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Neuroprotective Core Measure 2: Partnering with Families - Effects of a Weighted Maternally-Scented Parental Simulation Device on Premature Infants in Neonatal Intensive Care☆

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ABSTRACT

We sought to explore the effects of neuroprotective care with use of weighted maternally-scented parental simulation device on 24–38 week gestation infants in a level III NICU. A sample of 45 infants was randomized into 1 of 4 groups. Infants in 2 of the groups were positioned with a weighted parental simulation device with and without maternal scent. Infants in a third group were placed in a soft nesting device with maternal scent, but without the weighted parental simulation device. Infants in the control group were given routine care without maternal scent or parental simulation device. Infants were observed and physiologic and behavioral data were recorded for a continuous 12-hour period of time. Infants positioned with a weighted maternally-scented parental simulation device demonstrated significantly more self-regulatory behaviors and were less likely to experience episodes of apnea ($HR = 9.828$, $p < 0.02$) and bradycardia ($HR = 12.294$, $p < 0.006$). Neuroprotective care using a weighted maternally-scented parental simulation device resulted in increased physiologic stability of premature and early term infants through the promotion of self-regulation seen by reduction of stressful behaviors, and decreased apnea, and bradycardia.

Infants born prematurely (<37 of 40 completed weeks of gestation) are a significant perinatal health concern, contributing to substantial economic, social, and medical costs across the globe. In the United States alone, the estimated costs are $26.2 billion with one in eight infants born prematurely each year.[1,2] Premature infants are at greater risk for cognitive, health, developmental, and behavioral disabilities than term infants (39–40 weeks completed gestation).[3] Although the majority of premature infants are free of major morbidities, major morbidities account for 17–29% of the impairments found in this population.[4] Major morbidities include impairments with vision, hearing, and cognition including cerebral palsy.

Most infants born LBW (<2500 grams) or very LBW (<1500 grams) exhibit minor morbidities (50–70%) that include motor delays, executive dysfunction (EDF), attention deficit disorder (ADD), attention deficit hyperactivity disorder (ADHD), language deficits, learning disabilities, auditory dyssynchrony, visual motor difficulties, and social emotional dysregulation.[5–8] These morbidities impact daily living and educational attainment and have been well established in the literature since early 2000.[6,9–13] Morbidities rates are also higher in early term infants (37–38weeks completed gestation) as compared to term infants.[14,15] Short-term outcomes of early term infants include increased NICU stays (>7 days), sepsis, hyperbilirubinemia, respiratory distress, and feeding difficulty.[14]

To minimize the risks of these morbidities, healthcare professionals caring for infants in the neonatal intensive care unit (NICU) require an understanding of neuroprotective care. Rapid brain growth occurs between 28 and 38 weeks gestation during the sensitive time of neural pathway formation and is susceptible to environmental influences.[11,16,17] These environmental influences may also alter gene expression or cellular phenotype in a process referred to as epigenetics.[18] Environmentally induced epigenetic changes are documented in the literature in animal models and can persist across the adult lifespan.[19,20] The early developmental experiences of premature infants may have epigenetic effects on their developing brain leading to phenotypical changes.[21]

According to the Synactive Model of Newborn Behavioral Organization and Development,[16] premature infants respond to stimuli in their environment with unique cues such as hiccups, or variations in alertness and tone, which may be categorized as stressful or self-regulating behaviors. The ability for premature infants to self-regulate is essential to their neurodevelopment. Providing care based on understanding family involvement and the infant's cues is an emerging field of study. Care aimed at neuroprotective care has been shown to positively affect neurobehavioral outcomes such as self-regulation and early brain development.[22–25] Neuroprotective care, protection of sleep, and support of evolving self-regulatory skills should be incorporated into the care of premature and early term infants to facilitate optimal brain development.[11] Furthermore,

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the evaluation and promotion of neuroprotective care are essential in minimizing the consequences of the altered and distorted brain development in the premature brain.[26] Clinical research which evaluates neuroprotective care is needed to better understand the impact of care within the environment of the NICU.

The primary practice model in most NICUs is a model that supports the physical separation of the mother and infant, which heightens the traumatic event sequelae. The infant is transported to the NICU while the mother recovers on another unit. Subsequently, it may be hours after delivery before the mother is able to visit her infant. This disruption of the parental–infant relationship has molecular, physiologic, and behavioral consequences for the infant and mother.[27] Maternal stress, grief, and depression are intensified by the preterm birth and traumatic separation impacting maternal interactions, confidence, and attachment.[28,29] Research supports minimizing the effects of this physical separation with the use of skin-to-skin contact and family-centered care.[30,31]

In the mother's absence, sensory stimulation such as the mother's voice and scent has been shown to have positive effects on premature infants. Infants in the NICU are exposed to many negative olfactory experiences. One study revealed that during their hospital stay, premature infants were exposed several thousand times on average to negative nosocomial odors (skin preps, alcohol pads, and adhesive remover).[32] Detection and discrimination of odors develop between 28 and 29 weeks gestation with evidence to support infant familiarization and preferences for odors such as their amniotic fluid, their mother's breast milk, and their mother's scent.[33,34] Research supports that infants respond to sensory stimulation with both positive and negative behaviors. Positive benefits from exposure to these preferred odors include self-regulation, pain reduction, and reduction in occurrences of apnea.[35–37] In a sample of 49 premature infants, researchers found that infants who received an intervention with a multimodal approach using sensori-tonico-motor touch with oils had increased weight gain, shorter hospital stays, and better neurological/psychomotor scores compared to the control group.[38] Healthcare professionals providing care in the NICU need to minimize noxious stimuli and promote care that incorporates positive sensory stimulation.

Evidence-based nursing interventions that support the fragile premature infant and mother are challenging in the current health care system. Interventions aimed at neuroprotective support and positive sensory modalities such as the mother's scent may improve the infant's stability. Interventions using scent and neuroprotective care have been explored in other studies, but no research has combined these methods with use of a parental simulation device. The purpose of this pilot study was to explore the effects of 24 to 38 week gestation infants in a level III NICU receiving neuroprotective care using a maternally-scented parental simulation device.

The intervention for this study included use of a weighted maternally-scented parental simulation device that mimics holding. Infants who received the intervention were compared with infants receiving nursing care without the simulation device. The weighted maternally-scented parental simulation device used in this study is called The Zaky®, a human hand mimetic and pediatric bolster support device with patent pending from Nurtured by Design, Incorporated (Fig. 3). The Zaky® is ergonomically designed to provide family-centered developmental care to infants by conserving the scent of the parent and simulating the shape, touch, weight (500 grams), and warmth of the parents' hands and forearms that stay with the infant when not being held in skin-to-skin contact.

Methods

In this pilot study, infants were randomly assigned to 1 of 4 groups: 1) standard care (control group); 2) standard care with a weighted unscented parental simulation device that mimics holding; 3) standard care with a weighted maternally-scented parental simulation device that mimics maternal holding, or 4) standard care with an unweighted nesting device with a maternally-scented insert placed inside. Infants were observed and physiological and behavioral data were collected every 2 hours for a period of 12 continuous hours. Mothers of infants 24–38 weeks gestation who met the inclusion criteria were recruited for the study from a 42-bed level III NICU, in a large hospital in the Southeastern United States.

All staff nurses for this unit were previously trained by the unit nurse educator and maintained competency in using the Premature Infant Pain Profile (PIPP) for assessing pain with premature infants.[39] The NICU nurses in the unit for this study provided cue-based nursing care with the support of a unit-based occupational therapist.[40]

Infant inclusion criteria included infants admitted to the level III NICU, gestational age of 24–38 weeks, with no history of drug

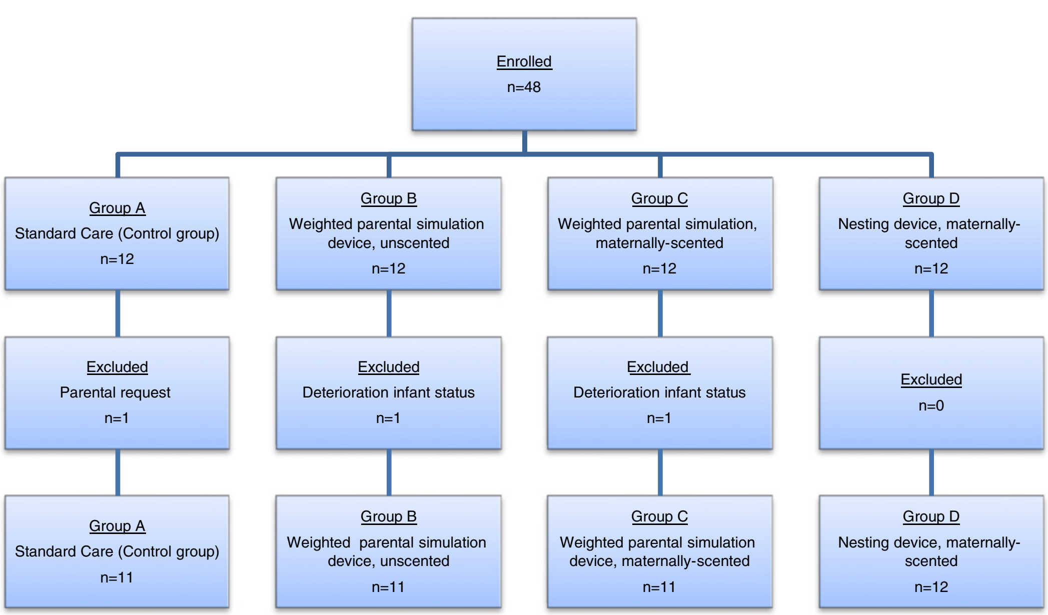

Fig. 1. Flow diagram of the number of infants enrolled, the number recruited to the control and intervention groups, the number excluded from each group, and the number analyzed in each group.

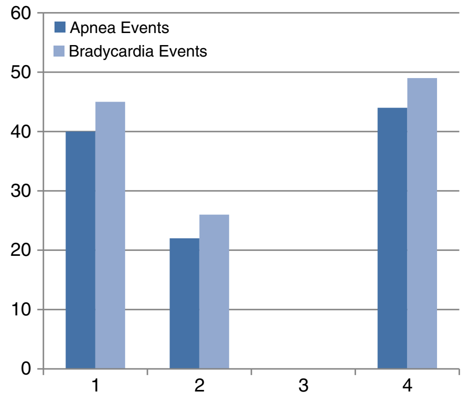

Fig. 2. Apnea and bradycardia events (N = 45).

withdrawal and not receiving end-of-life care, continuous narcotic administration, or humidity therapy. Infants receiving these therapies were not included due to potentially altered physiologic and behavioral status. The parents of infants who were admitted into the level III NICU were approached by a staff RN regarding participation in the research study. Data collection began May 2010 and ended in December 2010.

Participants

Forty-eight infants were enrolled in the study; data were completed for 45 infants (Fig. 1). Of the 48 infants recruited into the study, three infants were removed from the study. One infant was removed from the study due to parental request (control group) and two infants were removed from the study due to deterioration in the infants' status (one infant from the intervention group with maternally-scented parental simulation device and the other infant from the intervention group with unscented parental simulation device). A total of 45 infants with completed data were used.

Demographic data recorded included the date of birth, method of delivery, day of life, Apgar scores, gender, admitting diagnosis, gestational age at birth, adjusted gestational age, birth weight and current weight, co-morbidities, and medications. The demographic data for the infants for this study are provided in Table 1.

Estimate of Sample

A minimal sample size of 11 infants per group was required with each infant providing six observations for power of 0.87. With a total of 21 comparisons (alpha = 0.0024), the family comparison alpha rate was 0.05. Accepting an alpha of 0.0024 allowed for a Bonferroni correction.

Fig. 3. An example of application of Zaky® side-lying position.

Table 1
Demographic characteristics of neonates (N = 45).

Characteristics	n	Percentage
Race		
Caucasian	11	24.4%
African American	32	71.1%
Hispanic	2	4.4%
Gender		
Male	27	60%
Female	18	40%
Type of delivery		
Vaginal	22	48.8%
Cesarean section	23	51.1%
Delivery		
Singleton	37	82%
Multiple	8	18%
Acute phase illness		
Early term	3	7%
Preterm	42	93%
Respiratory distress	43	95%
Sepsis	3	6.6%
Other	2	4.4%
Comorbidities		
Patent ductus arteriosus	2	4.4%
Necrotizing enterocolitis	1	2.2%
Intraventricular hemorrhage	4	8.8%
Sepsis	4	8.8%

Treatment Groups

Infants were sequentially assigned to one of four groups. Folders with treatment assignments were randomized by number selection prior to the initiation of the study. Maternal scenting was provided through placement of the device/insert on the mother's bare chest or behind her neck for one hour to provide scent.

Group A (control) was provided with standard care. The care includes a quiet environment with minimal stimulation, uninterrupted periods of sleep, individual infant beds shielded from light, dimming and cycling of overhead lighting, positioning, containment, and boundaries with blankets. Standard care was defined as care provided with maintenance of alignment with the infant's extremities in a flexed position, close to body. No study intervention was provided.

Group B (intervention) was provided standard care, but for positioning two weighted unscented parental simulation devices that mimic holding were used. A pair (left and right hands) of the Zaky® was used per infant. This intervention provided a boundary with weight but without maternal scent.

Group C (intervention) was provided standard care, but for positioning two weighted maternally-scented parental simulation devices that mimic holding were used. A pair (left and right hands) of the Zaky® was used per infant. This intervention provided a boundary with weight and with maternal scent.

Group D (intervention) was provided standard care with positioning and developmental support maintained with a nesting device. The nesting device used in this study is a two inch padded bumper sewn onto a quilted fleece pad, with two straps for additional containment. The nesting device is handmade for the unit by volunteers. The insert used with the nesting device is a piece of nylon fleece. This intervention device was placed under the infants and was maternally-scented. This intervention provided containment and a boundary without weight but with maternal scent.

Measures

The data collection tool used in this study was designed for collection of demographic data, vital signs, pulse oximetry oxygenation saturation (SpO_2), fractional inspired oxygen (FiO_2), pain score (PIPP), physiological and behavior indicators of stress or self-regulation.

Cardiorespiratory Monitor

The cardio-respiratory monitors that were used in this study are HP M1165/66/67/75/76/77A Viridia Component Monitoring System by Philips. The HP system measures and displays multiple physiological parameters and waves and generates alarms and recordings. The limits were set to alarm for episodes of decreased respiratory rate and bradycardia. The respiratory rate alarm was set to alarm at breaths below 20 breaths per minute. Apnea was defined as a cessation of breathing for more than 20 seconds. Episodes of apnea were correlated with SpO_2 and heart rate as indicated. Bradycardia was defined as heart rate below 100 beats per minute. For this study, heart rate, respiratory rate, and SpO_2 data were recorded using the ECG and respiratory settings. The ECG accuracy was +1% and the sensitivity was ≥200 μV peak. The respiratory rate accuracy was +1 rpm at 60 rpm (Hewlett-Packard, 2009). Pulse oximetry alarms were set to alarm at less than 88%. For this study, SpO_2 readings were recorded for all infants.

Premature Infant Pain Profile (PIPP)

The PIPP is a 7-item, 4-point scale used for assessment of pain with premature infants with a reported Cronbach's alpha of 0.71.[39]

Physiological and Behavioral Indicators

Physiological and behavioral indicators were defined within the categories of organized (self-regulatory) and disorganized (stress) indicators and were based on the Synactive Model of Newborn Behavioral Organization and Development.[16]

Organized (Self-regulatory) Indicators

Organized physiologic indicators were cardiorespiratory stability, color, and feeding tolerance (gastrointestinal status). Cardiorespiratory stability was defined as stable heart and/or respirations rate as regular, slow respirations. Organized behavior indicators were smooth, synchronous movements, good tone, flexed extremities, well-defined sleep and wake states, exhibiting self-quieting behaviors, and attentive behaviors. Self-quieting behaviors were defined as hand to mouth, hand or foot clasping, finger folding or grasping, sucking, foot or leg bracing. Attentive behaviors were defined as alert gaze; ceases to suck or slows suck rate, and responds to auditory stimuli.[16]

Disorganized (Stress) Indicators

Disorganized physiologic indicators were cardiorespiratory instability-irregular respirations, apnea, bradycardia, blood pressure instability, sneezing, hiccoughs, mottling, duskiness, cyanosis-central or generalized, pallor or plethora, abdominal distention, spitting, vomiting, or gagging. Disorganized behavior indicators were tremors, jittery jerking movements, hypo- or hypertonia, inability to modulate sleep and wake states, and limited use of self-quieting behaviors.[16]

Procedure

Staff nurses who were a part of the research team attended a 30-minute on-line training about the research study and completed a check-off on the correct positioning using the infant positioning device. Ten of these staff nurses collected data for this study. Data collectors recorded physiologic indicators from the cardio-respiratory monitor. Episodes of apnea and bradycardia were also recorded. Data were recorded every 2 hours for 12 consecutive hours for each infant for a total of six observations per infant. Infant physiological and behavioral indicators were observed and recorded as "organized" or "disorganized" by staff nurses who had completed the training and the return demonstration. Infants exhibiting three or more of the defined physiological and behavior indicators were noted as being in either an organized or disorganized state.

Data Analyses

Physiological data were analyzed using a linear mixed-model repeated measures analysis of variance. A linear mixed model allows for both random effects and fixed effects. With this design, the experimental treatments are considered a fixed effect and subjects within treatments are random effects. There are several advantages of using a mixed model in analysis of repeated measures. One advantage is that if a subject is missing one observation, that missing observation has no effect on the other observations. A second advantage is that time does not have to be consistent. The third advantage is that a mixed model does not enforce strict requirements on the correlation between time measurements and allows for a model of the correlation of responses over time.[41] Apnea and bradycardia events were analyzed using the Kruskal–Wallis test and Conover–Inman all pairwise comparisons to determine a difference in the per infant apnea and bradycardia events. Logistic regression was used to compute the odds ratios for the occurrence of disorganized behaviors among the three experimental groups compared to the control group.

Results

Characteristics of the infants for this study are provided in Table 2. There were no statistically significant differences among groups with adjusted gestational age, Apgar scores, or day of life.

Physiological Indicators

The infants' SpO_2, diastolic blood pressure, systolic blood pressure, FiO_2, heart rate, respiratory rate, temperature and PIPP score were analyzed using a mixed-model repeated measures analysis of variance. This analysis failed to detect any statistically significant differences between the four treatment groups.

The results in Fig. 2 indicate there was twice the number of apnea and bradycardia events for infants in both group A (control) and group D (maternally scented nesting device) than was seen for infants in group B (weighted unscented parental simulation device). There were no observed apnea or bradycardia events for group C (weighted maternally-scented parental simulation device). There was a statistically significant difference among groups as compared to the control group for apnea ($HR = 9.828$, $p < 0.02$) and bradycardia ($HR = 12.294$, $p < 0.006$).

Disorganized (Stress) Indicators

These results are presented in Table 3. As there were no disorganized behavior responses for group B (weighted unscented parental simulation device) or group C (weighted maternally-scented parental simulation device) with respect to tolerating feedings, an estimate for those odds ratios could not be computed. For all variables, except self-regulatory feeding, the odds of seeing a disorganized response were greater for group A (Control) than for group C (weighted maternally-scented parental simulation device) ($p < .05$).

Group A (control) also had greater odds of exhibiting cardio-respiratory instability (OR 10.5, 95% C.I. 3.0, 37), self-regulatory body movements (OR 10.1, 95% C.I., 4.5, 0.7) and self-regulatory sleep/wake (OR 10.4, 95% C.I. 4.5, 23.8) than group B (weighted unscented parental simulation device). For self-regulatory body movements and self-regulatory sleep/wake, group A (control) had greater odds of exhibiting disorganized behavior than group D (maternally-scented nesting device) (OR 4.6, 95% C.I. 2.1, 9.8; OR 2.2, 95% C.I. 1.0, 5.1).

Discussion

The purpose of this pilot research study was to investigate the effects on premature and early term infants receiving neuroprotective care

Table 2
Group demographic characteristics of neonates (N = 45).

Characteristics	Group A (n = 11)	Group B (n = 11)	Group C (n = 11)	Group D (n = 12)
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)
Gestational age in weeks	30.5 (4.6)	30.1 (3.7)	31.0 (3.9)	28.1 (4.0)
Apgar score at 1 minute	5.5 (2.7)	5.9 (2.4)	5.7 (1.9)	4.8 (2.4)
Apgar score at 5 minutes	7.2 (2.3)	7.3 (2.0)	7.3 (1.6)	7.5 (1.3)
Day of life	18.9 (23.9)	15.1 (19.7)	6.7 (6.4)	17.3

Group A – standard care; group B – parental simulation device, unscented; group C – parental simulation, maternally-scented; group D – nesting device, maternally-scented.

using a weighted maternally-scented parental simulation device. The intervention of interest for this study provided containment, maternal scent, and weight which supports positive sensory stimulation for premature and early term infants. This multi-modal approach demonstrates that the provision of weight, containment, and maternal scent together results in positive effects including: 1) an increase in physiologic stability as seen by reduced episodes of apnea and bradycardia and 2) a reduction in infant stress behaviors, which is known to promote self-regulation and optimal brain development.

These findings are supported in other studies using positive sensory stimulation. However, no study has explored the combined effect of weight, scenting, and containment on premature and early term infants when the mother is not available to provide skin-to-skin holding. For this study, the infants positioned with the weighted maternally-scented parental simulation device exhibited the least amount of stressful behaviors and had no episodes of apnea and bradycardia for the observation period. Other studies had reported similar positive effects in infants from the familiarity of maternal scent. Maternal scent has been shown to reduce crying and pain in newborns and premature infants.[42–45] Maternal scent presented prior to and after heel stick with a sample of 50 preterm infants significantly reduced PIPP scores compared to the control group.[46]

The primary odor explored in other studies to reduce apnea has been vanillin.[35] Researchers found a significant difference between groups by day 5 after birth ($t = 8.32, p < 0.05$) for those infants receiving olfactory stimulation with vanillin.[37] For this study, maternal scenting alone was not a significant factor. However, scenting with the combined effect of the weighted parental simulation device significantly reduced the number of episodes of apnea and bradycardia. Research also supports the use of neuroprotective supportive care to reduce stressful behaviors in premature infants. A significant reduction in the number of stressful behaviors was found in premature infants with similar demographics as those in our study when they received developmentally supportive care (n = 114).[23] In contrast, another study reported no differences between the standard care group (n = 28) and the experimental group (n = 28) receiving neuroprotective supportive care. The different study outcomes could be explained by the differences in the measured variable. Temperament was measured at 4 months adjusted age and short-term effects were not measured in the study that found no differences between groups.[47] Self-regulation and physiological behaviors were also not explored.

As researchers continue to explore interventions to promote positive neurodevelopmental outcomes in an effort to reduce major and minor morbidities in premature and early term infants, more research with a multimodal approach is needed. Exploring weight, containment, and positive sensory stimulation with premature and early term infants provided positive results observed over a short time period for this study. More research is needed to determine if these positive effects can be sustained in the long term. Early neuroprotective care through using a weighted maternally-scented parental simulation device may facilitate secure maternal-infant attachment. Maternal-infant attachment promotes optimal infant brain development, and both are pivotal to survival with lasting effects on physical, cognitive, and emotional outcomes. Care practices that promote maternal infant attachment have the potential to impact brain development.

Limitations and Strengths

There were a number of limitations for this pilot study. First data collectors were not blinded to the treatment groups and inter-rater reliability was not reported. Staff nurses noted observed behaviors of infants based on self-regulatory indicators as either organized or disorganized. Although staff nurses completed training for observations and positioning with the assistance of an occupational therapist, variations may have occurred. Nurses who collected data may also have been biased based on their preferences for a particular positioning device.

Second, the sample was small and homogenous in regard to ethnicity and gender due to our NICU population. Homogeneity was controlled for regarding gestational age, day of life, and Apgar scores, but not in regard to gender or co-morbidities. Results may differ with a larger more diverse population controlling for comorbidities.

Lastly, observations occurred during various times for a twelve-hour consecutive period of time. Although the results are promising, the effects of the intervention may not be long lasting. Future studies should explore observations over longer periods of time. The strengths of the study were the statistical analysis and the novel intervention simulating

Table 3
Odds ratios comparing experimental groups to the standard care for organized and disorganized behaviors (N = 45).

Variable	Group B vs. group A (95% C.I.)	Group C vs. group A (95% C.I.)	Group D vs. group A (95% C.I.)
Cardio-respiratory	0.095 (0.027, 0.337)*	0.031 (.004, 0.236)*	0.482 (0.222, 1.293)
Color	0.803 (0.380, 1.701)	0.295 (0.120, 0.728)*	0.662 (0.312, 1.404)
Feeding	Cannot calculate	Cannot calculate	2.026 (0.558, 7.32)
Body movements	0.099 (0.044, 0.222)*	0.060 (0.025, 0.141)*	0.219 (0.102, 0.470)*
Sleep/wake	0.096 (0.042, 0.221)*	0.110 (0.048, 0.252)*	0.449 (0.197, 1.025)
Self-quieting	0.651 (0.327, 1.297)	0.301 (0.143, 0.632)*	1.177 (0.602, 2.301)
Attentive behaviors	0.565 (0.280, 1.142)	0.155 (0.072, 0.334)*	0.474 (0.238, 0.947)*

Group A – standard care; group B – parental simulation device, unscented; group C – parental simulation device, maternally-scented; group D – nesting, maternally-scented.
* $p < .05$.

maternal presence. The significance of the results and potential benefits for premature and early term infants support additional research.

Conclusions

The NICU environment and quality of care provided affect early brain development.[22,24,25] Research supports the benefits of neuroprotective care with long-term benefits reported in preterm infants at school age.[25] Healthcare providers need to be aware of physical and sensory environmental factors that impact outcomes of premature and early term infants such as brain development and self-regulation. While neuroprotective care has many benefits for premature infants, interventions that facilitate containment only may not provide the optimal support for these vulnerable infants. In this study, use of a weighted maternally-scented parental simulation device that mimicked holding had the most beneficial findings in relation to decreased stressful behaviors and number of episodes of apnea and bradycardia for the observed period of time. When a premature or early term infant is not being held by parents skin to skin in the NICU, healthcare professionals may use a weighted maternally-scented parental simulation device that mimics holding to support infant self-regulation and parental involvement.

Human Participant Protection

The study was approved by the Georgia College & State University and Medical Center of Central Georgia institutional review boards.

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