Abstract of thesis entitled

“An evidence-based oral simulation intervention to improve preterm infants’ oral feeding ability”

Submitted by

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in July 2016

As medical technology advances, the survival rate of preterm infants has been substantially increased over the past decade. In Hong Kong, preterm infants have been enjoying high quality healthcare services and dedicated nursing care during their stay in Neonatal Intensive Care Unit (NICU). However, currently most medical attention has been devoted to life-saving treatments. Very limited attention was given to oral feeding training of infants. In fact, oral feeding issue is one of the most commonly encountered problems and prominent reasons for delayed discharge in preterm infants. The lack of pre-feeding training leads to various undesirable outcomes. In view of the problem, it is worthwhile to develop an Evidence-based Practice (EBP) guideline to facilitate oral feeding training of preterm infants.

Recent researches have been studying the use of Oral Stimulation (OS) program on
medically stable preterm infants to facilitate oral feeding. The simple OS procedure not only ensures safe and successful oral feeding, but also shortens hospitalization, decreases medical cost and hastens mother-infant reunion.

This dissertation is a proposal on development of the guideline using the principle of translational nursing research. To begin with, literature was searched via three electronic databases. Applying a list of inclusion and exclusion criteria, finally seven Randomized Controlled Trials (RCTs) were selected as references. Information was summarized into tables of evidence.

The quality of seven articles was assessed and graded using the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist 2: controlled trials (version 2.0). After that, individual articles were graded using the grade methodology by SIGN. Based on the best available evidence, appropriate information was synthesized and utilized to develop an EBP guideline on implementation of OS program for premature infants.

Furthermore, the implementation potential of the proposed intervention was determined by addressing the transferability, feasibility and cost-benefit ratio. The detailed implementation and evaluation plans were generated. The implementation plan consists of formation of a working group, communication plan with three levels of stakeholders (management, clinical and client) and the pilot test plan. Evaluation plan includes assessment of primary patient outcome, secondary patient and nurse outcome. Last but not least, the basis for implementation was discussed to illustrate the effectiveness criteria for long-term implementation.

All the effort aims to prove that the EBP guideline could be implemented in any NICU settings in Hong Kong to improve patient outcome.
An evidence-based oral simulation intervention to improve preterm infants’ oral feeding ability

by

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B.Nurs. H.K.U.

A thesis submitted in partial fulfillment of the requirements for the Degree of Master of Nursing at The University of Hong Kong

July 2016
Declaration

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

Signed ________________________________

KEI SHUN TUNG
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<th>Full Form</th>
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<tbody>
<tr>
<td>APN</td>
<td>Advanced Practice Nurse</td>
</tr>
<tr>
<td>BOMI</td>
<td>Beckman Oral Motor Intervention</td>
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<tr>
<td>CMS</td>
<td>Clinical Management System</td>
</tr>
<tr>
<td>CO</td>
<td>Compensate Off</td>
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<tr>
<td>COS</td>
<td>Chief of Service</td>
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<tr>
<td>CPAP</td>
<td>Continuous Positive Airway Pressure</td>
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<td>DOM</td>
<td>Department Operation Manager</td>
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<tr>
<td>EBP</td>
<td>Evidence-based Practice</td>
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<tr>
<td>GA</td>
<td>Gestational Age</td>
</tr>
<tr>
<td>HA</td>
<td>Hospital Authority</td>
</tr>
<tr>
<td>ITT</td>
<td>Intention to Treat</td>
</tr>
<tr>
<td>LOS</td>
<td>Length of Stay</td>
</tr>
<tr>
<td>MO</td>
<td>Medical Officer</td>
</tr>
<tr>
<td>NICU</td>
<td>Neonatal Intensive Care Unit</td>
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<tr>
<td>NNS</td>
<td>Non-nutritive Sucking</td>
</tr>
<tr>
<td>NPO</td>
<td>Nil Per Oral</td>
</tr>
<tr>
<td>NTWC</td>
<td>New Territories West Cluster</td>
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<tr>
<td>OS</td>
<td>Oral Stimulation</td>
</tr>
<tr>
<td>OT</td>
<td>Overtime</td>
</tr>
<tr>
<td>PIOMI</td>
<td>Premature Infant Oral Motor Intervention</td>
</tr>
<tr>
<td>PMA</td>
<td>Postmenstrual Age</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>PRCC</td>
<td>Post Registration Certificate Course</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized Controlled Trial</td>
</tr>
<tr>
<td>RN</td>
<td>Registered Nurse</td>
</tr>
<tr>
<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network</td>
</tr>
<tr>
<td>WM</td>
<td>Ward Manager</td>
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Chapter 1: Introduction

1.1 Background

With the advancement in medical technology, the survival rate of preterm infants has substantially increased over the past decade (Arvedson, Clark, Lazarus, Schooling & Frymark, 2010; Blencowe et al., 2012; Younesian, Yadegari & Soleimani, 2015). An increasing number of preterm infants indicates growing demand on healthcare expenditure and manpower required to provide quality nursing care. Studies have documented increased healthcare costs in premature infants when compared with full term infants (McLaurin, Hall, Jackson, Owens & Mahadevia, 2009). Unfortunately, literatures revealed that this group of preterm infants is at higher risk of feeding difficulties due to the underdeveloped cardiorespiratory system, central nervous system and oral musculature; their suck-swallow-breath mechanism is immature (Fucile, McFarland, Gisel & Lau, 2012; Lyu et al., 2014).

Oral feeding issue is one of the most commonly encountered problems and prominent reasons for delayed discharge in preterm infants (American Academy of Pediatrics, 2008; Jadcherla & Shaker, 2001).

Undoubtedly, sucking is the best natural way to feed infants. By 28 weeks of Gestational Age (GA), sucking and swallowing are present; however, the sucking ability of infants can only become mature between 32 and 34 weeks (Kish, 2013; Pinelli & Symington, 2010; Rocha, Moreira, Pimenta, Ramos & Lucena, 2007). Therefore, preterm infants born under 32 weeks of GA may require parental nutrition to fulfill their nutritional requirements. To
facilitate the transition from tube feeding to oral feeding, pre-feeding oral stimulation (OS) and non-nutritive sucking (NNS) are proven to be beneficial to improve oral feeding skills and establish full oral feeding (Boiron, Nobrega, Roux, Henrot & Saliba, 2007; Lau & Smith, 2011). However, most of the Neonatal Intensive Care Units (NICUs) in local settings have not set up any guidelines to provide oral stimulation for preterm infants less than 32 weeks. As a result, when oral feeding is introduced to preterm infants, majority of them cannot tolerate very well and have unnecessarily slow progression. Oral feeding difficulty in turn leads to prolonged hospitalization, greater medical cost, long-term health problems and family stress (Bache, Pizon, Jacobs, Vaillant & Lecomte, 2014). The ultimate goal for preterm infant feeding is that all infants can enjoy safe, full oral feeding either via breast or bottle. Most importantly, full oral feeding is a criterion for hospital discharge (American Academy of Pediatrics Committee on Fetus and Newborn, 1998; Stark et al., 2008; Zimmerman & Barlow, 2009).

To better prepare infants for the oral feeding, it is high time for NICU nurses to make a change. Preterm infants born less than 32 weeks GA could benefit from OS program. What’s more is that, OS is safe and easy to administer. The benefits it bring are immense. Both nurses and parents can be educated to perform OS for preterm infants.

1.2 Affirming the Need
Every year, hundreds of preterm infants are admitted to the NICU in the New Territories West Cluster (NTWC) where I work. Nevertheless, there is no standardized protocol to train up oral feeding of preterm infants in the cluster.

By counting the number of cases on the admission book in my ward, approximately 400 infants born between 29 and 34 weeks were admitted in the past 12 months. When the infants were ready to start enteral feeding, providing tube feeding was the norm to help them transit to autonomous oral feeding. In between the period from birth to oral feeding training, little attention was paid to the preparation of future oral feeding training. In my ward setting, when infants’ Postmenstrual Age (PMA) reached 32 weeks with stable respiratory status, physicians started to train their oral feeding. As the training started, problems arise. From my observation, over 95% of the infants had immature sucking ability. At the early stage of introduction of oral feeding, infants usually encountered feeding difficulty. The most common cause was suck-swallow-breath incoordination presented as transient desaturation during feeding, using of accessory muscles when breathing, apnea or bradycardia. The underlying reason is due to their immature cardiorespiratory system, central nervous system and incomplete oral structure development (Bu'Lock, Woolridge & Baum, 1990; Fucile, Gisel & Lau, 2002; Gardner & Hagedorn, 1991; Kish, 2013).

From my observation, in many cases, both infants and their caregivers (nurses or parents) faced great difficulty in oral feeding training. Some parents expressed their frustration as it took long to fully train up the infants. For a group of extreme low birth weight infants, almost hundred percent of their parents described oral feeding a ‘disaster’ to them. No matter how much patience they provided, their beloved babies just ‘could not cooperate’. Some infants
responded with vomiting or desaturation. Some showed mild bradycardia and required many resting periods in between a meal. A large proportion of parents verbalized their disappointment on repeated trials but still their children failed to complete the feed orally. Upon an oral feed trial by parents, over half of the cases required to complete the milk feed by tube feeding (Premji, McNeil & Scotland, 2004).

Through informal observation, preterm infants born between 28-32 weeks GA generally required four to eight weeks of transition time to attain full oral feeding and achieve the minimum weight of 2.2kg to be discharged. Week after week, I witnessed cases required prolonged hospital stay solely due to poor oral feeding. In most of the cases, the preterm infants were clinically stable and parents were ready to take baby home, yet the newborn must be hospitalized due to incomplete oral feeding training. This illustrates that oral feeding ability is directly related to length of hospitalization. Successful oral feeding is one of the the gold standards for discharge readiness (American Academy of Pediatrics, 2008; McGrath & Braescu, 2004). Difficulty in oral feeding leads to prolonged hospital stay and hence increased medical cost.

In Hospital Authority (HA), running a NICU bed for one day requires HKD$23,000 (Hospital Authority, 2016). Adding up the expenditure spent on unnecessarily delayed hospital discharge, the expenses pose a heavy burden on our healthcare system. The consequences caused by the lack of preparation and training are undesirable.

Yet, the reasons for lack of training are understandable. Shortly after preterm infants’ birth, medical staff paid much attention to infants’ neurological, respiratory, cardiovascular and gastrointestinal condition. On the other hand, nurses put their emphasis on providing
quality nursing care to babies and parents, aiming at early detection of any condition changes. Not until infants are clinically stable and start oral feeding training, they then realize that they cannot do much to facilitate the training. Currently, the main strategy for oral feeding training is train and wait, wait until the infants reach a more mature PMA. A more mature PMA implies better sucking. The major problem with this strategy is time constraint. Not to mention the waiting process still occupies a NICU bed.

The reasons for poor oral feeding vary. The major problem is that preterm infants have disorganized sucking pattern and suck-swallow-breath incoordination (Kish, 2013). Some infants take an aversion of touch in the mouth; some are just hypersensitive to that touch (Lau, Sheena, Shulman & Schanler, 1997). Their hypersensitivity may be precipitated by the ‘unpleasant’ oral-motor stimulation during hospitalization. Before preterm infants can start oral feeding, most of the oral-motor stimulations they received were ‘unpleasant’. Stimulations include necessary life-saving medical procedures such as intubation, airway suctioning and insertion of orogastric tube (Schanler, Shulman & Lau, 1999). As a result, some infants develop resistance to anything put inside the oral cavity.

Currently, my ward colleagues are performing NNS by providing pacifiers to infants. However, the unstructured provision of pacifiers does not make much improvement. There is no evidence-based guideline on the use of NNS. Majority of the nurses do not know the preferred practice to facilitate oral feeding, they just perform their own practice according to their knowledge and experience.

In view of the problem, literature review has been done to see what we, as NICU nurses, can do to facilitate the transition from tube feeding to oral feeding. One systematic review on
the topic ‘non-nutritive sucking for promoting physiologic stability and nutrition in preterm infants’ has been published in 2010. After throughout search, no published systematic review on the effectiveness of adopting OS intervention could be obtained. For the benefit of patients, it is high time to review the available literature systematically.

My search of evidence suggested that an OS program was the most commonly researched method. It can be implemented on preterm infants to improve oral feeding performance.

1.3 Significance and Objectives

1.3.1 Significance

The relationship between feeding difficulty and delayed hospital discharge underline the significance of the urge need to facilitate feeding training of preterm infant (Younesian et al., 2015). Some of my colleagues realized the importance of pre-feeding oral training, the problem is that there is no guideline as reference. Nurses can only provide unstructured NNS as oral training. Healthcare professionals working in NICU should step up their effort to facilitate the transition form tube feeding to oral feeding. Study also proved that any interventions which can enhance preterm infants’ oral feeding skills not only ensure safe and successful oral feeding, but also shortens hospitalization, decrease medical cost and hastens mother-infant reunion (Lau, Fucile & Schanler, 2015).

As a result, it is worthwhile to develop an evidenced-based OS intervention to facilitate oral-motor skills development and improve oral feeding for infants less
than 34 weeks PMA. The research question is to develop an evidence-based oral simulation intervention to improve preterm infants’ oral feeding ability. The ultimate goals are improving oral feeding, shortening hospital stay and hence, reducing medical cost.

1.3.2 Objectives

✧ To extract constructive information from available literature regarding the implementation of OS program and summarize them in tables of evidence

✧ To critically appraise the literatures, synthesize and utilize appropriate information

✧ To develop an evidence-based intervention on implementation of an OS program for premature infants between 29-34 weeks of GA

✧ To determine the implementation potential of proposed intervention

✧ To generate implementation and evaluation plans
Chapter 2: Critical Appraisal

2.1 Search and Appraisal Strategies

2.1.1 Inclusion criteria for study selection

Study selection was based on language used in the article, availability of full text, the year of publication, study design, subjects included and the intervention implemented. All the studies selected were full articles written in English, published from 2002 to 2015. Only Randomized Control Trials (RCTs) are selected to ensure high level of evidence. All the studies targeted on preterm infants less than 34 weeks of GA in NICU. The intervention of the studies focuses on OS program.

2.1.2 Exclusion criteria for study selection

Studies which included preterm infants with medical complications or congenital abnormalities are excluded. Those conditions include medical complications (e.g. necrotizing enterocolitis, grade III or IV intraventricular hemorrhage or periventricular leukomalacia), congenital diseases (e.g. chromosomal or genetic abnormalities, neurological abnormalities, complex congenital heart disease, congenital gastrointestinal malformations or bronchopulmonary dysplasia), severe asphyxia and severe infections.

2.1.3 Search strategy
This paragraph is a brief description on the search strategy used to identify eligible studies. The details are stated in Appendix A. Three electronic databases, namely PubMed, British Nursing Index and Cochrane library, were searched in November and December 2015 from the University of Hong Kong library link. The keywords searched can be divided into three categories. They are population (‘prematurity’), intervention (‘oral stimulation’) and outcome (‘oral feeding’). For the population category, ‘prematurity’, ‘premature infant’, ‘premature infants’, ‘premature baby’, ‘premature babies’, ‘premature newborn’, ‘premature newborns’ were searched using the operator ‘OR’. For the intervention category, ‘oral stimulation’, ‘oral stimulation program’, ‘pre-feeding oral stimulation’, ‘oral sensorimotor program’ and ‘sensory-motor-oral stimulation’ were searched using the operator ‘OR’. For the outcome category, ‘oral feeding’, ‘full oral feeding’, ‘autonomous oral feeding’ and ‘oral feeding performance’ were searched using the operator ‘OR’.

After separate search on the three categories of keywords, then combined search was done using the operator ‘AND’. After combined search, potential articles were identified by scanning the titles. Abstracts were screened to assess the eligibility of studies. Once the studies were confirmed eligible, the reference lists were manually reviewed. Availability of relevant reviews was further searched in an effort to dig out the maximum number of relevant studies.

2.1.4 Appraisal strategy
The quality of seven articles is assessed and graded using the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist 2: controlled trials (version 2.0) (Sleith, 2015). Basically, the checklist consists of two sections in which the internal validity and overall assessment of study were analyzed. On completion of the checklist, individual study was graded into high quality (++)/acceptable (+)/unacceptable (reject 0). This grade provides an indicator on the overall quality of the study.

2.2 Results

2.2.1 Search results

After combing the three categories of keywords using the operator ‘AND’, in total 116 studies were yielded from the three electronic databases. Among the 116 studies, 45 duplicated articles were removed. After reviewing the title of the remaining 71 articles, 37 articles remained to be screened for the abstract. After scanning the abstracts of studies, the inclusion and exclusion criteria were taken into consideration. Therefore, seven Randomized Controlled Trials (RCTs) remained eligible. Unfortunately, one of the them was published in 1996 which was too old; it was excluded. Then, manual searches on the reference lists of the six eligible articles were performed and finally one more RCT was yielded. This makes up a total of seven RCTs available for critical appraisal (Asadollahpour, Yadegari, Soleimani & Khalesi, 2015; Boiron et al., 2007; Fucile et al., 2002; Lessen, 2011; Lyuet al., 2014;
Younesian et al., 2015; Zhang et al., 2014). The seven RCTs were published between 2002 and 2015.

### 2.2.2 PRISMA flowchart

A PRISMA flow diagram is attached in appendix B. The diagram briefly illustrates how the 116 studies were screened and excluded to the final seven RCTs.

### 2.2.3 Tables of evidence

Tables of evidence are constructed to summarize the results of the seven RCTs. The tables are attached in appendix C. The following is a brief description.

#### 2.2.3.1 Year of publication

Exact years of publication are as follows: one in 2002 (Fucile et al., 2002), one in 2007 (Boiron et al. 2007), one in 2011 (Lessen, 2011), two in 2014 (Lyu et al., 2014; Zhang et al., 2014) while the last two in 2015 (Asadollahpour et al., 2015; Younesian et al., 2015).

#### 2.2.3.2 Study type

All of the seven studies are RCTs carried out in NICU of different countries. All of them are single site studies. Two studies were done in the US (Fucile et al., 2002; Lessen, 2011). Two studies were done in China (Lyu et al., 2014; Zhang et al., 2014). Two studies were done in Iran (Asadollahpour et al., 2015; Younesian et al., 2015). Boiron et al.’s (2007) study did not state the country in which the study was carried out.


2.2.3.3 Patient characteristics

The number of preterm infants recruited varies from 20 to 120. All the infants are in-patients of NICU.

2.2.3.3.1 Inclusion criteria

Regarding the GA of subjects, in general, all seven studies recruited preterm infants between 26 and 34 weeks as determined by obstetric ultrasonogram and clinical examination. Infants recruited were of appropriate size for their GA. Two studies included infants born between 26-29 weeks GA (Fucile et al., 2002; Lessen, 2011). Two studies included infants born between 29-34 weeks GA (Boiron et al. 2007; Zhang et al., 2014). Two studies included infants born between 30-32 weeks GA (Asadollahpour et al., 2015; Younesian et al., 2015). The final study included infants born between 29-34 weeks GA (Lyu et al., 2014). Regarding the medical condition of the subjects, all seven RCTs recruited subjects with stable vital signs and receiving full tube feeding.

The study carried out by Lessen (2011) also included infants who were on high flow oxygen. Lessen explained that the inclusion of infants on high flow oxygen was necessary because his target infants had low PMA (i.e. 26-29 weeks).
In contrast, Boiron et al. (2007) specifically mentioned that only infants who do not receive any respiratory support in the preceding 48 hours were included.

2.2.3.3.2 Exclusion criteria

The exclusion criteria of the studies were similar. All the seven studies excluded infants with medical complications (e.g. necrotizing enterocolitis, grade III or IV intraventricular hemorrhage or periventricular leukomalacia), congenital diseases (e.g. chromosomal or genetic abnormalities, neurological abnormalities, complex congenital heart disease, congenital gastrointestinal malformations or bronchopulmonary dysplasia), severe asphyxia and severe infections.

2.2.3.4 Intervention

Six of the RCTs used the Beckman Oral Motor Intervention (BOMI) (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al. 2002; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). BOMI is an OS intervention consists of two parts (12 minutes of OS followed by 3 minutes of NNS). A detailed table of BOMI OS program was extracted from Fucile et al.’s study (2002) and attached in appendix D. Five of them had the OS program carried out for 10 to 14 successive days, 20 to 40 minutes before a tube feeding (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al. 2002; Younesian et al., 2015; Zhang et al.,
2014). Only in Lyu et al.’s (2014) study, the OS program was continued until full oral feeding was attained.

On the other hand, only the OS program in Lessen’s study (2011) was different from the six studies. Lessen modified the BOMI into a Premature Infant Oral Motor Intervention (PIOMI) which was only 5 minutes long. PIOMI was carried out at 29 weeks PMA and before introduction of oral feeding, for seven consecutive days.

2.2.3.5 Comparison

In all seven RCTs, the control group for comparison received the routine care, i.e. no OS program.

2.2.3.6 Length of follow up

The follow up period varies from five months to the date when all subjects were discharged.

2.2.3.7 Outcome measures

2.2.3.7.1 Primary outcome

All seven studies measured the transition time (from introduction of oral feeding to autonomous oral feeding) as the primary outcome.
Another primary outcome for Boiron et al. (2007) study was the NNS pressure and sucking ability of infants. Lyu et al. (2014) also measured PMA of infants at two feeding millstones.

2.2.3.7.2 Secondary outcome

A series of secondary outcomes were measured in different studies. The most commonly measured secondary outcome was hospital Length of Stay (LOS). Five out of the seven RCTs measured LOS (Fucile et al. 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014).

Three studies measured weight gain (Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014).

Fucile et al. (2002) and Zhang et al. (2014) also measured the rate of milk transfer and overall milk intake in the feed.

Last but not least, Lyu et al. (2014) calculated the oral feeding efficiency whereas Zhang et al. (2014) calculated the feeding proficiency of infants.

2.2.3.8 Effect size

Six of the results presented in the studies were interpreted in effect size calculated via the effect size calculator (Asadollahpour et al., 2015; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). In Boiron et al.’s study (2007), results were not presented with standard deviation,
so effect size could not be generated. Therefore, those results were typed in the table of evidence as reference.

2.2.4 Appraisal results

To critically appraise the seven studies, the SIGN methodology checklist was used. The checklists are attached as appendix E. The following are some important components extracted from the checklist with explanation.

2.2.4.1 Address of an appropriate and clearly focused question

All the seven RCTs have addressed a clearly focused question stating the population, intervention, comparison and outcome measured.

2.2.4.2 Random assignment of subjects to treatment groups

All the seven studies are RCTs.

2.2.4.3 Concealment method

In both Asadollahpour et al. (2015) and Younesian et al.’s (2015) studies, concealment method was not mentioned. These two studies only mentioned that subjects were assigned by simple randomization using convenience sampling. All the other five studies applied adequate concealment method. Two had randomization using computer generated blocks of varying sizes (Boiron et al., 2007; Lyu et al., 2014). The remaining three studies used stratified blocked randomization method (Fucile et al., 2002; Lessen, 2011; Zhang et al., 2014).
2.2.4.4 **Blinding**

Two studies were single blinded in which the interventions were administered by the investigators (Boiron et al., 2007; Zhang et al., 2014). Four of the studies were double-blinded (Asadollahpour et al., 2015; Fucile et al., 2002; Lyu et al., 2014; Younesian et al., 2015). The subjects and investigators were concealed from the group assignment. Only Lessen’s study (2011) was a triple-blinded design in which the statisticians analyzing the data were also blinded.

2.2.4.5 **Subject characteristics before the trial**

All the seven RCTs provided a clear paragraph/table stating the baseline characteristics of subjects to ensure there was no significant difference between the groups before treatment. Characteristics analyzed included GA, weight (at birth and at entry), sex, race, and Apgar scores at birth. Zhang et al.’s (2014) study also analyzed any significant difference in severity of illness using the neonatal medicine index. They concluded that all the patient groups looked reasonably similar before the trial.

2.2.4.6 **Only difference is the treatment under investigation**

In all the seven RCTs, the only difference between the intervention and control group was the treatment under investigation. No subjects received any additional treatments.

2.2.4.7 **Validity and reliability of outcome measures**
All the outcomes measures were clearly described. The measures were objective and could be quantified. Transition time, LOS and PMA were measured in days. Weight gain was measured using an electronic balance in grams. Overall milk intake, rate of milk transfer and oral feeding efficiency/proficiency were calculated from objective observation. NNS pressure was measured using a pressure transducer which was connected to a computer. All of the outcomes documented are objective data.

2.2.4.8 Drop out rate

The drop out rate for six studies varies from 0 to 12.5% which is acceptable (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al., 2002; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). However, Lessen’s (2011) study had a relatively high drop out rate of 37.5%. The author clearly explained the reason for drop out from the study. Reasons included infants being transferred out to other hospitals, late recalculation of birth PMA making the data invalid, intubation, nil per oral (NPO) status prescribed by physician.

2.2.4.9 Intention to treat (ITT) analysis

All the seven studies applied ITT analysis.

2.3 Summary and Synthesis

2.3.1 Level of evidence
After critical appraisal, three studies (Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014) are graded as high quality (++). It is because majority of the checklist criteria are fulfilled so there is little risk of bias. The other four studies are graded as acceptable (+) (Asadollahpour et al., 2015; Boiron et al., 2007; Younesian et al., 2015; Zhang et al., 2014). The reasons for lower grading are as follows. Boiron et al. (2007) and Zhang et al.’s (2014) studies are only single-blinded. Asadollahpour et al. (2015) and Younesian et al.’s (2015) studies do not specify adequate concealment method. These flaws may lead to possible bias.

All of the seven RCTs recruited preterm infants between 26 and 34 weeks. The studies aimed at investigating the effectiveness of using OS program to improve oral feeding performance in preterm infants.

2.3.2 Summary

2.3.2.1 Transition time

All seven studies reported a reduction in transition time from tube feeding to autonomous oral feeding. Among them, six studies reached statistical significance. The reduction in transition time ranges from 3.63 to 13.7 days with p value=0.000-0.05 (Boiron et al., 2007; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). Only Asadollahpour et al.’s (2015) study reported a reduction of 6.07 days but did not reach statistical significance(p=0.282). Yet, this result is still of great clinical and economic significance.
2.3.2.2 LOS

Six studies measured LOS as an outcome. In all the six studies, infants who received the OS program were discharged sooner than those in the control group. Among the six studies, only Asadollahpour et al.’s (2015) study reached statistical significance, subjects in the OS group were discharged 5.85 days sooner than the control group (p=0.007). The other five studies’ results are between 1.28-6 days, yet do not reach statistical significance (p=0.459-0.724) (Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). This may be explained by small sample size leading to lower possibility of achieving statistical significance. In addition, infants might experience other medical events (e.g. infection, deterioration of respiratory status, not reaching minimum body weight for discharge) which required continue hospitalization. Some social reasons like unavailability of caregivers could lead to delayed discharge. Besides, there is no standardized protocol for infant discharge. All these factors contribute to prolonged LOS. These may be confounding variables to achieve statistical significance.

2.3.2.3 Weight gain

Three studies measured weight gain as outcome. Younesian et al.’s (2015) study reported significant weight gain at three time intervals. They are the weight gain from 1 to 4 oral feedings per day, from 4 to 8 oral feedings per day and from 8 oral feedings per day to discharge. When compared with the control group, the weight gain at the three time intervals are 50g (p=0.001), 51g (p=0.002) and 253g (p=0.001) respectively. On the other hand, Lyu et al. (2014) and Zhang et al.’s (2014) studies
also reported a positive trend in weight gain, yet the results do not reach statistical significance. Many factors might influence the weight change of an infant. The difference in significance may be explained by different approaches used to manage oral feeding progression (Lyu et al., 2014).

**2.3.2.4 Rate of milk transfer/efficiency**

Three studies measured rate of milk transfer/efficiency as the outcome. Zhang et al.’s (2014) study reported statistically significant increase in milk transfer rate (p<0.001). Indeed, rate of milk transfer reflects the overall oral motor ability. On the other hand, Fucile et al. (2002) and Lyu et al. ’s (2014) studies also reported an improved milk transfer rate when compared with the control group, yet the results do not reach statistical significance (p=0.053 & 0.805). Small sample size can be the reason.

**2.3.2.5 Overall intake**

Two studies measured the overall milk intake as the outcome. In Fucile et al.’s (2002) study, the overall intake in OS group was greater than the control group (p=0.0002). Zhang et al.’s (2014) study also reported an increased overall intake, however, the result is not statistically significant.

**2.3.2.6 Oral feeding proficiency**

Only Zhang et al.’s (2014) study measured the feeding proficiency of infants. Proficiency in the OS group was 0.1% higher than control group at day 1 observation. The statistical significance was not mentioned in the article. NNS elicits the infants’
sucking behavior. This aids the developmental of muscles needed for sucking and feeding. This poses a positive effort to the behavioral aspect. The stimuli of OS directly contribute to sucking and swallowing development. This explains the additive effect of implementing OS and NNS together so as to improve oral feeding performance. (Zhang et al., 2014)

2.3.2.7 NNS pressure and sucking ability

Only one study measured NNS pressure and sucking ability of infants. Boiron et al.’s (2007) study found that the NNS pressure for OS and oral support group is significantly increased between day 7 and day 14 of oral feeding training. The NNS pressure of the OS and oral support groups exceeds the control group by 0.21mmHg (p<0.001). Furthermore, the sucking ability of infants in the OS and oral support group is greater than the control at day 14 (an increase of 19% with p<0.001). This shows that OS and support enhance sucking parameters and improve feeding performance.

2.3.3 Synthesis

2.3.3.1 Target group

Based on the review and appraisal of selected studies, there is sufficient evidence to conclude that implementation of OS program poses beneficial effect on the attainment of autonomous oral feeding in preterm infants. The majority of the RCTs targeted infants between 29-34 weeks GA, I would propose my target population is preterm infants born between 29-34 weeks GA in NICU. Infants younger than 29 weeks PMA are at higher risk of respiratory distress which required assisted ventilation; infants older than 34
weeks generally have mature sucking ability. Therefore, they are excluded from the target subjects.

2.3.3.2 Proposed innovation

All the studies described the OS program as a safe and effective intervention to improve oral feeding performance of preterm infants. Effectiveness of OS has been proved to improve oral feeding. Here, OS means stroking and providing pressure to oral structures. When compared with full term infants, preterm infants have relatively poor oral motor control because of weaker mouth muscle tone and tongue strength; these lead to weaker sucking strength and endurance (Lessen, 2011).

The rationale of OS program is stated as follows. The 15-minute OS program used by six of the RCTs would be adopted. The first part lasts for 12 minutes. It involves stroking the oral structures. It strengthens the oral musculature necessary for adequate sucking. The second part is 3 minutes of NNS. It allows infants to engage the neuromuscular structures more efficiently and improve endurance. Infants can experience sucking with NNS. NNS not only facilitates sucking behavior development, but also improves enteral feed digestion. NNS has been proven to stimulate secretion of certain hormones and enzymes, which facilitate digestion, by vagal innervation in the oral mucosa. (Bosma, Hepburn, Josell & Baker, 1990)

The program enhances maturation of central and peripheral neural structures and provides a patterned input to the brainstem central pattern generator circuitry. This combination of OS and NNS enhances suck-swallow-respiration coordination. It contributes to improved sucking skills. Study has revealed that maturation of sucking not only depends on physiologic maturation, but also from learning experience. (Fucile
Six of the studies followed the OS program carried out by Fucile et al. in 2002. Five of which performed the OS program for 10 consecutive days (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al., 2002; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). The majority of the studies started the intervention 15-30 minutes before a tube feeding. The time frame is reasonable and feasible to achieve the optimal result.

Based on the above rationale, it is believed that implementation of an OS program in NICU for preterm infants between 29-34 weeks can improve their oral feeding and shorten LOS.
Chapter 3: Implementation Potential and Clinical Guideline

As stated in the previous chapter, OS intervention is proven to be effective to improve preterm infants’ oral feeding. In this chapter, the transferability, feasibility and cost-benefit ratio of implementing the innovation will be discussed. Finally, an evidence-based practice guideline will be developed.

3.1 Transferability

3.1.1 Details of target setting

The target setting is the NICU of a public hospital in the NTWC. In all the reviewed studies, the intervention was carried out in NICU in public hospitals (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). Two were carried out in developing countries; the other five in developed countries. The medical technology, healthcare system and economic status in those developed countries are mostly similar to that in Hong Kong, which means the findings highly applicable to my proposed setting.

3.1.2 Target population

In my target setting, approximately 400 infants born between 29 and 34 weeks were admitted every year. Initially after admission, all those premature infants required intravenous nutrition or tube feeding to ensure proper nutritional requirement. When
infants reach appropriate PMA, physicians start to prescribe oral feeding training for them. As stated in Chapter 2, the target population of the reviewed studies is premature infants between 26 and 34 weeks of gestation, required the transition from tube feeding to oral feeding. This indicates that the proposed target population is similar to the reviewed studies.

### 3.1.3 Philosophy of care

All the reviewed studies aimed to improve premature infants’ oral feeding ability and shorten LOS. The ultimate goals of the innovation are to promote earlier discharge and parent-infant reunion, which benefit patients and their families. The outcome is both patient-oriented and family-oriented. This resonates with the mission of my working cluster that ‘we are committed to providing people-oriented healthcare services’ (Hospital Authority, 2016). It is worthwhile to implement this innovation.

### 3.1.4 Sufficient patients being benefited

According to data from Census and Statistics Department (2016), the crude birth rates (number of live births per 1,000 population) in Hong Kong in 2014 and 2015 were 8.6 and 8.2 respectively. A steady crude birth rate over 8 implies steady birth of premature infants and admissions to NICU. In my target setting, there are 13 NICU beds. In the past five years, an average of 400 infants born between 29 and 34 weeks were admitted every year. Upon implementation of the intervention, over 90% of clinically stable premature infants on tube feeding could benefit from it. The 10% left may not be suitable to be enrolled in the program due to medical complications or congenital abnormalities.
Generally speaking, at least 90% (i.e. ~360 infants/year) of the admitted infants could be benefited.

3.1.5 Time frame for implementation and evaluation

The estimated time frame required for launching a pilot program is 14 weeks. In the first week, a working group will be formed. The working group takes three weeks to develop the implementation proposal. They use two weeks to communicate with three stakeholders and finalize the Evidence-based Practice (EBP) guideline. The three stakeholders are hospital Chief of Service (COS) and Department Operation Manager (DOM) of the pediatric department, and also Ward Manager (WM) of NICU. After approval of guideline, all NICU nurses will attend a training session within two weeks. After staff training, a 6-week pilot test will be run before long-term implementation. After the pilot test and evaluation, the program can be carried out to other eligible patients in the long run. A table showing the time frame is attached as appendix F.

3.2 Feasibility

3.2.1 Nurses’ autonomy to carry out and terminate the intervention

Nurses have sufficient autonomy to determine when to carry out and terminate the intervention. In NICU, infant feeding is one of the everyday nursing duties provided to patients. Oral feeding training is the responsibility of nurses. Once the infant reach medical stability (i.e. discontinue assisted ventilation for 48 hours), they should be prepared for oral training. This intervention is nurse-initiated. In case of medical instability, nurses used
tomake clinical decision to omit or stop oral feeding training. Therefore, if infants’
condition deteriorates during feeding progression, nurses should have the right to terminate
the intervention based on own clinical judgment.

3.2.2 Interference with current staff functions

Introduction of the innovation causes minimal interference with current staff
functions. In NICU, currently the nurse to patient ratio in daytime is 1:1 or 1:2. The
intervention only required daily 15-minute stimulation to each infant’s oral cavity before
any one of the scheduled feedings. Therefore, no extra manpower is required in daily
operation. With this intervention to decrease the transition time to full oral feeding, the
accumulative time saved on each feed is probably greater than the 15 minutes spent to
provide the intervention.

3.2.3 Organizational and administrative support

The administrative level of my working organization is always willing to support
innovation. It is because this intervention fulfills the mission of the cluster to provide
people-oriented healthcare services. The intervention is an EBP with proven effectiveness
by high quality researches. The benefits are well supported by literature. In addition, the
reviewed studies proved that the intervention helps to shorten infants’ LOS. It relieves the
financial burden for unnecessarily prolonged hospitalization only because of poor oral
feeding. With the above-mentioned reasons, my organizational climate tends to support
research utilization. Last year, my working place, NICU, has just implemented the use of
colostrum in oral care. The administration fully supported the innovation and provided
funding for necessary equipment. For instance, an extra refrigerator was purchased for storage of colostrum. This experience reflects that the organization encourages research utilization.

3.2.4 Consensus among staff and administrators

Generally speaking, nurses are willing to step up their effort to improve patient outcome. As the intervention is proven to be beneficial to patients, the majority of nurses would be willing to make a small step forward for the sake of patients. Nevertheless, possible resistance from minority should not be overlooked. Some staff may oppose the innovation due to misconception. Some may consider the 15-minute intervention nothing more than an ‘extra’ routine. Therefore, education and training are crucial beforehand. Training should not only include the procedural component, but also the rationale. Besides, the opinion of the nursing staff who always resists to change should be considered. The genuine needs and worries of resistant nurses must be identified. Show respect to staff by regular collection of feedback.

3.2.5 Friction within organization

No friction is expected from other departments. The intervention is proposed to implement in only one NICU of the pediatric department. The EBP is nurse-initiated and merely carried out by NICU nurses. No other healthcare professionals need to be involved.

3.2.6 Skills needed to carry out the intervention

Staff training is required before implementation. Nurses need to attend a 2-hour training session to learn the skills required. During the session, skills and procedure will be
demonstrated and return demonstration is required. A printed guideline will be available in NICU mini-library for quick reference. A demonstration video will be produced and uploaded to the Intranet of pediatric department. Staff can get easy access to the link using computer in the ward. During the 6-week pilot run, at least one staff from the working group will work in ‘A’ and ‘P’ shifts to act as the resource person and answer questions from nurses.

3.2.7 Likelihood to release staff for training

Nurses only need to attend a 2-hour training workshop beforehand. The 2 hours spent will be counted as overtime (OT) working hours. Nurses will take compensate off (CO) later when ward operation is not affected. This method is very commonly adopted by wards when staff have to work overtime for operational need. It should be approved by the management level.

3.2.8 Availability of equipment and facilities

3.2.8.1 Staff training

For staff training, the pediatric activity room can be used. Other necessary equipment like computer, projector, microphone, video recorder and baby manikins for practice are readily available in the hospital. The main expenditure is printing the training materials and posters for promotion.

3.2.8.2 Upon actual implementation
Upon actual implementation, the infants are comfortably placed inside the incubators for oral stimulation. The incubators are the one that they are already occupying since admission. No other equipment is required.

3.2.9 Evaluation

3.2.9.1 Outcome evaluation

The intervention outcome can be evaluated by calculation of transition time to attain autonomous full oral feeding and LOS. All the seven reviewed articles used transition time as the primary outcome (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). Six of them also measured LOS to evaluate the effectiveness of innovation (Asadollahpour et al., 2015; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014).

3.2.9.2 Program evaluation

Nurses compliance and level of satisfaction would be assessed to evaluate the program. Questionnaires would be distributed to collect nurses’ opinions on the program. Feedback will be analyzed by the working group and reported during monthly clinic meetings. Modification to guideline can be made if necessary.

3.3 Cost-Benefit Ratio

3.3.1 Potential risks of maintaining current practice
The potential risks of maintaining current practice are tremendous. Currently, physicians only start to prescribe oral feeding training until infants reach 32 weeks PMA and medical stability. The lack of pre-feeding oral training lead to various problems. A large proportion of infants suffer from oral feeding difficulty. In the short run, it leads to prolonged hospital stay and higher medical costs (Amaizu, Shulman, Schanler & Lau, 2008; Asadollahpour et al., 2015; Bache et al., 2014; Fucile et al., 2012).

Moreover, oral feeding problem poses significant negative impact on infants’ long-term growth and development. Prolonged hospitalization poses a negative influence on the whole family’s well-being (Dodrill et al., 2004; Gisel, 2010). Another inevitable consequence is altered parent-infant bonding (Feldman, Rosenthal & Eidelman, 2014).

3.3.2 Potential benefits from implementation of intervention

Implementation of the intervention brings substantial benefits. First of all, the intervention improves infants’ oral feeding ability and reduces the transition time from tube feeding to autonomous oral feeding (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). In turn, it shortens hospital LOS (Asadollahpour et al., 2015; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). Some studies proved that it is positively associated with better weight gain (Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014); increased rate of milk transfer (Fucile et al., 2002; Lyu et al., 2014; Zhang et al., 2014); greater overall intake (Fucile et al., 2002; Zhang et al., 2014); better oral feeding proficiency (Zhang et al., 2014); greater NNS pressure and sucking
ability (Boiron et al., 2007). OS provides a golden opportunity for premature infants to practise and enhance the necessary oral motor skills for future successful feeding (Simpson, Schanler & Lau, 2002). The ultimate goals are to shorten LOS and reduce medical cost.

3.3.3 Potential risks during implementation of intervention

No adverse reactions were reported in the seven reviewed studies. The intervention is safe and non-invasive. The only potential risk is that infants may develop desaturation during OS. Therefore, nurses must keep close monitoring on infants’ condition and allow sufficient resting periods during intervention.

3.3.4 Potential nonmaterial benefits of implementation of intervention

3.3.4.1 To nurses

Before proposal of this innovation, nurses have already recognized the need to provide pre-feeding oral training. Previously, as clinical guideline is not available, nurses simply provided unstructured NNS based on their own experience. Nurses felt powerless to facilitate the training. If an EBP guideline is available, nurses can play a more active role to facilitate the transition. Hopefully, infants would have better oral intake. This increases job satisfaction and improves staff morale.

3.3.4.2 To infants and parents

Study revealed that mothers of very low birth weight infants, who experienced prolonged separation, have high level of worries on infants’ safety and well-being. They also have high level of distress compared with mothers of full-term infants.
Mothers spend more time away from the infants due to infants are hospitalized, the cumulative time of caretaking the premature infants is low. Mothers show diminished investment in the attachment relationship following prolonged separation. (Feldman, Weller, Leckman, Kuint & Eidelman, 1999)

Earlier discharge alleviates this problem and improves parent-infant bonding. As this nursing intervention improves infants’ feeding, parents’ satisfaction towards nursing care would be increased accordingly. This enhances rapport between nurses and parents.

**3.3.5 Material cost of implementing the innovation**

The estimated material cost can be divided into the set-up cost and running cost per year.

**3.3.5.1 Set-up cost**

The major expenditure includes the training salary for 40 nurses (2-hour training session for each nurse), production of demonstration video, printing handouts for training and posters for promotion. One Advanced Practice Nurse (APN) in the working group would be responsible for recording the demonstration, then edit and upload the video on the Intranet for staff quick reference. She needs to spend two hours on that. All these contribute to a total set-up cost of $18,546.

**3.3.5.2 Running cost per year**
From my observation, roughly 10% of the 400 infants are excluded based on the exclusion criteria. Every year, it is estimated that ~360 preterm infants can be enrolled in the OS program. For each eligible infant, the nurse spends 15 minutes each day to perform OS for 10 consecutive days. This makes up to a total nursing time of 900 hours/year. The yearly running cost is $174,600. Detailed calculation is attached in appendix G.

3.3.6 Nonmaterial cost of implementing the innovation

The estimated nonmaterial cost to implement the innovation includes the training venue and equipment required for staff training. Training session will take place in the pediatric activity room which is department owned. Other hardware required includes computer, projector, microphones, video recorder and baby manikins; all of them are department owned. Details are attached in appendix H.

3.3.7 Cost of not implementing the innovation

If the innovation is not implemented, infants required a longer LOS for oral feeding training. In Asadollahpour et al.’s (2015) study, subjects in the OS group were discharged 5.85 days sooner than the control group (p=0.007). This result reached statistical significance. This implies that on average each infant stayed for an extra 5.85 days due to poor oral feeding if the innovation is not implemented. 360 infants staying in NICU for an extra 5.85 days makes up to a total of 2106 days/year. Operation of one NICU bed costs $23,000/day. If the innovation is implemented, a total cost of $48,438,000/year can be saved. Detailed calculation is attached in appendix I.
Besides the material cost, when infants could not finish an oral feed after prolonged training, parents verbalized their frustration. Prolonged feeding training encompassed negative emotions (Stevens, Gazza & Pickler, 2014). Overall staff morale would be negatively affected.

3.4 Evidence-based Practice Guideline

The grade methodology by SIGN is applied to develop the EBP guideline. All the recommendations stated in the guideline are based on review of available evidences and assessment on quality of evidence. Results are summarized into tables of evidence. Quality of evidence is rated in one of the four categories, ranging from low (4) to high (1++). Based on the quality of evidence, strength of recommendations (grade A to D) can be established. Appendix J shows details of the key to evidence statements and grades of recommendations (Scottish Intercollegiate Guideline Network, 2016). Finally, an EBP guideline is developed and attached in appendix K.
Chapter 4: implementation Plan

After development of the EBP guideline, the intervention must be introduced to stakeholders so as to obtain their approval and cooperation for implementation. In this chapter, a communication plan is outlined. Besides, the plans for pilot study and programme evaluation are developed.

4.1 Communication Plan

4.1.1 Identification of stakeholders

Prior to the introduction of guideline, potential stakeholders must be identified and sufficiently communicated with. Literature suggested that if a given stakeholder has the ability to derail a project, the project manager must form a working relationship with this stakeholder no matter how difficult (Roeder, 2013). Therefore, it is crucial to ensure effective communication with the stakeholders. The stakeholders can be divided into three levels. The first is management level. Key people include COS, DOM of pediatric department and WM of NICU. They play a decisive role in determining the feasibility of the guideline, allocate resources for training and approve the guideline. The second level is clinical level. This level includes frontline staff such as Medical Officers (MOs), APNs, nurse specialists and Registered Nurses (RNs) in NICU. MOs are responsible for supporting nurses in case there is any adverse reactions. Nurses are responsible for recruiting eligible patients and implementing the guideline. The third level is client level which includes premature infants and their parents.

4.1.2 Communication process

4.1.2.1 Formation of working group
To begin with, a working group of five members would be formed. The nurse specialist in NICU acts as the leader. Other members include an APN and three experienced RNs. All the members have completed the Post Registration Certificate Course (PRCC) training in NICU and have at least five years of NICU working experience. The formation of the working group takes one week and writing up the the innovation proposal takes three weeks. The working group is responsible for coordination and evaluation of the innovation.

4.1.2.2 Communication with management level

The management level has the ultimate authority to make the final decision on adoption of new guideline. Thus, ensuring effective communication with them is of prime importance. Gaining administrative support is essential to obtain necessary resources required to implement the guideline. A study proved that organization support directly affects nurses’ job performance (Nabirye, Brown, Pryor & Maples, 2011). Therefore, earning the full support from administrative level not only implies resources backup, but also improved staff performance.

The following is the communication process. After formation of the working group, the prepared innovation proposal would be submitted to DOM. The proposal includes details of guideline like the background, affirming needs, anticipated effectiveness with evidence support by reviewed literatures, guideline details, involved staff training, annual budget plan and manpower involved in daily operation. Upon permission by DOM, the working group would give a presentation in a monthly department meeting in which all the stakeholders are present. The presentation must be precise and impressive so as to earn their approval. Highlights
should be given on the anticipated benefits to patients and the limited interference on current staff function. Immediately after the presentation, a question and answer session would be arranged to clarify any queries from the stakeholders. The comments from stakeholders can be collected and wait for their approval.

4.1.2.3 Communication with staff

Once the guideline is approved by the management level, the guideline would be introduced to staff during monthly clinic meeting. When introducing the guideline, the working group would reassure staff that training session would be provided before implementation. All the forty nurses are required to attend a compulsory training session which lasts for two hours. Two identical training sessions would be held on two different days with twenty nurses in each session. During the training session, skills and procedures of OS would be demonstrated by the nurse specialist; return demonstration by each nurse is required. Apart from the procedural component, the rationale and benefits of implementing the guideline would be explained in detail. The working group would reassure nurses that the two hours spent on training would be counted as OT working hours. Nurses can take CO later when ward operation is not affected. Besides, a demonstration video would be produced and uploaded on the Intranet of pediatric department for staff quick reference. Staff could get access to the video using any computers in ward.

At the end of the training session, nurses can raise questions in the question and answer session. There is an anticipated question from frontline nurses. Some nurses may have concerns regarding interference on current ward routine. The working group should emphasize that nurses have the autonomy to choose when to
perform the 15-minute OS training before any one of the scheduled feedings. For example, if nurses are occupied with the treatment prescribed by MO in A shift, they can handover the condition to the nurse in charge in P shift. Based the the reviewed literature, by providing OS training to infants to improve their oral feeding ability, the nursing time saved is greater than the time spent on carrying out the OS.

4.1.2.4 Communication with client level

To promote the guideline to parents, posters would be designed and posted on the notice boards in NICU. If infants are scheduled to start oral stimulation training in near few days, nurses would inform parents during visiting hours so that parents have an idea that their infants would soon undergone OS training. To easily identify eligible infants and remind nurses to perform the training, a signage would be posted in infants’ bedside for easy identification.

Last but not least, a pilot test would be launched before full-scale implementation to test for feasibility. During the pilot test, at least one member from the working group will work in ‘A’ and ‘P’ shifts to act as the resource person. The resource person is responsible for answering questions from nurses. At the same time, the resource person collects any comments from nurses and bring up the points for discussion in future clinic meetings. Any amendments or updates on the guideline would also be announced via internal electronic mail. Evaluation would be done after pilot test to review for improvement.

4.2 Pilot Study Plan
The term 'pilot study' refers to mini versions of a full-scale study, as well as the specific pre-testing of a particular research instrument such as a questionnaire or interview schedule (Teijlingen van & Hundley, 2002).

Conducting a pilot test brings various benefits. By conducting the pilot test, the feasibility of a full-scale innovation and the workability of protocol can be assessed. If the pilot test can be smoothly implemented, the working group can easily convince stakeholders that a full-scale implementation is worth supporting. This increases the likelihood of success during full-scale implementation. (Teijlingen van, Rennie, Hundley & Graham, 2001)

4.2.1 Pilot test timeline

After getting approval from the stakeholders and staff training, a pilot test would be launched. The timeframe is six weeks. The recruitment of eligible infants and implementation last for four weeks, followed by two weeks of evaluation and modification of guideline. Appendix F is an outline of the timeframe.

With reference to the admission statistics in the NICU, on average 30 eligible preterm infants were admitted each month. Inclusion and exclusion criteria are as stated in the previous chapter. During the pilot test, nurses actively recruit eligible infants. The transition time from introduction of oral feeding to autonomous oral feeding, which is the primary outcome of the guideline, would be recorded in the Clinical Management System (CMS).

4.2.2 Evaluation for pilot test

Firstly, at the end of the four-week pilot implementation, questionnaires would be distributed to all nurses to collect their opinions. The questionnaire composed of two parts. The first part adopts a five-point Likert scale rating system in which ‘5 marks’
represents the highest level of satisfaction (‘strongly agree’) whereas ‘1 mark’ represents
the lowest level of satisfaction (‘strongly disagree’). A total of eleven items are asked.
Interested areas include nurses’ competency to implement the innovation, clarity of
guideline, adequacy of training and support and effectiveness of innovation. The second
part is an open-ended question in which nurses are invited to write down any other
comments regarding the innovation. The questionnaire is attached as appendix L.

Secondly, focus group interview led by the working group would be organized.
Nurses are highly recommended to join the interview. Discussion topics include nurses’
competency to implement the innovation, effectiveness of innovation, any interference
with routine nursing duty, strengths and weaknesses of innovation and any other topics
concerned by nurses.

Both the questionnaire results and feedback would be reviewed and analyzed. The
analysis result would be summarized in a written report which would be submitted to
DOM and WM. This pilot test aims to determine the feasibility of programme before
full-scale implementation. Based on the pilot results, the guideline will be refined if
necessary.

4.3 Evaluation Plan

After conducting the pilot study, the innovation can be implemented in full-scale for 36
weeks. Before this, demographic data of the infants would be collected. For example, infants’
gender, GA and birth weight.

4.3.1 Primary patient outcome

As mention in previous chapter, the primary patient outcome of the innovation is to
improve preterm infants’ oral feeding ability. The improvement is measured by a reduction in the transition time from introduction of oral feeding to autonomous oral feeding. The transition time is adopted as the primary outcome because it is measured in all the seven reviewed studies (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). The nurses in charge of the infant should record the date and time at two time points. The first point is when the infant first starts oral feeding; the second point is when the infant attains eight successful oral feeding per day for 48 hours.

4.3.2 Secondary patient outcome

The secondary patient outcome is the hospital LOS. Six of the reviewed studies measured LOS to evaluate the effectiveness of innovation (Asadollahpour et al., 2015; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). Infants’ LOS are recorded on ward admission books. The data can be retrieved by nurses from the working group. Simple calculation would generate the LOS.

4.3.3 Secondary nurse outcome

4.3.3.1 Nurses compliance

Nurses compliance can be measured via the CMS record.

4.3.3.2 Nurses level of satisfaction

After 36 weeks of implementation, a questionnaire would be distributed to all nurses to collect their feedback, mainly on the level of satisfaction towards the guideline. The questionnaire composed of two parts. The first part adopts the five-point Likert scale in which seven items are asked; the second part is an opened-ended question to collect any opinions on the innovation. The questionnaire
for satisfaction level is attached in appendix M.

4.3.4 Nature of clients involved

Eligible infants to be recruited in the programme are preterm infants born between 29 and 34 weeks as determined by obstetric ultrasonogram and clinical examination. The infants should be of appropriate size for their GA, with stable vital signs and receiving full tube feeding. Infants with the following conditions are excluded: medical complications, congenital diseases, severe asphyxia or severe infections.

4.3.5 Sample size calculation

The sample size calculator Piface was utilized for sample size calculation. The one-sample t test was adopted. According to the reviewed studies, the effect size varies from 0.65 to 3.01 (Asadollahpour et al., 2015; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). In order to strike a balance between statistical significance and sample recruitment, a medium effect size of 1.83 was adopted. The SD ranges from 2.7 to 9.18 (Asadollahpour et al., 2015; Fucile et al. 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). The SD of 9.18 was adopted in order to recruit the largest number of samples. Taking the effect size of 1.83 and SD of 9.18; considering level of significance at 5% and power at 80%, Piface calculated the required sample size to be 200.

Furthermore, the drop out rate must be taken into consideration so that more samples are recruited to accommodate for possible drop out from the intervention. The drop out rate for the reviewed studies varies from 0 to 37.5% (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). The mean drop out rate of 19% would be adopted. This makes
up to the sample size 200/0.81, which rounds up to ~247 infants.

4.3.6 Data analysis plan

The collected data would be input into the computer software Statistical Package for the Social Science (SPSS) version 22.0 for data analysis. The demographic data of the infants would be analyzed using chi square test. Moreover, the pre-intervention and post-intervention transition time and LOS would be compared. The transition time and LOS before implementation of guideline (in 2015) would be used as the control for comparison. The two-tailed paired t-test would be used for significance testing. Nurses’ compliance would be recorded as a percentage. For the questionnaire results, the percentage of nurses graded each item would be measured.

4.4 Basis for Implementation

In this paragraph, the criteria in which the working group would grade the program as effective would be discussed. The criteria are set with reference to the literature.

4.4.1 Primary patient outcome

The pre-intervention and post-intervention transition time are calculated. In the reviewed studies, the mean transition time improved ranges from 3.63 to 13.7 days (Asadollahpour et al., 2015; Boiron et al., 2007; Fucile et al., 2002; Lessen, 2011; Lyu et al., 2014; Younesian et al., 2015; Zhang et al., 2014). The minimum reduction in transition time by at least 3.63 days would be considered effective (Lyu et al., 2014).

4.4.2 Secondary patient outcome

Asadollahpour et al.’s (2015) study measured LOS as secondary patient outcome with the result reached statistical significance. The mean LOS of infants should
bereduced by at least 5.85 days in order to be considered effective.

4.4.3 Secondary nurse outcome

By checking the documentation on CMS, nurses’ compliance can be monitored. The compliance rate should be at least 90% to be considered effective. For nurses’ satisfaction measured by the questionnaire, at least 80% of nurses should grade each item as four marks or above.

After launching the pilot test, the guideline would be refined based on the evaluation result. The revised guideline would be approved by the management level stakeholders before full-scale implementation. The first phase of full-scale implementation would last for 36 weeks in order to recruit enough infants (i.e. 247 infants) to reach statistical significance. Evaluation which lasts for two weeks will be followed. During the two weeks, all the required data would be retrieved from CMS for analysis to determine if the results can reach the effectiveness criteria. If the criteria can be fulfilled, the decision to continue implementation of the innovation can be made. To sum up, continuous evaluation is crucial to monitor the effectiveness of innovation.

4.5 Overall Conclusion

Oral feeding training is an inevitable process every preterm infant may pass through before they can be discharged. Currently, there is no pre-feeding stimulation provided to facilitate their training. Hopefully, with the implementation of this OS guideline, infants’ oral feeding ability can be enhanced and thus, LOS can be shortened and medical expenditure can be saved.
### Appendix A: Summary table of literature search

<table>
<thead>
<tr>
<th>Details</th>
<th>Number of studies identified</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electronic database used</strong></td>
<td>PubMed</td>
</tr>
<tr>
<td>Keyword category (1)</td>
<td></td>
</tr>
<tr>
<td>Keyword category (2) Intervention:</td>
<td></td>
</tr>
<tr>
<td>‘oral stimulation’/ ‘oral stimulation program’/ ‘pre-feeding oral stimulation’/ ‘oral sensorimotor program’/ ‘sensory-motor-oral stimulation’</td>
<td>20325</td>
</tr>
<tr>
<td>Keyword category (3) Outcome: ‘oral feeding’/ ‘full oral feeding’/ ‘autonomous oral feeding’/ ‘oral feeding performance’</td>
<td>16282</td>
</tr>
<tr>
<td>Searched (1) AND (2) AND (3)</td>
<td>52</td>
</tr>
<tr>
<td>After review of the title, potential studies identified</td>
<td>16</td>
</tr>
<tr>
<td>After review of the abstract and narrow down by using the inclusion and exclusion criteria, eligible studies identified</td>
<td>5</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>Elimination of duplicated studies and manually reviewed the reference lists of potentially eligible articles, one extra article identified</td>
<td></td>
</tr>
</tbody>
</table>
Appendix B: PRISMA 2009 Flow diagram

Identification

Studies identified from PubMed (n=52)

Studies identified from British Nursing Index (n=2)

Studies identified from Cochrane library (n=62)

Studies identified by manual search of the reference list of potential eligible studies (n=1)

Studies after duplicates removed (n=71)

Studies accessed by screening at the title & abstract (n=37)

Studies which do not fulfill the inclusion criteria are excluded (n=34)

Full-text articles accessed for eligibility (n=8)

Full-text article excluded, study carried out in 1996 is too old (n=1)

Studies included in quantitative synthesis (n=7)
Appendix C: Tables of evidence


<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asadollahpour, Yadegari, Soleimani &amp; Khalesi, 2015/ RCT (+)</td>
<td>32 preterm infants at 30-32 weeks of GA from NICU in Iran</td>
<td>2 intervention groups: (1) received pre-feeding OS program (consisted of once daily stroking of cheeks, gums and tongue and followed by 3 mins of NNS for 15 mins) (n=10) (2) received NNS (consisted of thrice daily stroking of the palate for 5 mins to elicit a suck; started during initial 5 mins of tube feeding and were administered for 10 consecutive days) (n=11)</td>
<td>received a sham intervention (n=11)</td>
<td>6 months</td>
<td>Primary outcome (I) Time needed to attainment of independent oral feeding (defined as introduction to 8 successful oral feeding per day for 48 hours) (days)</td>
<td>Primary outcome (I) pre-feeding OS: 0.65 NNS: 0.82 (p &gt;0.05)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Secondary outcome (II) Hospital LOS (days) (III) Weight gain at discharge (g)</td>
<td>Secondary outcome (II) pre-feeding OS: 0.50 NNS: 0.53 (p = 0.007) (III) pre-feeding OS: 0.67 NNS: 1.57 (p &gt;0.05)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiron, Nobrega, Roux, Henrot &amp; Saliba, 2007/ RCT (+)</td>
<td>43 preterm infants born between 29 and &lt; 34 weeks GA (23 males, 20 females)</td>
<td>3 experimental groups: (1) Stimulation (n=11) (2) Support (n=12) (3) Stimulation + support (n=9)</td>
<td>received the standard care (n=11)</td>
<td>Until onset of autonomous feeding</td>
<td>Primary outcome (I) Transition time (defined as the duration to obtain autonomous oral feeding) (days) (II) NNS pressure (mmHg) at the initiation of the procedure (D1), and at 7 (D7) and 14 (D14) days later. The first recording during transition was made 3 days after</td>
<td>Primary outcome (I) <strong>only number of days are reported so effect size cannot be calculated:</strong> Stimulation: 7.8 Support: 6.5 Stimulation + support: 5.6 Control: 11.2 (p&lt;0.001) (II) D1: no significant difference for</td>
</tr>
</tbody>
</table>
Details:

**OS consisted of 12 mins of stimulation delivered once a day, 30 mins before gavage, for the last 14 consecutive days of the period of gavage.**

**Oral support was administered twice a day for a maximum of 10 mins, with at least one bottle session between, during the transition period until autonomous feeding.**

**Sucking activity (the percentage of time involved in sucking) (%)**

<table>
<thead>
<tr>
<th>(III)</th>
<th>Stimulation:</th>
<th>Support:</th>
<th>Stimulation + support:</th>
</tr>
</thead>
<tbody>
<tr>
<td>D7 &amp; D14:</td>
<td>0.35</td>
<td>/</td>
<td>0.39</td>
</tr>
<tr>
<td>Control:</td>
<td>0.18</td>
<td>(p&lt;0.001)</td>
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</tr>
</tbody>
</table>

**NNS pressure was significantly increased for the stimulation and the stimulation + support groups at D7 & D14.**

(III) D1: no significant difference for the 4 groups

D14:
- Stimulation: 47.1
- Support: /
- Stimulation + support: 46.9
Control: 27.9
(p<0.001)

** sucking activity was significantly increased at D14 for the stimulation + support and stimulation groups

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fucile, Gisel &amp; Lau, 2002/ RCT (++)</td>
<td>32 preterm infants between 26 to 29 weeks GA completed the study, recruited from a NICU in the US</td>
<td>Experimental group: received an OS program for 15 mins ** administered once per day for 10 consecutive days, 48 hours after discontinuation of nasal CPAP, 15 to 30 mins before tube feeding (n=16)</td>
<td>received a sham stimulation program (n=16)</td>
<td>monitored from the time of entry into the study until discharge from the hospital</td>
<td>Primary outcome (I) Time to attainment of independent oral feeding (defined as the first time an infant reached 8 oral feedings per day for 2 consecutive days); in addition, the number of days to reach one and 4 successful oral feedings per day was also recorded (days) Secondary outcome (II) Overall intake (defined as the percent volume transferred during an entire feeding session over the prescribed volume to be taken)</td>
<td>Primary outcome (I) 1 oral feeding/day: 1.05 (p=0.10) 4 oral feeding/day: 0.98 (p=0.19) 8 oral feeding/day: 1.23 (p=0.005) Secondary outcome (II) better overall intake than the controls (p=0.0002) ** only percentages were reported so effect size cannot be calculated</td>
</tr>
<tr>
<td></td>
<td>Rate of milk transfer (defined as the volume transferred per unit time (mL/min) during an oral feeding session)</td>
<td>Experimental group showing higher rates of milk transfer (p=0.805) **only rates were reported so effect size cannot be calculated</td>
<td></td>
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<tr>
<td><strong>Overall intake &amp; rate of milk transfer were monitored for 3 oral feeding intervals, once when the infant was taking 1 to 2, 3 to 5, and 6 to 8 oral feedings per day</strong></td>
<td><strong>LOS (days)</strong></td>
<td>0.26 (p=0.459)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>(III)</td>
<td>(IV)</td>
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<thead>
<tr>
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<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lessen, 2011/ RCT (++)</td>
<td>Total of 30 infants born between 26 and 29 weeks GA enrolled; 19 infants remained in the study, from a NICU in the US</td>
<td>Experimental group: received the Premature Infant Oral Motor Intervention (PIOMI) for 5 minutes per day (8 steps) for 7 consecutive days (n=10) <strong>beginning at 29 weeks postmenstrual age (PMA), before oral feedings were introduced</strong></td>
<td>received a sham intervention (n=9)</td>
<td>Until the date of discharge</td>
<td>Primary outcome (I) Feeding Progression (calculated from the day when oral feedings were initiated to the day when full oral feedings were attained) Secondary outcome (II) LOS (defined as the number of days from the entry point of 29 weeks PMA to the date of discharge)</td>
<td>Primary outcome (I) 1.09(p=0.043) Secondary outcome (II) 0.42(p=0.541) (<strong>Two outliers in the intervention group were identified&amp; removed</strong>)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow-up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lyu et al., 2014/ RCT (++)</td>
<td>72 preterm infants between 29 and 34 weeks GA at a NICU in China</td>
<td>Experimental group: received routine care &amp; OS (exact program developed by Fucile et al., which consisted of 12 mins of OS &amp; 3 mins of NNS) (n=32) <strong>Intervention started 48 h after discontinuation of nasal CPAP, and was continued until the newborn began an exclusively oral diet. The OS program was administered once a day 15-30 min before the beginning of a scheduled feeding</strong></td>
<td>received routine care (n=31)</td>
<td>7 months</td>
<td>Primary outcome (I) PMA at the two feeding milestones (weeks) was measured at (i) Introduction of oral feeding (defined as the first oral feeding (&gt;=5 mL/each time) (ii) Independent oral feeding (defined as the point at which the nasogastric tube was removed for 48 h and all milk volume per day was taken from a bottle at 120 mL/kg d&lt;sub&gt;_1&lt;/sub&gt;) (III) Transition time (defined as the number of days between the introduction of oral feeding to obtaining autonomous oral feeding) (days) (III) Parenteral nutrition duration (days)</td>
<td>Primary outcome (I) (i) 0.35 (p=0.393) (ii) 0.75 (p=0.004)</td>
</tr>
<tr>
<td>Secondary outcome</td>
<td>Secondary outcome</td>
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<tr>
<td>-----------------------------------------------------------------------------------</td>
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<tr>
<td>(IV) Oral feeding efficiency at independent oral feeding (defined as the volume of milk consumed relative to the duration of the oral feeding session) (ml/min)</td>
<td>(IV) 0.50 (p=0.053)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>(V) Weight gain rate [g/(kg x d)]</td>
<td>(V) 0.09 (p=0.728)</td>
<td></td>
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<tr>
<td>(VI) LOS (days)</td>
<td>(VI) 0.08 (p=0.724)</td>
<td></td>
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</table>

<table>
<thead>
<tr>
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<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
</table>
| Younesian, Yadegari & Soleimani, 2015/ RCT (+) | 20 preterm infants at 30-32 weeks of GA, from a NICU in Iran | Experimental group: received oral sensory motor stimulation of the oral structures (15 mins/day) for 10 successive days, 20 to 40 mins before the initiation of tube feeding | received standard care (n=10) | 5 months | Primary outcome  
(I) Days elapsed to achieve oral feeding  
(The first time an infant achieved 8 oral feedings per day for 2 consecutive days was defined as the time to gain full oral feeding) | Primary outcome  
(I) 3.01(p=0.000)  
(II) 2.34(p=0.000)  
(III) 2.04(p=0.002) |

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zhang et al., 2014/ RCT (+)</td>
<td>Total 120 infants born between 29 and 34 weeks of GA enrolled; 112 infants remained, at NICU in China</td>
<td>3 intervention groups</td>
<td>received the standard care (n=28)</td>
<td>first observation was made on the day oral feeding was introduced (D1), and the second observation was conducted 3 days later (D4), D7, and a final recording was made on the day when the infants reached autonomous</td>
<td>Primary outcome (I) Transition time (defined as the number of days needed from introduction of oral feeding to autonomous oral feeding)</td>
<td>Primary outcome (I) NNS: 0.77 OS: 0.85 NNS + OS: 1.26 (p=0.000)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1) NNS group: infants suck on pacifiers for 5 mins, 7-8 times a day (n=27)</td>
<td></td>
<td></td>
<td>Secondary outcome (II) Rate of milk transfer (ml/min)</td>
<td>Secondary outcome (II) <strong>no exact figures provided so effect size cannot be calculated.</strong> - Post hoc group tests indicated that all 3 intervention groups had significantly greater rate of transfer than the control group (p &lt; 0.001) at D4, D7 &amp;DA</td>
</tr>
</tbody>
</table>
started 48 hours after discontinuation of nasal CPAP and were continued; all infants in the 3 groups received the interventions 30 mins before beginning of scheduled feeding

<table>
<thead>
<tr>
<th></th>
<th>feeding (DA)</th>
<th>(III) Proficiency (intake first 5 min/volume ordered), volume transfer (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(IV) volume transfer (volume transferred during entire feeding/volume prescribed) (%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(V) weight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(VI) LOS</td>
</tr>
</tbody>
</table>

(III) **no exact figures provided so effect size cannot be calculated.**

- proficiency in the combined intervention group was higher than that in the control group at D1

(IV) **no significant difference among the 4 groups**

(V) **no significant difference among the 4 groups**

(VI) **no significant difference among the 4 groups**
## Appendix D: Details of BOMI OS program

<table>
<thead>
<tr>
<th>Structure</th>
<th>Stimulated area</th>
<th>Purpose</th>
<th>Frequency</th>
<th>Duration</th>
</tr>
</thead>
</table>
| Cheek     | 1. Place index finger at the base of the nose.  
           | 2. Compress the tissue, move finger toward the ear, then down and toward the corner of the lip (6a, C pattern).  
           | 3. Repeat for other side. | 4× each cheek | 2 min |
| Upper lip | 1. Place index finger at the corner of the upper lip.  
           | 2. Compress the tissue.  
           | 3. Move the finger away in a circular motion from the corner toward the center and to the other corner.  
           | 4. Reverse direction. | 4×  | 1 min |
| Lower lip | 1. Place index finger at the corner of lower lip.  
           | 2. Compress the tissue.  
           | 3. Move the finger away in a circular motion from the corner toward the center and to the other corner.  
           | 4. Reverse direction. | 4×  | 1 min |
| Upper and lower lip curl | 1. Place index finger at corner of lip.  
                               | 2. Apply sustained pressure, stretch downward toward the midline.  
                               | 3. Repeat for lower lip - apply sustained pressure, and stretch upward toward the midline. | 2× each lip | 1 min |
| Upper gum | 1. Place finger at the center of the gum, with firm sustained pressure, slowly move toward the back of the mouth.  
           | 2. Return to the center of the mouth.  
           | 3. Repeat for opposite side. | 2×  | 1 min |
| Lower gum | 1. Place finger at the center of the gum, with firm sustained pressure, slowly move toward the back of the mouth.  
           | 2. Return to the center of the mouth.  
           | 3. Repeat for opposite side. | 2×  | 1 min |
| Internal cheek | 1. Place finger at inner corner of lip.  
                          | 2. Compress the tissue, move back toward the molars and return to corner of lip.  
                          | 3. Repeat for other side. | 2× each cheek | 2 min |
| Lateral borders of the tongue | 1. Place finger at the level of the molar between the side blade of the tongue and the lower gum.  
                                      | 2. Move the finger toward midline, pushing the tongue towards the opposite direction.  
                                      | 3. Immediately move the finger all the way into the cheek, stretching it. | 2× each side | 1 min |
| Middle blade of the tongue | 1. Place index at the center of the mouth.  
                                  | 2. Give sustained pressure into the hard palate for 5 seconds.  
                                  | 3. Move the finger down to contact the center blade of the tongue.  
                                  | 4. Displace the tongue downward with firm pressure.  
                                  | 5. Immediately move the finger to contact the center of the mouth at the hard palate. | 4×  | 1 min |
| Ellicit a suck | 1. Place finger at midline, center of the palate.  
                          | 2. Gently stroke the palate to elicit a suck. | | N/A  | 1 min |
| Pacifier | 1. Place pacifier in mouth. | | | N/A  | 5 min |

(Fucile et al., 2002)
**Methodology Checklist 2: Controlled Trials**

**Study identification**  
*Include author, title, year of publication, journal title, pages*


**Guideline topic:**  
**Key Question No:**  
**Reviewer:** Kei ST

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐  2. Other reason ☐ (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study…**

<table>
<thead>
<tr>
<th></th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomised.</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
</tr>
</tbody>
</table>
### Appendix E: SIGN methodology checklist

<table>
<thead>
<tr>
<th>1.5</th>
<th>The treatment and control groups are similar at the start of the trial. (^v)</th>
<th>Yes (no significant difference in pre-test stage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation. (^vi)</td>
<td>Yes</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way. (^vii)</td>
<td>Yes</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? (^viii)</td>
<td>0% (0/32 X 100%)</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). (^ix)</td>
<td>Yes</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites. (^x)</td>
<td>Does not apply</td>
</tr>
</tbody>
</table>

#### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias? *Code as follows.* \(^xii\) | Acceptable (+) ** the concealment method was not clearly stated, this may lead to possible bias |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | Both NNS and pre-feeding OS contribute to the improvement of independent oral feeding. Both interventions bring beneficial effects to preterm infants’ weight gain. |

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*File name: Checklist 2 – Controlled Trials  Version 2.0  28/05/2012  Produced by: Carolyn Sleith  Page of 22  Review date: None*
Appendix E: SIGN methodology checklist

**Methodology Checklist 2: Controlled Trials**

**Study identification** *(Include author, title, year of publication, journal title, pages)*


Guideline topic:  

<table>
<thead>
<tr>
<th>Key Question No:</th>
<th>Reviewer: Kei ST</th>
</tr>
</thead>
</table>

**Before completing this checklist, consider:**

3. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

4. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question 2. Other reason (please specify):

**SECTION 1: INTERNAL VALIDITY**

*In a well conducted RCT study…*

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question.</td>
</tr>
<tr>
<td><strong>1.2</strong> The assignment of subjects to treatment groups is randomised.</td>
</tr>
<tr>
<td><strong>1.3</strong> An adequate concealment method is used.</td>
</tr>
<tr>
<td><strong>1.4</strong> Subjects and investigators are kept 'blind' about treatment allocation.</td>
</tr>
</tbody>
</table>
### Appendix E: SIGN methodology checklist

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Verification</th>
</tr>
</thead>
</table>
| 1.5  | The treatment and control groups are similar at the start of the trial.  
1.5   | Yes (All participants had statistically similar baseline characteristics) |
| 1.6  | The only difference between groups is the treatment under investigation.  
1.6   | Yes |
| 1.7  | All relevant outcomes are measured in a standard, valid and reliable way.  
1.7   | Yes |
| 1.8  | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?  
1.8   | 0% (0/43 X100%) |
| 1.9  | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).  
1.9   | Yes |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites.  
1.10  | Does not apply |

#### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
</table>
| 2.1  | How well was the study done to minimise bias?  
2.1   | Acceptable (+), ** the 2 investigators who were responsible for the administration of interventions were not blinded |
| 2.2  | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?  
2.2   | Can’t say |
| 2.3  | Are the results of this study directly applicable to the patient group targeted by this guideline?  
2.3   | Yes |
| 2.4  | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.  
2.4   | Transition time was reduced (p<0.0001) for the stimulation + support and support groups. |
Appendix E: SIGN methodology checklist

Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>Guideline topic:</th>
<th>Key Question No:</th>
<th>Reviewer: Kei ST</th>
</tr>
</thead>
</table>

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:**
1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

**SECTION 1: INTERNAL VALIDITY**

*In a well conducted RCT study*…

<table>
<thead>
<tr>
<th>Key Question</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes (RCT)</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Yes (randomized into the control or experimental groups by using a stratified blocked randomization method with a block size of 4)</td>
</tr>
</tbody>
</table>
### Appendix E: SIGN methodology checklist

| 1.4 | Subjects and investigators are kept ‘blind’ about treatment allocation. | Yes. double-blinded (Both doctors & nurses were blinded to group assignment; a screen was placed around the infant’s isolette to blind the caretakers & family members) |
| 1.5 | The treatment and control groups are similar at the start of the trial. | Yes (Both groups were comparable with regard to baseline characteristics) |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 0% (0/32 X 100%) |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Does not apply |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias? |
| Code as follows: | High quality (++) |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| 2.4 | Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. |
| The implementation of an OS program can shorten the time from gavage feeding to full oral feeding. |
and improve oral feeding performance.
### Methodology Checklist 2: Controlled Trials

#### Study identification

*Include author, title, year of publication, journal title, pages*


### Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

#### Reason for rejection:

1. Paper not relevant to key question
2. Other reason (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study...**

<table>
<thead>
<tr>
<th>Key Question No:</th>
<th>Reviewer: Kei ST</th>
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</thead>
<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question.</td>
<td>xxxiv</td>
</tr>
<tr>
<td><strong>1.2</strong> The assignment of subjects to treatment groups is randomised.</td>
<td>xxxv</td>
</tr>
<tr>
<td><strong>1.3</strong> An adequate concealment method is used.</td>
<td>xxxvi</td>
</tr>
<tr>
<td><strong>1.4</strong> Subjects and investigators are kept 'blind' about treatment allocation.</td>
<td>xxxvii</td>
</tr>
<tr>
<td><strong>1.5</strong> The treatment and control groups are similar at the start of the trial.</td>
<td>xxxviii</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Yes (RCT)</td>
</tr>
<tr>
<td>Yes (randomly assigned into the intervention or control group in blocks of 2)</td>
</tr>
<tr>
<td>Yes, triple-blind experimental design (group assignments were blinded to nursing and medical staff and parents)</td>
</tr>
<tr>
<td>Yes (The intervention &amp; control groups did not differ statistically)</td>
</tr>
</tbody>
</table>
### Appendix E: SIGN methodology checklist

| 1.6 | The only difference between groups is the treatment under investigation. \[xxx\] | Yes |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. \[xix\] | Yes |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? \[xii\] | 36.7% (11/30 X 100%) |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). \[xlii\] | Yes |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. \[xliii\] | Does not apply |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias? \[xliiv\] | High quality (++) |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | |

Implementing the Premature Infant Oral Motor Intervention (PIOMI) for 5 minutes per day for 7 days shows positive trends in both feeding success and LOS. Infants who received the once-daily PIOMI transitioned from their first oral feeding to total oral feedings 5 days sooner than controls and were discharged 2.6 days sooner than controls.
### Methodology Checklist 2: Controlled Trials

#### Study identification
*Include author, title, year of publication, journal title, pages*

#### Guideline topic: Key Question No: Reviewer: Kei ST

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:**
1. Paper not relevant to key question
2. Other reason

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study...**

<table>
<thead>
<tr>
<th>Does this study do it?</th>
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</thead>
<tbody>
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<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question. xliv</td>
</tr>
<tr>
<td><strong>1.2</strong> The assignment of subjects to treatment groups is randomised. xvi</td>
</tr>
<tr>
<td><strong>1.3</strong> An adequate concealment method is used. xvii</td>
</tr>
<tr>
<td><strong>1.4</strong> Subjects and investigators are kept ‘blind’ about treatment allocation. xviii</td>
</tr>
</tbody>
</table>
## Appendix E: SIGN methodology checklist

| 1.5 | The treatment and control groups are similar at the start of the trial. | Yes (All participants had statistically similar baseline characteristics) |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 12.5% (9/72 X100%) |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Does not apply |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias? *Code as follows.* | High quality (++) |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. |  
The time from initiation of oral feeding to full oral feeding was significantly shorter in the experimental group (p < 0.05) while feeding efficiency was higher in the experimental group (p < 0.05) compared with controls. No significant differences existed in hospital LOS or weight gain rate. |
### Methodology Checklist 2: Controlled Trials

#### Study identification
*Include author, title, year of publication, journal title, pages*

<table>
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<tr>
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<tbody>
<tr>
<td>Before completing this checklist, consider:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Is the paper a <strong>randomised controlled trial</strong> or a <strong>controlled clinical trial</strong>? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a <strong>controlled clinical trial</strong> questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 1: INTERNAL VALIDITY

#### In a well conducted RCT study...

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
<td>Yes</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomised.</td>
<td>Yes (RCT)</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
<td>Can’t say (mentioned simple randomization method &amp; convenience sampling; but not specified)</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes, double-blinded (Both nurses &amp; physicians were blinded to group assignments)</td>
</tr>
</tbody>
</table>
## Appendix E: SIGN methodology checklist

| 1.5 | The treatment and control groups are similar at the start of the trial. Yes (no significant differences in terms of GA & birth weight between the two groups) |
| 1.6 | The only difference between groups is the treatment under investigation. Yes |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. Yes |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? 0% (0/20 X100%) |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). Yes |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. Does not apply |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias? 
Code as follows. Acceptable (+) ** the concealment method was not clearly stated, this may lead to possible bias |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? Yes |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? Yes |
| 2.4 | Notes. Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. The number of days to reach oral feeding in our preterm babies was decreased by oral motor stimulation, which in turn conferred earlier hospital discharge. The weight changes from 1 to 4 oral feedings per day, 4 to 8 and 8 to the time of discharge were significant. |
## Methodology Checklist 2: Controlled Trials

### Study identification
Include author, title, year of publication, journal title, pages

### Guideline topic: Key Question No: Reviewer: Kei ST

#### Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial**, questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

#### Reason for rejection: 1. Paper not relevant to key question  □  2. Other reason □ (please specify):

### SECTION 1: INTERNAL VALIDITY

In a well conducted RCT study...

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Yes (RCT)</td>
</tr>
<tr>
<td>Yes (stratified blocked randomization)</td>
</tr>
<tr>
<td>No, only single-blinded (Two experienced researchers were responsible for the administration of all interventions; they were not blinded)</td>
</tr>
</tbody>
</table>

| 1.1 The study addresses an appropriate and clearly focused question. |
| 1.2 The assignment of subjects to treatment groups is randomised. |
| 1.3 An adequate concealment method is used. |
| 1.4 Subjects and investigators are kept 'blind' about treatment allocation. |
### Appendix E: SIGN methodology checklist

| 1.5 | The treatment and control groups are similar at the start of the trial. | Yes (age, gender, birth weight, Apgar score, and severity of illness did not show significant differences in infants’ characteristics among the four groups) |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 3.57% (4/112 X100%) |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Does not apply |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimise bias? _Code as follows._ | Acceptable (+), ** the 2 researchers who were responsible for the administration of interventions were not blinded, this may lead to possible bias |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Can’t say |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| 2.4 | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | The combined NNS + OS intervention reduced the transition time from introduction to independent oral feeding and enhanced the milk transfer rate. The combination of NNS + OS will have an additive effect on oral feeding proficiency. |
### Appendix F: An outline of the timeframe

A table showing the timeline for various stages:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
<th>Week 7</th>
<th>Week 8</th>
<th>Week 9</th>
<th>Week 10</th>
<th>Week 11</th>
<th>Week 12</th>
<th>Week 13</th>
<th>Week 14</th>
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<td>Communication with stakeholders</td>
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<td>Pilot test implementation</td>
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<tr>
<td>Pilot test evaluation &amp; modification of</td>
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<tr>
<td>guideline</td>
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<td>Full-scale implementation</td>
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<td>Evaluation</td>
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<tr>
<td>Ongoing implementation &amp; evaluation</td>
<td>Complete</td>
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</tbody>
</table>
## Appendix G: Tables showing material cost of implementing the innovation per year

### Set-up cost

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Unit price</th>
<th>Calculation</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salary of nurses for attending</td>
<td>Salary of APNs</td>
<td>Mid-point hourly salary of APN: $308 (*calculation at mid-point salary $54220; ~4 weeks/month; 44 working hours/week)</td>
<td>$308x2x10</td>
<td>$6160</td>
</tr>
<tr>
<td>2-hour training workshop</td>
<td>Salary of RNs</td>
<td>Mid-point hourly salary of RN: $194 (*calculation at mid-point salary $34180; ~4 weeks/month; 44 working hours/week)</td>
<td>$194 x2x30</td>
<td>$11,640</td>
</tr>
<tr>
<td>2-hour training workshop</td>
<td>Time spend to edit the demonstration video &amp; upload on the Intranet (2 hours)</td>
<td>Mid-point hourly salary of working group APN: $308</td>
<td>$308 x 2</td>
<td>$616</td>
</tr>
<tr>
<td>2-hour training workshop</td>
<td>Printing 40 10-page handouts for training</td>
<td>$0.2/page</td>
<td>$0.2x10 pagesx40 copies</td>
<td>$80</td>
</tr>
<tr>
<td>Item</td>
<td>Description</td>
<td>Unit price</td>
<td>Calculation</td>
<td>Subtotal</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------</td>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Number of eligible infants</td>
<td>On average 400 infants born between 29 and 34 weeks were admitted each year</td>
<td>~90% of them are eligible to be enrolled in innovation</td>
<td>400 x 90%</td>
<td>360 infants</td>
</tr>
<tr>
<td>Staff nursing time</td>
<td>15-minute OS intervention each day x 10 consecutive days for 360 infants</td>
<td>Mid-point hourly salary of RN: $194</td>
<td>$194 x 0.25 x 10 days x 360 infants</td>
<td>$174,600</td>
</tr>
</tbody>
</table>

Remarks: *salaries of APN and RN refer to government Master Pay Scale (w.e.f. 1/4/2015)
### Appendix H: Table showing nonmaterial cost of implementing the innovation

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Nature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venue for training</td>
<td>pediatric activity room</td>
<td>Department owned, required booking in advance</td>
</tr>
<tr>
<td>Computer, projector, microphone, video recorder &amp; baby manikins</td>
<td>For training purpose</td>
<td>Department owned</td>
</tr>
</tbody>
</table>
**Appendix I: Table showing the estimated cost saved yearly on implementation of innovation**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Calculation</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>On average 400 infants born between 29 and 34 weeks were admitted each year</td>
<td>~90% of them are eligible to be enrolled in innovation</td>
<td>400x90%</td>
<td>360 infants</td>
</tr>
<tr>
<td>Hospital stay cost</td>
<td>NICU stay cost=$23,000/day</td>
<td>360 infants x 5.85days x $23,000</td>
<td>$48,438,000</td>
</tr>
<tr>
<td></td>
<td>Shortened length of stay by 5.85 days/infant</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total:</td>
<td></td>
<td>$48,438,000</td>
</tr>
</tbody>
</table>
## Appendix J: SIGN Key to evidence statements and grades of recommendations

<table>
<thead>
<tr>
<th>Levels of evidence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic reviews of case control or cohort or studies</td>
</tr>
<tr>
<td></td>
<td>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</td>
</tr>
<tr>
<td>2+</td>
<td>Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>
### Grades of recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
</table>
| **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+ |

(SIGN, 2016)
Appendix K: Evidence-based Practice (EBP) guideline

Title

An EBP guideline of using an oral simulation (OS) intervention to improve preterm infants’ oral feeding ability.

Target Users

Nurses working in NICU of NTWC who participate in oral feeding training of preterm infants.

Target Population

Preterm infants who are born between 29 to 34 weeks that are fed via a tube in NICU.

Objectives

1. To standardize pre-feeding oral training and provide an evidence-based guideline for nurses to follow.
2. To improve premature infants’ oral feeding ability and shorten length of stay in NICU.

Evidence-based Recommendations

Recommendation 1: Characteristics of Target Population

1.1 Preterm infants born between 29 to 34 weeks of Gestational Age (GA) as determined by obstetric ultrasonogram and clinical examination.

➤ Evidence: Three reviewed studies have proved that the intervention is effective in
preterm infants born between 29 to 34 weeks of GA. (Boiron et al., 2007 [1-]; Lyu et al., 2014 [1++]; Zhang et al., 2014 [1-])

Grade of recommendation: A

1.2 Infants should be of appropriate size of their GA.

Evidence: Five studies stated that infants with intrauterine growth retardation were excluded. (Boiron et al., 2007 [1-]; Fucile et al., 2002 [1++]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

Grade of recommendation: A

1.3 The birth weights of infants are between 1000 to 2000 grams.

Evidence: Five reviewed studies recruited preterm infants with birth weight between 1000 to 2000 grams. (Asadollahpour et al., 2015 [1+]; Boiron et al., 2007 [1-]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

Grade of recommendation: A

1.4 Infants should be receiving full tube feeding.

Evidence: All the seven reviewed studies were carried out in infants who were receiving full tube feeding. (Asadollahpour et al., 2015 [1+]; Boiron et al., 2007 [1-]; Fucile et al., 2002 [1++]; Lessen, 2011 [1++]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

Grade of recommendation: A
1.5 Infants should not be receiving any respiratory support in the preceding 48 hours.

- Evidence: Six reviewed studies mentioned that the intervention should start 48 hours after discontinuation of nasal Continuous Positive Airway Pressure (CPAP) or other respiratory support. (Asadollahpour et al., 2015 [1+]; Boiron et al., 2007 [1-]; Fucile et al., 2002 [1++]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

- Grade of recommendation: A

1.6 Infants should be without congenital anomalies or chronic medical complications.

- Evidence: All the seven reviewed studies excluded infants with congenital anomalies or chronic medical complications such as metabolic disorders, genetic syndromes, oral-motor defects, neurological disorders, bronchopulmonary dysplasia, perinatal asphyxia, intraventricular hemorrhage grades III and IV, necrotizing enterocolitis, severe jaundice with exsanguination transfusion, severe infections, had a history of prenatal illicit drug exposure, etc. (Asadollahpour et al., 2015 [1+]; Boiron et al., 2007 [1-]; Fucile et al., 2002 [1++]; Lessen, 2011 [1++]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

- Grade of recommendation: A

1.7 Apgar scores of infants are greater than or equal to 3 at 1 minute and greater than or equal to 5 at 5 minutes.
Evidence: One study mentioned the Apgar score required to be enrolled in the intervention. (Zhang et al., 2014 [1-])

Grade of recommendation: B

Recommendation 2: Intervention Details

2.1 Time to start the OS program

2.1.1 The intervention starts 48 hours after discontinuation of nasal Continuous Positive Airway Pressure (CPAP).

Evidence: Six studies started the program 48 hours after discontinuation of nasal CPAP. (Asadollahpour et al., 2015 [1+]; Boiron et al., 2007 [1-]; Fucile et al., 2002 [1++]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

Grade of recommendation: A

2.1.2 The intervention is administered 15 to 30 minutes before a scheduled feeding.

Evidence: Six studies stated that the intervention is more effective if administered 15 to 30 minutes before a scheduled feeding. (Asadollahpour et al., 2015 [1+]; Boiron et al., 2007 [1-]; Fucile et al., 2002 [1++]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

Grade of recommendation: A
2.2 Position of infants during OS

- The infants are positioned supine in the incubator.
- Evidence: Four of the reviewed studies placed the infants in supine position in the incubator when administering the intervention. (Asadollahpour et al., 2015 [1+]; Fucile et al., 2002 [1++]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+])
- Grade of recommendation: A

2.3 OS duration

- The OS program is named Beckman Oral Motor Intervention (BOMI). It is a 15-minute stimulation program consisted of two parts. The first part is 12 minutes of OS, followed by 3 minutes of NNS. Details of the program is attached in appendix D.
- Evidence: Six of the reviewed studies applied exactly the same 15-minute BOMI OS program in infants. The first 12 minutes involved stroking the cheeks, lips, gums, and tongue, and the final 3 minutes consisted of sucking on a pacifier routinely used in the nursery. (Asadollahpour et al., 2015 [1+]; Boiron et al., 2007 [1-]; Fucile et al., 2002 [1++]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])
- Grade of recommendation: A

2.4 Discontinue the program if infants become clinically unstable.
Evidence:

- Oral stimulation was undertaken when the preterm infants’ cardiopulmonary parameters were optimal (i.e. no bradycardia or desaturation). (Boiron et al., 2007 [1-])

- The program was stopped if infants were medically unstable or had any episodes of oxygen desaturations or apnea or bradycardia during the intervention. (Fucile et al., 2002 [1++])

- Interventions were not administered in the case of medical instability, decreased oxygen saturation, proven apnea or bradycardia. (Lyu et al., 2014 [1++])

- The program is discontinued if the infants had medical instability such as oxygen instauration, apnea or bradycardia throughout the intervention. (Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

Grade of recommendation: A

2.5 Intervention is not administered if there is major disruption to infants 30 minutes before.

Evidence:

- The program was not administered if infants were disturbed 30 minutes before the intervention (e.g. ophthalmologic examination). (Fucile et al., 2002 [1++])

- In case the infant had been stressed by medical or nursing procedures such as intravenous restart or temperature instability immediately before the scheduled time of intervention. The Premature Infant Oral Motor Intervention
could then be postponed until the next feeding period. (Lessen, 2011 [1++])

- Intervention is not administered in case of major disruption 30 minutes before the session, like an auditory examination. (Zhang et al., 2014 [1-])

  - Grade of recommendation: A

### 2.6 Intervention frequency

- **The program is administered once per day.**
- Evidence: All the seven reviewed studies suggested to administer the OS program once per day. (Asadollahpour et al., 2015 [1+]; Boiron et al., 2007 [1-]; Fucile et al., 2002 [1++]; Lessen, 2011 [1++]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

  - Grade of recommendation: A

### 2.7 Intervention duration

- **The program is administered for 10 consecutive days.**
- Evidence: Four studies proved that administering OS for 10 consecutive days is optimal to improve feeding outcome. (Asadollahpour et al., 2015 [1+]; Fucile et al., 2002 [1++]; Younesian et al., 2015 [1+]; Zhang et al., 2014 [1-])

  - Grade of recommendation: A

### Recommendation 3: Outcome Measure

- **Assess the transition time (days) from introduction of oral feeding to autonomous**
oral feeding.

- Evidence: All the seven reviewed studies measured the transition time (days) as the primary outcome. Autonomous oral feeding is defined as the first time an infant reached 8 oral feedings per day for two consecutive days. (Asadollahpour et al., 2015 [1+]; Boiron et al., 2007 [1-]; Fucile et al., 2002 [1++]; Lessen, 2011 [1+]; Lyu et al., 2014 [1++]; Younesian et al., 2015 [1+] ; Zhang et al., 2014 [1-])

- Grade of recommendation: A
Appendix L: Questionnaire on pilot test

Dear nurses,

Thank you for your effort in performing the oral stimulation training for infants. To continuously improve our services, please kindly spend a few minutes to complete this questionnaire. Your opinion is highly valued.

*Please choose the best answer that represent your feelings the best. Put a ‘tick’ in appropriate boxes.

<table>
<thead>
<tr>
<th>Description</th>
<th>Strongly disagree (1)</th>
<th>Disagree (2)</th>
<th>Neutral (3)</th>
<th>Agree (4)</th>
<th>Strongly agree (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competency to implement the innovation</td>
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<tr>
<td>1. The innovation is easy to administer</td>
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<tr>
<td>2. Implementation of the guideline does not disrupt my usual nursing routine</td>
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<tr>
<td>Clarity of guideline</td>
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<td>3. The steps on how to perform the oral stimulation training is clear</td>
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<td>4. The guideline is easy to follow</td>
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<tr>
<td>Adequacy of training and support</td>
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<td>5. Adequate staff training is provided beforehand</td>
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<td>6. Adequate support is available</td>
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<td>7. The working group members can be easily approached when in doubt</td>
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<td>8. The resource person is helpful in clarifying questions</td>
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<td>9. The online demonstration video is useful</td>
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</table>

<table>
<thead>
<tr>
<th>Effectiveness of innovation</th>
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<tbody>
<tr>
<td>10. The innovation benefits premature infants</td>
</tr>
<tr>
<td>11. Overall, the innovation is worth supporting</td>
</tr>
</tbody>
</table>
Any other comments on the innovation? Please write here. (optional)

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

~The end, thank you for your time! ~
Appendix M: Questionnaire on staff satisfaction

Dear nurses,

Thank you for your effort in performing the oral stimulation training for infants. To continuously improve our services, please kindly spend a few minutes to complete this questionnaire. Your opinion is highly valued.

*Please choose the best answers that represent your feelings the best. Put a ‘tick’ in appropriate boxes.

<table>
<thead>
<tr>
<th>Description</th>
<th>Strongly disagree (1)</th>
<th>Disagree (2)</th>
<th>Neutral (3)</th>
<th>Agree (4)</th>
<th>Strongly agree (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The innovation is easy to administer</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>2. Implementation of the guideline does not disrupt my usual nursing routine</td>
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<tr>
<td>3. Adequate support is available</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>4. The working group members can be easily approached when in doubt</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. The innovation benefits premature</td>
<td></td>
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</tbody>
</table>
6. Overall, the innovation is worth supporting

Any other comments on the innovation? Please write here. (optional)

___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
___________________________________________________________________________
~The end, thank you for your time! ~


