ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อการจัดการของพฤติกรรมระบบประสาทของทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก

นางสาวพัชรี จันทรักษา

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาพยาบาลศาสตรดุษฎีบัณฑิต

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ปีการศึกษา 2552

EFFECTS OF INDIVIDUALIZED ENVIRONMENTAL MODIFICATION PROGRAM ON NEUROBEHAVIORAL ORGANIZATIONS OF THE VERY LOW BIRTH WEIGHT INFANTS

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A Dissertation Submitted in Partial Fulfillment of the Requirements

for the Degree of Doctor of Philosophy Program in Nursing Science

Faculty of Nursing

Chulalongkorn University

Academic year 2009

Thesis Title	EFFECTS OF INDIVIDUALIZED ENVIRONMENTAL MODIFICATION PROGRAM ON NEUROBEHAVIORAL ORGANIZATIONS OF THE VERY LOW BIRTH WEIGHT INFANTS
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พัชรี จันทรักษา : ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อการจัดการของพฤติกรรมระบบประสาทของทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก. (EFFECTS OF INDIVIDUALIZED ENVIRONMENTAL MODIFICATION PROGRAM ON NEUROBEHAVIORAL ORGANIZATIONS OF THE VERY LOW BIRTH WEIGHT INFANTS) อ.ที่ปรึกษาวิทยานิพนธ์หลัก : ศ. ดร. วีณา จีระแพทย์, 151 หน้า.

การศึกษานี้มีวัตถุประสงค์เพื่อเปรียบเทียบผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อการจัดการของพฤติกรรมระบบประสาทของทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก โดยศึกษาทารกเกิดก่อนกำหนดที่มีอายุครรภ์ 37 สัปดาห์หรือน้อยกว่า และมีน้ำหนักแรกเกิดน้อยกว่าหรือเท่ากับ 1,500 กรัม เข้ารับการรักษาในหออภิบาลทารกแรกเกิด จำนวน 25 คน ทารกจะได้รับการดูแลตามแผนการรักษาพยาบาลมาตรฐานของโรงพยาบาลในช่วงควบคุม และได้รับโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลร่วมด้วยในช่วงการทดลอง ได้แก่การปรับระดับแสงแบบกลางวัน – กลางคืน การเปิดเพลงบรรเลง และการให้กลิ่นลาเวนเดอร์ กิจกรรมการพยาบาลที่จัดให้ขึ้นอยู่กับพฤติกรรมตอบสนองและการทนต่อสิ่งเร้าหรือสิ่งแวดล้อมของทารกเกิดก่อนกำหนดเป็นสำคัญ โดยประเมินจากขีดความสามารถในการจัดการตนเองและความต้องการของทารก แบบสังเกตพฤติกรรมทารก Naturalistic Observation of Newborn Behavior (NONB) จะใช้ในการวัดพฤติกรรมระบบประสาทของทารกเกิดก่อนกำหนด ก่อนการศึกษา หลังช่วงควบคุม (post-control) และหลังช่วงทดลอง (post-experiment) สถิติเชิงพรรณา และ การวิเคราะห์ความแปรปรวนแบบทางเดียว มีการวัดซ้ำ (One way repeated measures ANOVA) ใช้สำหรับเปรียบเทียบค่าเฉลี่ยพฤติกรรมระบบประสาทของทารกเกิดก่อนกำหนดระหว่างช่วงควบคุมและช่วงทดลอง

ผลการศึกษาพบว่า ทารกเกิดก่อนกำหนดแสดงการจัดการของพฤติกรรมระบบประสาทในช่วงการทดลองดีกว่าในช่วงควบคุม และทารกมีระยะเวลาการหลับในช่วงการทดลองนานกว่าในช่วงการควบคุม การส่งเสริมการจัดการของพฤติกรรมระบบประสาทของทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก ด้วยโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคล จะสามารถช่วยส่งเสริมพัฒนาการทางระบบประสาทของทารก และพัฒนาองค์ความรู้ที่มีอยู่เดิมเกี่ยวกับการปรับเปลี่ยนสิ่งแวดล้อมให้เหมาะสมกับการพัฒนาระบบประสาทและพฤติกรรมของทารกเกิดก่อนกำหนดให้ดียิ่งขึ้น

สาขาวิชา พยาบาลศาสตร์ ลายมือชื่อนิสิต

ปีการศึกษา 2552 ลายมือชื่ออ.ที่ปรึกษาวิทยานิพนธ์หลัก

4677974736 : MAJOR NURSING

KEYWORDS : VLBW INFANTS / NEONATAL UNIT / NIDCAP / NEUROBEHAVIORAL ORGANIZATION / INDIVIDUALIZED ENVIRONMENTAL MODIFICATION

PATCHAREE JUNTARUKSA : EFFECTS OF INDIVIDUALIZED ENVIRONMENTAL MODIFICATION PROGRAM ON NEUROBEHAVIORAL ORGANIZATIONS OF THE VERY LOW BIRTH WEIGHT INFANTS. ADVISOR : PROF. VEENA JIRAPAET, RN, PHD, 151 pp.

This study was aim to evaluate the effects of individualized environmental modification (IEM) program on neurobehavioral organizations of VLBW infants who admitted in neonatal unit. Twenty-five preterm infants weighing less than 1500 g. and born before 37 weeks' gestation were studied. All infants were served as their own control which received conventional nursing care during control period. IEM program was provided during experimental period which consists of day-night lighting, classical music playing and lavender smelling. The activities were adjusted to the appropriate level of intensity and duration based on each infant's responses. Naturalistic Observation of Newborn Behavior (NONB) was used to observe infants' neurobehavioral organization at baseline, control period and experimental period. Descriptive statistic was used to analyze infants' demographic data. Repeated measures ANOVA was used to compare mean different of neurobehavioral outcomes of infants between control period and experimental period.

The research results showed that infants in experimental period had significantly showed better positive autonomic responses, positive motoric behaviors and positive attention behaviors comparing to control period. Additionally, infants in the experiment period sleep longer and spent fewer times in transitional and arousal states than in the control period.

In conclusion, VLBW infants were benefited from IEM program in term of neurobehavioral organization. Promotion of VLBW infants' neurobehavioral organization admitted in a sick newborn unit can be implemented by integrated the IEM program in a routine nursing care for VLBW infants.

Field of Study : Nursing

Academic Year : 2009

Student's Signature Patcharee J.

Advisor's Signature Veena Jirapaet

ACKNOWLEDGEMENTS

Special gratitude to Prof. Dr. Veena Jirapaet, my advisor, who has provided valuable guidance, support and encourage throughout the study. My gratefulness to the Board of Assumption University who provided a full scholarship for my PhD program and the 90th Anniversary of Chulalongkorn University Fund and Thailand Nursing Council for financial supporting my dissertation.

My appreciations go to Miami Aromatherapy Inc. for donating lavender essential oils and Assoc. Prof. Dr. Heidelise Als, the President of the NIDCAP Federation International, for her permission of using NONB in my dissertation. Special thanks are extended to Asst. Prof. Dr. Paul F. Cook, Asst. Prof. Dr. Madalynn Neu, Mr. Theerawut and team for statistical advising, knowledgeable sharing, facilitating and technical supporting. Many thanks go to the VLBW infants and their parents who participated in the study and to health care staffs of neonatal unit at Queen Sirikit National Institute of Child Health for providing the study setting and great facility during study.

Sincere thanks are extended to all five expertises, Prof. Dr. Kraingsak Jirapaet, Asst. Prof. Dr. Santi Punnahitanon, Assoc. Prof. Wilai Lerthamtewe, Ms. Vimonwan Varolarn and Ms. Pikun Khamsribus for sharing valuable knowledge and useful comments. My expression of appreciation to all dissertation defense committees, Associate Professor Dr. Yupin Aungsuroch, Assistance Professor Dr. Chanokporn Jitpunya, Associate Professor Dr. Fongcum Tilokskulchai, Assistance Professor Dr. Pramote Praisuwanna, and Associate Professor Dr. Siripaarn Suwanmonkha who provided sharpened view point, insightful comments and valuable suggestions for the completion of this dissertation.

Deepest thanks to Asst. Prof. Dr. Nanthaphan Chinlumprasert, my lovely Dean, for providing the great opportunity and support throughout my study. Ms. Phat Prapawichar, my closest friend, for praying, helping, encouraging, and working hard during my study leave.

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CHAPTER I

INTRODUCTION

Background and significant of the study

Healthy term babies were born probably with developed organs and, for the most part, possible function from birth. With extrauterine life, the newborns received stimulation from the new environment via their sensory systems. The developing of central nervous system (CNS) functions in a manner that allowed it to control the bodily systems, as well as, the body's response to environmental stimuli known as neurobehavioral organization (Als, 1986; 1999). For instance, after birth, healthy newborns were disturbed by environment that surrounded them; full of stimuli such as bright light, loud noises, unpleasant odors and too frequent handling, and their CNS could interact with those stimuli in order to stabilize their physiological and behavioral responses. This condition was called neurobehavioral organization, and it commonly occurred in healthy term infants (Als, 1986; Peters, 2001). Unlike the term babies, premature infants had difficulties adjusting to their environment. They also had various level of immature CNS, which led to neurobehavioral disorganization. The very low birth weight (VLBW) infant who born before 37 weeks of gestation and had body weight less than 1500 grams at birth was at a high risk for having neurobehavioral disorganization and having inappropriate responses to environment around them (Als, 1986; Taquino & Lockridge, 2004; Perlman, 2001).

The unavoidable environmental stimuli in the neonatal unit that VLBW preterm infants received via their sensory system included bright light, loud noise, unpleasant odor and frequent handling could effect infants' brain development (Perlman, 2001), physiological and behavioral responses, and had been associated with the development of neurobehavioral disorganization in VLBW preterm infants (Taquino & Lockridge, 1999). Additionally, neurobehavioral disorganization effected morbidity and mortality rate of VLBW premature infants by causing poor disease prognosis, delayed neurological development, and permanent sensory impairment (Taquino & Lockridge, 2004). For example, the neurobehavioral disorganized infants who had apnea and bradycardia needed advance technology such as ventilator to support and monitor their physiological imbalance which indicated clinical distress. Consequently, infants who had neurobehavioral disorganization required hospitalization longer in neonatal unit. The average hospital stay for a very low birth weight infant (under 1,500 gm) was about 5 to 7 weeks with high hospital expense, thus they had a higher cost of hospitalization than neurobehavioral-organized infants (Browne, 2003; Field, Hernandez-Reif & Freedman, 2004).

While VLBW preterm infants were hospitalized, neonatal nurses would certainly provide conventional nursing care by offering continuous clinical monitoring via the use of both nursing observation, technology, and the use of life support systems. Conventional nursing activities were based on the principle of newborn care including thermal regulation, nutrition, infectious control, respiratory care, bonding and attachment, and specific care related to particular illness which focused on the basic needs of newborns and specific care related to current illnesses. Practically, the principles of newborn care that were used as conventional neonatal nursing care in neonatal unit in Thailand were not tailored to combat neurobehavioral disorganization which was a phenomenon presented in this study. Therefore, neonatal nursing innovation as individualized environmental modification was needed to promote neurobehavioral organization in VLBW preterm infants.

The study of environmental modification which manipulated environment in the neonatal unit was focused in order to improve neurobehavioral disorganization. Studies of various environmental stimuli such as light, smell/odors, and noise modifications were reviewed. Additionally, multiple environmental modification studies were also reviewed to determine state of science in environmental modification area.

Day-night lighting was a modification of light environment to promote the longer sleep period in premature infants. Some evidence confirmed that providing cycle light had improved health outcome and development in VLBW infants (Brandon, 2000; 2002), and improved oxygen saturation (Chawaphanth, 2004). When the baby was in the womb, the fetus usually perceived the biological clock, known as circadian rhythm from the mother. With extrauterine life, infants needed to continue developing their circadian rhythm. The circadian rhythm was thought to play an important role of behavioral responses as a sleep-wake cycle and essential growth hormone regulation. Therefore, day-night lighting was provided to the infant in the neonatal unit to promote the circadian rhythm.

Music was thought to be a modified sound strategy to sooth premature infants. VLBW infants who exposed to music displayed increased daily weight gain (Caine, 1991; Standley, 1998, Lubetzky, 2010), improved oxygen saturation level (Chou, et al., 2003; Bruke et al., 1995; Standley & Moore, 1995; Collins & Kuck, 1991), shortened hospital stay (Caine, 1991), reduced heart rate (Arnon et al., 2006), reduced stress behaviors (Caine, 1991; Butt & Kisilevsky, 2000), had deeper sleep (Burke et al., 1995) and improved behavioral state (Collins & Kuck, 1991; Kaminski & Hall, 1996). Music with the softer and slower melody was also thought to buffer the negative sounds which actually occurred in the neonatal unit (Standley, 2002).

Lavender odorant was a modified smell environment to promote relaxation (Styles, 1997; Saeki, 2000; Wheatley, 2005; Zwelling, Johnson & Allen, 2006), calm and improve sleep patterns (Cannard, 1996), improve agitated behaviors (Holmes, 2002; Lin et al., 2006), reduce stress (Muzzarelli, Force & Sebold, 2006), reduce anxiety (Buckle, 1993; Kim et al., 2006), decrease stress hormone (Atsumi & Tonosaki, 2007), reduce pain intensity and unpleasantness (Gedney et al., 2004), aid to sleep (Wheatley, 2005) and alleviate insomnia (Jones & Kassity, 2001), increase deep sleep and decrease rapid eye movement (REM) sleep (Goel, Kim & Lao, 2005). Those studies were confirmed the benefits of lavender which had significantly affects in healthy adult, aging people with dementia, adolescent and child underwent an operation. Although, there was no study of lavender inhalation in VLBW infant in the neonatal unit, certain benefit from previous studies such as relaxation, deeper sleep, reduced stress and agitated behavior could be expected in the VLBW in neonatal unit. The study of Schaal, Hummel and Soussignan (2004) confirmed that premature infants had ability to sense and differentiate administered odorants. VLBW infants were also able to discriminate pleasant and unpleasant odor. Following sense of smell, the amygdala was actuated (Perez, 2003). The amygdale was an area of the brain that influences emotional response. It was believed that the input of lavender scent went to the amygdale in the VLBW infant's brain resulting in relaxation and promoted calmness that facilitated quiet sleep (Fontaine, 2005).

In this study, the Individualized Environmental Modification (IEM) program was established to maintain and promote the maturation of VLBW infants' neurobehavioral organization. The IEM was designed base on the Synactive Theory of Development (Als, 1982). The activities component consisted of exposure to day-night lighting, soothing music and lavender scent. The activities were adjusted to the appropriate level of intensity and duration based on each infant's responses.

Objective of study

The aim of this study was to evaluate the effects of individualized environmental modification program on neurobehavioral organizations, which measured the organized autonomic, motoric, state and attention system performance in VLBW preterm infants who were admitted in neonatal unit.

Research questions

1. What was the effect of individualized environmental modification (IEM) program on four components of neurobehavioral organizations of VLBW infants?
   1.1) What were the different autonomic system responses of neurobehavioral organizations in VLBW infants between period of IEM program and control?
   1.2) What were the different motoric system responses of neurobehavioral organizations in VLBW infants between period of IEM program and control?
   1.3) What were the different state system responses of neurobehavioral organizations in VLBW infants between period of IEM program and control?

1.4) What were the different attention system responses of neurobehavioral organizations in VLBW infants between period of IEM program and control?

Hypotheses

1. Neurobehavioral organizations responses of VLBW infants when received IEM program (experimental period) are better than when received conventional nursing care (control period). The sub-hypotheses are as following:
   1.1) VLBW infants will present more positive autonomic responses and present less negative autonomic responses during experimental period than control period.
   1.2) VLBW infants will present more positive motoric behaviors and present less negative motoric behaviors during experimental period than control period.
   1.3) VLBW infants will spend more time in sleep state and spend less time in transitional and arousal state during experimental period than control period.
   1.4) VLBW infants will present more positive attention behaviors and present less negative attention behaviors during experimental period than control period.

Scope of study

The aim of this study was to evaluate the effects of individualized environmental modification program on neurobehavioral organizations of VLBW preterm infants who were admitted in neonatal unit at Queen Sirikit National Institute of Child Health, Bangkok, Thailand, during August, 2008 – March, 2009.

Operational definitions

Very Low Birth Weight (VLBW) Infants

The very low birth weight (VLBW) infant referred to infant who had an estimated gestational age of less than 37 weeks by using Ballard Maturation Score assessment and had a body weight of less than 1,500 grams at the time of delivery.

Individualized Environmental Modification Program

Individualized Environmental Modification (IEM) was a program consisting of nursing activities to maintain and promote the maturation of VLBW infants' neurobehavioral organization by modifying environment. The design of IEM program was based on the Synactive Theory of Development (Als, 1982). The activities component was provided based on the VLBW preterm infants' tolerance and responses to enhance comfort and stability to reduce stress and agitation for the infants. There were two phases of nursing activities as environmental modification for the infants in experimental period in neonatal unit including preparation phase and modification phase (see Appendix A).

Neurobehavioral organizations

Neurobehavioral organizations were the developmental ability of VLBW infant in maintaining the physiological and behavioral stability in his/her interactions with the environmental stimuli. Assessment of the developmental ability of neurobehavioral organization performance included autonomic, motoric, state and attention system of VLBW preterm infants (Als, 1986; 1999; NIDCAP Program Guide, 2007) as followed:

1. Autonomic system (Als, 1982; 1999; NIDCAP Program Guide, 2007) referred to 2 categories including:

   1.1) Positive autonomic responses score referred to the number of heart rate, oxygen saturation and positive skin color counted and divided by 30 (number of observation X number of response types). The observation of heart rate, oxygen saturation and positive skin color were as followed:

   1.1.1) Heart rate referred to the average score of regular heartbeats episode which measured in beats per minute. The normal heart rate was between 120 and 160 beat/min (Als & Lawhon, 2004).

   1.1.2) Oxygen saturation referred to the average score of normal arterial oxygen saturation of hemoglobin episode which measured in percent oxygen. The normal oxygen saturation range was between 92% and 95% (Jirapaet & Jirapaet, 2002; 2005).

   1.1.3) Positive skin color referred to the average score of pink skin color episode which observed by infant showed good perfusion with pink color throughout the face, including mouth and temple area.

   1.2) Negative autonomic responses score referred to the number of tremor, startle, twitch face, twitch body, twitch extremities, spit up, gag, burp, hiccough, bowel movement grunt, sounds, sigh and gasp counted and divided by 130 (number of observation X number of response types). The observation of tremor, startle, twitch face, twitch body, twitch extremities, spit up, gag, burp, hiccough, bowel movement grunt, sounds, sigh and gasp were as followed:

   1.2.1) Tremor was observed when infant showed trembling or quivering in any part of or whole body (e.g., leg tremor, chin tremor)

1.2.2) Startle was observed when infant showed sudden large amplitude jumping movement of arms or trunk or legs or whole body.

1.2.3) Twitch face was observed when infant showed small amplitude, brief contractile response of a skeletal muscle, elicited presumably by a single maximal volley of impulses which the neurons supplied; marked as to the location of face.

1.2.4) Twitch body was observed when infant showed small amplitude, brief contractile response of a skeletal muscle, elicited presumably by a single maximal volley of impulses which the neurons supplied; marked as to the location of body.

1.2.5) Twitch extremities was observed when infant showed small amplitude, brief contractile response of a skeletal muscle, elicited presumably by a single maximal volley of impulses which the neurons supplied; marked as to the location of extremities.

1.2.6) Spit up was observed when infant showed any bringing up of feeding or saliva; more than a drool required.

1.2.7) Gag was observed when infant showed gulp or choke momentarily; the respiratory pattern was disrupted during a gag.

1.2.8) Burp was observed when infant showed bringing up air in an expiratory burst.

1.2.9) Hiccough was observed when infant showed hiccough; made one or several repetitive sharp inspiratory sounds with spasm of the glottis and diaphragm.

1.2.10) Bowel movement (BM) grunt was observed when infant showed BM grunting or straining. The infant’s face and body displayed the straining often associated with bowel movements and/or infant emits the grunting sounds and/or actually passes gas or defecates.

1.2.11) Sounds was observed when infant showed emitting undifferentiated whimper like sounds that resemble diffusely disinhibited vocal discharges.

1.2.12) Sigh was observed when infant showed inhale and exhales, perhaps audibly, in a breath longer and deeper than the current respiratory pattern observed.

1.2.13) Gasp was observed when infant showed drawing in a respiration sharply or laboriously, often after a respiratory pause. Infant might not apparently complete the inspiration and did not move smoothly to the next expiration.

2. Motoric system (Als, 1982; 1999; NIDCAP Program Guide, 2007) referred to 2 categories including:

2.1) Positive motoric behaviors score referred to the number of hand on face, smile, mouthing, suck search, sucking, tuck trunk, flexed arms, flexed legs, smooth movement arms, smooth movement trunk, smooth movement legs, leg brace, hand clasp, foot clasp, hand to mouth, grasping and holding on counted and divided by 170 (number of observation X number of behavior types). The observation of hand on face, smile, mouthing, suck search, sucking, tuck trunk, flexed arms, flexed legs, smooth movement arms, smooth movement trunk, smooth movement legs, leg brace, hand clasp, foot clasp, hand to mouth, grasping, and holding on were as followed:

2.1.1) Hand on face was observed when infant placed hand or both hands onto the face or head, or over the ears and maintained this for at least a brief, or for a prolonged period. Hand on Face movement or posture was different from active grasping. It was more protective, appeared occluding, and usually involved a soft movement or posture that created a barrier between the face and the outside world. The hand(s) might be placed palm down or palm up against the face.

2.1.2) Smile was observed when infant’s smiling required facial relaxation without flaccidity and was formed by an at least slightly upward curving of the corner(s) of the mouth, often accompanied by a momentary or prolonged softening of the cheeks.

2.1.3) Mouthing was observed when infant made one or several repetitive lip and/or jaw opening and closing movements. These were distinguished from suck searching. In mouthing, the lips stayed usually soft and relaxed and were not directed forward.

2.1.4) Suck search was observed when infant actively extended the lips forward or sideways and/or opened the mouth in a searching, rooting fashion; the infant often moved the head while doing so, as if seeking something to suck on.

2.1.5) Sucking was observed when infant sucked on hand or fingers, on clothing, bedding, the caregiver’s finger or a pacifier or other object that the infant had either obtained or that the caregiver had inserted into the infant’s mouth.

2.1.6) Tuck trunk was observed when infant showed trunk flexion activity or maintained flexor posture. The infant curled or tucked trunk and/or shoulders into flexion; often the infant might pull the legs up into flexion or pull the arms in simultaneously.

2.1.7) Flexed arms were observed when infant showed the current flexor movement or act of tucking in of the arm(s). This might be repetitive activity or one adjustment.

2.1.8) Flexed legs were observed when infant showed the active flexor movement or act of tucking in of the leg(s), regardless it was then maintained or not. It might be repetitive activity or one flexor adjustment.

2.1.9) Smooth movement arms were observed when infant showed smooth movement of arms.

2.1.10) Smooth movement trunk was observed when infant showed smooth movement of arms, legs or trunk, balanced in terms of extensor and flexor component, indicating modulated movement control.

2.1.11) Smooth movement legs were observed when infant showed smooth movement of legs.

2.1.12) Leg brace was observed when infant extended leg(s) and/or feet toward the edge or wall of the incubator, crib, etc., or the caregiver's hand or body, as if in an effort to stabilize, brace, and gain boundary and inhibit extensor movement or posture. Once touched, the infant might flex the legs and relax while maintaining the bracing, or might restart the active bracing effort. Even if no surface was available, effort at apparently seeking such a surface were also marked in this category. The infant might be actively pressing one or both feet against the mattress or a blanket roll, etc.

2.1.13) Hand clasp was observed when infant grasped one hand with the other or clutched the hands in midline to the body. Each hand might be closed, yet they held onto each other or actively pressed against each other. Interdigitation of fingers of one hand with those of the other hand was a subcategory of hand clasp and was marked here.

2.1.14) Foot clasp was observed when infant positioned one against the other, either foot sole to foot sole or one foot sole against the other ankle or leg, or the infant folded the legs in a crossed position with feet grasping the legs or resting against them.

2.1.15) Hand to mouth was observed when infant attempted to bring one or both hands or fingers to the mouth in an apparent effort to suck them. The effort did not have to be successful to be marked.

2.1.16) Grasping was observed when infant made grasping movements with the hands, either directed at the face or body, or in midair, or to the caregiver's hands or fingers or body, the infant's own bottle, tubing or bedding, the side of the incubator or bassinet, etc.

2.1.17) Holding on was observed when the infant was holding on to the examiner's hands or finger or arm, etc.; the infant might have initiated the holding on, or the caregiver might have positioned finger in the infant's hands and the infant then actively held on.

2.2) Negative motoric behaviors score referred to the number of tongue extension, grimace, gape face, flaccid arms, flaccid legs, extend arms, extend legs, stretch/drown, diffuse squirm, arch, finger splay, airplane, salute, sitting on air and fisting counted and divided by 150 (number of observation X number of behavior types). The observation of tongue extension, grimace, gape face, flaccid arms, flaccid legs, extend arms, extend legs, stretch/drown, diffuse squirm, arch, finger splay, airplane, salute, sitting on air and fisting were as followed:

2.2.1) Tongue extension was observed when infant's tongue protruded in extension beyond the lips or extended encased in the lower lip. The behavior was marked either the infant maintains this tongue posture or engaged in repeated extension and flexion or relaxation movements of the tongue. Soft modulated speech-like tongue movements or mouthing were not marked in this category.

2.2.2) Grimace was observed when infant showed a facial extension configuration often accompanied by lip retraction and facial retraction and distortion.

2.2.3) Gape face was observed when infant showed a drooping open mouth configuration that was the result of decreased lower facial tone. It gave the appearance of exhaustion and facial limpness. It might be paired with eyes open and even environment inspection. It was also seen in active sleep.

2.2.4) Flaccid arms were observed when infant showed the very low tones of one arm or both arms and the arm(s) lied, held, or moved flaccidly or limply.

2.2.5) Flaccid legs referred to the very low tone of one leg or both legs and the leg(s) lied, held, or moved flaccidly or limply.

2.2.6) Extend arms were observed when infant showed the active extension movement of one arm or both arms. This might be a single or several consecutive actions.

2.2.7) Extend legs were observed when infant showed the active extension movement of one leg or both legs. This might be a single or several consecutive actions.

2.2.8) Stretch/drown was observed when infant showed a configuration of labored trunk extension, often also accompanied by arm extension and occasionally leg extension, which was then followed by an apparent effort to move the trunk back into flexion. This pattern of stretching and tucking might be repeated several times.

2.2.9) Diffuse squirm was observed when infant showed small writhing, wriggling motions of the trunk, often accompany with movements of the extremities.

2.2.10) Arch was observed when infant showed trunk arching or trunk extension into an arch and/or head extension, in prone, supine, side lying or upright position. The upper extremities might or might not extend; nevertheless the legs often extend.

2.2.11) Finger splay was observed when infant's hand(s) open and the fingers were extended and separated from each other.

2.2.12) Airplane was observed when infant's arm(s) were either fully extended out to the side at approximately shoulder level or upper and lower level which were at an angle and were extended out at the shoulder.

2.2.13) Salute was observed when infant's arm(s) were fully extended into mid air in front of the infant, either with single armor simultaneously.

2.2.14) Sitting on air was observed when infant's legs were extended into mid air either with single leg or simultaneously.

2.2.15) Fisting was observed when infant appeared to hold on to the infant's own hand by flexing the fingers and forming a fist. Occasionally fisting was observed with an object in hand (e.g., the edge of a blanket, etc.). The tightness of the flexion differentiated the softer holding on from fisting.

3. State system (Als, 1982; 1999; Brazelton, 1984) referred to 3 categories of consciousness including:

3.1) Sleep state consisted of 2 items including:

3.1.1) Deep sleep referred to the amount of time when infant exhibited the following behaviors: eyes closed; no spontaneous activity except startled or jerky movements at quite regular intervals; external stimuli produced startles with some delay; suppression of startles was rapid, and states changed were less likely than other states. No eye movements.

3.1.2) Light sleep referred to the amount of time when infant exhibited the following behaviors: eyes closed; rapid eye movements could often be observed under closed lids; low activity level, with random movements and startled or startled equivalents; movements were likely to be smoother and frequently monitored than in state1; responded to internal and external stimuli with startle equivalents, often a resulting change of state. Sucking movements occurred off and on. Eye opening might occurred briefly at intervals.

3.2) Transition consisted of 1 item including:

3.2.1) Drowsy referred to the amount of time when infant exhibited the following behaviors: eyes might be open but dull and heavy-lidded, or closed, eyelids fluttering; activity level variable, with interspersed, mild startles from time to time; reactive to sensory stimuli, but response often delayed; state change after stimulation frequently noted. Movements were usually smooth. Dazed look was observed when the infant was not processing information and was not 'available'.

3.3) Arousal state consisted of 3 items including:

3.3.1) Alert referred to the amount of time when infant exhibited the following behaviors: bright look; seem to focus invested attention on source of stimulation, such as an object to be sucked, or a visual or auditory stimulus; impinging stimuli might break through, but with some delay in response. Motor activity was at a minimum. There was a kind of glazed look which could be easily broken through in this state.

3.3.2) Active referred to the amount of time when infant exhibited the following behaviors: eyes open; considerable motor activity, with thrusting movements of the extremities, and even a few spontaneous startles; reactive to external stimulation with increase in startles or motor activity, but discrete reactions difficult to distinguish because of general activity level. Brief fussy vocalizations occurred in this state.

3.3.3) Crying referred to the amount of time when infant exhibited the following behaviors: intense crying which was difficult to break through with stimulation; motor activity was high.

4. Attention system (Als, 1982; 1999; NIDCAP Program Guide, 2007) referred to 2 categories including:

4.1) Positive attention behaviors score referred to the number of frown, ooh face, face open, cooing and speech movement counted and divided by 50 (number of observation X number of behavior types). The observation of frown, ooh face, face open, cooing and speech movement was as followed:

4.1.1) Frown was observed when infant knitted the eyebrows or darkened the eyes by contracting the periocular musculature, engaging in a flexion of the upper face.

4.1.2) Ooh face was observed when infant rounded the mouth and pursed the lips or extended them forward in an ooh configuration. This might be with eyes opened or closed.

4.1.3) Face open was observed when infant lifted the eyebrows high up either with eyes opened or eyes closed. This might occurred in sleep state or in arousal state.

4.1.4) Cooing was observed when infant emitted a soft, pleasurable, modulated cooing sound.

4.1.5) Speech movement was observed when infant's tongue and lips moved in soft, rhythmical, speech-liked fashion, while the face was typically relaxed and animated or the gaze was animatedly engaged with the environment.

4.2) Negative attention behaviors score referred to the number of fuss, yawn, sneeze, eye floating, avert and locking counted and divided by 60 (number of observation X number of behavior types). The observation of fuss, yawn, sneeze, eye floating, averts and locking was as followed:

4.2.1) Fuss was observed when infant showed an audible vocal expression of discomfort, uneasiness, unhappiness and/or upset.

4.2.2) Yawn was observed when infant opened the mouth widely, usually with a deep inspiration.

4.2.3) Sneeze was observed when infant expelled air forcibly from the mouth and nose in an explosive, spasmodic action.

4.2.4) Eye floating was observed when infant's eyes moved in floating, apparently disinhibited fashion, often disjugately. This might be in semi-opened eye position or with fully opened eyes.

4.2.5) Avert was observed when infant actively averted the eyes from a social target. The infant might momentarily close them.

4.2.6) Locking was observed when infant locked onto an object or sight in the environment or his caregiver or might be maintaining a steady gaze fastened in one direction. The sound component of an environmental event might appear to contribute to the locking.

Expected benefits

Promotion of neurobehavioral organizations through the Individualized Environmental Modification (IEM) Program for VLBW infants may promote neurological development, prevent sensory impairment, shorten the length of hospital stay and contribute to the nursing knowledge base.

CHAPTER II

LITERATURE REVIEW

The literature reviewed in this study was obtained from the CINAHL, MEDLINE, OVID, University of Colorado Denver databases and Chulalongkorn University databases. Literature reviewed included research articles which published both in Thai and English language. The topics of literature reviewed were listed as followings.

1. Very low birth weight (VLBW) infants
2. Synactive theory of development
3. Neurobehavioral organizations in VLBW infant
4. Effect of environmental modification

Very Low Birth Weight (VLBW) Infant

Low birth weight had been defined as different group of infants. Some of them were born prematurely or born with growth retardation or they were born with combined conditions of premature and growth retarded (UNICEF & WHO, 2004). The World Health Organization (WHO) has defined low birth weight (LBW) infant as the baby who had body weight less than 2,500 gram at birth, whereas, the very low birth weight (VLBW) infant had body weight less than 1,500 gram at the time of delivery, and extremely low birth weight (ELBW) infant referred to the baby born with body weight less than 1,000 gram. Additionally, the baby who born before completed 37 weeks of gestational age was classified as premature infant (UNICEF & WHO, 2004). The very low birth weight (VLBW) infant, who born prematurely at gestational age before 37 weeks and had body weigh less than 1,500 grams at the time of delivery were the focus in this study.

In Thailand, approximately 700, 000 babies were born each year which about 102,000 babies were born with low birth weight (Ministry of Public Health, 2004). A retrospective study conducted by Sritipsukho, Suarod & Sritipsukho (2007) also reported 16,114 of live births in Thammasat University Hospital between July 1, 2003 and June 30, 2006. There was incidence of VLBW infants 4.9 cased per 1,000 live births. The birth weight distributions were 31% between 1,000 to 1,249 grams, and 42% between 1,250 to 1,499 grams. Gestation age contributions were 32% of infants born less than 28 weeks and 49% of infants born between 28 to 32 weeks of gestation. The survival rate of VLBW infants in this study was 81% with duration of hospital stay between 15 to 46 days. Statistically, VLBW infants were the major population admitted to neonatal unit with longer hospital stay and higher expense comparing to normal infants (Browne, 2003; Field, Hernandez-Reif & Freedman, 2004; Sritipsukho, Suarod & Sritipsukho, 2007).

There were evidence confirmed that VLBW infants had been suffering due to their inherent vulnerability and multiple clinical problems of prematurity (Perlman, 2001) including respiratory distress syndrome, chronic lung disease, Necrotizing enterocolitis, intraventricular hemorrhage, retinopathy of prematurity (Jirapaet & Jirapaet, 2002; Sritipsukho, Suarod & Sritipsukho, 2007), patent ductus arteriosus, metabolic disorders, hyperbilirubinemia, apnea (Perlman, 2001; Jirapaet & Jirapaet, 2002), neurodevelopmental delay/deficit, neurosensory impairment (Taquino & Lockridge, 1999; Browne, 2003; Verma, Sridhar & Spitzer, 2003; Hack, 2006), and neurobehavioral deficit (Perlman, 2001; Browne, 2003). Complexity of these medical and behavioral problems, congruently with noxious environment in neonatal unit caused neurobehavioral disorganization and vulnerability to remain in VLBW infants after discharge from neonatal unit (Blackburn, 1998; Perlman, 2001).

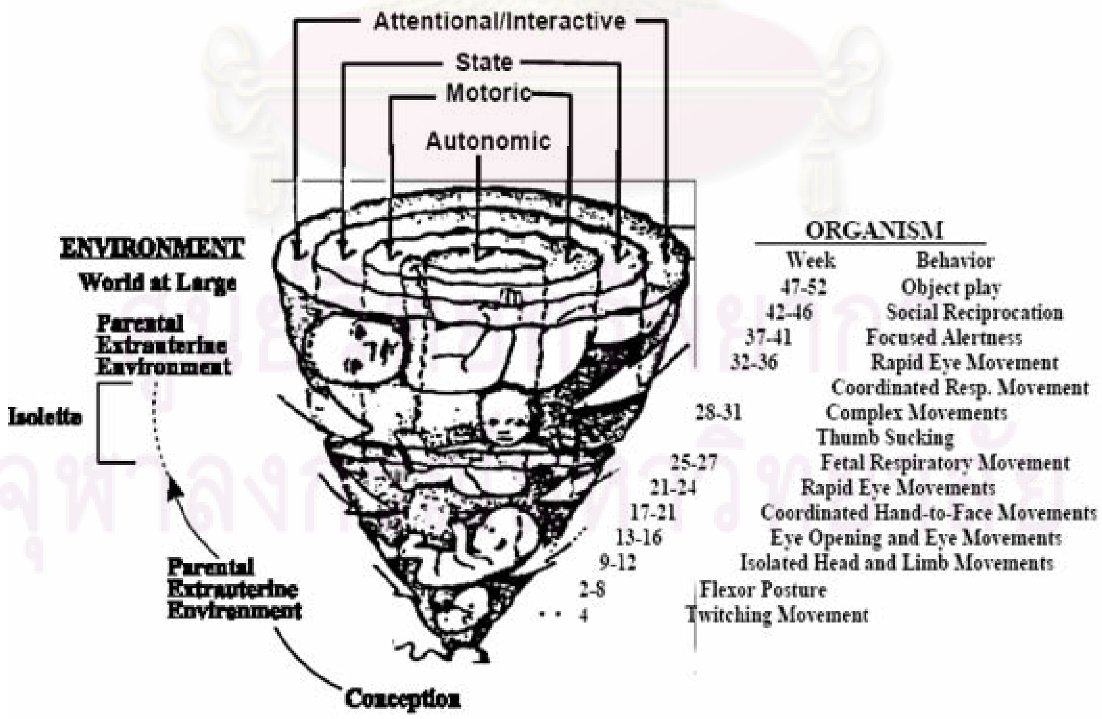
Neurobehavioral disorganization effected morbidity and mortality rate of VLBW premature infants by causing poor disease prognosis, delay neurological development, and permanent sensory impairment (Taquino & Lockridge, 1999). For instance, neurobehavioral disorganized infant who had apnea and irregularity of heart rate needed advance technology such as ventilator to support and monitor their physiological imbalance and clinical distress. Consequently, infants who had neurobehavioral disorganization were required longer hospitalization in neonatal unit. Therefore, they had a higher hospitalization cost than neurobehavioral organized infants do. In addition, VLBW preterm infants were very sensitive to and influenced by environmental stimuli such as bright light, loud noise, unpleasant odor and frequent handling in neonatal unit (Als, 1982; 1986; Becker, Grunwald, Moorman & Stuhr, 1991; Blackburn, 1998; Perlman, 2001). According to an explanation of synactive theory of development, neurobehavioral organization of VLBW preterm infants had been effect mostly by environmental stimulation, even small amount of stimuli might have great effect on VLBW preterm infants.

Synactive Theory of Development

Synactive theory of development was developed by Dr. Heidelise Als (1982). It was used in this study as theoretical framework for understanding the neurobehavioral development of VLBW preterm infants, influencing of environmental care on neurobehavioral organization of VLBW preterm infants and guiding and designing nursing interventions in this study.

The model of synactive theory of development provided the understanding of interconnection between the infant's five distinct subsystems with the reception organs and the surrounding environment (Figure 2.1). Als' synactive theory (1982) views VLBW preterm infant as an organism ideally suited to intrauterine life who must make dramatic adaptations to the environment of neonatal unit in order to survive. Survival rate depended on infant's ability to stabilize and grow in extrauterine environment. This theoretical model identified five distinct systems within VLBW infant including a) autonomic system, b) motoric system, c) state system, d) attentional/interactive system, and e) self-regulatory system.

Figure 2.1 Synactive Theory of Development



The synactive developmental model (Als, 1982) described the four concentric cones representing from inner to outer part. The first cone was autonomic system. It served the baseline functioning of organism such as heart rate, respiratory rate, and visceral function. The second cone was motoric system. It developed from embryonic stage which had been seen in flexor posture, extremities and trunk movements. The third cone was state system. It represented state of consciousness including sleep, wake, and arouse which developed from diffused to differentiated state. The forth cone was attention system. It represented attention and interaction process between organism and environment.

Autonomic organization includes regular cardiorespiratory activity and good peripheral skin blood flow. Motoric organization entails regulation of muscle tone, flexed posture and smooth of movement. State organization includes increasing quiet sleep, decreasing active sleep and putting sleep cycles together which make longer sleep periods. The attention organization involves infant’s ability to attend and interact with stimuli (Als, 1982; 1986; Blackburn, 2007). Self-regulatory system represents the ability of infants to utilize physiologic, motor, and state strategies to manage environmental stimulation and self-organization (Als, 1982; 1986; Wyly, Pfalzer & Speth, 1995).

The order of development begins with autonomic followed by motoric, state and attention systems. All four system functions are observed in hierarchical and interdependent developmental pattern. The state organization is dependent on organization and stability of the motoric and autonomic systems, as well as, attention system requires organization of the state, motoric and autonomic systems. While they are influencing and supporting each other, they are infringing on stability of another as well

(Als, 1986). Synactive theory of development (Als, 1982; 1986) and the study of Blackburn (2007) explained that the organization of all four systems including autonomic, motoric, state and attention systems are absolutely prerequisites for emergence of self-regulatory system.

In this study, the samples were VLBW preterm infants who born with immaturity of autonomic, motoric, state and attention system development. This condition entailed disorganization of all four systems while interacting with noxious environment and caused VLBW preterm infants unachieved self-regulatory system organization (Als, 1982; 1986; Blackburn, 2007; Wyly, Pfalzer & Speth, 1995). According to synactive theory of development (Als, 1982; 1986), the organization of autonomic, motoric, state and attention systems are a primary goal for VLBW preterm infants to achieve as it reflected organization of self-regulatory system as well. Therefore, autonomic, motoric, state and attention systems were mainly focused in this study.

Neurobehavioral Organizations in VLBW infant

Neurobehavioral organization was VLBW preterm infant’s ability to maintain and manage autonomic, motoric, state and attentional stability while interacting with the environment. During preterm infants’ interaction with the environment, their signals and communicative behaviors were functions of neurobehavioral organization. VLBW preterm infant who was organized in autonomic, motoric, state and attention system could respond to environmental stimuli without disrupting responses of all four systems (Als, 1982; 1986; 1999; Als & Lawhon, 2004; Ferber, 2004; Wyly, Pfalzer & Speth, 1995).

Autonomic system was the first system to emerge. This system encompassed the infant's bodily functions including heart rate, respiratory rate, skin color and digestive functions such as vomiting, hiccoughs, gagging, and bowel movements (Als, 1982; 1986). The occurrence and intensity of system's function indicated how well the infants' respond to environment. During particular stressful times, VLBW preterm infant who was disorganized could be observed with irregularity of heart rate, paused in breathing, increased gastric residuals, bowel movement straining, and skin color changed (Als, 1986; 1999). The ineffective of autonomic system function could cause critical ill in VLBW preterm infant which was a primary concern of medical care (Als, 1982). The emergence of functioning of other systems depended on stability within this system. Thus, the goal of organization was to stabilize autonomic system functioning (Als, 1986; 1999).

Motoric system included behaviors associated with muscle tone, posture, and generalized body movements (Als, 1982; 1986). The infant's ability to move and position its body was a gradually emerging activity. VLBW preterm infants had less control over purposeless movements. Random and disorganized body movements indicated motor disorganization. VLBW preterm infants also tended to overreact to environmental stimuli by exhibiting gross motor movements. Twitching and jerking limb movements were typical in VLBW preterm infants and very weak muscle tone made them difficulty in movements (Als, 1982; 1986). Poor positioning such as extension of extremities could cause an enormous amount of energy loss that's why VLBW preterm infants would often seek a position of comfort such as hands on face or mouth. Thus, energy would be better used to preserve for infants' growth (Wyly, Pfalzer & Speth, 1995). Therefore, the goal of organization was to minimize purposeless movements and promote comfort positioning in order to preserve energy.

State organization system incorporated a range of states from sleep to the arousal. There were six states of consciousness (Brazelton, 1984) which included a) deep sleep, which was characterized by regular respiration, very few body movements, b) light sleep, which was observed by rapid eye movements, irregular, primarily abdominal respiration, and some body movement, c) drowsy, which was a transitional state between asleep and awake. Infants' eyes might be opened or closed, exhibited facial grimacing, variable motor activity, fluttering eyelids, and irregular respirations, d) alert, which could be observed by minimal movement and focus on a source of stimulation, regular respiration. Eyes were bright and shiny, e) active, which could be observed by increased movement, fussiness and irritability, and f) crying, which was indicated by intense, rhythmic crying and increased motor movement. State-organized infant could transit appropriately between states (Als, 1982; 1986). VLBW infants who were over-stimulated by neonatal unit environment presented 60 – 70% of light sleep time. Understanding the infant's state was important because it provided signals that indicated to caregivers that the infant's readiness to interact or its need to be left alone (Wyly, Pfalzer & Speth, 1995).

VLBW infants had a limited repertoire of conscious states. In addition, VLBW infants moved quickly between states which made diagnosis difficult. These infants slept restlessly most of the time and had only fleeting moments of alertness. They seem to be oblivious to their environment and might not ever react to painful interventions (Wyly, Pfalzer & Speth, 1995). Crying was absent, and a weak facial grimace might be the only observable reaction. In the neonatal unit this situation could be very dangerous because, in a crisis situation, these infants would quickly decompensate physiologically with very little warning. Alert states that enable social interaction were extremely rare in VLBW infants (Wyly, Pfalzer & Speth, 1995). As VLBW infants matured, they had regular occurrences of the active alert state. Caregivers could watch for those infant behaviors that indicated a readiness to interact, for example, eyes opening in response to touch or auditory stimulation, regular respiration, and no body movements, or controlled body movements (Als, 1982; 1986). In VLBW infants, however, the active alert state could be easily disrupted. If an interaction became too stressful, VLBW infants might try to look away or became hyper-alert. Frantic motor movements and crying might follow. If the stressor continued, this behavior could deteriorate and result in physiologic decompositions. They might develop apnea, lack of breathing, with a concomitant decrease of heart rate that could be life threatening (Wyly, Pfalzer & Speth, 1995). Thus, the goal of organization was to maximize deep sleep.

Attention system referred to the quality of an infant's alert state. It was the ability of an infant to interact with people and objects in their environment. Als (1982) referred this system as the essence of humanity. In her opinion, the survival of the human species depended on the ability to interact with others. Certainly, parents were very anxious for their infants to begin opening their eyes and interacting with them. Even with very sick infants, parents might encourage them to try to open their eyes (Wyly, Pfalzer & Speth, 1995). Thus, the goal of organization was to promote infant's ability to attain, maintain and withdraw from the state of attentiveness. Unfortunately, this capacity was dependent on the maturation and stability of the autonomic, motor, and state systems.

Self-regulatory system represented the ability of infants to utilize physiologic, motor, and state strategies to independently manage environmental stimulation and self-organization. Successful self-regulation enabled infants to maintain stability by protecting themselves from stressors. Some of these "self-regulatory" behaviors include hand-to-mouth movements, sucking, grasping, hand clasping, and/or postural change. A high level of neurobehavioral maturity had been achieved when an infant successfully managed environmental stimuli without physiologically decompensation (Als, 1982; 1986; Wyly, Pfalzer & Speth, 1995). Thus, the goal of organization was to promote infant's ability to achieve and maintain a balance of all systems.

Effect of environmental modification

Environmental stimulations have played a significant role in organization and associated with the neurobehavioral development in VLBW preterm infants. The negative environmental stimuli in the neonatal unit that VLBW preterm infants received via their sensory system including bright light, loud noise and unpleasant odors could effect on VLBW preterm infants' neurobehavioral responses (Taquino & Lockridge, 1999). Manipulated environment in the neonatal unit was focused on improving neurobehavioral disorganization. Studies of various environmental stimuli such as light, noise and odor modifications were reviewed and described in term of basic environmental and individualized modifications.

Basic environmental modification

The basic environmental modification consisted of light, sound and odor. The literature review was focus on effect of light, sound and odor on physiological and behavioral stabilities of VLBW preterm infants. Also, environmental modification study were reviewed and scoped on light, sound and odor modification in term of intensity and duration that promote autonomic, motoric, state and attention systems organization of VLBW preterm infants.

1. Light

VLBW preterm infants were generally exposed to an irregular dark-light cycle. The light level in neonatal unit was reported 5 – 1,488 lux with higher intensity during day rather than night hours (Chawaphanth, 2004; Vandenberg, 2007). The recommendation of light level was 10 – 600 lux (Jirapaet & Jirapaet, 2006) which 300 – 500 lux ranging at daytime and 10 – 100 lux ranging at nighttime (Chawaphanth, 2004). There were evidences confirmed that bright light caused poor oxygen saturation and sleep-wake disturbance in VLBW preterm infants (Chawaphanth, 2004; Morag & Ohlsson, 2009). Therefore, several studies have been conducted to modify appropriated light environment in neonatal units to improve physiological stability and state organization of preterm infants.

Many neonatal units have been modified the light level by covering the incubator to shield the infant, so that the light became near darkness most of the time to reduce stimuli for the preterm infants. A meta-analysis study of cycled light in the intensive care unit for preterm/low birth weight infants (protocol) conducted by Morag and Ohlsson (2009) suggested that cycled light could promote circadian rhythms in preterm infants which effected the production of hormones such as melatonin, cortisol and growth hormone. Circadian rhythms also influenced respiratory and cardiac function, sleep-wake state, level of alertness and body temperature.

Rivkees and team (2004) studied Rest-activity patterns of premature infants are regulated by cycled lighting. Light level was provided between 210 – 268 lux at 7 am – 7 pm and the light level < 25 lux was provided at 7 pm – 7 am. The results revealed that experimented preterm infants exhibit more active during the day and presented more rest during the night time. The study conducted by Brandon, Holditch-Davis and Belyea (2002), confirmed the preterm infants born at less than 31 weeks' gestation have improved growth in cycled light compared with continuous near darkness. The near darkness was provided 5 – 10 lux at 07.30 pm – 06.30 am, whereas 200 – 225 lux was provided from 07.30 am – 06.30 pm. The results significantly showed that cycled light had a greater effect on weight gain and development of preterm infants than near darkness did. In addition, Chawaphanth (2004) studied the effects of gradual cycled lighting (CL) versus abrupt CL on heart rate, oxygenation and weight gain in preterm infants. The light level provided from 200 – 250 lux at day time (08.30 am to 08.30 pm) and 10 – 20 lux at night time (08.30 pm to 08.30 am). The results showed that the abrupt CL implementation could improve regular heart rate, oxygen saturation levels and weight gain in preterm infants.

Previous literature review confirmed that an appropriated cycled light could stabilize heart rate, improve oxygen saturation and promote good skin perfusion. The modification of light environment should be initiated in neonatal unit to improve autonomic and state systems organization of preterm infants. Recent research studies also pointed out that circadian rhythm involved diurnal lighting cycles or 12 hours interval of biologic clock as day and night lighting (Mirmiran & Ariagno, 2000; Mirmiran, Baldwin & Ariagno, 2003; Rivkees, Mayes, Jacobs & Gross, 2004). Therefore, day-night lighting should be scheduled as 12 hours interval to promote circadian rhythm, autonomic and state organization of VLBW preterm infants.

2. Sound

VLBW infants were possibly subjected to noxious sound in neonatal unit. The sound level was reported ranging between 65 – 85 dB (Zahr & Balian, 1995) whereas the recommendation of sound level in neonatal unit should be maintained at 45 – 58 dB (Johnson, 2001). A review of the research studies found that the noxious sound in neonatal unit had effect on the infants both physiological and behavioral responses (Slevin, Farrington, Duffy, Daly & Murphy, 2000). The Committee on Environmental Health of the American Academy of Pediatrics (2005) reported that staff conversation and monitor on and off produced 60 – 70 dB of sound in incubator and monitor alarming and tapping incubator with fingers raised 75 – 80 dB of sound level. The sound level of 55 dB could arouse the preterm infant from light sleep (Harrison, Lotas & Jorgensen, 2004). The sound level of 60 – 80 dB caused preterm infant startle, fussy, crying, changes in heart rate and oxygen saturation, color changes, sleep disturbance. The sound level higher than 80 dB caused hearing loss in preterm infant (Committee on environmental health, 2005; Harrison, et al, 2004; Graven, 2000; Kertrit, 2002; Sehgal & Stack, 2006; Slevin, et al, 2000; Zahr & Balian, 1995). Thus, several studies were conducted to modify an appropriated sound environment in neonatal units to improve physiological stability, motoric, state and attention organization of preterm infants.

A few neonatal units have been modifying sound environment by encouraging mother to sing a song for her baby to promote bonding and attachment and induce positive auditory stimuli for VLBW preterm infant. Standley and Moore (1995) studied the therapeutic effects of music and a mother's voice on premature infants. The researchers mentioned that in situations involving the clinical use of the mother's voice, there were problems with accessibility. Obtaining a recording of the mother's voice was the most difficult part of their study because many infants came from different geographic areas, and their mothers were not available. Thus, music would be readily available to use in the neonatal unit, and further research should be conducted in order to determine how and when music was the most effective in promoting oxygen saturation with minimal side effects.

Music therapy was a well known sound modification which widely used in neonatal unit. Collins and Kuck (1991) studied music therapy in the neonatal intensive care unit. They combined recorded uterine sounds with female lullaby singing for 17 infants who had agitated state. The results revealed that oxygen saturation and behavioral state improved significantly under the music condition. The study of effects of music therapy on oxygen saturation in premature infants receiving endotracheal suctioning was conducted by Chou, Wang, Chen and Pai (2003). The samples were 30 premature infants born at gestational age between 28 – 36 weeks with respiratory distress syndrome, assisted with ventilator through endotracheal tube, received suctioning every 2 to 4 hrs. Tape player was placed approximately 20 cm from infants’ ear with measured and maintained sound level at 60 dB. The oxygen saturation of all subjects was first measured at one minute before suctioning as baseline data and again while they were receiving endotracheal suctioning during a four-hour control period with regular care. Then, four hours after the control period was completed, an experimental period began in which the music was played. Oxygen saturation was recorded every minute during the period of 30 minute after suctioning. Results showed that experimented infants exhibited significantly higher SPO_2 than the control did. The level of oxygen saturation returned to the baseline level faster than the level of those did not receive music therapy.

Phuekvilai (1987) suggested that a slow rhythm music which equivalent to human heart rate can make calm and relax in premature infants. Standley (2002) conducted a meta-analysis of the efficacy of music therapy for premature infants and recommended that the music should be provided in short intervals of 30 minutes with the volume lower than 70 dB. The music playing should be soothing, stable and constant rhythm. Repeated music listening can improve positive clinical effects and neurologic organization of VLBW preterm infants (Kemper & Danhauer, 2005).

Previous literature review confirmed that modification of sound environment should be initiated in neonatal unit to improve oxygen saturation, stabilize heart rate, reduce stress and agitation and improve behavior state of premature infants. Therefore, the decision to provide soothing music for 30 min was base on findings from previous studies of music therapy in which positive neurobehavioral outcomes were noted.

3. Odor

VLBW preterm infants possibly experienced unpleasant odor such as betadine, skin preparation agent and alcohol which were often present in neonatal unit (Bartocci, et al., 2001). The study of Schaal, Hummel and Soussignan (2004) found that premature infants had ability to sense and differentiate administered odorants. VLBW preterm infants were also able to discriminate pleasant and unpleasant odor. There were evidence confirmed that unpleasant odor caused altered respiration, decreased oxygenated hemoglobin, increased heart rate and physical movements in an attempt to push themselves away from the unpleasant odor. Bartocci and team (2001) also confirmed the effect of unpleasant odors such as disinfectant agents or detergents on preterm infant’s physiological responses. Both oxygenated Hb and total Hb decreased with exposure to these odors. These findings suggested that a cortical hemodynamic response might occur when infants were exposed to odors commonly used in the neonatal unit.

Olfactory studies had potential application in clinical settings, for instance, eliminated unpleasant odor and provided biologically meaningful olfactory experiences to VLBW preterm infants. Als (1982) recommended that pungent smells need to minimize and pleasurable smell should be promoted such as low concentration of mother's perfume can be used on a gauze pad in the infant's incubator or crib.

Lavender odor is used in a wide range of therapeutic settings and had been reported of a pleasant smell of infants (Cavanagh & Wilkinson, 2002). A number of studies have investigated the psychological and physiological effect of lavender inhalation. Fernandez and team (2004), studied the changed of EEG activity and behavior of newborns during lavender and rosemary exposure. The result showed that lavender exposure can alter EEG patterns in a positive direction which is greater shifting toward left frontal EEG activation. This positive EEG pattern indicated that the lavender exposed infants exhibited approaching pattern of behavior which is the response of infant to positive stimuli. The study also had no report of allergy or unwanted side effect in newborns. Mcneilly (2004) also recommended that lavender oils are the most commonly used for children with purportedly the safest essential oil and no side effects having been reported. Artificial odor of lavender was studied by Kawakami and team (1997), 5 day olds infants were induced lavender smelling blotter of 1.5 cm depth from the tip was put in a bottle filled with the lavender and then placed in front of the nose (2-3 cm from nasal cavity) during heelstick. The result showed that infants had less adrenocortisol release in saliva compared to the control group. The findings confirmed that lavender odor can mitigate stressful responses to aversive procedures in newborn.

Previous studies have noted that lavender odor can promote positive emotional states, better mood, relax, decreased anxiety, help combat unpleasant odor which present in neonatal unit (Cavanagh & Wilkinson, 2002). Thus, the decision to provide 30 minutes of lavender smelling for VLBW preterm infants were base on findings from previous studies of lavender odor in which positive motoric, state and attention organization outcomes were noted.

According to individual difference concern, VLBW preterm infants who had different gestation ages would have different level of neurological maturation. They also had different levels of toleration which adapted and responded to the environmental stimuli in a unique way (Als, 1999; 2004; Zahr & Balian, 1995). Although, findings from previous studies confirmed that basic environmental modification such as day-night light, music play and lavender odor could promote positive neurobehavioral outcomes, the individualized modification of environment should be provided base on individual neurosensory capability and tolerance of VLBW preterm infants.

Individualized modification

The individualized modification aimed to prevent sensory overload and provide appropriate environmental care for individual VLBW preterm infants. The neonatal individualized developmental care and assessment program (NIDCAP) proposed by Als (1986) recommended that caregiver needs to sensitively observe each infant’s behavioral response to each environment event (Young, 1996). A meta-analysis of developmental care for promoting development and preventing morbidity in preterm infants conducted by Symington and Pinelli (2007) confirmed that individualized assessment is needed to measure VLBW preterm infant's tolerance to the environmental stimulation. Also, the study of outcomes of developmentally supportive nursing care for VLBW infants conducted by Becker, Grunwald, Moorman and Stuhr (1991) suggested that individualized care is required assessment of physiological disorganization and adjustment of environmental stimuli to enhance autonomic, motoric, state and attention organization. According to the recommendation of previous studies, individualized modification had two steps including assessment and adjustment sections.

Additionally, base on individual difference, Vandenberg (2007) explained that neonatal sensory development emerges in specific sequence over the course of fetal life. It is assumed that preterm infant neurosensory development follows the same sequence. Sensory development begins with touch, smell, hearing and vision (Graven, 2000). Each emerging event takes place in a biologically ordered chain of events. For example, the maturation of auditory and olfactory systems in the fetus is most intense during the specific time that vision is not developing and is not being stimulated by light (Vandenberg, 2007). Therefore, sense of hearing and smell were focused in individualized modification. The assessment of VLBW preterm infants' autonomic responses and adjustment of music playing and lavender smelling was provided to VLBW preterm infant in order to achieve the aims of individualized modification.

Individualized modification consisted of two steps including assessment of VLBW preterm infant's sign of stress and adjustment of music playing and lavender smelling sections. The details were provided as following.

1. Assessment section

The initial overriding responses of preterm infant to environmental stimuli can be assessed by physiologic measures such as changed in heart rate and oxygen saturation (Als, 1999; Zahr & Balian, 1995). For instance, preterm infant responded to noxious smells and sound by an increase or decrease heart rate and oxygen saturation (Gardner, Garland, Merenstein & Lubchenco, 1993). The study of Kertrit (2002) identified preterm infants' physiological and sleep-wake behavioral responses to sound level in NICU environment. The observation of VLBW preterm infants' heart rate and oxygen saturation were red from pulse oximeter and recorded every 5 minutes. Jirapaet & Jirapaet (2002; 2005) explained the method of adjusting positive end-expiratory pressure (PEEP) by reading oxygen saturation every 5 minutes from pulse oxymeter. Oxygen saturation level ranging 90 – 95 % was accepted as infant had adequate oxygen consumption. Thus, VLBW preterm infants' heart rate and oxygen saturation were assessed while playing music and inducing lavender odor by reading from pulse oximeter every 5 minutes in order to obtain sufficient data for the judgment of VLBW preterm infants' thresholds of stability of heart rate and oxygen saturation.

Preterm infants' loss of control and stress responses were remained unless the nurse read the infants' messages and thresholds for sensitivity and adjust environmental stimulation base on the infant's behavioral communications, needs and toleration (Vandenberg, 2007). VLBW preterm infants' heart rate was <100 beats/min or >200 beats/min for 12 seconds or longer and oxygen saturation level dropped below 90% for longer than 30 seconds were indicated stress responses to environmental stimuli (Harrison, Williams, Berbaum, Stem & Leeper, 2000; Jirapaet & Jirapaet, 2002; 2005; Stark, 2008). Therefore, the VLBW preterm infants' heart rate and oxygen saturation were assessed every 5 minutes during music playing and lavender smelling as nursing activities in assessment section.

2. Adjustment section

In case of VLBW preterm infants showed sign of stress during music playing and lavender smelling such as heart rate was <100 beats/min or >200 beats/min for 12 seconds or longer and/or oxygen saturation level dropped below 90% for longer than 30 seconds, lavender smelling was first priority considered to manipulate for intensity reduction according to sequential pattern of neurosensory development. Preterm infants are able to response to odors by as early as 23 weeks of gestation (Blackburn, 2007) whereas preterm infants have physiologically response and orient to sound evidently at approximately 25 week of gestation (Blackburn, 2007; Graven, 2000). It is assumed that olfactory system had more capabilities than auditory system in term of neurosensory development. Therefore, lavender smelling was selected for adjusting prior to music playing.

In addition, lavender essential oil was reduced 1 drop at a time according to the recommendation of personal injury trial attorney at Miami Aromatherapy, Inc. A 5 dB, sound level decrease is considered to be clearly detected changing in sound (Krueger, Wall, Parker & Nealis, 2005; Turnage-Carrier, 2004). Therefore, lavender essential oil was reduced 1 drop and music sound was reduced 5 dB at a time.

The basic environmental modification (e.g., day-night lighting, music playing and lavender smelling) and individualized modification (e.g., assessment and adjustment section) were the main components of individualized environmental modification (IEM) program. The IEM program was derived based on Als' Synactive theory of development

(1982) which widely accepted in international academic society as a theoretical framework. The benefit of each nursing activity that showed from previous studies could be incorporated together and used for designing IEM program to promote better neurobehavioral organization maturity of VLBW preterm infants. Therefore, the framework of consideration was provided in Table 2.1 showing the nursing activities in individualized environmental modification program. The evidence bases were chosen regarding the four systems of synactive theory of development including autonomic, motoric, state and attention system which promoted organization of autonomic, motoric, state and attention system as well as inhibited sign of disorganizations in VLBW infants.

Table 2.1 Framework considering evidence base for designing Individualized Environmental Modification Program

Concept (Als, 1986)	**Sign of disorganization** (Als, 1986)	**Individualized Environmental Modification Activities**	
		Basic environmental modifications	**Individualized modifications**
1. Autonomic system	• Irregular heart rate • Decrease oxygen saturation level • Poor skin perfusion	• Day-night lighting (Brandon, Holditch-Davis & Belyea, 2002) • Played music (Standley, 2002)	• Assessment section, in case of infant showed signs of stress as follows: o Heart rate was <100 beats/min or >200 beats/min for 12 seconds or longer. o Oxygen saturation level dropped below 90% for longer than 30 seconds. • Adjustment section would be applied if infant present signs of stress. The adjustment stepped as follows: o reduce intensity of stimulation o reduce duration of stimulation
2. Motoric system	• Negative motoric behaviors	• Played music (Standley, 2002) • Induced lavender essential oil (McNeilly, 2004; Fernandez, et al., 2004)	
3. State system	• Diffused state of consciousness • Spent more time in arousal state	• Day-night lighting (Brandon, Holditch-Davis & Belyea, 2002) • Played music (Standley, 2002) • Induced lavender essential oil (McNeilly, 2004; Fernandez, et al., 2004)	
4. Attention system	• Negative attention behaviors	• Played music (Standley, 2002) • Induced lavender essential oil (McNeilly, 2004; Fernandez, et al., 2004)	

Remark: The autonomic, motoric, state and attention systems are absolute prerequisites for the emergence of neurobehavioral organization (Als, 1982). Therefore, the autonomic, motoric, state and attention systems are the main focus of this study.

Base on previous studies of environmental modification, the individualized environmental modification (IEM) program was derived by using evidences base and synactive theory of development as a framework. The IEM program (Appendix A) consisted of nursing activities aimed to maintain and promote neurobehavioral organization of VLBW preterm infants. There were two phases including preparation and modification phases. The modification phase consisted of basic environmental modification (e.g., day-night lighting, music playing and lavender smelling) and individualized modification (e.g., assessment and adjustment sections). IEM program was provided for improving neurobehavioral organizations which involve autonomic, motoric, state and attention systems. Autonomic system consisted of positive autonomic responses and negative autonomic responses. Motoric system consisted of positive motoric behaviors and negative motoric behaviors. State system consisted of duration of sleep state and duration of transitional and arousal state. Attention system consisted of positive attention behaviors and negative attention behaviors. The summarization of research framework was showed in the diagram.

Research framework

IEM Program

A program consisted of nursing activities to maintain and promote the maturation of neurobehavioral organization of VLBW preterm infants. There were two phases including preparation and modification phase. Modification phase consisted of:

1. Basic environmental modifications including:
    - Day-night lighting
    - Music playing
    - Lavender smelling
2. Individualized modifications including:
    - Assessment section
    - Adjustment section

→

Neurobehavioral Organizations

1. Autonomic system
    - Positive autonomic responses: HR, O_2 saturation and positive skin color
    - Negative autonomic responses: tremor, startle, twitch face, body and extremities, spit up, gag, burp, hiccough, bowel movement grunt, sounds, sigh and gasp
2. Motoric system
    - Positive motoric behaviors: hand on face and to mouth, smile, mouthing, suck search, sucking, tuck trunk, leg brace, grasping, holding on, flexed arms and legs, smooth movement arms, trunk, and legs, hand and foot clasp
    - Negative motoric behaviors: tongue extension, grimace, gape face, flaccid arms and legs, extend arms and legs, stretch/drown, diffuse squirm, arch, finger splay, airplane, salute, sitting on air and fitting
3. State system
    - Duration of sleep state
    - Duration of transitional and arousal state
4. Attention system
    - Positive attention behaviors: frown, ooh face, face open, cooing and speech movement
    - Negative attention behaviors: fuss, yawn, sneeze, eye floating, avert and locking

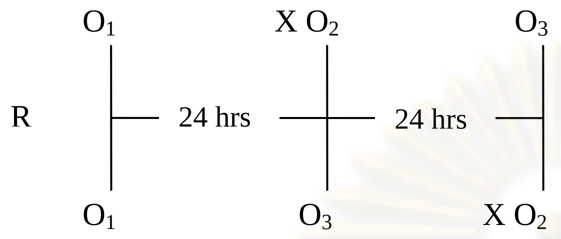
CHAPTER III

METHODOLOGY

The aim of this study was to evaluate the effect of individualized environmental modification program on neurobehavioral organizations that was measured in the organized state, autonomic, motoric and attention system performance of very low birth weight infants who admitted in neonatal intensive care unit.

Research design

The samples in this study were VLBW infants which had individual differences such as behaviors, medical problems, and level of maturation. These differences were part of the error variance which decreased the likelihood of finding a significant result. In order to remove individual differences, all samples must be assigned to all treatments (Munro, 2001). Therefore, this study was designed as single group or within-subjects design in which samples were used as their own control; all samples underwent a control period receiving conventional nursing care and experimental period receiving conventional nursing care and IEM program. The samples' behaviors were observed three times throughout the study including baseline, post-control and post-experiment. Thus, cross-over analysis and one way repeated measures ANOVA or single group repeated measure was utilized in this study. The method of study was shown in the diagram.



R = random assignment of order

X = IEM program

O_1 = baseline observation of neurobehavioral organization

O_2 = observation of neurobehavioral organization after experimental period (IEM program)

O_3 = observation of neurobehavioral organization after control period

Population and Sample

The population used in this study was derived from very low birth weight (VLBW) infants who admitted to Neonatal Unit at Queen Sirikit National Institute of Child Health, Thailand. VLBW infants who meet the inclusion criteria were recruited to the study. The inclusion criteria and exclusion criteria were set as following.

<u>Inclusion criteria</u>

The infants' profiles were reviewed in order to screen for inclusion criteria as following:

1. Gestational age was less than 37 weeks at birth which was assessed with Ballard Maturational Score by pediatrician
2. Birth weight was less than 1,500 grams
3. Postnatal age was 5 days old or more

4. Growing preemies with stable condition which included:
   4.1. received full feeding between 120 – 150 Kcal/kg/day
   4.2. had metabolic and hemodynamic stable such as blood sugar between 40 – 97 mg/dl, Calcium serum between 7 – 10 mg/dl, heart rate between 120 – 160 beats/min, and respiratory rate between 40 – 60 breaths/min
5. Not receive any medications that effect neurobehavioral responses such as aminophyllin, indomethacin, hydralazine, nicardipine, labetalol, propranolol, caffeine and sedative drugs
6. Received approval from the attending pediatrician

Exclusion criteria

VLBW infants who presented this criterion before or during the study were excluded or terminated from the study.

1. Had major genetic anomalies and/or severe complication such as Sepsis, Necrotizing Enterocolitis (NEC), Patent Ductus Arteriosus (PDA) which was pending for surgery, Intraventricular Hemorrhage (IVH) grade III or more, Hyperbilirubinemia that needed phototherapy, and severe Respiratory Distress Syndrome (RDS)

Sample size and sampling method

The determining sample size is involved power, effect size and significance level. A power analysis of .80 is generally appropriated level to avoid type II error (rejecting H_0). Effect size is the impact made by the independent variable on the dependent variable (Munro, 2001). The calculation of effect size are considered, if few relevant studies have been conducted in the area of interest and pilot studies are not feasible, then effect size can be estimated by small, medium or large (Burns & Grove, 2001). A small effect is defined as *d* = 0.2, a medium effect as *d* = 0.5 and a large effect as *d* = 0.8 (Cohen, 1987 cited in Munro, 2001). There was a criterion to select small, medium or large effect size for research study.

In this study, large effect size is selected base on research design, sensitivity of the measurement and significance of a statistical test results from previous studies. Firstly, large effect size is mostly used in clinical studies and experimental studies with within-subject design or single group repeated measure (Fern & Monroe, 1996; Freedman & Bernstein, 2001; Valentine & Cooper, 2003). Secondly, biophysiological measures are usually very sensitive. It can measure phenomena accurately and make fine discriminations in values. When measuring tools are precise and insusceptible to errors, small samples are needed to test hypotheses adequately (Polit & Beck, 2008). Lastly, regarding the measurement of individualized developmental care on neurobehavioral response, oxygen saturation, heart rate and weight gain by using bio-physiological instruments, and also used small sample sizes such as 10 to 25 subjects per group, the results revealed significance of a statistical test results (Brown & Heermann, 1997; Buehler, 1995; Chawaphanth, 2004; Collins & Kuck, 1991; Cordero, 1986; Gaebler, 1996; Keller 2003; Korner, 1975; Kramer, 1976; Westrup, 2000).

Therefore, sample size in this study was calculated base on criteria mentioned previously by using the Java Applets for Power and Sample Size program which, developed by Lenth (2006). A total of 25 very low birth weight infants were chosen to attain a power of .80 with α equal to .05 to detect large effect size, *d* = .80 (Lenth, 2006).

All 25 infants were assigned randomly to 24 hours of control period and 24 hours of experimental period. A group of infants first started with control period and followed by experimental period while another group of infants started with experimental period first and followed by control period. Therefore, 12 infants started with control period for 24 hours, and then followed by 24 hours of experimental period, as well as, 13 infants started with experimental period for 24 hours, and then followed by 24 hours of control period.

Research instruments

Four research instruments were used in this study including: 1) Individualized Environmental Modification (IEM) Program used as an experiment, 2) Infant's demographic sheet was used to collect infant's data, at the beginning and the end of study, 3) Naturalistic Observation of Newborn Behavior (NONB) tool were used to observe infant's behaviors at baseline, post-control period and post-experimental period, and 4) Neurobehavioral observation scoring sheet was used to group and calculate the frequency scores of infants' behaviors in each behavioral categories.

Individualized Environmental Modification Program

Individualized Environmental Modification (IEM) was a program (see Appendix A), consisting of nursing activities to maintain and promote the maturation of VLBW preterm infants' neurobehavioral organization by modifying environment. The design of IEM program was based on the Synactive Theory of Development (Als, 1982). The activities component was provided based on the infants' tolerance and responses to enhance comfort and stability to reduce stress and agitation for the infants. There were two phases of nursing activities as environmental modification for the infants in experimental period in neonatal unit including: 1) preparation phase, and 2) modification phase.

1. Preparation phase was objected to collect the infants' baseline data, promote good relationship with parents, and reduce parent's anxiety from unfamiliar program and environment. There were two steps including in this phase.

   1.1) Collected infants' demographic data such as gender, gestational age, postnatal age, birth weight, weight at study entry, weight at study end and apgar score at 1 and 5 min, medical history, medication before study time, respiratory care and type of feeding. All of information was obtained from infant's profile, and then, recorded on infant's demographic sheet.

   1.2) Established rapport relationship with parents by orienting parents to the unit and introduced IEM program to parents.

2. Modification phase consisted of two groups of activities including 2.1) basic environmental modifications, and 2.2) individualized modifications.

   2.1) Basic environmental modifications consisted of three components including: a) day-night lighting, b) music playing, and c) lavender smelling. All activities were provided and scheduled in a certain period of time.

      2.1.1) Day-night lighting (Brandon, 2000; 2002; Chawaphanth, 2004) was aimed to promote physiological and behavioral organization and minimize visual and auditory sensory overload. At the research setting for this study, neonatal unit has policy for visiting hours as 9 am to 6 pm which the parents were not allowed to stay in the unit after 6 pm. Therefore, day-night lighting was provided for VLBW preterm infants according to the visiting hours which yielding visualization and enhancing parents-infant interaction. Day light was started from 7 am to 7 pm with

200 – 400 lux of light level. Night light was another 12 hours starting from 7 pm to 7 am with 10 – 90 lux of light level. An incubator cover sheet was used to provide day-night lighting by covering the incubator with an incubator cover sheet during night time from 07.00 p.m. to 07.00 a.m. and then uncover the incubator in the day time from 07.00 a.m. to 07.00 p.m.

2.1.2) Music playing (Standley, 2002; Chou, et al., 2003) was aimed to buffer the negative sound level in incubator and to promote infant's deep sleep. A record of classical music (Mead Johnson) and MP3 player (iPod nano Model A1236) were used to play soothing music for a 30 minute period at 01:00 p.m., and 07:00 p.m., which was one hour after feeding. The earphones were placed at 10 centimeters from both sides of infants' ears. The level of sound was maintained at 40 – 50 decibels (dB).

2.1.3) Lavender essential oil smelling (Cavanagh & Wilkinson, 2002; Fernandez, et al., 2004; McNeilly, 2004; Sanders, et al., 2002) was aimed to modify unpleasant smell, promote infant's calmness and deep sleep. Lavender essential oil (donated by Miami Aromatherapy, Inc.) and 2 cotton swabs were used to induce lavender odor to infants by sticking two cotton swabs with two drops of lavender essential oil at the edge of the infant's bed by the head-side, 15 centimeters away from the infants' nose for a 30 minute period at 01:00 p.m., and 07:00 p.m., which was one hour after feeding.

2.2) Individualized modifications were aimed to assess and adjust environment base on individual needed of infants. There was consisting of two sections including 2.2.1) assessment section and 2.2.2) adjustment section.

2.2.1) assessment section was aimed to determine VLBW infant needed and tolerance individually. Pulse oximeter (Masimo SET Rad-5v) was used to assess the infants for signs of physiological distress, during the induction of basic environmental modifications (music playing and lavender essential oil smelling) at 01:00 p.m. and 07:00 p.m. In case of infant showed signs of stress as follows:

2.2.1.1) Heart rate was <100 beats/min or >200 beats/min for 12 seconds or longer (Harrison, Williams, Berbaum, Stem & Leeper, 2000; Jirapaet & Jirapaet, 2002; 2005; Stark, 2008).

2.2.1.2) Oxygen saturation level dropped below 90% for longer than 30 seconds (Harrison, Williams, Berbaum, Stem & Leeper, 2000; Jirapaet & Jirapaet, 2002; 2005; Stark, 2008).

The adjustment section would start whenever infant showed either one or two signs of stress that listed above.

2.2.2) adjustment section was aimed to modify and minimize the excessive environmental stimulation. These activities would facilitate physiological stability and behavioral organization. The activity of adjustment section was described below:

2.2.2.1) reduced intensity of lavender smelling and music playing every 5 minutes as follows:

2.2.2.1.1) removed one cotton swab with lavender essential oil from the incubator, once at a time, but not more than two times.

2.2.2.1.2) decreased volume of music playing 5 dB, once at a time, but not more than two times.

The reduction of lavender essential oil intensity was the first consideration. Then, the reduction of music volume intensity was the second consideration (Blackburn, 2007; Graven, 2000). An assessment of infant's signs of stress was performed 5 minutes later following each adjustment. The adjustments steps were to reduce intensity of lavender, followed by assessment, reduce intensity of music, and followed by assessment, respectively. The intensity adjustment of lavender essential oil and music playing was limited to two times per each. For example, researcher removed a cotton swab with lavender essential oil from incubator. Then, 5 minutes later, infant's signs of stress were assessed. In case that infant was persisted signs of stress, volume of music playing was decreased 5 dB (Krueger, Wall, Parker & Nealis, 2005; Turnage-Carrier, 2004). After 5 minutes, infant's signs of stress were assessed again. In case of infant still showing signs of stress after two times of lavender adjustment and music volume adjustment, all environmental stimulation was terminated immediately.

2.2.2.2) reduced duration of lavender smelling and music playing by considering reducing duration of lavender first, and reducing duration of music playing as second consideration. Step of reductions were as follows:

2.2.2.2.1) reduced duration of lavender essential oil, 5 minutes per one adjustment of lavender

2.2.2.2.2) reduced duration of music playing, 5 minutes per one adjustment of music playing

The infant's demographic sheet

The infant's demographic sheet (see Appendix B) was used to collect infant's gender, date of birth, apgar score (at 1 and 5 min), gestational age, postnatal age, birth weight, medical history, type of feeding, medication before study time, and etc. This instrument aimed to control confounding factors in the study. All of information was obtained from infant's profile, and then, recorded on infant's demographic sheet. The infant's data was recorded on the first day of engaging to study, and again, at the end of the study.

The Naturalistic Observation of Newborn Behavior (NONB) tool

The Naturalistic Observation of Newborn Behavior (NONB) tool (see Appendix B) was used to observe VLBW preterm infants' neurobehavioral responses at baseline, post control period and post experimental period. NONB observation sheet was segmented into 2-minute time intervals and set up in a frequency checklist format for continuous recording of behavior. This method did not permit the accurate documentation of duration of a behavior, only its frequency. In case of an infant showed an arm extension for 5 seconds, this was marked with a check in the respective 2-minute time block. The infant who extends an arm for the entire 2-minute epoch was received the same check mark. For statistical data analysis, only the occurrence of the event itself would be available. In this study, the observation of respiratory characteristic and rate were excluded as the recommendation of an expert. The reason of exclusion was to eliminate possibility of inaccurate observation of respiratory characteristic and respiratory rate counting in case of infants' crying.

The behavioral data were recorded in continuous fashion whereas the autonomic data (heart rate and oxygen saturation) were recorded in a time sampling fashion. The observation of heart rate and oxygen saturation were recorded every 2 minutes by reading from pulse oximeter, which displayed digitally at the beginning of each 2-minute block. The observer continues to watch the infant for the remainder of the 1:55 minutes until the next 2-minutes block started.

The observation took 20 minutes each time of baseline (on the day that infant engaged to the study), post-control period and post-experimental period for every single infant. The observation was started 10 minutes before the nurse changed diaper for infant. Additionally, every single observation was recorded by using computer software (Digital Video Recording System) and write infant's video to Video Compact Disc (VCD) throughout the 20 minutes of observation period. The research assistant observed the infants' behaviors by watching video recording and then marked on NONB sheet. The groups of infant's behaviors rated in this study based on definitions used in the Newborn Individualized Developmental Care and Assessment Program (Als, 1999).

<u>Neurobehavioral observation scoring sheet</u>

The infant's behavior was grouped into four main systems (Als, 1982; 1999) including 1) autonomic system, 2) motoric system, 3) state system, and 4) attention system (see Appendix B).

1. The autonomic system (Als, 1982; 1999) consisted of 2 categories including 1.1) positive autonomic responses (e.g., regular heart rate, normal oxygen saturation and positive skin colors and 1.2) negative autonomic responses (e.g., tremor, startle, twitch face, twitch body and twitch extremities, spit up, gag, burp, hiccough, BM grunt, sounds, sigh and gasp).
2. The motoric system (Als, 1982; 1999) consisted of 2 categories including 2.1) positive motoric behaviors (e.g., hand on face, smile, mouthing, suck search, sucking, tuck trunk, flexed arms, flexed legs, smooth movement arms, smooth movement trunk, smooth movement legs, leg brace, hand clasp, foot clasp, hand to mouth, grasping and holding on) and 2.2) negative motoric behaviors (e.g., tongue extension, grimace,

gape face, flaccid arms, flaccid legs, extend arms, extend legs, stretch/drown, diffuse squirm, arch, finger splay, airplane, salute, sitting on air and fisting)

3. The state system (Als, 1982; 1999; Brazelton, 1984) consisted of 3 categories of consciousness including 3.1) sleep state (e.g., deep and light sleep), 3.2) transitional state (e.g., drowsy), 3.3) arousal state (e.g., alert, active and crying).
4. The attention system (Als, 1982; 1999) consisted of 2 categories including 4.1) positive attention behaviors (e.g., frown, ooh face, face open, cooing and speech movement), and 4.2) negative attention behaviors (e.g., fuss, yawn, sneeze, eye floating, avert and locking).

Method of scoring

In this study, the method of scoring was adopted from Ferber’s technique (Ferber, 2004). The NONB tool was used to score on neurobehavioral responses of VLBW preterm infants. RA observed the infant’s neurobehavioral responses by watching video recording of infant and using NONB tool to mark the frequency of infant’s neurobehavioral responses. The researcher counted the frequency of infant’s neurobehavioral responses from NONB sheet and calculated into Neurobehavioral Observation Scoring sheet for each behavior’s category.

Each behavior’s frequency within a category was prorated to the length of observation of 20 minutes. As infant’s behaviors observation conducted for 20 minute, thus, it yielded a maximal frequency count of 10 per item.

Autonomic system was composed of 2 categories including positive autonomic responses (e.g., heart rate, oxygen saturation and positive skin color) and negative autonomic responses (e.g., tremor, startle, twitch face, twitch body and twitch extremities, spit up, gag, burp, hiccough, BM grunt, sounds, sigh and gasp). Heart rate and oxygen saturation were read from pulse oximeter every 2-minute time block. The exact number read from the monitor was written down into column. The regular heart rate which was between 120 and 160 beat/min was counted and divided by 10. The normal oxygen saturation which was 92% and 95% was counted and divided by 10. The positive skin color (e.g., pink skin color) was counted and divided by 10. Then, heart rate score, oxygen saturation score and positive skin color score were sum and divided by 3.

Heart rate score = number of regular heart rate ÷ 10

Oxygen saturation score = number of normal oxygen saturation ÷ 10

Positive skin color score = number of pink skin color ÷ 10

Thus, positive autonomic responses = Heart rate score + Oxygen saturation score + Positive skin color score ÷ 3

Negative autonomic responses consisted of 13 items were observed and recorded into the column every 2-minute time block. The mark of ✓ were recorded in each column which matched to infant's autonomic responses. The observation was conducted for 20 minutes, thus a maximal frequency count was 10 per behavior. The score were calculated by counting the number of behaviors in each items, then, divided by (10 x number of behavior types).

Negative autonomic responses = total number of 13 behaviors ÷ (10 x 13)

Motoric system was composed of 2 categories including positive motoric behaviors (e.g., hand on face, smile, mouthing, suck search, sucking, tuck trunk, flexed arms, flexed legs, smooth movement arms, smooth movement trunk, smooth movement legs, leg brace, hand clasp, foot clasp, hand to mouth, grasping and holding on) and negative motoric behaviors (tongue extension, grimace, gape face, flaccid arms, flaccid legs, extend arms, extend legs, stretch/drown, diffuse squirm, arch, finger splay, airplane, salute, sitting on air and fisting) which consisted of 32 items. The infant's behaviors were observed every 2-minute time block and the mark of ✓ were recorded in each column. The observation conducted for 20 minutes, thus a maximal frequency count was 10 per behavior. The score of each category were calculated by counting the number of behaviors in each category, and then divided by (10 x number of behavior types).

Positive motoric behaviors score = total number of 17 behaviors ÷ (10 x 17)

Negative motoric behaviors score = total number of 15 behaviors ÷ (10 x 15)

State system consisted of 3 categories of consciousness including sleep state (e.g., deep and light sleep), transitional state (e.g., drowsy) and arousal state (e.g., alert, active and crying). Infant's state was observed every 2-minute time block. The mark of ✓ were recorded in each column. The state scores were counted the length of time in each state. The highest scores for a particular state possibly were 20. In case that there was no scoring for a particular state, the score of zero were given.

Attention system was composed of 2 categories including positive attention behaviors (e.g., frown, ooh face, face open, cooing and speech movement) and negative attention behaviors (e.g., fuss, yawn, sneeze, eye floating, avert and locking) which consisted of 11 items. The infant's behaviors were observed every 2-minute time block and the mark of ✓ were recorded in each column. The observation conducted for 20 minutes, thus a maximal frequency count was 10 per behavior. The score of each category were calculated by counting the number of behaviors in each category, then, divided by (10 x number of behavior types).

Negative attention behaviors score = total number of 6 behaviors ÷ (10 x 6)

Positive attention behaviors score = total number of 5 behaviors ÷ (10 x 5)

The example of using NONB and Neurobehavioral observation scoring sheet was provided in Appendix C to figure the method of scoring in this study. For data analysis, all the calculated scores were entered to Statistical Package for Social Sciences (SPSS for Windows Release version 15.0).

Human subject protection

This study was approved by Institutional Review Broad of Chulalongkorn University and Human Research Ethics Committee of Queen Sirikit National Institute of Child Health (see Appendix D). After a staff nurse of neonatal unit introduced the researcher to parents of the eligible infant, the parents were respectfully invited to participate in the study and received a participant information sheet which contained the research details (see Appendix E). The researcher explained all information about research. Parents were informed that there was no cost for parents to participate in this study. Also, the parents were allowed to test all experiment used in the study such as listening to music, smelling lavender essential oil, and over seeing the incubator cover sheet. Researcher provided time for parents to discuss and ask questions before making decision.

The parents were informed that their infant's participation in this study was voluntary, and they might withdraw their infant from the study at any time without affecting a treatment of their infant in any way. The parents were reminded that they also had rights to refuse to participate in the study. In case the parents gave permission to have their infant participated in the study, researcher obtained a written informed consent (see Appendix E) from infant's mother and had a staff nurse signed on the consent form as a witness.

The parents were informed the starting time of the study and when the study was ended. All participants were observed closely by the researcher throughout the study. In case the researcher possibly found unexpected findings which developed during the course of the research study which might affect the parents' willingness to continue to participate in the study, researcher would inform parents as soon as possible.

The parents were informed that their infant's behaviour was recorded to VCD, three times throughout the study. In order to keep participant's confidentiality, there was no personal identification information contained in the research records and VCD. VCD of infant's behaviour was coded as a number before sending to research assistance who was blinded to infant's data and identity for rating purposed of infant's behaviour only. The research assistance was not allowed to copy VCD or exposed VCD to the public and must return VCD to researcher immediately after finished rating infant's behaviour. Infant's data and VCD of infant's behaviour were kept in a locked drawer which was limited to researcher's access only. The personal computer of researcher that saved infant's data was set up to required username and password for logging on the computer in order to protect participant's confidentiality. All infant's data and VCD were reserved for five years after completing this study in order to provide as a reference and answer for further doubt and inquiry. Then, all infant's data and VCD were destroyed before discarding into the public waste-bin.

The data collected from infant's participation were used for a dissertation and possibly other published studies. The exposure of infant's data was done in case of necessity with academic reason. In case of the parents had any concerns about the research, they were allowed to contact the researcher at all time. Also, if they had any further concerned or complained regarding the way the research was, or had been conducted, they could contact the Ethics Officer of the Human Research Ethics Committee at Chulalongkorn University.

At the end of the study, there was no identified risk or anticipated injuries related to this study and no withdraw or drop out of the participants from the study.

Pre-Data Collection

Pre-data collection was a preparation process and activities which had to be done before the start of data collection. There was the preparation for experimental materials (e.g., incubator cover sheet, light meter measurement, lavender essential oil, classical music, MP3 player, sound level meter, and pulse oximeter), preparing for research instrument (e.g., IEM Program, Infant's Demographic Sheet, Naturalistic Observation of Newborn Behavior (NONB), and Neurobehavioral Observation Scoring Sheet), and preparing for data collection (e.g., researcher, research assistance, computer and video recording, IRB approval).

Preparation for experimental materials

1. Incubator cover sheet

The length, width and height of the incubator were measured in order to make a cover sheet. The researcher bought all material including cotton sheet and synthesized thread from fabric's shop. The tailor was told to make a cover sheet which had double layer of cotton sheet and had synthesized thread inserted at the middle. Therefore, the cover sheet was thick enough to prevent the light penetrating into the incubator. The cover sheet was used to provide night light for the infant. The cover sheet was place on the infant's incubator which covered four sides of the incubator including 1 side on the top, 2 sides lateral and 1 side back.

2. Light meter measurement

The ANA-F9 Lux Meter was use to measure light level in the incubator. This model could measure light level ranging from 0 to 19999 lux. In term of instrument reliability, the ANA-F9 Lux Meter needed to be calibrated before use in this study. The researcher received a personal support from an engineering instructor from Faculty of Engineering, Kasetsart University for using the calibrated ANA-F9 Lux Meter (serial number 950193) throughout the study. The ANA-F9 Lux Meter was used to measure the light level in the infant incubator during the time the researcher provided day-night lighting for the infant, of which the day light needed to be maintained between 300 – 500 lux, and the night light needed to be maintained between 10 – 100 lux.

3. Lavender essential oil

Miami Aromatherapy, Inc., a non-profit organization had supported the non-commercial and therapeutic use of essential oil in medicinal and health profession. There was a scale of 10 grade of essential oil production. Grades 1 to 3 were considered to be medicinal or therapeutic, and 4 to 10 were considered to be commercial (Galamaga, 1998). In USA, The National Formulary was a compendium to certify for quality essential oils of grades 1 – 3 which described the properties a substance must had in order to be used in medicinal compounds. Therefore, the essential oil listed in the National Formulary (NF), was NF grade and considered to be therapeutic grade oil. The Miami Aromatherapy, Inc. had supplied NF grade of lavender essential oil for health related research. Researcher contacted The Miami Aromatherapy, Inc. asking for the support of NF grade of lavender essential oil. After discussing the details of study via e-mail, it took three months for the contact approval. Finally, The Miami Aromatherapy, Inc granted to donate NF grade of lavender essential oil for this study with an agreement including 1) the researcher had to pay for all cost of shipment, 2) NF grade of lavender essential oil from The Miami Aromatherapy, Inc would be the only oil used in the study, and 3) Miami Aromatherapy, Inc. is identified as the provider of the oil in the study. The researcher opened a FedEx account and sent the account number to Miami Aromatherapy, Inc. Four small bottles of NF grade of lavender essential oil was delivered to researcher by FedEx service which the cost of shipment was charged to researcher’s account.

4. Classical Music

The classical music from Mead Johnson was used in this study. There were six songs in this album (Smart Symphonies for A+ Baby). The song named *Kuai Pay*, created by Nimit Jittanon, was played repeatedly for 30 minutes by using MP3 player (iPod nano Model A1236). The music sound was maintained between 40 – 50 decibel (dB) measuring from the ear phone. The sound level meter (Digicon DS-40) was used to measure music sound level in order to adjust the volume as to the requirement. Researcher received the personal support of sound level meter (Digicon DS-40) from a nursing supervisor, Pediatric Department, Ramathibodi Hospital throughout the study. After calibrating the sound level meter, the music was played and the ear phones were placed 10 centimeter away from the sound censor. Then, the volume was adjusted and marked on the volume adjustor at the point in which the sound level was reading between 40 – 50 dB on the screen. Additionally, the volume was adjusted and marked for every 5 dB decrement in order to prepare for adjustment section in IEM program.

5. Pulse oximeter

The Masimo SET Rad-5v was a pulse oximeter used to measure infant's heart rate and oxygen saturation in this study. This pulse oximeter was a property of neonatal unit, which the researcher asked permission from the nurse manager for using this instrument throughout the study. The Masimo SET Rad-5v was maintained and calibrated at regular schedule of neonatal unit.

Preparation for Research instruments

IEM Program, Infant's Demographic Sheet and Neurobehavioral Observation Scoring Sheet were sent to five experts (the name listed in Appendix F) to determine the content regarding validity, appropriateness and feasibility of instrument. Then, the researcher made a correction based on every single comment. In addition, the pilot study was conducted with five VLBW infants at Neonatal Unit, Queen Sirikit National Institute of Child Health. This study trial was aimed to determine the possibly experimental problem and feasibility of IEM program in the setting.

Naturalistic Observation of Newborn Behavior (NONB) was created by Dr. Heidelise Als, the author of the NIDCAP observation methodology and President of NIDCAP Federation International, the copyright holder of the materials. The researcher contacted and asked permission from Dr. Als for using NONB as a research instrument in this study. After discussing in person and e-mail, the researcher received a letter of permission to utilize NONB in dissertation on October 16, 2008 (see Appendix G).

Preparation for data collection

1. Researcher

In order to be qualified for using the Naturalistic Observation of Newborn Behavior (NONB) as a research instrument for this study, the researcher had been trained for Newborn Individualized Developmental Care and Assessment Program (NIDCAP) which included the use of behavior observation sheet called Naturalistic Observation of Newborn Behavior (NONB). NIDCAP provided education and training in developmental observation and assessment of high-risk newborn, preterm infants, and families/relevant staff involved in care implementation. NIDCAP majorly focused on individualized, neurodevelopmentally supportive, and family-centered framework, as well as better understanding of infants' competence and behavioral reactions to stress and caregiving or environment. The researcher was engaged in training on February 15, 2007 at Colorado NIDCAP Training Center, which involved a one-day didactic session and clinical demonstration of the observational tool, then, continued the practicum session, 3 – 4 days/week at The Children's Hospital, Colorado, USA. The NIDCAP training incorporated several levels of developmental training which required minimum of two years training. The trainee needed to complete a specified number of observations on infants of different gestational age, post-birth age, and health status. This observation period is followed by an assessment of reliability for certification by the trainer. The researcher was in the level 1 of training which was able to use NONB tool for this study. Instead of NIDCAP certification, the researcher received the letter of progression (see Appendix G) as a qualified supported document from the trainer, Dr. Joy V. Browne, RN, PCNS-BC, Associate Professor of Pediatrics and Psychiatry, Director of Center for Family and Infant Interaction, and Director of Colorado NIDCAP Training Center. In addition, the researcher attended the 24^{th} Annual Conference of Developmental Interventions in Neonatal Care held in Denver, Colorado, USA, on October 1 – 4, 2008 in order to refresh and update the practice of developmental care in infants.

2. Research assistant

The research assistance (RA) was a physical therapist, who had been working for The Children's Hospital, Colorado, USA. She was a NIDCAP qualified and obtained NIDCAP certification from the Colorado NIDCAP Training Center. She had been practicing NIDCAP in her work. Additionally, she had been doing NIDCAP reliability with her trainer every two years and had an active NIDCAP certification. In this study, RA was hired for rating infants' behavior in order to prevent probably bias of the researcher who conducted and scheduled all experiment throughout the study.

The verbal contact and agreement between RA and researcher were made in RA's office at The Children Hospital, Colorado, USA on October 28, 2008. The agreement was set as the following:

1. RA was not allowed to make copy or replicate the VCD of infants' behavior.
2. The VCDs were played in a private room which seriously concerned of exposure to the public or other reviewers.

3. The VCDs were kept in a locked cabinet which limited to RA accessed only.
4. The definition of infants' behavior was base on NIDCAP manual and NONB tool was used to rate the infants' behaviors frequency.
5. RA was blinded to infants' data, identities, and/or experimental schedules, only VCD coded was used for communication between RA and researcher.
6. All materials including VCDs and NONB sheets were sent via FedEx services which mostly be ensured the arrival date.
7. RA and researcher were agreed of being available on the date that the package was arrived which required receiver's signature to ensure that nobody accessed or opened the package before hands.
8. RA needed to return all VCDs to researcher immediately after finished rating infants' behavior via FedEx service.
9. Researcher was responsible for all cost of shipment. The payment of shipping and the fee was paid in US Dollar by US Bank cheque.

The infants' VCD were sent to RA's address in USA by FedEx services. The tracking number of the shipping and the estimated date of arrival were sent to RA via e-mail to let RA knew the date of package delivery. The video recordings were played with RA's personal computer in the office privately. The VCDs had number of infants' coded on which RA needed to copy that number on the NONB sheets. The observation took 20 minutes which required two NONB sheets per one observation. RA needed to watch video from both cameras to view infant's face and entire body. All NONB sheets and VCDs were sent to researcher via FedEx service after RA had finished the rating. After RA had sent the tracking number to researcher via e-mail, the package was tracked and researcher was available for package picked up on the arrival date. The fee was paid after RA had completed work.

3. Computer and video recording

Personal computer base was modified to serve as the Digital Video Recording (DVR) System and increase memory capacity. There was CPU Dual Core with RAM 1 GB and Hard Drive 350 GB, monitor LCD 15” wire screen, case, keyboard, mouse, camera CCD infrared 2 set, camera CCD chipset Sony 2 set, cable RG-6 with electric wire, and power supply 12 volt. DVR system was the software that created specific operation used for this study only, thus, this software never release to the IT market. The DVR system provided two functions of recording including 1) continuous recording, and 2) automatic recording when movement detected. DVR system had ability to record several cameras by one click which all cameras were started recording at the exact time. The system could serve up to 32 cameras at one recording. The video record was automatically saved in hard drive of computer which each camera had saved in a separated file. The system also provided back up data automatically in drive C and allowed researcher to write video files on VCD. The computer had antivirus program to protect the database and required username and password in order to log on the computer for participant’s confidentiality. In this study, the continuous recording function was used with two cameras at one recording. Therefore, there were two files saved in hard drive which could replay together, at the same time.

The neonatal unit had limited the visitor policy. Only parents were allowed to enter the unit. In using two digital video cameras recording required at least two research assistants (RA) which against the unit policy. The use of DVR system helped researcher to conduct video recording with two cameras without RA. Also, DVR system reduced the possible error of time recording when using two digital video cameras which required excellent cooperated and organized from two RA to begin recording at the same starting point.

After getting IRB approval from Queen Sirikit National Institute of Child Health, researcher asked permission from the nurse manager to bring computer set, equipment, and engineering instructors to neonatal unit in order to set up and trial the equipment. Computer, all equipment and DVR system installation were set up under supervision of engineer instructors from Faculty of Engineering, Kasetsart University. All of them were placed on movable cart which was easier to move around from one incubator to another incubator. One infant needed two cameras of which the camera CCD infrared was used to view the infant's entire body while the camera CCD chipset was used to view the infant's face. The camera CCD infrared was placed at the right corner by the infant's leg-side in the incubator which gave a diagonal angle view of infant's entire body. The camera CCD chipset was held at the middle of incubator's ceiling which gave front view of infant's face. Both cameras were set at the time of video record and were removed from the incubator after finished the recording. Therefore, camera holders were designed base on convenient purpose which easy to setup and remove.

4. Institutional Review Broad approval

The research project was submitted to Human Research Ethics Committee of Queen Sirikit National Institute of Child Health on February 15, 2008. Researcher was scheduled for oral presentation to the Human Research Ethics Committee on February 27, 2008. After making correction base on committee's comment, the research project was approved on March 11, 2008 and valid till March 10, 2009 (see Appendix D). The research project was again submitted to Institutional Review Broad (IRB) of Chulalongkorn University on May 14, 2008. The research project was approved after minor correction made according to committee's comment on August 1, 2008 and valid till July 31, 2009 (see Appendix D). The research project was approved from Human Research Ethics Committee of Queen Sirikit National Institute of Child Health earlier than IRB from Chulalongkorn University because the researcher needed to enter the Neonatal Unit for setting up and trial the research instrument, as well as, identifying possible obstacle.

Data collection

After research project was approved by Human Research Ethics Committee of Queen Sirikit National Institute of Child Health, the researcher contacted nurse manager and staff nurse at Neonatal Unit in order to explain objectives and program of the study, as well as the relevance of research project such as research time frame, coordinated activities, etc. VLBW infants were screened by researcher and staff nurse for inclusion criteria. When VLBW infant who meet inclusion criteria was found, researcher was introduced to the parents of eligible infant by staff nurse. Then, researcher explained research details by using the participant information sheet. The parents were allowed to test all experiment used in the study such as listening to music, smelling lavender essential oil, and seeing the incubator cover sheet. Researcher provided times for parents to discuss and ask questions before making decision. The parents were informed with necessary information as following:

1. Infant's participation in this study was voluntary, and they might withdraw their infant from the study at any time without affecting the treatment of their infant in any way.
2. There was no cost for parents to participate in this study.
3. Infant's behaviour was recorded to VCD, three times throughout the study. There was no personal identification information contained in the research records and VCD.
4. VCD of infant's behaviour was coded as a number before sending to research assistance who was blinded to infant's data and identity for rating purposed of infant's behaviour only. The research assistance was not allowed to copy VCD or exposed VCD to the public and must return VCD to researcher immediately after finished rating infant's behaviour.
5. Infant's data and VCD of infant's behaviour were kept in a locked drawer which was limited to researcher's access only. All infant's data and VCD were reserved for five years after completing this study in order to provide as a reference and answer for further doubt and inquiry. Then, all infant's data and VCD were destroyed before discarding into the public waste-bin.
6. The data collected from infant's participation were used for a dissertation and possibly other published studies. The exposure of infant's data was done in case of necessity with academic reason.
7. All participants were observed closely by the researcher throughout the study. In case the researcher found unexpected findings that develop during the course of the research study which might affect the parents' willingness to continue to participate in the study, researcher would inform parents as soon as possible.
8. In case the parents had any concerns about the research, they were allowed to contact the researcher at all time. Also, if they had any further concerned or complained

regarding the way the research was, or had been conducted, they could contact the Ethics Officer of the Human Research Ethics Committee at Chulalongkorn University.

When parents gave permission to have their infant participated in the study, researcher would obtained a written informed consent from infant's mother and had a staff nurse signed on the consent form as a witness. Infants were assigned randomly to procedures either start with control period or experimental period. The nursing activities were provided according to assignment that the infant belonged to. As the within subject designed all infants underwent both control period and experimental period.

Control period

There was 24 hours of control period. VLBW preterm infants were received conventional nursing care including bathing in the morning, provided nesting at all time, feeding eight times around the clock, administered medications as order, obtained vital signs every four hours, changed diaper, turned position, and responded to infant's cry as occasion. When the mother visited, the VLBW preterm infant was tried for breastfeeding with his/her mother under supervision of staff nurse, mostly done at the feeding time.

Experimental period

There was 24 hours of experimental period, which VLBW preterm infants engaged in this period received conventional nursing care as described previously in the control period part. Moreover, VLBW preterm infants in this period received the IEM program adding in between the conventional nursing care scheduled. The IEM nursing activities (details in Appendix A) were provided as following:

1. Day light was provided by uncovered the incubator for 12 hours started from 07:00 a.m. to 07:00 p.m.
2. Music playing and Lavender essential oil smelling were provided for 30 minutes started from 01:00 p.m. to 01:30 p.m. The infant was assessed for his/her needed and tolerated throughout the period.
3. Night light was provided by covering the incubator for 12 hours started from 07:00 p.m. to 07:00 a.m.
4. Music playing and Lavender essential oil smelling were provided for 30 minutes started from 07:00 p.m. to 07:30 p.m. The VLBW preterm infant was assessed for his/her needed and tolerated throughout the period.

The video recording of VLBW preterm infant's neurobehavioral response was done during diaper changing, for three times throughout the study. The first time of video recording was done as baseline data which was on the day that VLBW preterm infant engaged to the study. The second and the third time of video record were done at the end of control period (post-control period) and the end of experimental period (post-experimental period). These video records were used to observe VLBW preterm infant's neurobehavioral responses as a part of data collection.

Method of observation

In the incubator, the VLBW preterm infant was placed in nesting with supine position and unwrapped to allow the infant moving freely. The pulse oximeter (Masimo SET Rad-5v) was placed in incubator beside the infant. The censor was attached on infant's foot and wrapped with adhesive tape. The pulse oximeter was turned on and check for its function. Researcher placed a camera CCD infrared with the holder in the incubator at the right corner by the infant's leg to provide a full view of entire infant's body movement and all episodes of care giving. Then, researcher hanged a camera CCD chipset with the holder at ceiling of incubator to provide a full view of infant's face behaviors. The computer was turned on, and researcher used personal password to log on, then the DVR program was automatically started. The researcher connected the wire from both cameras to the computer, then, the pictures of infant that viewed from both cameras were showed on the computer screen. Both cameras were adjusted the focus which allow the excellent view to identify behaviors, small movement of face, body, and extremities clearly of the position. The pulse oximeter was adjusted in order to be viewed clearly through the camera. When everything was set, the researcher made one click on start button by using the mouse. The video record started both cameras at the same time. After 10 minutes of recording, the researcher provided diaper changed for the infant while the video still recorded the entire of infant's movement and care giving. The diaper changing took 5 minutes approximately, the video continue to record till the total recording time reached 20 minutes. For example, the started recording time was 06:00 a.m., and the diaper changing time would be 06:10 a.m., then, the ended recording time was 06:20 a.m.

The researcher stopped video recording after 20 minutes by one click mouse on the stop button. Then, both cameras were disconnected from the computer and were removed from the incubator. The pulse oximeter was turned off, detached from the infant, and removed from the incubator. The computer was turned off and moved away from the incubator site as ending of one observation and record.

There were three times of video recording for observation purpose. The procedure of video recording for observation purpose was the same for all three times. The first time was recorded for the infant baseline on the day that infant engaged to the study. The infant was then provided to conventional nursing care and/or IEM program depending on what period (control period or experimental period) he/she was in. The second and the third time were recorded at the end of each period (post-control period and post-experimental period). The infant was terminated from the study after the third time of video record and the parents were informed.

Data analysis

In order to examine the effects of IEM program on neurobehavioral organizations of VLBW infants, the infant's behaviors were rated for the frequency of exhibiting. These frequency counted were taken for 20 minutes during diaper changing which observed throughout the video recording by RA. The frequency was marked on NONB tool which RA completed and sent to researcher. Then, researcher counted the frequency of behaviors that grouped in the same categories, then, calculated by using neurobehavioral observation scoring sheet. The final scores were entered to computer using Statistical

Package for Social Sciences (SPSS for Windows Release version 15.0) for data analysis. The statistic used in this study was listed below:

1. Descriptive statistic was used to describe demographic characteristic of infant such as gender, gestational age, postnatal age, birth weight, weight at study entry, weight at study end, and apgar score at 1 and 5 minutes, medical condition, medication, respiratory care, and type of feeding.
2. Pearson correlation coefficient was used to examine associations between demographic variables and to describe relationships between the neurobehavioral outcomes and infant demographic characteristics.
3. Kolmogorov-Smirnov used for testing the assumption of using repeated measures ANOVA such as normal distribution of all outcome data.
4. Repeated measures ANOVA was used to compare mean different of outcomes of infant between post control period and post experimental period which included autonomic system (e.g., negative autonomic responses and positive autonomic responses), motoric system (e.g., negative motoric behaviors and positive motoric behaviors), state system (e.g., sleep state, transitional state, and arousal state), and attention system (e.g., negative attention behaviors and positive attention behaviors).

<u>Clinical interpretation</u>

The neurobehavioral organizations of very low birth weight infants were clinically interpreted base on four main systems as the following:

1. Organization of autonomic system indicated by infant in experimental period showed higher scores in positive autonomic responses and showed lower scores in negative autonomic responses comparing to in control period.

2. Organization of motoric system indicated by infant in experimental period showed higher scores in positive motoric behaviors and showed lower scores in negative motoric behaviors comparing to in control period.
3. Organization of state system indicated by infant in experimental period spent longer duration of sleep state and spent shorter duration of transitional and arousal state comparing to in control period.
4. Organization of attention system indicated by infant in experimental period showed higher scores in positive attention behaviors and showed lower scores in negative attention behaviors comparing to in control period.

CHAPTER IV

RESULTS

The Statistical Package for Social Sciences (SPSS for Windows Release version 15.0) was used for all data analysis. There were no missing data. Descriptive statistic was used to describe demographic characteristic of infant such as gender, gestational age, postnatal age, birth weight, weight at study entry, weight at study end, and apgar score at 1 and 5 minutes, medical history, medication before study time, respiratory care and type of feeding. Pearson correlation coefficient was used to examine the associations among demographic variables and to describe relationships between the neurobehavioral outcomes and infant demographic characteristics.

In consideration of infant uniqueness or baseline different of behavior in each infant, neurobehavioral outcome data of infants were done as a baseline before engaging to the study. The mean of infant's outcome data at post control period was subtracted with the mean of infant's baseline data to give mean different of neurobehavioral outcomes in control period. Also, the mean of infant's outcome data at post experimental period was subtracted with the mean of infant's baseline data to give mean different of neurobehavioral outcomes in experimental period. Then, the mean different of neurobehavioral outcome data in control period was compared with mean different of neurobehavioral outcome data in experimental period.

Kolmogorov-Smirnov was used for testing the assumption in term of normal distribution of all neurobehavioral outcomes data. The initial analysis on the mean different data revealed that several of the variables violated appropriate expectations of skewness and kurtosis. Thus reflect and square root transformation was performed on the data to correct for a normal distribution (Pusee-on, 2008). Then, repeated measures analysis of variance (ANOVA) was used to test directional hypotheses and sub-hypotheses.

Repeated measures ANOVA was used to compare mean different of infant's neurobehavioral outcomes between control period and experimental period which included autonomic system (e.g., positive autonomic responses and negative autonomic responses), motoric system (e.g., positive motoric behaviors and negative motoric behaviors), state system (e.g., sleep state, transitional state, and arousal state), and attention system (e.g., negative attention behaviors and positive attention behaviors).

Description of Sample

Twenty-five preterm infants with very low birth weight (VLBW) who meet the inclusion criteria were enrolled and no drop-out rate in this study. A within-subjects design in which subjects were used as their own control, all subjects underwent a control period with conventional nursing care, and experimental period with IEM program. The demographic characteristics of the sample were presented in Table 4.1 and 4.2.

Table 4.1 Demographic characteristics of sample in frequency and percentage (n = 25)

Characteristics	Frequency	Percent (%)
Gender		
Male	10	40
Female	15	60
Gestational age *		
≤ 30 weeks	10	40
> 30 weeks	15	60
Classification of VLBW infants		
SGA	4	16
AGA	21	84
Respiratory care		
Room air	21	84
O_2 therapy	4	16
Type of feeding		
Oral gavage	22	88
Breast-feeding	3	12
Medical history		
Diagnosis: IVH (grade I or II)	3	12
RDS	5	20
PDA	4	16
IUGR	1	4
Suspected NEC	3	12
None	9	36
Medications history		
Aminophylline	5	20
Antibiotic	1	4
MVD and/or Fer-in-sol	14	56
None	5	20

* As defined by Als, et al., 2004

There were 25 infants engaged in this study. The table 4.1 reported infants demographic data in frequency and percentage base on the infants n = 25, which included 10 (40%) of male infants and 15 (60%) of female infants. Gestational age of infants was classified as very premature infants (GA was ≤ 30 weeks) and premature infants (GA was > 30 weeks). There were 10 (40%) very premature infants and 25 (60%) premature infants. Eighty-four percents of VLBW infants were classified as AGA. Thirty-six percents of infants presented no severe medical history while 20% were diagnosed respiratory distress syndrome (RDS) as main concern immediately after birth. Medication before study time, Fifty-six percents of infants were prescribed multivitamin and/or Fer-in-sol and 20% of infants were prescribed Aminophylline. There were two types of respiratory care classified in this study including room air and oxygen therapy (O_2 flow in incubator). Eighty-four percents of infants were on room air. There were two type of feeding including oral gavage and breastfeeding, in which 88% of infants were fed by oral gavage.

Table 4.2 Descriptive statistic of demographic characteristics of sample (n = 25)

Characteristics	Mean	SD	Range
Gestational age at birth (week)	31.12	2.33	25 – 35
Postnatal age (day)	28.92	19.07	10 – 96
Apgar score at 1 minute	6.84	2.51	1 – 9
Apgar score at 5 minute	8.36	2.41	1 – 10
Birth weight (gram)	1266.96	204.73	610 – 1500
Weight at study entry (gram)	1689.84	256.17	1322 – 2208
Weight at study end (gram)	1742.12	254.20	1390 – 2284

Infants' gestational age at birth in this study was ranging between 25 to 35 weeks which had the mean of 31.12 weeks. The mean of infants' postnatal age was 28.92 days which minimum of infant postnatal age was as young as 10 days and the maximum infant age was 96 days. Three infants were assigned in 1 – 3 scores of apgar score ranging at 1 minute whereas 22 infants were assigned in 4 – 9 scores of apgar score ranging. There was an infant assigned in 1 – 3 scores and 24 infants were assigned in 4 – 10 scores of apgar score ranging at 5 minutes. Mean of infants' birth weight was 1266.96 grams which had birth weight ranging from 610 to 1500 grams. Infants' body weights at study entry were ranging between 1322 to 2208 grams which had mean of 1689.84 grams whereas mean of infants' body weights at study end was 1742.12 grams and ranging between 1390 to 2284 grams.

Pearson correlation coefficient was used to examine associations between demographic variables and describe relationships between the neurobehavioral outcomes and infant demographic characteristics (Appendix H).

Research Hypotheses Testing

Neurobehavioral organizations responses of VLBW infants when received IEM program (experimental period) are better than when received conventional nursing care (control period).

Sub-hypothesis 1: VLBW infants will present more positive autonomic responses and present less negative autonomic responses during experimental period than during control period.

Table 4.3 Repeated measures ANOVA results of mean different for autonomic responses in control and experimental (IEM) period (n = 25)

Autonomic Responses	Control period (Mean different ± SD)	Experimental period (Mean different ± SD)	df	F	p-value
Negative autonomic responses	1.233 ± 0.09	1.169 ± 0.08	1, 24	7.601	.011
Positive autonomic responses	1.261 ± 0.18	1.463 ± 0.16	1, 24	27.150	.000

Table 4.3 showed the repeated measures ANOVA results of mean different for autonomic response. The negative autonomic responses (e.g., tremor, startle, and twitching of face, body and extremities, spit up, gag, burp, hiccough, bowel movement grunt, sounds, sigh and gasp) findings were significantly different (p = .011). The result showed that VLBW infants who received IEM program during experimental period were exhibited less frequent in negative autonomic responses comparing to the control period. In addition, the positive autonomic responses findings included regular heart rate, normal oxygen saturation and pink skin color were significantly different (p = .000). The result showed that VLBW infants who received IEM program during experimental period were exhibited more frequent in regular heart rate, normal oxygen saturation and presented pink skin color comparing to the control period.

According to Als's study (1999), neurobehavioral organization in term of autonomic responses can be observed by infant exhibited more frequency in regular heart rate, normal oxygen saturation and presented good and stabilized skin perfusion. The infants also exhibited less frequency in negative autonomic responses. Therefore, the results of this study confirmed that IEM program can improve neurobehavioral organizations of VLBW infants in term of autonomic responses.

Sub-hypothesis 2: VLBW infants will present more positive motoric behaviors and present less negative motoric behaviors during experimental period than during control period.

Table 4.4 Repeated measures ANOVA results of mean different for motoric behaviors in control and experimental (IEM) period (n = 25)

Motoric behaviors	Control period (Mean different ± SD)	Experimental period (Mean different ± SD)	df	F	p-value
Negative motoric behaviors	2.942 ± 0.21	2.788 ± 0.28	1, 24	8.047	.009
Positive motoric behaviors	1.133 ± 0.08	1.159 ± 0.08	1, 24	4.654	.041

Table 4.4 showed the repeated measures ANOVA results of mean different for motoric behaviors. The findings of negative motoric behaviors (e.g., tongue extension, grimace, and gape face, flaccid of arms and legs, extend arms and legs, stretch/drown, diffuse squirm, arch, finger splay, airplane, salute, sitting on air, and fisting) revealed significant difference (p = .009). The result showed that VLBW infants who received IEM program during experimental period exhibited less frequency in negative motoric behaviors comparing to the control period. In addition, the positive motoric behaviors (i.e., hand on face, smile, mouthing, suck search, sucking, tuck trunk, flexed arms and legs, smooth movement of arms, trunk and legs, leg brace, hand and foot clasp, hand to mouth, grasping, and holding on) findings revealed significant different (p = .041). The result showed that VLBW infants who received IEM program during experimental period exhibited more frequent in positive motoric behaviors comparing to the control period.

According to Als's study (1999), neurobehavioral organization in term of motoric behaviors can be observed by infant exhibited more frequency in positive motoric behaviors. The infants also exhibited less frequency in negative motoric behaviors. Therefore, the results of this study confirmed that IEM program can improve neurobehavioral organizations of VLBW infants in term of motoric behaviors.

Sub-hypothesis 3: VLBW infants will spend more time in sleep states and spend less time in transitional state and arousal states during experimental period than during control period.

Table 4.5 Repeated measures ANOVA results of mean different for duration of state in control and experimental (IEM) period (n = 25)

Duration of State	Control period (Mean different ± SD)	Experiment period (Mean different ± SD)	df	F	p-value
Sleep state	3.748 ± 1.19	4.473 ± 1.12	1, 24	9.371	.005
Transitional state	4.326 ± 0.84	2.628 ± 0.88	1, 24	63.557	.000
Arousal state	4.196 ± 0.95	1.169 ± 0.35	1, 24	257.197	.000

Table 4.5 showed the repeated measures ANOVA results of mean different for duration of state. The findings of sleep state included deep sleep and light sleep were significantly different (p = .005). The result showed that VLBW infants who received IEM program during experimental period spent more time in sleep state than the control period. The findings of transitional state (i.e., drowsy) and arousal state (i.e., alert, active and crying) were significantly different (p = .000). The result showed that VLBW infants who received IEM program during experimental period spent less time in transitional state and arousal state comparing to the control period.

According to Als's study (1999), neurobehavioral organization in term of duration of state system can be observed by infants spent more time in sleep state. The infants also spent less time in transitional and arousal states. Therefore, the results of this study confirmed that IEM program can improve neurobehavioral organizations of VLBW infants in term of duration of state system.

Sub-hypothesis 4: VLBW infants will present more positive attention behaviors and present less negative attention behaviors during experimental period than during control period.

Table 4.6 Repeated measures ANOVA results of mean different for attention behaviors in control and experimental (IEM) period (n = 25)

Attention behaviors	Control period (Mean different ± SD)	Experimental period (Mean different ± SD)	df	F	p-value
Negative attention behaviors	1.042 ± 0.02	1.028 ± 0.02	1, 24	17.294	.000
Positive attention behaviors	1.041 ± 0.02	1.072 ± 0.03	1, 24	22.721	.000

Table 4.6 showed the repeated measures ANOVA results of mean different for attention behaviors. The findings of negative attention behaviors (i.e., fuss, yawn, sneeze, eye floating, avert and locking) revealed significant different (p = .000). The result showed that VLBW infants who received IEM program during experimental period exhibited less frequent in negative attention behaviors comparing to the control period. In addition, the finding of positive attention behaviors (i.e., frown, ooh face, face open, cooing and speech movement) revealed significant different (p = .000). The result showed

that VLBW infants who received IEM program during experimental period exhibited more frequency in positive attention behaviors comparing to the control period.

According to Als's study (1999), neurobehavioral organization in term of attention behaviors can be observed by infants exhibited more frequency in positive attention behaviors. The infants also exhibited less frequency in negative attention behaviors. Therefore, the results of this study confirmed that IEM program can improve neurobehavioral organizations of VLBW infants in term of attention behaviors.

CHAPTER V

DISCUSSION

Summary of the Study

An experimental research with a repeated measure (a within-subject) design was used to determine the effects of individualized environmental modification (IEM) program on neurobehavioral organizations of VLBW infants. The subjects were 25 infants who had birth weight less than 1500 grams and had gestational age less than 37 weeks, admitted to Neonatal Unit at Queen Sirikit National Institute of Child Health, Thailand. All infants had postnatal age of 5 days old or more with metabolic and hemodynamic stable condition. Infants who presented major genetic anomalies, sepsis, NEC, RDS, PDA that was waiting for surgery, IVH grade III or more, Hyperbilirubinemia that needed phototherapy were excluded from the study. The infants were served as their own control. All 25 infants were randomly order assigned. Twelve infants were started with control period which received conventional nursing care, and then followed by experimental period which received conventional nursing care plus IEM program. Another 13 infants were began with experimental period, and then followed by control period.

IEM program aimed at maintaining and promoting VLBW infants' neurobehavioral organization by mean of environment modification. IEM program consisted of two main groups of nursing activities including 1) basic environmental modifications which were provided to enhance comfort and reduce stress for infants, and 2) individualized modification which was adjusted to an appropriate level of intensity and duration based on each infant's responses. Basic environmental modifications included day-night lighting, classical music playing and lavender smelling. The infant's incubator was uncovered from 07.00 a.m. to 07.00 p.m., and then was covered from 07.00 p.m. to 07.00 a.m. Lavender essential oil and classical music were induced to infant for a 30 minutes period at 01:00 p.m., and 07:00 p.m., which was one hour after feeding. The individualized modifications included assessment section and adjustment section. Pulse oximeter was used to assess the infants for signs of physiological distress, while basic environmental modifications (music playing and lavender smelling) were provided at 01:00 p.m. and 07:00 p.m. If infant showed signs of stress, the adjustment section would be applied. The intensity and duration of stimulation were reduced. The infants' behaviors were observed and recorded to video for 20 minutes during diaper changed. Frequencies of infants' behaviors were mark on NONB tool by RA who was blinded to infant's identity and experiment. Infant's neurobehavioral organizations were scored each time as baseline, post-control period and post-experimental period.

The result of study revealed that infants in experimental period exhibit more positive autonomic responses, positive motoric behaviors and positive attention behaviors statistical significant than in the control period. Additionally, experimented infants sleep longer and spent fewer times in transitional and arousal state than the control. The results of this study confirmed that IEM program can improve neurobehavioral organizations of VLBW infants in term of autonomic, motoric, state and attention responses. These findings also suggested that implementation of IEM program for VLBW infants in clinical practice can promote neurobehavioral organization in hospitalized preterm infants and can be more successful in contributing to nursing knowledge.

Discussion of the Findings

Samples

Twenty-five VLBW infants were studied which 40% were classified as very premature infants and 60% were premature infants. At the time of study, they were admitted for receiving special medical attention and promoting growth and development. The VLBW infants' samples were surrounded with typical neonatal unit environment that considered as negative stimuli for the infants, such as bright light, loud noise and unpleasant odor (Holditch-Davis, Blackburn & Vandenberg, 2003). At the time of study, the level of day light and night light in neonatal unit were exceeded the recommendation of light level. Day light level in neonatal unit was ranged from 220 – 712 lux and night light level was ranged from 100 – 274 lux. Additionally, the sound level in neonatal unit was recorded ranged from 50 – 69 dB as a background noise. The sound level was peaked from 70 – 82 dB during ward round, routine nursing care and/or monitor alarming whereas the sound level was recommended to maintain at 45 – 58 dB. The sound level in neonatal unit that the samples were exposed also exceeded the recommendation. These negative environment stimuli can cause negative effect in VLBW infant in this study.

The studies of Als (1986; 1999) and Holditch-Dvis, Blackburn & Vandenberg (2003) explained that premature infant's brain was excessively sensitive and lack of control which caused inability to buffer input of stimuli when the infant was force to deal with the mismatched environments. The preterm infant had difficulty to achieve and maintain organization of autonomic, motoric, state and attention. Therefore, the bright light, loud noise and unpleasant odor associate with neurobehavioral disorganization of the samples which included an irregular heart rate, decrease in oxygen saturation and disturb sleep pattern, motoric and attention disorganization (Als, 1986; Taquino & Lockridge, 2004; Perlman, 2001).

The IEM program were designed to buffer noxious environment with positive or pleasant environmental stimuli such as day-night lighting, music playing and lavender smelling which was provided for the VLBW preterm infants throughout their sensory functions base on the pre-determining gestational age appropriate activities and individual differences in neurobehavioral responses. Thus, the IEM program is suitable for these sample infants whose gestational age ranged from 25 – 35 weeks which had visual evoked potentials, ability to response to odors, orient to sound evidently with arousal and attention (Blackburn, 2007). Exposing the infants to positive environment with IEM program then suit the infants' needs and contribute to positive neurobehavioral outcomes.

The study of Allen (2005) and Als (1982) explained that neuromaturation of preterm infants is a dynamic process. Probably, the development of neuromaturation such as movement, visual, olfactory and auditory responses of the samples in this study have been influenced by neuromaturation and contributed to positive neurobehavioral outcome. However, the studies of Allen (2005) and Als (1982) recommended that the neuromaturation of preterm infants can be captured and determined every 1 – 2 weeks interval. In consideration of neuromaturation effect, the appropriate time to determine neurobehavioral outcomes at post-control period and post-experimental period against baseline data were measured at 24 hours interval. Therefore, the change in positive autonomic responses, positive motoric behaviors, state organization and positive attention behaviors of VLBW infants found in this study were not associated with neurological maturation effect of the samples. Moreover, the combination of visual, olfactory and auditory stimulation in this study had produced no adverse effects in samples.

Hypothesis and sub-hypotheses

Hypothesis: Neurobehavioral organizations responses of VLBW infants when received IEM program (experimental period) are better than when received conventional nursing care (control period).

Sub-hypotheses: The VLBW infants will present more positive autonomic responses, positive motoric behaviors, positive attention behaviors, and spent more time in sleep states during experimental period than during control period. Also, VLBW infants will present less negative autonomic responses, negative motoric behaviors, negative attention behaviors and spent less time in transitional and arousal state during experimental period than during control period.

Results from repeated measures ANOVA supported the hypothesis that VLBW infants in the experimental period presented neurobehavioral organizations better than in control period. In the experimental period, the VLBW infants presented more positive autonomic responses, positive motoric behaviors and positive attention behaviors and spend longer time in sleep states than in the control period. In contrast, they presented less negative autonomic responses, negative motoric behaviors, and negative attention behaviors and spend shorter time in transitional state and arousal states in experimental period than in the control period. The outcomes of these infants' neurobehavioral organization are supported by the synactive theory of development (Als, 1982). There are four neurobehavioral systems which are autonomic, motoric, state and attention systems.

Autonomic, motoric, state and attention systems which are dynamic interplay and have interdependent pattern. Thus, the infants receiving IEM program which was set improved positive environment and minimized negative environment presented better neurobehavioral organization outcomes.

The sub-hypotheses were supported and can be empirically explained in considering to each IEM program components as follows.

Day-night lighting was a component of basic environmental modifications in IEM program which included 12 hours of day light with 200 – 400 lux of light level providing to infant from 7 am to 7 pm and another 12 hours of night light with 10 – 90 lux of light level providing to infant from 7 pm to 7 am.

A meta-analysis study of cycled light in the intensive care unit for preterm/low birth weight infants (protocol) conducted by Morag and Ohlsson (2009) suggested that cycled light could promote circadian rhythms in preterm infants which effected the production of hormones such as melatonin, cortisol and growth hormone. Circadian rhythms also influenced respiratory and cardiac function, sleep-wake state, level of alertness and body temperature. The circadian clock in preterm infant was located in the suprachiasmatic nuclei (SCN) in the anterior hypothalamus and could response to light at 25 weeks of gestation. Therefore, day-night lighting that implemented to the VLBW infants by IEM program can contribute to autonomic and state organization of the samples which involved with circadian rhythms.

This study finding showed that VLBW infants exhibited more regular heart rate, normal oxygen saturation and spent longer time in sleep state, spent shorter time in transitional state and arousal state. This result was similar to the study of Chawaphanth (2004) which determined effects of cycled light in preterm infants. The study showed that cycled light had improved preterm infants' heart rate and oxygen saturation. Therefore, the appropriated visual or light stimulation such as day-night lighting in IEM program can promote better autonomic and state organization in VLBW infant samples in experimental period than in the control period.

Music playing was the second component of basic environmental modifications in IEM program which was introduced to VLBW infant for 30 minutes at the sound level of 40 – 50 decibels (dB) twice a day.

Music was perceived as intentional auditory stimulus because it had organized elements such as melody, rhythm, harmony, timbre, form and style. The study of Phuekvilai (1987) explained that the tempo of music was generally ranging between 50 and 120 metronom (mm). The optimum level was ranging between 60 and 80 mm. which can be equivalent to human heart rate. The music that has tempo faster than heart rates are considered as fast rhythm whereas tempo of music slower than heart rates are considered as slow rhythm. The music playing that has fast rhythm can cause alertness and nervous while slow rhythm can make calm and relax. Additionally, repetitive listening of music allows the VLBW infants to identify and predict sounds. The repeated exposure to music can enhance positive clinical effects to VLBW infants (Kemper & Danhauer, 2005). Therefore, IEM program provided slow rhythm of music playing twice a day to the

VLBW infant samples in order to promote calm, relax, regular heart rate, normal oxygen saturation and increase duration of sleep state.

This study finding was supported by the study of music therapy (Chou, et al., 2003; Standley & Moore, 1995; Lubetzky, et al., 2010) that confirmed significant benefit of music on heart rate and oxygen saturation of preterm infants, improving positive attention behavior, and lower resting energy expenditure in preterm infants. According to direct physiologic effects, music changed neuronal activity with entrainment to musical rhythms in the lateral temporal lobe and in cortical areas which dedicated to movement. Listening to classical music with steady or slow rhythms increased heart rate variability which reflected less stress and greater resilience (Kemper & Danhauer, 2005). Additionally, soothing music without lyric could buffer the noxious sound and release infant's stress. This effect can lead to regular heart rate, normal oxygen saturation, and facilitate deep sleep. From observation notes, when provided music playing at 7 pm, the VLBW infants' samples entered the state of calm, relax and deep sleep earlier than when provided music playing at 1 pm. This effect is associated with repeated exposure to music which enhancing positive clinical effects stated previously. Thus, music playing helps improve autonomic, motoric, state and attention organization in VLBW infant samples in experimental period than in control period.

Lavender smelling was the third component of basic environmental modifications in IEM program which introduced to infant for 30 minutes together with music playing twice a day.

Lavender essential oil was reported to involve with physical, mental and emotional levels of health such as decrease stress, regulate moods, aid restful sleep, minimize discomfort of illness and refresh room environment (Fontaine, 2005). Lavender essential oil was inhaled, then scents detected by cilia, the olfactory receptors in infant's nose which opened directly to the brain. The nerve cells transmitted scent information to amygdala of the limbic system which triggered memory and influenced behavior (Fontaine, 2005). Lavender scent also changed brain wave activity which indicated positive direction of EEG by increasing brain alpha wave activity. Lavender increased brain alpha wave activity leading to relaxation in VLBW infants (Fernandez, et al. 2004). It is important to note that lavender smelling can alter the unpleasant odor in incubator and make VLBW infants feel of relax which lead to regular heart rate, normal oxygen saturation, accelerate deep sleep, calm and reduce stress and agitation.

This study finding was supported by Fernandez, et al. (2004) that newborns who exposed to lavender scents exhibited calm and relax. In this study, the results revealed that VLBW infant samples in experimental period presented more positive motoric behaviors and positive attention behaviors than in the control period whereas VLBW infant samples in experimental period exhibited less negative motoric behaviors and negative attention behaviors than the control period. Additionally, VLBW infant samples in experimental period spent longer time in sleep state and spent shorter time in transitional and arousal state comparing to the control period. Thus, lavender essential oil used in IEM program can promote better motoric, state and attention organizations in VLBW infant samples.

In conclusion, infant's neurobehavioral organization was an internal function which work congruently with an appropriated environmental modification. Therefore, positive or pleasant environmental stimuli such as soothing music, cycled light and aromatic smelling can buffer the noxious environmental stimuli and also contribute the positive neurobehavioral developmental outcomes to VLBW infant samples in this study.

Strengths and Limitations of the Study

Strength of the study is IEM program. It was designed to serve infants' individual needs. Premature infant's responses in unique and individual ways to their environment, individual behavioral styles of premature infants were predictors of their responses to the environment (Als, 1982; Blackburn, 2007). Therefore, the adjustment section was tailored for the samples individually. The components of IEM program were positive environmental stimuli that modified the noxious environment. The combination of day-night lighting, music playing and lavender smelling are contribute to positive clinical effects with simple implementation and low cost. In addition, the duration of IEM program is 24 hours of implementation. The effectiveness of IEM program is supported by the results of the study that it can promote positive neurobehavioral outcomes in VLBW infant within a shorten period of time.

Limitation related to samples: the major limitation was the small samples that lead to limit the statistical power of the analysis. Therefore, the subjects of this study prohibit generalization of the findings. Limitation related to instruments: the NONB required the user to be trained in order to have good sensitivity to observe and interpret the infants' behaviors. Limitation related to setting: the most difficult obstacle to overcome was to control extraneous variables that had possible affect on outcome variables, and influenced neurobehavioral organizations of infants. Environmental variables such as noise, light, and caregiver activities can not always be specifically controlled. For example, the researcher can not control the noise from monitor alarming, speaking, hands washing, phone ringing, cribs rolling and radio, etc.

Research Implications

Implications for practice

The IEM program offer an evidences based a nursing method that have proven to impact on the VLBW infants' neurobehavioral development individually and present a safe nursing practice. As premature infant's responses in unique and individual ways to their environment, adjustment activities design in the IEM program provide a way to tailor nursing practice that suit the infant's individual behavioral styles. The IEM 24 hour's activity program includes the combination of day-night lighting, music playing and lavender smelling and method to assess and determine nursing care plan in responding to individual need of the preterm neuromaturation dynamic process.

The findings reveal effectiveness of IEM program on neurobehavioral organization of VLBW infants since the samples in the experimental period have presented statistic significantly more positive autonomic responses such as regular heart rate, normal oxygen saturation, and good tissue perfusion. All samples also exhibited more positive motoric behaviors and attention behaviors as well as presented less negative autonomic responses, negative motoric behaviors and negative attention behaviors than in the control. Experimented infants showed better state organization than in control period by spent more time in sleep state and spent less time in transition and arousal state. Therefore, the use of IEM program in neonatal unit has been considered to be a precious nursing implementation because of its cost-effective and attractive interventions.

Specific considerations for providing IEM program to VLBW infants included a) IEM program should be provided to infant who is medically stable, b) being sensitive to infants' behavior, cues and needs, c) monitor infant responses and tolerance closely while providing basic environmental modifications (day-night lighting, music playing and lavender smelling) and individualized modifications (assessment and adjustment section) to infant.

Implications for research

The findings in this study support the effects of IEM program on neurobehavioral organizations of VLBW infants. It will certainly be advantage to extend the sample size to find out whether the change in VLBW infants' neurobehavioral organizations observed in this study will remain significant. In this study, a within-subject design was used. This methodology is not definitively an experimental design because of the absence of a comparable control group. Further research should operate a two group randomized controlled trial design to determine the effects of IEM program.

Suggestion for future study

This is the first implementation of the IEM program for the VLBW preterm infants in Thailand. Although the research findings showed better neurobehavioral organization of the VLBW preterm infants, the future study is needed to determine the proper intensity and duration of music and lavender stimulation to meet the individual preterm infants' capacity, needs and tolerance. Regarding this study, adjustment of music and lavender were focused on the prevention of over stimulation by using decremented pattern such as reduction of intensity and duration, in case of preterm infants were stressed. The Committee on Environmental Health of the American Academy of Pediatrics (2005) reported that sound level of 55 dB could arouse the preterm infant from light sleep (Harrison, Lotas & Jorgensen, 2004). The sound level of 60 – 80 dB caused preterm infant startle, fussy, crying, changes in heart rate and oxygen saturation, color changes, sleep disturbance. The sound level higher than 80 dB caused hearing loss in preterm infant (Committee on environmental health, 2005; Harrison, et al, 2004; Graven, 2000; Kertrit, 2002; Sehgal & Stack, 2006; Slevin, et al, 2000; Zahr & Balian, 1995). The recommendation of sound level in neonatal unit should be maintained at 45 – 58 dB (Johnson, 2001). According to individual different of preterm infant, future study should be examine the proper level of music and lavender by using the incremented pattern by starting music and lavender with the minimum level of intensity and gradually increasing the intensity to reach the VLBW preterm infants' neurosensory capability to increase the benefits of VLBW preterm infant's needed. However, the music sound should be maintained within the level of recommendation (45 – 58 dB) to prevent detrimental effects to the VLBW preterm infants.

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APPENDICES

APPENDIX A

Individualized Environmental Modification Program

Individualized Environmental Modification (IEM) Program

Duration: 24 hours

Participant: 25 neonates who admitted to Neonatal Unit at Queen Sirikit National Institute of Child Health, Thailand and have:

1. Gestational age less than 37 weeks at birth which was assessed with Ballard Maturational Score by pediatrician
2. Birth weight less than 1,500 grams and postnatal age was 5 days old or more
3. Growing preemies with stable condition which includes:
   3.1. received full feeding between 120 – 150 Kcal/kg/day
   3.2. had metabolic and hemodynamic stable such as blood sugar between 40 – 97 mg/dl, Calcium serum between 7 – 10 mg/dl, heart rate between 120 – 160 beats/min, and respiratory rate between 40 – 60 breaths/min
4. Receive approval from the attending pediatrician
5. Not receive any medications that effect neurobehavioral responses
6. VLBW infants who present this criterion before or during the study were excluded or terminated from the study.
   6.1. has major genetic anomalies and/or severe complication such as Sepsis, Necrotizing Enterocolitis (NEC), Patent Ductus Arteriosus (PDA) that is waiting for surgery, Intraventricular Hemorrhage (IVH) grade III or more, Hyperbilirubinemia that needs phototherapy, and severe Respiratory Distress Syndrome (RDS)

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Researcher: as an experimenter

IEM Program description: There are two phases of nursing activities as environmental modification for the VLBW infants in experimental group in NICU including 1) preparation phase and 2) environmental modification phase.

Phase 1: Preparation phase consists of two steps including a) collect VLBW infants' demographic data, and b) establish rapport relationship with parents

Phase 2: Modification phase consists of two groups of activities including: 2.1) basic environmental modification, and 2.2) individualized modification.

Phase 1: Preparation phase

Steps	Objectives	Equipment	Activities
• Collect the VLBW infants' demographic data • Establish rapport relationship with parents	• To collect the VLBW infants' baseline data • To promote good relationship with parents • To reduce parent's anxiety from unfamiliar program and environment	• Infant's demographic sheet • infant's profile	• The demographic data such as gender, date of birth, apgar score (at 1 and 5 min), gestational age, postnatal age, birth weight, medical history, type of feeding, medication, and etc. All of information is obtained from infant's profile and recorded on infant's demographic sheet (see Appendix B). • Orient parents to the unit and introduce Individualized Environmental Modification (IEM) Program to parents.

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Phase 2: Modification phase

2.1) Basic environmental modification

Steps	Objectives	Equipment	Activities
• Provide day-night lighting (Brandon, 2000; 2002; Chawaphanth, 2004)	• To promote physiological and behavioral organization • Minimize visual and auditory sensory overload	• Covered-incubator sheet	• Uncover the incubator in the day time (from 07.00 a.m. to 07.00 p.m.) • Cover the incubator with a covered-incubator sheet during night time (from 07.00 p.m. to 07.00 a.m.)
• Play soothing music (Standley, 2002; Chou, et al., 2003)	• To buffer the negative sound level in incubator • To promote infant's deep sleep	• Classical music for rest (Mead Johnson) • MP3 player (iPod nano Model A1236)	• Play soothing music for a 30 minute period at 1 p.m., and 7 p.m., one hour after a feeding. The earphones were placed approximately 10 centimeters from both sides of infants' ears. The level of sound was maintained at 40 – 50 decibels (dB).
• Induce lavender essential oil (Cavanagh & Wilkinson, 2002; Sanders, et al., 2002; Fernandez, et al., 2004; McNeilly, 2004)	• To modify unpleasant smell • Promote infant's calmness and deep sleep	• Lavender essential oil (donated by Miami Aromatherapy, Inc.) • 2 cotton swabs	• Place two cotton swabs with two drops of lavender essential oil from the top of the infant's head, which approximately 15 centimeters away from the infants' nose for a 30 minute period at 1 p.m. and 7 p.m., one hour after a feeding.

2.2) Individualized modification

Steps	Objectives	Equipment	Activities
A. Assessment section	• To modify environment base on individual VLBW infant needs and tolerance	• Pulse oximeter (Masimo SET Rad-5v)	• Assess the infants for signs of physiologic distress, during the induction of basic environmental modification (at 1 p.m. and 7 p.m.) such as music playing, and lavender odor.
B. Adjustment section	• To design individually the appropriated environmental modification that promote VLBW infant physiological and behavioral stability • To facilitate physiological and behavioral organization	• Pulse oximeter (Masimo SET Rad-5v)	• If the infant show signs of physiologic distress as follows: 1. Heart rate is <100 beats/min or >200 beats/min for 12 seconds or longer 2. Oxygen saturation level drops below 90 % for longer than 30 seconds • Adjust the basic environmental modification activities as follows: 1. Reduce intensity • Remove one cotton swab with lavender essential oil away from the infant, once at a time, but not more than two times

Steps	Objectives	Equipment	Activities
			• Decrease volume of music playing 5 dB, once at a time, but not more than two times 2. Reduce duration • reduce duration of lavender essential oil, 5 minutes per one adjustment of lavender • reduce duration of music playing, 5 minutes per one adjustment of music playing If the signs of physiologic distress persist, all stimuli are terminated

APPENDIX B

Research Instrument for Outcome Measurement

Date of observation______________ Code of infant_________

Infant's demographic sheet

Sex: ☐ male ☐ female

Date of birth:_______________ **Gestational age at birth:**_________ weeks

Birth weight: ____________ grams

Apgar score: 1 min =______ 5 min =______

Medical History: ☐ None ☐ IUGR ☐ RDS ☐ IVH grade ______

☐ Others ____

Medications before study time: ☐ Ventolin ☐ Fentanyl ☐ Aminophylline

☐ Morphine ☐ Digoxin ☐ Phenobarbital

☐ MgSO4 ☐ Deruiam ☐ None

☐ Other ________________________________

Postnatal age: ______________ days

Respiratory care: ☐ Room air ☐ O_2 therapy

Type of feeding: ☐ Nasal gavage ☐ Oral gavage ☐ Breastfeeding

Weight at study entry: ____________ grams

Weight at study end: ____________ grams

OBSERVATION SHEET Name: ______________ Date: ______________ Sheet Number: ______

		Time:					
			0-2	3-4	5-6	7-8	9-10
Resp:	Regular						
	Irregular						
	Slow						
	Fast						
	Pause						
Color:	Jaundice						
	Pink						
	Pale						
	Webb						
	Red						
	Dusky						
	Blue						
	Tremor						
	Startle						
	Twitch Face						
	Twitch Body						
	Twitch Extremities						
Visceral/ Resp:	Spit up						
	Gag						
	Burp						
	Hiccough						
	BM Grunt						
	Sounds						
	Sigh						
	Gasp						
Motor:	Flaccid Arm(s)						
	Flaccid leg(s)						
	Flexed/ Tucked Arms	Act.					
		Post.					
	Flexed/ Tucked Legs	Act.					
		Post.					
	Extend Arms	Act.					
		Post.					
	Extend Legs	Act.					
		Post.					
	Smooth Mvmt Arms						
	Smooth Mvmt Legs						
	Smooth Mvmt Trunk						
	Stretch/Drown						
	Diffuse Squirm						
	Arch						
	Tuck Trunk						
	Leg Brace						
Face:	Tongue Extension						
	Hand on Face						
	Gape Face						
	Grimace						
	Smile						

	Time:					
		0-2	3-4	5-6	7-8	9-10
State:	1A					
	1B					
	2A					
	2B					
	3A					
	3B					
	4A					
	4B					
	5A					
	5B					
	6A					
	6B					
	AA					
Face (cont.):	Mouthing					
	Suck Search					
	Sucking					
Extrem.:	Finger Splay					
	Airplane					
	Salute					
	Sitting On Air					
	Hand Clasp					
	Foot Clasp					
	Hand to Mouth					
	Grasping					
	Holding On					
	Fisting					
Attention:	Fuss					
	Yawn					
	Sneeze					
	Face Open					
	Eye Floating					
	Avert					
	Frown					
	Ooh Face					
	Locking					
	Cooing					
	Speech Mvmt.					
Posture:	(Prone, Supine, Side)					
Head:	(Right, Left, Middle)					
Location:	(Crib, Incubator, Held)					
Manipulation:						
	Heart Rate					
	Respiration Rate					
	$TcPO_2/SaO_2$					

Neurobehavioral observation scoring sheet

Date:_______________ Time:__________ ☐ Pre-test ☐ Post-test

			Frequency	Calculation	Total score
Autonomic System	Positive autonomic responses	Heart rate (120 - 160 bpm)			
		Oxygen Saturation (92-95%)			
		Positive skin color			
	Negative autonomic responses	Tremor			
		Startle			
		Twitch face			
		Twitch body			
		Twitch extremities			
		Spit up			
		Gag			
		Burp			
		Hiccough			
		BM Grunt			
		Sounds			
		Sigh			
		Gasp			
Motoric System	Positive Motoric Behaviors	Hand on face			
		Smile			
		Mouthing			
		Suck search			
		Sucking			
		Tuck trunk			
		Flexed arms			
		Flexed legs			
		Smooth movement arms			
		Smooth movement trunk			
		Smooth movement legs			
		Leg brace			
		Hand clasp			
		Foot clasp			
		Hand to mouth			
		Grasping			
		Holding on			

Modified from behavioral definitions published in Heidelise Als: Reading the premature infant, in Goldson (ed), Developmental Interventions in the Neonatal Intensive Care Nursery, New York, Oxford University Press, 1999, pp 18 - 85.

			Frequency	Calculation	Total Score
Motoric system (continue)	Negative Motoric Behaviors	Tongue extension			
		Grimace			
		Gape face			
		Flaccid arms			
		Flaccid legs			
		Extend arms			
		Extend legs			
		Stretch/Drown			
		Diffuse squirm			
		arch			
		Finger splay			
		Airplane			
		Salute			
		Sitting on air			
		Fisting			
State system	Sleep state	1: Deep sleep			
		2: Light sleep			
	Transitional state	3: Drowsy			
	Arousal state	4: Alert			
		5: Active			
		6: Crying			
Attention system	Positive attention behaviors	Frown			
		Ooh face			
		Face open			
		Cooing			
		Speech movement			
	Negative attention behaviors	Fuss			
		Yawn			
		Sneeze			
		Eye floating			
		Avert			
		Locking			

Modified from behavioral definitions published in Heidelise Als: Reading the premature infant, in Goldson (ed), Developmental Interventions in the Neonatal Intensive Care Nursery, New York, Oxford University Press, 1999, pp 18 - 85.

NEWBORN MATURITY RATING & CLASSIFICATION

ESTIMATION OF GESTATIONAL AGE BY MATURITY RATING
Symbols: X - 1st Exam O - 2nd Exam

Side 1

Gestation by Dates ____________________wks

Birth Date ____________ Hour __________ am pm

APGAR ______________1 min __________5 min

NEUROMUSCULAR MATURITY

	-1	0	1	2	3	4	5
Posture							
Square Window (wrist)	>90°	90°	60°	45°	30°	0°	
Arm Recoil		180°	140°-180°	110°-140°	90°-110°	<90°	
Popliteal Angle	180°	160°	140°	120°	100°	90°	<90°
Scarf Sign							
Heel to Ear							

MATURITY RATING

score	weeks
-10	20
-5	22
0	24
5	26
10	28
15	30
20	32
25	34
30	36
35	38
40	40
45	42
50	44

PHYSICAL MATURITY

Skin	sticky; friable; transparent	gelatinous; red; translucent	smooth; pink; visible veins	superficial peeling &/or rash; few veins	cracking; pale areas; rare veins	parchment; deep cracking; no vessels	leathery; cracked; wrinkled
Lanugo	none	sparse	abundant	thinning	bald areas	mostly bald	
Plantar Surface	heel-toe 40-50 mm: -1 <40 mm: -2	>50 mm; no crease	faint red marks	anterior transverse crease only	creases ant. 2/3	creases over entire sole	
Breast	imperceptible	barely perceptible	flat areola; no bud	stippled areola; 1-2 mm bud	raised areola; 3-4 mm bud	full areola; 5-10 mm bud	
Eye/Ear	lids fused loosely: -1 tightly: -2	lids open; pinna flat; stays folded	sl. curved pinna; soft; slow recoil	well-curved pinna; soft but ready recoil	formed & firm; instant recoil	thick cartilage; ear stiff	
Genitals male	scrotum flat; smooth	scrotum empty; faint rugae	testes in upper canal; rare rugae	testes descending; few rugae	testes down; good rugae	testes pendulous; deep rugae	
Genitals female	clitoris prominent; labia flat	prominent clitoris; small labia minora	prominent clitoris; enlarging minora	majora & minora equally prominent	majora large; minora small	majora cover clitoris & minora	

Scoring system: Ballard JL, Khoury JC, Wedig K, Wang L, Eilers-Walsman BL, Lipp R. New Ballard Score, expanded to include extremely premature infants. *J Pediatr*. 1991;119:417-423.

SCORING SECTION

	1st Exam=X	2nd Exam=O
Estimating Gest Age by Maturity Rating	________Weeks	________Weeks
Time of Exam	Date ________ Hour ______am pm	Date ________ Hour ______am pm
Age at Exam	________Hours	________Hours
Signature of Examiner	____________ M.D./R.N.	____________ M.D./R.N.

APPENDIX C

Example of using NONB and scoring method

OBSERVATION SHEET Name: ID. 63A/1 Date: 03/08/08 Sheet Number: ______

6.30 am Time:		30	32	34	36	38
		0-2	3-4	5-6	7-8	9-10
Resp:	Regular					
	Irregular	✓	✓	✓	✓	✓
	Slow					
	Fast					
	Pause					
Color:	Jaundice					
	Pink					
	Pale					
	Webb					
	Red					
	Dusky					
	Blue					
	Tremor			✓		
	Startle					
	Twitch Face			✓		
	Twitch Body					
	Twitch Extremities	✓	✓✓	✓	✓✓	✓✓
Visceral/ Resp:	Spit up					
	Gag					
	Burp					
	Hiccough					
	BM Grunt					
	Sounds					
	Sigh					
	Gasp				✓	
Motor:	Flaccid Arm(s)					
	Flaccid leg(s)					
	Flexed/Tucked Arms Act.					✓
	Flexed/Tucked Arms Post.	✓	✓	✓	✓	✓
	Flexed/Tucked Legs Act.	✓	✓			
	Flexed/Tucked Legs Post.	✓	✓	✓	✓	✓
	Extend Arms Act.					
	Extend Arms Post.					
	Extend Legs Act.				✓	
	Extend Legs Post.	✓			✓	✓
	Smooth Mvmt Arms					
	Smooth Mvmt Legs					
	Smooth Mvmt Trunk					
	Stretch/Drown					
	Diffuse Squirm		✓			✓
	Arch					✓✓
	Tuck Trunk		✓			✓✓
	Leg Brace	✓				
Face:	Tongue Extension					
	Hand on Face	✓	✓	✓		✓✓
	Gape Face					
	Grimace					
	Smile					

Time:		30	32	34	36	38
		0-2	3-4	5-6	7-8	9-10
State:	1A					
	1B					
	2A	✓	✓	✓	✓	✓
	2B					
	3A					
	3B					
	4A					
	4B					
	5A					
	5B					
	6A					
	6B					
	AA					
Face (cont.):	Mouthing					
	Suck Search					
	Sucking		✓	✓	✓	
Extrem.:	Finger Splay			✓		✓✓
	Airplane					
	Salute					✓
	Sitting On Air	✓				
	Hand Clasp					✓
	Foot Clasp					✓✓
	Hand to Mouth					
	Grasping					
	Holding On					
	Fisting					
Attention:	Fuss					
	Yawn					
	Sneeze					
	Face Open					
	Eye Floating					
	Avert					
	Frown					
	Ooh Face					
	Locking					
	Cooing					
	Speech Mvmt.					
Posture:	(Prone, Supine, Side)	Sup.	Sup.	Sup.	Sup.	Sup.
Head:	(Right, Left, Middle)	R	R	R	R	R
Location:	(Crib, Incubator, Held)	Inc.	Inc.	Inc.	Inc.	Inc.
Manipulation:						
	Heart Rate	179	159	166	151	157
	Respiration Rate					
	$TcPO_2/SaO_2$	98	99	98	97	98

OBSERVATION SHEET Name: ID. 634/2 Date: 03/08/08 Sheet Number: ______

		Time:	40	42	44	46	48
			0-2	3-4	5-6	7-8	9-10
Resp:	Regular						
	Irregular		✓	✓	✓	✓	✓
	Slow						
	Fast						
	Pause						
Color:	Jaundice						
	Pink						
	Pale						
	Webb						
	Red						
	Dusky						
	Blue						
	Tremor						✓
	Startle				✓		
	Twitch Face						
	Twitch Body						✓
	Twitch Extremities		✓✓		✓✓	✓✓	✓
Visceral/ Resp:	Spit up						
	Gag						
	Burp						
	Hiccough						
	BM Grunt						
	Sounds						
	Sigh			✓			
	Gasp						
Motor:	Flaccid Arm(s)						
	Flaccid leg(s)						
	Flexed/Tucked Arms	Act.					✓
		Post.	✓	✓	✓	✓	✓
	Flexed/Tucked Legs	Act.	✓	✓		✓	✓
		Post.	✓	✓	✓	✓	✓
	Extend Arms	Act.					
		Post.					
	Extend Legs	Act.	✓				
		Post.	✓				
	Smooth Mvmt Arms				✓		
	Smooth Mvmt Legs						
	Smooth Mvmt Trunk						
	Stretch/Drown						
	Diffuse Squirm		✓	✓✓			✓
	Arch		✓				✓
	Tuck Trunk						✓
	Leg Brace		✓			✓	✓
Face:	Tongue Extension						
	Hand on Face		✓			✓	✓
	Gape Face						
	Grimace						✓
	Smile						

	Time:	40	42	44	46	48
		0-2	3-4	5-6	7-8	9-10
State:	1A					
	1B					
	2A	✓	✓	✓	✓	✓
	2B					
	3A	✓				
	3B					
	4A					
	4B					
	5A					
	5B					
	6A					
	6B					
	AA					
Face (cont.):	Mouthing					
	Suck Search					
	Sucking					
Extrem.:	Finger Splay	✓✓✓				✓
	Airplane					
	Salute					
	Sitting On Air					✓
	Hand Clasp					
	Foot Clasp					
	Hand to Mouth	✓				
	Grasping					
	Holding On					
	Fisting					
Attention:	Fuss					
	Yawn					
	Sneeze					
	Face Open					
	Eye Floating					
	Avert					
	Frown					
	Ooh Face					
	Locking					
	Cooing					
	Speech Mvmt.					

		40	42	44	46	48
Posture:	(Prone, Supine, Side)	Sup.	Sup	Sup	Sup	Sup
Head:	(Right, Left, Middle)	R.	R.	R.	R.	R.
Location:	(Crib, Incubator, Held)	Inc.	Inc.	Inc.	Inc.	Inc.
Manipulation:						
	Heart Rate	154	162	161	140	152
	Respiration Rate					
	$TcPO_2/SaO_2$	98	98	96	97	94

Neurobehavioral observation scoring sheet

Date: 03/08/08 Time: 6.30 ☐ Pre-test ☐ Post-test

			Frequency	Calculation	Total score
Autonomic System	Positive autonomic responses	Heart rate (120 - 160 bpm)	𝍸 |	7/3	2.33
		Oxygen Saturation (92-95%)	|		
		Positive skin color			
	Negative autonomic responses	Tremor	||	22/13	1.69
		Startle	|		
		Twitch face	|		
		Twitch body	|		
		Twitch extremities	𝍸 𝍸 𝍸		
		Spit up			
		Gag			
		Burp			
		Hiccough			
		BM Grunt			
		Sounds			
		Sigh	|		
		Gasp	|		
Motoric System	Positive Motoric Behaviors	Hand on face	𝍸 |||	51/17	3
		Smile			
		Mouthing			
		Suck search			
		Sucking	|||		
		Tuck trunk	||||		
		Flexed arms	𝍸 𝍸 ||		
		Flexed legs	𝍸 𝍸 𝍸 |		
		Smooth movement arms			
		Smooth movement trunk			
		Smooth movement legs			
		Leg brace	||||		
		Hand clasp	|		
		Foot clasp	||		
		Hand to mouth	|		
		Grasping			
		Holding on			

Modified from behavioral definitions published in Heidelise Als: Reading the premature infant, in Goldson (ed), Developmental Interventions in the Neonatal Intensive Care Nursery, New York, Oxford University Press, 1999, pp 18 - 85.

			Frequency	Calculation	Total Score
Motoric system (continue)	Negative Motoric Behaviors	Tongue extension			
		Grimace	I		
		Gape face			
		Flaccid arms			
		Flaccid legs			
		Extend arms			
		Extend legs	卌 I		
		Stretch/Drown		28/15	1.86
		Diffuse squirm	卌 I		
		arch	IIII		
		Finger splay	卌 III		
		Airplane			
		Salute	I		
		Sitting on air	II		
		Fisting			
State system	Sleep state	1: Deep sleep			
		2: Light sleep	卌 卌	19 min	
	Transitional state	3: Drowsy	I	1 min	
	Arousal state	4: Alert			
		5: Active			
		6: Crying			
Attention system	Positive attention behaviors	Frown			
		Ooh face			
		Face open	0/5	0	
		Cooing			
		Speech movement			
	Negative attention behaviors	Fuss			
		Yawn			
		Sneeze	0/6	0	
		Eye floating			
		Avert			
		Locking			

Modified from behavioral definitions published in Heidelise Als: Reading the premature infant, in Goldson (ed), Developmental Interventions in the Neonatal Intensive Care Nursery, New York, Oxford University Press, 1999, pp 18 - 85.

APPENDIX D

Institute Review Broad Approval Document

AF 01-11

คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย
อาคารสถาบัน 2 ชั้น 4 ซอยจุฬาลงกรณ์ 62 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330
โทรศัพท์: 0-2218-8147 โทรสาร: 0-2218-8147 E-mail: eccu@chula.ac.th

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COA No. 075/2551

ใบรับรองโครงการวิจัย

โครงการวิจัยที่ 059/51 : ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรมการจัดการด้วยประสาทของทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก

ผู้วิจัยหลัก : นางสาวพัชรี จันทรักษา นิสิตระดับดุษฎีบัณฑิต

หน่วยงาน : คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

คณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย อนุมัติในแง่จริยธรรมให้ดำเนินการศึกษาวิจัยเรื่องดังกล่าวได้

ลงนาม.. ลงนาม..
(รองศาสตราจารย์ นายแพทย์ปรีดา ทัศนประดิษฐ) (ผู้ช่วยศาสตราจารย์ ดร.นันทรี ชัยชนะวงศาโรจน์)
ประธาน กรรมการและเลขานุการ

วันที่รับรอง : 1 สิงหาคม 2551 **วันหมดอายุ** : 31 กรกฎาคม 2552

เอกสารที่คณะกรรมการรับรอง

1) โครงการวิจัย
2) ข้อมูลสำหรับกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัยและใบยินยอมของกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย
3) ผู้วิจัย
4) เครื่องมือที่ใช้ในการเก็บรวบรวมข้อมูล แบบสอบถาม โปรแกรมการอบรม

<u>เงื่อนไข</u>

1. หากใบรับรองหมดอายุ การดำเนินการวิจัยต้องยุติ เมื่อต้องการต่ออายุต้องขออนุมัติใหม่ล่วงหน้าไม่น้อยกว่า 1 เดือน
2. ต้องดำเนินการวิจัยตามที่ระบุไว้ในโครงการวิจัยอย่างเคร่งครัด
3. ใช้เอกสารข้อมูลสำหรับกลุ่มประชากรหรือผู้มีส่วนร่วมในการวิจัย, ใบยินยอม, และเอกสารเชิญเข้าร่วมวิจัย (ถ้ามี) เฉพาะที่ประทับตราของคณะกรรมการฯ เท่านั้น แล้วส่งสำเนาใบแรกที่ใช้ เอกสารดังกล่าวมาที่คณะกรรมการฯ
4. หากเกิดเหตุการณ์ไม่พึงประสงค์ร้ายแรง (SAE) ต้องรายงานคณะกรรมการฯ ภายใน 5 วันทำการ
5. หากมีการเปลี่ยนแปลงการดำเนินการวิจัย ให้ส่งคณะกรรมการฯ พิจารณารับรองก่อนดำเนินการ
6. โครงการวิจัยไม่เกิน 1 ปี ส่งแบบรายงานสิ้นสุดโครงการวิจัย (AF 03-11) และบทคัดย่อผลการวิจัยภายใน 30 วัน เมื่อโครงการวิจัยเสร็จสิ้น สำหรับโครงการวิจัยที่เป็นวิทยานิพนธ์ให้ส่งบทคัดย่อผลการวิจัย ภายใน 30 วัน เมื่อโครงการวิจัยเสร็จสิ้น
7. โครงการวิจัยเกิน 1 ปี ส่งรายงานความก้าวหน้าการวิจัยทุกปีก่อนใบรับรองหมดอายุ เมื่อโครงการวิจัยเสร็จสิ้นแล้ว ให้ดำเนินการเช่นเดียวกับข้อ 6

EC.07 T
Document No 51-022

EC. 082/2551

คณะกรรมการพิจารณาการศึกษาวิจัยในมนุษย์
ของสถาบันสุขภาพเด็กแห่งชาติมหาราชินี

11 มีนาคม 2551

โครงการวิจัย : ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรม การจัดการด้วยประสาทของทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก

ผู้ดำเนินการวิจัย : นางสาวพัชรี จันทรักษา / นางจริยา นกงาม

สถานที่ดำเนินการวิจัย : สถาบันสุขภาพเด็กแห่งชาติมหาราชินี

เอกสารที่พิจารณา :

1. แบบเสนอโครงการวิจัยเพื่อขอรับการพิจารณาจากคณะกรรมการพิจารณาการศึกษาวิจัยในมนุษย์ของสถาบันสุขภาพเด็กแห่งชาติมหาราชินี (ภาษาไทย ฉบับ Version date 10/ 03/ 08)
2. แบบบันทึกข้อมูลงานวิจัย (CRF) (ภาษาไทย ฉบับ Version date 10/ 03/ 08)
3. เอกสารแนะนำอาสาสมัคร และใบยินยอมด้วยความสมัครใจ (ภาษาไทย ฉบับ Version date 10/ 03/ 08)
4. ประวัติผู้วิจัยหลัก

คณะกรรมการพิจารณาการศึกษาวิจัยในมนุษย์ของสถาบันสุขภาพเด็กแห่งชาติมหาราชินี ได้พิจารณาโครงการฉบับภาษาไทย ฉบับ Version date 10/ 03/ 08 แล้ว คณะกรรมการฯ พิจารณาอนุมัติในแง่จริยธรรมให้ดำเนินการศึกษาวิจัยเรื่องข้างต้นได้ ตั้งแต่ วันที่ 11 มีนาคม 2551 ถึงวันที่ 10 มีนาคม 2552 อนึ่ง ท่านต้องรายงานสถานะของโครงการให้คณะกรรมการฯ ทราบทุกปี เพื่ออนุมัติดำเนินโครงการต่อ จนกว่าจะหมดอายุโครงการ

....

(นางสาวศศิชล คำเพราะ)
กรรมการและเลขานุการคณะกรรมการพิจารณาการศึกษาวิจัยในมนุษย์
ของสถาบันสุขภาพเด็กแห่งชาติมหาราชินี

....

(นายแพทย์ธนะรัตน์ ลยางกูร)
รองประธานคณะกรรมการพิจารณาการศึกษาวิจัยในมนุษย์
ของสถาบันสุขภาพเด็กแห่งชาติมหาราชินี

วันที่ประชุม 27 กุมภาพันธ์ 2551
รับรองตั้งแต่วันที่ 11 มีนาคม 2551 **ถึงวันที่** 10 มีนาคม 2552

ศูนย์วิจัยและพัฒนา
สถาบันสุขภาพเด็กแห่งชาติมหาราชินี
Tel./Fax. (+66) 0-2-644-8943

ที่ ศธ 0512.11/ 0125

คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
อาคารวิทยกิตติ์ ชั้น 12 ซอยจุฬา 64
เขตปทุมวัน กรุงเทพฯ 10330

17 มกราคม 2551

เรื่อง ขอความอนุเคราะห์ให้นิสิตทดลองใช้เครื่องมือและเก็บรวบรวมข้อมูลการวิจัย

เรียน ผู้อำนวยการโรงพยาบาลเด็ก

เนื่องด้วย นางสาวพัชรี จันทรักษา นิสิตขั้นปริญญาดุษฎีบัณฑิต คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย กำลังดำเนินการวิจัยเพื่อเสนอเป็นดุษฎีนิพนธ์ เรื่อง "ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรมการจัดการด้วยประสาทของทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก" โดยมี ศาสตราจารย์ ดร. วีณา จีระแพทย์ เป็นอาจารย์ที่ปรึกษาดุษฎีนิพนธ์ ในการนี้ใคร่ขอความอนุเคราะห์ให้นิสิตดำเนินการทดลองใช้เครื่องมือการวิจัย จำนวน 10 คน และเก็บรวบรวมข้อมูลการวิจัย จำนวน 25 คน จากกลุ่มตัวอย่างทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก ณ หอผู้ป่วยทารกแรกเกิดวิกฤต โดยใช้แบบสังเกตพฤติกรรมทารก และโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคล ทั้งนี้นิสิตจะประสานงาน เรื่อง วัน และเวลา ในการทดลองใช้เครื่องมือและเก็บรวบรวมข้อมูลการวิจัยอีกครั้งหนึ่ง

จึงเรียนมาเพื่อโปรดพิจารณาอนุเคราะห์ให้ นางสาวพัชรี จันทรักษา ดำเนินการทดลองใช้เครื่องมือและเก็บรวบรวมข้อมูลการวิจัยดังกล่าว คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย หวังเป็นอย่างยิ่งว่าจะได้รับความอนุเคราะห์จากท่าน และขอขอบพระคุณอย่างสูงมา ณ โอกาสนี้

ขอแสดงความนับถือ

(รองศาสตราจารย์ ดร. อรพรรณ ลือบุญธวัชชัย)
รองคณบดีฝ่ายวิชาการ
ปฏิบัติราชการแทนคณบดีคณะพยาบาลศาสตร์

สำเนาเรียน หัวหน้าฝ่ายการพยาบาล
งานบริการการศึกษา โทร. 0-2218-9825 โทรสาร. 0-2218-9806
อาจารย์ที่ปรึกษา ศาสตราจารย์ ดร. วีณา จีระแพทย์ โทร. 0-2218-9822
ชื่อนิสิต นางสาวพัชรี จันทรักษา โทร. 08-4460-9083

APPENDIX E

Participant Sheet and Informed Consent Form

ข้อมูลสำหรับประชากรตัวอย่างหรือผู้มีส่วนร่วมในการวิจัย

(Patient/Participant Information Sheet)

ชื่อโครงการวิจัย: ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรมการจัดการด้วยประสาทของทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก

ชื่อผู้วิจัย: นางสาวพัชรี จันทรักษา นิสิตปริญญาเอก คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

สถานที่ติดต่อ: 592 ซอยรามคำแหง 24 แขวงหัวหมาก เขตบางกะปิ กรุงเทพฯ 10240

โทรศัพท์มือถือ: 084 – 460 – 9083 (ตลอด 24 ชั่วโมง)

อีเมล์: juntaruksa@yahoo.com

เลขที่โครงการวิจัย 059/51

วันที่รับรอง 1 ส.ค. 2551

วันหมดอายุ 31 ก.ค. 2552

เหตุผลและความจำเป็นที่ต้องทำการศึกษาวิจัย

ทารกที่เกิดก่อนกำหนด ยังมีพัฒนาการทางประสาทไม่สมบูรณ์ เมื่อถูกรบกวนจากสิ่งแวดล้อม เช่น แสงจ้า เสียงดัง กลิ่นฉุน หรือการสัมผัสจับต้องบ่อย ทำให้เกิดความเครียดจากสิ่งแวดล้อมที่ไม่เหมาะสม ดังกล่าว การจัดสิ่งแวดล้อมที่เหมาะสมให้ทารก เช่น การปรับแสงสว่าง จัดท่านอน เปิดเพลง และดมกลิ่นลาเวนเดอร์ จะช่วยลดความเครียดและช่วยส่งเสริมการนอนหลับของทารกให้ดีขึ้น

วัตถุประสงค์ของโครงการวิจัย

เพื่อศึกษาผลของการปรับสิ่งแวดล้อมต่อพฤติกรรมและการนอนหลับของทารกเกิดก่อนกำหนด

ลักษณะของประชากรตัวอย่าง

ทารกเกิดก่อนกำหนด ที่มีน้ำหนักน้อยมาก *และอยู่ในระยะกำลังเติบโต มีสัญญาณชีพปรกติ อาการคงที่ ไม่มีความพิการแต่กำเนิดและไม่มีโรคแทรกซ้อนที่รุนแรง และผ่านความเห็นชอบของแพทย์ประจำหอผู้ป่วย*

จำนวนของประชากรตัวอย่างที่จะใช้ในการวิจัย

ทารกเกิดก่อนกำหนดที่มีนำหนักน้อยมาก (very low birth weight) จำนวน 70 คน ที่รับไว้รักษา ณ *หออภิบาลทารกแรกเกิดน้ำหนักน้อย สถาบันสุขภาพเด็กแห่งชาติมหาราชินี*

วิธีการศึกษาวิจัย

โครงการวิจัยนี้ จะแบ่งทารกเป็น 2 กลุ่ม คือ *กลุ่ม 1 และ กลุ่ม 2* โดยทารกจะได้รับการสุ่มเพื่อเข้ากลุ่ม 1 หรือ กลุ่ม 2 ถ้าทารกได้รับการสุ่มให้อยู่ในกลุ่มที่ 1 ทารกจะได้รับการดูแลรักษาพยาบาลตามปกติ ถ้าทารกได้รับการสุ่มให้อยู่ในกลุ่มที่ 2 ทารกจะได้รับการดูแลรักษาพยาบาลตามปกติ และจะได้รับการปรับสิ่งแวดล้อมร่วมด้วย โดยมีกิจกรรมการพยาบาลดังต่อไปนี้

1. ปรับแสงสว่างแบบกลางวัน ในช่วงเวลา 07:00 น. ถึง 19:00 น. และปรับแสงสว่างแบบกลางคืน ในช่วงเวลา 19:00 น. ถึง 07:00 น.
2. จัดท่านอนแบบรัง โดยการใช้ผ้านุ่มทำเป็นวงล้อมรอบตัวทารก
3. เปิดเพลงบรรเลง เป็นเวลา 30 นาที จำนวน 2 ครั้งต่อวัน คือในช่วงเวลา 13:00 น. และ 20:00 น.

4. ให้กลิ่นลาเวนเดอร์ เป็นเวลา 30 นาที จำนวน 2 ครั้งต่อวัน คือในช่วงเวลา 13:00 น. และ 20:00 น.

ผู้วิจัยจะทำการสังเกตพฤติกรรมทารกในระหว่างที่พยาบาลทำการวัดสัญญาณชีพและเปลี่ยนผ้าอ้อมให้ทารก ในขณะเดียวกัน ทารกทุกคนใน*กลุ่มที่ 1 และกลุ่มที่ 2* จะได้รับการถ่ายบันทึกวิดีโอในวันแรก และในวันสุดท้ายที่เข้าร่วมงานวิจัย เพื่อใช้สำหรับการสังเกตพฤติกรรมทารก เปรียบเทียบก่อนและหลังเข้าร่วมงานวิจัย มารดาและ/หรือบิดา จะได้รับการอธิบายให้เข้าใจถึงรายละเอียดของโครงการวิจัย และได้รับแจ้งจากผู้วิจัยถึงจุดเริ่มต้นโครงการและจุดสิ้นสุดการศึกษาวิจัย

ระยะเวลาที่ต้องร่วมโครงการวิจัย

ระยะเวลาที่ทารกจะเข้าร่วมโครงการวิจัยทั้งสิ้น จำนวน 3 วัน

ประโยชน์ที่คาดว่าจะได้รับจากโครงการวิจัย

ทารกใน*กลุ่มที่ 1* จะได้รับการดูแลรักษาตามมาตรฐานการพยาบาลตามปกติ ส่วนทารกใน*กลุ่มที่ 2* ที่ได้รับโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมร่วมกับการดูแลรักษาตามมาตรฐานการพยาบาล อาจจะได้รับผลดีในการส่งเสริมพัฒนาการทางประสาท และอาจช่วยลดจำนวนวันในการนอนโรงพยาบาลได้

ความเสี่ยงหรือความไม่สุขสบายที่คาดว่าจะได้รับในการเข้าร่วมงานวิจัย การป้องกันความเสี่ยงและการแก้ไขกรณีเกิดปัญหา

ขณะทำการศึกษา ผู้วิจัยจะเป็นผู้เฝ้าดูแลทารกที่เข้าร่วมโครงการวิจัยด้วยตนเองตลอดระยะเวลาที่ทารกเข้าร่วมโครงการ หากผู้วิจัยพบผลข้างเคียงที่อาจเกิดขึ้นจากกระบวนการวิจัย หรือหากทารกเกิดความเครียดจากการปรับสิ่งแวดล้อม เช่น มีการเปลี่ยนแปลงของการเต้นหัวใจ หรือ ระดับออกซิเจนในเลือด หากทารกเกิดมีอาการดังกล่าว ผู้วิจัยจะลดจำนวนและวิธีการปรับสิ่งแวดล้อมในขั้นต้น หากทารกมีอาการคงเดิมผู้วิจัยจะยุติการศึกษากับทารก และแจ้งให้แพทย์ทราบในทันที เพื่อให้ทารกได้รับการดูแลรักษาที่เหมาะสมต่อไป

สิทธิของผู้เข้าร่วมโครงการวิจัย และการถอนตัวออกจากโครงการวิจัยหลังจากได้ลงนามเข้าร่วมโครงการวิจัย

การอนุญาตให้ทารกเข้าร่วมในโครงการวิจัยนี้จะเป็นไปด้วยความสมัครใจ มารดาและ/หรือบิดา สามารถบอกเลิกการอนุญาตให้ทารกเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้ และการบอกเลิกนี้จะไม่มีผลต่อการรักษาพยาบาลที่ทารกจะพึงได้รับในปัจจุบันและในอนาคต

ทารกอาจถูกขอให้ออกจากโครงการวิจัยในกรณี มีการติดเชื้อรุนแรง หรือได้รับการส่องไฟรักษาอาการตัวเหลือง หรือมีอาการของโรคหัวใจ และรอการผ่าตัด

หากผู้วิจัยมีข้อมูลเพิ่มเติมที่เป็นประโยชน์ หรือโทษเกี่ยวกับการวิจัย *ผู้วิจัย*จะแจ้งให้มารดาและ/หรือบิดา ให้ทราบอย่างรวดเร็ว เพื่อให้มารดาและ/หรือบิดา ทบทวนว่ายังความสมัครใจที่จะคงการอนุญาตให้ทารกเข้าร่วมการวิจัยต่อไปหรือไม่

ขอบเขตการดูแลรักษาความลับของข้อมูลต่างๆ ของผู้เข้าร่วมโครงการ

ผู้วิจัยจะเก็บข้อมูลเกี่ยวกับตัวข้าพเจ้าและบุตรเป็นความลับ โดยจะเก็บข้อมูลและวิดีโอบันทึกภาพพฤติกรรมทารก ไว้ในตู้ล็อคกุญแจอย่างดี และจะไม่นำภาพวิดีโอของทารกไปฉายในที่สาธารณะ ผู้วิจัยจะ

เสนอผลงานวิจัยในรูปของสรุปผลการวิจัยในภาพรวม โดยไม่มีการเปิดเผยชื่อ – สกุล ของทารก การเปิดเผยข้อมูลเกี่ยวกับมารดาและทารกต่อหน่วยงานที่เกี่ยวข้องจะทำเฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น ผู้วิจัยจะเก็บรักษาข้อมูลและภาพวิดีโอของทารกไว้เป็นเวลา 5 ปี นับจากเสร็จสิ้นการศึกษาวิจัย เพื่อประโยชน์ในการแปลผลและอ้างอิงกรณีมีข้อสงสัยเกี่ยวกับงานวิจัย หลังจากนั้นผู้วิจัยจะหักแผ่นดีวีดีที่บันทึกภาพพฤติกรรมทารกทั้งหมด ก่อนทิ้งในถังขยะเพื่อป้องกันไม่ให้ผู้ที่ไม่เกี่ยวข้องกับงานวิจัยนำภาพของทารกไปใช้โดยไม่ได้รับอนุญาต

ค่าตอบแทนที่จะได้รับเมื่อเข้าร่วมโครงการวิจัย

ผู้เข้าร่วมโครงการวิจัยจะไม่ได้รับค่าตอบแทนในการเข้าร่วมโครงการวิจัยนี้

หากมีปัญหาหรือข้อสงสัยที่เกี่ยวข้องกับโครงการวิจัย

สามารถติดต่อผู้วิจัยหลัก นางสาวพัชรี จันทรักษา ได้ที่ 592 ซอยรามคำแหง 24 แขวงหัวหมาก เขตบางกะปิ กรุงเทพฯ 10240 หรือ โทรศัพท์ 084 – 460 – 9083 ตลอด 24 ชั่วโมง

ต้องการร้องเรียน หรือต้องการแจ้งเรื่องหากไม่ได้รับการปฏิบัติตามเอกสารแนะนำ

สามารถติดต่อคณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ ได้ที่ สถาบันวิจัยวิทยาศาสตร์การแพทย์ จุฬาลงกรณ์มหาวิทยาลัย อาคารสถาบัน 2 ชั้น 4 ถนนพญาไท แขวงวังใหม่ เขตปทุมวัน กรุงเทพฯ 10330

เลขที่โครงการวิจัย 059/51
วันที่รับรอง 1 ส.ค. 2551
วันหมดอายุ 31 ก.ค. 2552

ใบยินยอมของประชากรตัวอย่างหรือผู้มีส่วนร่วมในการวิจัย
(Informed Consent Form)

24 เม.ย 51

การวิจัยเรื่อง ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรมการจัดการด้วยประสาทของทารกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก

วันให้คำยินยอม วันที่...............เดือน...................................พ.ศ......................

ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการวิจัย ประโยชน์ รวมทั้งผลข้างเคียงที่คาดว่าจะเกิดขึ้นจากกระบวนการวิจัยอย่างละเอียด และมีความเข้าใจดีแล้ว

ผู้วิจัยรับรองว่าจะตอบคำถามที่ข้าพเจ้าสงสัยด้วยความเต็มใจ และไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ

ข้าพเจ้าอนุญาตให้บุตรเข้าร่วมในโครงการวิจัยนี้ด้วยความสมัครใจ โดยปราศจากการบังคับ และไม่ได้รับค่าตอบแทนใดๆ อันเป็นการชักจูงใจให้เข้าร่วมงานวิจัยครั้งนี้

ข้าพเจ้ามีสิทธิที่จะบอกเลิกการอนุญาตให้บุตรเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้ และการบอกเลิกนี้จะไม่มีผลต่อการรักษาพยาบาลที่บุตรของข้าพเจ้าจะพึงได้รับในปัจจุบันและในอนาคต

ผู้วิจัยรับรองว่าจะเก็บข้อมูลเกี่ยวกับตัวข้าพเจ้าและบุตรเป็นความลับ และจะเปิดเผยเฉพาะในรูปของสรุปผลการวิจัยโดยไม่มีการระบุชื่อนามสกุลของข้าพเจ้าและบุตร การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าและบุตรต่อหน่วยงานต่างๆ ที่เกี่ยวข้อง จะกระทำเฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ในกรณีที่มีปัญหาหรือข้อสงสัยเกี่ยวกับงานวิจัย ข้าพเจ้าสามารถติดต่อผู้วิจัย นางสาวพัชรี จันทรักษา ได้ที่ 592 ซอยรามคำแหง 24 แขวงหัวหมาก เขตบางกะปิ กรุงเทพฯ 10240 หรือ โทรศัพท์ 084 460 9083 ได้ตลอด 24 ชั่วโมง

ในกรณีที่ข้าพเจ้าไม่ได้รับการปฏิบัติตามเอกสารแนะนำหรือมีข้อร้องเรียน ข้าพเจ้าสามารถติดต่อ คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ ได้ที่ สถาบันวิจัยวิทยาศาสตร์การแพทย์ จุฬาลงกรณ์มหาวิทยาลัย อาคารสถาบัน 2 ชั้น 4 ถนนพญาไท แขวงวังใหม่ เขตปทุมวัน กรุงเทพฯ 10330

ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงประโยชน์ ความจำเป็น และวัตถุประสงค์ของการบันทึกภาพวิดีทัศน์บุตรของข้าพเจ้า รวมถึงวิธีการนำไปใช้ และวิธีการทำลายภาพวิดีทัศน์ ภายหลังเสร็จสิ้นการศึกษาวิจัย

ข้าพเจ้า ○ อนุญาต ○ ไม่อนุญาต ให้ผู้วิจัยทำการบันทึกภาพวิดีทัศน์บุตรของข้าพเจ้าเพื่อการศึกษาวิจัยในครั้งนี้

ข้าพเจ้าได้อ่านข้อความข้างต้นแล้ว มีความเข้าใจดีทุกประการ และลงนามในใบยินยอมนี้ด้วยความเต็มใจ

ข้าพเจ้า...ในฐานะเป็น...............ของ...

อนุญาตให้ ....เข้าร่วมในโครงการวิจัยในครั้งนี้

ลงนาม .... มารดา/บิดา
(...)

ลงนาม .... ผู้วิจัยหลัก
(...)

ลงนาม .... พยาน
(...)

เลขที่โครงการวิจัย ....059/51..........
วันที่รับรอง ....1 สี.ค. 2551..........
วันหมดอายุ ....3 1 ก.ค. 2552..........

APPENDIX F

List of Expertise and Letter of Invitation

รายนามผู้ทรงคุณวุฒิ

ชื่อ – สกุล	ตำแหน่งวิชาการ/หน่วยงาน
ศ. นพ. เกรียงศักดิ์ จีระแพทย์	ศาสตราจารย์ หัวหน้าหน่วยทารกแรกเกิด คณะแพทยศาสตร์ โรงพยาบาลศิริราช
ผศ. นพ. สันติ ปุณณะหิตานนท์	ผู้ช่วยศาสตราจารย์ หัวหน้าหน่วยทารกแรกเกิด คณะแพทยศาสตร์ โรงพยาบาลจุฬาลงกรณ์
รศ. วิไล เลิศธรรมเทวี	รองศาสตราจารย์ หัวหน้าภาควิชาการพยาบาลกุมารเวชศาสตร์ คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล
นางสาววิมลวัลย์ วโรฬาร	ผู้ตรวจการพยาบาล งานการพยาบาลกุมารเวชศาสตร์ โรงพยาบาลรามาธิบดี
นางสาวพิกุล ขำศรีบุศ	หัวหน้าหออภิบาลผู้ป่วยเด็กและผู้ชำนาญการ 8 โรงพยาบาลศิริราช

ที่ ศธ 0512.11/ 2673

คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
อาคารวิทยกิตติ์ ชั้น 12 ซอยจุฬา 64
เขตปทุมวัน กรุงเทพฯ 10330

๖ ตุลาคม 2550

เรื่อง ขออนุมัติบุคลากรเป็นผู้ทรงคุณวุฒิ

เรียน ผู้อำนวยการโรงพยาบาลศิริราช

สิ่งที่ส่งมาด้วย 1. โครงร่างวิทยานิพนธ์ (ฉบับสังเขป) จำนวน 1 ชุด
2. เครื่องมือที่ใช้ในการวิจัย 1 ชุด

เนื่องด้วย นางสาวพัชรี จันทรักษา นิสิตขั้นปริญญาดุษฎีบัณฑิต คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย กำลังดำเนินการวิจัยเพื่อเสนอเป็นดุษฎีนิพนธ์ เรื่อง "ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรมการจัดการด้วยประสาทของทารกแรกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก" โดยมี ศาสตราจารย์ ดร. วีณา จีระแพทย์ เป็นอาจารย์ที่ปรึกษาดุษฎีนิพนธ์ ในการนี้จึงขอเรียนเชิญ ศาสตราจารย์ นายแพทย์ เกรียงศักดิ์ จีระแพทย์ หัวหน้าหน่วยทารกแรกเกิด เป็นผู้ทรงคุณวุฒิตรวจสอบความตรงตามเนื้อหาของเครื่องมือการวิจัยที่นิสิตสร้างขึ้น เพื่อประโยชน์ทางวิชาการต่อไป

จึงเรียนมาเพื่อโปรดพิจารณาอนุมัติให้บุคลากรข้างต้นเป็นผู้ทรงคุณวุฒิตรวจสอบเครื่องมือการวิจัยดังกล่าว คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย หวังเป็นอย่างยิ่งว่าจะได้รับความอนุเคราะห์จากท่าน และขอขอบพระคุณอย่างสูงมา ณ โอกาสนี้

ขอแสดงความนับถือ

(รองศาสตราจารย์ ร.ต.อ.หญิง ดร. ยุพิน อังสุโรจน์)
คณบดีคณะพยาบาลศาสตร์

<u>สำเนาเรียน</u> ศาสตราจารย์ นายแพทย์ เกรียงศักดิ์ จีระแพทย์
<u>งานบริการการศึกษา</u> โทร. 0-2218-9825 โทรสาร. 0-2218-9806
<u>อาจารย์ที่ปรึกษา</u> ศาสตราจารย์ ดร. วีณา จีระแพทย์ โทร. 0-2218-9822
<u>ชื่อนิสิต</u> นางสาวพัชรี จันทรักษา โทร. 08-4460-9083

บันทึกข้อความ

ส่วนราชการ งานบริการการศึกษา คณะพยาบาลศาสตร์ จุฬาฯ โทร. 89825 โทรสาร 89806

ที่ ศธ 0512.11 / 2673 วันที่ 26 ตุลาคม 2550

เรื่อง ขออนุมัติบุคลากรเป็นผู้ทรงคุณวุฒิ

เรียน คณบดีคณะแพทยศาสตร์

สิ่งที่ส่งมาด้วย 1. โครงร่างวิทยานิพนธ์ (ฉบับสังเขป) จำนวน 1 ชุด

2. เครื่องมือที่ใช้ในการวิจัย 1 ชุด

เนื่องด้วย นางสาวพัชรี จันทรักษา นิสิตขั้นปริญญาดุษฎีบัณฑิต คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย กำลังดำเนินการวิจัยเพื่อเสนอเป็นดุษฎีนิพนธ์ เรื่อง "ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรมการจัดการด้วยประสาทของทารกแรกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก" โดยมี ศาสตราจารย์ ดร. วีณา จีระแพทย์ เป็นอาจารย์ที่ปรึกษาดุษฎีนิพนธ์ ในการนี้จึงขอเรียนเชิญ ผู้ช่วยศาสตราจารย์ นายแพทย์ สันติ ปุณณะหิตานนท์ หัวหน้าหน่วยทารกแรกเกิด เป็นผู้ทรงคุณวุฒิตรวจสอบความตรงตามเนื้อหาของเครื่องมือการวิจัยที่นิสิตสร้างขึ้น เพื่อประโยชน์ทางวิชาการต่อไป

จึงเรียนมาเพื่อโปรดพิจารณาอนุมัติให้บุคลากรข้างต้นเป็นผู้ทรงคุณวุฒิตรวจสอบเครื่องมือการวิจัยดังกล่าว คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย หวังเป็นอย่างยิ่งว่าจะได้รับความอนุเคราะห์จากท่าน และขอขอบพระคุณอย่างสูงมา ณ โอกาสนี้

ขอแสดงความนับถือ

(รองศาสตราจารย์ ร.ต.อ.หญิง ดร. ยุพิน อังสุโรจน์)
คณบดีคณะพยาบาลศาสตร์

<u>สำเนาเรียน</u> ผู้ช่วยศาสตราจารย์ นายแพทย์ สันติ ปุณณะหิตานนท์

<u>อาจารย์ที่ปรึกษา</u> ศาสตราจารย์ ดร. วีณา จีระแพทย์ โทร. 0-2218-9822

<u>ชื่อนิสิต</u> นางสาวพัชรี จันทรักษา โทร. 08-4460-9083

ที่ ศธ 0512.11/ 2673

คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
อาคารวิทยกิตติ์ ชั้น 12 ซอยจุฬา 64
เขตปทุมวัน กรุงเทพฯ 10330

26 ตุลาคม 2550

เรื่อง ขออนุมัติบุคลากรเป็นผู้ทรงคุณวุฒิ

เรียน คณบดีคณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล

สิ่งที่ส่งมาด้วย 1. โครงร่างวิทยานิพนธ์ (ฉบับสังเขป) จำนวน 1 ชุด
2. เครื่องมือที่ใช้ในการวิจัย 1 ชุด

เนื่องด้วย นางสาวพัชรี จันทรักษา นิสิตขั้นปริญญาดุษฎีบัณฑิต คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย กำลังดำเนินการวิจัยเพื่อเสนอเป็นดุษฎีนิพนธ์ เรื่อง "ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรมการจัดการด้วยประสาทของทารกแรกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก" โดยมี ศาสตราจารย์ ดร. วีณา จีระแพทย์ เป็นอาจารย์ที่ปรึกษาดุษฎีนิพนธ์ ในการนี้จึงขอเรียนเชิญ รองศาสตราจารย์ วิไล เลิศธรรมเทวี ภาควิชาการพยาบาลกุมารเวชศาสตร์ เป็นผู้ทรงคุณวุฒิตรวจสอบความตรงตามเนื้อหาของเครื่องมือการวิจัยที่นิสิตสร้างขึ้น เพื่อประโยชน์ทางวิชาการต่อไป

จึงเรียนมาเพื่อโปรดพิจารณาอนุมัติให้บุคลากรข้างต้นเป็นผู้ทรงคุณวุฒิตรวจสอบเครื่องมือการวิจัยดังกล่าว คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย หวังเป็นอย่างยิ่งว่าจะได้รับความอนุเคราะห์จากท่าน และขอขอบพระคุณอย่างสูงมา ณ โอกาสนี้

ขอแสดงความนับถือ

(รองศาสตราจารย์ ร.ต.อ.หญิง ดร. ยุพิน อังสุโรจน์)
คณบดีคณะพยาบาลศาสตร์

<u>สำเนาเรียน</u> รองศาสตราจารย์ วิไล เลิศธรรมเทวี
<u>งานบริการการศึกษา</u> โทร. 0-2218-9825 โทรสาร. 0-2218-9806
<u>อาจารย์ที่ปรึกษา</u> ศาสตราจารย์ ดร. วีณา จีระแพทย์ โทร. 0-2218-9822
<u>ชื่อนิสิต</u> นางสาวพัชรี จันทรักษา โทร. 08-4460-9083

ที่ ศธ 0512.11/ ๒๗๖๓

คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
อาคารวิทยกิตติ์ ชั้น 12 ซอยจุฬา 64
เขตปทุมวัน กรุงเทพฯ 10330

๒๖ ตุลาคม 2550

เรื่อง ขออนุมัติบุคลากรเป็นผู้ทรงคุณวุฒิ

เรียน คณบดีคณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล

สิ่งที่ส่งมาด้วย 1. โครงร่างวิทยานิพนธ์ (ฉบับสังเขป) จำนวน 1 ชุด
2. เครื่องมือที่ใช้ในการวิจัย 1 ชุด

เนื่องด้วย นางสาวพัชรี จันทรักษา นิสิตขั้นปริญญาดุษฎีบัณฑิต คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย กำลังดำเนินการวิจัยเพื่อเสนอเป็นดุษฎีนิพนธ์ เรื่อง "ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรมการจัดการด้วยประสาทของทารกแรกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก" โดยมี ศาสตราจารย์ ดร. วีณา จีระแพทย์ เป็นอาจารย์ที่ปรึกษาดุษฎีนิพนธ์ ในการนี้จึงขอเรียนเชิญ นางสาววิมลวัลย์ วโรฬาร ผู้ตรวจการพยาบาล งานการพยาบาลกุมารเวชศาสตร์ เป็นผู้ทรงคุณวุฒิตรวจสอบความตรงตามเนื้อหาของเครื่องมือการวิจัยที่นิสิตสร้างขึ้น เพื่อประโยชน์ทางวิชาการต่อไป

จึงเรียนมาเพื่อโปรดพิจารณาอนุมัติให้บุคลากรข้างต้นเป็นผู้ทรงคุณวุฒิตรวจสอบเครื่องมือการวิจัยดังกล่าว คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย หวังเป็นอย่างยิ่งว่าจะได้รับความอนุเคราะห์จากท่าน และขอขอบพระคุณอย่างสูงมา ณ โอกาสนี้

ขอแสดงความนับถือ

(รองศาสตราจารย์ ร.ต.อ.หญิง ดร. ยุพิน อังสุโรจน์)
คณบดีคณะพยาบาลศาสตร์

สำเนาเรียน นางสาววิมลวัลย์ วโรฬาร

งานบริการการศึกษา โทร. 0-2218-9825 โทรสาร. 0-2218-9806
อาจารย์ที่ปรึกษา ศาสตราจารย์ ดร. วีณา จีระแพทย์ โทร. 0-2218-9822
ชื่อนิสิต นางสาวพัชรี จันทรักษา โทร. 08-4460-9083

ที่ ศธ 0512.11/ 2763

คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
อาคารวิทยกิตติ์ ชั้น 12 ซอยจุฬา 64
เขตปทุมวัน กรุงเทพฯ 10330

26 ตุลาคม 2550

เรื่อง ขออนุมัติบุคลากรเป็นผู้ทรงคุณวุฒิ

เรียน คณบดีคณะแพทยศาสตร์ ศิริราชพยาบาล มหาวิทยาลัยมหิดล

สิ่งที่ส่งมาด้วย 1. โครงร่างวิทยานิพนธ์ (ฉบับสังเขป) จำนวน 1 ชุด
2. เครื่องมือที่ใช้ในการวิจัย 1 ชุด

เนื่องด้วย นางสาวพัชรี จันทรักษา นิสิตขั้นปริญญาดุษฎีบัณฑิต คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย กำลังดำเนินการวิจัยเพื่อเสนอเป็นดุษฎีนิพนธ์ เรื่อง "ผลของโปรแกรมการปรับเปลี่ยนสิ่งแวดล้อมแบบปัจเจกบุคคลต่อพฤติกรรมการจัดการด้วยประสาทของทารกแรกเกิดก่อนกำหนดที่มีน้ำหนักน้อยมาก" โดยมี ศาสตราจารย์ ดร. วีณา จีระแพทย์ เป็นอาจารย์ที่ปรึกษาดุษฎีนิพนธ์ ในการนี้จึงขอเรียนเชิญ นางสาวพิกุล ขำศรีบุศ หัวหน้าหออภิบาลผู้ป่วยเด็กและผู้ชำนาญการ เป็นผู้ทรงคุณวุฒิตรวจสอบความตรงตามเนื้อหาของเครื่องมือการวิจัยที่นิสิตสร้างขึ้น เพื่อประโยชน์ทางวิชาการต่อไป

จึงเรียนมาเพื่อโปรดพิจารณาอนุมัติให้บุคลากรข้างต้นเป็นผู้ทรงคุณวุฒิตรวจสอบเครื่องมือการวิจัยดังกล่าว คณะพยาบาลศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย หวังเป็นอย่างยิ่งว่าจะได้รับความอนุเคราะห์จากท่าน และขอขอบพระคุณอย่างสูงมา ณ โอกาสนี้

ขอแสดงความนับถือ

(รองศาสตราจารย์ ร.ต.อ.หญิง ดร. ยุพิน อังสุโรจน์)
คณบดีคณะพยาบาลศาสตร์

<u>สำเนาเรียน</u> นางสาวพิกุล ขำศรีบุศ
<u>งานบริการการศึกษา</u> โทร. 0-2218-9825 โทรสาร. 0-2218-9806
<u>อาจารย์ที่ปรึกษา</u> ศาสตราจารย์ ดร. วีณา จีระแพทย์ โทร. 0-2218-9822
<u>ชื่อนิสิต</u> นางสาวพัชรี จันทรักษา โทร. 08-4460-9083

APPENDIX G

Letter of Permission to Utilize NIDCAP Naturalistic Observation of Newborn Behavior (NONB)

Children's Hospital Boston
Director of Neurobehavioral Infant &Child Studies
Dept of Psychiatry

Harvard Medical School
Associate Professor of Psychology
Dept of Psychiatry

Heidelise Als, Ph.D.
Enders Pediatric Research Laboratories | EN-107
Children's Hospital Boston
320 Longwood Avenue
Boston, MA 02115
phone: 617-355-8249 fax: 617-730-0224
Email: heidelise.als@childrens.harvard.edu

16 October 2008

Ms. Patcharee Juntaruksa
UC Denver College of Nursing
13120 E. 19th Avenue, Box C288 -19
P.O. Box 6511
Aurora , CO 80045

Re: Permission to utilize NIDCAP Naturalistic Observation of Newborn Behavior (NONB)

Dear Ms. Patcharee Juntaruksa,

I herewith give you formal permission as the President of the NIDCAP Federation International (NFI) the copyright holder of the materials, and as the author of the NIDCAP observation methodology, to utilize this instrument for your dissertation research. I am aware that you are in the process of receiving training in the use of the NIDCAP methodology by Dr. Joy Browne, Denver. I expect that you will reference the materials appropriately in your dissertation as to their original source.

I wish you all the best success with your dissertation research and look forward to learn about the results that you may discover.

With best wishes,

I am sincerely yours,

Heidelise Als

Heidelise Als, PhD

The *first* place for children

nidcap

Colorado NIDCAP® Training Center

Center for Family and Infant Interaction Office 303-724-7668
University of Colorado Denver School of Medicine Fax 303-724-7664
Department of Pediatrics, JFK Partners
13121 E. 17th Avenue C 234
L-28 -5117
P.O. Box 6511
Aurora, Colorado
USA 80045

10/23/2008

To Whom it May Concern:

Re: Patcharee Juntaruksa

I am delighted to report that Patcharee Juntaruksa has made significant progress towards reliability in the Newborn Individualized Developmental Care and Assessment Program here at the Denver, Colorado Training Center. She had previously (in 2007) successfully engaged in the introduction and bedside training days. On this visit in October, 2008, she engaged in practice observations in our NICU at The Children's Hospital. She has received feedback from me on one written observation. We have identified next steps in her training process, which include observations and write ups of a variety of babies in her home NICU as outlined in the NIDCAP Training Guide (www.NIDCAP.org). Patcharee will keep in touch with me, so that I can monitor her progress and establish a time frame for scheduling a work day.

Should you have any questions for me, please feel free to contact me by email, post, or telephone.

Sincerely,

JBrowne, Ph.D.

Joy Browne, Ph.D., R.N., PCNS-BC; IMH-E (IV)
Infant Mental Health Mentor
Associate Professor of Pediatrics and Psychiatry
Director, Center for Family and Infant Interaction
Colorado NIDCAP Training Center
Browne.joy@tchden.org

Denver NIDCAP® Training Center

nidcap

@ The Children's Hospital
1056 E. 19th Ave. B-310
Denver, CO 80218
www.uchsc.edu/sm/peds/cfii

office (303) 861-6298
fax (303) 864-5511

8/31/2007

To Whom it May Concern:

I am delighted to report that Patcharee Juntaruksa has begun training in the Newborn Individualized Developmental Care and Assessment Program training here at the Denver, Colorado Training Center. She has successfully engaged in the introduction and bedside training days, and when she returns to Colorado after the first of the year will resume training days as outlined in the NIDCAP Training Guide (www.NIDCAP.org).

Should you have any questions for me, please feel free to contact me by email, post, or telephone.

Sincerely,

JBrowne, Ph.D.

Joy Browne, Ph.D., R.N., C.N.S.
Director, Center for Family and Infant Interaction
Denver NIDCAP Training Center
Browne.joy@tchden.org

APPENDIX H

Correlations between baseline data of infant demographic characteristics and neurobehavioral outcome

Correlations between baseline data of infant demographic characteristics and neurobehavioral outcome (n = 25)

Neurobehavioral outcomes/ Demographic characteristics	1	2	3	4	5	6	7	8	9	10	11	12	13
GA at birth	-												
Medical condition	.240	-											
Postnatal age	-.785**	-.360	-										
Birth weight	.635**	.443*	-.820**	-									
Positive autonomic response	-.204	-.078	.256	-.094	-								
Negative autonomic response	.324	.018	-.153	.015	.081	-							
Positive motoric behaviors	.394	.010	-.199	-.035	-.155	.676**	-						
Negative motoric behaviors	.137	.096	-.103	-.048	-.245	.520**	.832**	-					
Sleep state	-.264	-.279	.234	-.140	.257	-.504*	-.684**	-.720**	-				
Transitional state	.005	.250	-.012	.091	.009	.200	.340	.315	-.510**	-			
Arousal state	.073	.030	-.106	.041	-.370	.267	.661**	.850**	-.682**	.295	-		
Positive attention behaviors	-.034	-.175	-.011	.114	.235	.053	.138	.211	.081	-.383	.159	-	
Negative attention behaviors	-.024	.001	.021	.001	.328	-.352	.664**	-.899**	.671**	-.239	-.849**	-.175	-

* Correlation is significant at the 0.05 level (2-tailed);
** Correlation is significant at the 0.01 level (2-tailed).

BIOGRAPHY

Ms. Patcharee Juntaruksa was born in March 4, 1970 at Suratthani province, graduated Bachelor Degree in Nursing Science with Magna Cum Laude Cumulative at Assumption University in 2002. Working experiences included registered nurse at Out-patient Department, Camillian Hospital, and nurse-coordinator at International Medical Center, Bangkok Hospital. The current working position is nursing instructor at Faculty of Nursing Science, Assumption University.

The scholarship for pursuing Doctor of Philosophy Degree was granted by Assumption University, and the funding for dissertation was granted by the 90th Anniversary of Chulalongkorn University Fund and Thailand Nursing Council. The systematic review of effects of individualized environmental modification program on neurobehavioral organizations of very low birth weight infants was presented as a poster presentation at Research and Creative Activities Symposium, University of Colorado at Denver and Health Science Center, Colorado, USA, 2007.