

Groundbreaking results for NICUs, babies, and families: The Zaky® helps with neurodevelopment and protection of premies

by Yamile Jackson | Sep 14, 2015 | *Nurturing Care, Premature Infant, Prematurity, Research Articles*

The Zaky® is a product by Nurtured by Design and it is the ergonomic device designed to provide nurturing developmental care to babies in the NICU since it was released in 2004 after 3 years of development. It is now used in any unit in the hospital with babies and toddlers (pediatric/oncology/post-partum/cardiology/etc.) and with healthy babies and children including those with working or traveling parents. Now it was proven to aid the premature infants in the study by significantly improving self-regulation and significantly decreasing apnea/bradycardia (Zero episodes for babies using maternally scented The Zaky®). It is our distinct honor to announce that the results of the independent randomized control trial about The Zaky® have been published in the [2015 September issue of Newborn and Infant Nursing Reviews – click here for the publication.](#)

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

It was funded in its entirety by Georgia College and performed at the Regional Medical Center of Central Georgia. We want to congratulate and thank the principal investigators and all the team that worked on this groundbreaking research:

- Kendra Russell, PhD, RN – Macon Graduate Center, Georgia College & State University
- Barbara Weaver, RN
- Robert L. Vogel, Ph.D., – HSU College of Public Health, Georgia Southern University

Conclusion: Neuroprotective supportive 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.

The Zaky® is an ergonomic device designed to support neonatal developmental care by providing parent scent and supportive touch when parental visitation is not possible. Researchers in Georgia compared four different types of NICU developmental care practices to determine the effectiveness of the Zaky as a maternal simulating intervention (the four research groups are illustrated in figure 1). The study observed 45 infants born between 24-38 weeks gestation in a Level III NICU. The researchers measured the following: (1) infant self-regulation, (2) infant stress behaviors, and (3) pertinent infant physiologic data (infant pain scores, episodes of apnea/bradycardia, and vital signs). The infants were randomized into different groups so researchers could explore the effects of different developmental interventions over time. This study found that the unscented and scented Zakys® are

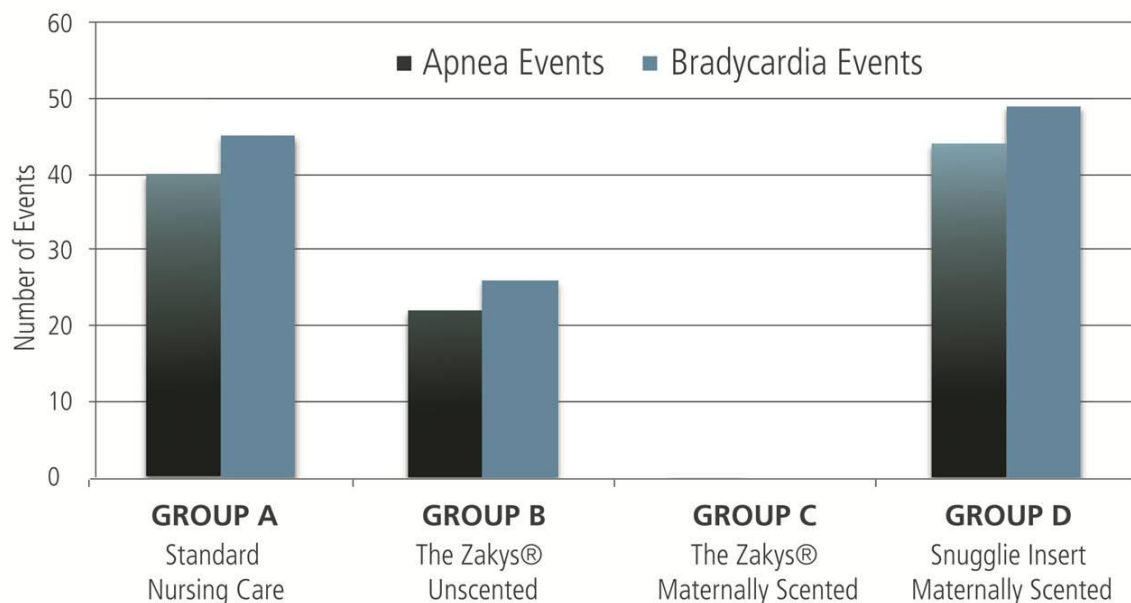
beneficial for infant development in comparison to standard hospital developmental care products, as infants receiving Zaky® care had fewer episodes of apnea and bradycardia. Infants cared for with Zakys® that had mother's scent demonstrated the most improvement on self-regulatory behavior tests when compared to all other developmental care groups.

Nurtured by Design recognizes that positive early experiences can promote health, sleep and brain development. It is our company's mission to design ergonomic early interventions that help promote positive development, improve health, attachment, and overall educational and social outcomes of children.

Based on the above research, research will be conducted to further determine the efficacy of 24/7 nurturing parental intervention with The Zaky® as it has the potential to provide tremendous public health benefits such as the ones found in this research:

EPISODES OF APNEA OF PREMATURETY AND BRADYCARDIA

Poisson regression results indicate the chances of seeing either apnea or a bradycardia event is about twice for standard nursing as opposed to The Zakys® Unscented. As there were no events for The Zakys® Maternally Scented, no estimate can be made. However, no events indicate a considerable benefit and the table below says it all.



(1) significantly reduce life threatening apnea of prematurity (pause in the regular breathing of a baby lasting longer than 15-20 seconds) and bradycardia episodes (heart rate too slow) while these infant were receiving medical care in the NICU. Zero episodes were experienced by the babies in this research when using The Zaky® maternally scented.

(2) Significantly improved self-regulation by all the babies using The Zaky®, especially using them maternally scented. (Scented by mother placing The Zaky® on the chest or behind the neck for one hour prior to the study.)

These in turn may result in the following:

- (1) It sheds light to the possibility that apnea/bradycardia of prematurity may be prevented. They may be due to the care provided and not necessarily only due to the immaturity of the lungs/heart/brain of the immature baby.
- (2) One pair of The Zaky® may improve the quality and standard of care while reducing supply chain (from inventory, ordering, storage, training, to quality control) and medical cost, number of invasive procedures, side effects related to treatment, and,
- (3) By promoting rest and self-regulation, it may improve sleep, neurological development and the quality of life of the baby (and parents) not only during hospitalization but for a lifetime.

Abstract

The Effect of a Maternal Simulated Intervention on Physiologic and Developmental Behaviors of 24-38 Week Gestation Infants in a Level III Neonatal Intensive Care Unit.

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Problem: Complications of preterm delivery are associated with numerous developmental abnormalities that may impact the overall quality of life of the infant. The literature supports the use of many developmental interventions for premature infants convalescing in the Neonatal Intensive Care Unit (NICU). Interventions have been shown to be beneficial to premature infants by helping to increase weight gain, shortened hospital stay, and improve bonding (Dodd, 2005). A number of devices that support developmental positioning of premature infants are currently in use in many NICU's. However, few of these support devices have been explored to determine the benefits for the infant. The purpose of this study was to explore a maternal simulated intervention on physiologic and developmental behaviors of 28-34 week gestation infants in a Level III NICU.

Method: Using a quasi-experimental design, a sample of 45 infants was randomized into four groups to explore differences over time when developmentally appropriate interventions were applied. Differences in pain scores, episodes of apnea/bradycardia, vital signs, and occurrences of self-regulatory and stress behaviors were observed.

Results: Infants receiving the maternal simulated intervention had fewer episodes of apnea/bradycardia ($p < 0.05$). The odds of observing stress behaviors over time were higher for the standard of care than the odds for the simulated intervention ($OR = 10.5, p < 0.05$).

Conclusion: Neuroprotective supportive care using a weighted maternally-scented parental simulation device [THE ZAKY] 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.

Go to the Video Presentation and Poster from the American Public Health Association's (APHA) Annual Meeting (Washington DC, Nov. 2011), and at the National Association of Neonatal Nurses (NANN) Annual Conference (Palm Springs, CA, Oct. 2012)

Poster Number 1096

Effect of a Maternal Simulated Intervention on Physiologic and Developmental Behaviors of 24-38 Week Gestation Infants in a Level III Neonatal Intensive Care Unit

Give Them A Hand To Develop Their Brain

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THE PROBLEM

Premature birth (babies born before 37 weeks of gestation) accounts for one in eight births (over 500,000 annually) in the United States and can lead to long-term health problems and lifelong disabilities.¹ The estimated societal economic impact for the country is at least \$26.2 billion annually.²

Complications of preterm delivery are associated with numerous developmental abnormalities that may impact the overall quality of life of the infant.

There is concern that an unfavorable environment in the Neonatal Intensive Care Unit (NICU) can negatively affect the infant's growth, with the brain being particularly vulnerable.

Although survival among premature infants has improved over the past two decades,³ the long-term morbidity of survivors remains of serious concern. Follow-up studies of preterm survivors into the school years consistently find reduced cognitive performance and increased behavioral problems in these children.

Developing Brain by Gestational Age

OBJECTIVE

- To assess the effectiveness of a nurse-driven maternal simulated intervention in providing developmental care to infants 24-38 weeks gestation by assessing:
 - self-regulatory versus stress behaviors;
 - physiologic data.
- To evaluate implications for nursing practice.

METHOD / DESIGN

- In a Single Blind Randomized Trial, a sample of 46 infants was randomized into four groups to explore differences over time when different developmental interventions were applied.
- Differences in pain scores, episodes of apnea or premature/bradycardia, vital signs, and occurrences of self-regulatory and stress behaviors were observed.
- Participants were infants admitted to the Level III Neonatal Intensive Care Unit (NICU) between 24-38 weeks gestation.
- IRB approval and informed consent from the parents was obtained.
- Exclusion criteria included surgical infants, infants in

THE RESULTS

DESCRIPTIVES

Variable	Group A n=11	Group B n=11	Group C n=12	Group D n=12
Age (weeks)	30.5 (4.6)	30.3 (3.7)	31.0 (3.8)	28.1 (4.0)
Apnea ⁴	5.5 (7.7)	5.9 (7.6)	5.7 (5.5)	4.8 (7.4)
Apnea ⁵	7.2 (2.3)	7.2 (2.0)	7.2 (1.6)	7.5 (1.2)
DOI	18.9 (23.9)	15.1 (18.7)	6.7 (6.4)	17.3 (19.3)

SELF REGULATORY (SR) VERSUS STRESS BEHAVIORS

There is evidence to suggest the presented and scored Zaky's[®] are beneficial based on the results below for SR, SR2, SR4, SR5, SR6, and SR7, with the Maternally Scored Zaky's[®] demonstrating a better response for all of the self-regulatory items. The Maternally Scored Snuggly Insert demonstrates modest benefit.

Variable	Standard Nursing Care (n=11)	The Zaky's [®] Unscorbed (n=11)	The Zaky's [®] Maternally Scored (n=12)	Snuggly Insert Maternally Scored (n=12)
SR1	0.000	0.000	0.000	0.000
SR2	0.000	0.000	0.000	0.000
SR3	0.000	0.000	0.000	0.000
SR4	0.000	0.000	0.000	0.000
SR5	0.000	0.000	0.000	0.000
SR6	0.000	0.000	0.000	0.000
SR7	0.000	0.000	0.000	0.000

DEVELOPMENTAL CARE MAKES THE DIFFERENCE

Early experience can modify the anatomy of the rapidly developing brain, which implies that early intervention may alter developmental paths and improve health, educational and social outcomes.^{4,7} Individualized developmental care is a framework for providing care that enhances the neurodevelopment of the infant through interventions that supports both the infant and family unit.

Research has shown that developmental care enhances the outcomes of high risk infants who require neonatal intensive care. Additionally, many interventions are still not well tested by research and require cautious implementation.

The process of providing nursing care should be adjusted in response to communication from the infant, or behavioral cues. The aim is to decrease associated stress and increase the potential of the available skills possessed by the infant to regulate and organize his/her responses. Evidence-based developmental care with the incorporation of the family unit is pivotal for the best long-term outcomes in this fragile population.

DATA COLLECTION

- Randomly assigned infants to one of four treatment groups.
- Recorded physiologic data every 2 hours (Temperature, heart rate, respiratory rate, FIO2 and PIPV pain score).
- Recorded infant behaviors on 7 indicators and categorized them (Self-regulatory versus Stress Behaviors) based on infant assessment.
- Recorded number of Episodes of Apnea of Prematurity and Bradycardia.

STATISTICAL ANALYSIS

Descriptives: Repeated Measures - ANOVA, and Poisson Regression.

THE DESIGN

GROUP A
Standard Nursing Care

Standard Nursing Care includes:
Dues 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 vertical devices.

GROUP B
The Zaky's[®] Unscorbed

The Zaky's[®] is a device readily available in the market, ergonomically designed to keep the scent of the parent and to simulate the abgac, touch, and sound of the parent's hands and forearms. Each weighs 120 grams.

GROUP C
The Zaky's[®] Maternally Scored

Alcohol soaks The Zaky[®] for one hour with her skin.

GROUP D
Snuggly Insert Maternally Scored

Snuggly is a fleece bedding that wraps around the infant to provide containment.
The maternally scored insert warms the infant.

THE PURPOSE OF THIS STUDY

The literature supports the use of many developmental interventions for premature infants convalescing in the NICU. Interventions have been shown to be beneficial to premature infants by helping to increase weight gain, shorten hospital stay, and improve bonding (Dodd, 2005).

A number of devices that support developmental positioning of premature infants are currently in use in many Neonatal Intensive Care Units, however, few of these support devices have been explored to determine the benefits for the infant.

The purpose of this study was to explore the impact of simulating maternal intervention in the development of those infants that are born prematurely and are hospitalized.

SUMMARY

The maternal simulated intervention used had positive effects on infants in the NICU.

- Infants that used the Zaky's[®] (maternal simulated intervention) experienced fewer episodes of apnea and bradycardia (p<0.05), especially those Maternally Scored.
- The odds of observing stress behaviors over time were higher for the infants receiving standard nursing care than for the odds for the infants receiving the simulated intervention (p<0.05, p<0.05).

CONCLUSIONS

The Zaky's[®], the maternal simulated intervention used in this study, suggests an efficacious method to reduce adverse physiologic and developmental behaviors of 24-38 week gestation infants in a Level III Neonatal Intensive Care Unit.

Further research is required to determine the efficacy of this intervention as it has the potential to provide tremendous public health benefits such as:

- Significantly reduce the threatening apnea of prematurity (pause in the regular breathing of a baby lasting longer than 10-20 seconds) and bradycardia (heart rate too slow) which are potentially detrimental to the developing brain. Current knowledge suggests immaturity of the cardiovascular, respiratory, and nervous systems of the premature baby as causes of apnea/bradycardia.
- Improvement in the quality and standard of care while reducing cost related to treatment.
- Improved neurological development thus quality of life of the baby, the

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Alan Fogel (2011), author of *A Topical Approach to Infant Development*, reports 543,000 infants (or one out of every eight infants) are born premature in the United States each year, and of these 543,000 infants approximately 40% develop neurological deficits like cerebral palsy, reoccurring seizures, learning difficulties, behavioral problems, hearing loss, and other life impacting developmental disorders. Preterm research initiatives, like that of the Burroughs Wellcome Fund, place importance on the advancements of medical technologies and interventions to care for preterm infants (Preterm birth initiative, 2014). Nurtured by design is committed to developing and researching intervention based care to address the medical and developmental needs of premature and full-term infants. Currently, researchers are studying how to improve developmental care, or nonmedical or drug-based care, in the Neonatal Intensive Care Unit (NICU).

Developmental care has the potential to mitigate the harmful effects hospitalization can have on the development of newborn infants. Researchers studying the NICU environment have determined that loud noises, bright lights, and other startling stimuli associated with medical care evoke a physiological stress response in infants that negatively impact the neurological and physiological development of preterm infants (Smith, et al., 2011). Stress exposure in the NICU is associated with increased negative reactivity and asymmetrical

differences in brain structure when premature infants were reassessed at two years of age (Smith et al., 2011) (Pineda et al., 2014). With this research it is now known that premature infants are not only at an increased risk for congenital abnormalities that may impact overall quality of life, but also developmental delays that come as a side effect from NICU hospitalization.

Nurtured by Design recognizes that positive early experiences can promote health brain development. It is our companies mission to design early interventions that help promote positive development, improve health, and overall educational and social outcomes of children. The Zaky®, one of Nurtured by Design’s developmental care interventions, has been researched at the Medical Center of Central Georgia, Georgia College and State University, and Jiann-Ping HSU College of Public Health to explore the impact of simulating maternal intervention in the development of hospitalized premature infants.



The results suggest that The Zakys significantly improve self-regulation and organization and decrease apnea and bradycardia in NICUs*



[*]"Effect of a Maternal Simulated Intervention The Zaky on Physiologic and Developmental Behaviors of 28-34 Week Gestation Infants in a Level III NICU" (Russell, Weaver, Vogel, 2011).