking, require your signature on delivery, and complete an overnight	This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. However, the time spent by your child playing on their tummy during the assessment period is beneficial for their development. The information from your participation in this research study will help us find out if sensors can be used to monitor infant development from home settings. This will support the development of safe child development assessment procedures during times like the COVID-19.

shipping. This will ensure that the recorded data that some families may mail us is safe. More details on protecting privacy is described in the "HOW WILL INFORMATION ABOUT ME BE PROTECTED?" below.	

WHAT ARE THE COSTS?

There are no costs for participating in this study other than the time you will spend for the assessment visit.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will receive a $100 compensation at the end of 3 days of this study to thank you for your participation. This compensation will be divided as follows: $25/ day for day 1 and day 2 and $50 for day 3 (Total $100). No compensation will be provided for days when data collection is not completed. For families who stay farther and have received the study materials through mail, compensation will be provided through a check. For this purpose, you will be required to complete a payment form that will be securely sent to you through DocuSign at the end of the study. Once you complete the form, we will immediately send the compensation check through a certified mail via UPS.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Information collected prior to your withdrawal will be retained, unless you request in writing that your information be destroyed. Tell the study staff if you are thinking about stopping or decide to stop. Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- you are found to not be eligible for the study
- you or your child have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

Potentially identifiable information about your child will consist of demographic forms and data collected during assessments. Data is being collected only for research purposes.
Your child's data will be identified by ID numbers, not names, and stored separately in a locked researched computer. All personal identifying information will be kept in password protected

files for 5 years after the study's last publication data and will be destroyed at that time. De-identified (all personal identification information removed) research data will be kept indefinitely.

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring, and overseeing this study:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.
In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information/samples could be used for other research studies by this study team or another researcher without asking you for additional consent.

You will be allowed to review each day's video recording at the end of the day. If you are uncomfortable with any event/situation that was recorded, you will be allowed to delete it after a quick consultation with the researcher. Consulting the researcher is voluntary and only needed if you need the researcher's help in either using the SD card reader or deleting the footage. The researcher does not need to know which footage was deleted and for what reason it was deleted. Video recordings will be stored electronically, and de-identified at the time of collection, labeled with only the numeric code assigned to each participant at the time of recruitment. The video recordings will be stored in a password-protected computer in a locked office.

Please select one:
☐ I consent to educational use of videos collected during this research study. Videos (labeled with only numeric code assigned to each participant) will be stored indefinitely.
☐ I do not consent to educational use of videos collected during this research study. Video recordings will be deleted 5 years after the last publication.

We will not share the video recording information with anyone. But, if after your reviewing, we still find video data that has illegal activities or incidences where your child is being hurt, the law says that we have to let people in authority know so they can protect your child.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. If this certificate is obtained, it will offer the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers may share information about you or your participation in the research project without your consent if: incidences of child abuse or neglect are identified, or if there is evidence for engagement in illegal activities.

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Virginia Chu, Ph.D., OTR/L
Principal Investigator
Assistant Professor

Department of Occupational Therapy
900 E. Leigh Street

Box 980233

Richmond, Virginia 23298
vchu@vcu.edu

[redacted]

and/or

Ketaki Inamdar, PT

PhD Candidate, Rehabilitation and Movement Science Program

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns, or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human-research/

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF PARENT/LEGAL GUARDIAN PERMISSION

I have been provided with an opportunity to read this permission form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this permission form, I have not waived any of the legal rights or benefits to which I and/or my child otherwise would be entitled. My signature indicates that I freely consent to participate and/or give permission for my child to participate in this research study. I will receive a copy of the permission form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Signature Block for Enrolling Child Participants - Parent/Guardian Permission	
_____ Name of Child/Youth Participant	
_____ Name of First Parent/Legal Guardian (Printed)	
_____ **Required** First Parent/Legal Guardian Signature	_____ Date
_____ **Optional** Second Parent /Legal Guardian's Signature	_____ Date
_____ Name of Person Conducting Parental Permission Discussion (Printed)	
_____ Signature of Person Conducting Parental Permission Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Vita

Ketaki Inamdar was born on July 3rd, 1991, in Karnataka, India. In Spring 2014, she received her Bachelors in Physical Therapy from KLE University, Karnataka, India. Ms. Inamdar then received her Masters in Physical Therapy, with a specialization in Pediatric Neurosciences, from Manipal University, Karnataka, India in Spring 2016. After graduating, Ms. Inamdar worked as a clinical therapist in a Neuro-Pediatric inpatient rehabilitation setup at the Centre for Advanced Neurological Research, Karnataka, India from Fall 2016 to Spring 2018. She joined the PhD in Rehabilitation and Movement Science program at Virginia Commonwealth University in Fall 2018 and received doctoral candidacy in Spring 2021. She cleared the PT License board exam and became a licensed physical therapist in the United States in October 2022. Ms. Inamdar successfully defended her dissertation research in November, 2022.