12-17-2009

Soothability and Growth in Preterm Neonates

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by

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A DISSERTATION

Submitted to the Graduate School of the

UNIVERSITY OF MISSOURI- ST. LOUIS
In partial Fulfillment of the Requirements for the Degree

DOCTOR OF PHILOSOPHY

in

Nursing

December 2009

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ACKNOWLEDGMENTS

I would like to express my heart-felt appreciation to all who assisted in the completion of this dissertation. My particular thanks go to the members of the dissertation committee, and the entire University of Missouri – St. Louis College of Nursing faculty who have supported and sustained me through my doctoral studies.

I am especially thankful to Dawn Garzon, RN, PhD and Donna Taliaferro, RN, PhD, my dissertation committee co-chairwomen, both of whom were integral in shaping my study and expediting the research process. Their systematic and nurturing method of support was invaluable. I also want to thank Kathy Borcherding, RN, PhD, Leigh Tenkku, PhD, and Wilma Calvert, PhD, for their assistance as members of my dissertation committee. Special thanks are given to Tom Burroughs, PhD for statistical advice and support.

I wish to express my sincere appreciation and gratitude to the parents who allowed their infants to participate in my research. Without their trust and consent, I would not have had the privilege to learn more about infants and ways to comfort them.

Others deserving thanks are my parents, Jack and Jan Diesel, for instilling a sense of commitment and service, my children Zoe and Calvin, for their patience with my frequent and prolonged absences from home, my cats Nikolai and Remy, who never left me be alone at the computer, and finally my husband Jack, for his unwavering love, support and ability to keep our home clean and the refrigerator full during my studies.
My deepest thanks go to Laura Ochoa, who made certain, that I chose a lane, stayed in it as she challenged me with her right brain thinking all the way to the end.

Abstract

This proposal seeks to understand the relationship between soothability, weight gain and length of hospital stay in premature infants when the infants receive a simple, non-invasive treatment to help them cope with the noxious environment of the special care nursery. Thousands of premature infants are born every year in the United States, and the numbers are increasing. Prematurity is the leading cause of mortality in infants. Despite numerous technological and medical advances in treatment and care, premature infants still have difficulty adapting to life outside the uterus as a result of immature nervous systems and significant differences in the pre and post delivery environments. Developmental Care and Family Centered Care have made significant improvements in the lives of hospitalized premature infants. However, care continues to be costly and complex, encouraging health care providers to continue to search for simpler and less expensive methods to care for these tiny patients.

This paper describes the effect of a flax seed pillow, placed on the back of premature infants in a prone position on their ability to sooth themselves, moderate their activity, gain weight and the length of hospital stay. Each infant will receive two 15 minute treatments, twice a day, over the course of five consecutive days. Measurements will be obtained on various physiologic parameters including temperature, heart rate, respiratory rate, and pain scores and activity. The design is a randomized control study, with infants stratified for birth weight.

Infants in the treatment group had decreases in heart rate, respiratory rate and pain scores significantly greater than infants in the control group. Infants in the treatment group also gained more weight in the first three weeks of life, however this difference

was lost by time of discharge. Hospital length of stay did not vary between the two groups.

The treatment of the flax seed pillow is a new method to assist premature infants to cope with the stressful environment of the nursery. The pillow is simple, easy to use and was not associated with any adverse events. Further research is recommended to explore the efficacy of this intervention in other populations.

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CHAPTER I

INTRODUCTION

General Problem Area

Prematurely born infants are faced with multiple challenges and obstacles on their path to continued growth and development, and they struggle to adapt to the unnatural environment of the neonatal intensive care unit (NICU). Some of the challenges are directly related to the stark differences between the environment of the uterus and that of the NICU. The uterus is relatively dark, with warm and muffled sounds, whereas the NICU is frequently illuminated, much cooler than normal core body temperature and full of unpleasant noise, causing the preterm infant unexpected stress. The premature infant is also negatively impacted since all of the premature infant's organ systems are immature. Immature organ systems can result in pathologies of the neurological, respiratory, and gastrointestinal systems. Importantly, the premature infant is unable to adequately manage arousal state, which in turn may affect her ability to maintain or control automatic postural movements. These stressors, individually or in combination, can cause pain and lead to fatigue. In this hostile environment, the premature infant is forced to use more of its limited resources to merely cope with the environment rather than to grow and develop.

Many interventions have been implemented in the effort to assist prematurely born infants cope with and adapt to life outside the uterus. Technological advances such as ventilatory support, temperature controlled incubators, feeding tubes, and extracorporeal membrane oxygenation have enabled premature neonates to survive until their organ systems are mature enough to take over without support. These interventions have been successful, and survival rates of ever-younger premature neonates have seen steady improvement over the last three decades (Hack, et al., 1995). Supportive treatments and therapies can also add to the stress the premature neonate experiences.

Two major frameworks address the stress of the NICU; Developmental Care (Als, 1982) and Family Centered Care (Shelton, Jeppson, & Johnson, 1987). Developmental Care (DC) attempts to structure both the care and the environment in ways that are different from the needs of full term infants. These changes in the care and environment are more developmentally appropriate for the premature neonate so that growth and development are maximized. Family Centered Care (FCC) acknowledges the importance of family relationships and the early, mutual attachment of both parents and the premature infant. Integrating both frameworks, DC and FCC, with interventions that are technologically complex adds another layer of stressful exposure (Bernbaum, Pereira, Watkins, & Peckham, 1983)

Part of the difficulty of integrating FCC and DC with technological interventions is related to the cost of the standard equipment in high risk nurseries and the necessary training required for the practitioners to use the equipment, as well as unclear or inconsistent definitions (Franck & Callery, 2004). In addition, there are no current methods available to readily evaluate the effects of FCC (Hanson, & Randall, 1999). These particular problems have encouraged investigators and practitioners to explore additional, simpler, and less expensive ways to assist premature neonates cope with the environment of the high-risk nursery.

Background

A growing body of literature examines the effectiveness of complementary and alternative therapies such as music, aromatherapy, and massage, and their effects on premature infants. Two primary reasons for the exploration of these approaches are related to the cost and degree of complexity. Although it is not always the case, many complementary or alternative therapies are relatively less expensive than other, more traditional therapies. In some instances, third party payers even cover these costs. These therapies are also often less complex than traditional therapies and are therefore implemented without requiring advanced education or training. In fact, many of the therapies are easily and effectively implemented at home with very little training or practice. A possible third reason to explore these therapies for premature neonates is the frustration or dissatisfaction that parents may experience with traditional modalities. Parents who are searching for answers and best outcomes for the premature infants are often willing to accept or implement any and all therapies available, including alternative therapies.

Recent studies look at interventions that parents are able to implement themselves with minimal training and education (Axelin, Salantera, & Lehtonen, 2006). Pain, stress, and fatigue are common factors affecting the growth of premature infants, and interventions to date have been moderately successful in reducing their impact on the premature infant. New interventions that can reduce or prevent these factors need to be identified.

Globally, the highest risk of death is for the very youngest. Each year, 10.8 million children die around the world, and 36% of those children will die in the first 28 days of life (Davanzo, 2004). Despite the efforts of maternal child health care providers and educators to reduce, and eliminate premature births, these births are increasing at alarming rates in the United States. Almost half a million premature infants are born in the United States each year (Maroney, 2003). In 2005, the preterm birth rate, or those babies delivered at less than 37 completed weeks of gestation, increased by 2%, which accounted for 12.7% of all births. Since 1990, the preterm birth rate has risen 20% (National Vital Statistics Reports, 2005).

The National Center for Health Statistics reports that most of the current increase is in infants born between 32 and 36 weeks gestation (National Vital Statistics Reports, 2005). Prematurity is the second leading cause of infant mortality, with a rate of 6.74 per 1000 live births in 2004 (National Vital Statistics Reports). A second report found that in 2004, 36.5% of all infant deaths in the United States were due to preterm-related causes. In addition, prematurity with related health problems caused nearly half of the infant deaths born to non-Hispanic black women, and 41% percent of infant deaths born to Puerto Rican woman. Both of these rates are significantly higher than non-Hispanic white women demonstrating an additional issue of health care outcome disparities.

One way to decrease infant mortality and prematurity associated morbidity is to ensure safe and effective care for premature infants. Awareness of the unique needs of premature infants has grown in part as a result of a multiyear initiative to address the distinct physiological and developmental needs of the prematurely born infant (Medoff-Cooper, Bakewell-Sachs, Buus-Frank & Santa-Donato, 2005). Premature infants have significantly higher risk of some medical problems that result in increased hospital costs compared to full-term infants (Wang, Dorer, Flemming, & Catlin, 2004). The seven conditions identified in this particular study that were more commonly seen in prematurely born infants were temperature instability, hypoglycemia, need for intravenous infusions, respiratory distress, apnea and bradycardia, symptoms prompting a sepsis evaluation and clinical jaundice.

To address these conditions or complications, premature infants are most often cared for in special care nurseries or neonatal intensive care units using a variety of technologies, care pathways, and nursing interventions (Campbell, 2006). Many changes have occurred in neonatal care in the past five decades, including the use of surfactant to treat respiratory distress syndrome (RDS). Antenatal steroids used to treat chronic lung disease, cesarean section delivery, and advances in tocolytic therapy have resulted in improved mortality and morbidity outcomes.

Intensive care for the newborn has improved significantly due to such measures as mechanical ventilation and parenteral nutrition. Survival rates have increased and hospital stays have decreased (Hack, et al, 1995). Most of the measures currently employed are expensive or require significant amounts of training and highly skilled health personnel. As a result of the increased survival rate, the rate of major morbidity among survivors has serious implications for the long term neurological development and survival of these infants. In addition to physiologic sequelae, studies have also shown a significantly greater risk of attention deficit/hyperactivity disorder, generalized anxiety, and symptoms of depression in infants born prematurely (Botting, Powls, Cooke, & Marlow, 1997). The immaturity of body systems is the primary obstacle to adaptation to extra-uterine life for the preterm infant.

In the last three years, local hospitals report an increase in obstetrical admissions and deliveries in the last three years (March of Dimes Birth Defects Foundation, 2007). The is an increase in premature births as well, in both actual numbers and percentages

(March of Dimes Birth Defects Foundation, 2007). Medicaid patients comprise approximately 49 % of these births, indicating a disparity in prenatal care. Length of hospital stay for premature infants in local nurseries ranges from 10 to 22 days, with a mean cost ranging from over $15,000 to $32,000 accordingly. Information from the March of Dimes indicates that the preterm birth rate in Missouri increased from 11.5% of all births in 1994, to 13.0% in 2004. This represents a thirteen percent increase overall, and is alarming when compared to the Healthy People 2010 goal of a preterm birth rate of 7.6% (March of Dimes Birth Defects Foundation, 2007).

It is not sufficient to solely identify the cost and societal impact of premature birth in the United States. The development of interventions to optimize the outcomes of premature born neonates is critical when measures to prevent premature birth fail. A number of theories explain and predict the stressors and experiences of premature infants. Two frameworks with particular application to the problem of premature infant growth and development are Developmental Care and Family Centered Care.

The framework of Developmental Care (DC) was originally developed by Heidelise Als (1982), who theorized with colleagues that the premature infant responded to external stimuli and maintained organization in ways different from full term infants. Als (1982) described a synactive model of development for the preterm infants that consists of integrated subsystems. The integrated subsystems include autonomic (breathing, heart rate), motor (mobility, muscle tone, position), and state (movement between states, and interaction and attention behaviors) (Als, 1986). This is a framework of providing care for infants in special care nurseries and neonatal intensive care units that takes into account the individualized needs of the infants and their families (Als, 1986). Two major goals of this framework are to individualize care by decreasing infant disruptions and handling, and modulating or attenuating infant responses to the care they receive. DC requires collaboration of all health professionals in the NICU who care for and interact with the preterm infant and is therefore a multidisciplinary approach (Aita, & Snider, 2003). Using developmentally supportive techniques is one method that enables the health care provider to be proactive rather than reactive.

The provision of care within SCNs and NICUs is changing as a result of advancements in technology, pharmacology and a better understanding of preterm infant behaviors and development. As a result, nursing practice has changed in many ways, one of which has been to include and involve families more in the care of their preterm infants. The families of preterm infants must undergo rapid adaptation in a demanding environment and are best supported through a framework of care called Family Centered Care (Shelton, Jeppson, & Johnson, 1987). This framework recognizes the pivotal role of the family related to child's outcome. The family and the healthcare team form an equal partnership committed to the care and support of the child.

Blending the two frameworks, DC and FCC, may allow health care providers to explore and implement a variety of interventions and approaches to improve the experience of the hospitalized premature newborn. As a result, most high risk nurseries have made changes so that lights are low and noise is minimal. Care modalities now incorporate more gentle touch and longer periods of rest between procedures and treatments. Investigation continues to search for methods and approaches that will make the environment less hostile and more supportive for the premature infant.

Premature infants represent a large proportion of all infants born in the United

States and around the globe. Their care is often complex and costly, and parents can feel that they personally have few ways in which to impact the care of their infants in a positive fashion. In addition to the parents and families, members of the health care team, look for ways to improve outcomes and involve the parents and family to a greater extent. Nurses are particularly well positioned to employ simple and cost effective interventions to achieve these goals (Van Riper, 2001). In addition, high risk nursery managers and hospital administrators search for ways to control cost. If all these stakeholders identify additional interventions that safely improve the outcomes for premature neonates in cost effective manner, then society as a whole will benefit.

Purpose

The purpose of this study is to test an intervention to improve the ability of premature infants to soothe themselves that is inexpensive, requires very little training, and could result in greater parental involvement. Specifically, this proposal seeks to compare the effectiveness of a flax seed pillow and standard special care nursery care for promoting soothability and weight gain, and decreasing hospital length of stay in premature infants in the first week of life outside the uterus.

Research Questions

There are three research questions examined in this study. The first question seeks to identify the relationship between the use of a flax seed pillow intervention and the soothability of preterm infant, and asks if preterm infants receiving twice daily applications of the flax seed pillow will demonstrate greater degrees of soothability than the control preterm infants. The second research question seeks to identify the relationship between soothability and growth, and asks whether preterm infants that are more soothable will demonstrate greater growth measured by weight gain in grams than the control preterm infants. The third and final question seeks to identify the relationship between growth and length of stay, and asks whether preterm infants who gain weight more quickly will have shorter lengths of stay in the high-risk nursery than infants with slower gains in weight

Summary

In summary, prematurely born infants face multiple challenges as a result of immature organ systems and decreased ability to cope with and adapt to the unnatural environment of the high-risk nursery environment. The need for specialized care has led investigators and practitioners to explore and develop alternative interventions to meet help prematurely born infants cope with and adapt to life outside the uterus. Technological advances enable premature neonates to survive until their organ systems are mature enough to take over without support. However, technology alone has not successfully decreased the rate of preterm births, nor solved the complexity of premature infant care. Two frameworks in particular, DC and FCC, are particularly relevant as practitioners and researchers explore additional, simpler, and less expensive ways to assist premature neonates cope with the environment of the high-risk nursery. This study explores the relationship of a new and simple intervention to help premature infants cope with their stressful environments. The second chapter examines the current literature relevant to this proposal.

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

The original question, that was the focus for this review, was “what is the efficacy of developmental care in high risk nurseries?” A review of the current literature was performed using Medline, Pub MED and CINAHL databases. The key words used for the search were: preterm infants, premature infants, touch, therapeutic touch, complementary and alternative medicine, infant care, developmental care, and family centered care. Other key words that were added to the searches upon identifying frequency of use were: infant massage, stimulation, and environment. The search was limited to articles written in English, and limited to publications after 1960.

Initially, over five hundred articles were identified. Due to the focus of the review on developmental interventions in high-risk nurseries, many articles were omitted. The remaining articles were reviewed and the results summarized in the following sections of this paper. Key concepts addressed in this paper are infant stimulation, infant organization and self-regulation. Two frameworks will be discussed which will provide a framework for preterm infant intervention. Those frameworks are Developmental Care (DC) and Family Centered Care (FCC).

Developmental Care

As described in the introduction, Heidelise Als (1982) and colleagues developed the framework of Developmental Care (DC) to describe the way in which premature infants respond to external stimuli and how that differs from full term infants. This framework suggests that care provided to preterm infants must change as a result of the different way premature infants respond to stimuli. The major goals of this framework are to individualize care by decreasing infant disruptions and handling, and modulating or attenuating infant responses to the care they receive. Infants exposed to environments that are not supportive and not structured appropriately experience numerous negative outcomes including delays in development, increased lengths of hospitalization and financial cost and increased risk for mental health disease (Botting, Powls, Cooke, & Marlow, 1997)

DC is based on a regular observation and a recommended cycle of care that allows for the promotion of and respect for newborn sleep. The DC framework suggests a variety of recommendations and operational strategies. The assessment and intervention strategy of DC works in tandem as the nurse uses autonomic, motor, and behavioral cues to assess the infant's needs, and then develops a plan to support the infant while increasing his or her abilities to stabilize and self-regulate (Als, 1986). This process makes the approach ultimately individualized and serves as a framework for an observational assessment tool, the Newborn Individualized Developmental Care and Assessment Program (NIDCAP). This assessment tool is used to assess the infant through observation of cues and behaviors that are related to the autonomic, motor and state organization systems (Als & Gilkerson, 1995).

Control of the environment is usually the first DC strategy employed by nursery nurses. Noise should be controlled and eliminated where possible by closing doors, decreasing alarm volumes and talking quietly. Covering the incubators or isolettes, using eye patch covers when possible and implementing a cycle of day/night lighting can decrease excessive lighting. Room temperature should be set to promote infant comfort as opposed to the comfort of the staff.

Another critical intervention addresses supportive positioning, where the infant is supported in a flexed position with cloth nests, or rolls. Swaddling with a blanket and facilitating nonnutritive sucking are two self-reassuring behaviors in the infant that DC encourages. Non-nutritive sucking has been studied extensively, and helps the preterm infants progress more rapidly to nipple feeding, shortened hospital stays and promotes more rapid weight gain (Bernbaum, et al., 1983).

Painful interventions should be paced to allow the infant to recover, and should be performed on a schedule to respect the sleep-wake cycle of the infant. Clustering care is one way to allow undisturbed and maximum sleep for the infant. Cluster care is the process of providing a number of interventions at one time, and allowing longer periods of non-stimulation and rest to occur in between the care episodes. In another strategy, the health care team involves the parents and family as partners to promote sleep via skin-to-skin or kangaroo care.

Few studies examine the effectiveness of a comprehensive DC program. Als (1986) used a phase lag design to investigate the effect of DC in 16 preterm infants. The results demonstrated improved medical status and improved developmental outcomes at nine months of age when compared to the control infants. A later randomized control of this study with a larger sample of 38 infants obtained similar results (Als, et al, 1994). The experimental group had a younger age at discharge, shorter hospital length of stay and reduced hospital costs. Another study used a randomized control design to study DC in a sample of 35 infants and found the experimental infants had significantly more organized performance in motor system function, state regulation and self-regulatory abilities at 42 weeks post-conception age (Fleisher, et al., 1995).

It is unclear why DC produces beneficial outcomes, although a more recent study (Als, et al., 2004) found that DC might actually alter brain function and structure. In this randomized controlled study, 30 premature infants received neurobiological assessments at two weeks and nine months corrected age. Infants in the experimental group showed significant differences in both function and developing structure of their brains than did the controls. The experimental group demonstrated significant improvement in the neuro-behavioral outcome as measured by motor system modulation (control mean 6.29, experimental mean 4.70, $p = .001$) and self regulation (control 6.11, experimental 4.94, $p = .01$) on the Assessment of Preterm Infants' Behavior (APIB), and broad motor organization and intensity of reaction measured on the Prechtl scale ($F = 3.35$, $p = .01$) (Als, et al, 2004). The APIB is a comprehensive and systematic neurobehavioral assessment that identifies infants' self regulatory efforts and disorganization thresholds (Als, Lester, Tronick & Brazelton, 1982). The Prechtl scale is a noninvasive, qualitative assessment method to evaluate infants for neurologic impairments (Prechtl, Einspieler, Cioni, Bos, Ferrari, & Sontheimer, 1997). Although this assessment tool is well suited to assess premature infants, it is somewhat lengthy and cumbersome to use. The results partly explain some of the mechanisms through which DC fosters an optimal environment that promotes behavioral stability, and improves neurological development. Another closely related study showed that infants and mothers benefited from the DC environment. The mothers reported that they felt their infants were better regulated and as a result, the mothers felt more of a sense of gratification which thereby improving feelings of maternal competence (Als, et al, 2003).

Even though DC is supported by most evaluative studies, implementation can be problematic due to the need for a developmental specialist. These specialists are generally in short supply due to the extensive training that is required, and there is little information available to assist hospitals and nurse implement this program of care. One case study (Goldberg-Hamblin, Singer, Singer, & Denney, 2007) described the process a hospital undertook to implement DC. After involving all stakeholders, five NICU nurses participated in a half –day training session with a DC experienced nurse. The training included the presentation of theory, demonstration of skills and techniques, and the opportunity to practice with coaching and feedback. After completion, nursing behaviors were observed, and all five nurses in the study demonstrated increased developmentally supportive behaviors. In addition, all five infants cared for by these nurses demonstrated less stress during their feedings.

Family Centered Care

The provision of care within SCNs and NICUs is changing as a result of advancements in technology, pharmacology and a better understanding of preterm infant behaviors and development. As a result, nursing practice has changed in many ways, one of which has been to include and involve families more in the care of their preterm infants. The families of preterm infants must undergo rapid adaptation to a demanding environment and are best supported through a philosophy of care called Family Centered Care (Shelton, et al., 1987). This approach recognizes the pivotal role of the family related to child's outcome. The family and the healthcare team form an equal partnership committed to the care and support of the child.

The term Family Centered Care (FCC) has been used in a variety of contexts for over forty years (Weidenbach, 1967). Initially, a group of parents and professionals came together in 1986, and defined the critical characteristics of the philosophy of care. The original eight elements of family-centered care were described in a monograph (Shelton, et al., 1987) that was later revised in 1994.

FCC is composed of the following eight elements: (1) the family is the constant variable, with the family being defined by the family, and is the center of the patient care, (2) collaboration between the family and the health care professionals, which allows for a humanized delivery of care, (3) exchange of complete and unbiased information, such that information, ideas and concerns are openly exchanged in an ongoing manner, (4) respect for the diversity of families whereby decisions about care incorporate all cultural, ethnic, racial, spiritual, social, economic, educational and geographic parameters, (5) recognization and respecting different methods of coping and the provision of developmental, educational, emotional, environmental and financial support, (6) encouragement and facilitation of family to family support and networking, (7) ensure service and support systems are coordinated in ways to maximize flexibility, accessibility and comprehensiveness, and (8) appreciation of families as families and children as children. It is also essential for health care professionals to recognize that the health condition may not always be the family's priority, and that these priorities may and will change over time (Shelton, & Stepanek, 1995). The definition of FCC continues to evolve and now includes administrative and emotional support for staff (Bruce & Ritchie, 1997).

The eight elements of FCC can be condensed into four basic concepts: dignity and respect, information sharing, family participation in care and family collaboration. Using these four concepts as a framework for design, changes can be made in nurseries to better facilitate FCC. Single room design, although costly, offers many advantages including privacy, safety, decreased noise levels, and opportunities for rooming in with the hospitalized infant (Griffin, 2006). Regardless of nursery layout, the other FCC practices should be implemented. Parental visitation must be unrestricted and encouraged, as studies show that separation from their infant is stressful and difficult for the parents (Affonso, et al. 1992).

An important requirement of FCC is that family members are involved in care giving of the child. Preterm birth threatens the well being of the family system in addition to the obvious threat to the preterm infant (Gennaro, 1996). Without question, the environments of SCN and NICU are stressful due to the complex array of machines, equipment, and the often regimented and structured practice of routine care. Additional factors stressful to the parents are the preterm infant's appearance and behaviors, and physical separation from the family. These factors and others contribute to parental feelings of loss, fear, anger, grief and helplessness (Kenner, 1990).

Parents who are allowed and encouraged to care for their infants, are less confused, tense and anxious, and are better able to connect with their baby (Hurst, 2001). Van Riper (2001) studied 55 mothers of preterm infants. This study found that mothers, who perceived their family's relationship with their child's primary health care providers as positive and family-centered, reported more satisfaction with the care received. These mothers also reported greater willingness to seek help from the health care providers. This willingness to seek assistance may have a profound influence on long-term outcomes for the preterm infants.

Nurses encourage parents to hold, comfort and bathe their hospitalized newborns from the beginning. Broader and deeper parental involvement can positively impact infant outcomes in significant ways (Griffin, 2006). FCC shifts the orientation from the health care team to that of the family, which can make a difference in the lives of premature infants and the parents and families who support them. The partnership between the family and the health care team member promotes normalized patterns of living for the family (Hutchfield, 1999). Ultimately, the purpose of FCC is to ensure the family is involved in the care of their newborn from the beginning, in order to make the transition to home and eventual full responsibility for the newborn smoother and more effective. This in turn, is expected to improve overall outcomes for the infant and the family.

Adaptation to Extra-uterine Life

Much is known about the optimal environments for promoting the health and well being of preterm or near-term infants (Barnard, 1998). “Currently, higher and larger percentages of the very young and low birth weight premature infants are surviving, but with concomitant increased rates for later developmental difficulties” (Barnard, page 12, 1973). The differences between extra-uterine life conditions and those that would have been present had they not been born early are numerous and significant. Infants born prior to 37 weeks gestation have more difficulty adapting to extra-uterine life than do full term infants. Barnard (1973) demonstrates that when preterm newborns are provided an environment that closely mimickes the intrauterine surroundings, the infants show greater weight gains (control = 358.8 grams, experimental 620.9 grams, $p <. 05$) and differences in the amounts of quiet sleep (control = 41.7 minutes, experimental = 26.2 minutes, p <

.05), active sleep (control = 22.0 minutes, experimental = 10.0 minutes, $p < .05$), and active awake states (control 21.0 minutes, experimental = 41.0 minutes, $p < .01$). The author of the study suggests newborns became accustomed to the rocking motions of the bed, and the sound of the constant heartbeat recording. This habituation to stimuli is believed to allow the newborns to release their attention to environmental stimuli, and relax and sleep. This difficulty in adaptation is primarily due to the preterm infant's immature nervous system. Understanding the characteristics of the preterm infant and how these characteristics impact the preterm infant's adaptation to the environment is critical to improving outcomes.

The premature newborn demonstrates difficulty adaptating to extra-uterine life in a variety of ways. The premature newborn may have respiratory distress, hyperbilirubinemia, temperature instability, weight loss or insufficient weight gain (Barnard, 1973). These difficulties arise because the environment is distinctly different from the intrauterine environment and because the infant is less mature than full term infants. The premature infant's immature neurological system is demonstrated by the varying levels of sleep stages (Barnard, 1973).

The intrauterine environment for the normally developing fetus provides stimulation that is vestibular, auditory and proprioceptive (Grimwade, Walker, & Wood, 1970). As a result of the amniotic fluid, these stimuli are presented as generalized and intensified input, as a liquid medium conducts movement and sound to all parts of the fetus' body. In addition, the mother's movements and vital functions such as heart beat and respiration add stimuli that have a temporal pattern. In stark contrast to the intrauterine environment, the preterm infant will likely be cared for in an isolette or incubator. Neither setting provides the temporal patterning of vestibular, auditory and proprioceptive stimuli that the fetus would experience in utero.

The preterm infant spends long periods of time in an artificial, relatively changeless environment. Stimulation is repetitive and noxious, and may be detrimental during a period of potentially important central nervous system maturation (Barnard, 1973). Animal studies have shown that sensory deprivation and stressful stimulation, such as cold temperature, for the very young organism can lead to significant learning difficulties later in life (Levine, 1960). This may support the hypothesis that preterm infants who are subjected to the noxious stimuli of the high risk nursery, and are deprived of appropriate, temporally patterned stimuli will have altered patterns of growth and development.

In direct contrast to the intrauterine environment, the environment of special care nurseries (SCN) and neonatal intensive care units (NICU) are dramatically different. Until very recently, most high-risk nurseries could be described as a continually bright, and full of noise world where preterm infants frequently experience irritating if not outright painful stimuli. In addition to being noxious, these stimuli can be classified as unpredictable and varied, because they are based on the needs of the staff more often than the needs of the newborns. The preterm infant is also subjected to fluctuations in temperature, and changes in touch and movement that would not have occurred in utero. These environmental differences led to a second line of research that deals with the development of the central nervous system in preterm infants.

Most of this research focuses on the neurologic control of the infant's state of arousal, movement and sleep. Activity suppression is a particularly important aspect of central nervous system development. Golde & Van Velzer (1965) demonstrated that as infants mature, sleep differentiates into two phases. Although the explanation for the decrease in activity is uncertain, the authors suggest that it is due to increasing central nervous system control as a result of more constant proprioceptive stimulation (Golde & Van Velzer). Normal, full term newborns show the ability to handle neural discharge and to organize periods of sleep and wakefulness. This developing ability may also be an aspect of maturing central nervous system control (Golde & Van Velzer; Grigg-Damberger, 2004; Scher, Anat, Tse, Hayes, & Tardif, 2008) Another area of noteworthy difference is the preterm infant's response to a gaseous environment as opposed to the liquid environment provided by amniotic fluid. As previously mentioned, antenatal steroids, surfactant and mechanical ventilation have been very successful in supporting preterm newborns that might otherwise be unable to survive extra-uterine life. Collins (1978) demonstrated that survival was enhanced by decreases in heart rate after respiratory therapy was initiated. This led to a study that focused on infant sucking as a measure of self-regulatory response (Ellison, Vidyasagar, & Anderson, 1979). This study showed that the suction pressure that occurs while an infant is sucking positively correlated with gestational age, birth weight, and health status. Premature newborns that were given sucking opportunities twice a day had improved blood pH compared to infants who were not provided the intervention. According to the investigators, this improvement in blood pH promoted neuromuscular coordination, alert activity and deep sleep.

The high-risk nursery environment lacks the intrauterine-like stimulation of maternal heartbeat and kinesthetic stimuli from maternal movement. The absence of these stimuli encouraged researchers to test the effects of auditory, tactile, kinesthetic and visual stimulation on preterm infants (Barnard, 1973). Most of these studies were single stimulus modalities; however, other studies used multi-modal interventions (Barnard, 1973).

Kramer, Chamorro, Green & Knudtson (1975), conducted a study in which preterm infants were provided with gentle, non-rhythmic stroking of the infant's body surface on a daily basis. No significant difference was found in the rate of physical development as measured by the regain of birth weight, $F = 3.10$, $df = 2, 4$. No differences were found in cortisol levels ($F = -12.53$, $p < .01$), physical (control 6.0, experimental 4.0, $p < .05$), fine motor (control 3.0, experimental 4.0, $p < .05$) or mental development as measured by the Bayley Mental and Physical Developmental Index and the Infant Scale Performance Profile. No differences were sustained three months later.

Rice (1979) studied mothers who systematically stroked and massaged their infants for the first four months after hospital discharge. The results of the study indicated that the experimental infants made significant gains in neurological development ($p < .001$), weight gain ($p < .04$), and mental development ($p < .05$) in comparison to the control infants.

When massage was paired with passive range of motion for preterm infants for 15 minutes a day, the infants who received the treatments had more stools, greater caloric intake and gained more weight than infants who were not similarly stimulated (Rausch, 1981). Although not statistically significant, the weight gain of the experimental infants was 73 grams greater than that of the controls. However, the mean feeding intake of the experimental infants was 89 ml., greater than the control infants' intake ($p < .0001$), and experimental infants stooled more (control 2.95/day, experimental 6.20/day, $p < .004$).

Auditory stimulation has also been studied by a variety of investigators (Chapman, 1978; Buckland, Austin, Jackson & Inder, 2003). Although Jacobson and Mencher (1981) found that noise levels in neonatal intensive care units are within ranges acceptable for adults, there is no evidence to support that these same noise levels are safe for premature infants. Oddly, the study also identified that noise level was not a factor influencing the initial infant hearing screening tests.

In another study, sound levels were not significantly louder than levels the fetus would be subjected to in utero (Malloy, 1979). The investigator studied infants exposed to recordings of maternal voices and Brahms lullabies, but failed to find statistically significant differences between intervention and control infants in weight gain, motor control or mental development. Studies document sound levels in NICUs that regularly reach 55 to 75 dB in comparison to a noise level of 45 dB which occurs in most home settings, and may result in alterations in sleep activity of preterm infants in high risk nurseries (Philiban & Gray, 2002)

The effects of lighting on the premature infant have also been studied. One study found a mean light level from seven neonatal nurseries to be 470 lux with a range of 236 to 905 lux, which is significantly brighter than well baby nurseries (Robinson & Fielder, 1992). Early studies focused on sleep disturbances related to lighting, and sleep/wake cycles. Blackburn and Patteson (1991) studied 18 newborns admitted to a tertiary neonatal intensive care unit, who were placed either in total light or cycled light environment. The cycled light was 14 hours of light and ten hours of darkness. The infants in constant light showed gradual increases in the amount of night sleep, but not as much total sleep as the infants in cycled lighting. Mean heart rate (cycled = 158, continuous = 162, $p < .05$) of the infants in cycled light group was significantly lower than the continuous light infants, although no significant differences were found when comparing levels of activity or respiration.

Another study found relationships between light/dark cycles and improved sleep patterns and weight gain (Mann, Haddon, Stokes, Goodley, & Rutler, 1986). Infants in the experimental group were exposed to reduced light and noise between 7 AM and 7 PM. Although not apparent at time of discharge, differences were noted at three months after the expected date of delivery. The experimental infants spent more time asleep (19.5 hours vs. 15 hours, $p < 0.005$), less time feeding (3.5 hours vs. 4.2 hours, $p < 0.02$) and gained more weight (.5 kg, $p < 0.02$) than the control infants at an age of expected date of delivery plus 12 weeks.

Care Requirements for Premature Infants

The literature identifies five main categories of best practices for premature infant during the newborn period. The evidenced-based categories include developmental issues, skin care, feeding, skin-to-skin care and pain management (Beal, 2005).

A recent survey conducted of neonatal nurseries in the United States (Field, Hernandez-Reif, Feijo, & Freedman, 2006) found that many types of interventions are used with varying rates including skin-to-skin in the delivery room (83%), containment (86%), music (72%), rocking (85%), kangaroo care (98%), non-nutritive sucking during tube feedings (96%) and preterm infant massage (38%). Additional topics including managing environmental factors were also identified. For the purposes of this review, feeding issues will not be addressed in that it lacks direct relevance to the topic of interest.

The framework for Neonatal Individualized Developmental Care and Assessment Program (NIDCAP) is a summary document founded on the concepts that care for the newborn is based on the infant's behavioral and psychological cues (Byers, 2003). Developmental care should include management of the environment, flexed positioning, clustering of care, promotion of nonnutritive sucking, kangaroo care and activities to promote self-regulation and state regulation. Parents should be included in the care to promote bonding and attachment (National Association of Neonatal Nurses, 2000). Specifically, the premature infants require care that decreases stimulation and minimizes stress so that oxygenation saturation improves. Developmental care also decreases the need for exogenous surfactant and total parental nutrition and decreases rates of feeding intolerance (White-Traut, et al., 2004).

In another study (White-Traut, et al., 2002), infants who received multisensory interventions demonstrated increased alertness, faster transition to nipple feeding and decrease lengths of hospital stay. The infants also exhibited better motor and mental performances at one year of age than did the infants who did not receive the interventions. A study of cocaine-exposed newborns that received this multisensory intervention also found that stimulation promoted normal physiological and behavioral function in both the non-exposed and drug exposed infants (White-Traut, Studer, Meleedy-Rey, Labovsky & Kahn, 2002). For optimal growth and development, the key seems to be minimizing noxious stimuli and implementing techniques or stimuli that are positive and promote premature infant growth and development.

Infant massage has been studied extensively. One study showed that infants gain more weight and sleep less after only five days of massage (Dieter, Field, Hernandez-Reif, Emory & Redzepi, 2003). In this study the infants receiving massage gained on average 53% greater daily weight, [$F(1, 30) = 13.91$, $p = .001$]. Although the mechanism for the greater weight gain was not identified, another study demonstrated that massage may facilitate metabolic efficiency (Scafidi, et al, 1990).

An integrative review of the literature was performed on comfort touch in the NICU (Harrison, 2001). This review reported that physiologically fragile infants who receive gentle stroking and massage respond well with both decreased motor variability and decreased distress. Modrcin-Talbott, Harrison, Groer, and Younger (2003) confirmed these findings, and concluded that gentle human touch as a nursing intervention does not add additional stress or result in negative outcomes for premature infants. Two qualitative studies found infant massage to be beneficial in relieving parental and preterm infant stress (Beyer & Strauss, 2002; Ramsey, 2001).

Kangaroo or skin-to-skin (SSC) care promotes bonding and attachment and is a means of promoting better growth and development. The term kangaroo care is commonly used interchangeably with SSC. The name was chosen for the similarity to marsupial care-giving where the baby kangaroo is kept warm and close to the breast in the maternal pouch (Ludington-Hoe, 1990). Drs. Rey and Martinez (Whitelaw & Sleath, 1985) initially developed SSC in Bogota, Colombia. This simple and inexpensive technique impacts the rate of neonatal deaths due to cross contamination from shared bedding space and equipment in the nursery. SSC is the practice of the parent holding a newborn clothed only in a diaper on the parental chest skin-to-skin. The practice is associated with short-term and long-term positive effects for both the parents and the infants (Anderson, et al., 2003).

There is a significant amount of nursing research related to skin-to-skin or kangaroo care (KC) for premature infants (Anderson, et al., 2003; Anderson, Moore, Hepworth, & Bergman, 2005; Engler, et al., 2002; Ferber & Makhoul, 2004; Feldman, 2004; Johnston, et al., 2003; Ludington-Hoe, 1990). A review of the research concluded that KC is therapeutic and safe for preterm infants. KC enhances growth, facilitates attachment, and decreases mortality for premature infants (McGrath & Brock, 2002).

A randomized clinical trial of 34 mother-baby dyads found that preterm infants who were given KC were more likely to have more quiet sleep, cry less and have higher temperatures than those infants who did not receive KC (Chwo, et al., 2002). Despite well-documented outcomes for KC for premature infants, many physicians, NICUs and nurses are still reluctant to incorporate the specific practices (Engler, et al., 2002), especially with infants who are intubated. Although unfounded, other barriers to KC include fears of risk for greater heat loss, safety, unavailability of staff or parents and work interruptions (Anderson, et al., 2003).

Since the implementation of kangaroo care in the United States, research associates it with reduced infant mortality, decreased infection rates, fewer apnea and bradycardia events, increased lactation and decreased rates of maternal abandonment (Anderson, 1997). SSC significantly increases quiet sleep and reduces activity and energy expenditure in infants (Ludington-Hoe, 1990).

In addition to supporting feeding success for the mother/baby dyad, SSC stabilizes infant temperature (Galligan, 2006), breathing and heart rate (Ludington-Hoe, 1990). In non-randomized trials, maternal temperatures self regulate either up or down as needed, to maintain the infant in a neutral thermal condition. Parental positioning in a semi-upright posture facilitates the infant's respiratory efforts (Smith, 2007). Parents who participate in SSC seem more confident and are able to sooth their babies better when they become restless. Infants exposed to SSC spend more time in quiet sleep, which is critical for weight gain and growth (Ludington-Hoe, 1990).

As mentioned earlier, skin-to-skin care was first developed in Bogota, Colombia in 1979 in response to high infant mortality and limited resources (Whitelaw & Sleath, 1985). Traditionally, the unclothed, but diapered infant is placed on the mother's chest, between her breasts for mutual skin to skin contact. A number of randomized, controlled trials show it to be effective for promoting maternal-infant bonding (Ludington-Hoe, Thompson, Swinth, Hadeed, & Anderson, 1994), decreasing newborn apnea and bradycardia (Ludington-Hoe, Ferreira, Swinth, & Ceccardi, 2003), promoting breastfeeding, and decreasing infant crying in both term and preterm infants (Anderson, et al., 2005; Moore, Anderson, & Berman, 2007). Another author suggests that this approach is also valid treatment for neonatal hypothermia (Galligan, 2006).

A crossover design of 74 preterm neonates serving as their own controls tested the efficacy of skin-to-skin care in diminishing pain response to heel sticks (Johnston, et al., 2003). The investigators found that the infants' pain scores using the Premature Infant Pain Profile (PIPP) were significantly lower for infants in the kangaroo care at 30 seconds (difference, 1.5 points, $p = .04$), at 60 seconds (difference, 2.2 points, $p = .002$) and 90 seconds (difference, 1.8 points, $p = .02$) after heel stick compared to those in isolettes. The investigator noted that obtaining the blood specimen with the infant in the skin-to-skin position, was more difficult than when the infant was in the isolette.

Infant Pain

In spite of early misconceptions to the contrary, it is well documented that infants experience pain. Development of the sensory fibers begins early in the early weeks of gestation and is complete by the twentieth week (Valman, & Pearson, 1980). Significant research focuses on the development of infant pain measurement scales (Debillon, Zupan, Ravault, Magny & Dehan, 2001; Grunau, Holsti, Whitfield & Ling, 2000; Stevens, Johnston, Petryshen, & Taddio, 1996). There are a number of infant pain measures available with good reliability and validity.

Newborn pain assessment has been described with univariate and multivariate indicators. Most scales use either physiologic or behavioral indicators rather than both types of indicators. Physiologic indicators include increased heart rate, respiratory rate, and variability of oxygen saturation, blood pressure, palmar sweating, intracranial pressure, and stress hormone elevation, color changes, nausea, vomiting, gagging, hiccoughing, diaphoresis and dilated pupils (Grunau, et al., 2000). Premature infant behavioral pain indicators are used to assess premature infant pain, and include facial activity, crying, and body movements. Each of these indicators has a number of limitations including that they are time consuming, difficult to interpret, and lack specificity and sensitivity (Stevens, 1996).

Some pain assessment tools have published reliability and validity and are considered promising (Debillon, Zupan, Ravault, Magny & Dehan, 2001; Grunau, Holsti, Whitfield & Ling, 2000). These include the neonatal infant pain scale (NIPS), the Crying, Requires Increased oxygen administration, increased vital signs, Expression, Sleeplessness (CRIES) measure, and the premature infant pain profile (PIPP) (Stevens, 1996). The Echelle Douleru Inconfort Nouveau-Ne (EDIN) was validated with 76 preterm infants, has acceptable reliability with a coefficient range of 0.59 to 0.74, high internal consistency and a Cronbach's alpha from .086 to 0.94.

Research examines non-pharmacologic interventions including non-nutritive sucking, oral sucrose, swaddling and facilitated tucking, with varying degrees of success depending on the method and the specific procedure (Stevens, 1996, Cignacco, et al., 2007). Other non-pharmacologic interventions include kinesthetic and vestibular experiences such as rhythmic, repetitive and cyclic stimulation. In response to pain, preterm infants demonstrate a rise in hormonal and metabolic activity, causing changes in heart rate, respiratory rate, blood pressure and decreases in oxygen saturation and vagal tone (Stevens, 1996). Preterm infants are at greater risk for the consequences of pain due to the frequent and numerous procedures that are part of their early experience of life in a high-risk nursery.

The goals of preterm infant pain management are similar to that of adults and include minimizing intensity, duration and physiologic and behavioral cost of pain. In addition, the intervention should provide maximum relief with minimum risk, while facilitating growth. The Developmental Care framework developed by Als (1986) and colleagues includes restructuring the environment to reduce light and noise levels, sequencing care-giving interactions to avoid over stimulating the infant, and utilizing positioning and nesting to provide boundaries in an attempt to replicate the confinement of the uterine environment. There is no direct evidence that Developmental Care interventions reduce pain. Nonetheless, improved respiratory and feeding status, earlier discharge from the hospital and improved neuro-behavioral organization, reduce the levels of morbidity for premature infants. Developmental interventions have also been associated with decreases in infant stress levels and increased pain tolerance (Stevens, 1996).

The energy that is required to respond to stress and pain quickly depletes the premature infant's reserves, and therefore is not available for normal growth and development (Stevens, 1996). Animal and human studies show that pain during the neonatal period can have long-term deleterious effects (Allegart, et al., 2005, Buskila, et al., 2003). In preterm infants, pain can result in insensitivity to pain, decreased learning ability and immunosuppression (Allegaert, et al., 2005).

Infants pain is often difficult to distinguish from stress and distress. Stress and distress may be caused by many things the preterm infant is subjected to simply because she or he is living an extra-uterine life. Muscle tone, changes in posture and other specific movements are indicators of stress in preterm infants (Als, 1986). One study (Grunau, et al., 2000) identified that finger splay, brow raising and leg extension as distress signals, whereas twitches, startles, squirms and other body activity are associated with light sleep.

In a randomized controlled study of 54 preterm infants, using the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) coding system, changes in facial activity and heart rate were found to be the most sensitive markers of premature infant pain (Holsti, Grunau, Oberlander, Whitfield, & Weinberg, 2005). Crying is not specific to any particular stimulus, and may not be as well developed a pain signal in preterm infants as in full term infants (Fuller, 1991).

Sleep is absolutely essential for life, and necessary for normal growth and development. In the early newborn period, full term infants sleep 16 to 20 hours a day (McGrath, 2007). During sleep, the brain restores neurotransmitters and hormones such as melatonin and growth hormone and regeneration and healing takes place as protein production is increased (Bertelle, Sevestre, Laou-Hap, Nagahaptiye, & Sizun, 2007). For normal maturation of the neonatal brain to occur, deep sleep is necessary in addition to two other sleep states in the newborn; active sleep and quiet sleep (Bertelle, et al., 2007). Although preterm infants are able to sleep in SCNs and NICUs, the duration and quality of that sleep may be less than optimal. The constant light, noise and caregiving activities do not promote infant sleep, let alone the deep sleep that is necessary for neurological development. Temperature, sleep position and formula type are other factors that modify newborn sleep (Bertelle, et al., 2007).

A variety of interventions have been studied related to the promotion of preterm infant sleep. Some of the interventions that have been found to be effective include decreasing extremely bright light, cycled lighting to increase nocturnal sleeping (Brandon, Holditch-Davis, & Beylea, 1999), decreasing activity around the bedside and clustering care (Holsti, Grunau, & Whitfield, 2006), skin-to-skin holding (Messmer, Rodriguez, Adam Wells-Gentry & Washburn, 1997) and infant massage (Field, 1990). One study looked at the sleep of 33 preterm infants who did not have any ventilation support requirements. The study was prospective and utilized a crossover design, with each infant serving as its own control. Using computerized polysomnography the researchers were able to find that total sleep time was significantly higher for the DC conditions than in the control conditions (Bertelle, et al., 2007). When in the DC conditions, the total sleep time was 156.2 vs. 139.2 minutes, $p = .024$.

Complementary and Alternative Medicine

Almost fifteen years ago, the landmark complementary and alternative medicine (CAM) article was published and showed that approximately 33% of Americans were regular users of CAM modalities in 1990 (Eisenberg, et al., 1993). By 1998, the percentage had risen by 38% (Eisenberg, et al, 1998). Although these surveys showed that the typical CAM user is middle-aged, female, college-educated and with high income, other patient populations have adopted these approaches. A survey completed five years ago identified that 33% of American parents report using CAM for their child including infant massage, vitamin therapy and botanical products (Loman, 2003). In another study, nearly 50% of Turkish parents interviewed in a pediatric oncology unit reported the use of one or more CAM therapies (Gozum, Arikan, & Buyukavci, 2007). Current data suggest that 36% of adults in the United States use complementary or alternative therapies regularly, and when megavitamins and prayer specifically for health reasons are included, that number rises to 62% (National Center for Complementary and Alternative Medicine, National Institutes of Health, 2007).

Defining CAM can be challenging. The National Institutes of Health National Center for Complementary and Alternative Medicine (NCCAM) provides a simple and comprehensive definition. CAM is "a group of diverse medical and health care systems, practices, and products that are not presently considered part of conventional medicine" (NCCAM, page 1, 2007). Another way of further clarifying the difference between complementary and alternative is that complementary medicine is used with conventional medicine, while alternative medicine is used instead of or in place of conventional medicine. More recently, another term has emerged to describe the combination of mainstream medical therapies and CAM therapies. This new term is integrative medicine. The integrative medicine framework has encouraged the provision of some high quality scientific evidence of safety and effectiveness (NCCAM, 2007).

CAM continues to evolve and occurs in many different modalities and therapies. Guerrera (2003) describes five main categories: alternative medical systems, mind-body interventions, biologically-based therapies, manipulative and body-based methods, and energy therapies. Many of CAM interventions overlap or fall into more than one of the five aforementioned categories.

Examples of alternative medical systems include homeopathic and naturopathic medicines such as Traditional Chinese medicine and Ayurveda. Homeopathy is based on a principle of like cures like, such that medicine or interventions prescribed will match a patient’s symptoms. Conversely, allopathic or western medicine prescribes a substance that opposes the patient’s symptoms (Schnare, 2000). Naturopathy is the combination of herbs, dietary changes, massage and relaxation. Traditional Chinese medicine includes acupuncture, acupressure, moxibustion, and herbal therapy and specific exercises such as T’ai Chi. Ayruvedic medicine originated in India and includes practices relating to diet, massage, enemas, purging and meditation to balance three basic body humors. The practice of yoga might also be considered to be CAM due to its complementary relationship to Ayurvedic medicine.

The main stream population now accepts and uses many mind-body interventions. These interventions include the use of support groups and cognitive behavioral therapy. Prayer, meditation, art, music and dance are still considered to be truly CAM. Biofeedback utilizes monitoring equipment to provide feedback of muscle and autonomic nervous system activity in visible or audible signs. Aromatherapy uses smells, both pleasant and unpleasant to induce health benefits including relaxation and emotional dampening.

Biologically based therapies use natural substances such as herbs, foods and vitamins and includes homeopathy and naturopathy. Interest in the treatment of some diseases and chronic symptoms with vitamins and minerals remains high. It is unclear if either type of supplement is necessary if an ideal diet is followed. A systematic review by Bjelakovic, Nikolova, Gludd, Simonetti & Gluud (2007) concluded that treatment with beta-carotene, vitamin A and vitamin E might increase mortality in adults, while the effectiveness of vitamin C and selenium need further study. Many of our current standard medications such as aspirin, narcotics and hormonal contraceptives have origins in herbs and plants. Herbal therapies are abundantly available in grocery stores, health food stores and pharmacies, although their safety and efficacy in children is not established.

Practitioners of chiropractic treatments are the most commonly consulted CAM care providers in the United States, and their work falls under the category of manipulative and body-based therapies (Schnare, 2000). Exercise may also be considered in this category in that there is a wealth of information that suggests regular exercise decreases the risk of heart disease and diabetes improves mood and increases flexibility. Massage is another body therapy that has been used in many cultures for a variety of symptoms and conditions.

There are two types of energy therapy, biofield and bioelectromagnetic-based. Examples of biofield therapies are Reiki, Qi Gong and therapeutic touch. The bioelectromagnetic therapies employ the unconventional use of electromagnetic fields such as pulsed fields or alternating current fields (Guerrera, 2003).

Complementary and Alternative Therapies in the Nursery

The following section will discuss utilization and efficacy of CAM therapies are most frequently employed in SCNs and NICUs. CAM in the nursery is most often used to replicate the intrauterine environment and is referred to as developmental care.

Many types of sensory stimulation are beneficial for preterm infants. The least mature sensory systems of the preterm infant are visual and auditory, yet those two systems receive most of the stimulation in a SCN or NICU setting (Liaw, 2000). In contrast, the more mature systems, tactile, gustatory and vestibular receive the least amount of stimulation (Liaw, 2000).

Light

The negative effects of light on the preterm infant have previously been discussed. Light does have significant positive value when one considers phototherapy's recognized effects of diminishing bilirubin and activation of vitamin D. Using this as a basis, practitioners speculate that other light wavelengths might have other physiologic effects (Jones & Kassity, 2001).

Generalized lighting in the nursery helps to establish circadian rhythms that decrease alterations in endocrine function that result from unremitting light stimulation. As early as the late 1970's, practitioners began to advocate a dimly lit environment (LeBoyer, 1978). One method to support the development of mature day/night rhythms in SCNs and NICUs is to cycle between normal and low level lights. Studies exposing preterm infants to cycled lighting find increased maturation of behavioral organization, (Blackburn, & Patteson, 1991), faster weight gain (Mann, et al., 1986), and development of rhythms in temperature, heart rate, and activity levels (D'Souza, et al., 1992).

Noise

As discussed earlier, noise has many well-known adverse effects related to hearing damage and contributes to fatigue, hyper-alerting, insomnia and decreased appetite. Sound can be detrimental to preterm infants, and correlates with a decrease in oxygen saturation and increases in heart rate and sleep disturbances (Kellman, 2002).

In addition to minimizing sound, and decreasing volume, sound can be used in positive ways. Music is one positive method that is low cost and beneficial to patients as well as caregivers. Music therapy has become increasingly popular in the last 15 years, and a number of auditory stimuli are therapeutic or at least soothing including simulated heartbeats, classical music and record maternal voices. A number of studies have investigated these claims. In one study, newborns showed significant decreases in agitation (experimental 463 vs. control 596, $p < .001$) after listening to transitional tapes of music with a flowing, lyrical melody and a rhythm that approximates the heart rate of an adult (62 and 80 beats per minute) (Kaminski, & Hall, 1996).

Walker, Grimwade & Wood (1971) demonstrated changes in fetal heart rate that corresponded to auditory stimulation. In another study where infants received music therapy six times daily, preterm infants had shorter hospital stays ($df = 25$, $t = 1.912$, $p < .05$), and lower initial weight loss ($df = 25$, $t = 1.962$, $p < .05$) (Caine, 1991). The music therapy group had significantly lower weight at discharge than the control infants ($df = 25$, $t = 2.762$, $p < .01$). The investigators believed this may have resulted in shorter NICU stays.

Lullabies and classical music increase weight gain and non-nutritive sucking, and decrease episodes of oxygen desaturation, and distressed behaviors (Standley, 2002). In one study, preterm infants were randomized to three groups, live music, recorded music and no music (Aron, et al., 2006). The experimental groups were exposed to music at 55 to 70 dB over three days. Infants exposed to live music demonstrated significantly reduced heart rates (150 beats/min before therapy vs 127 beats/min after therapy, $p < .001$) and improved behavioral scores (3.1 before therapy vs. 1.3 after therapy, $p < .001$), while infants exposed to recorded music or no music had no significant change in these parameters. Premature infants listening to music become quiet, and appear to fall asleep. These activity decreases may decrease energy expenditure and enhance weight gain (Kemper, & Danhauer, 2005).

Aromatherapy

Aromatherapy involves using aromatic and essential oils obtained from herbs and flowers to alter a person's mood or behavior. Humans respond immediately to scents by releasing neurotransmitters that in turn can cause calming, reduction in pain or stimulating effects (Gentz, 2001). Lavender has been studied the most with insomnia and stress in adults. Although aromatherapies are frequently recommended to reduce parental stress and infant anxiety associated with colic, the literature is sparse on the use of aromatherapy in high-risk nurseries. One study examined the use of a familiar odor during venipuncture. Infants who were presented with a familiar odor during venipuncture showed no significant increase in crying during the procedure compared to baseline levels. However, infants presented with an unfamiliar odor or with no odor during the venipuncture had a significant increase in crying (mean 12.28 seconds, SD =

7.43 unfamiliar odor group) (mean = 7.15 seconds, SD = 8.86 familiar odor group) (Goubet, Rattaz, Pierrat, Bullinger, & Lequien, 2003). This is a potential area of research since studies show that all infants have very sensitive abilities to detect and identify smells (Jones & Kassity, 2001).

Touch

The tactile system is the first system to develop in the preterm infant and therefore is the most mature. As a result, many studies explore treatments that use of touch in one form or another. One study (Garcia & White-Traut, 1992) found that preterm infants recovered quicker from apneic periods when receiving combined oral, tactile and olfactory intervention tactile stimulation compared to babies who received tactile stimulation alone (5.99 seconds vs. 6.59 seconds, p = .0101). These findings suggest that particular attention should be focused on interventions that are tactile in nature.

Preterm infants can be highly sensitive to stimulation and some authors describe a term called tactile vulnerability (Case-Smith, Butcher, & Reed, 1998). Tactile vulnerability (TV) involves hyper-reactivity to, and lack of tolerance for touch. Research results to date are somewhat conflicting. Some studies find that preterm infants may be less responsive to tactile stimulation (Barnard, 1973), while other studies suggest that preterm infants have a higher incidence of tactile defensiveness and negative responses (Case-Smith, et al., 1998). Another study suggests that infants with longer hospital stays develop tactile aversion as a result of the many painful procedures they undergo (Weiss, & Wilson, 2006).

Sensory deprivation in older children can result in failure to thrive. It is less clearly understood how the preterm infant is affected by the lack of the tactile stimulation than would normally occur in utero. Phillips & Moses (1996) studied the effects of touching and holding on preterm infants. Although there were no significant differences in caloric (experimental 133, control 123, $p = 0.564$) or volume (experimental 307, control 293, $p = .469$) intake, the experimental infants had 42% greater weight gains (experimental 236 gms, control 181 gms, $p = .046$). As a result of these and other findings, neonatal nurses adopt a variety of interventions including kangaroo care, infant massage, positioning and containment in an attempt to replicate intrauterine stimulation.

Massage is another touch modality that the health care team and the parents can use to impact infant outcomes. Massage is performed in a variety of styles or modes. Massage relieves muscle tension, reduces stress, and evokes calm feelings. Infant massage is by no means a new concept and is found in Indian texts as far back as 1800 BC and in China as early as 2760 BC (Maninous, 2002). Western culture has been slower to adopt this modality, but it has been gaining popularity since the early 1980s (Field, 1990).

Massage is a component of developmental care in nurseries but in no means is a main stay or routinely practiced. The vast majority of studies investigate infant massage with preterm infants. A meta-analysis of 19 studies on stimulation, researchers estimate that 72% of infants who receive some form of tactile stimulation are positively affected (Ottenbacker, et al., 1987). The medical and nursing literature identifies 30 physical and psychological benefits, 20 of them of particular benefit to the neonate (Beachy, 2002). Infant massage enhances the mother-infant interactions of substance abusing recovering mothers (Porter & Porter, 2004), decreases crying in infants with cerebral injuries (Ohgi, Akiyama, Arisawa, & Shigemori, 2004) and improves infant weight gain and sleep after only five days of massage (Dieter et al., 2003). Other studies on infant massage show significant weight gain in cocaine and HIV-exposed infants (Wheeden, et al., 1993; Scafidi, & Field, 1997). Infant massage is controversial because of the minimal touch policies that exist in many SCNs and NICUs (Field, 2002). These policies may have been developed due to a misinterpretation of the data reviewed in the Cochrane report (Moore, Anderson, & Bergman, 2007).

Another study demonstrates weight gain in preterm infants who receive massage, but also suggests positive effects on later growth and development (Field, Scafidi, & Schanberg, 1987). The massaged infants gained more weight (experimental 25 gms, control 17 gms, $p = .0005$), and their hospital length of stay was six days shorter on average with a cost savings of approximately $10,000 per infant. Researchers in another study (Scafidi et al., 1990) found that treatment infants had greater daily weight gain ($m = 33.6$ gms) than control infants ($m = 28.4$) $p < .003$.

Facilitated tucking

Facilitated tucking is another approach that stimulates the preterm infant's tactile system. Facilitated tucking is defined as the gentle positioning of an infants arms and legs in a flexed midline position, close to the body while the infant is in either a side-lying, supine or prone position (Cignacco, et al., 2007). Newborns are accustomed to containment within the confines of the uterus and are comforted by the boundaries exerted upon the top of their head, extremities and feet. Swaddling is a specific example of containment. Swaddling is the art of snugly wrapping the neonate in a blanket for warmth and security. It keeps the neonate from being disturbed by its own startle reflex, and helps to calm the neonate.

Boundaries also take the form of caregiver's hands, rolled blankets and specifically designed nests. A prematurely born infant is not able to independently maintain itself in a position of flexion. The use of facilitated tucking allows the infant to gain a sense of postural security, promotes normal motor development, and aids in energy conservation through heat retention (Cignacco, et al., 2007). In this position, the premature infant is able to use her hands to grasp and hold and for non-nutritive sucking. These are self-regulatory skills and allow the infant to better cope with minor pain or stress (Als, 1986).

A prospective randomized crossover examined the effectiveness of facilitated tucking on behavioral pain reduction in preterm infants during endotracheal suctioning (Ward-Larson, Horn & Gosnell, 2004). The investigator enrolled a purposive sample of 40 infants who served as their own controls. When the infants received facilitated tucking during the suctioning periods, they were found to have a lower, statistically significant difference in pain. When tucked, the mean score was 8.95 (SD 2.06), a mean of 13.75 (SD 2.24) with $p < .001$ when not tucked (Ward-Larson, et al., 2004).

Using a repeated measures design, another study enrolled 30 preterm neonates to test the effectiveness of facilitated tucking to manage of heel stick pain (Corff, Seideman, Venkataraman, Lutes & Yates, 1995). These investigators found that neonates who received the treatment demonstrated lower mean heart rates (experimental 149.1, control 154.9, $p < .04$), shorter mean crying times (experimental 0.261 minutes, control 2.289 minutes, $p < .001$), shorter mean sleep disruption (experimental 1.856, control 9.345, $p < .001$) and fewer sleep state changes (experimental 2.867, control 6.067, $p < .003$) than those who did not. The authors concluded that facilitated tucking is an effective comfort measure.

A third study looked at the effects of facilitated tucking during routine care of preterm infants (Hill, Engle, Jorgenson, Kralik, & Whitman, 2005). This study used repeated measures, a random sequencing design, and a convenience sample of 12 preterm infants. The infants served as their own controls. The researchers evaluated the infants with the Premature Infant Pain Profile (PIPP) during two care giving conditions. The results showed a significant difference in the stress levels with facilitated tucking. Nine of the twelve infants had lower PIPP scores during the treatment intervention (experimental 8.5 ± 0.8, control 11.3 ± 0.7, $p = .013$).

Swaddling

Swaddling, a specific form of containment, is used in many instances, and modifies the premature infant’s tactile system. When swaddling is incorporated into neonatal care, flexed, midline arm postures should be achieved, allowing enough space for the neonate to move the arm, especially with hand to mouth maneuvers for self soothing (Sweeney & Gutierrez, 2002).

In a study by Fearon, Kisilevsky, Hains, Muir and Tranmer (1997), 15 premature infants in a random crossover trial were observed during blood sampling procedures. Swaddling infants 31 weeks post-conceptual age or greater significantly reduced behavioral disturbances ($SaO2$: swaddled 92.7, control 94.1, p , .05, facial activity: swaddled 2.5, control 2.7, $p < .05$, state score: swaddled 2.3, control 2.5, $p < .05$).

In another study, ten preterm infants underwent serial video recording. The infants were observed in the supine position, both when lying in a nest and outside the nest at three different post-conceptual ages (Ferrari, et al, 2007). This study examined the effects of nesting, or partial containment provided by two rolled blankets on posture and spontaneous movements. While nesting, infants more often displayed a flexed position. The investigators also found reduced abrupt movements and frozen postures in the infants when lying in the nest.

One study compared swaddling and containment (Huang, Tung, Kuo, & Ying-Ju, 2004). This crossover experimental study compared 32 infants during and after heel stick procedures. Infants who were swaddled displayed a return of heart rate and oxygenation saturation measurements back to baseline sooner than the infants who were contained ($p < .05$). The PIPP pain scores of the swaddled infants were also lower. However, none of these differences were found to be significant.

Positioning

Although positioning is not specifically considered a tactile approach it is developmentally appropriate for the preterm infant and a critical component of developmental care. When the infant's cues suggest over-stimulation, caregivers use positioning strategies and reduction of stimulation to help the infant self-regulate. Positioning is pivotal because premature infants often lack the capability to maintain flexion of arms and legs, which is necessary for self-soothing and proper muscular development (Griffin, 2000). Effects of this type of positioning on infant's autonomic, motor and self-regulatory systems have been studied.

An early study by Brackbill, Douthitt, & West (1973) focused on the differences between prone and supine positioning and found that full term infants in the prone position had increased sleep state times(prone 36.00, supine 24.55, $p < .05$), moved less (prone 0.59, supine 1.49, $p < .01$) and cried less (prone 3.19, supine 15.82, $p < .01$).

Levy, et al. (2006) studied positioning and found that preterm and low birth weight infants in a prone position show significantly lower rates of energy expenditure as measured by inspiratory work of breathing (mean scores: prone 0.46, supine 0.52, $p = 0.46$), and respiratory rate (mean scores: prone 60, supine 53, $p = .08$)

There are four primary aims of positioning procedures for neonates. Those aims are to support posture and movement; optimize skeletal development and biomechanical alignment; provide controlled exposure to varied proprioceptive, tactile, and visual stimuli; and promote a calm, regulated behavioral state (Sweeney & Gutierrez, 2002). A common measure used to relieve discomfort in neonates is placing the infant in a prone position. It is believed this position is effective due to the counter pressure of the mattress against the chest wall that decreases discomfort. These are similar to the calming affects observed when an infant is placed chest to chest with a parent or caregiver. In addition, the prone position promotes better breathing and oxygenation in premature infants (Fox & Molesky, 1990). It is important to note that the benefits of prone positioning for premature infants are documented before and after back to sleep guidelines. This has led to some confusion, since the current positioning recommendations from the American Academy of Pediatricians for full term infants is supine.

A retrospective descriptive study of 15 preterm infants tested the effects of positioning on infant self-regulatory behavior (Grenier, Bigsby, Vergara, & Lester, 2003). The number of self-regulatory and stress behaviors was related to side-lying and un-nested position (1.985, $p = .001$) in the highest ratios, and to the nested prone position (-0.477, $p = .717$) in the lower ratios. Infants performed the fewest number of stress related behaviors in the prone nested (-0.439, p = .719), prone un-nested (-0.344) and side lying positions (-0.308, p = .0325). The authors suggested that these positions may benefit preterm infants by reducing the need for motor based self-regulatory behaviors and as a result, conserving energy for growth.

A randomized controlled trial investigated the effects of prone position, normal saline and oral sucrose with non-nutritive sucking on 31 premature infants (Stevens, et al., 1999). Positioning the infant in the prone position alone did not decrease PIPP pain scores (F = 2.24, p = .137) (Stevens, et al., 1999). Infants who received either the normal saline (F = 16.20, p <. 0001) or sucrose (F = 24.09, p < .0001) via a pacifier demonstrated significantly reduced PIPP pain scores. The authors note the frequency of the painful procedures significantly influences the pain response (F = 3.59, p = .01) (Stevens, et al., 1999).

Another randomized controlled trial compared prone versus supine positioning in 32 premature infants (Grunau, Linhares, Holsti, Oberlander, & Whitfield, 2004). This study found that the prone position promoted deep sleep when the infants were left undisturbed. However, prone and supine position did not mitigate the pain elicited with heel sticks (F [1, 36] = 0.88, p = .35).

A fourth study examined the effects of prone versus supine positioning on the behavioral states of mechanically ventilated premature infants (Chang, Anderson, & Lin, 2002). Using a crossover design, 28 infants were randomly assigned to supine/prone or prone/supine sequence. Behavioral states and stress signs were recorded and analyzed. Premature infants in the prone position cried less, had less active sleep, more quiet sleep states and fewer stress responses of startle, tremor and twitch.

Positioning is of particular importance for neonates who experience withdrawal from intrauterine drug exposure, as well as in the prevention of sudden infant death syndrome (SIDS). Neonates withdrawing from the substances they received while in utero are better able to self-calm themselves when placed with the hands near their mouth, (Beauman, 2005). According to American Academy of Pediatrics (AAP) the incidence of SIDS decreased significantly since the release of the AAP recommendation regarding supine sleep positioning (American Academy of Pediatrics, 1992). The recommendation states that term infants should be placed for sleep in non-prone positions; however, the AAP no longer recognizes side sleeping as a reasonable alternative to supine sleeping (AAP, 2005)

Containment

Containment is a practice whereby the preterm infant is positioned and tactilely stimulated in a way that mimics the posture a fetus assumes in the uterine environment. Containment provides a restriction of motor movement that would occur in the close confines of the uterus. Theoretically, this type of positioning attenuates the preterm infants' physiologic and behavioral response to its environment.

There is little research that documents the effectiveness of this practice although it is widely advocated (Lotas & Walden, 1996). One study noted that contained infants had significantly lower mean heart rates (154.9 vs. 149.1, $p < .04$), shorter mean crying (mean scores: 0.261 vs. 2.289, $p < .001$) and sleep disruption times (mean scores: 1.856 vs. 9.345, $p < .001$) and fewer sleep stage changes (mean scores: 2.867 vs. 6.067, $p < .003$) after painful heel-stick procedures than non-contained infants (Corff, et al., 1995). When contained correctly, the infant regulates itself by sucking his/her hands or pacifier as well.

Over time, containment should be decreased, which allow the infant to hold its' limbs in flexion as competency in autonomic and motor stability is developed (Als, 1994).

Stress Response and Management

Stress response in preterm infants is demonstrated by changes in their autonomic and motor systems and changes in behavioral states. According to the synactive theory postulated by Als, (1982) all three systems continuously interact with one another, and an instability in one system may very well produce instability in others. The synergistic effect of this strain on premature infants is a compelling reason to identify causes of stress and develop methods to alleviate or minimize stress. A reduced stress environment is theoretically more supportive of normal growth and development and may in turn lead to improved outcomes and shortened length of costly high risk nurseries stays.

Stress and pain management in preterm infants is managed with either pharmacological or non-pharmacological methodologies. The pharmacological approach is the preferred method for managing severe pain; and is generally limited to very invasive surgical procedures. Pharmacological pain management is not without risks including respiratory depression and physical dependence (Stevens & Franck, 1995). Non-pharmacological methods to support the preterm infant through periods of stress or pain are more commonly used for minor pain and stress. These measures are assumed to work by activation of the gate control mechanism (Melzack & Wall, 1965).

Infant Pain and Pain Management

One of the issues with preterm infant pain management is determining what signs constitute severe pain in a premature infant. Both preterm and full term infants escalate hormonal and metabolic responses to pain or stress including increases in cortisol, catecholamines and insulin (Allegarert, et al., 2003). Changes in behavior also occur, including the typical facial expression of pain consisting of bulging brows, eyes tightly squeezed shut, vertically stretching and horizontally opening the mouth with the tongue tautly cupped (Grunau, et al., 2000). Physiologic changes include increased heart rate, and respiratory rate, and variability in oxygen saturation, palmar sweating, gagging, hiccoughing and sweating (Grunau, et al., 2000). Multivariate measures that have some published reliability and validity include the Neonatal Facial Coding System (Grunau & Craig, 1987), the Neonatal Infant Pain Scale (NIPS) (Attia, Amiel-Tison, Mayer, Shnider, & Barrier, 1987), the crying, requires increased oxygen administration, increased vital signs, expression, sleeplessness (CRIES) (Krechel & Bildner, 1995), and the premature infant pain profile (PIPP) (Ballantyne, Stevens, McAllister, Dionne, & Jack, 1999, Jondisdottir & Kristjansdottir, 2005).

There are a number of simple non-pharmacological methods to support the premature infant in times of pain and stress. Containment, swaddling and facilitated tucking have already been discussed. Another effective method to comfort premature newborns is non-nutritive sucking. Non-nutritive sucking (NNS) is a non-pharmacological approach that effectivly stabilizes and supports infant physiological and behavioral organization (Pickler & Reyna, 2004). NNS refers to the placement of a pacifier in an infant's mouth to promote sucking behaviors without the nutrition that would be supplied by breast milk or formula. NNS will not receive further attention in this paper due to its lack of context to the therapeutic pillow. A third method that has been previously discussed to manage pain and stress is positioning (Grunau, et al., 2004).

A review of the literature identifies a number of recommendations for further research with regards to non-pharmacological and tactile methods to help preterm neonates cope with their stressful environments. Results for a number of the developmental care interventions have been mixed, while others show evidence for inclusion into clinical practice. None of the studies reviewed included any information on cost effectiveness analysis. No studies were identified that discussed or explored treatments similar to the application of warmed, flax seed pillows.

In order to provide effective care to premature newborns, health care providers must be knowledgeable about recognizing stress in these infants, and how that differs from full term infants. In addition, clinicians must provide care with proven effectiveness. Left untreated, stress in premature infants has the potential for lifelong consequences including cognitive disorders, poor motor performance and psychosocial disorders (Hack, Klein, & Taylor, 1995). Many treatments are currently available and are very effective in assisting the premature infant to deal with pain and stress.

All humans, including premature infants, who are repeatedly exposed to painful and stressful environments eventually, are unable to successfully respond due to fatigue (Hart, Freel & Milde, 1990). In normal situations, the prematurely born infant would still be in utero, and not undergo the frequent, unusual and painful sorts of tactile stimulation that she is subjected to as a part of typical high-risk nursery care. For all intents and purposes, the fetus would rest as needed without interruption. The ability to regularly rest allowsthe fetus to use its resources for growth and development, rather than to expend energy coping with a relatively toxic environment.

Soothability

No articles were found during the review of the literature that identified a single variable that impacted “soothability”. Soothability is the ability of a newborn to use resources within its environment to calm and comfort itself. Soothability is a complex concept, and as a result, requires a number of markers to measure it.

Soothability markers include absence of pain, increased weight gain and decreased activity. Examining or measuring one marker alone is not sufficient. Selecting only pain or absence of pain as the marker for soothability implies that merely narcotizing a premature infant sufficiently will enable them to adjust to the high-risk nursery environment. No studies were identified that supported this premise. Secondly, decreased activity alone does not suffice as a marker of soothability, as not studies demonstrated that sedated or paralyzed infants are soothed and gain more weight. Finally, weight gain alone also is inadequate to measure soothability. Merely oversupplying the premature infant with increased caloric intake does not increase the soothability of the infant. Overfeeding infants is associated with negative outcomes due their less developed gastrointestinal tract and results in retention, vomiting and abdominal distension (Broussard, 1995). By definition in the model, soothability is an infant that able to gain weight due to the effective management of pain or discomfort that result from stressful events or procedures. A comfortable and relaxed infant copes with her environment better and optimally uses her resources to gain weight. In order to measure the soothability of premature infants, multiple markers are required.

Recognizing that need for rest and to prevent or minimize fatigue, caregivers use a number of strategies and interventions to support premature infants. Methods found to be effective and supported by research include facilitated tucking, oral sucrose (Pasero, 2004; Stevens, Yamada & Ohlsson, 2004), and kangaroo care. Other interventions, such as positioning, have mixed results, and other areas are yet to be investigated. More research is needed to evaluate touch and heat as pain or stress management (Byers & Thornley, 2004). While medications are necessary to alleviate moderate to severe pain, non-pharmacological pain management strategies can be used, during mild procedural pain to eliminate stress and fatigue and sooth premature neonates.

Pillows are one positioning option that is popular in the literature (Baharestani, & Ratliff, 2007; Libster, 2008; Vaivre-Douret, & Golse, 2007; Bonner & Mainous, 2008; Hackley, & Merritt, 2008). Specifically, pillows are filled with a variety of substances including, rice, flax seed, and an assortment of herbs. This study hypothesis proposes that a pillow provides both compression and retention of warmth to tissues. A cotton flannel, flax seed filled pillow was placed on the premature infant's back. It is suggested that the action of compression helps to decrease tension and pain (Melzack & Wall, 1965).

In adult populations, compression and heat are used for pain management. Intuitively, the use of both therapies in the premature population may seem appropriate, especially given the difficulties that premature infants experience with thermoregulation. Hypothermia is an unwanted, yet common complication of preterm infants and results from increased heat loss and immature or absent thermoregulatory mechanisms (Dollberg, Demarini, Donnovan, & Hoath, 2000; Simbruner, Ruttner, Schulze, & Perzlmaier, 2005). Premature infants often require an environment with ambient temperatures that exceed their skin temperatures in the first few days of life, and are therefore placed in incubators that provide warmer than normal conditions. Premature infants have a thinner stratum corneum, and the placement of a heated pillow may place them at risk for skin damage (Lyon, Pikaar, Badger, & McIntosh, 1997; Ducker, Lyon, Ross-Russell, & Bass, 1985). As a result of all these factors, in this study, the pillow was not be heated any more than the ambient temperature surrounding the infant.

Gaps in the Literature

Nurse researchers have made significant contributions to nursing management of preterm infants. These nursing interventions focus on areas including developmental care, neonatal skin care, skin-to-skin care and pain management (Als, 1982; Moore, Anderson, & Bergman, 2007; Stevens, et al., 1996; Pasero, 2001). As a result of this, these are research guidelines for neonatal skin care, and many pain assessment tools have been developed that are valid and reliable. However, not all aspects of developmental care have been examined, nor have all types of interventions been studied to identify the impact on premature infant growth.

Family centered care is ripe for further enquiry and development. Much of the research focuses on children who are accompanied or visited by their parents. No real advancement has been made in the care of the unaccompanied child or infant, nor for the infant whose parents provide sub-optimal care. Investigations of the types of parental involvement that most benefit the newborn while being acceptable to the parents are needed.

Numerous studies identify best practices for preterm infants. Many of the studies are descriptive in nature, or included small sample sizes, thereby limiting the generalizability. Still other studies are limited by qualitative design or use of case studies. Perhaps of greater concern is the limited degree to which neonatal nurses employ many of the research specified techniques. Nurse researchers must work collaboratively with bedside nurses, administrators and parents to study those clinical issues that are of great importance to all the involved stakeholders. Of particular interest are interventions that are simple, cost effective and that require minimal training and education, so that parents may have a larger role to play in the care of their infants.. Further research must be done on the effective use of pain scales, outcomes of skin-to-skin care and infant massage for all infants. Tactile stimulation and positioning also need further exploration to develop interventions that improve short and long term infant outcomes. Although there is no scientific literature regarding the benefits of compression in preterm infants, this simple and inexpensive intervention requires exploration as a potential method to assist premature newborns adapt to environment that is considerably different from their experience in utero.

Theoretical Framework

Both of the frameworks, Developmental Care and Family Centered Care, previously discussed, offer insights into the care of premature neonates for nursing and other disciplines. These two frameworks uniquely apply to the parents and families of these prematurely born babies. Neither theory, however, fully describes the experience of premature newborn in special care nurseries with regards to response to stimuli and measures that facilitate transition to extra-uterine life. In an effort to more fully describe the premature infant's experience and test interventions, a new theory is proposed. This theory, called Soothability in Premature Neonates attempts to represent this lived experience.

Theory is an articulated view of reality. The model presented below begins with the schematic depiction of the exchange of information via the interaction between the nurse and the parent(s). This interaction allows the nurse and the parent(s) to make decisions regarding the care of the newborn in order to optimize outcomes for the newborn. The model depicts the bombardment of stimuli, both positive and negative, that may overwhelm the newborn, thereby causing the newborn to become fatigued. In order for the premature neonate to cope with the environment which is so very different from the intrauterine experience, the premature newborn must be supported by interventions provided by caregivers, including the nurse and the parent(s). These interventions, regardless of method or format, theoretically allow the preterm neonate to soothe him/herself. Ultimately, the neonate then is able to devote more resources towards growth and development as opposed to using precious energy to respond to the environmental stimuli that is interpreted as stressful or negative. Figure #1 is a visual depiction of the theory and its components.

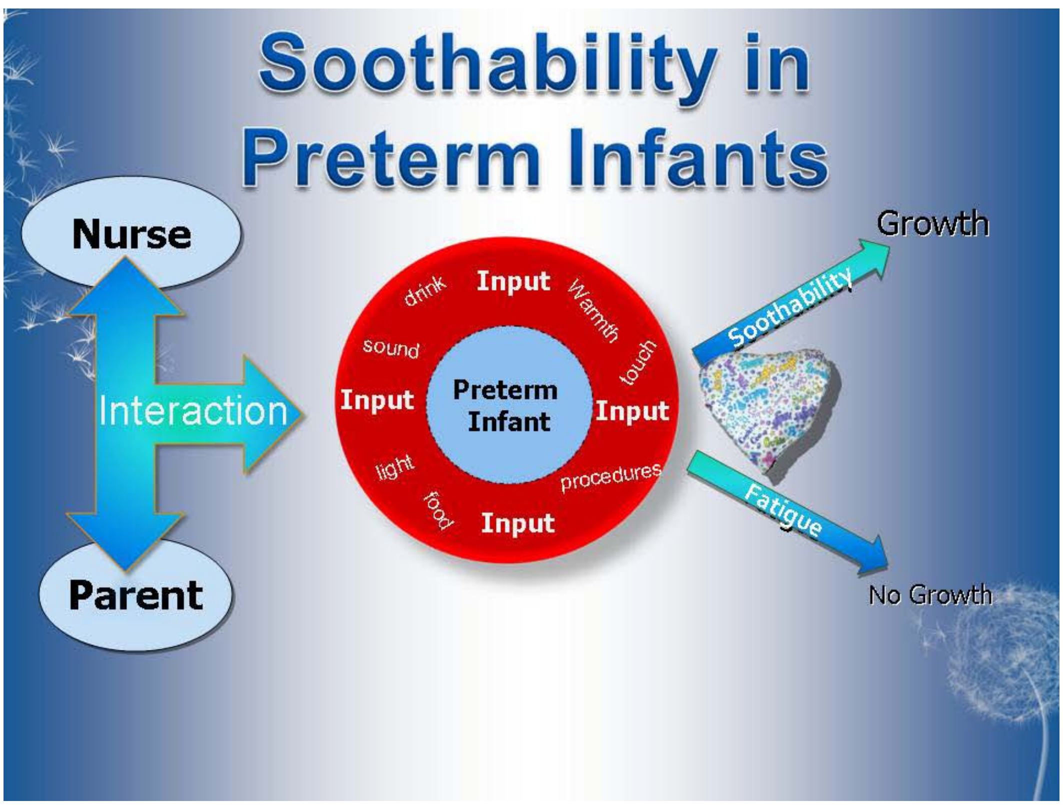

Figure 1: Soothabilty in Preterm Infants Model

Infant Organization and Self-Regulation

As a result of being born early, the premature infant is not ideally equipped to deal with her new and very different environment. The uterine environment is dark and warm, filters sound, and provides snug boundaries and frequent vestibular changes. The isolette is often bright, noisy and full of frequently occurring noxious stimuli. A major concern is the influence of this environment on the organization and development of behavior in the preterm infant.

An important consideration in the development of the premature infant is the consolidation of states of consciousness, which occurs over a period of time but is not consistent between premature infants (Kang & Barnard, 1979). Initially, the premature infant is generally unresponsive and indifferent to stimuli. With maturity, the infant develops more defined states and is more responsive to stimuli in the environment. Due to a general lack of maturity in all organ systems, the premature infant has less ability to handle incoming stimuli of any type, and to adapt her or his responses, or in this model, less ability to soothe him or herself. The stressful environment of the high-risk nursery tends to cause inhibition of normal growth and development (Craig, Whitfield, Grunau, Linton, & Hadjistavropoulos, 1993).

One way of assessing the premature infant's readiness or ability to respond to the environment is through measuring state system organization. This system is a fundamental component of the infant's neuro-developmental function. State organization allows term infants to adapt to their environment, achieve biological rhythms and regulate interactive sequences with their caregivers (Als, 1986). The full term infant demonstrates an increasing state organization as measured by the capacity to control their sleeping and waking periods. This requires the ability to tune out negative stimuli to maintain restful sleep. State organization allows the full term infant to interact with caregivers, or shift its gaze, look away and comfort or soothe itself. In contrast, the preterm infant has more difficulty coping with all the stimuli, and lacks the ability to tune it out when needed (Als, 1986).

Premature infants have more difficulty filtering out noxious stimuli and, are less prepared to be able to self-comfort themselves. Premature infants demonstrate hyper-responsivness to the environment and spend more energy coping with the environment, and result in signs of stress such as changes in muscle tone, irregular respirations, irritability and looking away (Als, 1986). State organization means that the newborn is able to manage behavioral and physiologic systems in response to changes or stimuli from the environment. The lack of state organization resulted in the development of a variety of interventions to assist the premature infant to adapt to the extra-uterine environment including facilitated tucking, containment and developmental positioning. The model, shown above, visually represents this series of events. This model includes the use of flax seed pillows to assist the premature infant to adapt to the environment and enable them to soothe themselves, and better utilize ph physiologic reserves for growth.

Key Terms and Concepts of Soothability in Premature Neonates

Concepts that are important in this model are FCC, DC, Soothability, interaction and fatigue. FCC and DC were previously defined. Soothability is the third key concept within the model, and speaks to the ability of a newborn to use resources within her environment to calm and comfort herself. Soothability is defined as the ability of the newborn to quiet and calm itself with assistance provided by the nurse or parent(s).

Assistance from caregivers may take many forms, however in this study the assistance comes in the form of the flax seed filled pillow. It was hypothesized that infants who are soothed would demonstrate decreases in pain scores and heart and respiratory rates and have improved behavioral state regulation and growth.

Growth in the model is measured by weight gain in grams. Infants who are unable to be soothed will gain less weight because these infants have greater nonoptimal expenditures. As a result of sub-optimal energy utilization, the infants who are not soothable don’t demonstrate acceptable growth patterns. In addition to failure of weight gain, these infants may experience weight loss beyond expected parameters.

Newborns cry to express a variety of feelings or conditions including hunger, pain and wetness. Newborns require caregiver assistance to deal with the causes. Nurses and parents may assume the role of the caregiver either individually or in a collaborative, partnering relationship. The caregiver creates a calming environment when they remove the negative stimuli, as well as when they provide positive stimuli. Either approach allows the infant to be soothed. Examples of positive interventions include the provision of food when hungry or the removal of a wet or soiled diaper.

Not all negative stimuli can realistically be removed from the premature neonate’s environment. As previously discussed, light is noxious to preterm neonates. But nurses and parents require some level of light in order to provide safe an effective care. In this particular instance, the newborn requires some intervention that allows the newborn to relax and calm itself. The soothed newborn can calm herself with the assistance of an external resource.

A variety of interventions to assist premature newborns deal with their adaptation to extra-uterine life and show varying degrees of success. Interventions that have been used include gentle touch, massage, kangaroo care, skin-to-skin care, rocking and even very minimal touch or hands off approach (Mainous, 2002).

Interaction is an important aspect within the Soothability model and Family Centered Care. Interaction in the Soothability model is defined as any verbal, non-verbal and/or written communication undertaken by the parent(s) and the nurse to exchange information and gain understanding. Interaction allows the parents and nurse to share complete and unbiased information about the newborn, and implies a two way process. Health care professionals' judgments about the credibility of parents' reports must be avoided to ensure that important assessments are not dismissed or overlooked. Interactions between the nurse and the parent must take place in an appropriate and supportive manner.

Interaction and information sharing empowers the parents and diminishes the dependence on nurses, allowing all involved to see the parents as partners in care and decision making. Explaining medical information clearly and in a manner the parents can understand is necessary. It is critical that parental understanding is achieved in order to maximize their decisions. Discussing options, complications, and desired outcomes are important components of the parental/nurse interaction. After providing information, the nurse must allow the parent's time to assimilate it, formulate questions and possibly receive further information. Family Centered Care underscores the need for ongoing interaction and communication (Shelton, et al., 1987).

As the parents and nurse interact over a period of time, the sharing of information will allow understanding to evolve. Initially, nurse led care predominates, and parents have minimal involvement. Over time, through increasing parental participation and decreasing leadership by the nurse, a partnership relationship evolves where each party has equal status. Finally, the care is completely parent led as the newborn transitions to the home setting. True collaboration demands that the parents/families and the nurses/health care professionals openly exchange information, ideas and concerns. This type of interaction and communication is critical within the Soothability model.

Fatigue is another key concept within the Soothability model. Fatigue is a complex, multi-causal, nonspecific and multidimensional concept that has been studied by a variety of disciplines, including nursing (Lindqvist, Widmark & Rasmussen, 2004). Fatigue occurs with almost every illness, physical or mental, and can be a premonitory symptom as well (Hart, Freel & Milde, 1990). Fatigue is generally an abnormal symptom, but can be normal when it indicates a need for rest and time for the body to repair itself. Because fatigue can affect individuals at all phases of the life span, it can also have societal, financial, economic and sociologic ramifications (Davies, Whitsett, Bruce & McCarthy, 2002).

Fatigue has many causes and affects cancer patients (Lindqvist, et al., 2004), adolescents (Ream, et al., 2006), young children (Hinds, et al., 1999), persons with HIV infection (Rose, Pugh, Lears, & Gordon, 1998) and newly delivered mothers (McQuenn & Mander, 2003). Studies identify fatigue and its relationship to functional limitations among the patients studied. Fatigue is seldom regarded as a serious problem among healthy individuals, due to its transient nature (Richardson, Ream, & Wilson-Barnett, 1998). However, the Soothability model proposes that fatigue left unresolved results in inadequate growth in premature newborns.

The nursing viewpoint incorporates how fatigue impacts the individual in relationship to various elements within the environment. Nursing interventions prevent or remove fatigue. When fatigue is prevented or removed, the premature newborn is able to function in such a way as to meet basic order needs, in this particular case, the need to grow. Hilfinger-Messias, Yeager, Dibble, & Dodd (1997) propose that rest does not relieve fatigue. Others take the opposite stance (Ream & Richardson, 1996) and imply that fatigue causes physiologic restriction of oxygen uptake, and altered metabolism, nutritional and hydration status.

Although fatigue may be a pathological physical or psychological condition, it generally requires a cognitive evaluation of one's feelings. In the Soothability model, the physical aspect was assessed as premature newborn cognition and feelings cannot be measured. The specific consequences of fatigue in newborns are weakness and reduced vigor. There may be an increased dependence on others for help even beyond what healthy, full term newborns require.

The literature suggests the subjective nature of fatigue and its multidimensionality makes it unsuited to objective measurement (Ream & Richardson, 1996). Despite this assertion, a variety of tools or measures attempt to quantify fatigue; however, none are appropriate for use in the newborn.

Since it is not possible to measure fatigue accurately in the newborn, another measurement must be considered in order to quantify the energy drains on the newborn. As discussed previously, the high-risk nursery environment is stressful to the premature newborn. This model proposes that the as a result of the stressful environment, the premature spends precious energy attempting to cope with and adjust to an environment dissimilar to the uterine environment. The premature infant is exposed to painful stimuli. Pain causes the newborn to divert energy from growth and weight gain. Pain can be monitored in the premature newborn, and one effective tool is the Premature Infant Pain Profile (Stevens, 1996). In light of the relationship between pain and fatigue, pain measurement will be used to quantify one aspect of soothability in the premature infant.

Additional definitions are necessary to fully understand the Soothability model. These definitions are presented below.

<u>Nurse</u> – a registered nurse caring for premature newborns in a special care nursery setting

<u>Parent</u> – an adult female or male person who identifies herself or himself as the “father”, “mother” or person legally responsible for the care of the newborn

<u>Input</u> – a variety of energy forms, both positive and negative, that premature newborns receive in the form of food, drink, light, touch, sound, warmth (temperature) and procedures

<u>Special care nursery</u> – a level II nursery where premature and special needs newborns reside within the confines of a hospital to grow and develop in preparation for discharge to a home setting

<u>Premature newborn</u> – a baby within the first 28 days of life who currently resides with the confines of a special care nursery, whose gestation age is greater than 32 weeks but less than 38 weeks

<u>Flax seed pillow</u> – a small, commercially made object, sized appropriately to the size and weight of the premature newborn, covered in soft cloth and loosely filled with raw flax seeds, which will be the temperature of the neonate’s the isolette. The warmed pillow

will be in placed on the premature newborn twice during the day for 15 minutes each time

Growth – the premature newborn gains weight at expected rates. To be accurately measured daily on the third shift, using one scale over a period of time

No growth – the premature newborn fails to gain weight, or loses weight over a period of time. To be accurately measured daily on the third shift, using one scale over a period of time

Unacceptable growth – the premature newborn fails to gain weight at acceptable levels when compared to growth charts as outlined by the American Pediatric Association, accurately measured daily on the third shift, using one scale over a period of time

The Soothability in Premature Neonates model allows nurses and health care providers to better understand how premature newborns adapt to life outside the uterus. In general terms, this model enables changes in practice that ultimately promote improved adaptation of premature newborns. Specifically, nurses and parents use the model to identify how infants soothe themselves and which factors prevent or negatively impact the premature newborn soothability. The model also identifies which inputs are particularly detrimental and how altering them may provide the premature newborns with an environment that is more conducive to growth and weight gain. In addition, the model identifies other forms of input that are not currently considered to have a role in the growth of premature newborns.

The Soothability in Preterm Neonates model provides a better understanding of how parents and nurses work together to support premature newborns. As conceptualized, the model assumes that the parents and nurses interact to exchange information. This information exchange implies that the nurse/parent team is better prepared to identify ways to alter the newborn's environment to promote growth. The model then could help discover which modes of interaction are best suited to specific nurse/parent dyads or triads.

The Soothability in Preterm Neonates model provides better understanding of Family Centered Care framework. Although the Soothability in Preterm Neonates model is based on parents only, Family Centered Care speaks to recognizing the family as defined by the family. As a result, the Soothability in Preterm Neonates model identifies non-traditional families as equal partners in the support of premature newborns. The model provides clearer definitions of parental involvement, partnership and participation. The interface of FCC and the Soothability in Preterm Neonates models is a critical component, and relies on open and ongoing exchange of information. This model identifies additional forms of information exchange or how to better adapt them to meet specific family needs.

Summary

In summary, this chapter reviews the literature regarding the challenges prematurely born infants face as they adapt to life outside the uterus. Two frameworks, DC and FCC are particularly important for care delivery to this fragile population. As a result of these frameworks, researchers better understand the specialized needs of the premature infant with regards to state and organization. Studies show that relationships exist between stress response, stimulation and premature infant outcomes. As a result, many high risk nurseries reduce noxious stimuli while using techniques to appropriately stimulate the premature infants. Based on work previously done by other investigators, the Soothability in Preterm Neonates model describes the relationship between stressful stimuli, soothability and growth. The following chapter describes the methods used for an investigation of the relationship between a new, untested intervention and premature infants' soothability.

CHAPTER III

METHODS

Study Design

The purpose of the study was to identify the effect of flax seed pillows on the premature infants'soothability, weight gain and length of stay. This study used a stratified, randomized control, pre and post assessment design. A randomized controlled trial (RCT) is a type of scientific experiment commonly used in testing healthcare services and clinical studies. According to Lachin (1998), RCTs are the most reliable form of scientific evidence in healthcare because they eliminate or minimize illegitimate causality and biases.

RCTs involve the random allocation of different interventions to subjects. This process ensures that known and unknown confounding factors are evenly distributed between treatment groups. Trials establish treatment efficacy and often identify the most frequently occurring side effects. RCTs take into account the human complexities, and the problem with making inference from a single clinical report.

RCTs have the added strength in the requirement of a control group. The control group is used to evaluate the performance of the experimental group on the dependent variable. The inclusion of a control group allows the investigator to make inferences regarding the relationship between the treatment and the dependent variable. This study used two groups, the control group received standard nursing care, and the experimental or treatment group, received the flax seed pillow treatment twice a day for five days in addition to standard nursing care.

The randomized, controlled design with pre and post-assessment measurement was particularly well suited for this study for a variety of reasons. Assigning the preterm infant participants randomly to either the treatment or control group equalized the groups and minimized bias. This allowed the investigator to assume that any differences that emerged between the two groups were directly attributed to the experimental treatment. The participants were stratified according to weight. This step was undertaken to minimize bias, since newborn weight is correlated with gestational age, and gestational age is correlated with maturing central nervous system and infant state regulation (Als, 1982). The pre- and post-assessment design involved observation of a dependent variable, in this case, soothability as measured by activity, pain, and weight gain and length of stay in hospital. The infants were assessed before and after the treatment, and inferences were made about the effectiveness of the pillow on soothability/activity, weight gain and length of stay.

The intervention used in this study was the placement of a flax seed pillow on the upper body of the premature neonate. The pillows were expected to improve the soothability of prematurely born infants, and increase weight gain, and reduce the length of stay in hospital. At present, there are no tools or instruments designed to measure premature infant soothability.

Research Questions

Three research questions were explored in this research study. The first research question explored whether premature infants who received the intervention of the flax seed pillow were soothed and exhibited less activity. The second research question asked if treated infants, who were more soothed, were less active, and spent more time at rest resulting in more weight than non-treated infants. The final research question asked whether infants who gained weight quicker experienced a shorter hospital length of stay. This study adds to the empirical understanding of the factors related to soothability and growth in preterm neonates.

Pilot Study

The feasibility study was conducted with the first infant enrolled in the study and included practicality testing of study procedures. No issues arose with the protocol, and no changes were required, so the first enrolled infant was included in the final sample. Prior to the enrollment of the first infant, the PI performed ten pain assessments with special care nurses using the Neonatal Infant Pain Scale (NIPS) assessment tool and Kappas of .95 validated the PI's ability to assess the infants' pain scores accurately (Attia, Amiel-Tison, Mayer, Shnider, & Barrier, 1987, Lawrence, Alcock, McGrath, Kay, MacMurray, & Dulberg, 1993). Recruitment and enrollment for the remainder of the study began after the first infant's five days of treatment were concluded, as no further adaptations to the protocol were needed. Timing of treatment protocol was adjusted to allow for routine physician and nursing care and parental visits.

Setting

The Barnes-Jewish Hospital special care nursery (SCN) was the site used for this study. The SCN has a total capacity of 21 infants with possible overflow to another location one floor above. Sixteen days prior to the end of the study, the physical location of the SCN moved. The primary change that resulted from the move was increased square footage. The old space had a total of 3,669 square feet, compared to the new location of 4,941 square feet. The original square footage (s.f.) per baby was 193 s.f. per bassinet, whereas the s.f per bassinet in the new location was 275. The lighting in both the new and the old locations is primarily fluorescent. Lighting in the new space comes partially from skylights, an sconce lighting at each crib site. No comparison measurements were taken of the levels of lighting before and after the move. Ceiling tiles and floor in both the old and new spaces are sound deadening. In addition, the new space has a large central station that partially blocks sound. No comparison sound/noise measurements were taken before or after the move. Additional changes to the SCN included rocker/gliders for parents, and privacy curtains at each infant bed.

Specially trained registered nurses staff the nursery. No unlicensed assistive personnel are used to staff the SCN. Physical therapists, respiratory therapists, and other disciplines supplied additional care and support the nursery under the direction of full time attending physicians from St. Louis Children's Hospital. The SCN setting had sufficiently high censuses to provide an adequate sample size for this study. No changes were made to the staff or the delivery care model as a result of the SCN relocation to the new space.

Participants

Upon admission to Labor and Delivery (L&D) at Barnes-Jewish Hospital, the L&D nurses identified eligible patients and provided them with initial information regarding the study. The initial information was provided in the form of a flyer that contained contact information for the PI and a basic study outline. The PI contacted parents who expressed an initial interest. When the mother expressed interest, nurses obtained permission to release of the patient's name to the PI in order to remain Health Insurance Portability and Accountability Act (HIPAA) compliance. The PI contacted potential participants and explained the study in detail, obtained written informed consent, and enrolled all participants. No remuneration was offered as an incentive for participation; however, all participants in both the control and experimental groups were given a soothing pillow upon completion of the study.

The PI was responsible for all data collection. Labor and delivery and special care nursery staff, and other employees who might have contact with the study received basic, background information regarding the study and data collection prior to study inauguration. This information was provided via staff meetings and posted flyers to ensure that all staff was aware of the study, that all required data were consistently documented in the medical record, and that staff knew whom to contact for questions.

Eligible patients were those women who gave birth to a medically stable premature infant, whose gestational age is ≥ 30 weeks and ≤ 38 weeks. This information came solely from the medical record. Medically stable was defined as infants who required no other support than warmed environments, who were on full enteral feedings either orally or by orogastric or nasogastric tube, who had short-term intravenous therapy, or who required supplemental oxygen. The protocol was slightly changed with regards to gestational age. It was noted early in the study, that infant of 36 weeks to 38 weeks gestation were not hospitalized for the required 5 days of treatment and therefore unable to complete the study protocol. As a result, the parameter for potential candidates was slightly changed to be infants whose gestational age is ≥ 30 weeks and ≤ 36 weeks.

Mothers were excluded if they (a) did not speak English, (b) had a pregnancy < 30 or > 36 weeks, (c) were under investigation by the Department of Family Services (d) had a psychiatric diagnosis (e) carried a fetus with multiple anomalies, (f) carried a fetus expected to need surgery, or (g) were identified drug or alcohol users prior to delivery.

This information was obtained from the initial history and physical or prenatal record completed by the nurses or physicians. Neonates were excluded if they were not premature, required surgery or respiratory support via endotracheal intubation, had congenital anomalies, and/or central nervous system dysfunction. Infants considered nonviable by the neonatologist or who had active sepsis, were excluded from the study. Demographic information obtained from the preterm infants' medical record included gender, birth weight and length, method of feeding (breast or bottle), and gestational age at birth. Demographic information obtained from the maternal record included maternal age, gravity and parity, race and method of birth (vaginal or cesarean section).

Human Subjects Protection

In order to protect the participants, approval for this study was obtained from the Institutional Review Board (IRB) of Washington University School of Medicine and from the University of Missouri – St. Louis. The PI provided all mothers of the premature infants with written informed consent at the beginning of recruitment. The PI recorded all data. Each participant was assigned a unique study identifier and all records were de-identified. All data were maintained in locked file cabinets in a locked office for the life of the study and will be so maintained for five years afterward the completion of the study. Only de-identified, collated information will be published.

Protocol

The PI enrolled infants into the study after permission was received to speak with the mother. Enrollment occurred on a rolling basis, with a maximum of four infants actively in the study at any one time. After enrollment and consent, the PI gathered all study data. As premature infants were identified, they were enrolled into the study with parental consent. The infants were randomly assigned, using a table of random numbers to either the control group receiving standard nursery care, or the experimental group based on weight categories. This was done in such a way that both groups had approximately equal sets of infants in each of the weight categories using a stratified sampling methodology. The two weight stratification groups were (1) < 2000 grams and (2) > than 2000 grams. These strata were selected after reviewing the birth weights for premature infants born at Barnes-Jewish Hospital for four months during 2008, and based on statistical expert opinion.

Continued growth is one of the primary goals of any care provided to premature infants. Accurate growth assessment is therefore vital, and is typically been assessed with measurements of the premature infant's head circumference and weight. Weight measurements are easily and reliably obtained. Weight measurements can be affected by alterations in hydration; therefore the best overall indicator of lean body mass may be linear growth (Babson & Bramhall, 1969; Lawn, et al., 2004). Despite better accuracy of growth, linear growth or length measurements are rarely taken in the sick or the preterm infant since this measure requires a significant amount of handling and can cause additional stress to the infant. Since this study is focused on soothing infants, weight and not length was used as the end measure of growth.

Relevant information from the medical history was gathered, including weight gain per day per neonate, and physiologic measurements including heart rate, respiratory rate, and axillary temperature. Measurements of the preterm infants' heart rate, temperature, respiratory rate, NIPS score and activity were obtained at two different times during the day. Each data collection period lasted approximately 20 minutes. The initial measurement was considered baseline and obtained prior to any intervention or further observation. The second measurement was obtained just prior to the removal of the pillow or approximately 15 to 20 minutes after the initial measurement. The first treatment or observation of the day occurred during the morning hours of the day shift (0700-1900) approximately 30 to 60 minutes after a feeding for all participants. The second treatment occurred no sooner than 2 hours and no later than 6 hours after the first treatment or observation.

Treatment

All participants received standard nursery care during the course of the study, including continuous monitoring. The infants in the experimental group received the flax seed pillow treatment in addition to standard nursery care. In addition to the physiologic measurements obtained from the SpaceLabs monitor and WelchAllyn® thermometer, all the neonates wore a data collection device called the Minimetter Actiwatch which measured activity levels (minimetter.respironics.com).

The Actiwatch uses principles of actigraphy to provide information about sleep schedule variability, sleep quantity and activity patterns. The Actiwatch was placed on the premature neonate's ankle by the PI using a Comfy Cuff® bracelet. This bracelet is the standard device used in the SCN to hold identification information of the infants. The Actiwatch measures objective activity data of the tiniest motion, and also allows for subjective scores in any parameter that can be set at 0-15. The software provides a number of data points, including, total activity, average activity, time intervals, accumulated time within each activity range and ratio of accumulated time within each activity range in percentages.

Activity level is a valuable indicator of medical problems and provides answers to many research questions regarding sleep and disease states. Activity levels correlate with sleep/wake patterns, pain level, mood, energy expenditure, fatigue/alertness and other quantifiable parameters (So, et al., 2005; Werner, Molinari, Guyer, & Jenni, 2008; Lahti, Leppamaki, Lonnqvist, & Partonen, 2008; Attarian, Brown, Duntley, Carter, & Cross, 2004). The Actiwatch objectivly records normal and abnormal sleep/wake patterns (So, et al., 2005).

Only the primary investigator provided the treatment and obtained the observations. Each premature infant in the experimental group received the treatment for five consecutive days beginning within the first 36 hours after birth. On each day, the infants in the experimental group received two treatments. Each treatment was delivered on the day shift (0700-1900) over a period of approximately 20 minutes. The first and second treatments were delivered approximately 30 to 60 minutes after a feeding. This time was selected to avoid a period of the day when many intervening variables are likely to occur such as shift report, incoming medical team and new orders. This time frame also increased the likelihood of the presence of family members, which is important according to the framework of Family Centered Care. The second treatment for the day occurred no sooner than two hours after the first treatment and no later than 6 hours after the first treatment.

The first treatment of the day began with obtaining the infant's vital signs (heart rate, respiratory rate, and temperature) and NIPS score. Depending on the infant's position, the flax seed pillow was centered on the infant's upper back or upper chest, with care taken to guard the infant's airway. The pillow remained in place for 15 minutes.

When spontaneous movement by the infant dislodged the pillow, the PI gently replaced it. After the elapsed 15 minutes, the pillow was gently removed, and the infant was allowed resettle itself. In order to maintain infection control, each infant had her own pillow made of hypoallergenic 100% cotton, flannel material. The pillow was filled with organic, untreated, non-scented golden flax seed and weighed 170 grams ± 2 grams.

The weight of the pillow was selected without empirical evidence, but rather as a result of common practices observed in the nursery. Often, when newborns are crying or displaying other cues indicating distress, a parent or caregiver gently places their hand on the infant and pats, or rocks the infant. When measured with the Scaletronix® scale in the nursery, this gentle pressure of an adult human hand is approximately 150-250 grams.

In order to maintain acceptable levels of infection control, the pillow remained in the premature neonates' incubator or bassinette when not in use. Each infant in the experimental group had her own pillow, and no sharing of pillows occurred. The pillows were obtained from a local company and made to the PI's specifications. Neonates in the control group received only standard special care nursery care, which already incorporated standard practices of infection control. If, at any time, the newborn showed signs of significant distress, such as oxygen desaturation, the treatment was discontinued and postponed until nursery staff assessed the infant and determined the infant was stable to continue treatment. This event did not occur for any of the infants in the study. The infants were continually monitored during the treatment periods, and no negative occurrences were noted. The PI performed a standard two minute hand scrub with disinfectant and water every time upon entry to the nursery. The PI also used alcohol hand foam between treatments of each participant.

Variables and Measurement

In this study, the independent variable was the use of treatment pillow versus no treatment. The independent variable is the variable that is deliberately manipulated to invoke a change in the dependent variable or variables. The treatment was the placement of the flax seed pillow on the premature infant's back or upper chest while in a reclining position. The operational definition of the pillow is a heart shaped soft object, covered in 100% cotton flannel, filled with untreated, unscented, organic, golden flax seed. The pillow temperature was the ambient temperature of the premature neonate's isolette, crib or warming table.

The dependent variables are the variables that are noticed to change in response to the independent variables. In this study, the dependent variables include infant weight, heart rate, respiratory rate, axillary temperature, activity level, pain and hospital length of stay. Table 1 lists variables that were measured and the tool used. See Table 1.

Table 1

Variables and Measurement Tools

Variable	**Measurement**
Demographic data	Demo data tool (see appendices, Tool #1)
Infant weight	ScaleTronix Electric Scale 4802
Infant heart and respiratory rates	SpaceLabs UCW Monitor
Infant axillary temperature	WelchAllyn 692 Electric Thermometer
Infant activity	Minimetter Actiwatch
Infant Pain	Neonatal/Infant Pain Scale (NIPS)
Length of Stay	Hospital Medical Record

Weight Gain

Weight gain was defined for the purposes of this study as the number of grams the infant gained over the course of its hospitalization. Infant weight was measured in grams on the third shift each day, typically between 2300 and 2400, using the ScaleTronix® Pediatric Scale, style 4802. The scale was re-zeroed prior to weighing each infant. This scale accurately weighs the neonate to the tenth of an gram and has a repeatability specification of plus or minus 5 grams when placed in the 5-gram resolution setting, and has a linearity specification of plus or minus 1 gram per 1000 grams (obtained from their website). The scale re-zeros automatically after each weight. Nursery staff is trained on this equipment upon hire, and competency is validated during annual skills training days.

Infant Heart Rate and Respiratory Rate

Infant heart rate was the rate at which the infant's heart beats over the course of one minute, and was measured by the SpaceLabs® physiologic monitor attached to the infant chest wall via electrodes placed by the nursery staff. The infant respiratory rate was the number of respirations the infant takes over the course of one minute and was measured by the SpaceLabs® apnea monitor. This monitor provides electrocardiogram, non-invasive blood pressure, and pulse oximetry patient data. Moment to moment pulse oximetry was measured but not recorded as a data point. This decision was made for two reasons; 1) oxygen saturation was used to determine if the infant was tolerating the treatment and as an indicator of an adverse response, and 2) the data was not used for analysis as it changes so quickly as not to be reliable for comparison over the fifteen minutes of the intervention. Twenty four hours of trend data can be graphically displayed, and data are stored in one minute resolution. These monitors receive annual preventative maintenance and performance inspection in addition to service as indicated.

Temperature

Temperature data was measured and evaluated using the nursery's standard WelchAllyn® SureTemp Plus, Model 692 electric thermometer. The thermometer automatically resets and self tests after each use. All temperatures were taken using the PED AXILLARY setting, using the Centigrade scale. All six thermometers regularly used in the Special Care Nursery receive regular, annual preventative maintenance and performance monitoring by biomedical engineering technicians, in addition to any as needed servicing or recalibration based on reports of failure by the nursing staff. In one study (WelchAllyn, 2003) this instrument was used on twenty newborns, with an average error of 0.08 Fahrenheit (0.444 Centigrade) and a standard deviation of 0.360 Fahrenheit (0.199 Centigrade). Nursery staff is trained on this equipment upon hire, and competency is validated during annual skills training days.

Activity

Activity was defined as the gross and fine motor movements made by the premature infant. The Minimetter Actigraph Actiwatch was used to measure activity. Actigraphy is a comparatively non-invasive method of monitoring human rest/activity cycles. The neonates wore a small actigraph unit to measure gross motor activity. Motor activity is often measured by an actigraph in a wrist-watch-like package worn on the wrist or ankle. The unit continually records the movements it undergoes based on the movement of the participant. The data is later read to a computer where it can be analyzed. One study found an overall agreement rate for actigraphy and polysomnography of 93.7 ± 1.3 in use with infants younger than 6 months (So, et al., 2005).

The Actiwatch was placed on the infant after enrollment by the primary investigator, who received training from the Minimetter® representative. The device was attached to the infant by a standard, flexible, identification ankle bracelet used in the SCN called the Comfy Cuff®. The Actiwatch remained on the infant until the infant completed the study or was otherwise dropped from the study. All data obtained by the Actiwatch was downloaded at the end of each five-day period of treatment from each infant and then analyzed. After download of information, the Actiwatch was cleaned using mild soap and water, and then wiped down with rubbing alcohol and allowed to dry completely before application to the next participant. Cleaning was performed in accordance with standard infection control practices.

Neonatal/Infant Pain Scale

The next dependent variable is the infant pain score, which measured the typical sensory experience caused by unpleasant awareness of a noxious stimulus or bodily harm. The Neonatal Infant Pain Scale (NIPS) was used to measure infant pain. The NIPS is a behavioral measure of pain in premature infants (Lawrence, et al., 1993, Stevens, et al., 1996). The NIPS is a six indicator, validated, composite measure, multi-dimensional assessment tool and assesses acute pain in preterm and term neonates (Lawrence, Alcock, McGrath, Kay, MacMurray, & Dulberg, 1993). The NIPS requires assessment of facial expression, cry, breathing patterns, arm movement, leg movement and state of arousal. This tool has been validated using synchronized videotaping of infants undergoing procedures. Inter-rater reliability is high, with Pearson's correlations of 0.92 to 0.97. Cronbach's alpha range from 0.87 to 0.95, and a concurrent validity of 0.53 to 0.84 when compared with visual analog scale. The NIPS is widely used in the nursery setting used for this study, for both random and post procedural pain measurement that was the.

Pain was measured as a way to quantify the energy the premature infant expended in response to the amount and type of environmental stimuli. The NIPS was originally developed to measure post procedural pain; however, is now frequently used for standard pain assessments. The NIPS is the standard pain assessment tool used in the SCN. The nurses use the NIPS both as a post-procedural pain assessment and as a and random assessment of premature infants' comfort status in conjunction with assessment of vital signs

Length of Hospital Stay

Length of stay was defined as the length of stay in this hospitalization beginning at the time of birth and ending at the time of discharge from the special care nursery. Length of stay was measured using the medical record information, and is translated into days and parts of a day based on hours from time of admit to time of discharge. A small steno notebook was used to track daily weight and hospital length of stay for all infants enrolled in the study. This approach allowed the PI to accurately track length of stay measurement without the need for notification from nursery staff when infants were discharged.

Additional Evaluation Measures

Process evaluation potentially identifies why a study does or does not ultimately achieve the stated goals. In addition to collecting the direct study data, notes were collected by the primary investigator regarding program implementation. Specifically, information was collected including extent of staff support; time spent enrolling and collecting data, attrition rates, and any organizational or situational variability during implementation. Issues with any measuring devices; electric thermometers, electric scale, physiologic monitors and Minimetter Actiwatch was tracked. No issues occurred. All of the aforementioned measures were individually collected in an attempt to quantify the extent to which the intervention reached the neonates and impacted individual outcomes. This level of detailed information is of value for replication or future adaptations to the intervention. No negative or unexpected outcomes of the intervention were identified

Procedures for Data Collection

The power of a statistical test is the probability that the test will correctly reject a false null hypothesis (e.g., the probability that a statistical test will correctly detect a significant difference when it in fact exists) and is undertaken to reduce the risk of making a Type II error (e.g., failing to conclude that something is not significant when in fact it really is). Power analysis is typically done during the planning stage of a study in order to determine the minimum sample size required to correctly detect real significant differences. Statistical power is dependent on the statistical significance level used in the test and the size of the effect to be detected.

The significance level indicates how rare a result must be, if the null hypothesis is true, to incorrectly be deemed significant. The most commonly used significance levels (á) are probabilities of 0.05 (5%, 1 in 20), 0.01 (1%, 1 in 100), and 0.001 (0.1%, 1 in 1000). Alpha of 0.05 indicates that if a statistical test were repeated 100 times, a false positive would occur five times. Alpha of 0.01 indicates that a false positive would only occur one time out of 100 tests.

Power Analysis

Power analysis was performed using G*Power 3.0.10, (Hintze, 2006) using á = 0.05, an effect size of 12 grams, and a standard deviation of 12 grams for both groups was selected as it was the most frequently occurring parameters in similar studies. The analysis determined that group sample sizes of 23 (control) and 23 (intervention) would provide 83% power to correctly detect a difference of 10.0 grams of weight gain between the infants in the treatment group and the infants in the control group. The null hypothesis stated that both group means will be less than 12-gram difference in weight gain. The alternative hypothesis stated that the mean of the treatment group would be at least 12 grams of weight gain greater than the control group, with a significance level (á) of 0.05000 using a one-sided two-sample t-test. Allowing for an expected 80% retention rate, 61 participants were recruited into the study to ensure a final sample size of 46 preterm neonates.

Statistical Analysis

Statistical analysis was conducted using SPSS 17.0, and set at á = 0.05. Prior to formal data analysis, the distributional characteristics of each variable were examined visually for outliers and summarized using descriptive statistics. T-tests and chi-square tests were used to detect any differences in demographic characteristics, including baseline weight, gestational age, gender and race. If any such differences are found, these variables will be controlled for in subsequent analysis. The following figure, Figure 2, visually depicts the path of the statistical analyses. Specific analytical methods were then used separately to examine and describe the three primary research questions.

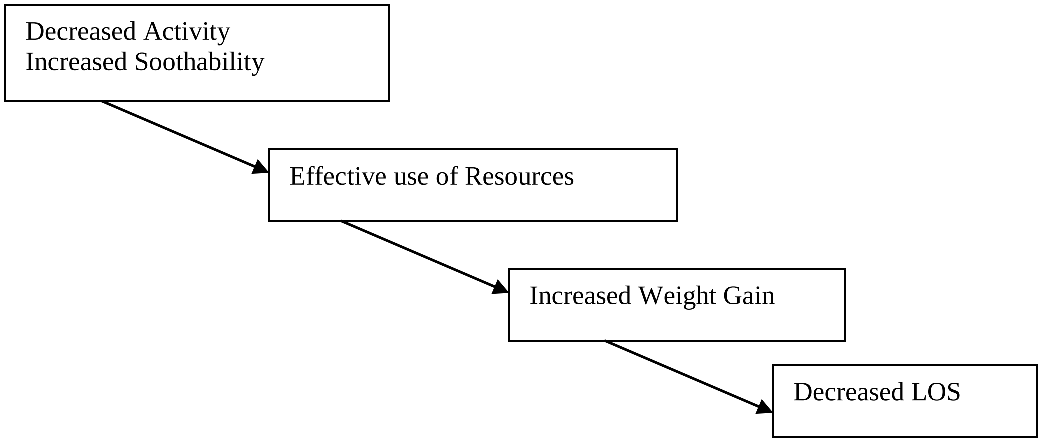

Figure 2. Statistical Analysis Path

Research Question 1

A one-sided t-test determined whether the application of a flax seed pillow was associated with greater levels of soothability in premature infants. To further examine this relationship, analysis of covariance was used and included the following variables as covariates; gestational age, gender, baseline weight and race.

Research Question 2

Analysis of covariance examined the effect of soothability on infant weight gain. This analysis was extended to a multivariate model that includes the following demographic characteristics: gestational age, gender, baseline weight and race, and experimental condition (pillow vs. no pillow).

Research Question 3

A paired t-test was determined whether dichotomized weight gain was associated with length of hospital stay. Then a repeated measures analysis of variance tested whether dichotomized weight gain was associated with length of stay, gestational age, gender and race.

Summary

This chapter outlines the methods that were used in this study. The design was a stratified, randomized control, using a pre and posttest measurement. The study sought to identify the effects of the flax seed pillow on activity, heart rate, respiratory rate, temperature, weight gain and length of stay. The methods section addressed human subjects' protection and recruitment. The setting and participants were fully described, as was the protocol including tools and treatment. Variables were defined and measures quantified. The statistical tests were outlined and the strengths and limitations of the study were described. The following chapter describes the data and results obtained from the statistical analyses.

CHAPTER IV

RESULTS

Overview

Chapter 4 summarizes the findings of a randomized control study to evaluate the effectiveness of a flax seed pillow in order to increase soothability and preterm infant outcomes. The infant outcomes evaluated were soothability, weight gain and hospital length of stay. Additionally, this study provides information regarding these findings which adds to the empirical understanding of soothability.

Data Analysis

Data were analyzed descriptively using the SPSS 17.0 statistical analyses package. Chi-square and t-tests were used to detect any differences in demographic characteristics, including baseline birth weight and length, gestational age, gender and race. General linear modeling was used to examine outcomes over time. The significance level ά was set at 0.05 for analysis.

Human Subjects Protection

Institutional Review Board approval was obtained from both the Washington University School of Medicine and the University of Missouri – St. Louis prior to beginning the study. The PI obtained written informed consent from all mothers at the beginning of recruitment and recorded all subsequent data. Confidentiality was maintained for all data collected and analyzed. Each participant was assigned a unique study code, which was kept separate from the key which matched participant names to code numbers. All documents pertaining to the study were stored separately in a locked cabinet when not in the physical possession of the PI during data collection. All data bases were stored on the principal investigator's (PI) computer and encrypted. No identifiable or individual information was shared with any other individual. Data are reported only in the aggregate and only de-identified, collated information will be published. There were no violations of the Human Subject Protection protocol.

Recruitment

Labor and delivery (L&D) and special care nursery (SCN) staff, including management personnel, and other employees who might have contact with the study received basic background information regarding the study and data collection prior to study inauguration. The study background information was provided to ensure that all required data was consistently documented in the medical record and that staff knew whom to contact for questions or other issues related to the study.

L&D and SCN nursing staff identified potential participants based on the inclusion and exclusion criteria and provided them with an informational flyer regarding the study. When the woman communicated an interest in obtaining additional information regarding the study via the flyer, the nursing staff notified the PI. The PI contacted the potential participant no later than 24 hours after the infant's birth and explained the study in detail. The PI obtained written informed consent from the pregnant or newly delivered mothers and subsequently enrolled the premature infant participants.

The participants were recruited from the obstetrical unit at Barnes Jewish Hospital, a major medical center in the Midwest, between February 13thth and June 10th, 2009. Data collection ended on August 1, 2009 with the hospital discharge of the final participant.

Labor and delivery and special care nursing staff identified sixty-nine potential participants who gave permission to be approached for enrollment in the study. After permission was received, the PI provided these sixty-nine women with information about the study protocol. Of these sixty-nine mothers, 9 declined to participate, and 52 mothers gave consent, resulting in a participation rate of 75%. Three mothers declined because they did not want their infants to be subjected to any extra interventions or manipulation. One mother declined due to previous negative experience with research. The remaining five individuals declined for no disclosed reason.

Of the 52 premature infants who were initially enrolled in the study, six failed to complete the protocol, for an attrition rate of 11.5%. One participant was discharged prior to the five days required by the study protocol, and one participant did not begin the study due to lack of actigraphy watch availability. The remaining four participants disenrolled due to participant transfer to the level III nursery shortly after birth. All four participants were transferred prior to receiving any treatment with the flax seed pillow. The remaining 46 participants completed the study as described. Figure 3 presents the information regarding the enrollment and attrition allocation information.

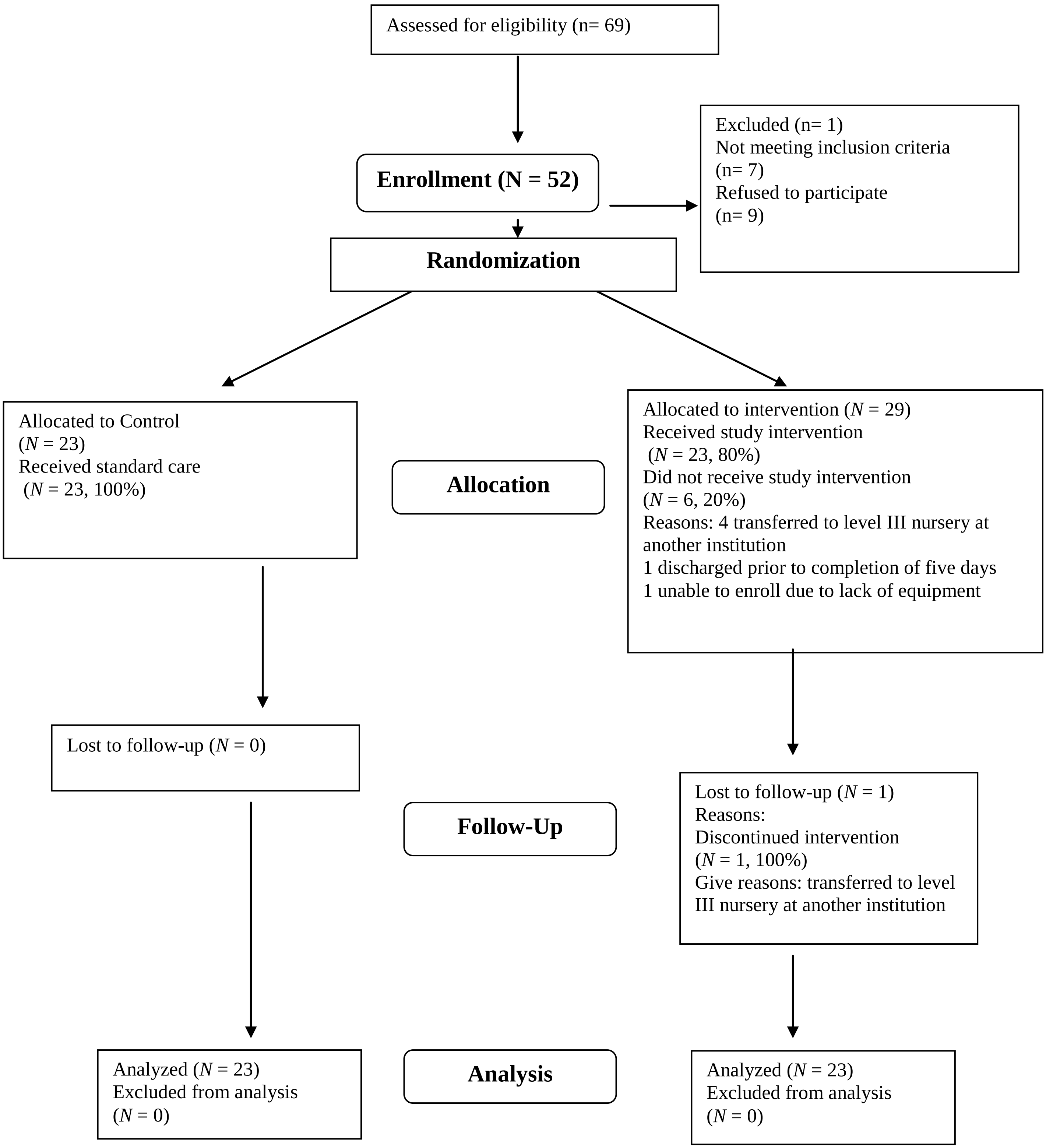

Figure 3. Recruitment Allocation

Characteristics of the Sample

The participants were medically stable premature infants between the ages of 30 and 36 completed weeks gestation born at Barnes Jewish Hospital between February 2009 and June 2009. Medically stable was defined as any premature infant who did not require endotracheal intubation, surgery or transfer to the level III nursery at St. Louis Children's Hospital. Infants with medical conditions that were primarily related to immaturity were not excluded. Examples of these medical conditions included, elevated bilirubin, respiratory distress syndrome, apnea and mild hypoglycemia.

After informed consent was obtained the infants were randomized into two groups using a table of randomized numbers obtained from the online program Random.Org. All infants received standard level II nursery care appropriate for the individual infant. The standard nursery care addressed the needs of the premature infants. The needs addressed included fluid status, nutritional needs, thermoregulation, infection control, hygiene, musculoskeletal management, oxygenation status and establishment of attachment to their parents.

One participant was enrolled and not included in the analysis because no Actiwatch was available within the first 36 hours after birth. Four participants, who were enrolled, went to the NICU immediately after birth, or within the five days of data collection. Nine potential participants declined enrollment during the explanation of the study. The study began on February 13, 2009 with the enrollment of the pilot baby, and enrollment ended on June 10 with the completion of the protocol for the 46th and final baby. The study was ultimately completed on August 1, upon hospital discharge of the final baby.

Protocol

Standard nursery care provided infants with intravenous therapy for fluid management or medication administration including prophylactic antibiotic therapy. Nutritional needs were met via formula or maternal breast milk delivered via naso- and oro-gastric tubes, volufeeders with rubber nipples, or breast fed directly by their mothers. Thermoregulation was provided with overhead radiant heaters on stabilization tables, heated isolette/incubators, or with T-shirts and knit caps in conjunction with swaddling in blankets.

All infants were continuously monitored with pulse oximetry. Although no specific data points were collected for this parameter, it provided information on oxygenation stability during the course of the intervention. Eventually, all infants made the transition to an open air crib and ambient room temperature prior to discharge.

Infection control was achieved with standard hand hygiene practices, personal protective equipment and isolation as needed. Infants received basic hygiene with each diapering change, and more complete bathing as needed. Physical therapists provided passive range of motion and positioning interventions daily. Infants received oxygen via nasal prongs or added to the isolette/incubator environment as needed. All infants transitioned to basic room air prior to discharge.

In addition to receiving standard nursery care, the infants in the intervention group received two fifteen minute treatments with the flax seed filled pillow per day, for five consecutive days after the infant received standard nursery care, including feedings or treatments ordered by the physicians. The commercially produced pillows consisted of organic cotton flannel fabric, in the shape of a heart, filled with non-treated, organic flax seed. Each baby received their own individual pillow which weighed 170 grams.

Prior to placing the pillow on the infant, the PI obtained measurements including Neonatal Infant Pain Scale (NIPS) score, and vital signs which included heart and respiratory rates and an axillary temperature. The PI placed the pillow on the infant's upper torso, either the upper back or chest, depending on the position that the infant had been placed by the nursing staff. After 15 minutes elapsed, the PI removed the pillow and obtained a second set of measurements as previously described. The pillow was stored in the infant's immediate vicinity, crib, isolette/incubator or stabilization table between treatments to ensure availability and to comply with infection control procedures. Throughout the time the flax seed pillow treatment, the infants were monitored for signs of adverse events such as oxygen desaturation, apnea or bradycardia. Special care nursery personnel were immediately available should adverse responses be identified. The second treatment of the day occurred no sooner than three hours after the first treatment and followed the same steps outlined above. No negative outcomes associated with the intervention were identified for any of the infants in the intervention group. There were no episodes of bradycardia, bradypnea or oxygenation desaturation, hyperthermia or hypothermia associated with the application of the flax seed pillow. Infants in the control group received their own flax seed pillow at discharge as a gift for participation and were not exposed to the intervention during hospitalization.

The physical location of the SCN moved on May 26, 2009, 68 days prior to the end of the study. The primary change resulting from the move was increased square footage. The original nursery space had a total of 3,669 square feet, compared to the new location of 4,941 square feet. The square footage (s.f.) per baby in the original nursery was 193 s.f. per bassinet, whereas the s.f per bassinet in the new location was 275 s.f. No data were collected to identify if this change had an impact on the study.

The lighting in both nurseries is primarily fluorescent. Lighting in the new space is partially supplemented with natural light via skylights with additional lighting provided by sconce lights at each crib site. No measurements were taken regarding the levels of lighting before and after the move for comparison.

There are sound deadening ceiling tiles and flooring tiles in both the original and new nursery. In addition, the new space has a large central station that provides a partial barrier to auditory and visual stimuli. No sound/noise measurements were taken before or after the move for comparison purposes. Additional changes in the new SCN included rocker/gliders for caregivers including parents, and privacy curtains at each infant bed.

Registered nurses with specialized education and training provided care in the original and relocated sites. No unlicensed personnel were involved in direct patient care. Assignments were based on patient acuity and census, and took into account nursing expertise.

Parents were occasionally present for the treatment or observation periods. The specific information related to frequency and duration of parent's or family members' presence was not part of data collection.

Demographic Characteristics

The maternal demographic characteristics were assessed using chi-square and independent sample t-tests. The data were normally distributed; no violations of normalcy were identified. Mothers self selected the category of ethnicity from a list which included

Caucasian, African American, Hispanic/Latina, Asian/Pacific Islander or Other. Most mothers described themselves as African American (n=28, 61%). This was consistent with the general preterm population that gives birth at this location

The mean age of the mothers in the sample was 26.5 years (SD = 7.2) with a range of 17 to 43 years of age. There were no significant differences between the groups with respect to maternal age t = 1.125, p = 0.267. The mean age of the mothers in the control group was 24.9 (SD = 7.2) with a range of 18 - 43, in comparison to the intervention group, which had a mean age of 27.3 (SD = 7.2) with a range of 18 - 43 (SD = 7.2).

Most of the sample births were vaginal (n = 28, 61%), with the remaining 18 (39%) occurring via cesarean section. The institutional cesarean rate is 28% and there were no significant differences in birth method.

The gravity of the intervention group was 3 (SD = 2.1) and of the control group was 2.4 (SD 1.6), t = 1.193, p = 0.239. The parity of the intervention group was 2.3 (SD = 1.5) and the control group was 1.83 (SD = 1.2), t = 1.082, p = 0.285. The maternal demographic characteristics are represented below in Table 2.

Table 2

Maternal Demographic Comparisons

	Intervention N = 23 (%)	Control N = 23(%)	*t(p)*
Ethnicity of Birth Mother			
Caucasian/white	5 (22%)	12 (52%)	
African American	17 (74%)	11 (48%)	
Hispanic/Latino	0	0	
Asian/Pacific Islander	1 (4%)	0	
Other	0	0	
Maternal Age			
Mean (sd)	27.3 (7.2)	24.9 (7.2)	1.125 (0.267)
Range	18-43	17-43	
Delivery Method			
Vaginal	15 (65%)	13 (57%)	-.593 (0.556)
Cesarean	8 (35%)	10 (43%)	
Maternal Reproductive History			
Gravity Mean (sd)	3.0 (2.1)	2.4 (1.6)	1.193 (0.239)
Parity Mean (sd)	2.3 (1.5)	1.8 (1.2)	1.082 (0.285)

Infant demographic data were also assessed for means and frequencies. Ethnicity of the newborn was determined by the mother, who identified the ethnicity of her child from a list of options presented in the table above. The infants in the sample were equally distributed in gender between males (50%) and females (50%). The gender distribution between the control and the intervention groups was inverted, with 61% of the control group being female, and 65% of the intervention group being male; however, this was not statistically significant.

Mean age of the 46 premature infants was 33.5 weeks gestation (SD = 1.76) with a range of 30 weeks to 37 weeks. Mean age of the control group was 33.2 weeks gestation (SD = 1.75), and the mean age of the intervention group was 33.8 weeks gestation (SD = 1.77), t= 1.13, p = 0.265.

Mean birth weight of the 46 premature infants in the total sample was 2110 grams (SD = 451.4). The mean birth weight of the infants in the control group was 2100 grams (SD = 439.0), and the mean birth weight of the infants in the intervention group was 2120 grams (SD = 473.0), t = .143, p = 0.887. Mean birth length of the infants in the total sample was 45.0 centimeters (SD = 2.6). Mean birth length of the infants in both the control and intervention group was 45.1 centimeters (SD = 2.6), t = .028, p = 0.978.

Apgar scoring is a simple and repeatable method which allows the clinician to quickly assess the health of infants immediately after birth. The scale is based on five criteria, each measured from 0 to 2, resulting in a range from zero to ten. The five criteria are appearance or color, pulse, grimace, activity and respiration (Apgar, 1953). Scores 3 and below are generally regarded as critically low, 4 to 6 as fairly low, and score of 7 to 10 generally normal. Initial low scores at one minute indicate that the infant needs medical attention. Low scores at one minute are not necessarily associated with poor long term outcomes, however, continued low scores at the five minute period increases the risk for long term neurological damage (Apgar, 1953). One and five minute mean Apgar scores for the infants in the total sample was 7.35 (SD = 1.48), t = -.141, p = .17 and 8.6 (SD = .65) with a range of 2-9 and 7-9 respectively, t = .000, p = 1.0. There were no statistically significant differences between the two groups in Apgar scores at both one and five minutes.

There were no statistically significant differences between the two groups with regards to gestational age, birth weight, birth length or gender. Differences in ethnicity were approaching significance with p = 0.075. SPSS does not perform a Fisher’s exact test on anything but two by two tables. As a result, another calculator was used and found a p = 0.065. Table 3 summarizes the demographic characteristics of the infants in the study.

Table 3

Infant Demographic Comparisons

	Intervention 23 (50%)	Control 23 (50%)	*t (p)*
Ethnicity of Infants			
Caucasian/white	5 (22%)	12 (52%)	
African American	17 (74%)	11 (48%)	
Hispanic/Latino	0	0	
Asian/Pacific Islander	1 (4%)	0	
Other	0	0	
Gestational Age in Weeks			
Mean (sd)	33.8 (1.77)	33.2 (1.74)	1.13 (0.265)
Range	30-36	31-36	
Gender			
Female	8 (35%)	14 (61%)	1.79 (0.080)
Male	15 (65%)	9 (39%)	
Birth weight grams Mean (sd)	2120 (473)	2100 (439)	.143 (0.887)
Birth length centimeters Mean (sd)	45.1 (2.6)	45.1 (2.6)	.028 (0.978)
Apgar Scores			
One minute Mean (sd)	7 (1.77)	8 (1.07)	-1.41 (0.17)
Five minute Mean (sd)	9 (0.66)	9 (0.66)	.000 (1.0)

Infants in level II nurseries require physiologic support in a variety of forms including feeding tubes, supplemental oxygen, intravenous therapy and ultraviolet light therapy (White-Traut, et al., 2004). On the first day of life, 43 (93%) of the infants in the sample received intravenous therapy, 19 (41%) received oxygen therapy, 7 (15%) received ultraviolet therapy, and 31 (67%) required feeding tubes. By day five of the study, the study participants required less support, and the above mentioned supportive measures had dropped to 12 (26%), 2 (4%), and 5 (10%) respectively. Feeding tube support increased in the sample to a total of 36 infants (78%) of the total group. There was no statistical significance for any of the four supportive measures between groups.

Linearity

A one-way between-groups multivariate analysis of variance was performed to investigate differences between the control and intervention groups. The independent variable was the application of the flax seed filled pillow. Preliminary assumption testing was conducted to check for normality, linearity, univariate and multivariate outliers, homogeneity of variance-covariance matrices, and multicollinearity, with no serious violations noted. There was a statistically significant difference between the control and intervention group on the combined dependent variables: F (6, 39) = 2.72, p = .027: Wilks' Lambda = .71; partial eta squared = .30. When the results for the dependent variables were considered separately, the only difference to reach statistical significance, using a Bonferoni adjusted alpha level of .01 was heart rate: F (1, 44) = 7.78, p = .008, partial eta squared = .15, and respiratory rate: F (1, 44) = 10.50, p = .002, partial eta squared = .19. An inspection of the mean scores indicated that the infants with the intervention pillows had slightly lower heart rates (M = 139.7, SD = 13.7) and respiratory rates (M = 48.4, SD = 9.3) than the infants in the control group, (M = 151.3, SD 14.7) and (M = 58.6, SD = 11.9). Although not statistically significant, the changes in the pain scores for the intervention group were approaching significance at p = 0.045. Overall, analyses of the data from the actiwatch revealed no outliers. A scatter plot of the data from the actiwatch did not identify any outliers with respect to wake, sleep or mobile time on any of three days used for comparisons of the intervention and control groups.

Soothability

In the model, soothability is defined by the components of heart rate, respiratory rate, pain and activity. Temperature was included in the scale as a component predicted to remain stable regardless of soothability status. These four physiologic measurements were examined individually to describe soothability. The data were compared between the control and the intervention groups on day two, day three and day four after both the first and second interventions. As expected, no differences were found between the groups with changes in temperature pre and post intervention. Differences were found, however, in the remaining physiologic measures, heart rate, respiratory rate and pain score. These differences are explored in detail in the following paragraphs with respect to each of the three research questions.

Research Question 1

The first research question asked if infants who received the intervention of the flax seed pillow were more soothed than the control group infants. Soothability is a reduction in heart rate, respiratory rate, and pain score. The definition also states that Soothability alters the distribution of sleep and wake state. Therefore, soothed infants spend more time awake (Field, Scafidi & Schanberg 1987, Wheeden, et al., 1993). Soothed infants demonstrate decreases in the physiologic variables and increases in wake states after the application of the flax seed pillow. Infants who are not soothed show no changes or increases in heart rate, respiratory rate or pain score and decreases in wake state.

No violation of normalcy was found in the data. An independent sample t-test was used to determine whether the application of a flax seed pillow was associated with greater levels of soothability in premature infants as measured by changes in heart rate, respiratory rate, pain scores, and activity. The activity metrics were obtained from the actiwatch and included wake time, sleep time and mobile time, all measured in full or complete minutes per 24 hour epoch. Each physiologic measurement was obtained prior to and after the fifteen minute period of the intervention. For the control group, the measures were obtained over a fifteen minute time span; pre and post observation as they did not receive an intervention.

Comparisons of heart rate changes from pre to post intervention found significant differences between the intervention and control groups. Data from three days were analyzed; day two, three and four, as these days provided information over 24 hours consistently for all participants. Day one was used for baseline setting. On all three of the days analyzed (day two, day three, day four), the infants in the intervention group had statistically significant decreases in heart rate after the application of the flax seed pillow. These differences were found at both the initial morning intervention and the subsequent intervention three to five hours later. Table 4 presents the data specific to heart rate changes.

Table 4

Pre- and Post-Intervention Heart Rate (HR) Response Mean Scores

	Intervention			**Control**		
Day Time	HR Pre Mean(sd)	HR Post Mean(sd)	t (p)	HR Pre Mean(sd)	HR Post Mean(sd)	t (p)
D2 T1	148 (8.8)	137 (11.7)	-2.46 (0.018)	149 (12.0)	151 (13.5)	-.294 (0.77)
D2 T2	154 (10.0)	139 (11.9)	-3.18 (0.003)	150 (15.7)	152 (15.1)	.916 (0.37)
D3 T1	152 (12.2)	139 (9.5)	-5.02 (0.000)	152 (9.6)	154 (11.9)	-.040 0(.97)
D3 T2	153 (12.2)	141 (9.4)	-4.73 (0.000)	148 (9.7)	157 (13.2)	1.61 (0.11)
D4 T1	153 (12.8)	138 (12.1)	-4.02 (0.000)	146 (12.0)	151 (10.6)	1.77 (0.08)
D4 T2	159 (10.3)	143 (11.3)	-2.91 (0.005)	152 (12.1)	155 (15.7)	2.21 (0.03)

Comparisons of changes in respiratory rate from pre to post intervention also found significant differences between the intervention and control groups. On all three of the days analyzed (day two, day three day four), the infants in the intervention group had statistically significant decreases in respiratory rate after the application of the flax seed pillow. These differences were found at both the initial morning intervention and the subsequent intervention three to five hours later. Table 5 presents those data.

Table 5

Pre- and Post-Intervention Respiratory Rate (RR) Response Mean Score

	Intervention			**Control**		
Day Time	RR Pre Mean(sd)	RR Post Mean(sd)	t (p)	RR Pre Mean(sd)	RR Post Mean(sd)	t (p)
D2 T1	57 (14.9)	43 (12.5)	-3.419 (0.001)	58 (11.2)	56 (13.6)	-.17 (0.868)
D2 T2	58 (13.6)	53 (9.33)	-3.014 (0.004)	53 (12.4)	53 (13.0)	1.40 (0.169)
D3 T1	57 (13.1)	40 (10.3)	-3.995 (0.000)	53 (8.9)	52 (9.7)	.58 (0.566)
D3 T2	56 (13.7)	40 (8.3)	-5.135 (0.000)	52 (8.6)	56 (12.9)	1.16 (0.252)
D4 T1	58 (13.5)	42 (10.1)	-3.111 (0.003)	54 (12.1)	53 (13.5)	.93 (0.356)
D4 T2	62 (10.2)	44 (10.6)	-2.863 (0.006)	54 (11.7)	55 (14.9)	2.38 (0.022)

Comparisons of pain scores using the Neonatal Infant Pain Scale (NIPS) from pre to post intervention found significant differences between the intervention and control groups with regards to pain. On all three of the days analyzed (day two, day three, day four), the infants in the intervention group had statistically significant decreases in their pain scores after the application of the flax seed pillow. These differences were found during both the initial morning intervention and the subsequent intervention three to five hours later. Table 6 presents the pre and post intervention mean scores for pain.

Table 6

Pre- and Post-Intervention Pain (NIPS) Response Mean Scores

	Intervention			**Control**		
Pain	NIPS Pre Mean(sd)	NIPS Post Mean(sd)	t (p)	NIPS Pre Mean(sd)	NIPS Post Mean(sd)	t (p)
D2 T1	1.5 (1.31)	.65 (1.02)	-2.46 (0.018)	1.2 (1.16)	1.4 (1.12)	0.71 (0.48)
D2 T2	1.8 (1.67)	.30 (.559)	-3.29 (0.003)	1.0 (0.95)	1.5 (1.60)	1.95 (0.06)
D3 T1	1.1 (1.13)	.22 (.518)	-3.73 (0.001)	0.9 (.90)	1.0 (0.93)	1.26 (0.21)
D3 T2	1.4 (1.37)	.17 (.385)	-5.58 (0.000)	1.0 (1.19)	1.9 (1.44)	0.92 (0.36)
D4 T1	1.3 (1.42)	.22 (.846)	-2.78 (0.008)	1.0 (1.43)	1.1 (1.32)	0.72 (0.47)
D4 T2	2.3 (1.33)	.48 (.788)	-2.39 (0.023)	0.8 (0.90)	1.4 (1.55)	4.54 (0.00)

Actigraphy Watch Data

Data for each participant were downloaded from the Minimetter Respironics® actigraphy watch after it was removed from the infant on day five. Actigraphy is a noninvasive tool that provides wake/sleep assessments in a variety of patient populations (Gironda, Lloyd, Clark & Walker, 2007). The actigraphy device records limb movement occurrences and then sums the frequency of movements for a given length of time. Specially developed algorithms then score the movements into wake or sleep states (So, Buckley, Adamson, & Horne, 2005). Actigraphy is based on the assumption that there are fewer limb movements in sleep states than in wake states (American Sleep Disorders Association, 1995). Close correlations have been shown between the rest/activity measured by actigraphy and the sleep wake cycles measured in polysomnography in many populations, from infancy to the elderly (Sadeh, Hauri, Kripke , & Lavie, 1995).

The wake and sleep time data collected by the actiwatch was extrapolated from the watch in complete minutes over each twenty four hour day period. For each participant, the wake and sleep time calculations were generated over a 24 hour period beginning at 2400 hours or midnight. Therefore, the total of wake and sleep minutes for each participant are 1440 minutes per day or 60 minutes over 24 hours.

Actigraphy data collected on day one were used to establish a baseline and were not included in analysis. Actiwatch data from day five were not analyzed as they did not consistently represent a full 24 hours of data based on the time of hospital discharge for any given infant. The comparison of mean wake and sleep time is presented in Table 7. The infants in the intervention group spent more time awake and less time asleep than did the infants in the control group, although this was not statistically significant on any of the three days analyzed.

Table 7

Actigraphy Data by Day of Life

	Wake Time Mean (sd)			Sleep Time Mean (sd)		
Day	Intervention	Control	t (p)	Intervention	Control	t (p)
2	440 (152)	361 (152)	1.77 (0.084)	918 (290)	1079 (152)	-2.37 (0.022)
3	475 (258)	365 (181)	1.68 (0.100)	919 (309)	1077 (182)	-2.11 (0.042)
4	380 (181)	320 (124)	1.32 (0.195)	1069 (180)	1119 (125)	-1.09 (0.283)

Research Question 2

The second research question asked whether the infants who are more soothed gained more weight than less soothed infants. Univariate analysis of the components of soothability was performed and those data were presented in the previous section titled Research Question 1. An independent sample t-test was used to determine whether infants in the intervention group gained more weight than infants in the control group. The figure below provides graph of the initial weight loss and subsequent weight gain of the intervention infants in comparison to the control infants. Infants in both groups lost weight in the first few days. This is an expected finding as infants typically lose 5-8% of their birth weight in the first week of life (Wright & Parkinson, 2004). The intervention group ceased losing weight at day seven and had nearly recouped all losses by day twenty. In comparison, the control group was still in transition at day twenty. Infants in the intervention group gained more weight in the first three weeks than the control group, although that difference was lost by time of discharge when the mean weight for the intervention group was 2379.8 grams (SD = 323.6) and the mean weight for the control group was 2373.0 grams (SD = 333.4), t = .070, p = 0.945. Figure 4 depicts the comparison of mean daily weights for the intervention and control groups through twenty days of life.

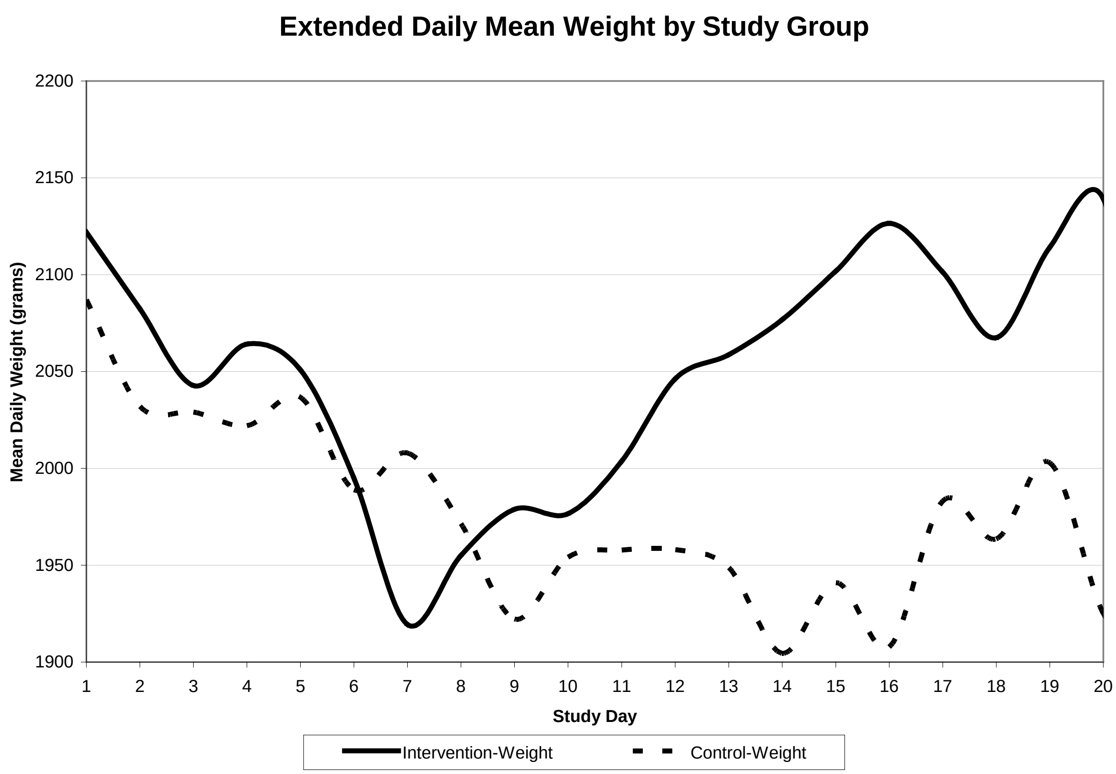

Figure 4. Extended Daily Mean Weight

Research Question 3

The final research question asked whether infants who gained weight more quickly experienced a shorter hospital length of stay. Analysis identified that the data were normal. An independent sample t-test determined whether weight gain was associated with length of hospital stay. There were no significant differences in weight gain, as described previously. No differences were found in length of stay between the study and control group. The mean length of stay for the intervention group and the control group respectively were 16.5 days (SD = 9.5) and 16.4 days (SD = 12.4), t = .013, p = 0.989. Table 8 compares the means of weight gain and length of stay.

Table 8

Comparison of Weight Gain and Hospital Length of Stay Means

	Intervention (sd)	Control (sd)	t (p)
Weight Gain - Grams	2379.8 323.6)	2373.0 (333.4)	.070 (0.945)
Length of Stay - Days	16.5 (9.5)	16.4 (12.4)	.013 (0.989)

Summary

This chapter reviewed the results of statistical analyses obtained from the data in this study. Analyses found that the intervention and control groups were comparable; no violations of the assumption of normal distribution were identified. Using a randomized controlled design with pre and post-intervention measurements, data analysis demonstrated that infants in the intervention group had significant decreases in heart rate, respiratory rate and pain scores after the flax seed pillow intervention. Although not statistically significant, the intervention group also spent more time awake than the control group. The intervention group had greater weight gains by 21 days; however, this difference vanished over time as the discharge weights of both the intervention and control group were nearly identical. Infants in both groups had comparable hospital lengths of stay. The next chapter provides a discussion of the study data including implications for nursing and future research.

CHAPTER V

DISCUSSION

Review of the Problem

Rising numbers of premature births and increasing health care costs continue to be issues of concern in the United States (National Vital Statistics Reports, 2005). Although much technological and pharmacological advancement have greatly improved the mortality and morbidity rates of premature infants, the human and financial costs of prematurity remain high. Nursing has the ability to impact these issues and improve health outcomes for this vulnerable population. Two theoretical frameworks that have informed research and nursing practice within this population are Developmental Care and Family Centered Care. Within those frameworks, research demonstrates a number of effective interventions to improve outcomes for infants born prematurely. Outcomes of specific interest relate to improving adaptation to extra-uterine environment, weight gain, decreasing hospital length of stay.

Review of the Purpose

The purpose of this study was to evaluate the efficacy of the flax seed pillow. Previous research has examined interventions based on tactile stimulation which have shown to be effective in addressing the outcomes of pain and stress, weight gain and length of stay (Rice, 1979; Scafidi et al., 1990: Modrcin-Talbott, Harrison, Groer, and Younger, 2003). The literature also supports the use of interventions to increase parental involvement in the care of premature infants (Anderson, et al., 2003). Incorporating those perspectives suggested that an intervention that is simple, easy to use, inexpensive, and is predicated on the positive effects of gentle touch and developmentally appropriate care improves the soothability of premature infants. This study investigated the effect of a flax seed pillow on soothability, weight gain and hospital length of stay in a sample of premature infants.

General Findings

The data suggest that the tactile stimulation provided by the flax seed pillow demonstrated changes in the components of soothability and improved the early clinical course of premature infants. There was conclusive statistical evidence of changes in heart rate, respiratory rate, pain scores on the second, third and fourth days of life. There were also clinically significant differences in weight gain at three weeks of life between the intervention and control group.

The infants in the intervention group demonstrated changes in heart rate, respiratory rate and pain scores which were significantly lower than those parameters in the control group. Infants in the intervention group also spent more time awake than infants in the control group. More infants had nasogastric tubes placed for feeding at day five than at day one. This likely indicates a degree of stabilization, as the infants progressed from NPO status to being able to tolerate feedings. The data show that the weight gain of preterm infants was improved by tactile stimulation provided by the flax seed pillow in the initial weeks after birth. Despite these early findings, no differences were found in discharge weight or hospital length of stay. The flax seed pillow did not have any adverse effects on this sample of premature infants as indicated by their stable physiologic status and the lack of avoidance behaviors. Further discussion of each of these components is presented below

Heart Rate Findings.

When premature infants demonstrate significant behavioral distress, such as crying, it often leads to physiologic over-reactivity which may include tachycardia. Prior to the intervention, heart rate baseline measures were similar between the two groups. This similarity allowed for comparisons of heart rates after the intervention. The infants in the intervention group demonstrated statistically significant decreases in heart rate after the flax seed pillow intervention during the three days of data examined. This study confirms the findings of previous studies regarding heart rate changes during interventions employed to decrease pain or calm premature infants (Dieter, et al., 2003; Field, Scafidi, & Schanberg, 1987, Whitely & Rich, 2008). One indication of decreased pain or stress in humans, including premature newborns, is a decrease in the heart rate. The soothability model proposed this change as a result of decreasing discomfort and/or stress in the infant. Soothability also proposes that the tactile stimulation of the flax seed pillow helps premature infants compensate for the natural imbalance of their immature nervous systems. The benefit of a more relaxed state may be exhibited as decreased heart rate after the intervention.

Respiratory Rate Findings

In addition to fluctuations in heart rate, homeostatic regulation in premature infants is manifested by fluctuations in respiratory rate (Katona, Frasz & Egbert, 1980). Differences in respiratory rate were also identified between the two groups. Pre-intervention respiratory rates were comparable in the intervention and control groups. Data were examined on days two, three and four. Infants in the intervention group displayed respiratory rate decreases after the application of the flax seed pillow that were significantly greater, while respiratory rates were virtually unchanged for infants in the control group. These findings indicate that the flax seed pillow was effective in decreasing the infants' stress response, and facilitating relaxation which may also decrease the need for supplemental oxygen and assisted ventilation. These findings were consistent with previous research and physiologic changes in response to tactile stimulation (Johnston, et al., 2007).

All infants in the study were monitored by continuous pulse oximetry. Although the information regarding oxygen saturation was not collected as a variable during the study, observation of oxygen saturation during the intervention allowed the PI to identify adverse responses during the intervention. Oxygen saturation was not collected as a specific data point in this study, as it varies from moment to moment and as a result could not be used to demonstrate changes in soothability. Per the protocol, any occurrences of desaturation would have resulted in immediate discontinuation of the intervention. No adverse events occurred.

Pain Findings

Tachycardia, tachypnea and oxygen desaturation, can be an indicator of stress or pain in premature infants (White-Traut & Pate, 1987; Whitely & Rich, 2008). The infants in the study were assessed for pain, pre and post treatment using the Neonatal Infant Pain Scale (NIPS). The NIPS is a tool used to evaluate infant pain based on behavioral characteristics and breathing patterns. Infants can communicate pain only via physiologic or behavioral changes, which include decreased oxygen saturation, increased heart and respiratory rates, posturing, grimacing and crying (Anand, 1998). The NIPS tool is widely used, because it is quick, simple and has been shown to have good construct validity and reliability (Lawrence, et al., 1993).

Pre-intervention infant pain scores in the two groups were comparable; however, the post intervention pain scores of the infants in the study group were significantly lower than the pain scores in the control group. In some cases, the pain scores in the control group increased during the 15 minutes of observation despite standard nursery care of providing a pacifier for non-nutritive sucking.

Assessing for and responding to pain in any patient is a critical aspect of nursing care. Premature infants experience acute pain directly as a result of many of the therapeutic procedures and treatments they require. Most pain studies in neonates examine acute pain models, and test both pharmacological and non-pharmacological interventions to reduce or eliminate pain (Anand, 2007). Managing pain may have even more significant implications for the preterm infant population, as pain in preterm infants increases the sensitivity to pain later in life (Allagaert, et al., 2005). Application of the flax seed pillow resulted in significant decreases in pain scores and no adverse responses occurred during the course of the study. Additional benefits of this particular intervention are that it is non-invasive and does not necessarily require additional movement or repositioning of the infant, both of which can be stressful in and of themselves (Byers & Thornley, 2004).

Activity Sleep/Wake Findings

This study incorporated a novel measure of premature infant activity using the approach of the actigraphy watch. Previous research has found increases in quiet alertness and wake states in response to interventions to calm infants (White-Traut, 2002). Results obtained and analyzed from the actiwatch were sleep and wake time, measured in full minutes. Results were used from days, two, three and four in order to have a full 24 hour period for comparison. Infants in the intervention group demonstrated more time in the wake state as measured by activity than the control group for each of the days analyzed, although not at a statistically significant level. Over time, both groups demonstrated decreasing time in minutes in the wake state, and conversely more time in sleep. This equalization of sleep and wake time between the two groups may be as a result of normal neurodevelopmental maturation.

Studies show that premature birth is associated with neurodevelopmental impairment with problems of behavioral state organization and attention (Als, et al., 2005; Perlman, 2001). A variety of supplemental stimulation techniques enrich the premature infants' environment including music, massage and acupressure with the intent of maturing the neurological system of the neonate (Dieter, et al., 2003: Diego, et al., 2005; Chen, et al., 2008). Across studies, infants spend more time in active an alert state, which is a wake state and similar to the findings of more wake time measured with the actiwatch in this study. Premature infants compensate and protect themselves when over-stimulated or stressed by closing their eyes, turning away their heads and sleeping (Als, et al., 2003). The results of this study indicate that infants who received the pillow were not over-stimulated and in fact demonstrated physiologic and behavioral findings which indicated that they were less stimulated and better able to manage their behavioral state organization.

Weight Findings

Infants in the intervention group had a slightly higher birth weight. Both groups lost weight over the first five days, as is expected in all newborn populations (Wright &

Patterson, 2004). The weight loss of the infants in the sample did not exceed the expected ten percent of birth weight. Mean weight loss at five days was 4.7% for the intervention group and 5.9% for the control group. Both groups ceased losing weight at approximately day seven; however the intervention group gained weight quicker than the control group. The gap in weight gain continued through the first three weeks of life. This advantage decreased over time, so that by discharge from the hospital there were no differences in weight between the groups. It is possible that when treatment was discontinued at day five, the benefit was lost for the intervention group, and thus the weight gain of the two groups became similar by time of discharge. Weight gain in premature infants is a complex issue. Although it is influenced by stress, the impact of soothability may be too subtle to demonstrate increases in weight.

Weight gain is further affected by the neurological maturity of the infant, as they must have ability to suck and swallow to maximize nutritional intake. Co-morbidities and other illnesses may exert a greater influence than mere increased soothability can overcome. Medications commonly given to premature infants such as diuretics and steroids can affect weight gain. No effort was made to account for any systematic differences in the types of medications the infants received. This study confirms previous work that shows weight gain to be a complex issue impacted by many variables.

Length of Stay Findings

Weight is one of the variables that contribute to the timing of hospital discharge for premature infants. The premature infant must reach a critical threshold of weight, which traditionally has been around five pounds or 2200 grams. At this weight the infant has reached an acceptable weight to surface area relationship which allows the infant greater stability with regards to thermoregulation and fluid status. In addition to reaching an acceptable ideal body weight, the infant must demonstrate a steady, predictable weight gain. Although infants in the study all eventually established an acceptable and consistent pattern of weight gain, evaluation of the discharge weight of all infants in the sample failed to identify a weight range consistent with the timing of discharge. The fact that the discharge weights of infants in the sample varied greatly indicates that weight alone is not a sufficient or even primary indicator of premature infants' readiness for discharge.

Serendipitous Findings

A number of serendipitous findings were identified over the course of the study. The first finding was the impact that support or lack of support from the staff had on this study. On the labor and delivery unit, only a small handful of nurses consistently presented potential participants with the informational study flyer despite the daily presence of the PI. The nurses in the special care nursery consistently identified potential participants and informed the parents of the study. As a result of this situation, more than three quarters of the participants were enrolled after the birth of the premature infant. Identification of the potential participants was much simpler after the birth in that it was much clearer whether the infant met inclusion criteria

Many factors other than weight gain impacted discharge timing and length of hospital stay for the infant. Although consistent weight gain and total weight were important components in the discharge decision, they were not the only two factors. The importance of weight gain may have been superseded by factors such as parental readiness to assume the primary role in care giving, and the individual physicians' discharge criteria preferences. The physician's decision to discharge the infant was greatly influenced by the nurses' perceptions of infant and parent readiness. The nurses' interpretations of discharge readiness were not based on consistent nor objective criteria.

Parental participation in treatments was not specifically collected. The PI was the only individual to place the pillows, but there is the possibility that the infants were additionally soothed by the presence of their parents. There was no attempt made to control for this variable.

Strengths of the Study

The primary strength of this study is its focus on new and exploratory research that identifies a subset of variables to quantify soothability in premature infants. This study identified an intervention that may help premature infants' soothe themselves. One of the benefits of this intervention is ease of application. The simplicity of the flax seed pillow increases the potential for utilization by parents, in that it requires a negligible amount of education and training required to use this intervention. The parents are not intimidated by the pillow as it has a familiar appearance to soft, stuffed toys, and in no way appears highly technical. Both aspects allow parents to easily understand its application and use.

A particular strength of this study is the design, which was a randomized control, pre/post intervention design. This design minimized the threat of selection bias. Reliability was enhanced in that there was only one person responsible for data collection regarding assessing the neonates' state using the NIPS, and treatment fidelity was controlled, as only the primary investigator performed the intervention. Physiologic data was obtained via instrumentation (apnea monitor, cardiac monitor, and thermometer), which minimized subjectivity. Activity was collected by the Minimetter® Actigraph Actiwatch, which again minimized the issue of subjectivity. Data was downloaded and reviewed by only the primary investigator. Additional major strengths of this proposal include multiple measures of assessment with demonstrated validity and reliability for premature neonates, and only demographic data were self reported

The theory used to support this study was straightforward and provides additional strength to the study. The theory proposed that infants who are better able to adapt to the stressful environment of the special care nursery will expend less energy. Infants who expend less energy will utilize the nutritional calories they consume and gain weight more quickly.

Teaching parents about the necessity of appropriate stimulation and how to use gentle touch is an important aspect of newborn care, and the flax seed pillows may be a way to facilitate premature infant well being. It is essential that nurses and other health care providers caring for premature infants provide interventions, education and support to both the parents and the premature infants

The data also confirm prior research which demonstrates that tactile interventions help premature infants adjust to extra-uterine life (Dieter, et al., 2003; Field, Scafidi, & Schanberg, 1987). Successful adaptation for premature infants includes the ability to take in nourishment and gain weight. Promoting soothability may assist infants to adapt in such a way as to reduce stress, and subsequently promote weight gain as well as fostering alert/awake states.

A number of other interventions focusing on positive tactile stimulation such as massage and facilitated tucking have been shown to reduce pain in premature infants

(Axelin, Salantera, &Lehtonen, 2006; Ward-Larson, Horn & Gosnell, 2004; Grunau, et al., 2004). Infants in this study had significantly lower pain scores after receiving the intervention of the flax seed pillow as well as decreases in heart rate and respiratory rate. These findings indicate decreased stress or pain in the treated neonates. This study is the first step in a process to better understand how touch via the flax seed pillow impacts premature infant outcomes. The pillow is simple to use, and was not associated with any negative outcomes during the course of the study.

This study also adds to the body of knowledge by exploring the value of actigraphy in premature infants. Actigraphy has been used to study activity and sleep in a variety of populations including adults, adolescents and infants with good validty and reliability (Werner, Molinari, Guyer, & Jenni, 2008: Sadeh, 1994: So, Buckley, Adamson, & Horne, 2005); however no published research was found that utilized this technology in premature newborns at the time of data collection.

Limitations of the Study

Despite encouraging results, this study has limitations that must be considered. The first limitation is related to issues concerning the sample population. The sample population was predominantly African American, and had a wide variation in gestational age, ranging from 30 to 37 weeks. The infants were born at one Midwestern teaching hospital. Although not statistically significant, the intervention and control groups were not similar with respect to gender. A larger proportion of males were randomized to the study group, and it is not known if a sex difference in response to touch exists in premature infants. As race and gender are significant factors in premature infant outcomes, caution should be used to prevent inappropriate generalization to other groups.

None the less, the distribution of males and females in the sample was consistent with the gender birth ratios in the United States from data in 2002, where 1048 males were born for every 1000 females (Mathews & Hamilton, 2005).

A second limitation regards the relocation of the nursery during the course of the study. The relocation resulted in significant increases in total square footage per crib, in addition to changes in the amount and quality of lighting. Although the model of nursing care delivery remained the same in both the original and relocated space, nurses commented that the space seemed more peaceful. The nurses attributed this sense of increased peacefulness to having more space and being less likely to cluster together and socialize. Feelings of peacefulness in the staff and potentially the parents may have had an impact on the soothability of the infants, although no measurements were made to quantify this. A potential difference in method of care delivery therefore could be a confounding variable affecting the results. Due to sample size, a comparison of outcomes in infants before and after the move could not be computed.

Another variable related directly to nursing concerns the variation in nursing care provided by individual nurses. The study did not control for variance of caregiver effects, and the quality of care given by the assigned nurse may play a significant difference in each of the premature infant’s soothability and subsequent weight gain. The actigraphy watch measures motion and some of the motion detected by the watch would be the result of the care delivered by the nurse. Based on anecdotal observation alone, the PI noticed that some nurses delivered care more frequently and more vigorously than their peers. The actigraphy watch does quantify degrees of motion, but without further investigation to account for the motion related to nursing care, less can be determined about the actual motion of the infants.

Further complicating the measurement of infant activity is the practice of swaddling. Swaddling is used to calm infants and manage thermoregulation. Infants who are swaddled are far less able to move their extremities. Determining if the swaddling calmed the infants or merely restricted their movement was not controlled for during the study. This is a further limitation to the study in that activity was one of the dependent variables. Infants are also temporarily unwrapped on a regular basis for diapering, bathing and other procedures. Infants may also be unwrapped for ultraviolet light therapy for prolonged periods of time. The time periods can be hours or even days in duration. Although the use of ultraviolet light therapy was documented, the specific time parameters were not collected to the degree needed to make assumptions about how being unswaddled affected infant movement.

Another limitation is actigraphy watch data availability that primarily resulted from differences in time of watch placement or removal. Birth time, time of stabilization, discharge time and availability of an actigraphy watch or the PI were reasons for this discrepancy. As a result of this discrepancy, the decision was made to use only the data from actigraphy watch from days two, three and four, as they represented full 24 hours worth of data. Studies designed to replicate this research should consider extending the duration of treatment to seven days, in order to capture a full five days of actigraphy data. Other limitations specific to the watch are that the data is difficult to interpret and is expensive technology, therefore it may not readily available to all researchers.

The data gathered were limited by the observational perception of the one observer and the presence of the infants' clothing and swaddling blankets. No inter-rater reliability was established as there was only one investigator conducting the study. Future research should consider the use of two observers to address reliability. The investigator was aware of the timing of the control and experimental conditions and that may have biased the investigator's observations.

Self-selection occurs when individuals select themselves into a group. Self-selection makes it difficult to determine causation, and may bias this sample. Parents of premature infants are often desperate to identify and utilize interventions that they believe may facilitate their infant's well being for both short and long term outcomes. Parents who perceived their children as sicker, more premature or more unstable may have consented to participate more frequently than parents who perceived their premature infants to be more stable or healthy.

The original protocol planned to stratify the infants into four weight categories. However, due to a small numbers of infants in some weight strata, the decision was made to collapse the strata down to one for both the intervention and control groups. This limited the ability to identify if the intervention had different effectiveness based on infant weight.

Initial research on interventions designed to promote weight gain in premature infants employed treatments with a length of over ten days (Rice, 1977; Field, Scafidi, & Schanberg, 1987;White-Traut, 2002, Chen, et al., 2008). These studies found statistically significant increases in weight gain and decreases in hospital length of stay. Subsequent research (Arnon, et al., 2006, Diego, Field, & Hernandez-Reif, 2005, Whitley, & Rich, 2008) shortened the treatment to five days to test whether the interventions were still effective with shorter duration. That step was not taken in the design of this study and may have been a reason for the limited findings, as an initial study of ten days might have identified variables or conditions to adjust in subsequent studies with the flax seed pillow.

The pillow itself is also a limitation in that the pillow is not readily available in all markets. Pillows in the bed of any baby, regardless of gestational age or maturity who is not under continuous observation could be associated with morbidity. The American Academy of Pediatrics (AAP) specifically recommends that no toys be placed in bed with babies to prevent or minimize the risk of Sudden Infant Death Syndrome (SIDS). This precaution may limit the applicability of use of the pillow for parents in the home setting. Future studies should not use the intervention of flax seed pillows without continuous supervision. The risks associated with the use of the pillow are also not known, although no adverse or negative outcomes were identified in this study. Safety in the study was as important as the findings associated with the intervention itself since it was new exploratory research. A conservative approach with regards to the timing of the intervention was a reasoned choice.

Internal and external threats to reliability such as subject maturation and history were minimal in that the participants were enrolled for no more than five consecutive study days. Attrition was not a significant issue as only a total of 6 participants were unable to complete the study protocol. One participant was discharged prior to the five days.

Diffusion, resentful demoralization and compensatory equalization of treatments were not threats for the neonates since they are too young and cognitively immature to share study information amongst themselves, and since the infants were in separate isolettes and cribs, and effectively isolated from the other participants. There was a possibility that these threats might be actualized for the parents of the neonates. To minimize this, parents of infants in the control group were given flax seed pillows upon their infants' discharge from the hospital

The rolling enrollment format may also be a limitation to the study. As such, the number of infants enrolled at any one was limited by the number of Actiwatches available to the PI. There were twelve potential participants who could not be enrolled as a result of the lack of equipment

The Hawthorne effect was an unlikely threat to external validity in this study due to the age of the participants. The Hawthorne effect is an event, which describes a temporary change to behavior or performance simply in response to a change in the environmental conditions. Typically the response change is an improvement. Landsberger (1958) defined the *Hawthorne effect* as "a short-term improvement caused by observing worker performance". Blinding the nurses and other special care nursery staff was not be possible, since the nursery staff was able to observe which infants received the pillow intervention simply as a result of the simultaneous presence of the PI and the nurses in the SCN.

The threats to external validity were primarily related to generalizability. Generalizability may be a limitation since there was only a single rater, which may make it difficult for future replication. Standard care in the study nursery is unlikely identical to other high risk nurses in other locations. The participants may be different with regards to gestational age, gender and race from other populations. The general model of care within the study nursery may be another variable that affects generalizability. Final sample size and possible homogeneity may also limit generalization the larger population.

Implications for Nursing Practice

Despite the limitations, the results of this study have clear implications for the nursing care of premature infants in special care nurseries and the counseling of parents. Fostering the nurse's understanding of the synactive theory of Developmental Care has both clinical and educational implications for practice. Nurses who understand the implications of developmental care can teach parents to employ interventions to promote soothability in their infants. As the initial sleep patterns of newborns do not vary much over the 24 hour day, caregivers would be able to provide this intervention at any time of the day or night. When parents can participate more fully in the care of the infant, there may be noteworthy long-term benefits to the parent-child relationship. This relationship can be strengthened with the use of the flax seed pillow throughout the 24 hour day thereby accommodating unpredictable visitation time frames as a result of other parental priorities

Although the infants in the intervention group did not gain more weight by discharge or have shorter hospital lengths of stay, the infants in the intervention group exhibited changes in heart rate, respiratory rate and pain scores that indicated decreased levels of discomfort and greater soothability. Increased awareness of infant pain coupled with a simple intervention to resolve it, can impact daily nursing care.

In addition to changes in physiologic responses, the infants in the study group also demonstrated less time asleep. Early research indicated that infants who demonstrate increased alertness and wake time are more likely to progress, while those who are overwhelmed, spend more time asleep and are more likely to do poorly (Brazelton, 1962). This information provides the nursing profession with reason to continue to research this area of study as well as a heightened awareness to the importance of changes identified in the newborns vital signs.

Advances in technology have improved both mortality and morbidity of premature infants, but not without cost. Technology has caused the premature infants' environment to become more mechanized, whereas the flax seed pillow allows caregivers an option that provides positive, tactile stimulation in a simple, noninvasive format. Nursing care must include the provision of more opportunities for positive touch, and the involvement of parents in the care of their premature infants. Nurses are the primary caregivers of premature infants in high risk nurseries. The findings suggest that providing positive, gentle touch in the form of the flax seed pillow helped premature infants adjust to an environment significantly different than the uterine environment. The study findings underscore the need for nurses to comfort their patients and support the claim that behavioral interventions make a difference in infant soothability. This intervention has the potential to improve premature infants' comfort and therefore is one of primary concern for nursing.

Research demonstrates the need for nurses to recognize the potential of noxious stimuli. Noxious stimuli can come in the form of noise, excessive light, temperature variations and negative touch from procedures and treatments. Premature infants are less able to filter out noxious stimuli than full term infants and, are less able to self-comfort themselves. Negative touch disrupts the normal state patterns of premature infants and causes increases in physiologic stress. Premature infants demonstrate a hyper-responsive reaction to the environment and spend more energy coping with the environment, exhibiting signs of stress such as changes in muscle tone, irregular respirations, irritability and looking away (Als, 1986). Nurses should make every effort to avoid negative touch and use positive, gentle touch to improve soothability in their patients.

Implications for Future Research

This study is the first to examine the efficacy of tactile stimulation in the form of a flax seed pillow. This study provides researchers with information on soothability in premature infants that specifically relates to changes in physiologic measures of heart rate, respiratory rate and pain scores, in addition to sleep and wake time. Although this sample of infants did not demonstrate differences in either weight gain by time of discharge or length of hospital stay, it is new exploratory research and changes to the protocol may have different findings.

One suggested change for future research is the use of a larger cohort. A larger cohort would allow for better analysis of affects on specific populations and would address issues identified in this study with regards to gender, race and gestational age of the participants. The sample size, although adequately powered for this study, may not have been sufficient to capture nuances of premature infant outcomes with respect to weight gain and length of stay. A more sophisticated statistical examination of the data could be performed if the number of subjects was larger, and the sample more homogenous with regards to gestational age and gender. Future studies should also examine the effect of the pillow using a matching approach on the participants. Controlling for gender, race and gestational age could identify whether there is a genetic component to soothability as gender and race may be factors.

Future research could establish causality by decreasing confounding factors and examine weight gain only during the period of intervention. As mentioned previously, earlier research which examined new interventions to promote weight gain in premature infants did so over a ten day period. After positive findings were identified, subsequent studies shortened the duration to five days. This study may have found more significant results had the duration of the intervention been a full ten days.

In addition to extending the duration issues related to timing of intervention can also be further explored. Nursing has made changes in care delivery to cluster treatments and procedures for premature infants providing the infants with more quiet or undisturbed time. During these prolonged periods of quiet, the pillow could be placed on the infant for extended periods of time thus increasing the dose effect. Refinement in the methodology should also include pillows that are weight adjusted to the infant's birth weight. The 170 gram pillow used in this study represented 4% to 15% of the infant's birth weight.

The selection of pillow placement soon after feeding was intentionally selected so that hunger or limited energy would not be a factor. Perhaps other time periods may be more effective, including those times immediately after a painful or stressful procedure or treatment. The temperature of the pillow should also be examined in future research, as warmed pillows may be more soothing than room temperature pillows. No information indicates the optimal frequency, duration, temperature or intensity of tactile stimulation of the flax seed pillow. These issues could be clarified with further study. Some research has been completed examining the effect of odor with newborns, particularly that of the scent of the infant's mother. Future research could examine the efficacy of flax seed pillows impregnated with the mother's scent on infant soothability.

At present, little published research ascertains the applicability of actigraphy in premature infants. This scarcity of information supports further study of the use of the actigraphy watch and premature infants, but caution is needed to account for the motion or activity that is exogenous to the infant. This study provides initial exploration and identifies that the use of actigraphy requires further exploration to determine its value in this population. Future research should examine the effect of placing the watch on the upper extremities versus the lower extremities, as they are less likely restrained in the process of facilitated tucking, swaddling or containment. Understanding the applicability of actigraphy in the population of premature infants is recommended to determine if it is an aid in predicting outcomes.

Future studies should examine how the duration and frequency of nursing and other care provider generated stimulation affects soothability and other outcomes of premature infants. Pairing nurses so that each nurse has infants in the intervention and control groups, could identify if care giver stimulation is a factor in premature infant soothability.

Premature infants are not the only group of newborns that struggle with the stressful environment of the nursery and adaptation to life outside the uterus. Infants born to mothers with alcohol, tobacco and drug addictions also undergo a stressful adaptation to a new environment. Research to examine the effectiveness of the flax seed pillow for infants with Neonatal Abstinence Syndrome is also recommended.

Summary

Chapter V provided discussion of the findings of a study, based on previous research, which investigated the effect of a flax seed pillow on the soothability of preterm infants. This study examined the Soothability in Preterm Neonates model to understand the relationship between stressful stimuli, soothability and growth. Soothability was the ability of the newborn to quiet and calm itself with assistance provided by the nurse or parent(s). Infants who were soothed, demonstrated decreases in heart rate, respiratory rate and pain scores, and improved behavioral state regulation measured by sleep and wake time through the use of actigraphy. This technology has the opportunity to provide new information regarding the relationship between activity and the general experience or premature infants in their initial days of extra-uterine life.

Interventions specifically directed to improve premature infant soothability can assist premature infants make the transition to life outside the uterus more smoothly both in the short and long term. Long term outcomes of weight gain and hospital length of stay appear to be complex enough that they may not be affected by soothability. Soothability is an unsupported model, using sleep time, wake time, and mobile time as proxies for soothability, in addition to the modulation of heart rate, respiratory rate and pain score. These proxies are not yet standardized nor currently accepted in the industry and therefore require further study.

Assistance from caregivers may take many forms; and in this study assistance was provided in the form of the flax seed pillow. The intervention offered an opportunity to assist premature infants, without associated stress or compromise, achieve improved infant outcomes. The pillow may well be an intervention to achieve faster weight gain and early discharge. The results of this study contribute to a more complete understanding of the developmental needs of preterm infants as well as responses to a specific caregiver intervention.

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APPENDIXES

APPENDEX A

IRB Approval – University of Missouri-St. Louis

University of Missouri St. Louis

OFFICE OF RESEARCH ADMINISTRATION

Interdepartmental Correspondence

The UM-St. Louis Human Subjects Committee reviewed the following protocol:

Name: Holly Diesel

Title: Soothability in Preterm Infants

This proposal was approved by the Human Subjects Committee for a period of one year starting from the date listed below. The Human Subjects Committee must be notified in writing prior to major changes in the approved protocol. Examples of major changes are the addition of research sites or research instruments.

An annual report must be filed with the committee. This report should indicate the starting date of the project and the number of subjects since the start of project, or since last annual report.

Any consent or assent forms must be signed in duplicate and a copy provided to the subject. The principal investigator is required to retain the other copy of the signed consent form for at least three years following the completion of the research activity and the forms must be available for inspection if there is an official review of the UM-St. Louis human subjects research proceedings by the U.S. Department of Health and Human Services Office for Protection from Research Risks.

This action is officially recorded in the minutes of the committee.

Protocol Number	Date	Signature - Chair
090105D	2/3/09	[signature]

APPENDIX B
IRB Approval – Washington University

Washington University in St. Louis

6/08
Human Research Protection Office
Box 8089
(314) 633-7479
Fax (314) 367-3041

Social-Behavioral-Educational Research
Request for Modification to a Currently Approved Study
[illegible]

Date: 1/21/09

Project Director:
Holly Johanna Diesel
Phone: 314 454-8471
Fax: 314 362-4870
Campus Box or Address:
Barnes-Jewish College Goldfarb School of Nursing 4483 Duncan, St. Louis, 63110
Email:
Hdiesel@bjc.org

Faculty Sponsor:
NA
Phone: Fax: Campus Box:
Email:

Administrative Contact (if applicable)
NA
Phone: Fax: Campus Box:
Email:

Project Title: Soothability in Preterm Infants

HRPO #: 08-1350

I assure that the requested changes will not be initiated without HRPO approval, except when necessary to eliminate apparent immediate hazards to research participants.

Project Director Signature Date

Faculty Sponsor Signature Date

For HRPO use: MODIFICATION APPROVED

Signature of Chair/designee Date

Behav Modification 6/08
Version date: 10/6/08

Page 1 of 2

APPENDIX C

Informed Consent

Washington University in St. Louis

Human Research Protection Office
Box 8089
(314)633-7479
Fax (314)367-3041

CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

Title of Project: **Soothability in Preterm Infants** HRPO Approval Number: **08-1350**

1. a) You and your baby are invited to participate in a research study conducted by Holly Diesel, RN, PhDc, a doctoral student at the University of Missouri - St. Louis, and faculty member at the Barnes-Jewish College Goldfarb School of Nursing. The overall purpose of this research is to measure the effects of a soothing pillow on premature infants' weight gain and hospital length of stay. During this study your baby will be randomly placed in either the control group or the experimental group for five days. Babies in the experimental group will have a soothing pillow placed on their back for 15 minutes two times a day. A small watch-like monitor will be placed on your baby's ankle for the five days of the study. All babies will be weighed daily, and their vital signs will be monitored.

   b) The amount of time required for your baby's participation will be 15 minutes twice a day for five consecutive days. There is no compensation for you or your baby; however, you will be given the soothing pillow as a memento after your baby has completed the study.

2. There are very few reasonably foreseeable risks or discomforts for your baby, but it is possible that your baby's heart rate or breathing or temperature may change as a result of the treatment. Your baby will be constantly monitored during the treatment, and if problems occur, the treatment will be stopped.

3. The possible benefits your baby may experience because of participation in this study are unknown at this time.

4. Your participation is entirely voluntary and you may choose not to participate in this study or withdraw your consent at any time. You will not be penalized in any way should you choose not to participate or withdraw.

   For studies with PHI without a Certificate of Confidentiality
   Protected Health Information (PHI) is health information that identifies your baby. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your baby's PHI for the study explained in this consent form.

   In addition to health information that may be created by the study, the research team may access the following sources of your health information to conduct the study: physicians' and nurses' notes.

   The research team will follow state and federal laws and may share your

information with:

- Government representatives, (including the Office for Human Research Protections or the Food and Drug Administration) to complete federal or state responsibilities
- Hospital or University representatives, to complete Hospital or University responsibilities
- Your primary care physician if a medical condition that needs urgent attention is discovered

Once your baby's health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your baby's information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

You may access the research record by contacting Holly Diesel, RN, PhDc at 314 454-8471...

If you decide not to sign this form, it will not affect

- Your baby's treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your baby's PHI for this research
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu (or use the direct link: http://hrpohome.wustl.edu/participants/WithdrawalTemplate.rtf) or you may request that the Investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared if necessary for safety reasons.
      - You will not be allowed to continue to participate in the study.

Please specify any contact restrictions you want to request for this study only.
(Example – no calls at home, no messages left for you, no –emails, etc.)

5. There are no alternative procedures or courses of treatment in the nursery at this time, however your baby will receive standard nursery care whether you participate in this study or not

6. We will do everything we can to protect your baby's privacy. As part of this effort, your baby's identity will not be revealed in any publication that may result from this study. In rare instances, a researcher's study must undergo an audit or program evaluation by Washington University or an external oversight agency (such as the Office for Human Research Protection). This may result in the disclosure of your baby's data as well as any other

information collected by the researcher. If this were to occur, such information would only be used to determine whether the researcher conducted this study properly and adequately protected your rights as a human participant. Importantly, any and all audits would maintain the confidentiality of any information reviewed by their office(s).

7. a) If you have any questions or concerns regarding this study, or feel that you have been harmed in any way by your participation in this research, please contact Holly Diesel, RN, PhDc at 314 454-8471.

   b) If you wish to talk with someone else or if you have questions about your rights as a research participant, please call Dr. Philip Ludbrook, Executive Chair of Washington University's Human Research Protection Office, at 3l4-633-7400 or 1-800- 438-0445.

I have read this consent form and have been given a chance to ask questions. I also will be given a signed copy of this form for my records. I agree to participate in the research study described above, titled *Soothability in Preterm Infants*.

Parents, Guardian or Legally Authorized Representative's consent on participant's behalf.

____________________________________ **Signature**	__________________ **Date**
____________________________________ **Printed Name**	____________________________ **Relationship to research participant**
____________________________________ **Signature of person obtaining consent**	__________________ **Date**
____________________________________ **Printed name of person obtaining consent**	

This form is valid only if the Human Research Protection Office's current stamp of approval is shown below.

APPENDIX D

Recruitment Flyer

Washington University in St.Louis

Are you interested in your baby participating in a study about improved weight gain?


I am recruiting research participants to study the effect of a soothing pillow on premature infant weight gain. To participate, your baby must be between the gestational ages of 30 and 37 weeks, and medically stable. The purpose of this study is to find out if premature babies who are soothed by the pillows will gain weight more quickly and have shorter hospital lengths of stay. The study will last for five days. At the end of the study, you will be given the soothing pillow as a keepsake of your baby's stay in our nursery.

Please call Holly at 454-8471 to find out more about this study, or let your L&D nurse know that you are interested.

APPENDIX E

Data Collection Tool

Pt ID No. ______________ Date: ___________

Maternal age		Birth Heart Rate	
Gravity/Parity		Birth resp. rate	
Race		Birth temperature	
Birth date/time		Blood glucose	
Birth weight		Weight at DC	
Birth length		Length of Stay	

Other information at birth:

Day 1 Time 1a		**Day 1 Time 2a**	
Daily weight			
NIPS score		NIPS score	
Minimetter time on			
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	
Day 1 Time 1b		**Day 1 Time 2b**	
NIPS score		NIPS score	
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	

Monitors: □ IV □ O2 □ Feeding Tube □ Pulse OX □ Other ____________

Day 2

Day 2 Time 1a	Pretreatment	**Day 2 Time 2a**	Pretreatment
Daily weight			
NIPS score		NIPS score	
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	
Day 2 Time 1b	Post treatment	**Day 2 Time 2b**	Post treatment
NIPS score		NIPS score	
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	

Monitors: □ IV □ O2 □ Feeding Tube □ Pulse OX □ Other ____________

Day 3

Day 3 Time 1a	Pretreatment	**Day 3 Time 2a**	Pretreatment
Daily weight			
NIPS score		NIPS score	
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	
Day 3 Time 1b	Post treatment	**Day 3 Time 2b**	Post treatment
NIPS score		NIPS score	
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	

Monitors: □ IV □ O2 □ Feeding Tube □ Pulse OX □ Other ___________

Day 4

Day 4 Time 1a	Pretreatment	**Day 4 Time 2a**	Pretreatment
Daily weight			
NIPS score		NIPS score	
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	
Day 4 Time 1b	Post treatment	**Day 4 Time 2b**	Post treatment
NIPS score		NIPS score	
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	

Monitors: □ IV □ O2 □ Feeding Tube □ Pulse OX □ Other ___________

Day 5

Day 5, Time 1a	Pretreatment	**Day 5, Time 2a**	Pretreatment
Daily weight			
NIPS score		NIPS score	
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	
Day 5, Time 1b	Post treatment	**Day 5, Time 2b**	Post treatment
NIPS score		NIPS score	
Heart rate		Heart rate	
Respiratory rate		Respiratory rate	
Temperature		Temperature	

Monitors: □ IV □ O2 □ Feeding Tube □ Pulse OX □ Other ___________

APPENDIX F

<u>Neonatal/Infant Pain Scale (NIPS)</u>

Recommended for children less than 1 year old
A score greater than 3 indicates pain

Pain Assessment

Criteria	Description	Score
Facial Expression • Relaxed muscles • Grimace	 • Restful face, neutral expression • Tight facial muscles, furrowed brow, chin, jaw	 • 0 • 1
Cry • No cry • Whimper • Vigorous cry	 • Quiet, not crying • Mild moaning, intermittent • Loud scream, rising, shrill, continuous	 • 0 • 1 • 2
Breathing Patterns • Relaxed • Change in breathing	 • Usual pattern for this infant • Indrawing, irregular, faster than usual, gagging, breath holding	 • 0 • 1
Arms • Relaxed, restrained • Flexed/extended	 • No muscular rigidity, occasional random movements • Tense, straight arms, rigid or rapid extension or flexion	 • 0 • 1
Legs • Relaxed, restrained • Flexed/extended	 • No muscular rigidity, occasional random movements • Tense, straight arms, rigid or rapid extension or flexion	 • 0 • 1
State of Arousal • Sleeping/awake • fussy	 • Quiet, peaceful sleeping or alert random movement • Alert, restless, thrashing	 • 0 • 1

The NIPS is a behavioral assessment tool for measurement of pain in preterm and full-term neonates. It can be used to monitor a neonate before, during and after a procedure.

SUM = points for all indicators. Interpretation: Minimum score = 0, Maximum score = 7

Limitations: a falsely low score may be seen in an infant who is too ill to respond

References:

Lawrence, J., Alcock, D., McGrath, P., Kay, J., MacMurray, S.B., & Dulberg, C. (1993). The development of a tool to assess neonatal pain. *Neonatal Network: Journal of Neonatal Nursing, 12*(6), 59-66.

APPENDIX G

PILLOW SPECIFICATIONS

Cover	100% Cotton Flannel
Contents	Organic, untreated, unscented golden flax seed
Weight	170 grams
Manufacturer	Mother Earth Pillows, St. Louis, Missouri

APPENDIX H

ACTIGRAPHY WATCH SPECIFICATIONS

Respironics Actiwatch

Size:	43 mm x 23 mm x 10mm
Weight:	16 grams (with band)
Case Material:	ABS Blend (biocompatible)
Battery Type:	Lithium cell (rechargeable at dock)
Battery Charge Time:	6 hours from empty to full
Logger Battery Life:	30 days at 1 minute epoch lengths
Memory:	Non-volatile 1 MBits
Moisture Protection:	Waterproof 1 m for 30 min
Operating Temperature:	5 to 40 degrees Celsius
Resistance:	Dust, water, heat, cold and perspiration

Accelerometer Details

Type:	Solid state "plezo-electric"
Range:	0.5- 2 G peak value
Bandwidth:	0.35- 7.5 Hz typical
Sensitivity:	0.025 G (a 2 count level)
Sampling Rate:	32 Hz

APPENDIX I

Holly Diesel, RN, PhDc
February 10, 2009

Dear ____,

Thank you so much for your decision to allow your baby to participate in my study.

As you know, nurses are always seeking the best ways to help their patients, even the youngest and tiniest ones.

With the generous support of people like you, I hope to be able to develop another way to help babies born too early, cope with their new environment. When your baby has completed the five days of the study, I hope you will take the little heart pillow as a reminder of your stay in the hospital, and as evidence of the support you both gave to helping premature babies.

Thank you again,

Sincerely,

Holly Diesel, RN, PhDc

APPENDIX J

I'm in Holly's Study

Please save the pillow and the little grey watch/ankle bracelet