Journal of Neonatal Nursing xxx (2017) 1–5

Contents lists available at ScienceDirect

Journal of Neonatal Nursing

journal homepage: www.elsevier.com/jneo

Original Article

Preterm neurodevelopmental outcomes following orosensory entrainment intervention

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ARTICLE INFO

Article history:
Received 31 August 2017
Accepted 8 November 2017
Available online xxx

Keywords:
Preterm
Orosensory
Entrainment
Cognitive
Language
Motor
Outcomes
Intervention

ABSTRACT

Previous research indicates that the NTrainer, a pressurized pacifier programmed to produce pulsed pneumotactile stimulation during gavage feeds, has been found to facilitate non-nutritive suck development and shorten the length of hospital stay when used in the Neonatal Intensive Care Unit (NICU). Four groups of children, including infants of diabetic mothers (IDM), healthy controls (HI), and those with respiratory distress syndrome (RDS), or chronic lung disease (CLD), were randomly assigned to an NTrainer therapy or sham 'control' condition when in the NICU. At 30 months of age, 113/223 study participants were assessed using standardized language, motor, and cognitive assessments. No significant group differences were evident between the NTrainer and sham groups in language, motor, or cognitive functioning. The NTrainer did not improve nor adversely impact language, cognition, or motor outcomes.

1. Introduction

The advent of new brain science technology has led to an increased understanding as well as discovery of new interventions for children born preterm. Children born preterm display differences in their brain development compared to children born full-term (Ortinau and Neil, 2015) and some differences predict later neurodevelopmental delays (Anderson et al., 2015). Approximately 10% of infants are born preterm each year (National Center for Health Statistics, 2016). Being born early places them at risk for a number of negative neurodevelopmental outcomes (Aylward, 2014). Areas impacted negatively include feeding, language, motor, and cognition skills (Adams-Chapman et al., 2013). With respect to feeding, children born preterm have been found to have impaired oromotor pattern generation (Barlow, 2009; Khaksar et al., 2012). Disorganized non-nutritive sucking as a result of poor oromotor pattern generation is present in infants born preterm (Poore et al., 2008; Stumm et al., 2008; Estep et al., 2008). In addition, meta-analyses of neurodevelopmental outcomes in children born preterm suggest an increased risk of language, motor, and cognitive delays and disorders (Aarnoudse-Moens et al., 2009; de Kieviet et al., 2009; Kerr-Wilson et al., 2011; Van Noort-Van Der Spek et al., 2012). Language abilities of children born preterm at the end of the second year of life have been found to be highly predictive of language abilities at a later time, suggesting the need for intervention services as early as possible (Putnick et al., 2017). Kalia and her colleagues (Kalia et al., 2009) report that about 70% of very preterm infants and about 30% of late preterm qualify for early intervention services in one or more developmental domains. They also found that few families pursue these early intervention services after hospital dismissal, suggesting a need for early and effective interventions that might be implemented while the infants and families are still in the NICU.

Supplemental sensory-based interventions across several modalities including auditory, olfactory, and vestibular input have been utilized within the preterm population (Filippa et al., 2013; Standley et al., 2010; Yildiz et al., 2011; Zimmerman and Barlow, 2008). These interventions seek to provide key sensory stimulation for the strengthening of neural pathways during a critical time of neurodevelopment. Children born preterm have been shown to respond positively to olfactory stimulation associated with their mother's breastmilk (Yildiz et al., 2011). Auditory stimulation in the

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https://doi.org/10.1016/j.jnn.2017.11.001
1355-1841/

form of lullabies (Standley et al., 2010) and maternal voice (Filippa et al., 2013; Zimmerman et al., 2013) also has yielded positive effects on short-term physiologic outcomes and growth of infants born preterm. Interventions providing vestibular stimulation including rocking (Tuck et al., 1982) and gliding (Zimmerman and Barlow, 2012) have similarly been shown to have therapeutic effects on preterm infants in the NICU.

Multimodal sensory interventions also have been investigated in this population. A multisensory intervention approach referred to as ATVV (auditory, tactile, visual, vestibular) (White-Traut et al., 2002) has been associated with improved feeding and alertness outcomes as well as decreased NICU stays. Another widely implemented multisensory intervention is Kangaroo Mother Care, which utilizes skin-to-skin contact between caregiver and child and provides the infant with tactile, kinesthetic, auditory, olfactory, and vestibular sensory inputs. The use of Kangaroo Mother Care in the NICU setting has been associated with increased physiologic regulation, improved oxygen saturation levels, and decreased length of NICU stay (Boundy et al., 2015).

One new sensory intervention that is gaining favor to promote ororhythmic patterning for non-nutritive suck development in the NICU is the NTrainer (Barlow et al., 2008, 2014a, 2014b). The NTrainer consists of a digitally-controlled pneumatic amplifier and a handpiece attached to a Philips AVENT Soothie® silicone pacifier. The NTrainer was developed to provide pulsed orocutaneous stimuli that is programmed to be similar in temporal and frequency dynamics to non-nutritive sucking (Barlow et al., 2008, 2014a; Barlow, 2009). The neurobiological hypothesis underlying the feasibility of the NTrainer for improving the feeding of infants born preterm is that orosensory entrainment of trigeminal primary afferents would facilitate the suck central pattern generator (sCPG) in the brainstem. These premotor internuncial circuits in the brainstem are important for the development of rhythmic motor patterns such as sucking, swallowing (swCPG), and respiration (rCPG), and may play a role in early vocalization and canonical speech (Grillner, 2003). It has been hypothesized that children born preterm may miss out on a critical sensory period of development for oromotor control or have compromised oromotor development as a result of sensorineural deprivation and decreased motor activity (Barlow and Estep, 2006). The use of orosensory entrainment therapy during gavage feeding in the NICU via the NTrainer increases trigeminal input that may modulate plasticity of pontomedullary and thalamocortical pathways during critical brain development (Barlow et al., 2014c). The NTrainer has been found to significantly improve the dynamics of non-nutritive sucking for children born preterm with respiratory distress syndrome (RDS) and chronic lung disease (CLD) and decrease the length of hospital stay (LOS) for children born preterm who displayed CLD (Barlow and Estep, 2006). In a multicenter trial involving 210 preterm infants (26–30.9 weeks of chronological age [GA]), Song et al., 2016 found that infants randomized to receive NTrainer therapy showed a significant reduction in the number of days to full oral feeds and a significant reduction in LOS when the orosensory entrainment intervention was introduced at approximately 31.8 weeks of post menstrual age (PMA). These results provide strong support for the notion of a critical sensory period for orocutaneous stimulation to accelerate suck and oral feeding skills in preterm. Similarly, Soos and Hamman (2015) reported anecdotal evidence of increased non-nutritive sucking pattern, improved sucking strength, increased readiness to feed, and overall increased neurodevelopmental functioning in children who received the NTrainer in their NICU. These results on the efficacy of the NTrainer for feeding are encouraging; however, it is unknown whether the use of the NTrainer positively or negatively impacts other neurodevelopmental outcomes, such as language, motor, or cognitive skills.

In this study, we compared the language, motor, and cognitive skills at a later point in development (i.e., 30 months of age) between children who received the NTrainer in the NICU and those skills of children who did not receive the NTrainer. Our specific research question was “Is there a difference in the language, motor, and cognitive abilities at 30 months of age between children born preterm who received the NTrainer in the NICU compared to children born preterm who did not receive the NTrainer?” We predicted that the children in the NTrainer condition might display greater language, cognition, and motor skills compared to those in the control condition if the NTrainer stimulations led to a benefit in the CPGs and/or related motor systems during a critical period of development. A negative impact of the NTrainer was not anticipated, but could not be ruled out because this type of intervention has not been previously utilized. A finding of negligible difference between the groups would indicate that the NTrainer neither assisted nor harmed language, motor, and/or cognitive outcomes.

2. Methods

2.1. Study design

This was a follow-up observational study of children born preterm who participated in a randomized controlled blind trial of the NTrainer while in the NICU. The NICUs at the Overland Park Regional Medical Center (Overland Park, KS), and Stormont-Vail Regional HealthCare (Topeka, KS) participated in this study. Both centers provided approval of the NTrainer research, which included written informed consent before the study began. The research protocol for the initial NTrainer intervention study was approved by the Institutional Review Board at the University of Kansas.

2.2. NTrainer protocol

While in the NICU, the infants were randomly assigned to either the NTrainer condition or a sham pacifier control. The protocol included stimulation with either the NTrainer or the sham pacifier three times per day during gavage feedings for 9 min over a period of two weeks (i.e., approximately 10 days) between 34 and 36 weeks of GA. The infants assigned to the sham condition received the same type of Soothie® pacifier that was on the NTrainer handpiece, however, they did not receive the pulsed orocutaneous stimuli. The infants assigned to the NTrainer condition received gavage feedings during the orocutaneous stimulation. The NTrainer and sham pacifiers were administered by a full-time neonatal nurse at each NICU site. Parents, care-providers administering the NTrainer in the NICU, and examiners of assessment (i.e., nursing care and medical staff) were blind as to the treatment assignment for any given study infant.

2.3. NICU participant characteristics

The children in the NTrainer NICU study were born between 23 and 36 weeks of GA ($M = 29.75$, $SD = 3.00$), with a weight between 410 and 3830 g ($M = 1402.54$, $SD = 629.65$). They were divided into four diagnostic categories by the neonatologist: Healthy preterm (HI), infants of diabetic mothers (IDM), infants with chronic lung disease (CLD), and infants with Respiratory Distress Syndrome (RDS). The children with RDS were diagnosed with RDS by x-ray and extended supplementary oxygen up to 36 weeks of GA; whereas, the children diagnosed with CLD had supplementary oxygen beyond 36 weeks of GA. The children in the HI and IDM groups had fewer than five days of supplemental oxygen. The children in the HI group also had no specific diagnosis and were medically stable. Children in the IDM group were born to mothers

Please cite this article in press as: Loeb, D.F., et al., Preterm neurodevelopmental outcomes following orosensory entrainment intervention, Journal of Neonatal Nursing (2017), https://doi.org/10.1016/j.jnn.2017.11.001