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# Systematic review protocol examining the effect of prefeeding oromotor stimulation on preterm neonate's feeding outcomes

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## Abstract

**Introduction:** Feeding difficulty is a common problem among preterm babies as sucking-swallowing and breathing coordination matures by 32-34 weeks of postmenstrual age. There is a growing consensus among healthcare providers worldwide that oromotor stimulation influences feeding outcomes of preterm babies, but limited evidence influences its clinical applicability. **Objectives:** To critically appraise the available evidence on the effect of prefeeding oromotor stimulation (OMS) on preterm neonate's feeding outcomes. **Methods and analysis:** This review will include only randomized controlled trials (RCTs). Electronic databases will be searched from January 2000 to December 2019. Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (PRISMA) will be followed for study selection. Modified Jadad Scale will be used for the methodological appraisal for RCTs. A narrative synthesis with or without a Meta-Analysis will be conducted considering the heterogeneity of available evidence. This review does not involve primary data thus ethical approval will not be required. Findings will be disseminated through conferences and publications in peer-reviewed journals. **Conclusion:** This review protocol will promote evidence-based decision-making in the specific area and will help in improving nurse-led interventions in preterm feeding.

**Keywords:** Feeding, oromotor stimulation, pre-feeding, preterm

## Introduction

Premature births (<37 weeks of postmenstrual age (PMA)) are the leading cause of under-five mortality worldwide, and a contributor of significant morbidity among the survivors due to prolonged hospitalization. In 2014, approximately 10.6% of all live births were born preterm globally (Lee, 2019; World Health Organization, 2014).

In utero, at around 10-12 weeks onwards fetus performs breathing, sucking, swallowing, and crying, which allows

for its survival after birth. Term neonates are born with active oral reflexes, which guarantee their feeding soon after birth. Preterm neonates predominantly rely on disorganized patterns of compression with weak vacuum, inconsistent and short suck burst patterns. The coordination of suck-swallow-breath reflexes matures around 32-34 weeks of PMA neonates because their physiological immaturity mostly depends on enteral feeding for survival. The transition from tube feeding gradually progresses to katori-spoon feeding and then towards independent oral feeding (Lau, 2016). Feeding difficulties among preterm babies also contribute to poor exclusive breastfeeding in later life, as low as 22.4% up to four months of age (Baker, Villela, Gomes, Tovar & Moreira, 2018; Hackman, Alligood, Martin, Zhu & Kjerulff, 2016).

A Chicago-based study by Khan and colleagues (2019) has shown, the median GA at which full oral feeding skills were reached was 37 + 1 weeks in extreme

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preterms and 34 + 5 weeks in very preterms. Feeding performances and weight increments during oral feeding steps depend on the gestational age at birth. Oral feeding is usually initiated based on neonate's weight, PMA, oral feeding skills, maternal readiness but there is a lack of empirically-derived guidelines for either starting or progressing oral feeds though it is an important criterion for considering discharge of preterm (Sakalidis & Geddes, 2016). A Cochrane review has even concluded that enough evidence is still lacking for the utility and implementation of the available instruments in the clinical area to assess feeding readiness in the preterm infant population (Crowe, Chang, & Wallace, 2016; Lau, Bhat, Potak & Schanler, 2015).

An Indian study (Narang *et al.*, 2005) found a negative association between oral feeding skill and gestational age with days of hospitalization indicating an increased risk of acquiring nosocomial infection among preterm leading to increased healthcare costs. The cost per hospital admission ranges from \$620- \$4, 950 based on the weight of preterm babies at birth, lower the birth weight, higher the cost. If feeding is achieved earlier in them, there can be potential cost savings from the above expenditure (Lessen, Morello & Williams, 2015).

In this review, oromotor stimulation (OMS) is defined as the manipulative actions of the lips, jaw, tongue, soft palate before feeding with or without nutritive sucking (NS) or non-nutritive sucking (NNS) events, intended to improve preterm infants sucking and feeding. In 2008, the first attempt was made by a nurse, Dr Brenda Knoll Lessen to apply the oromotor therapy in the care of preterm neonates until this OMS was solely provided by a developmental physiotherapist, speech-language pathologists, and physicians (Ericson, 2016; Fucile, 2002; Hwang, 2010; Pimenta, 2008).

Existing studies have reported that OMS when provided to preterms for at least 5-15 minutes before feeding, improves oral motor organization, range of motion, sensation, stability, and strength of oral musculature such as lips, tongue, jaw, and pharynx which helps in mature sucking and swallowing development, facilitate nutritive sucking, accelerate the transition from enteral feeding to independent oral feeding, increased

volume intake, greater weight gain, and lesser days of hospitalization (Asadollahpour, Yadegari, Soleimani & Khalesi, 2015; Bache *et al.*, 2014; Bala, Mukhopadhyay, Kaur & Kaur, 2016; Ghomi *et al.*, 2019; Khalessi, Nazi, Shariat, Saboteh & Farahani, 2015; Lyu *et al.*, 2014; Osman, Mohamed, Ahmed, Hassanein & Brandon 2016; Thakkar, Rohit, Das, Thakkar & Singh, 2018 ).

As per the Cochrane Collaboration recommendations, systematic reviews should be updated every other year, so that plenty of RCTs developed by this time can be reviewed (Takwoingi, Hopewell, Tovey & Sutton, 2013). Thus, this systematic review is aimed to gain a critical summary of evidence about the effect of OMS on preterm infant's feeding outcomes.

## Objective

This systematic review aims to summarize the existing evidence on the effect of prefeeding OMS on preterm neonate's feeding outcomes.

## Questions

This review will explore the following questions,

- What are the effects of prefeeding OMS on preterm neonate's transition towards oral feeding during hospitalization and in later life?
- How does pre-feeding OMS affects the preterm neonate's weight gain during hospitalization and in later life?
- Is there any effect of prefeeding OMS on preterm neonate's duration of hospitalization?

## Methods and analysis

Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA-P, 2015) is followed in preparing this protocol. A Prospero search carried out on 02/12/2019 found no similar review to be registered, thus the investigators applied for registration of this protocol. It has been registered on the PROSPERO database (registration number CRD42020165846). This review does not include any research on humans or animals.

## Information sources

Electronic databases PubMed/MEDLINE, Embase, CINAHL, MEDLINE, PsycINFO, Science Direct,

LILACS, and SciELO will be searched. Literature from January 2000 to December 2020 will be retrieved to reflect contemporary practices. References of the retrieved article will be thoroughly checked for additional relevant articles.

**Search strategy**

Three researchers (SS, SA, and SB) will search for literature independently. Reference manager, Mendeley will be used for storage, organization, and management of the references to ensure a systematic search and avoid duplicate references.

Boolean operators ‘AND’ and ‘OR’ will be used for combining free text words and MeSH terms, such as (Infant premature OR Premature infant OR Preterm infant OR Neonatal Prematurity OR Infant, Preterm) AND (prefeeding OR before feeding) AND (oral motor intervention OR oral motor exercise OR oral motor stimulation OR OMI OR oral stimulation OR PIOMI) AND random will be used. A filter will be added after the PICOS search strategy to locate clinical trials (such as RCT OR controlled clinical trial OR clinical trial OR nonrandomized controlled trials) and the search will be limited to full-text studies in English on human.

**Study selection criteria**

This review includes studies as per PICO’s strategy (Table 1).

Table 1:

**Study Selection Criteria**

| PICOS strategy | Inclusion criteria  | Exclusion criteria  |
|----------------|---|---|
| P- Population  | Hospitalized preterm neonates of any age  | Non-hospitalized preterm neonates                         |
| I-Intervention | Manually provided pre-feeding oromotor stimulation by a neonatal nurse, occupational therapist, speech and language therapist or developmental therapist, mother of any dose, duration, and frequency | Utilization of devices for providing oromotor stimulation |
| C- Comparison  | The usual standard of care as per institutional protocol or NNS without prefeeding oromotor stimulation   |   |

|                 |  |   |
|-----------------|--|---|
| O- Outcome      | Primary outcome: Any measures related to feeding outcomes in the neonatal period.<br>Secondary outcome: Any measures related to weight gain, duration of hospitalization in the neonatal period, and feeding outcomes in infancy | Studies that do not report primary outcomes   |
| S- Study design | RCTs reported in the English language  | Non-RCTs, crossover designs, pre-experimental designs, designs with multiple comparison groups, nonprimary literature, such as reviews, dissertations, theses, editorials, protocol studies and clinical guidelines |

Studies will be classified as RCTs if the trial involves at least one treatment for improving oral motor function and one control treatment, simultaneous enrolment, and follow-up assessment of the test group and control group; the treatments to be administered are allocated by randomization, such as using a random number table. Control measures must be mentioned clearly, which may include placebos, active treatment, no treatment, sham treatment, or standard institutional care.

**Screening**

Initial screening of all retrieved study’s title/abstracts will be conducted by two independent investigators (SS, SA). If any disagreement remains between reviewers, full-text articles will be scrutinized thoroughly and disagreement will be resolved through discussion. If the disagreement persists, a third reviewer (SB) will make the final decision for the review. Full-text articles will be evaluated by the same reviewers. In each screening phase, Cohen’s kappa will be used to measure the inter-coder agreement.

### Quality assessment and control

Modified Jadad Scale will be used for methodological quality assessment of the RCTs. On this scale score range is from 0 to 7 (studies scoring <3 is considered of low quality; 3-4 points is of moderate quality and >4 points are classified as high quality).

Two reviewers (SS, SA) will independently assess the methodological quality of eligible trials and will score the selected studies. Any disagreements between them will be resolved by a third reviewer (SB).

### Data extraction and management

A specific data extraction form will be used to extract quantitative data from individual RCTs. Data items will include author and country of study, randomization, sample size, sample characteristics, exclusion criteria, description of experimental intervention and comparator, outcomes measures, and findings.

### Data analysis

Heterogeneity is anticipated among the included studies. Therefore, a narrative synthesis approach will be utilized for analysis.

### Presentation and reporting of the results

PRISMA guidelines will be used for presenting the review result through a PRISMA flow diagram and a table for all included studies in the review.

### Dissemination

The results of this review will be submitted to peer-reviewed journals for publications and will be presented in conferences to ensure its accessibility.

### Discussion

This review will help to understand the impact of prefeeding OMS on feeding outcomes of preterm babies in the existing evidence and will further facilitate the improvement of OMS application. Based on the findings of this review, studies will be planned to identify the frequency of OMS that suits the need of preterm babies, and studies that identify the effect of OMS can be planned in the end.

This review has its strength, in the transparency of methods and processes to be utilized and it reduces the possibility of biases and duplication, which allows

peer review. This review will help in informed decision-making as the highest level of evidence in the specified area; as it will include RCTs over 19 years. Thus, will promote and improve nurse-led interventions in the area of preterm feeding.

There is a scarcity of RCTs with a large sample size, undertaken to prove the effect of oromotor stimulation in preterms. Moreover, excluding, grey literature and non-English language articles may become the main limitation of this study.

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