EFFECTS OF HOLISTIC COMFORT CARE ON THE PHYSIOLOGICAL AND BEHAVIORAL RESPONSES OF PREMATURE INFANTS UNDERGOING INSERTION OF BINASOPHARYNGEAL PRONGS

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A THESIS SUBMITTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR
THE DEGREE OF MASTER OF NURSING SCIENCE
(PEDIATRIC NURSING)
FACULTY OF GRADUATE STUDIES
MAHIDOL UNIVERSITY
2008

Thesis
Entitled

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was submitted to the Faculty of Graduate Studies, Mahidol University
for the degree of Master of Nursing Science (Pediatric Nursing)
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ACKNOWLEDGEMENTS

This research could not have been successfully completed without the assistance of many persons. I would like to express sincere appreciation and gratitude to my major advisor, Asst.Prof.Dr. Renu Pookboonmee and my co-advisor, Assoc.Prof. Pracha Nuntnarumit, for their kindness, encouragement, constructive guidance, and warmest support throughout this study. My gratitude is also extended to the thesis committee members, Asst.Prof.Dr. Srisamorn Phumonsakul and Pol.Col. Nares Wongpaitoon for their valuable comments and supervision. In addition, I would like to thank Asst.Prof.Dr. Jariya Witayasuporn, Asst.Prof. Kruawan Tinnasulanon, Dr. Pisamai Oratai and Miss Vimonwan Varolarn for their kindness in providing suggestions for improvement.

I would also like to thank all patients and parents who participated in my study. Additionally, I would like to express my sincerest thanks to the head nurse and all the staff members in Neonatal Intensive Care Unit (NICU) at Faculty of Medicine, Ramathibodi Hospital for their assistance and facilitation in data collection.

Finally, deepest thanks to Asst.Prof. Parichard Gooch, Assoc.Prof. Varathana Arjrith, Miss Suwatjana Noinam, Miss Sakuntala Sudsaneha and my family for their warmth, encouragement, understanding, support, and assistance throughout the study.

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ABSTRACT

The purpose of this quasi-experimental research was to determine the effects of holistic comfort care on the physiological and behavioral responses of premature infants undergoing insertion binasopharyngeal prongs. The conceptual framework was based on Kolcaba's Comfort Theory. Sixty-two episodes were selected from ten premature infant patients admitted to the Neonatal Intensive Care Unit (NICU) in Ramathibodi Hospital during a four-month period and underwent insertion of binasopharyngeal prongs. The samples were selected by purposive sampling. The crossover-experimental design was used to compare the physiological responses , including the mean of heart rate, oxygen saturation, and time for heart rate and oxygen saturation to return to baseline. The behavioral responses included the comfort behavior mean scores after suctioning. The data collection instruments included the demographic data form, and the observation record. The physiological responses were measured by bedside monitoring of Masimo Radical and the behavioral responses were scored by the modified COMFORT Behavior Scale. Two-way repeated measures and survival curve analysis was used to compare the physiological and behavioral responses between holistic comfort care with quiet hour group and usual care with non quiet hour after suctioning.

The results revealed that the holistic comfort care had a statistically significant lower level mean of heart rate ($p<.001$), a statistically significant higher level mean of oxygen saturation ($p<.05$), a statistically significant shorter time for heart rate to return to baseline ($p<.05$). Also the mean of the comfort behavior score was significantly lower ($p<.001$), but oxygen saturation using time return to baseline showed no statistically significant difference ($p<.05$) compared to usual care.

This study suggests that holistic comfort care with quiet hours in premature infants undergoing insertion of binasopharyngeal prongs resulted in better of the physiological and behavioral responses. Thus, this intervention should be developed as a clinical nursing practice guideline.

KEY WORDS: HOLISTIC COMFORT CARE / BINASOPHARYNGEAL PRONGS / PHYSIOLOGIC RESPONSES / BEHAVIORAL RESPONSES

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ผลของการดูแลเพื่อส่งเสริมความสุขสบายแบบองค์รวมต่อการตอบสนองด้านสรีรวิทยาและพฤติกรรมในทารกคลอดก่อนกำหนดที่ได้รับการใส่ท่อหายใจทางจมูก (EFFECTS OF HOLISTIC COMFORT CARE ON THE PHYSIOLOGICAL AND BEHAVIORAL RESPONSES OF PREMATURE INFANTS UNDERGOING INSERTION OF BINASOPHARYNGEAL PRONGS)

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บทคัดย่อ

การวิจัยกึ่งทดลองครั้งนี้ มีวัตถุประสงค์เพื่อศึกษาผลของการดูแลเพื่อส่งเสริมความสุขสบายแบบองค์รวมต่อการตอบสนองด้านสรีรวิทยาและพฤติกรรมในทารกคลอดก่อนกำหนดที่ได้รับการสอดใส่ท่อหายใจทางจมูก โดยใช้ทฤษฎีความสุขสบายของ (Kolcaba (Kolcaba's Comfort Theory) เป็นกรอบแนวคิดในการศึกษา กลุ่มตัวอย่างเป็นทารกคลอดก่อนกำหนดที่เข้ารับรักษาในหอผู้ป่วยอภิบาลทารกแรกเกิดของโรงพยาบาลรามาธิบดี ในช่วงเวลา 4 เดือน คัดเลือกกลุ่มตัวอย่างตามคุณสมบัติที่กำหนดไว้จำนวน 62 ครั้งจากกลุ่มตัวอย่าง 10 ราย การออกแบบงานวิจัยในครั้งนี้ผู้ป่วยทุกรายเป็นกลุ่มควบคุมในตนเอง เพื่อเปรียบเทียบการตอบสนองทางด้านสรีรวิทยา ได้แก่ ค่าเฉลี่ยของอัตราการเต้นของหัวใจ, ระดับความอิ่มตัวของออกซิเจน,ระยะเวลาที่อัตราการเต้นของหัวใจและระดับความอิ่มตัวของออกซิเจนกลับคืนสู่ค่าพื้นฐาน และการตอบสนองทางด้านพฤติกรรม ได้แก่ ค่าเฉลี่ยของคะแนนพฤติกรรมความสุขสบายภายหลังการดูดเสมหะ เครื่องมือที่ใช้ในการเก็บรวบรวมข้อมูล ได้แก่ แบบบันทึกข้อมูลส่วนบุคคล แบบบันทึกการสังเกต การตอบสนองทางสรีรวิทยาวัดโดยเครื่องติดตามสัญญาณชีพ และการตอบสนองทางด้านพฤติกรรมวัดโดย The modified COMFORT Behavior Scale วิเคราะห์ข้อมูลโดยใช้สถิติบรรยายเปรียบเทียบความแตกต่างของการตอบสนองทางสรีรวิทยาและพฤติกรรมระหว่างกลุ่มควบคุมและทดลองด้วยสถิติวิเคราะห์ความแปรปรวนสองทางที่มีการวัดซ้ำและการวิเคราะห์ด้วย survival curve

ผลการวิจัยพบว่า กลุ่มตัวอย่างที่ได้รับการดูแลเพื่อส่งเสริมความสุขสบายแบบองค์รวมมีระดับของค่าเฉลี่ยของอัตราการเต้นของหัวใจต่ำกว่าอย่างมีนัยสำคัญทางสถิติที่ระดับ .001, ระดับความอิ่มตัวของออกซิเจนสูงกว่าอย่างมีนัยสำคัญทางสถิติที่ระดับ .05, ระยะเวลาที่อัตราการเต้นของหัวใจกลับคืนสู่ค่าพื้นฐานสั้นกว่าอย่างมีนัยสำคัญทางสถิติที่ระดับ .05 และมีค่าเฉลี่ยของคะแนนพฤติกรรมความสุขสบายต่ำกว่าอย่างมีนัยสำคัญทางสถิติที่ระดับ.001 แต่ระยะเวลาที่ระดับความอิ่มตัวของออกซิเจนกลับคืนสู่ค่าพื้นฐานไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติที่ระดับ .05 เมื่อเปรียบเทียบกับกลุ่มที่ได้รับการดูแลตามปกติ

ผลที่ได้จากการศึกษาครั้งนี้สนับสนุนว่า การดูแลเพื่อส่งเสริมความสุขสบายแบบองค์รวมส่งผลดีต่อการตอบสนองทางสรีรวิทยาและพฤติกรรมของทารก ดังนั้นควรนำความรู้ที่ได้จากการศึกษาครั้งนี้พัฒนาไปสู่แนวทางการปฏิบัติการพยาบาลในการดูแลทารกคลอดก่อนกำหนด

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CHAPTER I
INTRODUCTION

Background and Rationale

Increasing technology in the area of Neonatal Intensive Care Unit (NICU) has resulted in survival of preterm infants. The premature infant mortality rate has decreased dramatically. Respiratory problems in the premature infants are the most common cause of admissions into NICU. Respiratory failure in the neonatal period remains a difficult challenge and is associated with high morbidity, mortality and cost. Application of mechanical ventilation has resulted in better outcomes and has been lifesaving in critically ill neonates over the past four decades. However, mechanical ventilation may contribute to lung injury. Bronchopulmonary dysplasia (BPD) remains a major complication in premature infants who require prolonged ventilatory support.

The medical specialties have demonstrated as much progress and success as has neonatology. Nasal ventilation (NV) is an attractive concept to determine its potential usefulness: (1) in preventing extubation failure; (2) in treating apnea of prematurity; and (3) as a primary mode of treating respiratory disorder. Meanwhile, NV would avoid potential complications of prolonged ventilatory support via an endotracheal tube (vulutrauma, subglottic stenosis, infections) (Wiswell & Srinivasan, 2003). Mode of NV, which commonly used for preterm infants are: 1) Continuous Positive Airway Pressure (CPAP) mode via nasal prongs (Nasal Continuous Positive Airway Pressure: NCPAP), via nasopharyngeal prongs (Nasopharyngeal Continuous Positive Airway Pressure: NPCPAP), via infant nasal mask (NM-CPAP); 2) Synchronized Intermittent Mandatory Ventilation mode via nasopharyngeal prongs (NSIMV); and 3) Intermittent Positive Pressure Ventilation mode via nasopharyngeal prongs (NIPPV) (Wiswell & Srinivasan, 2003). Present historical cohort study, the use of a CPAP-based approach to respiratory support of the preterm infants, resulted in a shorter and less invasive respiratory course, less chronic lung disease (CLD) at 28 days (and less death or CLD at 28 days), and no increase in non-respiratory morbidities in infants of 1,000 – 1499 grams birth weight (de Klerk & de Klerk, 2001). The binasopharyngeal prongs are the common device used to secure upper airway patency for premature infants and commonly used in clinical practice in the NICU.

Treatment of neonates is usually beneficial but therapeutic procedures may sometimes result in adverse side effects or cause iatrogenic damage (such as the binasopharyngeal prongs insertion aim to help premature infants get better). Sometimes binasopharyngeal prongs insertion procedure is a common cause that leads to discomfort in infants. The essential nursing activities for airway care in infants with binasopharyngeal prongs every 3-6 hours are: removing prongs from infant's nares; suctioning nares, mouth care and cleaning binasopharyngeal prongs; inserting distal shape prongs pass narrow nares to nasopharyngeal; and securing binasopharyngeal prongs with plaster and connect to ventilator. From the researcher's experience, the premature infants extremely suffered and experienced discomfort from each of these steps. Suffering and discomforting from trauma, pain, stress, and disrupt sleep create negative physiologic changes such as tachycardia, tachypnea, and oxygen desaturation.

The American Association for Respiratory Care or AARC (2004) identified sources of discomfort, which may alter the well-being of the premature infants undergoing inserting binasopharyngeal prongs, as follows: (1) decannulation or malpositioning or kinking of nasopharyngeal prongs; (2) nasopharyngeal symptoms; and (3) gastric insufflation and abdominal distention. Besides, excessive head rotation or neck extension may alter the position of binasopharyngeal prongs placement or obstruct upper airway structures resulting in diminished or altered pressure, flow, and effective CPAP. In addition, the decannulation or malpositioning of nasopharyngeal prongs are causing fluctuating or reduced CPAP levels. Obstruction of prongs from mucous plugging or kinking of prongs may interfere with delivery of CPAP and resulting in decrease in the fraction of inspired oxygen (FiO_2) through entrainment of room air via opposite naris or mouth. Complete obstruction of nasal prongs and nasopharyngeal tubes results in continued pressurization of the CPAP system (AARC, 2004). The amount of gas flow through the CPAP circuit is important. Insufficient set flow limits the flow available for inspiration, increasing airway pressure fluctuation, and raising the work of breathing. The flow required is affected by the degree of "leak" gas from the infant's nose and mouth. If the mouth is open, the pressure in the pharynx will fall and the flow will need to be increased to maintain it. If the mouth is tightly closed and the nasal prongs are a good fit, the flow required will be less. Insufficient gas flow to meet inspiratory demand will result in a fluctuating baseline pressure and an increase in the work of breathing (AARC, 2004).

Nasopharyngeal symptoms such as nasal irritation, mucosal swelling or erosion, excessive nasal dilatation or septal necrosis (Klein, 2006) nasal and throat dryness, rhinorrhea and sneezing are common in the initiation of CPAP treatment in patients with obstructive sleep apnea (Brander, Soirinsuo, & Lohela, 1999). One of the most common symptoms in such patients is nasal obstruction. Nasal obstruction leads to an increase in the inspiratory effort, with an increase in negative intraluminal pressure. This leads to upper airway instability and a greater tendency for pharyngeal collapse (Mirza & Lanza, 1999). Although nasal and pharyngeal symptoms are common in patients using CPAP (Mirza & Lanza, 1999; Lojander, Brander, & Ämmälä, 1999), it is not clear whether the symptoms were present prior to the initiation of treatment. Brander Soirinsuo, & Lohela (1999) described an increase in the frequency and intensity of most nasal symptoms after the use of CPAP that gastric insufflation and abdominal distention potentially leading to aspiration. Activation of manual breath may cause gastric insufflation and patient discomfort particularly if the peak pressure is set at appropriately high (AARC, 2004).

Besides, preterm infants are at risk for problems in a variety of areas. These problems related to the immaturity of their organ systems and to concurrent disease states. Interruption of intrauterine growth may have important consequences for the development and organization of the central nervous system of the preterm infant. Vulnerabilities of preterm infants include the transition to extrauterine life, physiologic limitations, and central nervous system immaturity (Blackburn, 1998). The preterm infant's sensory nervous system is able to capture environmental stimuli and process them through the central nervous system. However, the immaturity of the organization of this nervous system is such that autonomic, motor, and sensory functions are readily saturated. NICU provides excess stimuli; therefore, preterm infants can become overstimulated (Aita & Goulet, 2003). Four most commonly identified sources causing stress for these infants in the NICU environment are: (1) visual stimulation-ambient and bright light exposure; (2) auditory stimulation-noise pollution; (3) tactile simulation-frequent aversive procedures or excessive handling; and (4) vestibular stimulation-inappropriate position (Mahoney & Cohen, 2005).

The visual stimuli:- The American Association of Pediatrics for Guideline for Perinatal Care in 1992 recommended illumination maxima of 60 foot-candles (fc) (1 fc=10.76 lux) (650 lux) for observation, and 100 fc (1080 lux) for procedures. The fetus is transported from the uterus with its low level of illumination (maternal abdominal wall light transmission ~ 2%), into an environment quite different from that experienced at any other time of life (Fielder & Moseley, 2000). NICU illumination levels are different from that experienced in utero. Preterm neonates are cared in an environment which is continuously and brightly lit, and is very different to that experienced at any other time of life. Constant light may disturb body rhythm as bright light may not permit baby to open eyes and look around. Preterm infants in NICU with dimmed nightlight, progress more quickly in their sleep-wake patterns (Nair, Gupta, & Jatana, 2003). This rapidly increasing illumination may be a cause of stress to the younger gestationally and postnatally preterm neonate (Shogan & Schumann, 1993). Long-term deficits in visual acuity and color vision have been associated with biochemical and physiologic changes in the retina from lighting extremes in an NICU (Miller & Quinn-Hurst, 1994). The most well-known problem is retinopathy of prematurity, but preterm infants are also at increased risk for ocular defects (refraction and eye alignment) and cortical visual deficits (Lefrak & Lund in Klaus & Fanaroff, 2001; Glass, 2002).

The auditory stimuli:- The premature infants in NICU often are exposed to continuous loud noise, a major sources of stressful stimulation. Infant in intensive care units should incorporate a system of regular noise assessment. Sound limit recommendations are to maintain a nursery with an hourly loudness equivalent (Leq) of 50 dB(A), an hourly sound level that exceeded 10 percent of the time (L10) of 55 dB(A) and a 1-second maximum sound level (Lmax) of 70 dB(A), all A-weighted, slow response scale (Graven, 2000). Several recent studies have found exceedingly high noise levels in the NICU (Kent, Tan, Clarke, & Bardell, 2002; Levy, Woolston, & Browne, 2003); inside the incubator, measurements from 55 to 88 decibels (dB), with peak levels of 117 dB, have been reported. Damage to delicate auditory structures has been associated with prolonged exposure to over 90 dB in adults; in neonates, the decibels levels that result in hearing damage have not been identified. Noise is also a potential cause of stress in the neonatal unit, the threshold for stimulation of the adrenopituitary axis being 68 dB linear. Levels of noise as low as 70 dB have produced effects on the cardiovascular system, such as peripheral vasoconstriction, increased heart rate, and raised blood pressure and weakening of the vessel walls in the cerebral vasculature, with subsequent intracranial bleeding (Graven, 2000), the physiologic derangements such as hypoxia and hypotension during the neonatal period may occur during a variety of disparate illnesses and may lead to brain injury or abnormal brain development (Mattia & de Regnier, 1998). Noise levels of 50–75 dB have been shown to produce significant sleep disturbance in infants (Zahr & Balian, 1995; Morris, Philbin, & Bose, 2000; Lefrak & Lund in Klaus & Fanaroff, 2001; Bremmer, Byers, & Kiehl, 2003; Surenthiran, 2003). As stated the excessive noise movements throughout the NICU may contribute to non-beneficial health outcomes.

The tactile stimuli:- The extremely immature infants or those who are exposed to the NICU environment for long periods with his or her immature body systems, exhibits deleterious or life-threatening responses to the excessive physical manipulation of the infant for monitoring, therapeutic, or caregiver procedures and inappropriate stimulation. As the comforting and soothing touch may be minimal (D'Agostino, & Clifford, 1998). Exposure to excessive and often random stimulation may be coupled with a lack of sensory. Handling of preterm may lead to physiologic and behavioral stress which is shown as tachycardia, bradycardia, tachypnoea, apnea, and desaturation color changes to dusky (Nair, Guppta, Jatana, 2003). The extent of overall distress can be dramatically reduced when personnel modify their caregiving according to the infant’s responses. The monitoring of oxygenation and behavioral reactions suggests that caregiving practices can result in significant stress for hospitalized neonates (Lefrak & Lund in Klaus & Fanaroff, 2001). The adverse effects of the environment might also extend the infant's recovery from typical preterm illnesses. The preterm infant's rapidly developing brain is particularly vulnerable to a stressful environment. The detrimental effects of this stress could have short and long term implications for compromised neurobehavioural development (Pinelli & Symington, 2005).

The vestibular stimuli:- Premature infants are at risk for alterations in postural and motor development because of their weak muscle tone and inability to maintain flexion on their own. The physiological flexion develops in the last trimester of pregnancy in response to decreased space in uterus and as an active process in neurological development. Because body alignment is known to affect many physiologic and neurobehavioral parameters, the positioning of neonates is important. Premature infants may be routinely left to lie on their backs, a position that differs from the natural curved fetal position they would maintain in utero. The premature infants are lack of muscle strength to control movements of the body. These infants tend to lie with arms and legs straight, or extended, rather than flexed. All of these symptoms occur as a result of a shortening of the scapula muscles between the shoulder blades, causing a restricted range of motion and later motor problems. Thus, the older infant may be unable to appropriately reach for objects in front of him. The extended position for long periods can lead to abnormal tone with consequent delay in the motor development. Positioning can also alter respiratory physiology that effect on oxygenation, tidal volume, lung compliance, carbon dioxide exchange, energy expenditure, gastric emying, and skin intergrity (Lefrak & Lund in Klaus & Fanaroff, 2001).

As mentioned, numerous aspects create negative effects associated with discomfort in these premature infants who undergoing binasopharyngeal prongs response to aversive to internal and external stimuli in NICU environment. The responses create tachycardia, oxygen desaturation, tachypnea (Bremmer, Byers, & Kiehl, 2003), apnea, sudden increase in mean arterial blood pressure, may even produce intracranial haemorrhage, disturb sleep, startle the baby (Nair, Gupta, & Jatana, 2003), cause changes in a preterm infant’s glucose consumption and gastric activity (Graven, 2000), decrease calories available for growth (Catlett & Holditch-Davis, 1990), decrease levels of growth hormone (Zahr, 1998) as well as prolonged stress during a critical window associated with brain development (Anand, 2000; Mitchell & Boss, 2002). To summarize, discomfort may play a role in adverse physiological, behavioral, growth, and neurodevelopmental outcome.

Previous researches have investigated methods of comfort care and its effects on physiologic, behavioral, and phenomenologic responses that follow; Corff, Seideman, Venkataraman, Lutes, & Yates (1995) noted that “facilitated tucking” during the heel stick resulted in lower heart rates and less crying times. Miller & Anderson (1993) reported that nonnutritive sucking during invasive therapeutic procedures resulted in lower pulse rates and less frequent crying behavior compared to those receiving routine care. As Hill, Engle, Jorgensen, Kralik, & Whitman (2005) reported that the incorporating facilitated tucking during routine care events; the stress level may be reduced. Johnston & et al. (2003) showed that premature neonates who were 32 weeks postmenstrual age or older, kangaroo care could effectively decreased pain from heel lancing. Gibbins, Stevens, Hodnett, Pinelli, Ohlsson, & Darlington (2002) reported that the sucrose sucking during heel lancing could relief pain in neonates than nonnutritive sucking group. Punnee Comeoo, B.E. 2548 presented the effects of positioning on pain response from heel prick in preterm infants that were less than non-positioning. Modricin-Talbott, Harrison, Groer, & Younger (2003) found that providing the gentle touch intervention to the preterm infants would have less motor activity and behavioral distress and more quiet sleep during touch. A significant reduction in infant movement during the quiet period may imply greater neurobehavioural stability. Limb/body movements are a useful way of discriminating psychological and emotional stress in infants. The NICU can be made less noisy, less bright with less infant handling. The associated decrease in the infants' diastolic blood pressure and mean arterial pressure and movement activity imply that planned periods of quietness during the administration of neonatal intensive care may have benefits for sick infants in terms of improving their care and reducing their stress responses. From the previous researches, there were no mentions of care in providing holistic comfort for premature infants undergoing binasopharyngeal prongs in NICU environment. In this study, the researcher is interested in studying the effects of the holistic comfort care on physiological and behavioral responses for premature infants who undergoing binasopharyngeal prongs in NICU environment.

Conceptual Framework

Katherine Kolcaba's mid-range theory of holistic comfort was selected as the conceptual framework and guideline in this study. Kolcaba (1994) defined comfort as "the satisfaction (actively, passively, or cooperatively) of the basic human needs for relief, ease, and transcendence arising from healthcare situations that are stressful". According to Kolcaba (1992,1994), each of these comfort states represents a different intensity of comfort. Relief signifies the meeting of an urgent comfort need in the present, ease signifies a state of well-being or contentment, and transcendence signifies a state in which the patient is energized or inspired to perform optimally (Kolcaba, 1992). According to Kolcaba (1992, 1994, 2006), there are four contexts in which comfort occurs: the physical, psychospiritual, sociocultural, and environmental; all of which are interrelated. In other words, most discomforts that patients experience in the premature infants undergoing binasopharyngeal prongs in NICU environment setting, such as pain, stress, and suffer, may have physiological, psychological, sociocultural, and environmental comfort need components.

Physical comfort needs:- In premature infants who undergoing binasopharyngeal prongs, to suffer from physical discomfort related to the malpositioning of binasopharyngeal tube, nasopharyngeal symptoms, and gastric insufflation abdominal distention. Therefore, to relief discomfort in these infants will be able to prevent a cause of discomfort. Providing a physical comfort in the premature infants who undergoing binasopharyngeal prongs is able to prevent the decannulation or malpositioning or obstructing or kinking of nasopharyngeal prongs and to relieve gastric insufflation and abdominal distension. The infant then takes sufficient gas flow for inspiratory demand to result in a decreasing work of breathing whilst improving ventilation and oxygenation.

Psychospiritual and sociocultural comfort needs:- Psychospiritual and sociocultural discomfort related to the critical illness of premature infant in NICU environment. These premature infants cannot adjust to the hazardous extrauterine environment due to their limited psychosocial attributes and a preponderance of unmet basic needs that are more likely to perceive events as threatening and experience a maladaptive stress response. Sociocultural comfort needs are their needs for culturally sensitive reassurance, support, positive body language, and caring. One way of helping to achieve this is with the use of a comfort touch approach by touching. Touch is another method for caring expression. In a medical setting, most patients come to associate touch with fear and pain, since touch is used in the performance of painful or uncomfortable medical procedures (Ventegodt, Morad, & Merrick, 2004). In nursing, the term of comfort touch appears frequently in many research reports (Easter, 1997; Meehan, 1998; Wardell, 2001; Smith, Arnstein, Rosa, & Wells-Federman, 2002; Bond, 2003; Ventegodt, Morad, & Merrick, 2004; Frank, Frank, March, Makari-Judson, Barham, & Mertens, 2006; Dowd, Kolcaba, & Steiner, 2006; and Maville, Bowen, & Benham, 2008). Therapeutic touch is considered as a nursing intervention. Its proponents claim that it is integral to the art of nursing practice and can facilitate comfort and healing in a wide range of patients (Meehan, 1998). Social touch generally relates to concerns of social deprivation and social stimulation, promotes social bonds, attachment, and emotional integrity, enhance and foster the social, emotional, and physical development of preterm infant (Rose, 1984 cited in Jen-Juian, 2000). Positive touch as a caring to make it more gentle and humane in the present, and less damaging in term of outcome, by fostering a dialogue between the baby and family (Bond, 2003). Healing touch is a holistic therapy that has interrelated physical, psychological, social, and spiritual aspects, as a caring and healing modality (Maville, Bowen, & Benham, 2008).

Environmental comfort needs:- In premature infants who undergoing binasopharyngeal prongs, to suffer environmental discomfort related to the inappropriate sensory stimulation in NICU environment from visual stimulation-ambient and bright light exposure, auditory stimulation-noise pollution, tactile stimulation-frequent aversive procedures or excessive handling, and vestibular stimulation-inappropriate position. Therefore, a critical challenge for comfort care providers is improving the outcomes for premature infants. The issues of how to control various kinds of stimulation, provide appropriate sensory stimulation, and maintain the quality of life of premature infants become the central focus of care given in NICU.

In this study, the researcher believes that the vulnerable symptoms of premature infants from undergoing inserting binasopharyngeal prongs with intensive care in the NICU environment are being discomfort, over-stimulated from excessive handling and deprived of appropriates sensory input. These conditions are sources of stress and may affect state of well-being as there is no mention of the benefit of holistic comfort care in premature infants undergoing inserting binasopharyngeal prongs with intensive care in the NICU environment in any of the aforementioned studies. The holistic comfort care implementation is an intervention which uses developmentally supportive care to promote physical, psychological, sociocultural, and environmental comfort in premature infants undergoing inserting binasopharyngeal prongs with intensive care in the NICU environment. This protocol was developed by the researcher based on AARC guidelines: neonatal CPAP; the research works of Sakuntala Sudsaneha, B.E. 2548; and other related researches and articles. The holistic comfort care protocol is shown as follows:

1. Physical Comfort

1.1 Select the appropriate size prongs for the infant

< 1,500 g use binasopharyngeal prongs No. 2.5

1,500-2,000 g use binasopharyngeal prongs No. 3.0

1.2 Before insert binasopharyngeal prongs, provide him/her in the supine position by not excessive head rotation or neck extension.

1.3 Lubricate binasopharygeal prongs with water-soluble or 1% hydrocortisone.

1.4 Measure the nasopharyngeal tract length: the distance from the tip of the infant's nose to a point below the eye at the perpendicular to the middle of the eye.

1.5 Gently slide it along the floor of the nose while pushing the tip of the nose up and insert follow the natural curvature of the nasopharynx.

1.6 Secure binasopharyngeal prongs in appropriate position

1.7 Retain orogastric tube No. 8 and open distal tube.

2. Psychospiritual & Sociocultural Comfort

After securing binasopharyngeal prongs with plaster and connect to ventilator, apply gentle touch by placing one hand on the infant's head and the other hand on his/her back for 10 minutes and everytime when an infant awakes until he/she falls asleep.

3. Environmental Comfort (will be provided as quiet hour)

Providing optimal position; prone positions in a curled up, flexed position

Reducing light levels; < 60 ft-c

Reducing sound levels; < 50 dBA

Keeping handling at minimal

Therefore, the researcher is interested in studying the effects of the holistic comfort care on the physiological and behavioral responses including the means of heart rate, oxygen saturation, time for heart rate and oxygen saturation to return to baseline, and the mean of comfort behavior score of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in the neonatal intensive care unit. The conceptual framework of this study is shown in Figure 1.

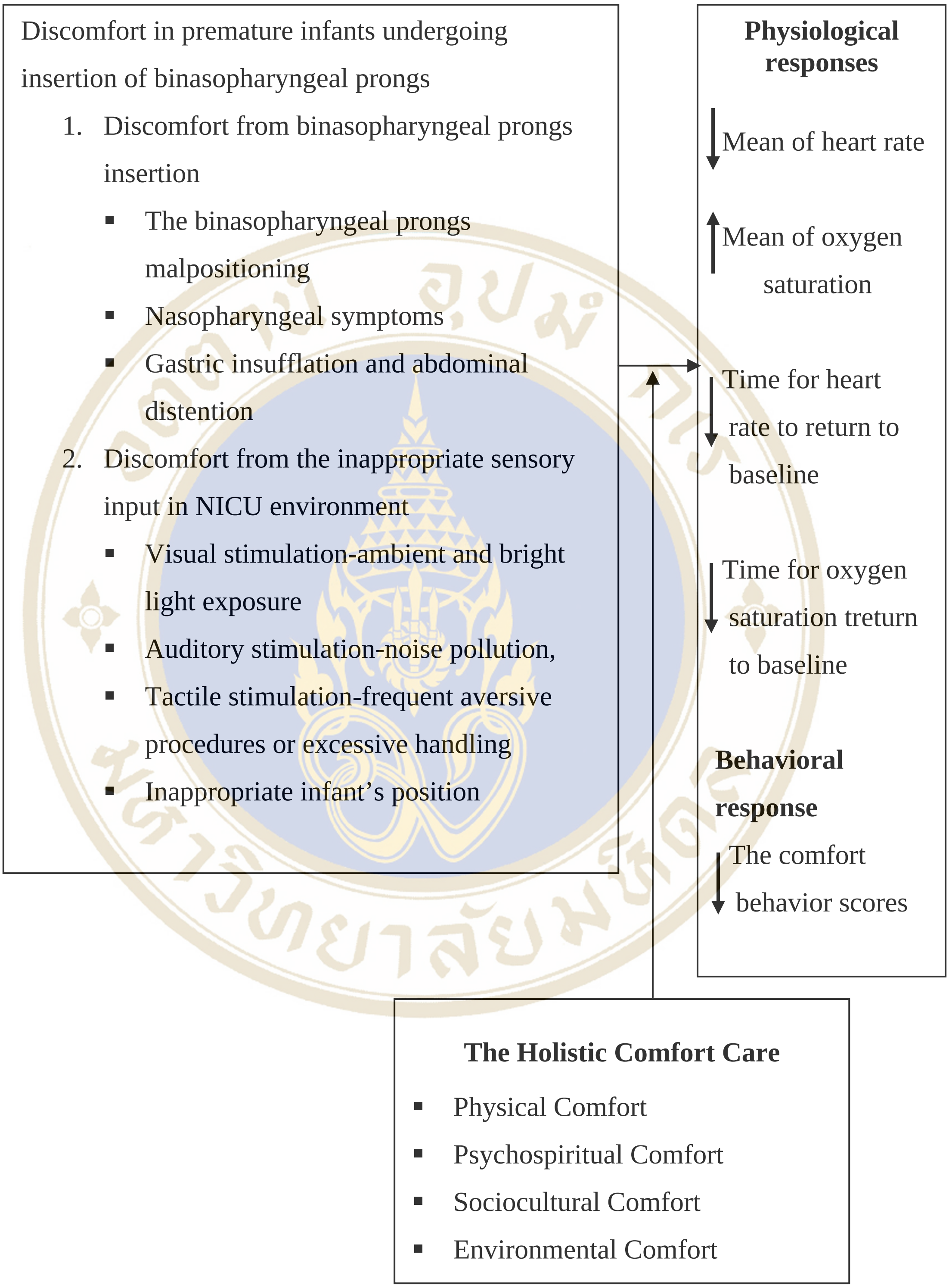


Figure 1 The conceptual framework of the study

Research Questions

Are there any differences of the mean of heart rate (HR), oxygen saturation (SpO_2), time for HR and SpO_2 to return to baseline, and the comfort behavior scores of premature infants undergoing insertion of binasopharygeal prongs after suctioning between holistic comfort care with quiet hour and usual care with non-quiet hour group?

Purpose of the Study

To compare the difference of the mean of heart rate (HR), oxygen saturation (SpO_2), time for of HR and SpO_2 to return to baseline, and the comfort behavior mean scores of premature infants undergoing insertion of binasopharygeal prongs after suctioning between holistic comfort care with quiet hour and usual care with non-quiet hour group.

Hypotheses

1. The mean of heart rate of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is lower than the usual care group.
2. The mean of oxygen saturation of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is higher than usual care group.
3. Time for heart rate to return to baseline of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is shorter than usual care group.
4. Time for oxygen saturation to return to baseline of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is shorter than usual care group.
5. The comfort behavior mean scores of premature infants undergoing binasopharyngeal prongs after suctioning in holistic comfort care group is lower than usual care group.

Scope of the Study

This study is a quasi-experimental research which aim at investigating the effects of the holistic comfort care on the physiological and behavioral responses including the mean of heart rate (HR), oxygen saturation (SpO_2), time for of HR and SpO_2 to return to baseline, and the comfort behavior mean scores of premature infants undergoing insertion of binasopharygeal prongs after suctioning. The subjects used in this study are sixty-two episodes from ten premature infants having been admitted to the neonatal intensive care unit, Ramathibodi Hospital, during December, 2007 and April, 2008.

Expect Outcomes and Benefits of this study

1. The holistic comfort care will promote comfort in four contexts of physical, psychospiritual, sociocultural and environmental in premature infants undergoing binasopharyngeal prongs after suctioning in the NICU.
2. A guideline will be set up to care for premature infants undergoing inserting binasopharygeal prongs after suctioning in NICU.

Definition of Terms

Holistic Comfort Care refers to care providing for premature infants undergoing insertion of binasopharyngeal prongs in which developed to prevent a cause of discomfort as to conduct stress and promote comfort of premature infants in four contexts of physical, environmental psychospiritual, and sociocultural comfort. The holistic comfort care will be provided as a 2-hour quiet period (from 11.30 a.m. to 1.30 p.m. for day shift and 6.00 to 8.00 p.m. for evening shift). During quiet hours, the infants are placed in prone position, sound and light levels are reduced whilst procedures and routine activities are kept at a minimum level in which the disturbance to the rest of premature infants is well protected.

1. Physical Comfort

    1.1 Select the appropriate size prongs for the infant

    < 1,500 g use binasopharyngeal prongs No. 2.5

    1,500-2,000 g use binasopharyngeal prongs No. 3.0

1.2 Before insert binasopharyngeal prongs, provide him/her in the supine position by not excessive head rotation or neck extension.

1.3 Lubricate binasopharygeal prongs with water-soluble or 1% hydrocortisone.

1.4 Measure the nasopharyngeal tract length: the distance from the tip of the infant's nose to a point below the eye at the perpendicular to the middle of the eye.

1.5 Gently slide it along the floor of the nose while pushing the tip of the nose up and insert follow the natural curvature of the nasopharynx.

1.6 Secure binasopharyngeal prongs in appropriate position

1.7 Retain orogastric tube No. 8 and open distal tube.

2. Psychospiritual & Sociocultural Comfort

After securing binasopharyngeal prongs with plaster and connect to ventilator, apply gentle touch by placing one hand on the infant's head and the other on his/her back for 10 minutes and everytime when an infant awakes until he/she falls asleep.

3. Environmental Comfort (will be provided as quiet hour)

Providing optimal position; prone positions in a curled up, flexed position

Reducing light levels; < 60 ft-c

Reducing sound levels; < 50 dBA

Keeping handling at minimal

Heart Rate (HR) refers to the rate of heart contraction in one-minute resulting from the pumping of lower left heart, which is expressed as beats/minute. It was measured by Masimo radical monitor and recording after insertion of binasopharyngeal prongs to infant's nares and after connecting the mechanical ventilator immediately, at minute 2, 4, 6, 8, 10 and every 10 minutes until completed 2 hours. The lower mean of heart rate, the better responses. However, it should be more than 100 beats per minute.

Oxygen Saturation (SpO_2) refers to the amount of oxygen bound to hemoglobin compared with hemoglobin's maximal ability for oxygen binding. Assess by Masimo radical monitor and recording after insertion of binasopharyngeal prongs to infant's nares and after connecting the mechanical ventilator immediately, at minute 2, 4, 6, 8, 10 and every 10 minutes until completed 2 hours. The higher mean of oxygen saturation, the better responses.

Time for Heart Rate to Return to Baseline refers to time duration of heart rate to return to baseline level of premature infants undergoing insertion of binasopharyngeal prongs after suctioning. Assess by Masimo radical monitor and the observation recording after inserting binasopharyngeal prongs to infant's nares and after connecting the mechanical ventilator. The shorter mean of time of heart rate to return to baseline, the better responses.

Time for Oxygen Saturation to Return to Baseline refers to time duration of oxygen saturation to return to baseline level of premature infants undergoing insertion of binasopharyngeal prongs after suctioning. Assess by Masimo radical monitor and the observation recording after inserting binasopharyngeal prongs to infant's nares and after connecting the mechanical ventilator. The shorter mean of time of oxygen saturation to return to baseline, the better responses.

Comfort Behavior refers to the behavior responses of a premature infant that exhibit relief, ease, and transcendence in four contexts: physical, psychospiritual, sociocultural, and environmental of comfort. The infant's comfort behaviors are scored by the modified COMFORT Behavior Scale (the modified COMFORT-B) that comprises of six behavioral items (alertness, calmness, muscle tone, movement, facial tension, and respiratory response), scores on the modified COMFORT scale are the observed variation of six items on 1 to 3 score. The total score is the sum of the six separate items scores (maximum 18). The lower the score the more comfort.

CHAPTER II
LITERATURE REVIEWS

This research is aimed to study the effects of holistic comfort care on physiological and behavioral responses of preterm infants undergoing insertion of binasopharyngeal prongs. The reviews of related literature and relevant studies are covered in the following topics:

1. Concepts of Comfort
2. Factors related to discomfort of premature infants undergoing insertion of binasopharyngeal prongs in NICU environment
3. Providing holistic comfort care for premature infants undergoing insertion of binasopharyngeal prongs in NICU
4. Outcomes measurement of holistic comfort care on the physiological and behavioral responses of premature infants

Concepts of Comfort

Definition of comfort

Four meanings of comfort occur in ordinary language, as reported in dictionary entries as follows : (1) comfort as a cause of relief from discomfort and/or of the state of comfort; (2) comfort as the state of ease and peaceful contentment; (3) comfort as relief from discomfort; and (4) comfort as whatever makes life easy or pleasurable (Kolcaba,1991). In nursing, the term of comfort appears frequently in clinical texts and the titles of many research reports (e.g. Gropper, 1992; Morse, Bottorff, & Hutchinson, 1994; Mcilveen & Morse, 1995; Wurzbach, 1996; Penrod, Morse, Wilson, 1999; Hawley, 2000; Morse, 2000; Kolcaba & Wilson, 2002). Comfort is therefore defined as a state, linked to outcomes such as ease, well-being and satisfaction (Tutton & Seer, 2003).

Kolcaba's Comfort Theory

Kolcaba identified comfort as associated with nursing care and comfort as a nursing outcome. She conceptualized comfort within the context of nursing and created the mid-range theory of comfort. The concepts are: (1) health care needs that include physical, psychospiritual, social, and environmental needs that arise for patients in stressful health care situation; (2) nursing interventions, an umbrella term for commitment by nurses and institutions to promote comfort care (intentional care by nurses directed to meeting comfort needs of patients); (3) interventing variables that will affect outcomes; (4) patient comfort, defined as the immediate state of being strengthened by having needs met in 4 contexts of human experience (physical, psychospiritual, social, and environmental); (5) health-seeking behaviors (HSBs), defined as patient actions of which they may or may not be aware and which may or may not be observed that are predictors or indicators of improved health, or as a peaceful death; HSBs are more accurate indicator of nurse productivity than the number of patients cared for; and (6) institutional integrity (Kolcaba, 2001).

In addition to holism, the concept of comfort is likewise not a new concept and has been a goal or outcome of nursing since Florence Nightingale. In their work on a concept analysis of comfort, Kolcaba (1991) discussed meaning of comfort and synthesized those meaning into three classes of comfort: the state (ease) sense, the relief sense, and the transcendence (renewal) sense. In the first sense, the state (ease) sense was defined as a state of calm or contentment, comfort does not mean absence discomfort but rather this state is relative to individual characteristics. That is persons differ in how they describe and experience discomfort and ease. In the second state, the relief sense was defined then as the experience of a patient who has had a specific comfort need met where there is relief from conditions that cause or contribute to discomfort. The final state, the transcendence (renewal) sense was defined as the state in which one rises above problem or pain, refers to a strengthened and having enhanced power and positive attitudes (Kolcaba, 2003).

Three basic assumptions of the theory of holistic comfort are as followings: people have holistic responses to complex stimuli; comfort is a desirable nursing outcome; and people strive to have their basic comfort needs met. There are two dimensions to the theory of holistic comfort. The first dimension has three states:

relief, ease, and transcendence (previously defined). The other dimension is the contexts of comfort: physical, psychospiritual, sociocultural, and environmental. Physical is pertaining to bodily sensations and homeostatic mechanism, immune function, etc. Psychospiritual is pertaining to internal awareness of self, including esteem, identity, meaning in one's life, and one's understood relationship to a higher order or being. Sociocultural is pertaining to interpersonal, family, and societal relationship in addition to family traditions, rituals, and religious practices. Environmental is pertaining to the external background of human experience (temperature, light, sound, odor, color, furniture, landscape, etc.) (Kolcaba, 2003).

The two dimensions (three states and four contexts) are arranged in two-dimensional grid resulting in 12 facets of comfort. The essentials of the theory are that needs (tensions induced by obstructing forces) originate from a stimulus. The stimulus situation consists of obstructing, positive, and interacting forces. Negative tension produces an imbalance between available obstructing and facilitating forces. Nurses identify needs for comfort and administer appropriate interventions intending to move tension in a positive direction. In turn, the patients determine whether the intervention has increased their comfort, whereas nurses may determine patients' perception of comfort through subjective and/or objective assessment. The endpoint of this theory is that there is an increase in comfort, indicating that negative tensions are decreased and positive tensions are increased (Koehn, 2000).

Factors Related Discomfort in Premature Infants Undergoing Inserting Binasopharyngeal Prongs in NICU Environment

Factors related discomfort in premature infants undergoing inserting binasopharyngeal prongs in NICU environment consist of: 1) discomfort from undergoing inserting binasopharyngeal prongs; and 2) discomfort from deprived of appropriates sensory input in NICU.

1. Discomfort from undergoing inserting binasopharyngeal prongs

These discomfort consist of the position of binasopharyngeal prongs, nasopharyngeal symptoms, and gastric insufflation and abdominal distention.

1.1 The position of binasopharyngeal prongs

Excessive head rotation or neck extension may alter the position of binasopharyngeal prongs placement or obstruct upper airway structures resulting in diminished or altered pressure, flow, and effective CPAP. In addition, the decannulation or malpositioning of nasopharyngeal prongs are causing fluctuation or reduced CPAP levels. Obstruction of prongs from mucous plugging or kinking of prongs may interfere with delivery of CPAP and resulting in decrease in FiO_2 through entrainment of room air via opposite naris or mouth. Complete obstruction of nasal prongs and nasopharyngeal tubes results in continued pressurization of the CPAP system (AARC, 2004).

1.2 Nasopharyngeal symptoms

Nasopharyngeal symptoms such as nasal irritation, mucosal swelling or erosion, excessive nasal dilatation or septal necrosis (Klein, 2006) nasal and throat dryness, rhinorrhea and sneezing are common in the initiation of CPAP treatment in patients with obstructive sleep apnea (Brander, Soirinsuo, & Lohela, 1999). One of the most common symptoms in such patients is nasal obstruction. Nasal obstruction leads to an increase in the inspiratory effort, with an increase in negative intraluminal pressure. This leads to upper airway instability and a greater tendency for pharyngeal collapse (Mirza, & Lanza, 1999). Although nasal and pharyngeal symptoms are common in patients using CPAP (Mirza, & Lanza, 1999; Lojander, Brander, & Ämmälä, 1999), it is not clear whether the symptoms were present prior to the initiation of treatment. Brander, Soirinsuo, & Lohela (1999) described an increase in the frequency and intensity of most nasal symptoms after the use of CPAP.

1.3 Gastric insufflation and abdominal distention

Gastric insufflation and abdominal distention occurs because the tone in the upper and lower esophageal sphincters is higher than the applied CPAP. Garrland (1985) reported an association between the use of ventilation via nasal prongs and increased risk of gastrointestinal perforation. Until recently, NIPPV was not synchronized with the infant's breathing. It is possible that gastrointestinal side-effects might be reduced if ventilator breaths were delivered in synchrony with laryngeal opening. Activation of manual breath may cause gastric insufflation and patient discomfort particularly if the peak pressure is set in appropriately high (ARCC, 2004).

2. Discomfort from deprived of appropriates sensory input in NICU

These discomfort consist of visual stimulation-ambient and bright light exposure, auditory stimulation-noise pollution, excessive handling, and inappropriate infant's position.

Visual stimulation-ambient and bright light exposure

The amount of light reaching the neonatal eye is governed by two groups of factors. Physical factors include intensity, spectral characteristics and duration of light exposure. Physiological factors are: frequency of eyelid opening, transmission of light through the closed eyelid, pupil reactivity and area transmission by the ocular tissues and retinal surface area. Retinal irradiance declines with increasing postmenstrual age. Mechanisms by which light may affect the neonatal eye and clinical conditions in which light have been implicated are considered (Robinson & Fielder, 1992). The womb generally is dark. After birth, ambient light increases markedly, although typically the room is kept dim and cycled with dark to some extent. In dim light, the newborn is more likely to open his or her eyes. A prolonged wake period linked to catecholamine release occurs during this transition to extrauterine life (Glass, 1999). Modern NICU are brightly lit environments with ambient light in excess of standard office light for adult. The general range reported has been 30 to 150 ft-c, with peaks over 1,500 ft-c from sunlight (Landry, Scheidt & Hammond, 1985). The intensity of ambient illumination for any individual infant is determined by the location of the crib in a room, the number of overhead light units, the size, location, and compass direction of windows. The duration of exposure generally is 24 hours a day over the length of hospital stay, which is a function of degree of immaturity and medical complications. Thus, light exposure is greater for those most vulnerable to visual problems. In animals, exposures to light have sustained damage to their photoreceptors, pigment epithelium, and choroid (Lanum, 1978; Williams, Baker, 1980 cited in Glass, 1999).

Bright light in an infant's face is a source of stress (Shogan & Schumann, 1993). Even routine ambient light level affects sleep and wake states in preterm infants. Lower ambient light is associated with significantly less active rapid eye movement sleep and significantly more quiet sleep among preterm infants at 35 to 36 weeks post conceptual age (Glass & Sostek, 1984 cited in Glass, 1999). Rapid eye movement is more destabilized state, with greater fluctuations of oxygen saturation and more frequent occurrence of apnea/bradycadia. Lower ambient light also is associated with increased eye opening and awakening periods. Light level influences an infant's response to sound. Under bright light, an infant shows an aversive response to a tone, whereas under a dim light the same tone elicits an orienting response (Haith, 1980 cited in Glass, 1999). Dimming the light has a quieting effect on caregivers, who are apt to behave as though someone was sleeping.

2.2 Auditory stimulation-noise pollution

Development of the auditory system during fetal life occurs within a uterine environment that contains rhythmic, structured, and patterned sound emanating predominantly from the mother. Internal sounds include maternal respirations, placental and heart rhythms, and the like. In the uterus, infant is exposed to sound level of about 40-60 dB. The NICU environment usually provides sound levels between 70-80 dB. It has been shown that when sound level exceeds 77 dB it causes discomfort to the baby (Garcia-Coll, 1990). The main sources of noise in NICU include telephone rings, equipment alarms, paging bleeps, air compressor, carting of equipment, and loud talking during the rounds, etc. Exposure of adults to excessive noise results in: (1) noise-induced hearing loss that shows a clear dose response relationship between its incidence and the intensity of exposure, and (2) noise-induced stimulation of the autonomic nervous system, which reportedly results in high blood pressure and cardiovascular disease (AAP, 1997). The physiological consequences of loud sound include startle response, apneic attacks, bradycardia or tachycardia and oxygen desaturation. At times, sudden elevation of blood pressure is a risk factor for development of intraventricular hemorrhage. The baby is unable to sleep and rest and may remain irritable or cranky. This may lead to depletion of energy reserves with poor weight gain due to constant state of arousal. High noise level may cause damage to the cochlea and even the adverse effects of ototoxic drugs may be enhanced. Preterm babies have 5 times greater risk of development of hearing loss compared to term babies (Robertson, Cooper-Peel, & Vos, 1999).

2.3 Excessive handling

After premature birth, tactile input is radically altered. He or she is exposed to air currents, cold stress, tape, instruments, handling by caregivers, and painful stimuli. Pressure is not uniform. The type and frequency of tactile stimulation imposed on a preterm newborn in the NICU would be overwhelming even for a healthy adult. Handling occurs more often among the sickest infant, typically related to procedures, generally is disturbing and often is discomfort and painful. On the average, sick preterm newborns are handled more than 150 times a day, with less than 10 minutes of consecutive uninterrupted rest (Tribotti, 1990 cited in Glass, 1999). Disturbance of sleep has biologic and immunologic consequences (Sassin, Paker, Mace, & et al, 1969 cited in Glass, 1999). Secretion of cortisol and adrenaline normally is inhibited during sleep. Growth hormone, which is released during quiet sleep, increases protein synthesis and mobilization of free fatty acids for energy use; thus, sleep facilitates healing (Glass, 1999). Excess handling has other significant physiologic consequences for the sick neonate. Blood pressure changes, alterations in cerebral blood flow, and episodes of oxygen desaturation are associated with noxious procedures, handling, or crying (Long, Philip, & Lucey, 1980; Perman & Volpe, 1983; Speidel, 1978 cited Glass, 1999). Fluctuations in blood pressure may contribute to intracranial hemorrhage in the unstable preterm infant (Volpe, 1989). Importantly, when caretakers monitor the infant's level of oxygenation during procedures, the severity of hypoxemic episodes can be reduced significantly (Long, Lucey, & Philip, 1980). Thus, handling could be stressful even for stable preterm infant.

2.4 Inappropriate infant's position

The premature infants have poor muscle tone and they lie with their arms and legs straight or extended. The extended posture for a long period of time may lead to abnormal tone with consequent delay in motor development. When a baby is handled roughly, he feels uncomfortable by squirming, crying and recoiling his arms and legs. There is evidence to suggest that rough handling may lead to hypoxemia and sudden elevation of blood pressure with risk of development of intraventricular hemorrhage (Weisel & Hubel, 1963). It has been shown that preterm babies maintain better oxygenation, temperature control and sleep pattern when they are nursed in a prone or lateral position (Gorski, 1991). Body position also affects gastric emptying and neurobehavioral development. All efforts should be made to provide babies with as comfortable a positioning as possible although it is impossible to achieve in utero comfort levels and cushioning.

Providing Holistic Comfort Care for Premature Infants Undergoing Inserion of Binasopharyngeal Prongs in NICU

Holistic comfort care entails the process of comforting actions and the product of enhanced comfort. The process of comfort includes the product of comfort, the construct of comfort care designates in 4 contexts of physical, psychospiritual, sociocultural, and environmental (Kolcaba, 1992).

Discomfort in infants undergoing binasopharyngeal prongs is a consequence of the malposition of binasopharygeal prongs, nasopharyngeal symptoms, and gastric insufflation and abdominal distention. Therefore, providing comfort for these infants by ways of prevention and relief causes of discomfort is important for holistic comfort care.

1. Prevention of the malpositioning of binasopharygeal

The malpositioning of nasopharyngeal prongs is relative to the position before/after inserting prongs. Infant's position before inserting binasopharyngeal prongs should be positioning in the supine position, if possible. Excessive head rotation or neck extension may alter the position of binasopharyngeal prongs placement or obstruct upper airway structures resulting in diminished or altered pressure, flow, and effective CPAP (AARC, 2004). Nasopharyngeal tract length measurement in infants and prongs are inserted to the nasopharyngeal level. The proper length of its insertion is important, especially in infants. When the prongs were inserted too far, problems including gastric distension, decreased aeration, and some bradycardia were noted. In extreme cases, laryngoscopic examination demonstrated the 4-cm prongs extending into the esophagus when inserted to their full length. Jackson, Vellucci, Johnson & Kilbride (2003) using a biomedical imaging visualization tool demonstrating measurement of the length of the nasopharynx compared with distances on the 3-dimensional model of the infant's head. The length of nasopharynx consistently correlated to the distance from the tip of the infant's nose to a point below the eye at the perpendicular to the middle of the eye.

2. Relief nasopharyngeal symptoms

While nasopharyngeal symptoms are relative to size and length, lubrication and method for insert prongs; it is important to use the right size nasal prongs for the infant. A common mistake is to use prongs that are too small, thinking that they will be more gentle than larger ones. However, the smaller prongs can advance too far into the nasal passage, eroding the tissue. The prongs should fit comfortably in the nares without distending them, yet provide an adequate seal (De Paoli, Morely, & Davis, 2003). Selection NP of the correct size, hold the airway next to the patient's cheek and compare the diameter of the airway to the diameter of the nostril. The airway diameter must be slightly smaller. Appropriate NP prongs size are usually the same or smaller than that required for intubation. If infant body weight lowers than 1500g, use binasopharyngeal prongs No. 2.5 and body weight 1500-2000g use binasopharyngeal prongs No. 3.0 (Klein, 2006). Lubrication the airway with water-soluble lubricant and insert it into the selected nostril is recommended. Then, gently slide it along the floor of the nose while pushing the tip of the nose. Once inserted, it should follow the natural curvature of the nasopharynx. If you encounter resistance, carefully twist the airway as insert it, but do not force it. If there is still resistance, try the other nostril or use a smaller airway. If you encounter resistance while removing the airway, apply water-soluble lubricant around the nares and the nasal end of the tube, and then gently rotate the tube until it can be removed (De Paoli, Morely, & Davis, 2003).

3. Relief discomfort from gastric insufflation and abdominal distension

It is common to see abdominal distension with CPAP due to discomfort from gastric insufflation and abdominal distension. Gas flow rates can be relatively high to maintain a CPAP pressure, and some gas will naturally take the path of least resistance and enter the gastrointestinal tract. Occasionally, the distension can be so great as to cause respiratory embarrassment. Radiographically, there is evidence of intestinal air, without features which would suggest other more sinister processes (i.e. intramural gas, free air, and thick-walled bowel loops). Treatment is to ensure that a large-bore intragastric tube is vented.

At the same time the premature infants who were admitted in NICU are experienced discomfort from deprived of appropriates sensory input in NICU which consist of visual stimulation-ambient and bright light exposure, auditory stimulation-noise pollution, excessive handling, and inappropriate infant's position. This holistic comfort care which included care for minimized discomfort from inappropriate sensory input in NICU environment such as: to provide comfort by reduce light and sound levels, providing appropriate infant's position, apply gentle touch, and keep handling at minimal.

1. Reduce light levels

Light sources include heat lamps, phototherapy lamps, ceiling lights, and daylight or the sun, which can increase the intensity of the light up to 2,500 foot-candles (ft-c) (Blackburn, 1996). These levels of lighting exceed the recommendations of the American Academy of Pediatrics (AAP, 1997) which suggests that ambient light level at each infant bedside should be adjustable from 1 to 60 ft-c. The visual stimuli in the NICU environment are often identified as sources of stimulation creating stress in preterm infants (Glass, 1999). Therefore, in order to provide comfort to reduce stress from light levels in preterm infants in NICU, the bright lights should be reduced below the recommended level.

2. Reduce sound levels

NICU sounds of concern are those produced by such equipment as incubator alarms, cardiorespiratory monitors, infusion pumps, and by health care professionals carrying out procedures, e.g. closing incubator doors without sufficient care, laughing, or talking loudly (Blackburn & Vandenberg, 1998). These sound levels exceed the recommendation of the AAP (1997), which suggests that NICU sound levels that exceed 45 dB are the cause for concern. Sound limit recommendations are to maintain a nursery with an hourly loudness equivalent (Leq) of 50 dB(A), an hourly sound level that exceeded 10 percent of the time (L10) of 55 dB(A) and a 1-second maximum sound level (Lmax) of 70 dB(A), all A-weighted, slow response scale (Graven, 2000). The excess auditory stimulation creates negative physiological and behavioral responses. Consequently, in order to provide comfort care activities to reduce negative response from undesirable sound in NICU, the ambient noise or the background sound should be reduced below the recommended level.

3. Keep handling at minimal

Handling is the most direct source of stress for preterm infants in the NICU. Excessive handling has significant physiological and behavioral stress, which is shown as adverse responses to handling include blood pressure changes, alterations in cerebral blood flow, increased intracranial pressure, hypoxia, bradycardia or tachycardia and episodes of oxygen desaturation, crying, or sleep disruptions that are associated with noxious procedures (Nair, Gupta & Jatana, 2003). In order to provide comfort for preterm infants in NICU, caregiving activities should be rescheduled with minimal disturbance.

4. Apply comfort touch

The kangaroo care may be an effective method to blunt pain responses because some of its components have been found to reduce the severity of responses to stress. For example, containment acts to prevent an increase in behavioral distress (Kurihara, Ciba, & Shimizu, 1996). The vestibular component of carrying, similar to the gentle stimulation of the mother's chest respiratory movements, produces a comforting effect during painful stimulation (Johnston, & et. al., 1997), but the kangaroo care is not suitable for this holistic intervention. A gentle touch could be done by placing one hand on the infant's head and one on its lower back while the infant was prone for 10 minutes. The findings related to gentle touch among premature infants suggest that touch may have positive effects such as lower oxygen requirement (Als, Lawhon, Duffy, & et al., 1994; Harrison, Leeper, & Yoon, 1990), fewer days on respiratory support (Als, Lawhon, Duffy, & et al., 1994), less apnea, better weight gain (Scafidi, Field, & Schangberg, 1993), shorter period of tube feeding (Scarr-Salapatek, & Williams, 1973 cited in Jen-Juian, 2000), better state organization, and improved neurobehavioral status (Kuhn, Schanberg, Field, & et al., 1991). The effects of gentle human touch in preterm infants has a soothing effect as evidenced by decreased levels of active sleep, motor activity, and behavioral distress (Harrison, Williams, Berbaum, Stem, & Leeper, 2000), and shorter duration of hospitalization (Kuhn, Schanberg, Field, & et al., 1991). Gentle touch may promote the infant's physical and emotional growth (Resnick, Eyler, Nelson, & et al., 1987). Furthermore, the findings document several positive, beneficial behavioral effects of the intervention on preterm infants and indicate this type of touching may be appropriate for infants in the neonatal intensive care unit (Modrcin-Talbott, Harrison, Groer, & Younger, 2003).

5. Providing appropriate infant's position

The comfort care activities in providing optimal position, a prone position, by placing the infant on a small folded strip from shoulder to hip could allow more physiologic flexion and adduction. For inside lying, it may be easier to position the infant in soft flexion. Maintenance of posture can be facilitated by nesting the infant in soft rolls but must not reach above the shoulder level. A nest promotes a flexed posture of the limbs with adduction of shoulders, facilitates elegant wrist movements and movements towards and across the midline and reduces abrupt movements and frozen postures of the arms and legs (Ferrari, Bertoncelli, Gallo, Roversi, Guerra, Ranzi, & Hadders-Algra, 2007).

Therefore, the conceptual framework of Kolcaba's theory can develop guideline for the holistic comfort care in premature infants undergoing inserting binasopharyngeal prongs in NICU to promote the physical, psychospiritual, sociocultural, and environmental comfort as follows:

1. Physical Comfort

1.1 Select the appropriate size prongs for the infant

< 1,500 g use binasopharyngeal prongs No. 2.5

1,500-2,000 g use binasopharyngeal prongs No. 3.0

1.2 Before insert binasopharyngeal prongs, to positioning him/her in the supine position not excessive head rotation or neck extension.

1.3 Lubricate binasopharygeal prongs with water-soluble or 1% hydrocortisone.

1.4 Nasopharyngeal tract length measurement: the distance from the tip of the infant's nose to a point below the eye at the perpendicular to the middle of the eye.

1.5 Gently slide it along the floor of the nose while pushing the tip of the nose up and insert follow the natural curvature of the nasopharynx.

1.6 Secure binasopharyngeal prongs in appropriate position

1.7 Retain orogastric tube No. 8 and open distal tube.

2. Psychospiritual & Sociocultural Comfort

After securing binasopharyngeal prongs with plaster and connect to ventilator, apply gentle touch by placing one hand on the infant's head and the other on his/her back for 10 minutes.

3. Environmental Comfort (will be provided as quiet hour)

3.1 Providing appropriate infant's position

To provide the appropriate infant's position is to encourage an infant's position as much flexed as possible. This could be done in sequence as follows:

Position an infant into flexed, prone and followed by placing a small-soft roll under the head and neck to tuck the head in neutral position or slightly extension. Provide a nest, which surrounds the infant with walls of a big-soft roll and supports the feet by bracing them with it. This containment prevents retraction of shoulders and external rotation of hips and extremities. Bring the hands to midline across the chest or near the mouth as well. Elevate the mattress to 15-30 degrees.

3.2 Reducing light levels: to reduce light level could be done by covering the top, left, right, and back sides of the incubator with a cloth.

3.3 Reducing sound levels at minimal: to reduce sound levels could be done with the eight step procedures as follows

3.3.1 Place the sign "Holistic Comfort Care" on the incubator while the holistic comfort care is applied.

3.3.2 Reduce the voice to a minimal when talking near the baby.

3.3.3 Decrease the telephone ringing volume and the equipment alarm to a minimum level in which observers could be easily alerted.

3.3.4 Avoid all physician rounds.

3.3.5 Avoid large equipment entering the unit. Make special effort not to slam doors, drawers, trash can, and incubator doors as well as drag chairs forward all phone calls to the main desk.

3.3.6 Respond rapidly to monitoring alarms or crying infants.

3.4 Keeping handling at minimal: to keeping handling at minimal could be done with the two step procedures as follows:

3.4.1 Wear diaper when the holistic comfort care protocol is applied.

3.4.2 Make special effort not to handling the infant and reschedule caregiving activities to minimal disturbance when the holistic comfort care is applied.

Outcomes Measurement of Holistic Comfort Care on Physiological and Behavioral Responses of Premature Infants

Premature infants hospitalized in NICUs are exposed to numerous stressors, including discomfort, painful stimuli, and disruption of sleep (Harrison, Roane, & Weaver, 2003). The organism's response to stress is multidimensional with three components: (a) physiologic (increase muscle tension, heart rate, blood pressure, hormonal response, etc.); (b) behavioral (agitated movement, grimacing, crying, avoidance, etc); and (c) phenomenologic (self-report of anxiety, fear, pain, etc). The assessment of the physiological and behavioral responses associated with the information about the infant's functional stability and response to stress (Holditch-Davis, Blackburn, & Vandenberg, 2003).

1. The Physiological Responses to the Holistic Comfort Care

Physiological indicators of stress, pain, and discomfort are similar and include changes in heart rate (HR), blood pressure, and oxygen saturation whereas breathing is the most frequently used physiologic indicator of stress, pain, and discomfort. Heart rate and blood pressure will rise, oxygen saturation will decrease and breathing will become shallow or irregular (Van Dijk, Simons, & Tibboel, 2004). Other indicators primarily used in research are intracranial pressure, skin color, vagal tone, palmar sweating, and plasma or salivary cortisol levels (Anand, 2000; Peters, 1998). In this study, heart rate and oxygen saturation are used to evaluate the physiological responses to the holistic comfort care.

Currently, monitoring is the permanent activity in continuously and evaluating the physiologic function of the patient in order to guide management decisions and to assess the impact of treatment. Monitoring may be invasive or noninvasive.

Invasive monitoring penetrates the body of the patient such as arterial blood pressure, central venous pressure (CVP), and pulmonary artery.

Noninvasive monitoring does not penetrate the body. They typically rest on the skin of the patient such as pulse oximeter, capnometer, noninvasive blood pressure (NIBP), and bedside monitoring. In this noninvasive monitoring, there is no pain, whilst reduce complications and reduce expenses including increase of comfort more than invasive monitoring.

1.1 Heart rate

The function of the heart is considered in terms of the electrical and mechanical activities of the myocardial muscle. The cellular aspects provide a better understanding of the process. The electrical events precede and initiate the mechanical response and require certain properties inherent to cardiac muscle cells: automaticity, rhythmicity, excitability, and conductivity. The mechanical events of cardiac contraction are the result of four major determinants: preload, afterload, contractility, and distensibility. The heart rate, normally an extrinsic influence, helps to determine cardiac output (Bullock, 2000).

The divisions of the autonomic nervous system (ANS) are consisted of: sympathetic and parasympathetic, exert external influences on myocardial contractility and rate. The cardiovascular center in the medulla receives input from other areas of the brain and relays messages throughout the body. In the heart, such messages include the autonomic nervous system adjustment of the heart rate and contractility to the body's demands. The autonomic nervous system has an enhancing or restraining effect on the inherent pacemaker system and can alter the automaticity of abnormal pacemaker systems.

1.1.1 Sympathetic nervous system (SNS)

The chemical mediators of the sympathetic nervous system are norepinephrine and epinephrine, collectively called catecholamines. The SNS releases these mediators during the stress reaction. These mediators stimulate α- and β-adrenergic receptors on target cells, which cause specific effects. Receptors from the sympathetic nervous system are present in the atrial wall, ventricles, and SA and AV nodes. When stimulated, these cardioaccelerator fiber release norepinephrine, which stimulates β_1-receptors to increase the rate of depolarization and impulse transmission through the conduction tissue. Increased sympathetic tone increases cardiac rate and the contractility of myocardial muscle. The increased contractility is due to enhanced calcium entry through the myocardial muscle calcium channels. The sympathetic nervous system stimulation predominantly affects the SA node and causes a sinus tachycardia.

The effects of the sympathetic nervous system on the coronary arteries are somewhat more complex. Norepinephrine causes coronary artery vasoconstriction and increased oxygen extraction by the myocardial cell. Some individuals have a hyperactive response to norepinephrine and exhibit coronary artery vasospasm during stressful situations. Epinephrine, which is released from the adrenal glands, has a secondary dilating action on the coronary arteries. Its main actions are to produce tachycardia and increase contractility (a positive inotropic effect).

Prostaglandins, a group of chemically related substances, may be stimulated secondarily in the sympathetic stress response. They are synthesized by the myocardial cells and arteries and usually dilate the coronary arteries.

Normally, autoregulation of coronary blood flow appears to counteract the effects of neural stimulation. The changes of perfusion pressure are counteracted by changes in vascular resistance, so that blood flow remains rather constant. Autoregulation is probably due to the response of smooth muscle in the arterioles to stretch, so that when the local blood pressure rises the vessels constrict, and when it falls, they dilate. When SNS stimulation induces coronary vasoconstriction, coronary autoregulation usually overrides the mechanism and ischemia is prevented.

1.1.2 Parasympathetic nervous system (PSNS)

The parasympathetic nervous system is mediated through the chemical transmitter acetylcholine, which is released from vagal fibers. The major effects of vagal stimulation are a restraining or allowing influence on the SA node, atrial muscle, and AV node. Vagal stimulation slows the heart rate by restraining the rate of diastolic depolarization in the conduction tissue. It causes only a slight decrease in ventricular contractility.

A balance exists between sympathetic nervous system and parasympathetic nervous system stimulation of the heart, but the predominant system appears to be the parasympathetic nervous system. Evidence supporting this is that resting heart rate is usually lower than the inherent automatic SA pacing rate (Banasik, 1995; Bullock, 2000).

In addition to baroreceptors and chemoreceptors, other sensory fibers that detect pressure are located within the cardiac chambers. These sensory receptors respond to changes in the intrachamber pressure, which reflect the volume of blood in the chamber. Atrial or ventricular overdistention activates the sympathetic system and increases heart rate. Heart rate may also be influenced by higher central nervous system activities that do not involve reflex pathways.

In general, an increase in heart rate will result in an increase in cardiac output. However, at very high heart rates, cardiac output may actually fall. At high heart rates, the time for diastolic ventricular filling is significantly reduced, resulting in a low stroke volume. The benefit of increased heart rate is; therefore, undermined by impaired pumping efficiency (Banasik, 1995).

In the NICU, the measurement of heart rate can be monitored by the bedside monitoring that shows electrical wave of heart (Decker, 1987 referred in Saowaluk Jiritamkun, B.E. 2534).

1.2 Oxygen saturation: SpO_2

Basic principles of oxygenation are best explained in relation to the partial pressure of oxygen (PO_2) and the percentage of hemoglobin oxygen saturation (SpO_2).

Oxygen in the blood is carried in two ways: dissolved in the liquid part of the blood plasma and in chemical combination with hemoglobin. Most oxygen is transported in the second manner.

The amount of dissolved oxygen carried in the plasma is directly proportional to the partial pressure of oxygen (Henry’s law). There is 0.003 ml of oxygen dissolved in each 100 ml of blood for each 1 mmHg partial pressure of oxygen. Thus, at an ideal PaO_2 of 100 mmHg, only 0.3 ml of oxygen would be carried per 100 ml of plasma. The individual’s normal resting cardiac output is 5 L/minute.

Most of oxygen in the body is transported to the cells in combination with hemoglobin. Oxygen combines loosely and reversibly with the heme portion of hemoglobin. When the PO_2 is low, as in the tissue capillaries, the oxygen is released from the hemoglobin.

The amount of oxygen carried in the blood by hemoglobin is directly dependent on the concentration of hemoglobin. The average individual has about 15 g of hemoglobin in each 100 ml in blood. Each gram of hemoglobin has the maximum capability to combine with 1.34 ml of oxygen. Therefore, a hemoglobin level of 15 g/ 100 ml would result in 20.1 ml of oxygen combined with hemoglobin and saturation (Hazinski, 1992).

The percentage of hemoglobin saturation with oxygen maybe abbreviated as % HbO_2 saturation. In a clinical setting, oxygen saturation is defined as the amount of hemoglobin actually combined with oxygen and divided by the amount of hemoglobin available. The formula is written as follows:

$$\% \ HbO_2 \text{ saturation} = \frac{\text{Hb combined with oxygen}}{\text{Total hemoglobin}} \times 100\%$$

The relationship between the PaO_2 and the hemoglobin saturation is expressed by the oxyhemoglobin dissociation curve as shown in Figure 3. The curve is not linear; instead, it is S shaped, with a large plateau at the higher levels of PaO_2. There are several important parts of the oxyhemoglobin dissociation curve. The curve flattens when the PaO_2 exceed 80 to 100 mmHg. This means that although the PaO_2 continues to rise beyond 100 mmHg, the hemoglobin cannot become more saturated than 100%; it cannot carry any more oxygen. Thus, any further rise in the PaO_2 will result in only small increases in the amount of dissolved oxygen in the blood. Therefore, a rise in PaO_2 from 100 to 700 torr does not mean the seven times more oxygen is carried in the blood. In fact, this rise is associated with only approximately a 10% increase in oxygen content. Because the hemoglobin is fully saturated once the PaO_2 reaches 100 mmHg, there is usually no advantage in maintaining the patient's PaO_2 any higher than this value.

The slope of the oxyhemoglobin dissociation curve becomes very steep once the PaO_2 is less than 60 mmHg. Thus, when the patient's PaO_2 falls below 60 mmHg, even small decreases in the PaO_2 are associated with a significant fall in the hemoglobin saturation and the arterial oxygen content. Therefore, if possible, the patient's PaO_2 should be maintained above 60 mmHg.

The shape of the oxyhemoglobin curve may be altered by several factors. If the curve is shifted to the right, this means that hemoglobin binds less oxygen at any partial pressure of oxygen. Conversely, if the curve is shifted to the left, hemoglobin binds more oxygen at any given PaO_2. Factors that shift the curve to the right include acidosis, hypercapnia, and hyperthermia. Under these conditions, less oxygen is bound at any given PO_2, but within the normal range the amount of oxygen released to tissues is enhanced. In contrast, the oxyhemoglobin dissociation curve may be shifted to the left by alkalosis, hypocapnia, and hypothermia. While these factors increase hemoglobin saturation with oxygen at any given partial pressure of oxygen, hemoglobin release to tissues may be impaired (Hazinski, 1992).

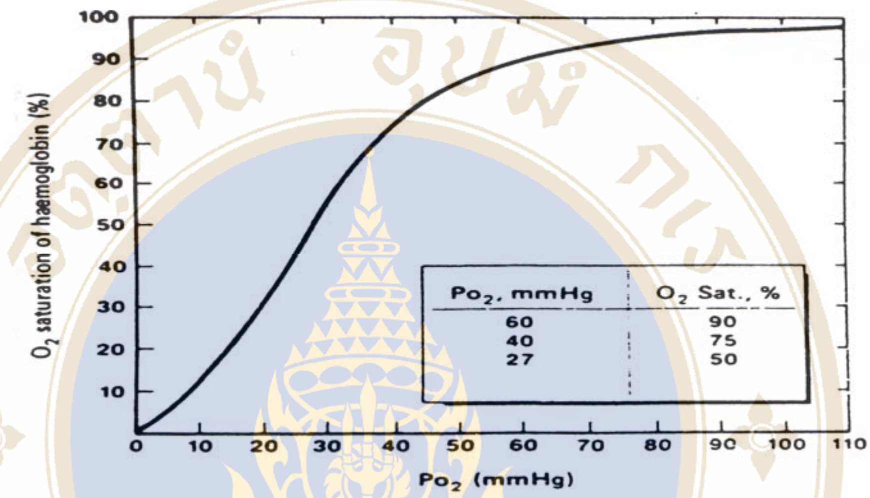


Figure 2 Oxygen-hemoglobin dissociation curve
(Supitcha Sangchote, B.E. 2543: 109)

The assessment heart rate and oxygensaturation tools in premature infants

Pulse oximeter

Pulse oximeter is a device that provides continuous and noninvasive measurements of arterial oxygen saturation.

Pulse oximeter is based on two primary principles of light transmission and reception called spectrophotometry and photoplethysmography. It is used to measure arterial oxygen saturation non-invasively. Spectrophotometry measures the percentage of oxygenated hemoglobin in the blood and photoplethysmography is used to differentiate arterial from venous blood.

The measurements of hemoglobin and its derivatives by spectrophotometry are based on the Lambert-Beer laws of absorption. This law combines Lambert's law and Beer's law, both of which describe transmission of radiation through an absorbing substance. Lambert's law states that the optical density of a homogeneous medium is directly of a homogeneous absorbing substance. Lambert-Beer laws specify the relationship of the optical density to both path length and concentration of the absorbing substance.

Spectrophotometry can be used to accurately measure hemoglobin and its derivatives. Given the condition according to the Lumbert-Beer laws that the blood must be hemolyzed before analysis, it must be withdrawn from a subject. These in vitro measurements of hemolyzed blood by spectrophotometry are conducted by a device called co-oximeter or hemoximeter. Photoplethysmography uses reflection or transmission of light through vascular tissue to measure arterial pressure waveforms generated by the cardiac cycle (McCarthy, Decker, & Stoller, 1993).

Pulse oximeter estimates arterial oxygen saturation by measuring the absorption of light (of 2 wavelengths, approximately 660 nm and 940 nm) in human tissue beds. The wavelengths of red light (600 nm) is more absorbed by deoxygenated hemoglobin than by oxygenated hemoglobin, whereas the wavelengths of infrared light (940 nm) is more absorbed by oxygenated hemoglobin than by deoxygenated hemoglobin. As light passes through human tissue, it is absorbed in various degrees by tissue, bone, blood vessels, fluids, skin, venous blood, and arterial blood, including various types of hemoglobin. The light absorption changes as the amount of blood in the tissue bed changes and as the relative amounts of oxygenated and deoxygenated hemoglobin change. Measuring the changes in light absorption allows estimation of heart rate and arterial oxygen saturation. To measure accurately, the oximeter must distinguish between the background (or constant) absorption and the pulsatile changes in absorption caused by the changing blood volume with each heartbeat. The background absorption can change when there is a change in the shape or position of the tissues through the light passes, which can cause false readings (Salyer, 2003).

Accuracy of pulse oximeter

There are numerous studies of the accuracy and precision of pulse oximeters in various populations. The methods for describing accuracy are differed in those studies, making an overall summary of accuracy challenging. There are considerable performance differences among the various brands of pulse oximeter, which are probably due to differences in the signal processing software and calibration curves. The bias of the pulse oximeter is the mean difference between simultaneous pulse oximetric and co-oximetric measurements of oxygen saturation. Most manufactures claim confidence limits in any given pulse oximeter reading of ± 4% for readings above 70%. At the oxygen saturation below 80%, the accuracy is worse, although its clinical importance is still questionable (Salyer, 2003).

Limitations of pulse oximeter

Pulse oximeter has several well known limitations as follows (Aroonwan Pruettipan, B.E.2545; Salyer, 2003):

1. Poor perfusion

The accuracy of pulse oximeters depends on the function of pulsating vascular bed. Under the conditions of low blood flow such as cardiac arrest or severe peripheral vasoconstriction, pulse oximeter becomes unreliable.

2. Ambient light

If the finger probe of pulse oximeter does not fit correctly, light can be shunted directly from the LEDs to the photodetector. This will cause a falsely low or elevated SpO_2. High intensity of light from fluorescent lights and operation-room lights has been reported to interfere with pulse oximeter performance.

3. Dyshemoglobinemia

Because pulse oximeters are unable to distinguish between oxygenated hemoglobin and the various dysfunctional hemoglobins, such as methemoglobin and carboxyhemoglobin, they are unable to bind with and carry oxygen.

4. Skin pigmentation

As skin pigmentation darkens, pulse oximeter performance deteriorates. Several studies have shown that the accuracy and performance of pulse oximeters are affected by deeply pigmented skin.

5. Motion artifact

Motion of probe can produce unreliable and inaccurate pulse oximeter readings.

6. Anemia

Although pulse oximeters are generally reliable over a wide range hemoglobin levels, they become less accurate and reliable with conditions of severe anemia (Hb < 8 g/dl at low saturations, and hematocrit < 10% at all saturation).

In this study, the researcher selected pulse oximeter (Masimo pulse oximeter) as an instrument to measure the heart rate and oxygen saturation. This device continuously monitors and displays arterial blood oxygen saturation (SpO_2), heart rate.

This oximeter determines oxygen saturation and heart rate by passing two low intensity wavelengths of light, one red and one infrared, through body tissue to a photodetector. Heart rate identification is accomplished by using plethysmographic techniques and oxygen saturation measurements which are determined by using spectrophotometric oximetry principles. A few seconds after the patient is attached, the oxygen saturation measurement and heart rate measurement should be shown.

Normal of heart rates in children (Hazinski, 1992)

Age	Awake heart rate (per min.)	Sleeping heart rate (per min.)
Neonate	100-180	80-160
Infant	100-160	75-160

Normal of oxygen saturation in preterm infants : Oxygen saturation 91 to 95% (Brady & Ceruti, 1966).

2. The Behavioral Responses to the Holistic Comfort Care

The behavioral responses to comfort may also be considered indicators of pain, distress and disruption of sleep because distress, pain and comfort are interrelated (Frazier, Moser, Riegal et al., 2002). The alleviation of distress and pain is leading to promotion of comfort (McKinley, Stein-Parbury et al., 2004). The ability to rest and sleep is considered indicators of overall comfort (Hummel & Van Dijk, 2006). The tools designed to assess comfort that comprises behavioral responses items are described as follows:

2.1 Facial expression

Facial expression is generally considered the most sensitive indicator of acute pain and short pain in neonates (Grunau & Craig, 1990; Craig, 1998). Total facial activity and a cluster of specific facial features (brow bulge, eye squeeze, nasolabial furrow and open mouth) have been shown to be significantly associated with acute and postoperative pain (Grunau & Craig, 1990; Grunau, Johnston, & Craig, 1990).

2.2 Body movement and (muscle) tone

Body movement as pain indicator focuses on observation of arm and leg activity. Increased activity is though to indicate more pain. Posture and muscle tone are thought to be more tense when pain is present. Posture is assessed by observation. Muscle tone is described by observation of clenched fists and toes or by feeling an arm or leg after the observation period (Hummel & van Dijk, 2006).

2.3 Crying

Crying features have been extensively studied using spectrographic devices. Short latency to onset of cry, longer duration of the first cry cycle, higher fundamental frequency and greater intensity in the upper ranges may be pain specific cry feature (Grunau, Johnston, & Craig, 1990).

2.4 Behavioral state/sleep pattern

Behavioral state is included in many pain instruments even though it is a modifying factor rather than an indicator of pain. The ability to rest and sleep is considered indicators of overall comfort (Hummel & van Dijk, 2006). The underlying idea is that infants in pain are thought to have more difficulty falling asleep (van Dijk, Simons, & Tibboel, 2004).

2.5 Consolability

Consolability is a subjective and vague concept, as there is no standard method to console a crying or distress neonate. Recently developed instrument-the Echelle Douleur Inconfort Nouveau-Ne, neonatal pain and discomfort scale (EDIN) (Debillon, Zupan, Ravault, Magny, & Dehan, 2001)-have nevertheless incorporated consolability, perhaps because, clinical nurses rely on consolability as a measure of comfort.

The assessment comfort tools in premature infants

1. The COMFORT Scale

The COMFORT scale (Ambuel, Hamlett, Marx, & Blummer, 1992) was originally designed to assess distress/discomfort in ventilated children in an intensive unit. Scores on the COMFORT scale are the observed variation of eight items on 1 to 5 scale. The total score is the sum of the eight separate items scores (maximum 40), the higher the score the lower the comfort. The COMFORT scale comprises of eight items with five response categories, each consisting of distinct behavioral descriptions. Six behavioral items (Alertness, Calmness, Muscle tone, Movement, Facial tension, and Respiratory response), and two physiological items: Heart rate (HR) and mean arterial pressure (MAP) are described in Figure 3.

Items	Score
Alertness	
Deeply asleep	1
Lightly asleep	2
Drowsy	3
Alert and awake	4
Hyper-alert	5
Calmness/Agitation	
Calm	1
Slight anxious	2
Anxious	3
Very anxious	4
Panicky	5
Respiratory response	
No coughing or no spontaneous respiration	1
Spontaneous respiration	2
Occasional cough/resists ventilator	3
Actively breathes against ventilator	4
Fights ventilator-coughs/chokes/gags	5
Physical movement	
None	1
Occasional, slight movements	2
Frequent, slight movements	3
Vigorous movement of extremities only	4
Vigorous movement of extremities, torso and head	5
Blood pressure (MAP) baseline	
Blood pressure below baseline	1
Blood pressure consistently at baseline	2
Infrequent elevations of 15% or more	3
Frequent elevations of 15% or more	4
Sustained elevation greater than or equal	5

Figure 3 The COMFORT Scale

Items	Score
Heart rate baseline	
Heart rate below baseline	1
Heart rate consistently at baseline	2
Infrequent elevations of 15% or more	3
Frequent elevations of 15% or more	4
Sustained elevation greater than or equal	5
Muscle tone	
Relaxed/None	1
Reduced muscle tone	2
Normal muscle tone	3
Increased tone/flexion-fingers/toes	4
Extreme rigidity/flexion-fingers/toes	5
Facial tension	
Relaxed	1
Normal tone	2
Some tension	3
Full facial tension	4
Hyper-alert	5

Figure 3 The COMFORT Scale (continued).

2. The COMFORT-Behavior (COMFORT-B)

Ambuel, Hamlett, Marx, & Blummer (1992) devised the COMFORT scale, which assessed the behavioral distress and the physiologic distress in a child admitted to the pediatric intensive unit (PICU). The COMFORT scale seems to be the most practical scoring system for PICU use. Although the COMFORT scale was described and validated for measuring discomfort in ventilated pediatric patients, the use of this instrument in the clinical PICU setting is disputed. The correct use of the physiologic variables of the COMFORT scale implies that reference values for heart rate and arterial blood pressure are adjusted each day. Because these physiologic variables are titrated by inotropic and other drugs often used in PICU, the assessment on the usefulness of physiologic variables in judgment of sedation and determining new cutoff points for the COMFORT "behavioral" scale (COMFORT-B), was using only for observational purpose. The COMFORT-B scale is a reliable alternative to the original COMFORT scale (Ista, van Dijk, Tibboel, & de Hoog, 2005), as described in Figure 4.

Items	**Score**
Alertness	
Deeply asleep	1
Lightly asleep	2
Drowsy	3
Alert and awake	4
Hyper-alert	5
Calmness/Agitation	
Calm	1
Slight anxious	2
Anxious	3
Very anxious	4
Panicky	5
Respiratory response	
No coughing or no spontaneous respiration	1
Spontaneous respiration	2
Occasional cough/resists ventilator	3
Actively breathes against ventilator	4
Fights ventilator-coughs/chokes/gags	5
Physical movement	
None	1
Occasional, slight movements	2
Frequent, slight movements	3
Vigorous movement of extremities only	4
Vigorous movement of extremities, torso and head	5

Figure 4 The COMFORT-Behavior (COMFORT-B)

Items	Score
Muscle tone	
Relaxed/None	1
Reduced muscle tone	2
Normal muscle tone	3
Increased tone/flexion-fingers/toes	4
Extreme rigidity/flexion-fingers/toes	5
Facial tension	
Relaxed	1
Normal tone	2
Some tension	3
Full facial tension	4
Hyper-alert	5

Figure 4 The COMFORT-Behavior (COMFORT-B) (continued).

3. The Echelle Douleur Inconfort Nouveau-Ne, neonatal pain and discomfort scale (EDIN)

To develop and validate a scale suitable for use in clinical practice as a tool for assessing prolonged pain in premature infants, pain indicators identified by observation of preterm infants and selected by a panel of experts were used to develop the EDIN scale. A cohort of preterm infants was studied prospectively to determine construct validity, inter-rater reliability, and internal consistency of the scale. The EDIN scale uses five behavioral indicators of prolonged pain: facial activity, body movements, quality of sleep, quality of contact with nurses, and consolability (Debillon, Zupan, Ravault, Magny, & Dehan, 2000), as described in Figure 5.

Item	Score
Facial activity	
Relaxed facial activity	0
Transient grimaces with frowning, lip purse and chin quiver or tautness	1
Frequent grimaces, lasting grimaces	2
Permanent grimaces resembling crying or blank face	3
Body movements	
Relaxed body movements	0
Transient agitation often quiet	1
Frequent agitation but can be calmed down	2
Permanent agitation with contraction of fingers and toes and hypertonia of limbs or infrequent, slow movement and prostration	3
Quality of sleep	
Falls asleep easily	0
Falls asleep with difficulty	1
Frequent, spontaneous arousals independent of nursing, restless sleep	2
Sleepless	
Quality of contact with nurses	
Smiles, attentive to voice	0
Transient apprehension during interactions with nurses	1
Difficulty communications with nurses. Cries in response to minor stimulation	2
Refuses to communicate with nurses. No interpersonal rapport. Moans without stimulation	3

Figure 5 The Echelle Douleur Inconfort Nouveau-Ne, neonatal pain and discomfort scale (EDIN)

In this study, the researcher used the modified COMFORT-B (as described in Chapter 3) to assess the behavioral responses to comfort care undergoing binasopharyngeal prongs. This tool was appropriated for directly measuring discomfort in premature infants with mechanical ventilation. Whist the mean arterial pressure item in the COMFORT scale and quality of contact with nurses in EDIN are not suitable for the holistic comfort care because these measurement will manipulate these infants.

CHAPTER III
MATERIALS AND METHODS

Research Design

This study was a crossover-experimental design, aimed to compare the effects of the holistic comfort care on the physiological and behavioral responses of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in the neonatal intensive care unit.

Population and Sampling

The population of this study was premature infants, both male and female, undergoing inserting binasopharyngeal prongs. These infants were admitted to the NICU, Faculty of Medicine, Ramathibodi Hospital, Mahidol University. The sample was selected by purposive sampling under the inclusion criteria.

The inclusion criteria consisted the following:

1. Male or female premature infant whose post menstrual age (PMA) are between 27-36 weeks as determined by doctor using the Ballard score assessment and postnatal age between 1-28 days;
2. Being undergoing binasopharyngeal prongs and support by mechanical ventilation with heated humidifier. The temperature control of the non-heated wire is set at level 2 to 3 whilst the heated wire humidifier is set at 37ºC and at level -2 of the control chamber since these settings can provide the humidify for the patient.
3. Warming with incubator or radiant warmer and have range body temperature between 36.5ºC and 37.1ºC on the day that the case is selected and the data are collected;
4. Having a stable haemodynamic longer than 6 hours before study, i.e.,

   Heart rate was at a range of 130-180 beats/min.

   Normal blood pressure was between 39-90/16-60mm.Hg

   Respiratory rate was at a range of 40-60 beats/min.

5. Receiving informed consent from parents for participating in this research.

The exclusion criteria were infants who:

1. Having congenital heart disease (except asymtomatic PDA), major congenital anomaly, orthopedic problems, and neurological problems;
2. On high frequency ventilator;
3. On participating phototherapy;
4. On umbilical catheter;
5. On sedative and/or analgesic drugs;
6. Receiving Aminophylline or Salbutamol less than 3 hours.

Sample Size

The sample size use in this study was estimated by calculation based on the power analysis. Since the main statistics was the repeated measure ANOVA with alpha = .05, power of the test = .8, and effect size as a medium effect size = .5, the sample size of the study was 62 episodes in each study group in which all subjects serve as their own control in this study.

The sampling used in this study was based on the above criteria where they were assigned with 2 alternate methods under a crossover design. One of them was a method A (the holistic care then the usual care) and the other was method B (the usual care then the holistic comfort care). The sequence of two different conditions was randomly assigned by drawing lots from 1-62 without replacement. When the subjects have received an odd number (1, 3, 5, …, 61), the method was A. On the other hand, an even number (2, 4, 6, … , 62) has the sequence of method B.

Research Setting

This research was conducted in the NICU, Faculty of Medicine, Ramathibodi Hospital, Mahidol University. The observed NICU unit was situated inside a large rectangular-shape hall providing rooms for administration personnel and patients to be settled along side of the longer walls. The area assigned to the patients was the side that bright sunshine was able to pass through the glass windows during the daytime. The patient’s area was divided up into two rooms in which each room had distinct purpose. The first and second rooms were designed for the patients with critical and semi-critical condition as they were located directly in front of the nurse's counter where the patients in these rooms would be under watchful eyes of the nurses for 24 hours. A nurse was assigned to the two rooms to closely monitor the condition of the patients. Moreover, the whole area was artificially lit with overhead fluorescent lamps, arranged in long banks, and turned on around the clock.

Total capacity of this unit was eight beds in which each bed was equipped with modern life supporting equipments according to the needs of the patients. Each room was equipped with basic supporting equipments such as incubator, pulse oximeter, photo lamp, infusion pump, syringe pump, and oxygen supplier whilst some incubators were covered with blankets. The environment and approach existed in the observed NICU was similar to the caregiving activities, light and sound condition experienced in any other typical intensive care unit. Day to day process of this unit was taken care by a group of staffs, which comprised of registered nurses and nursing students, medical specialists, medical interns and medical students.

In usual care for premature infants undergoing binasopharyngeal prongs that was done according to normal NICU routine care, the necessary procedures that are often painful in every 3-6 hours are: 1) removing prongs from infant's nares; 2) suctioning the nares, mouth care, and cleaning binasopharyngeal prongs; 3) inserting shape of distal prongs to pass from narrow nares to nasopharyngeal; and 4) securing binasopharyngeal prongs with plaster and connect to ventilator. The important parameters affecting the environment existing in this NICU were sound levels, light levels, and handling techniques. Sakuntala Sudsaneha (2005) was studied in this NICU. This study showed that the sound levels during non-quiet time (n = 864 observations) was ranging from 46.80 to 87.00 dB-A, having the mean value of 55.01 dB-A and standard deviation of 5.50 dB-A. The light levels during non-quiet time were between 3 and 661 lux with the mean value and standard deviation of 136.67 and 86.95 respectively. The frequency of handling state most observed was no handling 83.64 percent of total handling observation pointing to this state. The total frequency of handling states belongs to some level of physical handling was only at 16.4 percent, which disturbance handling (6.9 percent), discomfort handling (6.6 percent) and painful handling (2.9 percent). The quiet hour was visibly displayed on a bulletin board during the day shift (11.30-13.30 a.m.), evening shift (6-8 p.m.), and night shift (3-5 a.m.).

Instrumentations

The instrument used in this research could broadly be divided into two groups regarding to their utilization. The instruments belong to the first group was represented as guideline and supporting instruments in implementation of this research work while the second group was classified as instruments utilized in data collection process. The broader explanation about instruments belonging to the two groups can be seen as follows:

1. Instruments for intervention:

1.1 The holistic comfort care protocol

The holistic comfort care was an intervention that using care to promote comfort in premature infants undergoing binasopharyngeal prongs after suctioning in a neonatal intensive care unit. This care was developed by the researcher to achieve the goal of enhancing the patients' total comfort. The four contexts of the holistic comfort care for premature infants undergoing inserting binasopharyngeal prongs were as follows:

1. Physical Comfort

1.1 Select the appropriate size prongs for the infant

< 1,500 g use binasopharyngeal prongs No. 2.5

1,500-2,000 g use binasopharyngeal prongs No. 3.0

1.2 Before insert binasopharyngeal prongs, to positioning him/her in the supine position not excessive head rotation or neck extension.

1.3 Lubricate binasopharygeal prongs with water-soluble or 1% hydrocortisone.

1.4 Nasopharyngeal tract length measurement: the distance from the tip of the infant's nose to a point below the eye at the perpendicular to the middle of the eye.

1.5 Gently slide it along the floor of the nose while pushing the tip of the nose up and insert follow the natural curvature of the nasopharynx.

1.6 Secure binasopharyngeal prongs in appropriate position

1.7 Retain orogastric tube No. 8 and open distal tube.

2. Psychospiritual & Sociocultural Comfort

After securing binasopharyngeal prongs with plaster and connect to ventilator, apply gentle touch by placing one hand on the infant's head and the other on his/her back for 10 minutes.

3. Environmental Comfort (will be provided as quiet hour)

3.1 Providing appropriate infant's position

To provide the appropriate infant's position is to encourage an infant's position as much flexed as possible. This could be done in sequence as follows: Position an infant into flexed, prone and followed by placing a small-soft roll under the head and neck to tuck the head in neutral position or slightly extension. Provide a nest, which surrounds the infant with walls of a big-soft roll and supports the feet by bracing them with it. This containment prevents retraction of shoulders and external rotation of hips and extremities. Bring the hands to midline across the chest or near the mouth as well. Elevate the mattress to 15-30 degrees.

3.2 Reducing light levels: to reduce light level could be done by covering the top, left, right, and back sides of the incubator with a cloth.

3.3 Reducing sound levels at minimal: To reduce sound levels could be done with the eight step procedures as follows:

3.3.1 Place the sign "Holistic Comfort Care" on the incubator while the holistic comfort care is applied;

3.3.2 Reduce the voice to a minimum level when talking near the baby;

3.3.3 Decrease the telephone ringing volume and the equipment alarm to a minimum level in which observers could be easily alerted;

3.3.4 Avoid all physician rounds;

3.3.5 Avoid large equipment entering the unit. Make special effort not to slam doors, drawers, trash can, and incubator doors as well as drag chairs. forward all phone calls to the main desk; and

3.3.6 Respond rapidly to monitoring alarms or crying infants.

3.4 Keeping handling at minimal: To keep handling at minimal could be done with the two step procedures as follows:

3.4.1 Wear diaper when the holistic comfort care protocol is applied; and

3.4.2 Make special effort not to handling the infant and reschedule caregiving activities for minimal disturbance when the holistic comfort care is applied.

1.2 Equipment for inserting binasopharyngeal prongs and positioning the infants and the binasopharyngeal prongs

- Binasopharyngeal prongs
- 1% Hydrocortisone cream
- Plaster
- A small cotton blanket for neck and shoulder support.
- A large cotton blanket for nest making.

1.3 Equipment for measuring light and sound

- Sound level meter model: DS-40**.** The sound level meter was a small, battery operated, electric condenser microphone, which could be used as a meter for measuring sound ranging between 35 and 130 dB-A. The sound measuring procedure was applied by placing this instrument near the noise source and pointing the microphone to it. Then, the intensity value of noise would be displayed on screen of the equipment showing digital numbers in unit of decibels-A weighting (dB-A).
- Digital lux meter model: LX-50. The lux meter was a small, battery operated equipment, which measured the intensity of light. It was used in measuring light by placing the instrument at the required point. The illuminant value would be displayed on monitor of the equipment showing digital numbers in unit of lux.

2. Instruments for Data Collection:

2.1 Masimo radical pulse oximeter was used to measure and oxygen saturation and heart rate parameters. The instrument was calibrated prior to this study to ensure its accuracy.

2.2 The COMFORT-Behavior (COMFORT-B)

Ambuel, Hamlett, Marx, & Blummer, (1992) was originally designed the physiological and behavioral variables to assess distress/discomfort in ventilated children in an intensive unit. The correct used of the physiologic variables of the COMFORT scale implied that reference values for heart rate and arterial blood pressure were adjusted each day. Because these physiologic variables were titrated by inotropic and other drugs often used in PICU, the assessment on the usefulness of physiologic variables in judgment of sedation and determining new cutoff points for the COMFORT "behavioral" scale (COMFORT-B), was using only for observational purpose. The COMFORT-B scale was a reliable alternative to the original COMFORT scale (Ista, Van Dijk, Tibboel, & de Hoog, 2005). Scores on the COMFORT-B scale were the observed variation of six items on 1 to 5 scales. The total score was the sum of the six separate items scores (maximum 30); the higher the score the lower the comfort. The COMFORT-B scale comprised of six items with five response categories, each consisting of distinct behavioral descriptions. The COMFORT-B scale was described in Figure 2.

Validity

Van Dijk, Peter, Van deventer, & Tibboel (2000) related the COMFORT scale as a postoperative pain instrument for children aged 0-3 years. Trained nurses rated the children's pain at 3, 6, 9 hours postoperative on the Pediatric Surgical Intensive Care Unit (PSICU) using the COMFORT and Visual Analogue Scale (VAS) for pain. The analyses showed that the structure of the COMFORT data was best represented by three latent variables: the COMFORT-B with loadings from the behavioral items (Alertness, Calmness, Muscle tone, Movement, Facial tension, and Respiratory response/Crying) with separate latent variables for 'Heart rate baseline' and Mean arterial pressure baseline. Factor loading of the items were invariant across time, indicating stability of the structure. The latent variables COMFORT-B and VAS pain were high interrelated indicating congruent validity on three assessments (0.96, 0.89, and 0.90 respectively). Stability of the COMFORT-B and VAS pain was moderate (0.59 and 0.58, respectively) which might be due to varying painful episodes in this sample.

Wielenga, De Vos, De Leeuw, & De Haan (2004) assessed the clinimetric properties and diagnostic quality of the COMFORT scale on 19 ventilated prematurely born babies (mean gestational age (GA) 30 weeks, mean birth weight 1385 g), one clinical expert and 9 observers made 30 paired observations. The criterion validity the COMFORT scale was good (Pearson's r of 0.84).

Reliability

Van Dijk, Peter, Van Deventer, & Tibboel (2000) tested the validity of the COMFORT scale as a postoperative pain instrument for children aged 0-3 years. Trained nurses rated the children's pain at 3, 6, 9 hours postoperative on the PSICU using the COMFORT and VAS for pain. Interrater reliability of the COMFORT items proved to be good (Kappa 0.63-0.93) for all items with the exception of the 'Respiratory response' item which was moderate (Kappa 0.54).

Wielenga & Leeuw (2004) assessed the clinimetric properties and diagnostic quality of the COMFORT scale on 19 ventilated prematurely born babies (mean gestational age (GA) 30 weeks, mean birth weight 1385 g), one clinical expert and 9 observers made 30 paired observations. The interobserver reliability of each item varied from good to almost perfect (weighted Kappa of 0.64 to 1.00). The reliability of the total COMFORT scale score was satisfying (intraclass correlation coefficient of 0.94).

In this study, the researcher assessed the scores of the COMFORT-B scale to clinical judgment of discomfort. The procedure for assessing the reliability of the COMFORT-B scale was conducted by the researcher in relation to the three research assistants on 10 premature infants. The interobserver reliability of the clinical judgment of the researcher and three research assistants were analyzed by using a weighted Kappa. A weighted Kappa was calculated by assigning a weight (1-[1/number of cathegories-1]) to the frequencies in each cell of a table of agreement, with the distance to the diagonal representing the optimal agreement. In general, a Kappa of 1 was known to represent a perfect agreement and 0.8-1 as almost perfect, 0.6-0.8 as substantial, 0.4-0.6 as moderate, 0.2-0.4 as fair and 0.0-0.2 as slight agreement (Fleis, 1981 cited in Wielenga, de Vos, de Leew, & de Haan, 2004).

On the first time, the researcher translated the scoring form of COMFORT – B Scale as described in Figure 3 from English version to Thai version (Appendix 1) and consulted three experts to test the validity of the COMFORT scale, when related to the three research assistants on 10 premature infants, calculated weighted of the interobserver reliability of the COMFORT-B scale = 0.55.

Since the COMFORT-B scale had no detail about the alertness, the researcher itemized the information by using the COMFORT-B with the Anderson Behavioral State Scale (ABSS). This instrument was developed by Gene Cranston Anderson and translated in Thai cited in Sakuntala Sudsaneha, B.E. 2548, when related to the three research assistants on 10 premature infants, calculated weighted of the interobserver reliability of the COMFORT-B scale = 0.55.

Therefore, the researcher consulted the experts and van Dijk's own tool. The experts suggested to group the scale to new score of the COMFORT-B Scale from 5 to 3 scales, as follows: 1 = comfort from original scale 1; 2 = mild – moderate discomfort from original 2, 3; and 3 = severe discomfort from original 4, 5 as described in Figure 6, when related to the three research assistants on 10 premature infants, calculated weighted of the interobserver reliability of the COMFORT-B scale = 0.85.

Items	**New Score**
Alertness	
Deeply asleep	1
Lightly asleep / Drowsy	2
Alert and awake / Hyper-alert	3
Calmness/Agitation	
Calm	1
Slight anxious / Anxious	2
Very anxious / Panicky	3
Respiratory response (on ventilator)	
No coughing or no spontaneous respiration / Spontaneous respiration	1
Occasional cough/resists ventilator Actively breathes against ventilator/	2
Fights ventilator-coughs/chokes/gags	3

Figure 6 The modified COMFORT-B Scale

Items	**New Score**
Crying (Spontaneous breathing)	
Quiet breathing, no crying sounds	1
Occasional sobbing or moaning/Whining (monotone)	2
Crying / Screaming or shrieking	3
Physical movement	
None	1
Occasional, slight movements / Frequent, slight movements	2
Vigorous movement of extremities only / Vigorous movement of extremities, torso and head	3
Muscle tone	
Relaxed/None /Reduced muscle tone	1
Normal muscle tone	2
Increased tone/flexion-fingers/toes/ Extreme rigidity/flexion-fingers/toes	3
Facial tension	
Relaxed	1
Normal tone	2
Some tension/Full facial tension/Hyper-alert	3

Figure 6 The modified COMFORT-B Scale (continued).

2.3 Timer (Model sport timer) was used to measure the time in operation in which it was calibrated to the standard time.

2.4 Data record forms are comprised of:

2.4.1 Demographic data form, which included data on gender, post-natal age, date and time of birth, gestational age, post-conceptual age, type of delivery and indication, birth weight, current weight, mode of mechanical ventilator, duration of binasopharyngeal prongs usage, frequency of suctioning during 24 hours, period of suctioning, health problem and treatment;

2.4.2 Physiological comfort response data record form, which included data on the mean of heart rate, oxygen saturation, time of heart rate and oxygen saturation that return to baseline. These parameters were recorded as baseline (before data collection), after inserting binasopharyngeal prongs to infant's nares and after connecting the mechanical ventilator immediately, at minute 2, 4, 6, 8, 10 and every 10 minutes until completed 2 hours;

2.4.3 Behavioral comfort response data record form, which included data on six behavioral items of the modified COMFORT Behavior scores (Alertness, Calmness, Muscle tone, Movement, Facial tension, and Respiratory response). These parameters were recorded after inserting binasopharyngeal prongs to infant's nares and after connecting the mechanical ventilator immediately, at minute 2, 4, 6, 8, 10 and every 10 minutes until completed 2 hours.

Protection of Human Subjects

The data collection procedure in this study was encompassed by the protection of human subjects. Permission to conduct the study was submitted to the Institutional Review Board (IRB), Faculty of Medicine, Ramathibodi Hospital, Mahidol University. The researcher began to collect data after permission was obtained to conduct the study and it was performed based on the protection of human subjects. In the process of selecting test subjects, the researcher introduced herself to the parents of the premature infants and informed them about the research work including objectives, processes, benefits, and right of refusal to participate in the study. The parents of the test subjects were then given the right to request information from the researcher at any time if they do not understand well about the study as well as the right to cancel their participation at any time without affecting the nursing and medical care receiving during perioperative period. The parents of the test subjects who agreed to participate in this study were again informed and assured that the data would be kept confidential and would be reported as group data. Finally, the data collection process could be started after the consent forms were signed by the parents.

Training of the Research Assistants

To reduce a possibility of data bias on the measurement regarding the three research assistants; they were trained on determining oxygen saturation, heart rate, sound levels, and light levels for correctness and accuracy, and recording it on the data collection sheet. The training process was first conducted by the researcher with detailed explanation on the research procedure including scoring method of the modified COMFORT-B and providing practice for observation skills. Then, the researcher and research assistants had accessed on the behavioral comfort response of the premature infants in the NICU and reliability assessment of each research assistant had been evaluated according to her performance.

Data Collection

The data collection was conducted by the researcher in the following orders:

1. The data collection procedure commence once the approval was obtained from the Dean of the Faculty of Graduate Studies, Mahidol University; the head of Department of the Faculty of Medicine; the Director of Nursing Department of the Faculty of Medicine; and the head of Pediatric Nursing Department of the Faculty of Medicine, Ramathibodi Hospital to allow data collection at the Neonatal Intensive Care Unit (NICU). Regarding the human subjects protection procedures, all parents of eligible subjects were approached by the researcher. The informed consents were; thus, obtained from the parents' subjects to ensure their willingness to participate in the study.

2. The head of the NICU was contacted whilst the concerned nurses in this study were asked for their cooperation.

3. Three registered nurses from the NICU were selected as the research assistants in this study and were acted as data collectors. The procedure was carried out as follows: in method A, the setting of holistic comfort care was set for 11.30 a.m. to 1.30 p.m. and the usual care was set for 2.30 p.m. to 4.30 p.m. whilst in method B, the setting of usual care was set for 2.45 to 4.45 p.m. and the setting of holistic comfort care was set for 6.00 to 8.00 p.m. respectively. After suctioning, the setting of holistic comfort care was arranged by the researcher to sixty-two episodes for ten subjects and alternated with usual care by nurses in the NICU.

4. The sequence of experimental method of 10 eligible subjects was randomly assigned by drawing lots (number 1 to 62) without replacement from the researcher.

- Odd number (1, 3, 5, …, 61): an experimental method was A.
- Even number (2, 4, 6, …, 62): an experimental method was B.

Note: Method A was the holistic comfort care that would be provided as quiet hour during day shift in four contexts of physical, environmental, psychospiritual, and sociocultural comfort of premature infants undergoing inserting binasopharyngeal prongs after suctioning. Then, the usual care for premature infants undergoing inserting binasopharyngeal prongs after suctioning in every 3-6 hours was followed: 1) removing prongs from infant's nares; 2) suctioning the nares, mouthcare, and cleaning binasopharyngeal prongs; 3) inserting shape of distal prongs to pass narrow nares to nasopharyngeal; and 4) securing binasopharyngeal prongs with plaster and connect to ventilator.

Method B was the usual care of premature infants undergoing inserting binasopharyngeal prongs after suctioning in every 3-6 hours: 1) removing prongs from infant's nares; 2) suctioning the nares, mouthcare, and cleaning binasopharyngeal prongs; 3) inserting shape of distal prongs to pass narrow nares to nasopharyngeal; and 4) securing binasopharyngeal prongs with plaster and connect to ventilator. Then, the holistic comfort care will be provided as quiet hour during evening shift in four contexts of physical, environmental, psychospiritual, and sociocultural comfort of premature infants undergoing inserting binasopharyngeal prongs after suctioning.

5. The experiment was performed as follows:

Physical Comfort

1. Selected the correct size prongs for the infant

   < 1,500 g use binasopharyngeal prongs No. 2.5

   1,500-2,000 g use binasopharyngeal prongs No. 3.0

2. Before insert binasopharyngeal prongs, provided him/her in the supine position by not excessive head rotation or neck extension.

3. Lubricated binasopharygeal prongs with water-soluble or 1% hydrocortisone.

4. Measured nasopharyngeal tract length: the distance from the tip

of the infant's nose to a point below the eye at the perpendicular to the middle of the eye.

5. Gently slid it along the floor of the nose while pushing the tip of the nose up and inserted following the natural curvature of the nasopharynx.
6. Secured binasopharyngeal prongs in appropriate position.
7. Retained orogastric tube No.8 and open distal tube.

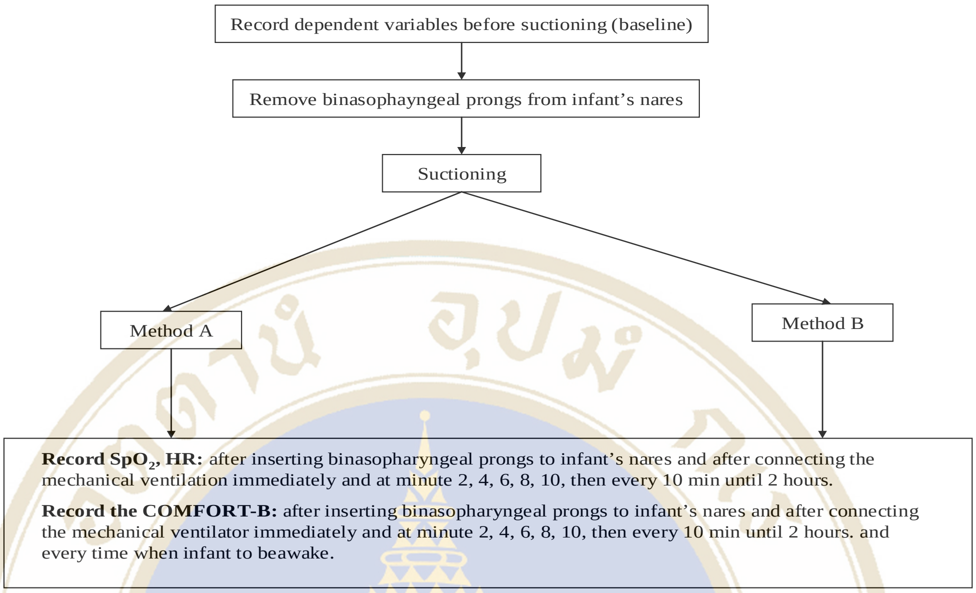
Psychospiritual Comfort & Sociocultural Comfort

After securing binasopharyngeal prongs with plaster and connected to ventilator, the gentle touch was applied by placing one hand on the infant's head and the other hand on his/her abdomen or back for 10 minutes and every time when an infant awaked until he/she falls asleep.

Environmental Comfort

1. Providing the position; prone positions in a curled up, flexed position
2. Reducing light levels; < 60 ft-c
3. Reducing sound levels; < 50 dB-A
4. Keeping the handling at minimal

6. Before suctioning 10 minutes and after connecting the mechanical ventilator immediately, at minute 2, 4, 6, 8, 10 and every 10 minutes until completed 2 hours; heart rate, oxygen saturation, and the comfort behavior score were recorded by the research assistant. The step of the experiment and record was shown in Figure 7.



Method		**Time**	
Method A		11.30-13.30 Quiet hour	14.30-16.30
		The holistic care	The usual care
Method B			
		14.45-16.45	18.00-20.00 Quiet hour
		The usual care	**The holistic care**

Figure 7 Step of the Experiment and Record

Data Analysis

The data was calculated by computer using the Statistical Package for Social Science for Window Version 11.5 (SPSS/FW) as follows:

1. Frequency and percentage were applied to describe the demographics data of the samples such as gender, post-natal age, gestation age, post-conceptual age, birth weight, current weight, mode of mechanical ventilator, duration of binasopharyngeal prongs usage, frequency of suctioning during 24 hours, period of suctioning time in each episode, and health status and treatment.

2. Mean and Standard deviation were conducted to describe the mean of heart rate, oxygen saturation, time for heart rate and oxygen saturation to return to baseline, and the comfort behavior scores after suctioning in holistic comfort with quiet hour and usual care with non-quiet hour after suctioning.

3. The Two-way ANOVA with repeated measure on two factors were conducted to compare the difference of the physiological (heart rate and oxygen saturation) and behavioral responses (the comfort behavior scores) between holistic comfort care with quiet hour group and usual care with non-quiet hour after suctioning.

4. Since some of time for heart rate and oxygen saturation to returned to baseline after connecting the mechanical ventilator immediately both in holistic comfort care and usual care group (30,13 respectively). Therefore, in this study the survival curve was conducted to compare time for heart rate and oxygen saturation to return to baseline after suctioning in holistic comfort with quiet hour and usual care with non-quiet hour after suctioning.

CHAPTER IV
RESULTS

In this chapter the result of the data analysis were presented in three parts according to their characteristics as follows:

Part I: Demographic characteristics of the samples

Part II: Description of NICU environment during control and experimental periods

Part III: Results from hypothesis testing

Part I: Demographic Characteristics of the samples

The samples of this study were premature infants who were admitted in the NICU, Ramathibodi Hospital and their data were collected during December 2007 and April 2008. The samples were performed with 62 episodes from 10 premature infants. According to the crossover-experimental design in this study, each subject was required to complete both methods: the holistic comfort care with quiet hour and the usual care with non-quiet hour which were randomly assigned.

Demographic characteristics of the samples were shown in Table 1. According to the gender, the test subjects were comprised of 7 subjects, which 70 % of the total was baby boys. Their ages were in the range of 2 to 28 days and the mean age was 18.24 days (SD = 5.92). The percentage distribution of the test subjects belong to late neonatal period (defined as the age of the test subjects being between 7 and 28 days) was 80%. In gestational age (GA), 70 percents for premature infants, whose GA is ranging between 26-31 weeks, while 30% were from extremely premature infants with GA 33-35 weeks. The mean GA of the test subjects was 28.99 weeks (SD=2.07). Regarding postmenstrual age (PMA), the percentage distribution became 67.70% for premature infants, whose PMA was ranging between 31-35.2 weeks, while 32.30 % came from extremely premature infants with PMA ranging less than 31 weeks. The mean PMA of test subjects was 31.49 weeks (SD=1.88). The birth weights of premature infants were ranging from 800-1,520g with the mean weight was 974.35g (SD=163.98). By the date of observation, the current weights of the premature infants were ranging from 780 to 1,710g and the mean weight was recorded as 1,144.50g (SD=250.60). Regarding weight, birth and current weight of the premature infants were recorded into separate levels: low weight, very low weight and extremely low weight. Extremely low weight status was assigned to the group of the premature infants weighing below 1,000g while very low weight and low weight status were labeled to the infants weighing between 1,000 to 1,500g, and 1,500 to 2,499g respectively. The percentage distributions of different level of the birth weights were 40, 50, and 10% for extremely low weight, very low weight and low weight status respectively and 41.90, 46.80 and 11.30% respectively for different level of current weight. Total subjects were using the mechanical ventilators in CPAP mode. Duration of using the binasopharyngeal prongs ranged from 2 to 25 days whlist the most common of duration of using the binasopharyngeal prongs are multiple mode exist at 5, 6, 8, 14 days. The samples of 54.8% (n=34) received Aminophylline/Theophylline. The samples in both groups of care received suctioning ranged from 3 to 8 times per day, the period of suctioning time in each episode ranged from 3 to 10 minutes (Mode=5) in both groups.

Table 1 Frequency and Percentage of Sample Baseline Characteristics (n=10, 62 episodes)

Characteristics		Frequency	Percentage
Gender (10 subjects)			
Girl		7	70.00
Boy		3	30.00
Age (days) (10 subjects)			
(Min=2, Max=28, Mean=18.24, SD=5.92)			
< 7	(early neonatal period)	2	20.00
7-28 days	(late neonatal period)	8	80.00
GA (weeks) (10 subjects)			
(Min= 26, Max=35, Mean= 28.99, SD=2.07)			
< 31	(extremely premature infant)	7	70.00
31-36	(moderately premature infant)	3	30.00
PMA (weeks) (62 episodes)			
(Min=28, Max=35.20, Mean=31.49, SD=1.88)			
< 31	(extremely premature infant)	20	32.30
31-36	(moderately premature infant)	42	67.70
Birth weight (g) (10 subjects)			
(Min=800, Max=1,520, Mean=974.35, SD=163.98)			
< 1,000	(extremely low birth weight)	4	40.00
1,000-1,499	(very low birth weight)	5	50.00
1,500-2,499	(low birth weight)	1	10.00
Current weight (g) (62 episodes)			
(Min=780, Max=1,710, Mean=1144.50, SD=250.60)			
< 1,000	(extremely low weight)	26	41.90
1,000-1,499	(very low weight)	29	46.80
1,500-2,499	(low weight)	7	11.30

Table 1 Frequency and Percentage of Sample Baseline Characteristic (n= 10, 62 episodes) (continued)

Characteristics	Frequency	Percentage
Medication effecting on heart rate (62 episodes)		
Yes	34	54.80
No	28	45.20
Type of the mechanical ventilator mode (62 episodes)		
CPAP	62	100.00
NIPPV	-	-
Duration of using NP (days) (62 episodes) **(Min=2, Max=25, Mode=5,6,8,14)**		
1-7	17	27.40
8-14	24	38.70
> 14	21	33.90
Holistic Comfort Care Group		
Frequency of the suctioning (times/day) (62 episodes)		
(Min=3, Max=8, Mean=5.68, SD=.97)		
1-5	29	46.80
6-10	33	53.20
Period of suctioning time in each episode (minutes) (62 episodes)		
(Min=5, Max=10, Mode=5)		
1-5	20	37.10
5.01-10	42	62.90
Usual Care Group		
Frequency of the suctioning (times/day) (62 episodes)		
(Min=3, Max=8, Mean=5.71, SD=.93)		
1-5	22	35.50
6-10	40	64.50
Period of suctioning time in each episode (minutes) (62 episodes)		
(Min=3, Max=10, Mode=5)		
1-5	26	41.90
5.01-10	36	58.10

Note:- GA= Gestational Age, PMA= Postmenstrual Age

Part II: Description of NICU environment during control and experimental periods

The important parameters affecting the environment existing in the NICU are sound levels, light level, and handling techniques. These parameters are mentioned in details in this part. To represent the NICU environment in details, the sound level, light levels, and the handling scores were recorded to the observation record sheets after inserting binasopharyngeal prongs to infant's nares and after connecting the mechanical ventilation immediately and times at 2, 4, 6, 8, 10, then every 10 minutes until completed 2 hours during both usual care with non-quiet hours and holistic comfort care with quiet hours. Total of 36 data sets in which belong to the one test episode with 62 test subjects participating in this study were recorded for one type of parameter in each period under each episode.

The level of the sounds appeared in the NICU were shown in Table 2. The sound levels during usual care with non-quiet hours and the holistic comfort care with quiet hours (n= 2,232 observations), was ranging from 41.7 to 66.4 dB-A, having the mode value of 44.4 dB-A. The usual care with non-quiet hours, the range of sound level recorded was between 42.1 and 66.4 dB-A with the mode value of 45.8. In the holistic comfort care with quiet hours implementation, the range of sound level recorded was between 41.7 and 56.8 dB-A with the mean value of 44.4 dB-A.

Table 2 Min-max, and mode of sound levels (dB-A) as measured in NICU between the usual care and holistic comfort care

Group of care	n	Min-max	Mode
Usual care	1,116	42.1-66.4	45.8
Holistic comfort care	1,116	41.7-56.8	44.4
Total	**2,232**	**41.7-66.4**	**44.4**

The illumination status inside the NICU is displayed in Table 3. The light levels during usual care with non-quiet hours and the holistic comfort care with quiet hours (n= 2,232 observations), was ranging from 1 to 217 lux, having the mode value of 1 lux. The usual care with non-quiet hours, the range of light level recorded was between 2 and 217 lux with the mode value of 30 lux. In the holistic comfort care with quiet hours implementation, the range of light level recorded was between 1 and 130 lux with the mode value of 1 lux respectively.

Table 3 Min-max, and mode of light levels (lux) as measured in NICU between usual care and holistic comfort care.

Group of care	n	Min-max	Mode
Usual care	1,116	2-217	30
Holistic comfort care	1,116	1-130	1
Total	**2,232**	**1-217**	**1**

According to the handling evaluation process, the handling score ranging from 0 to 3 was assigned to the handling states, between no handling and painful handling, whenever the observation was made to the test subject. The frequency of handling scores during the usual care with non-quiet hours and holistic comfort care with quiet hours are shown in Table 4. According to the result regarding usual care with non-quiet hours period, the handling state most observed was no handling with 94.2 % of total handling observation pointing to this state. The total frequency of handling state belong to some level of physical handling was only at 5.8% , which included comfort handling (0.9%) disturbance handling (3.9%), discomfort handling (1%) and no painful handling. Regarding total handling observed during holistic comfort care with quiet hours, no handling state occurred at 65.8% and comfort handling (33%), the other handling states with some disturbance handling 1%, discomfort handling (0.2%) and no pain handling (0%).

Table 4 Frequency and percentage of handling scores between usual care and holistic comfort care

Handling score	Usual care		Holistic comfort care	
	Frequency	Percentage	Frequency	Percentage
0 = no handling	1,051	94.2	734	65.8
1 = comfort	10	0.9	369	33.1
2 = disturbance	43	3.9	11	1.0
3 = discomfort	12	1.1	2	0.2
4 = pain	-	-	-	-
Total	**1,116**	**100**	**1,116**	**100**

Part III: Hypothesis Testing

To test the effects of holistic comfort care on the physiological and behavioral responses in premature infants undergoing inserting binasopharyngeal prongs. The dependent variables in hypotheses were the mean of heart rate, oxygen saturation, time for heart rate and oxygen saturation to return to baseline, and the comfort behavior scores. One-Sample Kolmogorov-Smirnov test was used to determine the distribution of each parameter of the physiological responses (the mean of heart rate, oxygen saturation) and the behavioral responses (the comfort behavior mean scores).

It was indicated that all dependent variables in this study (the mean of heart rate, oxygen saturation, and the comfort behavior scores) met the normality assumption (Appendix C). Thus, two-way ANOVA with repeated measure on two factors was used to compare the difference of the physiological and behavioral responses between holistic comfort care with quiet hour group and usual care with non-quiet hour after suctioning. It was tested on correlation and homogeneity of variance between groups with Mauchly's Sphericity Test. The results showed no statistically difference ($p>.99$) (Appendix D).

The results of the hypothesis testing are presented as follows:

Hypothesis I: The mean of heart rate of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is lower than the usual care group.

Hypothesis II: The mean of oxygen saturation of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is higher than the usual care group.

Hypothesis III: Time for heart rate to return to baseline of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is shorter than the usual care group.

Hypothesis IV: Time for oxygen saturation to return to baseline of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is shorter than the usual care group.

Hypothesis V: The comfort behavior mean scores of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is lower than the usual care group.

Hypothesis I: The mean of heart rate of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is lower than the usual care group.

Heart rate was measured by Masimo radical monitor, which was a noninvasive device. The two-way ANOVA with repeated measure on two factors was used to detect the differences in the mean of heart rate between holistic comfort care with quiet hours and usual care with non-quiet hour. The result indicated that in the control group, there were significantly differences of mean of heart rate from the experimental group ($F_{1,61}$ = 47.877, $p < .001$) (See Table 5).

Table 5 A Comparison of the Mean of Heart Rate between Holistic Comfort Care and Usual Care Group After Suctioning (n=62)

Sources of Variation	SS	df	MS	F	p
Within-Subjects					
Treatment	1295.342	1	1295.342	47.877	<.001
Error	1650.394	61	27.056		
Time	1535.036	1	1535.036	40.948	<.001
Error	2286.714	61	37.48		

(SS=Sum of squares; df=degree of freedom; MS=Mean square; F=F-test)

Hypothesis 2: The mean of oxygen saturation of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is higher than the usual care group.

Oxygen saturation referred to the amount of oxygen bound to hemoglobin compared with hemoglobin's maximal ability for oxygen binding as measured by pulse oximeter, Masimo radical monitor, which was a noninvasive device. The two-way ANOVA with repeated measure on two factors was used to detect the difference of mean of oxygen saturation in holistic comfort care with quiet hours and usual care with non-quiet hour. The result showed that in the control group, there were significantly differences of mean of oxygen saturation from the experimental group ($F_{1,61} = 7.874$, $p < .05$) (See Table 6).

Table 6 A Comparison of the Mean of Oxygen Saturation between Holistic Comfort Care and Usual Care Group After Suctioning (n=62)

Sources of Variation	SS	df	MS	F	p
Within-Subjects					
Treatment	27.603	1	27.603	7.874	.007
Error	213.841	61	3.506		
Time	.003	1	.003	.001	.97
Error	191.240	61	3.13		

(SS=Sum of squares; df=degree of freedom; MS=Mean square; F=F-test)

Hypothesis 3: Time for heart rate to return to baseline of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is shorter than usual care group.

Time for heart rate to return to baseline referred to time duration of heart rate that return to baseline level in premature infants after suctioning after connecting the mechanical ventilator and was assessed by Masimo radical monitor and the observation recording form. The survival analysis was used to detect the difference of time of heart rate return to baseline in the holistic comfort care with quiet hours and the usual care with non-quiet hour.

The survival curve showed that time for heart rate to return to baseline level in holistic comfort care were significantly differences from usual care group ($p < .05$) (See Figure 8). In holistic comfort care, estimation of 65% of heart rate return to baseline within 2 minutes and within 20 minutes after suctioning heart rate return to baseline were completed. Unlike in usual care group, estimation of 40% of heart rate return to baseline within 2 minutes but heart rate return to baseline were completed at 120 minutes after suctioning.

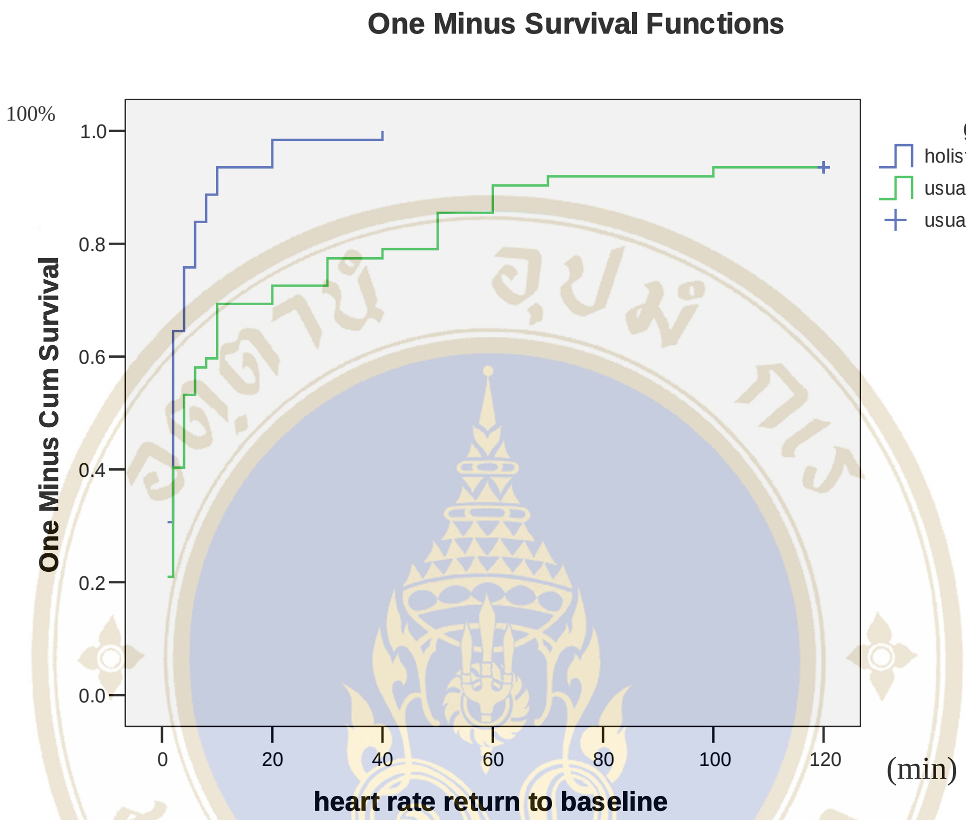


Figure 8 Survival curve of time of heart rate return to baseline

Hypothesis 4: Time for oxygen saturation to return to baseline of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is shorter than usual care group.

Time for oxygen saturation to return to baseline referred to time duration of oxygen saturation that return to baseline level of premature infants after suctioning after connecting the mechanical ventilator. Assess by Masimo radical monitor and the observation recording form. The survival analysis was used to detect the differences of time of oxygen saturation return to baseline in holistic comfort care with quiet hours and usual care with non-quiet hour. In holistic comfort care, estimation of 90% of oxygen saturation return to baseline within 2 minutes and within 40 minutes after suctioning oxygen saturation return to baseline were completed. As in usual care group, estimation of 70% of oxygen saturation return to baseline within 2 minutes until completed at 120 minutes after suctioning. The survival curve showed that time duration of heart rate that return to baseline level in the holistic comfort care were not significantly differences from usual care group (p < .05) (See Figure 9).

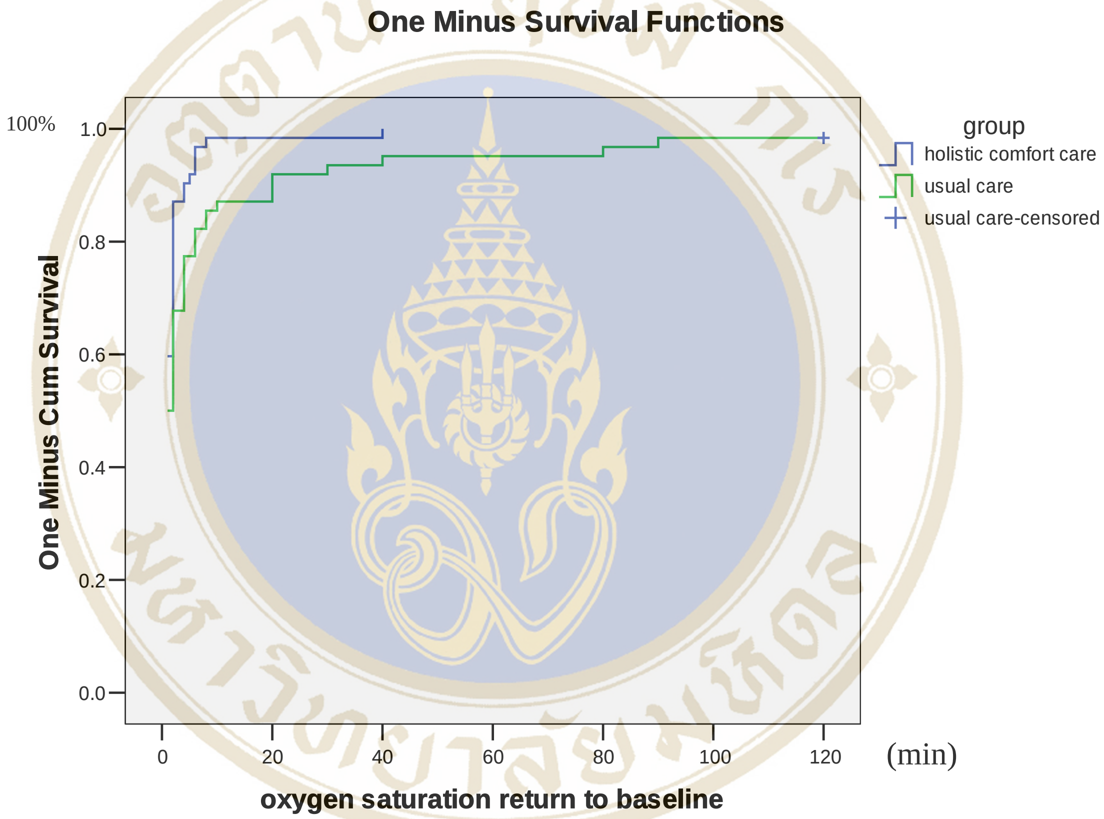


Figure 9 Survival curve of time of oxygen saturation return to baseline

Hypothesis 5: The comfort behavior mean scores of premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort care group is lower than the usual care group.

The comfort behavior scores were scored by the modified COMFORT Behavior Scale (the modified COMFORT-B) that comprised of six behavioral items (Alertness, Clamness, Muscle tone, Movement, Facial tension, Respiratory response), being scored and observed on the variation of six items based on 1 to 3 scale. The total score was the sum of the six separate items scores (maximum 18), the higher the score the more discomfort. From Table 7, the two-way ANOVA with repeated measure on two factors was used to detect the differences of the comfort behavior scores in holistic comfort care with quiet hours and usual care with non-quiet hour. The result indicated that in the control group, there were significantly difference of the mean of the comfort behavior scores from the experimental group ($F_{1,61} = 7.874$, $p < .001$).

Table 7 A Comparison of the Comfort Behavior Mean Scores between Holistic Comfort Care and Usual Care After Suctioning (n=62)

Sources of Variation	**SS**	**df**	**MS**	**F**	**p**
Within-Subjects					
Treatment	279.587	1	27.603	7.874	.007
Error	173.862	61	2.85		
Time	505.306	1	505.306	104.507	.000
Error	294.944	61	4.83		

(SS=Sum of squares; df=degree of freedom; MS=Mean square; F=F-test)

CHAPTER V
DISCUSSION

This research demonstrated the holistic comfort care as a nursing intervention that effects on the physiological and behavioral responses of premature infants undergoing insertion of binasopharyngeal prongs. This chapter focuses on the research findings on the physiological and behavioral responses, which partially supported the research hypotheses.

Characteristics of the samples

The test subjects participated in this study were mostly baby boys, 70% of the samples. Ages range from 2-28 days, the mean age was 18.2 days. In gestational age of the test subjects at the time of birth, the population of 70% belongs to extremely premature infants. The mean gestational age, 29 weeks, indicated the extreme preterm situation of the observed infants at birth. The distribution of postmenstrual age at 64.5% of the test subjects were in the moderate preterm period at the time of observation. Among the three levels defined for weight levels, the extremely low weight level has the distribution value of 60% in current weight of the test subjects. The fact that the average age of the test subjects participating in this research was closer to the neonatal period signified the effect of the result received from this study. Lack of adaptability and vulnerability of the premature infants highlighted the importance of test subjects regarding their ages. This finding emphasized that the test subjects were not well prepared for extra-uterine life. After birth, rapid physiologic changes and immature homeostatic mechanisms limit their abilities to adapt in NICU environment.

Total subjects were using the mechanical ventilators in CPAP mode. Duration of using the binasopharyngeal prongs ranged from 2 to 25 days whilst the most common duration of using the binasopharyngeal prongs ranged from 2 to 17 days (n= 40, 80.6 %). About 45.2% (n=28) of samples received Aminophylline/Theophylline that may cause tachycardia. The samples in the holistic comfort care with quiet hours group received suctioning ranged from 4 to 8 times per day. The period of suctioning time in each episode ranged from 3 to 15 minutes, and the most period of suctioning time in each episode was 5 minutes (n=18, 29%). In the usual care without quiet hours group, the samples received suctioning ranged from 3 to 8 times per day. The period of suctioning time in each episode ranged from 3 to 15 minutes, and the most period of suctioning time in each episode was 5 minutes (n= 23, 37.1 %). However, the subjects served as their own control.

The effects of holistic comfort care on the physiological and behavioral responses of premature infants undergoing insertion of binasopharyngeal prongs were noted. The holistic comfort care which utilized quiet time approach and the usual care with non-quiet time participated. Therefore, the NICU environment included sound levels, light level, and handling that impact in the control and experimental period, were discussed as follows. The significant difference was seen in the maximum noise level in which the highest value was 66.4 dB-A, the minimum noise level recorded with 41.7 dB-A. As the maximum and minimum noise levels in the experimental period were recorded with, 56.8 and 41.7 respectively. When we compared the noise level of this improved environment with base case, being the conventional NICU environment, the highest noise level was dramatically decreased from 66.4 to 56.8 dB-A, which 14.5% noise deduction was achieved during holistic comfort care implementation. Although, the mean sound level in the control period was 48.1 dB-A and not over 50 dB-A but there were 296 observations (26.5 percent) of peak sound levels (over 50 dB-A) were recorded. In the experimental period, there were only 50 peak sound levels (4.5 percent) occurred while the holistic comfort care with quiet hours was implemented. In considering the total mean sounds between the two periods, the mean sound level in the control period was 48.1 dB-A and became 46.2 dB-A in the experimental period. Although it was 1.8 dB-A deduction of the mean sound between the two periods, it could be concluded that the reduction of sound plays an important role in enhancing the comfort of prematurity.

In case of light level, the highest and lowest illuminations recorded during the control period in the NICU are 217 and 1 lux respectively. During holistic comfort care, the highest and lowest illuminations were recorded with 130 and 1 lux respectively. In case of highest illumination comparison, the light levels were decreased to 130 from 217 lux with a new approach, which controlled the light level. For the mean comparison, the light levels were dramatically decreased to 4.1 from 38.2 lux with reduction of 89.3% achieved from the conventional NICU environment. Since the existing environment for the test subjects was easy to control the lighting, the illumination level of the experimental period was able to be reduced to the required level. Based on these data, it was possible to conclude that the infants had more enhanced comfort during the experimental period than the control periods with the reduced light levels.

As in handling process, it was generally divided into two broad categories: no handling and handling with better representation. Between the two periods, the total frequent handling (34.2%) received by the test subjects during the holistic comfort care was occurring more than during the usual care (5.8%). Although the handling in the experimental period was more than the control period, there were 363 observations (33.1%) of the comfort handling whilst the disturbance and discomfort handling were recorded as 11 (1%) and 2 (0.2%) observations respectively. Contrarily, in the control period, there were 10 observations (0.9%) of the comfort handling whilst the disturbance and discomfort handling in the experimental period was recorded as 43 (3.9%) and 12 (1.1%) observations respectively. The observed result indicated that the stress occurred in the preterm infants due to excessive disturbance and discomfort handling which could be reduced with imposing restriction on handling. Based on the above data, it was concluded that minimal amount of disturbance and discomfort handling could promote comfort handling needed to enhance the comfort of an infant. This exercise was considered as direct effect of comfort responses of the premature infant.

The NICU environment and insertion of binasopharyngeal prongs are always fought with discomfort for the premature infants. The environment and the procedures received by infants provoke discomfort, which in turn influences the physiological and behavioral reaction of the premature infants. The beneficial effect of the holistic comfort care for the NICU infants who were undergoing insertion of binasopharyngeal prongs was demonstrated in the hypotheses testing in this study.

The physiological responses:

- Heart rate and Oxygen saturation

The finding of the present study revealed that the mean of heart rate and oxygen saturation during the holistic comfort care group was statistical significant difference from the usual care group (p< .001, <.05 respectively) (Table 5, 6). This result supports hypothesis I and II. The premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort group, the mean of heart rate is lower and oxygen saturation is higher than usual care group.

Heart rate and oxygen saturation are the specific indicators of stress, discomfort, and painful procedures, representing the integrated response to ongoing and dynamic changes in autonomic, cortical, environmental, and other inputs. The premature infants undergoing inserting binasopharyngeal prongs in the usual care with non-quiet hours were suffered from discomfort that related to the binasopharyngeal prongs insertion and the inappropriate sensory input in NICU environment. The NP malpositioning, nasopharyngeal symptoms, gastric insufflation and abdominal distention were inducing the physical discomfort. As the environment in the usual care group such as bright light, loud noise, excessive disturbance and discomfort handlings were not promoting sleep; with discomfort, an increase in the activation of sympathetic nerve fibers innervating the heart causes the sinoatrial node to produce an increase in the heart rate. Heart rate is low during restful situations and sleep, and becomes elevated during periods of activity, stress, and pain (Fouad, Tarazi & Ferrario, 1984). As oxygen saturation decreases in response to discomfort (Rush, Rush, & Ighani, 2003), during episodes of vigorous crying may decrease in oxygen saturation for duration of discomfort procedure. The holistic comfort care interventions were concerned about the deleterious effects vigorous stimulation has on the integrative functioning of the fragile systems of the preterm infant and a behavioral intervention to promote physical, psychospiritual, sociocultural and environmental comfort were designed to maintain homeostasis and helped the patient maintain or regain physical function (Wilson & Kolcaba, 2004).

The more discomfort in usual care group can produce, more autonomic responses disrupting homeostasis should increase stress activating the sympathetic nervous system, as manifested by an increased heart rate and decreased oxygen saturation. Therefore, the mean of heart rate at immediately (166.71), 1 hour (159.25), 2 hours (160.68) in the holistic comfort care generally were significantly different than immediately (168.45), 1 hour (164.86), 2 hours (164.52) in the usual care ($F_{1,61}$=47.87, p<.001). Whereas the oxygen saturation at immediately (96.19), 1 hour (96.95), 2 hours (96.70) in the holistic comfort care generally were significantly different than immediately (96.35), 1 hour (96.00), 2 hours (95.85) in the usual care ($F_{1,61}$=7.87, p<.05). The finding in this study was partly consistent with the previous study of the comforting from kangaroo care.

Comfort in distressed states is a basic maternal role. The kangaroo care may be an effective method to blunt pain responses because some of its components have been found to reduce the severity of responses to stress. For example, containment acts to prevent an increase in behavioral distress and plasma cortisol after heel stick, and the presence of maternal heart beat, a sound can be perceived by the infant as he/she lies against the maternal chest, prevents full-term newborn from significant increasing and salivary cortisol levels after painful stimulation (Kurihara, Ciba, & Shimizu, 1996). The vestibular component of carrying, similar to the gentle stimulation of the mother's chest respiratory movements, produces a comforting effect during painful stimulation (Johnston, & et. al., 1997). Sajedi, Kashaninia, Rahgozar, & Noghabi (2007) studied a comforting on the effect of kangaroo care on physiologic responses to pain of an intramuscular injection in one hundred healthy term neonates. They were assigned to intervention and control group. In the intervention group, the neonate was held in kangaroo care for 10 minutes before the injection until 3 minutes after injection. In the control group, the neonate was in the prone position in the isolette. The primary outcome measures were heart rate and blood oxygen saturation rate before, during and 3 minutes after injection. The findings in this study were confirmed in hypothesis I and II with heart rate during and 3 minutes after injection for neonates given kangaroo care were significantly lower than for neonates in control group (p <.001). The blood oxygen saturation rate during and 3 minutes after injection for neonates given kangaroo care were significantly higher than for neonates in control group (p <.001).

- **Time for heart rate to return to baseline**

The finding of the present study revealed that the mean time of heart rate return to baseline in premature infants undergoing binasopharyngeal prongs after suctioning during the holistic comfort care group was statistical significant difference from the usual care group (p <.05). This result supports hypothesis III. The premature infants undergoing binasopharyngeal prongs after suctioning in the holistic comfort group, the mean time of heart rate return to baseline is shorter than the usual care group.

The more discomfort in the usual care group can produce, more autonomic responses disrupting homeostasis should increase stress activating the sympathetic nervous system, as manifested by an increased heart rate. As stated, the comfort care intervention was designed to maintain homeostasis and helped the patient maintain or regain physical function (Wilson & Kolcaba, 2004). The mean of heart rate decreased during holistic comfort care to be in line with time for heart rate to return to baseline that the estimation of 65% of heart rate return to baseline within 2 minutes and within 20 minutes after suctioning heart rate return to baseline were completed. Unlike in usual care group, the estimation of 40% of heart rate return to baseline within 2 minutes but the heart rate return to baseline were completed at 120 minutes after suctioning(p <.05). The finding in this study was partly consistent with the previous study.

Johnston & et.al. (2003) reported the effect of comfort care on kangaroo mother care in preterm neonates (n = 61) between 28 and 32 weeks gestational age in NICU comprised the sample. In the experimental condition, the infant was held in kangaroo mother care for 15 minutes prior to and throughout heel lance procedure. In the control condition, the infant was in prone position swaddled in a blanket in the incubator. The secondary outcome was time to recover, defined as heart rate return to baseline. The findings in this study were confirmed in hypothesis III. The time for heart rate to return to baseline following the application of the adhesive bandage signifying the end of blood sampling was significantly different, 123 seconds (95%CI 103–142) for the kangaroo mother care condition and 193 seconds for incubator condition (95% CI 158–227) ($F_{1,61} = 13.6$, $p < .000$).

- **Time for oxygen saturation to return to baseline**

The finding of the present study revealed that the mean time of oxygen saturation return to baseline of premature infants undergoing insertion of binasopharyngeal prongs after suctioning during holistic comfort care group was not statistical significant difference from usual care group ($p < .05$). This result did not support hypothesis IV.

Although the mean of oxygen saturation increased during holistic comfort care from the more discomfort in the usual care group can disrupt more homeostasis but the time for oxygen saturation to return to baseline in the holistic comfort care was statistical significant difference from usual care group. This phenomenon can be explained so, during care in both groups if oxygen saturation drop from normal range. Nurses have responsibility to adjust FiO_2 on oxygen supply to the infants for oxygen saturation return to normal range rapidly. The possibility that the adjusted FiO_2 helped the oxygen saturation return to baseline so time for oxygen saturation to return to baseline in both groups were not statistical significant difference. The finding in this study was partly consistent with the previous study.

Rush, Rush, & Ighani (2003) provided comfort care in the retinopathy of prematurity (ROP) screening examination. This study was a prospective, randomized, controlled trial of 30 stable preterm infants who underwent initial ROP screening examinations. Fourteen studied infants were swaddled, held, and given 24% sucrose solution during the examination. Sixteen controls were examined while lying in their cribs. Vital signs (i.e., pulse rate, respiratory rate, and oxygen saturation), crying time, and time for the vital signs to return to baseline values were recorded at different times during the examination. The results showed that the time required for the oxygen saturation to return to their baseline values did not vary significantly. In this study the research explained the results that ROP screening was very distressful for preterm infants. The routine use of comfort care to reduce pain during the examination could not be supported by this study.

The behavioral responses:

- The comfort behavior scores

The finding of the present study revealed that the mean of the comfort behavior scores during holistic comfort care group was statistically significant difference from usual care group ($p < .001$) (Table 9). This result supports hypothesis V. The premature infants undergoing insertion of binasopharyngeal prongs after suctioning in holistic comfort group, the mean of the comfort behavior scores is lower than usual care group.

Preterm infants hospitalized in NICU received the discomfort from the binasopharyngeal prongs insertion. Moreover, they were suffered from discomfort that related to the inappropriate sensory input in NICU environment. The environment in usual care group were disruption of sleep from excessive noise and light levels, and frequent handling associated with medical or nursing procedures. The behavioral indicators are important markers of discomfort signals in infants. In premature infants, higher procedural discomfort exposure is associated with alter behavior reactivity. The more discomfort in usual care group, the more it can alter behavior reactivity than the holistic comfort care group because the holistic comfort care serves as a comforting and caring intervention for reducing the discomfort in premature infants undergoing binasopharyngeal prongs after suctioning. Therefore, the mean of comfort scores at immediately (11.06), 1 hour (7.21), 2 hours (7.59) in holistic comfort care generally were significantly different than immediately (11.68), 1 hour (9.95), 2 hours (9.43) in the usual care ($F_{1,61}=47.87$, $p<.001$) (the higher scores the more discomfort). In conclusion, the more comfort in the holistic comfort care group the more comforting and caring. The finding in this study was partly consistent with the previous study of gentle touch. The gentle touch can facilitate comfort, enhances the immature infant's experience in harsh NICU environment, avoiding prolonged stress, tactile aversion, avoidance acute distress could have the behavioral benefits (Bond, 2002) and promotes extrauterine adaptation in premature infants (Modrin-Talbott, Harrison, Groer, & Younger, 2003). Harrison, Olivet, Cunningham, Bodin, & Hicks (1996) conducted a similar pilot study to observe the effects of the gentle touch on preterm infants between 26 and 32 weeks of gestation. Data were gathered 10 minutes before the intervention, 15 minutes during the intervention, and 10 minutes after the intervention utilizing a video camera to assist with the data collection. The results of this study were that the comforting from gentle touch did appear soothing as evidenced by decreased levels of active sleep, motor activity, and behavioral distress. The findings in this study were confirmed in hypothesis V.

In summary, the findings of this study indicated that the holistic comfort care with quiet hours group were also at a significantly lower level of the mean of heart rate, higher level of the mean of oxygen saturation, and lower level of the mean of the comfort behavior scores than the usual care with non-quiet hours group with a statistically dirrerence. This study has shown that the holistic care implementation are available in dealing with premature infants' discomfort and effective in comforting infants when they face discomfort procedures like inserting binasopharyngeal prongs. These interventions are simple, feasible, and accessible and can be easily given by those caring for premature infants in NICU.

Limitations of the Study

1. A small, convenient sample of 10 participants is not a representative of all premature infants undergoing inserting binasopharyngeal prongs in Ramathibodi Hospital, Mahidol University. Therefore, the results cannot be generalized.
2. Medications that the samples received i.e., Aminophylline / Theophylline, that the researcher tried to control the equivalent conditions regarding the medication e.g., the time interval before receiving the medication and the time schedule for starting the experiment by crossover design.
3. About the carry-over effect, the researcher tried to control this effect by setting up two design treatments that are not conducted concurrently. The time period provided was 1 hour 15-30 minutes between holistic comfort care and usual care group, both method A and method B.
4. Since this research cannot use a blind technique, it might cause a bias by the research assistants.

CHAPTER VI
CONCLUSION

In this chapter, the conclusion of the study is presented, followed by the recommendations for nursing practice, nursing education, and further nursing research.

Conclusion of the study

This study was a crossover-experimental design that aimed to determine the effects of the holistic comfort care on physiological and behavioral responses of premature infants undergoing insertion of binasopharyngeal prongs. This study was based on Katherine Kolcaba's Comfort theory. The subject in this study was selected by purposive sampling which consisted of sixty-two episodes from ten premature infants patients undergoing inserting binasopharyngeal prongs in the Neonatal Intensive Care Unit (NICU) at Faculty of Medicine, Ramathibodi Hospital. The samples were premature infants who were postmenstrual ages 26 to 36 weeks providing their hemodynamic conditions were stable longer than 6 hours before the studying. Whereas the data were collected during the period of December 2007 to April 2008.

The instruments used in this research could broadly be divided into two groups regarding their utilization. The instruments belong to the first group was represented as a guideline of holistic comfort care with quiet hours protocol, which was developed by the researcher and Sakuntara Sudsaneha. The instruments belong to the second group were classified as instruments utilized in data collection process such as the demographic data collection form, observation record sheets, assessment of premature infant handling, digital lux meter, and sound level meter. The data used in the physiological responses of premature babies were collected by the Masimo radical pulse oximeter, was used to measure heart rate and oxygen saturation parameters. The modified COMFORT-Behavioral scales used in the behavioral responses measurement of premature babies were collected by three reliable research assistants who had the inter-rater reliability=0.85.

The data collection procedure in this study was encompassed by the protection of human subjects. First, permission to conduct the study was submitted for approval to the Institutional Review Board, Faculty of Medicine, Ramathibodi Hospital, Mahidol University. Afterward, a crossover-experimental design was used in this study, in which each subject served as their own control. Upon receiving the written inform consent from the parents, each subject was exposed to both methods: the usual care with non-quiet hours protocol period and the holistic comfort care with quiet hours protocol implementation. In usual care with non-quiet hours, the subject generally receives typical routine nursing care while holistic comfort care with quiet hours includes provision of physical, psychospiritual, sociocultural and environmental comfort, reduction of sound/light level, and promotion of comfort handling by gentle touch and reduction of disturbance/discomfort handling. The sequence of experimental method of eligible subjects was assigned by drawing lots (number 1 to 62) without replacement. The subjects were recorded on heart rate and oxygen saturation parameters as baseline, immediately connecting the mechanical ventilator and after suctioning at minute 2, 4, 6, 8, 10, and every 10 minutes until completed 2 hours. The duration between each method was 1 hours 15-30 minutes before starting the other method.

Sixty-two episodes from ten premature infants on the binasopharyngeal prongs with mechanical ventilation were purposively selected for the study according to the inclusion criteria. The subject consisted of 7 males and 3 females who were premature infants admitted to the NICU during December 2007 and August 2008, Ramathibodi Hospital, Mahidol University; postmenstrual ages ranged between 28 to 35.20 weeks. The mean age of the test subjects was 18.24 days with the average PMA of 31.49 weeks. 40% of them were born with extremely low weight and average weight became 1,144.50g at the time of observation.

All data were analyzed by using repeated measures and survival analysis with a powerful statistical analysis program, SPSS for Windows version 11.5 and 13.0 with statistical approach. The findings of the study are as follows:

1. The mode of sound, light level inside incubator measured in the NICU during the holistic comfort care with quiet hours is lower than during the usual care with non-quiet hours.

2. Frequency of the comfort handling received by the premature infants in the NICU during the holistic comfort care with quiet hours is more as compared to the disturbance and discomfort handling received in the usual care with non-quiet hours that is less.

3. The mean of heart rate in premature infants undergoing binasopharyngeal prongs after suctioning in the holistic comfort care with quiet hours is lower than the usual care with non-quiet hours ($F_{1,61} = 47.877$, $p < .001$).

4. The mean of oxygen saturation in premature infants undergoing binasopharyngeal prongs after suctioning in the holistic comfort care with quiet hours is higher than the usual care with non-quiet hours ($F_{1,61} = 7.874$, $p < .05$).

5. The mean time of heart rate return to baseline in premature infants undergoing binasopharyngeal prongs after suctioning in the holistic comfort care with quiet hours is shorter than the usual care with non-quiet hours. The survival curve showed the estimation of 65% of heart rate return to baseline within 2 minutes and 20 minutes after suctioning heart rate return to baseline were completed. Unlike in usual care group, estimation of 40% of heart rate return to baseline within 2 minutes but heart rate return to baseline were completed at 120 minutes after suctioning($p < .05$).

6. The comfort behavior mean score in premature infants undergoing binasopharyngeal prongs after suctioning in the holistic comfort care with quiet hours is lower than the usual care with non-quiet hours. The higher scores the more discomfort ($F_{1,61} = 7.874$, $p < .001$).

Recommendations of the study

The finding of this study provided the important information for nursing practice, nursing education, and nursing research as follows:

Recommendation for Nursing Practice

Although, the researcher cannot conclude a direct effect from the holistic comfort care on decreasing discomfort in premature infants undergoing inserting binasopharyngeal prongs, the partial credit supported the holistic comfort care can improve the physiologic and behavioral responses. Therefore, the holistic comfort care implementation is considered a part of total care and can be used as a guideline to promote comfort, reducing the stressful stimulation in the noxious NICU environment and discomfort from procedures. The findings have important implications for nursing practices in the NICU where comfort management is an essential element for the support of immature infants. Given that nurses have positive attitudes about the holistic comfort care basis over other procedures, which is an approach care for the premature infants in NICU.

Recommendation for Nursing Education

The concepts related the holistic comfort care should be integrated into the nursing curriculum regarding nursing care. The nursing instructor can use these research findings to teach nursing students in promoting the holistic comfort care based on the Comfort Theory.

Recommendation for Further Nursing Research

The sample size in this study was relatively small; therefore, further studies on the investigation of the effects of holistic comfort care in another setting with larger sample size should be conducted. Moreover, the studies should be conducted in soothing interventions to the other procedures, in which appear to be a worthwhile intervention for promoting comfort, sleep, growth and development in infants in the NICU.

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APPENDIX

APPENDIX A

คณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล
ถนนพระราม 6 กทม. 10400
โทร. (662) 354-7275, 201-1296 โทรสาร (662) 354-7233

Faculty of Medicine, Ramathibodi Hospital, Mahidol University
Rama VI Road, Bangkok 10400, Thailand
Tel. (662) 354-7275, 201-1296 Fax (662) 354-7233

เอกสารรับรองโดยคณะกรรมการจริยธรรมการวิจัยในคน

คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี

มหาวิทยาลัยมหิดล

เลขที่ ๒๕๕๐/๔๔๘

ชื่อโครงการ	ผลของการดูแลเพื่อส่งเสริมความสุขสบายแบบองค์รวมต่อการตอบสนองด้านสรีรวิทยาและพฤติกรรมในทารกคลอดก่อนกำหนดที่ได้รับการสอดใส่ท่อหายใจทางจมูก
เลขที่โครงการ/รหัส	ID ๑๐ – ๕๐ – ๒๒ ว
ชื่อหัวหน้าโครงการ	นางสาวเอื้ออารี วงษ์สวัสดิ์
ที่ทำงาน	ภาควิชาพยาบาลศาสตร์ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล

ขอรับรองว่าโครงการดังกล่าวข้างต้นได้ผ่านการพิจารณาเห็นชอบโดยสอดคล้องกับแนวปฏิญญาเฮลซิงกิ จากคณะกรรมการจริยธรรมการวิจัยในคน คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี

ลงนาม ....
กรรมการและเลขานุการจริยธรรมการวิจัยในคน (รองศาสตราจารย์ แพทย์หญิงดวงฤดี วัฒนศิริชัยกุล)

ลงนาม ....
ประธานกรรมการจริยธรรมการวิจัยในคน (ศาสตราจารย์ นายแพทย์บุญส่ง องค์พิพัฒนกุล)

วันที่รับรอง ๑๗ ตุลาคม ๒๕๕๐

คณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล
ถนนพระราม 6 กทม. 10400
โทร. (662) 354-7275, 201-1296 โทรสาร (662) 354-7233
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Rama VI Road, Bangkok 10400, Thailand
Tel. (662) 354-7275, 201-1296 Fax (662) 354-7233

Documentary Proof of Ethical Clearance Committee on Human Rights Related to Researches Involving Human Subjects Faculty of Medicine, Ramathibodi Hospital, Mahidol University

No. MURA2007/448

Title of Project	Effects of Holistic Comfort Care on the Physiological and Behavioral Responses in Premature Infants Undergoing Inserting Binasopharygeal Prongs
Protocol Number	ID 10– 50 – 22
Principal Investigator	Miss Ua-aree Wongsawat
Official Address	Department of Nursing Faculty of Medicine, Ramathibodi Hospital Mahidol University

The aforementioned project has been reviewed and approved by Committee on Human Rights Related to Researches Involving Human Subjects, based on the Declaration of Helsinki.

Signature of Secretary Committee on Human Rights Related to Researches Involving Human Subjects	.... Assoc. Prof. Duangrurdee Wattanasirichaigoon, M.D.
Signature of Chairman Committee on Human Rights Related to Researches Involving Human Subjects	.... Prof. Boonsong Ongphiphadhanakul, M.D.
Date of Approval	October 17, 2007

คณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล
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ที่ จวค ๑๖๐๖/๒๕๕๐ คณะกรรมการจริยธรรมการวิจัยในคน

วันที่ ๒๕ ตุลาคม ๒๕๕๐

เรื่อง แจ้งผลการพิจารณาของคณะกรรมการจริยธรรมการวิจัยในคน

เรียน นางสาวเอื้ออารี วงษ์สวัสดิ์

อ้างถึงโครงการวิจัยเรื่อง ผลของการดูแลเพื่อส่งเสริมความสุขสบายแบบองค์รวมต่อการตอบสนองด้านสรีรวิทยาและพฤติกรรมในทารกคลอดก่อนกำหนดที่ได้รับการสอดใส่ท่อหายใจทางจมูก

หมายเลขโครงการวิจัย ID ๑๐ - ๕๐ – ๒๒ ว

ในนามของคณะกรรมการจริยธรรมการวิจัยในคน ผมขอแสดงความยินดีที่โครงการวิจัยดังกล่าวข้างต้นของท่านได้ผ่านความเห็นชอบ จากคณะกรรมการฯแล้ว

เพื่อให้สอดคล้องกับระเบียบปฏิบัติคณะแพทยศาสตร์โรงพยาบาลรามาธิบดี ว่าด้วยการศึกษาวิจัยและการทดลองในมนุษย์ พ.ศ. ๒๕๔๔ คณะกรรมการฯ ขอให้ท่านถือปฏิบัติโดยเป็นไปตามข้อแนะนำดังต่อไปนี้

๑. การดำเนินการวิจัยจะต้องเป็นไปตามโครงร่างวิจัยล่าสุดที่ผ่านการพิจารณาจากคณะกรรมการจริยธรรมการวิจัยในคนแล้ว
๒. การดำเนินการวิจัยจะต้องไม่เบี่ยงเบนไปจากโครงร่างวิจัยหรือมีการเปลี่ยนโครงร่างการวิจัยก่อนที่การแก้ไขเพิ่มเติมโครงร่างวิจัยนั้นจะได้รับการอนุมัติและเห็นชอบจากคณะกรรมการจริยธรรมการวิจัยในคนก่อน ยกเว้นในกรณีจำเป็นที่จะต้องกระทำไปก่อนเพื่อขจัดอันตรายเฉพาะหน้าที่เกิดขึ้นกับผู้ยินยอมตนให้ทำวิจัย
๓. ในกรณีที่มีการเปลี่ยนแปลงชื่อโครงการไปจากชื่อเดิมที่เสนอไว้ ต่อคณะกรรมการฯ ต้องแจ้งชื่อมายังคณะกรรมการฯ เพื่อออกหนังสือรับรองให้เสมอ
๔. ผู้ยินยอมตนให้ทำวิจัยจะต้องได้รับเอกสารชี้แจงข้อมูล/คำแนะนำแก่ผู้ยินยอมตนให้ทำวิจัย (Patient/Participant Information Sheet) และลงนามในหนังสือยินยอมโดยได้รับการบอกกล่าวและเต็มใจ (Informed Consent Form) ก่อนเริ่มดำเนินการวิจัย
๕. ในเอกสารชี้แจงข้อมูล/คำแนะนำแก่ผู้ยินยอมตนให้ทำวิจัย (Patient's Information Sheet) จะต้องพิมพ์ข้อความดังต่อไปนี้ไว้ ด้วยทุกครั้ง

" ถ้าท่านมีข้อข้องใจหรือมีความกังวลใจเกี่ยวกับวิธีดำเนินการวิจัยของโครงการวิจัยนี้ ท่านสามารถติดต่อได้ที่ ประธานกรรมการ จริยธรรมการวิจัยในคน คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี หน่วยจริยธรรมการวิจัยในคน สำนักงานวิจัยคณะฯ อาคารวิจัยและสวัสดิการ ชั้น ๓ (ห้อง ๓) โทรศัพท์ ๐๒–๒๐๑ ๑๕๔๔ ในเวลาราชการ"

๖. ความลับของผู้ยินยอมตนให้ทำวิจัย จะต้องถูกปกปิดไว้ตลอดเวลา ยกเว้นถ้าเป็นคำสั่งตามกฎหมาย

สุดท้ายนี้ ขอให้โครงการวิจัยของท่านประสบผลสำเร็จตามความมุ่งหมายอันจะนำมาซึ่งความเจริญก้าวหน้าทางวิชาการและเพื่อประโยชน์ของมนุษยชาติสืบต่อไป

ขอแสดงความนับถือ

(ศาสตราจารย์บุญส่ง องค์พิพัฒนกุล)
ประธานกรรมการจริยธรรมการวิจัยในคน

INFORMED CONSENT FORM (THAI VERSION)

หนังสือยินยอมโดยได้รับการบอกกล่าวและเต็มใจ

สำหรับผู้เข้าร่วมการวิจัยที่ไม่สามารถแสดงความยินยอมได้ด้วยตนเอง

ชื่อโครงการ ผลของการดูแลเพื่อส่งเสริมความสุขสบายแบบองค์รวมต่อการตอบสนองด้านสรีรวิทยาและพฤติกรรมในทารกคลอดก่อนกำหนดที่ได้รับการสอดใส่ท่อหายใจทางจมูก

ชื่อผู้วิจัย นางสาว เอื้ออารี วงษ์สวัสดิ์

*ชื่อผู้เข้าร่วมการวิจัย...

อายุ......................เลขที่เวชระเบียน..

คำยินยอมของผู้มีอำนาจกระทำการแทนผู้เข้าร่วมการวิจัย

ข้าพเจ้า นาย/นาง/นางสาว..ซึ่งเป็นผู้มีอำนาจกระทำการแทนนาย/นาง/นางสาว/ด.ช./ด.ญ..ในฐานะ..............................ได้ทราบรายละเอียดของโครงการการวิจัย ตลอดจนประโยชน์ และข้อเสี่ยงที่จะเกิดขึ้นต่อผู้เข้าร่วมการวิจัยจากผู้วิจัยแล้วอย่าง ชัดเจนไม่สิ่งใดปิดบังซ่อนเร้นและยินยอมให้ทำการวิจัยในโครงการที่มีชื่อข้างต้น และข้าพเจ้ารู้ว่าถ้ามีปัญหาหรือ ข้อสงสัยเกิดขึ้นข้าพเจ้าสามารถสอบถามผู้วิจัยได้ และข้าพเจ้าสามารถไม่ให้ผู้เข้าร่วมการวิจัยเข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบต่อการรักษาที่ผู้เข้าร่วมการวิจัยได้รับ นอกจากนี้ผู้วิจัยจะเก็บข้อมูลเฉพาะเกี่ยวกับ ตัวผู้เข้าร่วมการวิจัยเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวผู้เข้าร่วมการวิจัยต่อหน่วยงานต่างๆที่เกี่ยวข้อง กระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ลงชื่อ... (ผู้มีอำนาจกระทำการแทน)

.... (พยาน)

.... (พยาน)

วันที่ ....

คำอธิบายของแพทย์หรือผู้ทำวิจัย

ข้าพเจ้าได้อธิบายรายละเอียดของโครงการ ตลอดจนประโยชน์ของการวิจัย รวมทั้งข้อเสี่ยงที่อาจจะเกิดขึ้นแก่ผู้เข้าร่วมการวิจัยให้ผู้มีอำนาจกระทำการแทนทราบแล้วอย่างชัดเจนโดยไม่มีสิ่งใดปิดบังซ่อนเร้น

ลงชื่อ.. (แพทย์หรือผู้วิจัย)

วันที่.................................

---

* ผู้เข้าร่วมการวิจัย หมายถึง ผู้ยินยอมตนให้ทำวิจัย

APPENDIX B

แบบบันทึกข้อมูล

INSTRUMENTS FOR DATA COLLECTION

DEMOGRAPHIC DATA FORM

Date……………………No………

HN…………Birth Date………………..Time……Sex…..Age……...days

Type of Delivery…………………….Indication……………………….....

Gestation age……………………weeks Birth weight………………...g

Postmenstrual age……………weeks Current weight……..............g

Mode of mechanical ventilator……………………………………………

Duration of using binasopharyngeal prongs………………………..days

Frequency of suctioning in 24 hours………………………………times

Period of suctioning time in each episode…………………………mins

Diagnosis…………………………………………………………………

……………………………………………………………………………

Health status and Treatment

………………………………………………………………………………

………………………………………………………………………………

………………………………………………………………………………

………………………………………………………………………………

………………………………………………………………………………

………………………………………………………………………………

OBSERVATION RECORD SHEET

Time	Sound level (dB-A)	Light level (lux)	Handling score	HR (BPM)	SO_2 (%)	COMFORT-B scale	Remark
Baseline							
Immediately							
2 mins							
4 mins							
6 mins							
8 mins							
10 mins							
20 mins							
30 mins							
40 mins							
50 mins							
60 mins							
70 mins							
80 mins							
90 mins							
100 mins							
110 mins							
120 mins							

Method □ **A**

□ **B**

Group □ **Holistic Comfort Care**

□ **Usual Care**

Date………….NO……..

แบบประเมินการตอบสนองด้านพฤติกรรมต่อความสุขสบายของทารกเกิดก่อนกำหนด

*** ให้สังเกตพฤติกรรมทารกก่อนเป็นเวลา 60 วินาที

จึงทำการสรุปคะแนนการตอบสนองด้านพฤติกรรมต่อความสุขสบาย (1-5) ***

time at…………

การตอบสนอง	1	2	3	คะแนนที่ให้
ความตื่นตัว	หลับลึก.....	หลับตื้น และ / หรือ ง่วงซึม......	ตื่นตัว/ ตื่นตัวมาก.......	
ความสงบ	สงบ......	กระวนกระวายเล็กน้อย / กระวนกระวาย......	กระวนกระวายมาก / หวาดกลัวง่าย......	
การหายใจ	ไม่หายใจเอง /หายใจสัมพันธ์กับเครื่อง ………	หายใจต้านเครื่องเป็นบางครั้ง ………	หายใจต้านเครื่องตลอด / หายใจสู้เครื่อง........	
การเคลื่อนไหวร่างกาย	ไม่มีการเคลื่อนไหว........	มีการเคลื่อนไหวเล็กน้อย / มีการเคลื่อนไหวเล็กน้อยบ่อยครั้ง.......	มีการเคลื่อนไหวของศีรษะและแขนขาทุกส่วน/ มีการเคลื่อนไหวของร่างกายทุกส่วน บิดตัวหรือยกลำตัว.........	
ความตึงตัวของกล้ามเนื้อ	ผ่อนคลาย........	กำลังกล้ามเนื้อปกติ.......	กำลังกล้ามเนื้อเพิ่มขึ้น / กล้ามเนื้อแข็งเกร็ง........	
ความตึงเครียดของใบหน้า	ผ่อนคลาย.......	แรงตึงกล้ามเนื้อใบหน้าปกติ / บางกล้ามเนื้อมีแรงตึง.......	กล้ามเนื้อมีแรงตึงทั่วใบหน้า / สีหน้าบูดเบี้ยว........	
คะแนนรวม				

APPENDIX C

Table 10 Kolmogorov-Smirnov Test
(Heart Rate of the Holistic Comfort Care with Quiet Hour)

		holis tic heart rate baseline	holistic heart rate immediately	holistic average heart rate 1hr at 10 20 30 40 50 60min	holistic average heart rate 2hr at 70 80 90 100 110 120min
N		62	62	62	62
Normal Parameters(a,b)	Mean	164.65	166.71	159.2527	160.6828
	Std. Deviation	7.841	7.139	7.22099	7.22099
Most Extreme Differences	Absolute	.084	.120	.062	.057
	Positive	.065	.120	.052	.047
	Negative	-.084	-.077	-.062	-.057
Kolmogorov-Smirnov Z		.661	.947	.491	.451
Asymp. Sig. (2-tailed)		.775	.331	.969	.987

a Test distribution is Normal.
b Calculated from data.

Table 11 One-Sample Kolmogorov-Smirnov Test
(Heart Rate of the Usual Care with Non- Quiet Hour)

		usual heart rate baseline	usual heart rate immediately	usual average heart rate 1hr at 10 20 30 40 50 60min	usual average heart rate 2hr at 70 80 90 100 110 120min
N		62	62	62	62
Normal Parameters(a,b)	Mean	163.85	168.45	164.8629	164.5269
	Std. Deviation	8.224	8.481	7.22804	7.44061
Most Extreme Differences	Absolute	.117	.107	.078	.087
	Positive	.117	.077	.078	.045
	Negative	-.077	-.107	-.061	-.087
Kolmogorov-Smirnov Z		.918	.845	.611	.683
Asymp. Sig. (2-tailed)		.368	.472	.849	.739

a Test distribution is Normal.
b Calculated from data.

Table 12 One-Sample Kolmogorov-Smirnov Test

(Oxygen Saturation of the Holistic Comfort Care with Quiet Hour)

		holistic oxygen sat. baseline	holistic oxygen sat. immediately	holistic average oxygen saturation 1hr at 10 20 30 40 50 60min	holistic average oxygen saturation 2hr at 70 80 90 100 110 120min
N		62	62	62	62
Normal Parameters(a,b)	Mean	96.31	96.19	96.9516	96.7070
	Std. Deviation	1.532	2.231	1.26332	1.36729
Most Extreme Differences	Absolute	.142	.157	.103	.088
	Positive	.126	.079	.062	.062
	Negative	-.142	-.157	-.103	-.088
Kolmogorov-Smirnov Z		1.121	1.238	.808	.695
Asymp. Sig. (2-tailed)		.162	.093	.531	.719

a Test distribution is Normal.
b Calculated from data.

Table 13 One-Sample Kolmogorov-Smirnov Test

(Oxygen Saturation of the Usual Care with Non-Quiet hour)

		usual oxygen sat. baseline	usual oxygen sat. immediately	usual average oxygen saturation 1hr at 10 20 30 40 50 60min	usual average oxygen saturation 2hr at 70 80 90 100 110 120min
N		62	62	62	62
Normal Parameters(a,b)	Mean	96.89	96.35	96.0081	95.8548
	Std. Deviation	1.821	2.025	1.79896	1.66980
Most Extreme Differences	Absolute	.139	.124	.066	.068
	Positive	.139	.102	.066	.043
	Negative	-.103	-.124	-.063	-.068
Kolmogorov-Smirnov Z		1.091	.976	.522	.536
Asymp. Sig. (2-tailed)		.185	.296	.948	.936

a Test distribution is Normal.
b Calculated from data.

Table 14 One-Sample Kolmogorov-Smirnov Test

(The Comfort Behavior Mean Scores of the Holistic Comfort Care with Quiet Hour)

		holistic comfort baseline	holistic comfort immediately	holistic average comfort 1hr at 10 20 30 40 50 60min	holistic average comfort 2hr at 70 80 90 100 110 120min
N		62	62	62	62
Normal Parameters(a,b)	Mean	10.39	11.06	7.2151	7.5941
	Std. Deviation	2.830	2.388	.80887	1.22125
Most Extreme Differences	Absolute	.124	.156	.133	.144
	Positive	.124	.156	.133	.144
	Negative	-.075	-.097	-.075	-.096
Kolmogorov-Smirnov Z		.976	1.228	1.048	1.131
Asymp. Sig. (2-tailed)		.297	.098	.222	.155

a Test distribution is Normal.
b Calculated from data.

Table 15 One-Sample Kolmogorov-Smirnov Test

(The Comfort Behavior Mean Scores of the Usual Care with Non-Quiet Hour)

		usual comfort baseline	usual comfort immediately	usual average comfort 1hr at 10 20 30 40 50 60min	usual average comfort 2hr at 70 80 90 100 110 120min
N		62	62	62	62
Normal Parameters(a,b)	Mean	10.32	11.68	9.9597	9.4382
	Std. Deviation	2.501	2.815	1.56454	1.32691
Most Extreme Differences	Absolute	.151	.176	.067	.144
	Positive	.151	.176	.067	.144
	Negative	-.121	-.086	-.061	-.097
Kolmogorov-Smirnov Z		1.191	1.384	.524	1.137
Asymp. Sig. (2-tailed)		.117	.043	.947	.151

a Test distribution is Normal.
b Calculated from data.

Table 16 Mean and Median for Survival Time of Heart Rate Return to Baseline in Holistic Comfort Care and Usual Care

group	Mean(a)			
	Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
holistic comfort care	4.403	.811	2.814	5.992
usual care	21.855	4.260	13.506	30.204
Overall	13.129	2.305	8.612	17.646

group	Median			
	Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
holistic comfort care	2.000	.179	1.648	2.352
usual care	4.000	1.429	1.200	6.800
Overall	2.000	.348	1.319	2.681

Table 17 Test of Equality of Survival Distributions for Time of Heart Rate Return to Baseline in Holistic Comfort Care and Usual Care

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	17.821	1	.000

Table 18 Mean and Median for Survival Time of Oxygen Saturation Return to Baseline in Holistic Comfort Care and Usual Care

group	Mean(a)			
	Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
holistic comfort care	2.419	.645	1.156	3.683
usual care	8.726	2.717	3.400	14.052
Overall	5.573	1.424	2.781	8.364

group	Median			
	Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
holistic comfort care	1.000	.	.	.
usual care	1.000	.	.	.
Overall	1.000	.	.	.

a Estimation is limited to the largest survival time if it is censored.

Table 19 Test of Equality of Survival Distributions for Time of Oxygen Saturation Return to Baseline in Holistic Comfort Care and Usual Care

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	6.706	1	.010

APPENDIX D

Table 20 Mauchly's Test of Sphericity of Mean of Heart Rate, Oxygen Saturation, and the Comfort Behavior Scores.

Within Subject Effect	Mauchly'W	Approx. Chi-Square	df	p
Mean of heart rate				
Treatment	1.000	.000	0	.999
Time	.783	14.661	2	.001
Mean of oxygen saturation				
Treatment	1.000	.000	0	.999
Time	.605	30.117	2	.000
Mean of the comfort behavior scores				
Treatment	1.000	.000	0	.999
Time	.743	17.809	2	.000

APPENDIX E

TISTR

Request No. EE. 585/50

MTC No. EEL. BP. 64/0950

CALIBRATION CERTIFICATE

Submitted by : Mahidol University

Address : Department of Nursing Faculty of Medicine, Ramathibodi Hospital

Calibrated at : Electrical and Electronic Standards Laboratory, Industrial Metrology and Testing Service Center

Instrument Calibrated :

Description : Sound Level Meter

Manufacturer : Digicon

Model : DS-40

Serial No. : M114235

Microphone No. : -

Preamplifier No. : -

Ambient Environment

Temperature : (23 ± 3) °C

Relative Humidity : (55 ± 15) %

Ambient Pressure : (1 008 ± 5) hPa

Standards used :

Multifunction Acoustic Calibrator Brüel&Kjær 4226 S/N 2295571

with Coupler UA0915 S/N 2295571

Calibration Procedure : This procedure is developed by Electrical and Electronic Standards Laboratory based on ;

1. IEC 651(1979) Standard for Sound Level Meters
2. International Recommendation OIML R 58(1998) for Sound Level Meters

This instrument has been calibrated against standards mantained at Electrical and Electronic Standards Laboratory (EEL), which are traceable to ;

- National Institute of Metrology (Thailand)

Date of Receipt : 24 Sep. 2007

Date of Calibration : 27 Sep. 2007

1 / 3

The above results are valid exclusively for the tested / analysed sample(s) calibrated item(s) as mentioned in this report/certificate.
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Fax. (66) 0 2323 9165

TISTR

LABORATORY ACCREDITATION CALIBRATION No. 0015

Request No. BP-P 553 / 50 MTC No. PSL-P 389 / 50

CALIBRATION CERTIFICATE

Nomenclature : **Digital Lux Meter** Serial No. : L552583

Maker : DIGICON Model : LX-50

Customer : **MAHIDOL UNIVERSITY**

Address : Department of Nursing Faculty of Medicine, Ramathibodi Hospital

Date of request : 24 September 2007

Date of calibration : 9 October 2007

Place of calibration : Photometry Standards Laboratory, MTC. (Bangpoo)

Basis of calibration : Calibrated at 0 ~ 5000 lux.

Condition of calibration : - Ambient temperature : 25 ± 2^{o}C.

- Relative humidity : 60 ± 20 %

Reference Standard : Working Standard Luminous Intensity Lamp, Serial No.: SB50142C, which was calibrated on 5 July 2007, can be traceable to International System of Units (SI) through the National Measurement Institute (NMI), Australia calibration certificate No. RN45677, RN050210 and RN05211.

Support Equipment : 1. Photometric bench , 3.0 meter long

2. DC power supply, Serial No.: BC - 341006035007/2

3. Digital Multimeter , Model : R 6551 , S/N : 42040037 and 42040048

Calibration Procedure : The measurement was done in accordance with WI.CP.10.

The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k = 2 , providing a level of confidence of approximately 95 %.

page 1 of 2

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TISTR

Request No. EE. 585/50 **MTC No.** EEL.BP. 65/0950

CALIBRATION CERTIFICATE

Submitted by : Mahidol University.

Address : Department of Nursing Faculty of Medicine, Ramathibodi Hospital.

Calibrated at : Electrical and Electronic Standards Laboratory,Industrial Metrology and Testing Service Center

Instrument Calibrated :

Description : Digital Timer

Manufacturer :

Model : Timer-5

Serial No. :

Ambient Environment :

Temperature : $(23 \pm 2)^{\circ}C$

Relative humidity : (50 ± 15) %

Standards Used : Universal Counter Agilent 53132A S/N KR01202073.

Calibration Procedure : Measuring the int.ernally time base signal of unit under test.

This instrument has been calibrated against standards maintained at Electrical and Electronic Standards Laboratory (EEL), which are traceable to ;

- National Institute of Metrology (Thailand)

The information on actual reading is attached herewith and the uncertainty limits quoted refer to the measured values only.

The reported expanded uncertainty is based upon a standard uncertainty multiplied by a coverage factor k = 2, providing a level of confidence of approximately 95%.

Date of Receipt : 24 Sep. 2007

Date of Calibration : 18 Oct. 2007 1/2

The above results are valid exclusively for the tested / analysed sample(s) calibrated item(s) as mentioned in this report/certificate.
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BIOGRAPHY

NAME	Miss Ua-aree Wongsawat
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INSTITUTIONS ATTENDED	Mahidol University, 1994-1998: Bachelor of Nursing Science
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