Abstract of thesis entitled

**Effect of massage therapy in reducing signs of stress on premature infants**

Submitted by

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Prematurity is a common health issue worldwide. In Hong Kong, the rate of prematurity is in an increasing trend, from 4.7% in 1999 to 5.1% in 2004 (Tertiary-wide Obstetric & Gynecology Audit Report, 2004). Preterm infants are usually required to hospitalize in neonatal intensive care unit (NICU) which expose them to certain stressors such as noise, caregiver procedure, medical manipulations and pain (Harrison et al., 2003). Stress would lead to certain illnesses likes metabolic and cardiovascular disorders (Caldji, Diorio, & Meaney, 2000). Facing stress of preterm infants not only affects the developmental and neurodevelopment outcome but also increase the morbidity and mortality (Mitchell & Boss, 2002). Preterm birth is a complicated health problem which affects the infant itself and also increase the burden to society as it costs nearly US$26 billion dollars per year for both inpatient and outpatient care (Richard & Adrienne, 2007).

Although there were many known benefits of massage therapy in premature
infants and the safety of practicing was being acknowledged, massage therapy is still not being practiced in Hong Kong health care settings. Massage therapy was effective in reducing signs of stress on premature infants and could be performed by parents safely as evidenced by six researches (Dieter, Field, Hernandez-Reif, Emory, & Redzepi, 2003; Hernandez-Reif, Diego, & Field, 2007; Lee, 2005; Kuhn, Schanberg, Field, Symanski, Zimmerman, Scafidi, & Roberts, 1991; Smith, Kux, Haley, Beechy, & Moyer-Mileur, 2012; Wheeden, Scafidi, Ironson, Valdeon, & Bandstra, 1993). Based on the evidence, a new evidence-based practice was developed for reducing signs of stress of premature infant by using massage therapy in NICU. Implementation potential was reviewed in relation to target setting, transferability of findings and cost-benefit analysis. Implementation plan was developed. Stakeholders were identified and communication process was discussed in details. Pilot testing would be carried out to assess the feasibility of implementing the guideline. Finally, evaluation on patient, parents and healthcare providers’ outcome were required in implementing this new change smoothly.
Effect of massage therapy in reducing signs of stress on premature infants

By

Lai Ching Hung

A dissertation submitted in partial fulfillment of the requirements for
The Degree of Master of Nursing
At the University of Hong Kong
July 2013
Declarations

I declare that this dissertation represents my own work, except where due acknowledgment is made and that it has not been previously included in a thesis, dissertation or report submitted to this University or any other institution for a degree, diploma or other qualifications.

Signed __________________________________________________

Lai Ching Hung
Acknowledgements

I would like to offer my heartfelt thanks to my dissertation supervisor, Dr. Vivian Ngai, who has been giving me support, guidance which enables me to overcome several obstacles and develop a thorough understanding of the dissertation.

I would also like to thank Dr. Daniel Fong and Dr. William Li for their lectures. Without their explanation, this dissertation piece could not be possible.
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Chapter 1: Statement of the Problem

Introduction

Prematurity is a worldwide health problem. With the technological advancements in neonatal care, the survival rate of premature babies has significantly increased (Saigal & Doyle, 2008). Premature babies are nursed in the neonatal intensive care unit (NICU), which is a highly stressful environment for premature babies. Continuous exposure to an environmental or physical stressor increases the risk of certain illnesses such as intraventricular hemorrhage, disturb growth and development, as well as increase morbidity and mortality rate (Harrison, Roane, & Weaver, 2003). A “minimal handling” policy has been adopted in most NICU since the 1980s (Long, Philip, & Lucey, 1980). However, this policy leads to lack of tactile stimulation, which is important for the development of premature babies (Harrison, Williams, Berbaum, Stem, & Leeper, 2000). Massage therapy has been reported to benefit preterm infants by reducing stress, promoting weight gain, and enhancing development (Dieter, Field, Hernandez-Reif, Emory, & Redzepi, 2003; Harrison et al., 2000). In the present study, data from various studies are summarized to synthesize the best evidence-based practice in reducing signs of stress in premature infants.
Background

Babies born less than 37 weeks of gestation are considered premature. A report by the National Centre for Health Statistics in the United States showed a remarkable national preterm rate of 12% for 2010 (Hamilton, Martin, & Ventura, 2010).

Preterm infants are usually required to stay in the neonatal intensive care unit (NICU) of a hospital, which exposes them to certain stressors such as noise, caregiver procedures, medical manipulation, and pain (Harrison et al., 2003). Roy and Andrew (1991) defined stress as “a condition or adverse circumstance that disturbs, or is likely to disturb the normal physiological and psychological functioning of the individual.”

The autonomic nervous system (ANS), which includes the sympathetic and the parasympathetic nervous systems as well as the hypothalamic–pituitary–adrenal (HPA) axis, is involved in managing stressful stimuli (Longin, Gerstner, Schaible, Lenz, & Konig, 2006). However, an immature ANS and HPA axis in premature infants can induce exaggerated stress response and delay recovery from stimuli (Longin et. al, Gerstner, Schaible, Lenz, & Konig, 2006). Stress exerts a harmful effect on preterm infants (Field, 2003).

Stress can be reflected by immediate and long term outcomes. Immediate outcomes include physiological and behavioral signs, whereas long-term outcomes are reflected by hormonal changes inside body (Harrison et al., 2000; Kuhn et al.,...
1991). According to Harrison et al. (2003) and Modrcin-McCarthy (1997), the response of a preterm infant to stress includes physiological stress signals and behavioral stress response. Changes in heart rate (HR) (bradycardia and tachycardia), respiratory rate (RR) (tachypnea), and blood pressure (BP) (hypertension), as well as $O_2$ saturation (desaturation), are among the physical changes caused by stress. As indicated by Harrison et al. (2003) and Modrcin-McCarthy, behavioral signs include self-regulatory behaviors such as sucking and grasping, which help infants maintain balance and cope with stress. Once the self-regulatory mechanism fails, stress cues such as arching, leg extension, kicking, arm waving, fussing, crying, and grimace are observed. Moreover, preterm infants who are under stress show changes in sleep-wake states and prolonged alert state. Regardless of severity, any of the above behavioral cues can indicate stress (Modrcin-McCarthy, 1997). Reduced levels of stress are indicated by decreased levels of these cues (Harrison et al., 2000).

To improve quality care and outcome for preterm infants, the focus of care should be directed to supportive therapy (Blackburn, 1998). Massage therapy, also known as tactile-kinesthetic stimulation, is definitely an effective intervention in developmentally supportive care (Dieter et al., 2003; Hernandez-Reif, Diego, & Field, 2007; Horrison et al., 2000; Lee, 2005).

Massage procedures vary in duration and the frequency, but the sequence of
massaging body parts is consistent to a certain extent in different studies (Dieter et al., 2003; Hernandez-Reif et al., 2007; Horrison et al., 2000; Lee, 2005). Generally, the start time of massage begins approximately one hour after feeding, three times daily for a 15-minute duration. Each 15-minute massage includes five minutes of tactile stimulation, five minutes of kinaesthetic stimulation, and ended with another five minutes of tactile stimulation. Infants are placed in a prone position during the first five-minute tactile stimulation. Six 10-second periods of stroking are performed on the different parts of the body, including the head, neck, shoulder, buttocks, lower limbs, and upper limbs. It comprises five 1-minute segments for each body part. The second phase involves placing the infant in a supine position and still using the five 1-minute segments. Each segment has six passive flexions or extensions of arms and legs for 10 seconds. The third phase involves placing the infant in a prone position again and repeating the step in the first phase (Dieter et al., 2003; Hernandez-Reif et al., 2007; Wheeden, Scafidi, Ironson, Valdeon, & Bandstra, 1993).

A review by field revealed that more than nine studies suggested the safety of massage therapy performed on premature infants. Horrison et al. (2000) and Lee (2005) also indicated the stable physiological conditions, such as stable HR and O₂ saturation, during and after massage. Ferber and Kuint (2002) and Ferber, Kuint, Weller, Feldma, Dollberg, Arbel, et al. (2002) also mentioned the effectiveness of
massage therapy performed by parents and healthcare professionals. Massage therapy is a useful intervention to administer in an acute care hospital setting to reduce the signs of stress in premature infants and thus prevent postnatal complications.

Affirming Needs

In Hong Kong, the rate of prematurity increased from 4.7% in 1999 to 5.1% in 2004 (Tertiary-wide Obstetric & Gynecology Audit Report, 2004). Prematurity remains common in Hong Kong; in 2010, approximately 88,000 premature babies were born, and a considerable NICU admission rate was reported (談, 2011). Survival rate reached 96% in 2004 (Tertiary-wide Obstetric & Gynecology Audit Report, 2004). Preterm birth is a complex health problem that costs nearly US $26 billion per year (Richard & Adrienne, 2007). The average cost of hospitalization for a preterm infant is nearly 16 times that for a normal infant because the former requires a longer duration of hospital stay; this expenditure related to inpatient and outpatient care of premature infants is significant in the medical sector (Center for Health Care Research & Transformation, 2010).

NICU can provide treatment for preterm infants but also given sensory overload to them (Blackburn, 1998). The energy conservation model developed by Sammons and Lewis (1985) indicates that energy expenditure would be the result of
neonatal stress. Infants primarily need calories and nutrients to overcome physiological and behavioral demands before reserving them for growth and development. Decreased alveolar ventilation and O₂ level, which lead to hypoxia, are observed during stress or when crying (DePaul & Chambers, 1995). Increased blood pressure and intracranial pressure during stressful events increase the risk of intraventricular hemorrhage, which can result in brain damage and other serious consequences (Modrcin-McCarthy, 1997). Therefore, stress consumes energy and disturbs the healing and recovery process of preterm infants, as well as affects the organization of the central nervous system. Chronic exposure to stressors without intervention leads to HPA activity suppression, which inhibits the ability of infants to cope with acute stressors (Harrison et al., 2003). When the stress cannot be managed, stress would lead to certain illnesses such as metabolic and cardiovascular disorders (Caldji, Diorio, & Meaney, 2000). Repeated stress is associated with adverse neurodevelopment in neonates (Mitchell & Boss, 2002). Therefore, stress in preterm infants affects the developmental and neurodevelopmental outcomes, as well as increases morbidity and mortality.

Preterm infant care does not only focus on survival but promotes better development as well. A “minimal handling” policy has long been implemented since the study by Long et al. (1980), which indicates that the risk of desaturation of
preterm infants increases with handling. The NICU in the local setting continues to adopt this principle. However, several studies contradict this principle and argue that massage therapy can benefit preterm infants and increase weight gain, reduce stress, promote neurodevelopment, and reduce the duration of hospital stay (Field, 2002; Hernandez-Reif et al., 2007; Scafidi et al., 1990). Lower cortisol levels were found in massaged babies, indicating a reduction in stress level (Acolet et al., 1993). Behavioral Distress Scores were significantly lower in infants who received massage than those who received no massage (Harrison et al., 2000; Lee, 2005). The mechanism of reducing stress by massage is not well investigated but would probably due to the impact on the HPA axis, promoting the maturation and adaptation of stress (Scafidi et al., 1990) The pressure and movement applied to infants during massage could decrease the production of hormone stress markers (Lee, 2005).

Despite the many known benefits of massage therapy for premature infants and the acknowledgement of its safety, this intervention is still not practiced in Hong Kong healthcare settings.

**Questions**

How effective is massage therapy in reducing signs of stress in premature infants in NICU?
**Objectives**

The objectives of this study are listed as follows:

1. To search available literature discussing the effects of massage therapy in reducing signs of stress in premature infants in NICU

2. To summarize the study findings and generate a table of evidence

3. To perform a quality assessment of selected studies

4. To analyze and synthesize the collected data

5. To review the implementation potential of performing massage therapy on premature infants in NICU

6. To generate an evidence-based practice guideline and evaluation plan for massage therapy on premature infants in NICU

**Stating the significance**

**Preterm infants**

Preterm infants who receive massage therapy show reduced stress behavior and improved orientation performance because of the stabilizing effect of the treatment (Dieter et al., 2003; Hernandez-Reif et al., 2007). Better conservation of energy leads to fewer postnatal complications and better growth development (Beachy, 2003; Blackburn, 1998; Hernandez-Reif et al., 2007). It also promotes
neurobehavioral organization when exposed to stress, improves pain tolerance, and enhances the quality of life of premature infants (Acolet et al., 1993).

**Parents**

Massage therapy administered by parents on their infant can increase bonding and interaction between them (Ferber & Kuint, 2002). Participating in infant care allows parents to gain a better understanding of infant cues, which can promote satisfaction and confidence in parents (Beachy, 2003). Therefore, massage therapy reduces the stress level of parents and the incidence of parental depression (Onozawa, Glover, Adams, Modi, & Kumar, 2001).

**Healthcare professionals**

The value of massage therapy is highly appreciated by healthcare professionals. Nurses have given massage therapy moderate to high satisfaction ratings (Livingston et al., 2009). Moreover, reduced postnatal complications in preterm infants can reduce nursing workload (Beachy, 2003).

**Hospitals**

Massage therapy shortens the length of stay of preterm infants by about three days to six days (Scafidi et al., 1990; Field, 2002). Moreover, massage therapy reduces complications and promotes better neurodevelopment, thereby decreasing medical costs and resource allocation for premature infant care (Blackburn, 1998).
Chapter 2: Critical Appraisal

The criteria, search keywords, and strategies for the selection of studies are discussed in this chapter. A table of evidence provides information on the selected studies. Quality assessment, information summary, and data synthesis of these studies are conducted.

Selecting Studies for Review

Inclusion criteria

All studies written in English should be included. The study design should be randomized controlled trials (RCTs) or quasi-experimental studies. The study should involve only premature infants with gestational ages less than 37 weeks and medically stable. In addition, the intervention of the study should focus on massage therapy or tactile and kinesthetic stimulation. If the study includes a control group, this group should consist of infants not receiving massage therapy. The outcome measure should be signs of stress in premature infants, including physiological or behavioral changes.

Exclusion criteria

Study designs with no control group will be rejected. Preterm babies who are persistent ventilator dependent and exhibit genetic anomalies, congenital heart malformations, sepsis, central nervous system dysfunctions, and inborn error of
metabolism will be excluded because these problems can influence stress measures.

Studies comparing the effects of different types of oil in massage therapy and gentle human touch will be disregarded.

**Search strategies**

To investigate the effect of massage therapy on reducing signs of stress in preterm babies, a database search (on PubMed, Ovid SP, and CINAHL databases) was conducted from November 2011 to July 2012. Keywords such as massage or tactile–kinesthetic stimulation, preterm infants/neonates/babies or premature infants/neonates/babies or prematurity, stress or distress were used. Different combinations of keywords were used to facilitate the search process. Main keyword components were connected using the conjunction “AND.” The search yielded 147 articles in PubMed, 17 of which were non-English; 219 articles in Ovid SP, 63 of which were non-English; and 21 articles in CINAHL, 1 of which was non-English. Only English articles were reviewed. Initial screening by title reduced the results to 47 articles, consisting of 25 studies from PubMed, 18 from Ovid SP, and 4 from CINAHL. Scanning the abstracts of the selected articles further narrowed the search to 13 articles from PubMed, 8 from Ovid SP, and 2 from CINAHL. After a review of the full texts and reference lists of the potentially relevant articles 13 articles remained: 7 from PubMed (2 RCTs were added after reviewing the article reference list); 4 from
Ovid SP (1 RCT was added after reviewing the article reference list); and 2 from CINAHL. With consideration of the inclusion and exclusion criteria as well as the review of these articles, the following studies were selected: an experimental study without a control group, four studies involving medically unstable participants, one study focusing on the gentle human touch as an intervention, and one study comparing various types of massage oil. In four studies, signs of stress reduction were not used as the primary outcome. By eliminating duplicate articles, six articles were finally selected (Appendix A, Flow chart 1).
By keyword search:
- massage or tactile–kinesthetic stimulation
- preterm infants/neonates/babies or premature infants/neonates/babies or prematurity
- stress or distress

PubMed: 147 articles (non-English: 17)
Ovid SP: 219 articles (non-English: 63)
CINAHL: 21 articles (non-English: 1)

Reviewed by title
- 25 articles
- 18 articles
- 4 articles

Reviewed by abstract
- 13 articles
- 8 articles
- 2 articles

Reviewed by full paper and reference list
- 7 articles (and 2 from reference lists)
- 4 articles (and 1 from reference lists)
- 2 articles

Total articles for review after elimination of duplicates: 6
Appraisal Strategies

Critical appraisal of the selected studies was conducted using the methodology checklist of Scottish Intercollegiate Guidelines Network (SIGN, 2008). An assessment of the internal validity of the studies included the appropriateness of the focus question, details used in the randomization process, adequacy of the concealment method used, level of blinding, differences between groups, standardized outcome measures, dropout rate, intention-to-treat analysis, and comparability of the results from all sites. Different descriptions, including “well-covered,” “adequately addressed,” “poorly addressed,” “not addressed,” “not reported,” and “not applicable,” were used for each category. Assessment of the methods used to minimize bias, correlation of the effect and the intervention, and the generalizability of the study result was conducted. Subsequently, the quality of the studies was evaluated based on level of evidence in SIGN (Appendix B). A rating scale was established, with 1++ as the highest and 4 as the lowest. The symbols “++,” “+,” and “-” indicate lower, low, and high chance of committing bias, respectively. Levels 1 to 4 are assigned according to the type of study design.
Results

Summary of study characteristics

Five randomized-controlled trials and one quasi-experimental study were selected. Five studies were from United States of America and one was from Korea. The publication years were from 1991 to 2012. Sample sizes ranged from 13 to 25, with follow-up periods ranging from 5 days to 4 weeks. All studies focused on massage therapy as the intervention to investigate the effects on the physiological or behavioral signs of stress (Table 1).
(ii) Assembly and evaluation of evidence (Table 1)

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Result</th>
<th>Effect size</th>
</tr>
</thead>
</table>
| Wheeden, Scafi, Ironson, Valdeon, & Bandstra, 1993 | RCT with stratification | - Mean gestational age 30 weeks  
- Mean birth/entry weight 1212/1473g  
- From intermediate care unit  
- Cocaine-exposed infants | Massage therapy  
(n=15) | No massage  
(n=15) | 10 days | (1) Neonatal Stress Behavioral Scale  
(2) Postnatal Complication Scale | (1) Day 1, Day 10: 2.7, 1.6<sup>a</sup>  
(2) Day 1, Day 10: 68.6, 95.7<sup>b</sup> | (1) Day 1, Day 10: 2.2, 2.3<sup>a</sup>  
(2) Day 1, Day 10: 71.3, 78.9<sup>b</sup> | (1) -4.29 (p=0.05)  
(2) 25.74 (p<0.001) |
| Hernandez-Reif, Diego, & Field, 2007 | RCT | - Mean gestational age 29.5 weeks  
- Mean birth | Massage therapy  
(n=18) | No massage  
(n=18) | 5 days | (1) Duration of infants’ stress behaviors | (1) first day, last day: 8.1, 5.9  
(2) first day, last day: 7.2, 7.8 | (1) first day, last day: 7.2, 7.8  
(2) first day, last day | (1) 4.81 (p<0.05)  
(2) 6.11 (p<0.05) |
<table>
<thead>
<tr>
<th>Weight (g)</th>
<th>From NICU</th>
<th>Massage therapy</th>
<th>Mean gestational age (weeks)</th>
<th>Mean birth/entry weight (g)</th>
<th>Graduated from NICU to intermediate care nursery</th>
<th>Week(s)</th>
<th>Sleep/awake pattern (% time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1261.4</td>
<td>30.6</td>
<td>15-minutes</td>
<td>30.6</td>
<td>1390.4/1638.2</td>
<td>Yes</td>
<td>5</td>
<td>Quiet sleep 33.1 Active sleep 8.3 REM sleep 11.7 Drowsy 16.8 Quiet awake 11.3 Active awake 13.1 Crying 5.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>protocol A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Quiet sleep 51.2 Active sleep 12.9 REM sleep 17 Drowsy 2.5 Quiet awake 2.9 Active awake 4.1 Crying 9.4</td>
</tr>
</tbody>
</table>

Dieter, Field, Hernandez-Reif, Emory, & Redzepi, 2003

RCT with stratification

(1) % time showing stress behaviors
(2) Duration of infants’ activity
(3) Mean gestational age
(4) Mean birth/entry weight
(5) Graduated from NICU to intermediate care nursery
(6) Week(s)
(7) Sleep/awake pattern (% time)
| Lee, 2005 | RCT | - Mean gestational age 220.8 days  
- Mean birth/entry weight 1441.6/1542.7g  
- From NICU | Massage therapy (n=13)  
15-minute massage twice daily by trained nurse  
Began at the end of sleep cycle and 1 hour after morning and afternoon | No Massage (n=13) | 10 days | (1) Vagal tone,  
O₂ saturation (%)  
and HR (per min)  
(2) Behavioral state(%)  
(3) Behavioral Distress Score (%) | (1) Vagal tone B, PT:  
2.31, 2.87 (Day 1)  
2.37, 2.59 (Day 10)  
- O₂ saturation B, PT:  
97.36, 97.83 (Day 1)  
97.35, 97.83 (Day 10)  
- HR B, PT:  
152.46, 149.80 (Day 1)  
156.91, 156.44(Day10)  
(2) Sleep (%)  
68.26 (Day 1)  
69.61 (Day 10)  
- Awake (%)  
27.50 (Day 1)  
24.80 (Day 10)  
- Fidget/ Cry (%) | (1) Vagal tone  
-2.21 (p=0.05)  
O₂ saturation  
-0.77 (p=0.45)  
HR  
0.33 (p=0.84)  
(2) Sleep  
26.12 (p<0.01)  
Awake  
26.52 (p<0.01)  
Fidget/ Cry  
8.57 (p=0.04)  
(3) 2.35 (p=0.126)|
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Interventions</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith, Kux, Haley, Beechy, &amp; Moyer-Mileur, 2012</td>
<td>RCT</td>
<td>(Protocol A)手腕部は日5回20分ごとに、(Protocol B)腕関節部は日3回30分ごとに、</td>
<td>Mean gestational age 31.5weeks Mean birth/entry weight 1628.3/1560g From NICU Receiving &gt;= 100ml/kg/day of enteral feeding</td>
<td>3.26 (Day 1) 5.57 (Day 10) (3) 17.5 (Day 1) 15.00 (Day 10) (1a) LF/HF: 6.34 +/- 0.04 c (1b) decrease in LF/HF (wk 0-4): -2.14 (1c) male with lower LF/HF in wk 3, 4 then wk 0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Massage therapy (n=27)</td>
<td>(1) LF/HF: 6.34 +/- 0.04 c (1b) decrease in LF/HF (wk 0-4): -2.14 (1c) male with lower LF/HF in wk 3, 4 then wk 0</td>
<td>(1a) LF/HF: 8.04 +/- 0.06 c (1b) increase in LF/HF (wk 0-4): +2.77 (1c) male with higher LF/HF in wk 3, 4 then wk 0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Massage therapy (n=25)</td>
<td>(1) ANS function (low frequency/high frequency ratio, LF/HF, analysed via ECG) (Hz)</td>
<td>(1a) 5.85 (p=0.016) (1b) 8.36 (p=0.001) (1c) 4.02 (p=0.004)</td>
</tr>
<tr>
<td>Kuhn, Schanberg, Field, Symanski, Zimmerman, Scafidi, &amp; Roberts, 1991</td>
<td>Quasi-experimental with stratification</td>
<td>Massage therapy (n=20)</td>
<td>24-hour urine sample for (1) norepinephrine (2) epinephrine (3) cortisol Blood sample for (4) cortisol</td>
<td>(1) Day 1, Day 10: 44, 66 d (2) Day 1, Day 10: 2.4, 3.8 d (3) Day 1, Day 10: 232, 274 (4) Day 1, Day 10: 48, 53 d (1) 4.19 (p&lt;0.05) (2) 4.26 (p&lt;0.05) (3) 8.23 (p&lt;0.007)</td>
</tr>
<tr>
<td>Lower score optimal</td>
<td>Higher score optimal</td>
<td>Decrease LF/HF indicate increase heart rate variability and increase parasympathetic activity</td>
<td>Increase LF/HF ratio indicate decrease heart rate variability and decrease parasympathetic activity</td>
<td>Higher level indicate greater maturity of sympathetic nervous system</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
</tr>
<tr>
<td>B: Baseline</td>
<td>T: Touch</td>
<td>PT: Post-Touch</td>
<td>Protocol A: Composed of three 5-minute phase: 1st, 3rd phase tactile stimulation, 2nd phase kinaesthetic stimulation</td>
<td></td>
</tr>
</tbody>
</table>

Tactile stimulation: infant placed in prone position, stroked for five 1-minute segments over each body region

(1) six 10-second strokes from the top of head down the side of face to neck and back up to the top of head
(2) six 10-second strokes from back of neck across the shoulders and back to neck
(3) six 10-second strokes from upper back down to waist and back to upper back, with stimulator’s fingertips placed on either side of the spine and the flats of the fingers on the back
(4) six 10-second strokes from the thigh to the foot and back to the thigh on both legs simultaneously
(5) six 10-second strokes from the shoulder to the wrist and back to the shoulder on both arms simultaneously

Kinaesthetic stimulation: infant placed in supine position. Each five 1-minute segments composed of 6 passive flexion-extension motion for 10 seconds, different body parts and sequence:
Protocol B: Application of six soft-tissue compression strokes to the following areas of the supine infant:

1. Top of thighs to ankles and feet
2. Chest over ribcage
3. Shoulders down the arms to hands
4. Head from crown to neck
5. Along the back from the neck to the waist.

Range of motion exercises with gentle compression, flexion and extension on both upper and lower limbs, sequence:

1. Wrist
2. Elbow
3. Shoulder
4. Ankle
5. Knee
6. Hip
## Internal Validity Assessment of Selected Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Clearly focused questions</th>
<th>Randomized allocation</th>
<th>Adequate concealment</th>
<th>Double blind treatment allocation</th>
<th>Group comparable</th>
<th>Only treatment different</th>
<th>Valid outcomes measurement</th>
<th>Drop out rate</th>
<th>Intention to treat analysis</th>
<th>Comparable results from all sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hernandez-Reif, Diego, &amp; Field, 2007</td>
<td>+++</td>
<td>+</td>
<td>-</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>11.1%</td>
<td>NR</td>
<td>NA</td>
</tr>
<tr>
<td>Wheeden, Scafidi, Ironson, Valdeon, &amp; Bandstra, 1993</td>
<td>+++</td>
<td>+</td>
<td>-</td>
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Well covered +++; Adequately addressed ++; Poorly addressed +; Not addressed –; Not reported NR; Not applicable NA
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Quality assessment

The controlled trial checklist of SIGN (2008) was adopted to assess all selected studies. All studies were assessed using ten questions, and the results will be discussed in subsequent sections.

The population, intervention, comparison, outcomes, and purpose of the study were clearly stated at the beginning of the article. The study by Smith, Kux, Haley, Beechy, and Moyer-Mileur, (2012) described the process of randomization by draw from an envelope, whereas the remaining studies only indicated the assignment as random without providing the details of such assignment. Dieter et al. (2003) and Wheeden et al. (1993) applied stratification to minimize sample bias. Kuhn et al. (1991) used a quasi-experimental design with recruitment of the treatment and control groups in alternating weeks.

Smith et al. (2012) used a sealed envelope to conceal participation, and Dieter et al. (2003) did not record in infant’s chart intentionally to conceal the participation. The remaining studies did not apply any concealment technique.

Blinding was adopted in the studies by Dieter et al. (2003), Hernandez-Reif, et al. (2007), Smith et al. (2012), and Wheeden et al. (1993). In Wheeden et al. (1993), the trained graduate students or research assistants who collected the data were blinded. In Smith et al. (2012), all NICU clinical staff, parents, and study personnel
were blinded while the treatment or control was conducted behind a privacy screen; only the massage therapists and the principal investigators were aware of the assignment. In Hernandez-Reif et al. (2007), the researchers were blinded to the group assignment, whereas in Dieter et al. (2003), nurses were aware of the treatment. Meanwhile, no blinding technique was stated in Kuhn et al. (1991), which is not an RCT. The researchers or research assistants who collected the data were blinded to the infant’s group assignment in Dieter et al. (2003), Hernandez-Reif et al. (2007), Smith et al. (2012) and Wheeden et al. (1993). Blinding helped minimize bias in the four studies.

The groups in all studies varied only in intervention. All infants received care according to the standard protocol. Frequency of family visits, was recorded in Dieter et al. (2003), with no difference found between groups. Demographic data pertaining to the treatment and the control groups were presented clearly in all studies, with a p-value > 0.05, except in Kuhn et al. (1991), which merely indicated that no difference in demographic data was observed between groups but provided no p-value.

For the outcome measures, Kuhn et al. (1991) measured the hormonal changes, Smith et al. (2012) measured the physiological changes, and Dieter et al. (2003), Hernandez-Reif et al. (2007), and Wheeden et al. (1993) determined the behavioral
changes induced by massage therapy. Lee (2005) measured both physiological and behavioral changes caused by massage therapy to show reduction in signs of stress.

Different studies used various measurement tools, which were valid and reliable. The Neonatal Stress Behavioral Scale, a widely adopted scale developed by the pediatrician Dr. Thomas Berry Brazlton (Tronick, 1987), was used in Wheeden et al. (1993). This scale specifically measures stress behavior in neonates in response to social stimuli. Eleven specific behaviors were operationally defined, including tremors, restlessness, irritability, excessive high-pitched crying, hypertonia, abnormal reflex items behavior, abnormal moro reflex, excessive mouthing, tachypnea, and autonomic instability, and gastrointestinal signs (Elisen et al., 1991). A positive score is assigned if any of the above signs is present; thus, a low score is considered optimal. Dieter et al. (2003) and Hernandez-Reif et al. (2007) simply measured the percentage of time of stress or sleep/awake behavior showed, criteria and coding checklist were set for these behavior. Hernandez-Reif et al. (2007) coded stress behaviors to include crying, grimacing, yawning, sneezing, jerky arm or leg movements, startles and finger flaring, whereas activity was coded to include simultaneous limbs movement or any body movement. Dieter et al. (2003) standardized the behavior coding as (1) quiet non-REM (rapid eye movement) sleep, (2) active sleep without REM, (3) REM sleep, (4) drowsiness, (5) quiet alertness (6) active alertness (7) crying. Sleep includes states
1, 2, and 3; awake includes 5, 6, and 7; quiet includes 1, 4, and 5 and active includes 2, 6, and 7. Inter-observer reliability was done in Hernandez-Reif et al. (2007) and Lee (2005), which ensured 90% criterion reliability. Lee (2005) used the Behavioral Distress Score developed by Scafidi et al. (1990). Coding behavior includes behavioral state, motor activity, and behavioral distress (Appendix G). The criteria for coding were well-defined and this scale is widely used (Lee, 2005). Direct observation with time sampling was applied. Each preterm infant was subjected to a 15 sec observation followed by 15 sec recordings within 10 min. One research assistant recorded the behavioral response (behavioral states, motor activity, and behavioral distress) on paper continuously at bedside. Inter-observer reliability was conducted by simultaneous observation and coding of 10 random participants. The total motor activity score and the Behavioral Distress Score were calculated as the summation of the percentage of time that the infant manifested any coded behavior. Meanwhile, the behavioral state score was calculated by the percentage of time that the infant was observed to exhibit any of the coded state (Lee, 2005). Longer percentage time of active and quiet alertness, fidgeting/crying, any coded motor activity, and coded behavioral distress indicated higher stress in the infant; longer percentage time of any sleep state and drowsiness, indicated lower stress in the infant (Scafidi et al., 1990). For the physiological study, changes in HR and O2 saturation
were used in Lee (2005) as the outcome measure because stress causes an increase in HR and a decrease in O$_2$ saturation. Over stimulation of the neonate may result in bradycardia and desaturation (Peng et al., 2009) (Appendix H). Smith et al. (2005) used HR variability (HRV), which was measured by 24 h ECG. The physiological relationship between the HRV and the ANS function, which reflects the regulation of stress, was clearly stated in the study. However, the normal range of HRV in infants was not standardized. Smith et al. (2005) adopted the normative value (low: 0.02 Hz to 0.2 Hz, high: 0.2 Hz to 2 Hz) in preterm infants from Chatow, who was the first to investigate this area (Chatow, Davidson, Reichman, & Akselrod, 1995). A 24 h urine sample was collected for norepinephrine, epinephrine, and cortisol, and blood sample was taken to determine cortisol levels as outcome measures in Kuhn et al. (1991). These hormonal levels vary with the level of stress. Therefore, all measurement outcomes in the studies were valid and could directly indicate signs of neonatal stress.

No drop out indicated except in Smith et al. (2012) with drop out rate 28.8% and Hernandez-Reif et al. (2007) with drop out rate 11.1%. The dropouts in Smith et al. (2012) were attributed to early discharge, deterioration of condition, and withdrawal of parental consent. The study stated that the occurrences of the drop out did not differ between groups and the remaining number of sample was still able to achieve the effect size 0.56 with power= 0.8. Hernandez-Reif et al. (2007) indicated
the data errors for the 5 infants (2 from the massage therapy group and 3 from the
control group) were attributed to equipment malfunction or experimental error;
however, the activity data for 1 infant in the control group were saved and remained
valid. No intention-to-treat analysis was performed.

All studies were conducted in one site only, that is, either the NICU or the
intermediate care unit in one hospital.

For the overall assessment of the study, Smith et al. (2012) satisfactorily
performed blinding and concealment and clearly explained the randomization
procedure in their study. Bias was considerably minimized. Dieter et al. (2003),
Hernandez-Reif et al. (2007), and Wheeden et al. (1993) obtained a satisfactory rating
in bias minimization. Hernandez-Reif et al. (2007) and Wheeden et al. (1993)
efficiently executed the blinding method but failed to clearly state the concealment
and randomization procedures. In addition, Wheeden et al. (1993) performed stratified
randomization to minimize sample bias. Dieter et al. (2003) adequately performed
concealment and blinding techniques, as well as stratification for group allocation, but
poorly described the randomization procedure. Kuhn et al. (1991) and Lee (2005)
performed poorly in bias minimization, and Lee (2005) failed to elaborate on the
concealment, blinding, and randomization procedures. Given that Kuhn et al. (1991)
demonstrate; however, stratification was conducted to minimize bias.
Therefore, the levels of evidence for the following studies were as follows:

Smith et al. (2012), 1++; Dieter et al. (2003), Hernandez-Reif et al. (2007), and Wheeden et al. (1993), 1+, Lee (2005), 1-; and Kuhn et al. (1991), 2+ (Appendix B).

Data Summary

Allocation

Five studies were identified as RCTs (Dieter et al., 2003; Hernandez-Reif et al., 2007; Lee, 2005; Smith et al., 2012; and Wheeden et al., 1993). Stratification was implemented in three studies (Dieter et al., 2003, Kuhn et al., 1991, and Wheeden et al., 1993) to ensure the even distribution of infants from different gestational age groups. Hernandez-Reif et al. (2007), Lee (2005), and Smith et al. (2012) randomized the samples without stratification, which could have led to bias because of the uneven distribution of the gestational age groups between the treatment and the control groups. However, no such problem occurred because the difference between the demographic data of the control and the treatment groups in the three studies were not significant (p>0.05). Only Kuhn et al. (1991) elaborated on their stratification procedure, and only Smith et al. (2012) thoroughly explained their randomization procedure. Among the studies, only Dieter et al. (2003) documented the frequency of family visit to exclude interventional bias.
Sample

Convenience sampling was adopted in all studies. The mean gestational ages of the samples in all studies ranged from 29.5 to 31.5 weeks, whereas the mean birth and the entry weights varied from 1176 g to 1628 g and 1313 g to 1638 g, respectively. All samples were from NICU, except those in two studies, Dieter et al., 2003 and Wheeden et al., 1993. The mean duration of NICU care in all studies was 22.4 days, excluding that in Lee (2005), which stated the day of hospitalization but not the duration of stay in NICU. All samples were considered medically stable with no congenital abnormalities.

Intervention

The only stated difference between the two groups in all studies was the intervention. The control group was used to minimize the confounding factors. All intervention protocols were clearly stated. Five days of massage therapy was chosen in Dieter et al. (2003) and Hernandez-Reif et al. (2007). The massaged infant received three 15-minutes massages during the interventions, which were performed 1 hour after morning feeding, 1.5 hour after midday feeding, and 45 minutes after completion of the second massage (9 a.m., 11 a.m., and 1 p.m., respectively). The infants were placed in a prone position and stroked on the head, shoulders, back, legs, and arms for 5 minutes with moderate pressure. The limbs of the infants placed in a supine position
were flexed and extended for 5 minutes. Finally, the infants were placed in a prone position in the last 5 minutes, and the first step was repeated. All other studies adopted the same massage protocol, with different practice times and performers, except in Smith et al. (2012). In Kuhn et al. (1991) and Wheeden et al. (1993), a 15-minute massage was performed for 3 consecutive hours each day for 10 days. In Lee (2005), the massage therapy continued for 10 days and was performed only twice daily by a trained nurse after morning and afternoon feedings. Massage therapy was conducted by trained research assistants in Wheeden et al. (1993) and massage therapists in Hernandez-Reif et al. (2007). Dieter et al. (2003) and Kuhn et al. (1991) did not mention who performed the massage. Smith et al. (2012) adopted a different massage protocol performed by a massage therapist twice daily for 20 minutes. Infants were placed in a supine position only for soft-tissue stroking from the top of the thighs to the ankles and feet, on the chest over the ribcage, from the shoulders down to the arms to hands, from the crown to the neck, and along the back from the neck to the waist. Subsequently, range-of-motion exercises were administered with gentle compression, flexion, and extension on both the upper and the lower limbs in the following sequence: from the wrist to the elbow, shoulders, ankles, knees, and hips. The longest follow-up duration was 4 weeks in all studies. All control groups received no massage therapy or touch therapy but received standard care.
Safety of the intervention

No adverse effect was reported from all studies and no infants required discontinuation of massage therapy. Lee (2005) indicated the stable physiological condition in heart rate and oxygen saturation in the treatment group. The loss of data Hernandez-Reif et al. (2007) was attributed to the failure of the recorder to monitor infants’ behaviors; however, handling of the missing data was not mentioned. The dropouts in Smith et al. (2012) were not attributed to the intervention. Therefore, performing massage therapy on preterm infants is a safe practice.

Outcome

The six studies using different, valid outcome measures showed that massage therapy can reduce signs of stress in premature infants. Hernandez-Reif et al. (2007) investigated the stress-reducing effects of massage therapy on preterm infants by recording infant stress behavior and activity on the first and the last days of the 5 days study and then quantified the percentage of time that the behavior was manifested. Reduced stress behavior and activity were observed at the end of the study period, suggesting the increase in relaxation of the infants. Wheeden et al. (1993) used the Neonatal Stress Behavior Scale to determine the therapeutic effect of massage therapy on preterm cocaine-exposed infants. Results showed that infants demonstrated reduced stress behavior by the end of the 10 days study. Lee (2005) evaluated the
physiological and behavioral effects of massage therapy. Physiological data were
evaluated by vagal tone, oxygen saturation, and heart rate, whereas behavioral data
were assessed by the Behavioral Distress Score and behavioral states. No significant
difference in heart rate and oxygen saturation between the pre-massage and
post-massage values were indicated in Lee (2005) and Smith et al. (2012). These
indicated that massage the safety of massage as a measure to stabilize premature
infants. The increased vagal tone in Lee (2005) and reduced LF/HF ratio in Smith et
al. (2012) were observed in massaged infants compared with the control group. These
results showed the maturation of parasympathetic function, which contributes to
improved stress management. The decreasing trend exhibited by the LF/HF ratio in
massaged infants from Week 0 to Week 4 also indicated that massage could increase
parasympathetic activity. Using their neuroendocrine findings, Kuhn et al. (1991)
demonstrated that massage therapy could reduce signs of stress in preterm infants.
Both the treatment and the control groups exhibited increases in urine cortisol levels;
however, no correlation was found between cortisol levels in the plasma and urine.
This finding was expected, considering that the plasma cortisol level is affected by
external stimuli every minute, whereas urine cortisol level reflects the effect over
24 hours. The significant increase in urine norepinephrine and epinephrine levels in
massaged infants shows the gradual maturation of the sympathetic system. For the
behavioral data in Lee (2005), it showed no group difference in the Behavioral Distress Score; however, the significant different in treatment group in awake state, fidgeting or crying after massage therapy than the control group indicated the better behavioural response to external stimuli. Increased drowsiness in massaged infants was observed in Dieter et al. (2003), suggesting reduced stress signs in the infants. Another finding in Smith et al. (2012) was that male infants had significant lower LF/HF ratio at week 2 and 3 when compared to control male group but no discrepancy showed in female group. Compared with female premature infants, premature male infants are at a higher risk of morbidity and mortality (Elsmen, Hansen Pupp, & Hellstron-Westas, 2004). Massage therapy can improve ANS development in male infants, who are more vulnerable to stress, thus contributing to improved stress management of these infants. The results obtained in the selected studies were not comparable because of the different measurement tools used but were consistent. Therefore, all selected studies demonstrated that massage therapy can comfort and reduce stress in premature infants.

**Data Synthesis**

Summarizing the results of all selected studies, successful massage therapy in premature infants in the NICU can be achieved by considering the factors below listed
below.

**Target population**

Premature infants with gestational ages from 30 weeks to less than 37 weeks in the NICU is the target population. The minimum birth weight is approximately 1180 g, and the optimal weight is about 1500 g; however, the infants should be medically stable with no congenital abnormalities, such as genetic defects, congenital heart malformations, central nervous system dysfunction, inborn error of metabolism. In addition, the infants should be free from sepsis or persistent ventilator dependence.

**Massage protocol**

Except for Smith et al. (2012), all studies adopted the same massage protocol. Three 5-minutes phases of tactile and kinaesthetic stimulation were applied, indicating a significant improvement in reducing signs of stress in premature infants. Therefore, this massage protocol should be selected. The frequencies of massage treatment and the times of intervention also varied among the different studies, but all were based on the criteria of practicality and comfort. Lee (2005) and Smith et al. (2012) adjusted the frequency to twice daily according to ward situations and manpower availability. Therefore, if the practical situation allowed, administering massage therapy three times daily is preferable. The time of intervention regarded as most comfortable for infants is at the end of the sleep cycle and after feeding.
Therefore, 1 hour after morning feeding, 1.5 hour after midday feeding, and 45 minutes after the completion of the second massage are the best times for massage therapy, as suggested by Dieter et al. (2003) and Lee (2005). A trained nurse, a licensed massage therapist, or research assistants administered the massage therapy in the selected studies; any of them can potentially achieve a positive outcome. Thus, any trained person can successfully administer massage therapy. Parents are considered good candidates because both the parents and the infant benefit from this practice, as indicated in numerous studies (Beachy, 2003; Ferber & Kuint, 2002; Onozawa et al., 2001).

**Outcome measure**

The outcome measures include only behavioral signs. Physiological signs (vagal tone, heart rate, oxygen saturation) used in Lee (2005) & Smith et al. (2012) are excluded because the changes in these signs are not as significant as those in behavioral signs. The changes in hormone level (norepinephrine, epinephrine, cortisol) adopted by Kuhn et al. (1991) will not be used because they involve invasive procedures and complex analyses. The Neonatal Stress Behavioral Scale used in Wheeden et al. (1993) and the sleep/awake behavior coding used in Dieter et al. (2003) are not selected because these coded items are complex and require professional knowledge. In conclusion, percentage time showing of coded stress behaviors such as
crying, grimacing, yawning, sneezing, jerk arm or leg movements, startles and finger flaring arching, leg extension, fussing and crying used in Hernandez-Rif et al. (2007) would be the tool for the outcome measure. It is because they are non-invasive measure and data can be easily obtained. Even parents are capable to do the evaluation.
Chapter 3: Implementation Potential

Transferability of the Findings

Target population and settings

The innovation is massage therapy administered by the parents of stable premature infants in the NICU of a Hong Kong public hospital. The main objective is to reduce the signs of stress of premature infants in a highly stressful environment. The target population includes medically stable premature infants with gestational ages from 30 weeks to less than 37 weeks and birth weights of at least 1180 g in the NICU. These characteristics are similar to those of the target population in all selected studies (Dieter et al., 2003; Hernandez-Reif et al., 2007; Kuhn et al., 1991; Lee, 2005; Smith et al., 2012; Wheeden et al., 1993). The clinical setting selected was similar to those in the selected studies. In the selected studies, the massage therapy was performed by healthcare professionals; however, in the present study, parents will perform the massage therapy because of manpower shortage and limited resources. Ferber and Kuint (2002) indicated that massage therapy given by parents can achieve the same effect as do those conducted by healthcare professionals.

Philosophy of care

The philosophy of care of this innovation involves providing a better quality of life to premature babies, maintaining their health, and increasing parental bonding.
This philosophy matches the mission of the hospital, which is “helping people stay healthy” as well as that of the paediatrics department, which is to provide the best care to patients and their family (Hospital Authority, 2012).

**Number of patients being benefit**

According to the Tertiary-wide Obstetrics & Gynecology Audit Report (2004), the rate of prematurity increased from 4.7% in 1999 to 5.1% in 2004. High admission rate in the local setting has been frequently reported. Approximately 88,000 premature babies were born in Hong Kong in 2010 (談, 2011). The survival rate of preterm infants also reached 96% (Tertiary-wide Obstetric & Gynecology Audit Report, 2004). Therefore, a sufficiently large number of preterm infants can benefit from this innovation.

**Time for implementation and evaluation**

The duration from the pilot to implementation and evaluation will continue for about six months. Prior to the pilot, a two-month training of the nursing staff and preparation of materials must be conducted. Launching the pilot for this innovation, including the mid-evaluation, will require two months. This two-month period includes two weeks of four-session training for the parents who will provide massage therapy for their babies in the NICU. Subsequently, the innovation can advance to the implementation phase, with duration of one to two months, considering that preterm
Infants mostly stay in the NICU only for this duration. Evaluation can finally be conducted.

Feasibility

Freedom to carry out innovation

Trained nurses can terminate this innovation if adverse effects occur. Studies showed that premature infants maintain a stable physiological condition throughout the massage therapy (Lee, 2005; Smith et al., 2012). Massage therapy is a safe procedure that requires no medication or specialized knowledge, thus allowing nurses and parents to administer this proposed innovation (Ferber et al., 2002).

Interference of current staff functions

Implementation of massage therapy in the NICU can interfere with current staff functions because staff members will be required to attend a training workshop to learn massage skills before they can educate parents. This requirement can lead to decreased manpower in the clinical environment. However, this shortage is expected to be a short-term problem. Providing an individual education to each pair of parents is more beneficial to infants with different conditions and developmental progress. Workload is expected to increase for nurses providing education and monitoring the massage technique of parents, who need to achieve adequate competence before they...
are allowed to perform the therapy independently. Visiting hours will be extended for 1 to 2 hours longer to allow parents to perform massage therapy on their baby at least twice daily, which may also disturb the busy ward conditions and treatment procedures. However, a 15-minutes massage therapy thrice daily can lead to reduced signs of stress in premature infants (Field et al., 1986; Hernandez-Reif et al., 2007; Dieter et al., 2003; Wheeden, 1993). Therefore, it is still possible to implement the innovation.

Support from administration and consensus among staff

The administration is expected to provide support to implement this innovation. Nursing officers at the NICU which I am working hold a weekly discussion on improving the care of infants. Any evidence-based practice is welcome to accomplish the objective. For example, a NICU is now piloting a neonatal pain assessment chart aimed at improving the quality of life for infants. Frontline staff show eagerness to learn and perform new evidence-based practices that can benefit patients. Consensus has been reached in our team. Around half of our staff further their study by attending master program or specialty nursing course. Kangaroo care, advocated by one colleague conducting a study under the master program, was previously implemented for a certain period to improve parent-to-baby bonding. However, the ward failed to provide a comfortable and spacious place in long term;
thus, this practice was suspended. Massage therapy, which allows skin-to-skin contact between the parents and the baby, improves quality care without the need for additional resources and space (Ferber & Kuint, 2002). Therefore, massage therapy is a feasible innovation in the NICU.

**Skills required**

Basic massage technique, assessment, and evaluation before and after massage therapy are required in implementing this innovation. These skills can be easily acquired and will be provided in the training workshop. Nurses are required to demonstrate effective communication skills and work independently in providing a clear education to parents. All competent nurses must be well-equipped with these skills prior to implementation of the program.

**Equipment and facilities**

A training room, 6 to 8 mattresses, and baby dummies are required during the training workshop. These materials are available in the pediatric department.

**Evaluation methods**

The outcome measures will include the behavioral aspect. The outcome evaluation measurement tools are similar to those employed in Hernandez-Reif et al. (2007), which measured the percentage of time that either coded stress behaviors are observed (crying, grimacing, yawning, sneezing, jerky arm or leg movements, startles,
and finger flaring). The use of this evaluation checklist will be taught during the training. A common evaluation method will be adopted in most baby massage courses (International Baby Massage Club, 2012). Parents will perform this evaluation on their own after massaging their baby. The Neonatal Stress Behavioral Scale and the Behavioral Distress Score are not selected as the evaluation tool because they are complex for parents to handle.

**Cost/Benefit Ratio of the Innovation**

**Risk of innovation**

Long et al. (1980) reported that massage therapy leads to hypoxia and bradycardia in premature infants. Despite this finding, recent investigations and selected studies indicate no adverse effects of the intervention. In addition, no case requiring the discontinuation of the therapy was reported. Lee (2005) also observed a stable physiological condition in massaged infants.

**Potential benefits**

Massage therapy benefits not only infants but also parents, healthcare professionals, and hospitals. Reduced stress behaviors and improvement in managing external stimuli were shown in massaged infants (Dieter et al., 2003; Hernandez-Reif et al., 2007). Improved energy conservation leads to enhanced growth and
development, which is important for premature infants. Therefore, decreased postnatal complications and improved quality of life of preterm infants are indicated (Beachy, 2003; Blackburn, 1998; Hernandez-Reif et al., 2007). Studies showed that the length of stay of massaged infants also decreased by 3 days to 6 days, thus decreasing the workload of healthcare professionals and medical costs (Scafidi et al., 1990; Field, 2002). Admission of infants to the NICU separates then from their parents for a certain period. Through massage therapy, interaction between the parents and their infants is expected to increase (Ferber & Kuint, 2002). Parents involved in infant care increase their confidence and improve their understanding of their babies (Beachy, 2003). Postnatal depression rate is also decreased (Onozawa et al., 2001).

**Risks of maintaining the current practice**

Massage therapy has been shown to effectively reduce signs of stress and allow better management of external stimuli in premature infants (Dieter et al., 2003; Hernandez-Reif et al., 2007; Kuhn et al., 1991; Lee, 2005; Smith et al., 2012; Wheeden et al., 1993). Without the innovation, the ability of premature infants in managing stress cannot be promoted. Ineffective stress management subjects infants to an increased risk of experiencing postnatal complications, such as intracranial hemorrhage and hypoxia, which can lead to long-term brain damage (DePaul & Chambers, 1995; Modrcin-McCarthy, 1997). Excessive nutrients and calories are
consumed to manage external stimuli, and less energy can be saved for premature infants to cope with growth and development (Sammons & Lewis, 1985).

Consequently, high medical costs related manpower, treatment, as well as prolonged hospital stay and long-term follow up are needed.

**Material cost of implementing the innovation**

The proposed innovation requires a training room, six to eight mattresses, baby dummies, massage oil, and lecture notes. Our department already has a training room and baby dummies. Massage oil is not required for real babies and training with dummies. This oil is used to reduce friction during massage therapy, but risks of skin allergy and irritation are present (Dieter et al., 2003; Scafidi et al., 1990). Positive outcome can be achieved through massage therapy without the need to use massage oil (Hernandez-Reif et al., 2007; Kuhn et al., 1991; Lee, 2005; Smith et al., 2012; Wheeden et al., 1993). Therefore, parents who choose to use massage oil should acquire the item through their own resources. The set-up cost for holding a training course for parents only requires $800 for eight mattresses ($100 each). The running cost requires $30 for one set of lecture notes for each parent. Two four-session courses continuing for a total of 12 h will be implemented every month, with 6 to 8 pairs of parents attending each course. Therefore, monthly and yearly costs allocated for lecture notes amount to $480 and $5760, respectively. A maintenance fee of $2000
will be allocated for the training room, baby dummies, and mattresses in case damage occurs.

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</table>

**Material cost of not implementing the innovation**

Higher risks of postnatal complications, such as intracranial hemorrhage, hypoxia, and brain damage, which require intensive care, may occur.

Non-implementation of the innovation may increase in the length of stay of premature infants by 3 days to 6 days (Scafidi et al., 1990; Field, 2002). At least US $26 billion per year is needed for the medication, treatment, and long-term follow up care of these premature infants (Richard & Adrienne, 2007).

<table>
<thead>
<tr>
<th>Total cost per year</th>
<th>Cost required if the length of stay increases by 3 days to 6 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>$26 billion</td>
<td>Cost required per day = $26 billion ÷ 365 days = $71 million</td>
</tr>
<tr>
<td></td>
<td>Cost required if length of stay is increased by 3-6 days $3 \times $71 million to 6 \times $71 million = $213 million to $426 million</td>
</tr>
</tbody>
</table>
Non-material cost of implementing the innovation

Staff training cost comprises the large proportion of the set-up cost for this innovation. First, a senior nurse will be appointed to undergo a professional baby massage therapist training course ($4950/21 hours) (International Baby Massage Club, 2012). Upon completion of this course, this nurse will be required to teach massage therapy skills to other colleagues. Approximately 7 hours will be needed for the nurses to acquire the skills. On training days, the staff will be absent from clinical work. A review of the average staff salary ($29000/month, $165/hour) reveals that $1155 will be spent for one colleague to attend the training day, $46200 for training 40 NICU staff members, and $2970 for training parents each month. Total non-material cost for the innovation is estimated at $54120, including the implementation cost (massage therapist course and ward nurse training) of $51150 and running cost of $2970 per month.
<table>
<thead>
<tr>
<th>Non-material</th>
<th>Cost</th>
<th>Total cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massage therapist course for 1 nurse</td>
<td>$4950 per course</td>
<td>$4950</td>
</tr>
<tr>
<td>Ward nurse training</td>
<td>Average monthly salary of a nurse = $29000/month, $165/h 7 h training for 40 nurses = $165 × 7 × 40 = $46200</td>
<td>$46200</td>
</tr>
<tr>
<td>Mentors fee for parents’ training</td>
<td>Hourly salary of a nurse = $165 2 courses/month=9 h/course × 2= 9 × 2 × $165 = $2970</td>
<td>$2970</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Total $54120</strong></td>
</tr>
</tbody>
</table>

**Non-material benefits of implementing the innovation**

The non-material benefit of implementing this innovation includes enhancing the bond between the parents and their baby (Ferber & Kuint, 2002). Decreasing postnatal complication and promoting growth for the preterm infants can decrease staff workload.
Chapter 4: Evidence-based Practice Guideline

Title

Massage therapy for premature infants in NICU by parents

Aim

To reduce signs of stress in premature infants in NICU

Objectives

1. Reduce the percentage of time showing coded stress behaviors in massaged infants after the intervention

2. Maintain stable heart rate and oxygen saturation during massage

3. Reduce the incidence of postnatal complications, such as intracranial hemorrhage, hypoxia, brain damage, and altered neurodevelopment

4. Enable parents to independently administer massage to their babies, including assessment, intervention, and evaluation after training

Target group

The target group includes premature infants with gestational age ranging from 30 weeks to less than 37 weeks in NICU, as well as their parents. These premature infants should weigh approximately 1180 g and are medically stable, free from sepsis, not ventilator dependent. Moreover, these infants have no congenital abnormalities, such as genetic anomalies, congenital heart malformations, central nervous system
dysfunctions, and inborn defect of metabolism.

**Recommendations**

1. The infant’s condition should be assessed and evaluated before and after massage therapy to avoid over stimulation and observe the effect of the intervention in preterm infants.

   Available evidence: The baby should be calm before massage therapy is started. Behavioral signs of stress include sucking, grasp, arching, leg extension, kicking, and arm waving. Physical signs of stress are indicated by changes in heart rate, respiratory rate, blood pressure, and oxygen saturation (Dieter et al., 2003) (1+).

2. A warm and comfortable environment with the incubator temperature ranging from 31 °C to 33 °C should be maintained during massage therapy.

   Available evidence: A warm and comfortable environment can keep the baby calm (Dieter et al., 2003) (1+).

3. Massage frequency is three times daily, and intervention is conducted 1 hour after morning feeding, 1.5 hour after midday feeding, and 45 minutes after completion of the second massage.

   Available evidence: Four selected studies adopted the massage frequency of three times daily [(Dieter et al., 2003) (1+); (Hernandez-Reif et al., 2007) (1+); (Kuhn et al., 1991) (2+); (Wheeden et al., 1993) (1+)]. The most comfortable time for infants
is at the end of the sleep cycle and after feeding. After a half-day of medication manipulation, the hospitalized premature infant is required to rest for half an hour after midday feeding prior to massage therapy to prevent activity overload. Therefore, 1 hour after morning feeding, 1.5 hour after midday feeding, and 45 minutes after completion of the second massage are the optimal times to administer massage, as suggested by two selected studies [(Dieter et al., (2003) (1+); Lee, 2005) (1−)].

4. The massage protocol is presented as follows: A 15-minutes massage includes 5 minutes of tactile stimulation, 5 minutes of kinaesthetic stimulation, and another 5 minutes of tactile stimulation. The infant is placed in a prone position during the first 5 minutes of tactile stimulation, and six 10-second periods of stroking was performed on different body parts: head, neck, shoulder, buttocks, lower limbs, and upper limbs. The massage should be performed for five 1-minutes segments for each body part. In the second phase, the infant is placed in a supine position, and massage is conducted for five 1-minutes segments. Each segment consists of six passive flexion or extension exercises of both arms and legs for 10 seconds. The third phase requires placing again the infant in a prone position and repeating the steps in the first phase.

Available evidence: Many studies adopted Field’s (1986) massage protocol with significant and positive outcomes, as discussed in the previous chapter.
53

[(Hernandez-Reif et al., 2007) (1+); Dieter et al., 2003) (1+); Wheeden, 1993) (1+)].

5. Parents can conduct massage therapy on their own after training.

   Available evidence: Performing massage on premature infants by healthcare professionals, parents, or any trained individual can achieve the same positive outcome (Wheeden, 1993)(1+).

6. Massage therapy can be performed without baby oil.

   Available evidence: Massage oil is used to reduce friction during massage therapy (Dieter et al.). However, massage therapy can also lead to positive outcome even without massage oil [(Hernandez-Reif et al., 2007)(1+); (Kuhn et al, 1991)(2+); (Lee, 2005)(1-); (Smith et al., 2012)(1++); (Wheeden et al., 1993)(1+)].
Chapter 5: Implementation Plan

Communication Plan with Potential Users

Stakeholders

The successful implementation of a new plan largely depends on effective communication between stakeholders (Melnyk & Fine-Overholt, 2005). Stakeholders may consist of administrators, users of the new proposed innovation, as well as those who support or oppose the plan.

Administrators of the pediatrics department, department operation managers (DOM), ward managers, and COS exhibit important functions in implementing the proposed innovation. Their approval and support should first be sought before changes in the clinical setting are initiated. These key persons can support the innovation by providing manpower and resources.

Other stakeholders include the users, such as the frontline staff including of registered nurses, nursing officer, and parents. Frontline staff members are responsible for teaching the parents to massage their baby, monitor, and evaluate the program outcome. Parents and their babies comprise the participants. All stakeholders are important in providing feedback regarding the new innovation.

Doctors and nurses may oppose this new innovation but are also regarded as important stakeholders. This opposition to the new innovation may be attributed to the
potential effect on the usual routine of doctors and interference with their treatment course. A common consensus should be reached so that the new innovation can be implemented smoothly.

**Communication process**

A period of time passes before consensus from stakeholders is obtained. Effective communication should be established to solicit input from stakeholders and compromise in a collaborative manner (Gallagher-Ford et al., 2011).

Communication should first be directed to the administrators because they are the key persons to decide on the implementation of a new innovation. A proposal is first sent to the NICU ward manager because of the accessibility and the level of authority in decision making of this personnel. Communication with the DOM and the COS regarding the proposal is expected to follow. If the approval of administrators is successfully obtained, the innovation will be introduced to all frontline nurses.

The content of the proposal includes the reasons for the need to change the current practice, supported by related studies and summarizing the benefits of infant massage, such as relieving stress, reducing postnatal complication, shortened hospital length of stay, and decreasing staff workload in the long run (Beachy, 2003; Blackburn, 1998; Dieter et al., 2003; Hernandez-Reif et al., 2007). A sense of urgency should be presented to the management team because this intervention is regarded as
the first step to a successful change (Kotter & Cohen, 2002). Effects on the usual routine and implementation cost should be stated, with these costs outweighed by the benefits. “Providing a stress-free life to prematurity” as the vision will be emphasized. This vision is the main focus of the new innovation, guided by evidence-based guidelines. Thus, the administrators can be persuaded to manage the new program and assume leadership in the implementation.

After the general concept is introduced to the administrators through the ward manager, an open discussion will be held to present the proposed massage therapy in premature infants, including the vision, guideline, and feasibility of the new innovation. This open discussion allows direct communication, which can clarify information and immediately obtain feedback. The entire communication process among administrators is estimated to continue for one month.

The next step is to introduce the new practice to the frontline staff expected to implement the proposed innovation. According to Kotter and Cohen’s Model of Change (2002), the staff should perceive “an urge to change.” The staff are expected to be motivated to implement the new practice by explaining the vision, the reasons behind the need for a change, and the benefits of massage therapy, as supported by evidence-based studies. Confidence is a critical component in implementing a change (Melnyk, 2001). To empower the staff, adequate knowledge, standard practice
guideline, and training workshop will be provided. Given the effect of the proposed innovation on some routines, the frontline staff is expected to oppose the proposed practice. An open discussion will be held among the frontline staff regarding the reasons and benefits of the proposal, as well as the details and the processes involved in the proposed innovation. The staff members are free to express their concerns and perceived barriers. With a thorough understanding of the innovation and their concerns addressed, the staff members are expected to exhibit willingness and motivation to conduct the proposed practice (Kotter & Cohen, 2002).

After the key persons gain a general concept of the new innovation, details of the implementation plan will be presented in an open discussion. These details include the “train the trainer” program, arrangement of massage classes for nurses and parents, implementation guidelines of massage therapy in premature infants in the ward, and outcome evaluation. Through this discussion and constructive opinions from the frontline staff, recommendations in the literature are implemented (Melnyk, 2001).

Posters and leaflets will be distributed to parents in the ward to promote awareness on the practice of infant massage therapy.

**Communication method**

Questionnaires will be distributed to frontline staff after they have handled three parents who have administered massage therapy to their baby (Appendix E).
The frontline staff can express their opinions and recommendations by e-mail, memo, or regular weekly ward meeting with the ward manager at any time. Feedback will be collected from parents regarding the response of the baby, skill management, time, and adequacy of material supply (Appendix D). The feedback will be gathered by the frontline staff and presented during the ward meeting.

A regular monthly meeting with the administrators will be held subsequently to discuss the progress of the proposed practice. Opinions, and concerns from parents and frontline staff will also be discussed to evaluate effects, identify barriers, and seek solutions.

**Sustaining the change process**

*Empowerment*

Clear vision and staff empowerment are essential components in sustaining change (Melnk & Fineout-Overholt, 2005). The staff can manage and implement change under a clear and concrete vision. Empowerment is needed to ensure confidence and competence of the frontline staff. Problem-solving skills will be taught during the training workshop. However, obstacles and resistance are expected to emerge during implementation. Thus, considering individuals’ concerns, understanding their reluctance, and assisting the frontline staff as much as possible are important. Explaining the benefit of the proposed practice can help reduce resistance.
Parents are also required to acquire empowerment. They are encouraged to share their own experience and skills to others during visiting hours to develop social and psychological support mechanisms.

*Updating information*

Nursing officers can act as auditors. They can observe the nursing staff and the parents during training workshops and when parents administer massage therapy to their baby. This function ensures that all participants are on the same track and in compliance with the new guideline. Nursing officers need to be updated with related studies and share this information with other staff. Suggestions on any improvement are provided after the audit.

*Continuous communication*

Opinions from the frontline staff and parents are welcome. All comments will be gathered and discussed thoroughly during the meeting.

**Pilot Testing**

Pilot testing is conducted before change is implemented in clinical practice to prevent unexpected difficulties, determine the feasibility of this change, and identify the weakness of the innovation (Melnyk & Fineout-Overholt, 2005). This procedure can also provide a buffering period for the staff to adapt the new practice.
Preparation before pilot testing

Massage therapy in preterm infants in the NICU is a newly introduced concept in Hong Kong. Prior to the pilot testing, one senior nurse with at least 10 years of experience working in the NICU will be appointed to attend a professional baby massage therapist training course for approximately 21 hours in 3 days. The ward manager will select the candidates for this course. The selected staff members are given a study day and department subsidy. Resources, such as mattresses, lecture notes, and EBP guideline, are required to implement the innovation, which will be prepared by the ward manager and the trained staff after the course is completed. Once the trainer is prepared and all materials are available, the two-day “train the trainers” program can begin. The first day will focus on the basic principle, assessment, preparation, safety issue, and aftercare of infant massage. Practice of massage skills on baby dummy will be demonstrated on the succeeding days and assessed by a nursing officer or a trained nurse (Appendix F). Therefore, the implementation of a pilot test requires approximately two months for the trainer and the resources to be prepared.

Sample recruitment strategies

The trained staff can start recruiting new cases to participate in the pilot testing. Clinically stable premature infants with gestational ages ranging from
30 weeks to less than 37 weeks in the NICU comprise the target population. The minimum birth weight and the optimal weights are 1180 g and approximately 1500 g, respectively (Dieter et al., 2003; Hernandez-Reif et al., 2007; Kuhn et al., 1991; Lee, 2005; Smith et al., 2012; Wheeden et al., 1993). The sample will be selected from various gestational ages or body weights to allow trial using samples with different clinical statuses. Eligible samples will be screened by trained staff. Six pairs of parents will be recruited, and their written consent will be obtained. The details of the pilot testing, as well as the benefits and risks of the innovation, will be explained. Recruitment period will be approximately 1 month.

**Implementation**

A 9 hours pilot class consisting of 6 pairs of parents will be conducted in 3 sessions by any trained staff. The content will include assessment, massage principles and skills, and evaluation of the effect. An evidence-based practice (EBP) massage therapy guideline will be discussed. Questions raised during class will be addressed. Demonstration and return demonstration will be conducted and at the end of the class to assess the skills of parents before they are allowed to administer massage therapy on their baby. During the training, the ward manager or the nursing officer will observe and evaluate the skills of the trained staff and gauge the level of understanding of the participants. Material storage and sufficient materials as well as
manpower allocation time will also be assessed. The massage skills acquired by the parents will be assessed by return demonstration by using a baby dummy during the last session. Parents should fulfill the critical components of the checklist, such as assessment, massage skill, and evaluation, to pass (Appendix C). Parents who pass can perform massage for the first time on their baby under the supervision of a trained staff. Subsequent massages can then be performed on their own. A spot check will be conducted by a trained staff who will observe at the bedside to ensure the compliance and competency of the parent in using the massage guideline. The entire process will require approximately one month.

**Evaluation**

Questionnaires will be distributed to parents and trained staff for them to provide feedback and express the difficulties encountered using the new innovation (Appendix D, E). A period of two weeks is allotted for collecting feedback, after which time a meeting with the trained staff and the ward manager will be held to discuss any barrier to and improvement on the innovation or the EBP guideline.
Chapter 6: Evaluation Plan

Patient Outcomes

The primary patient outcome is to reduce signs of stress in massaged preterm infants by reducing the time showing stress behaviors by at least 20% after five days of massage therapy. A selected study indicates that approximately 20% reduction in percentage time of manifesting stress behaviors is observed in massaged preterm infants (Hernandez-Reif et al., 2007). To obtain data, the case nurse of the selected sample will measure the duration of stress behaviors, such as crying, grimacing, yawning, sneezing, jerky arm or leg movements, startles, and finger flaring on the first and the last days of massage therapy (Hernandez-Reif et al., 2007; Modrcin-McCarthy, 1997). Another outcome is the parents’ satisfaction and confidence while undergoing training and performing massage on their baby. Questionnaires will be distributed to parents after five days of massage therapy (Appendix D).

Healthcare Provider Outcomes

The main outcomes for healthcare providers include the development of competence in infant massage and the ability to supervise parents to perform massage therapy on their baby. One core nurse will attend a professional massage therapist
course and obtain a certificate before teaching the “train the trainer” program. The core nurse will teach and assess the skills of other nurses, and one nursing officer will assess the standardization of the massage skill by observing during the training (Appendix F). Another outcome is the level of satisfaction and confidence of the healthcare provider in the training course as well as conducting massage therapy and supervising parents. Questionnaires will be distributed to the healthcare providers after the training and after supervising three pairs of parents (Appendix D).

**System Outcomes**

To measure the system effectiveness, costs and human resource will be evaluated after the innovation has been introduced to about 50 participants, which is estimated to take four months. A meeting with the frontline nurse, nursing officer, and ward manager will be held to discuss the additional time required for the innovation. The running cost will be evaluated again after data collection.

**Nature and Number of Clients**

**Eligibility criteria**

Premature infants admitted in the NICU and with gestational ages ranging from 30 weeks to less than 37 weeks and birth weight of at least 1180 g will be
included in the study. The infants should also be medically stable with no congenital
abnormalities, sepsis, or persistent ventilator dependence.

**Sample size**

Using the test for one proportion in Russ Lenth’s power and sample size calculation
(Lenth, 2006) and with reference to the study of Hernandez-Reif et al. (2007), the
percentage time of stress behavior of the massaged infants on the first and the last
days were 81% and 59%, respectively. The sample size was calculated with rounding
up to 40 by using the null value of 0.8, actual of 0.6, alpha of 0.05, and power set of
0.8. Approximately 30% participant loss is expected; thus, 55 participants will be
required (Smith, Kux, Haley, Beechy, & Moyer-Mileur, 2012).

**Data Analysis**

**Patient outcome**

*Design*

All selected subjects will receive massage therapy for five days.

*Outcomes*

The main outcome will be the percentage time of infants showing stress
behaviors.
**Evaluation Objectives**

To determine if the percentage time of infants showing stress behaviors is reduced after implementation of the five-day massage therapy.

**Method of Analysis**

By using significance testing and determining the percentage time of infants showing stress behaviors before and after the intervention, a two-tailed z-test for testing one proportion will be performed to analyze the obtained data.

**Parents and healthcare providers outcomes**

**Design**

1. All parents will be provided a questionnaire after all massage sessions have been completed.

2. All trained nurses will be given a questionnaire after they have attended the massage lesson and supervised three pairs of parents.

**Outcome**

1. The main outcome is the parents’ satisfaction level with the massage session and confidence level in handling the massage skill.

2. Another main outcome is the nurses’ satisfaction and confidence in conducting the massage therapy and supervising the parents.
**Evaluation Objective**

Operationally, overall satisfaction and confidence are defined to reach the average score of 50% and above in all the domains evaluated (Iloh et al., 2012).

**Method of Analysis**

Each satisfaction or confidence item is assigned a score on a five-point Likert scale ordinal response, which is converted to a percentage scale response, as follows: strongly agree = 5 points (100%), agree = 4 points (80%), natural = 3 points (60%), disagree = 2 points (40%), and strongly disagree = 1 point (20%). The operational percentage range definitions are excellent (90% to 100%), very good (70% to 89%), good (50% to 69%), fair (30% to 49%), and poor (0% to 29%) (Iloh et al., 2012). The average mean percentage for all domains will be calculated.

**Basis for an Effective Change in Practice**

Long-term outcomes, such as substantial clinical benefits and cost effectiveness, will be evaluated after implementing the innovation program for two years. Data on the length of stay of the massaged baby, reduced clinical complication such as intraventricular hemorrhage, intimacy level between parents and baby, and workload of staff will be collected to evaluate the substantial clinical benefits. To evaluate the cost effectiveness of the intervention, the operating cost with
the innovation implemented will be evaluated by comparing the medical cost spent without the innovation.

**Conclusion**

With a well-planned program and a clear evidence-based guideline, massage therapy administered by trained parents on premature infants admitted in the NICU is proven effective in reducing signs of stress in preterm infants. Prior communication with stakeholders will facilitate the implementation of this new innovation. Pilot testing is required to ensure that all participants have comparable levels of understanding and skills. Testing is also conducted to test for feasibility as well as to eliminate and address any difficulties beforehand. Finally, outcome evaluation should be performed to monitor the effectiveness of the program. A successful program benefits not only the premature infants but their parents and the healthcare providers as well.
## Appendix A

### Literature Search Results

<table>
<thead>
<tr>
<th>Database</th>
<th>Combination of keywords</th>
<th>Number of retrievals</th>
</tr>
</thead>
<tbody>
<tr>
<td>PubMed</td>
<td>(massage OR tactile kinesthetic stimulation) AND (preterm OR premature OR prematurity) AND (stress OR distress)</td>
<td>Systemic review: 5 Articles: 17</td>
</tr>
<tr>
<td></td>
<td>(massage OR tactile kinesthetic stimulation) AND (preterm babies OR preterm infant* OR preterm neonate*)</td>
<td>Systemic review: 6 Articles: 49</td>
</tr>
<tr>
<td></td>
<td>(massage OR tactile kinesthetic stimulation) AND (premature babies OR premature infant* OR premature neonate*)</td>
<td>Systemic review: 7 Articles: 63</td>
</tr>
<tr>
<td>OvidSP</td>
<td>Massage (limit “all infant birth to 23 months) AND premature.mp.</td>
<td>108</td>
</tr>
<tr>
<td></td>
<td>Massage (limit “all infant birth to 23 months) AND preterm.mp.</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td>Tactile kinesthetic stimulation (limit “all infant birth to 23 months)</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Massage (limit “all infant birth to 23 months) AND (stress.mp. OR distress.mp.)</td>
<td>43</td>
</tr>
<tr>
<td>CINAHL</td>
<td>Massage (limit “infant, newborn: birth-1 month) AND premature AND</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td>------------------</td>
<td>------------------------------------------------------------------</td>
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</tr>
<tr>
<td></td>
<td>Massage (limit “infant, newborn: birth-1 month) AND premature AND stress</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Massage (limit “infant, newborn: birth-1 month) AND preterm AND stress</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Massage (limit “infant, newborn: birth-1 month) AND preterm AND distress</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Tactile kinesthetic stimulation (limit “infant, newborn: birth-1 month)</td>
<td>2</td>
</tr>
</tbody>
</table>
Appendix B

Key to evidence statements and grades of recommendations

by

SCOTTISH INTERCOLLEGIATE GUIDELINES NETWORK

LEVELS OF EVIDENCE

1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+ Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1- Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++ High quality systematic reviews of case control or cohort or studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3 Non-analytic studies, e.g. case reports, case series
4 Expert opinion

GRADES OF RECOMMENDATIONS

A At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+

C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++

D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+

Good practice points
Recommended best practice based on the clinical experience of the guideline development
### Appendix C

**Assessment Checklist (for parents)**

<table>
<thead>
<tr>
<th>Content</th>
<th>Done</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Can indicate the benefits of massage therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Assessment before starting massage( Physical and emotional condition of baby)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Preparation for massage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1. Materials (Baby oil, warm and comfortable environment)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2. Time (1 hour after morning feed, 1.5 hour after midday feed, 45minutes after completion of second massage)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Massage procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Three 5-minute phase: 1st, 3rd phase tactile stimulation, 2nd phase kinaesthetic stimulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tactile stimulation: infant placed in prone position, stroked for five 1-minute segments over each body region</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) six 10-second strokes from the top of head down the side of face to neck and back up to the top of head</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2) six 10-second strokes from back of neck across the shoulders and back to neck</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(3) six 10-second strokes from upper back down to waist and back to upper back, with stimulator’s fingertips placed on either side of the spine and the flats of the fingers on the back</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(4) six 10-second strokes from the thigh to the foot and back to the thigh on both legs simultaneously</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(5) six 10-second strokes from the shoulder to the wrist and back to the shoulder on both arms simultaneously</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kinesthetic stimulation: infant placed in supine position. Each five 1-minute segments composed of 6 passive flexion-extension motion for 10 seconds, different body parts and sequence:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) right arm (2) left arm (3) right leg (4) left leg (5) both legs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Safety issue during massage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1. Continue assessment of infant’s condition during massage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.2. Massage suspended when infant with unstable condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. After care of massage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.1. Clean up baby if baby oil applied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.2. Evaluate baby’s condition</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Dieter et al., 2003 ; Field et al., 1986; Scafidi et al., 1990 ; Kuhn et al, 1991 ; Lee, 2005; Wheeden et al., 1993)
## Appendix D

### Questionnaire (for parents)

#### Satisfaction Level

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Natural</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Massage therapy is beneficial to baby</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. The training content is easy to understand</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. The training environment is suitable</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>4. The training equipment is enough</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. The teacher teaches well</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Duration of training session is suitable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. I would recommend massage class to other parents</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. I am satisfied with this training program</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Confidence Level

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Natural</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel good when performing massage on my baby</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I can interpret my baby’s response</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3. I am confident in performing massage on my baby</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4. I have a better intimacy level between me and my baby</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

(American Massage Therapy Association., 2012; Blackman, Crespigny, & Parker, 2006; Iloh et al., 2012)
Appendix E

Questionnaire (for nurses)

### Satisfaction Level

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Natural</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Training time is enough</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. The training content is suitable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. The training environment is suitable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. The training equipment is enough</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. The workload is affordable</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6. I enjoy the training session</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. I am satisfied with this training program</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Confidence Level

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Natural</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I can give instruction to parents confidently</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I can handle difficulties independently</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I am confident in supervising parents to perform massage on my baby</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I am able to provide care to parents and baby</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(American Massage Therapy Association., 2012; Blackman, Crespigny, & Parker, 2006; Iloh et al., 2012)
### Appendix F

#### Assessment Checklist (for nurses)

<table>
<thead>
<tr>
<th>Content</th>
<th>Done</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Can indicate the benefits of massage therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Assessment before starting massage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1. Physical and emotional condition of baby</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2. Parents’ emotion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Preparation for massage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1. Materials (Baby oil, warm and comfortable environment)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2. Time (1 hour after morning feed, 1.5 hour after midday feed, 45 minutes after completion of second massage)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Massage procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Three 5-minute phase: 1st, 3rd phase tactile stimulation, 2nd phase kinaesthetic stimulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tactile stimulation: infant placed in prone position, stroked for five 1-minute segments over each body region</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) six 10-second strokes from the top of head down the side of face to neck and back up to the top of head</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2) six 10-second strokes from back of neck across the shoulders and back to neck</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(3) six 10-second strokes from upper back down to waist and back to upper back, with stimulator’s fingertips placed on either side of the spine and the flats of the fingers on the back</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(4) six 10-second strokes from the thigh to the foot and back to the thigh on both legs simultaneously</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(5) six 10-second strokes from the shoulder to the wrist and back to the shoulder on both arms simultaneously</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kinaesthetic stimulation: infant placed in supine position. Each five 1-minute segments composed of 6 passive flexion-extension motion for 10 seconds, different body parts and sequence:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) right arm (2) left arm (3) right leg (4) left leg (5) both legs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Safety issue during massage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1. Continue assessment of infant’s condition during massage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.2. Massage suspended when infant or mother with unstable condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. After care of massage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.1. Clean up baby if baby oil applied</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.2. Evaluate baby’s and mother’s condition</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Dieter et al., 2003; Field et al., 1986; Scafidi et al., 1990; Kuhn et al., 1991; Lee, 2005; Wheeden et al., 1993)
# Appendix G

## Criteria of coding of Behavioral Distress Score

<table>
<thead>
<tr>
<th>Behavioral state</th>
<th>Coded behavior</th>
<th>Criteria</th>
<th>Method of score calculation</th>
<th>Score (%) interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) sleep state</td>
<td>quiet sleep, active sleep, less rapid eye movement sleep</td>
<td>The infant’s eye are closed and motor activity may or may not be present</td>
<td>The percent time of infant spent in any of these states</td>
<td>Level of stress decrease with the increase in score</td>
</tr>
<tr>
<td>(b) awake state</td>
<td>quiet alert, active alert, drowsiness</td>
<td>The infant’s eyes are open or may open with dull looking, and motor activity is present in the major parts of the interval</td>
<td></td>
<td>Quiet alert, active alert: Level of stress increase with the increase in score Drowsiness: Level of stress decrease with the increase in score</td>
</tr>
<tr>
<td>(c) fidgeting/crying</td>
<td>Fidgeting sounds or negative vocalizations are present</td>
<td></td>
<td></td>
<td>Level of stress increase with the increase in score</td>
</tr>
</tbody>
</table>
(If fidgeting/crying are coded, mouthing or facial grimace of behavioral distress cannot be coded)

<table>
<thead>
<tr>
<th>Motor activity</th>
<th>Single limb, multiple limbs, gross body movements, head turns and startles.</th>
<th>Summation of the percentage of time the infant spent in any category</th>
<th>Level of stress increase with the increase in score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral distress</td>
<td>Mouthing/ yawning movements, facial grimaces, and clenched fists.</td>
<td>Summation of the percentage of time the infant spent in any category</td>
<td>Level of stress increase with the increase in score</td>
</tr>
</tbody>
</table>

(Scafidi et al., 1990)
## Appendix H

**Physiological signs of stress and operational definitions**

<table>
<thead>
<tr>
<th></th>
<th>Operational definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Heart rate (HR)</strong></td>
<td>HR $&lt;$100 bpm or $&gt;$160 bpm, or increase in baseline 5 bpm/more</td>
</tr>
<tr>
<td><strong>Oxygen saturation</strong></td>
<td>$&lt;$90% or decrease of 2.5%/more</td>
</tr>
</tbody>
</table>

(Peng et al., 2009)
References


Care System & Blue Cross Blue Shield of Michigan.


Kuhn, A. M., Schanberg, A. M., Field, T., Symanski, R., Zimmerman, E., Scafidi, F.,


The Hong Kong Colleague of Obstetrician and Gynecologists Audit (2004).

Tertiary-wide Obstetric & Gynecology Audit Report.


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