ORIGINAL ARTICLE

Effectiveness of Oral-Motor Stimulation on Oral Feeding in Premature Infants: A Protocol for Systematic Review and Meta-Analysis of Controlled Randomized Trials

Faezeh Asadollahpour, PhD [1]; Kowsar Baghban, PhD [2]; Farhad Sakhai, PhD [3]; Mozhgan Asadi, PhD [4]

[1] Rehabilitation Sciences Research Center, Zahedan university of medical Sciences, Zahedan, Iran
[2] Department of speech therapy, school of rehabilitation, Hamadan University of medical Sciences, Hamadan, Iran
[3] Department of speech therapy, Faculty of rehabilitation, Semnan university of medical Sciences, Semnan, Iran

Keywords:

Oral Motor Stimulation

Preterm Infants

Oral Feeding

Received:

19-Jul-2023

Accepted:

30-Dec-2023

Published:

22- Jun -2024

ABSTRACT

Objectives

Premature infants (born before 37 weeks of gestational age) frequently experience feeding difficulties due to underdeveloped oral motor skills and poor chewing, swallowing, and breathing coordination. In order to improve oral feeding efficiency in these infants, Oral-Motor Stimulation (OMS) has been used in various studies. This systematic review study will aim to assess the effectiveness of OMS for oral feeding in preterm infants.

Materials & Methods

The authors will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. They will conduct a search in electronic databases, including PubMed, Scopus, Web of Science, Cochrane Central Register of Controlled Trials in The Cochrane Library (CENTRAL), Medline via PubMed, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) for nursing and related healthcare texts without language restrictions from the first month of 1991 to the fifth month of 2024 to achieve the study objectives. All Randomized Controlled Clinical Trials (RCT) examining the effect of OMS on oral feeding in preterm infants will be included in this study.

Results

The primary outcome of this systematic review will be oral feeding, and the secondary outcomes will include duration of hospitalization, weight gain, and feeding efficiency. Two independent reviewers will select and extract data for the study. The Cochrane Risk of Bias Tool (RoB2) will be used to evaluate potential biases in the study. Publication bias will be evaluated using funnel plots, Begg's, and Egger's tests. The degree of heterogeneity among the studies will be assessed using the I2 statistic and the $\chi 2$ test. Analyses of subgroups will also be carried out. All meta-analyses will be conducted using Stata V.14.

Conclusion

This systematic review protocol for preterm infants will aim to promote evidence-based decision-making and support the development of clinical practice guidelines in preterm feeding.

How to cite this article: Asadollahpour F, Baghban K, Sakhai F, Asadi M. Effectiveness of Oral-Motor Stimulation on Oral Feeding in Premature Infants: A Protocol for Systematic Review and Meta-Analysis of Controlled Randomized Trials. Iran J Child Neurol. Summer 2024; 18(3): 43-55. https://doi.org/10.22037/ijcn.v18i3.42755

*_Corresponding Author:_ Asadi M, PhD. Department of Speech Therapy, Faculty of Rehabilitation, Semnan University of Medical Sciences, Semnan, Iran. Email: mozhgan.asadist@yahoo.com

Introduction

The mastery of oral feeding necessitates the integration of various essential elements such as respiration, sucking, and swallowing, making it a multifaceted and intricate skill. Oral feeding development in preterm infants (those born before 37 weeks gestational age based on the last menstrual period) can be challenging due to prolonged hospitalization, respiratory difficulties, and other medical conditions associated with preterm birth (1). Many preterm infants experience delayed oral feeding and initially receive nutrition through feeding tubes or intravenous (IV) feeding, which can negatively impact their oral feeding skills (2).

Healthcare professionals employ a diverse array of interventions aimed at enhancing the sucking and feeding skills of premature infants. Fucile et al. (2002) introduced the Oral-Motor Stimulation (OMS) program to enhance oral feeding effectiveness in preterm infants (3). OMS refers to sensory stimulation and touch of structures inside and around the mouth using a gloved finger in a specific manner for a defined period before feeding (4-6).

These interventions are designed to reduce excessive oral sensitivity, improve the range of motion and muscle strength for chewing (3), enhance oral-motor organization (7), and activate facilitatory reflex behaviors for oral chewing (8, 9). In general, the goal of these techniques is to normalize sensory perception by restoring reflexes and creating natural movements of the lips, tongue, jaw, and throat to improve chewing and swallowing. In addition to facilitating the development of oral feeding skills, these interventions have positive effects, including facilitating a smooth transition from relying on tube feeding to being able to feed independently by mouth (10-12), advancement of chewing maturity (13), earlier achievement of oral feeding (14-17), reduced stress during bottle feeding (Pickler, 1992), increased volume of milk intake (18), weight gain (19, 20), and fewer hospitalization days (21, 22).

Despite the increase in the survival rate of preterm infants in recent decades, the inability to achieve oral feeding maturity negatively impacts their natural growth and may increase mortality in this population (23, 24). Previously published studies have shown that OMS may improve oral feeding in preterm infants (4, 19, 22, 25). However, the strength of evidence in these studies is compromised for reasons such as small sample size or methodological limitations.

Even though several systematic reviews and meta-analyses (9, 11, 18, 24) have examined the effectiveness of pre-feeding OMS in promoting oral feeding among preterm infants, and the evidence suggests that this intervention can improve oral feeding, previous reviews had broad objectives, leading to heterogeneity and wide variations among participants, interventions, and outcome measures (9). Moreover, these studies had language restrictions, and their meta-analysis showed that their findings were not conclusive. Furthermore, the Cochrane Library recommends updating systematic reviews every few years to include studies conducted since the last update. Given the aforementioned limitations, the relative advantage of this current systematic review over similar studies will include evaluating the relationship between outcome and quality, assessing the reasons for heterogeneity, expanding the search time frame, and removing language restrictions in the search strategy.

Therefore, the present study will focus on various types of primary RCT studies, which

are stronger and more reliable than quasi-experimental studies and have a higher level of evidence. The current review study will identify knowledge gaps in existing literature and will provide recommendations for future studies. It will assist healthcare providers in making clear policies regarding the use of this treatment for preterm infants and will provide evidence-based information about them. This systematic review and meta-analysis study will be very important for informing clinicians and patients regarding the effectiveness of OMS.

Objectives

The main objective of this study will be to systematically review and meta-analyze the effectiveness of OMS on oral feeding in preterm infants. Additionally, this review will pursue the following secondary objectives:

1) Review and examine the effects of OMS on the length of hospitalization in preterm infants compared to the control group, using meta-analysis of available studies (where possible) or summarizing data through systematic review without meta-analysis (in cases where meta-analysis is not feasible).

2) Identify and investigate the effects of OMS on feeding efficiency (mean sucking rate per minute) in preterm infants compared to the control group, using meta-analysis of available studies (where possible) or summarizing data through systematic review without meta-analysis (in cases where meta-analysis is not feasible).

3) Identify and report the effects of OMS on weight gain in preterm infants compared to the control group, using meta-analysis of available studies (where possible) or summarizing data through systematic review without meta-analysis (in cases where meta-analysis is not feasible).

4) Synthesize published research based on important demographic data and other factors related to oral feeding (preterm neonate's postmenstrual age, level of healthcare services based on the region, gender, and the like).

5) Evaluate heterogeneity (standardized mean difference) in the included studies and identify potential sources of heterogeneity (study design, methodological quality, and the like).

The current study protocol has been registered in the Prospective Register of Systematic Reviews and Meta-Analyses (PROSPERO) system with the code CRD42022369514.

Materials & Methods

This study will be used a systematic review and meta-analysis methodology, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Furthermore, the PRISMA flow diagram will be utilized to illustrate the number of primary studies included and excluded at each stage of the selection process, providing a visual representation of the study selection procedure (Figure 1).

Data Source

The search strategy will be constructed around two main components: participants and intervention, or intervention and outcome. Both commercial and non-commercial databases, including gray literature, will be included to achieve the most comprehensive search. Thesaurus systems (such as MeSH) and the free text method were employed to identify keywords for the outcome component of the search. The free text method will include gathering expert opinions, articles, and abstracts through a targeted search in published articles, systematic review articles specifically focusing on pre-feeding oral stimulation, and published documents related to oral feeding. A trial search

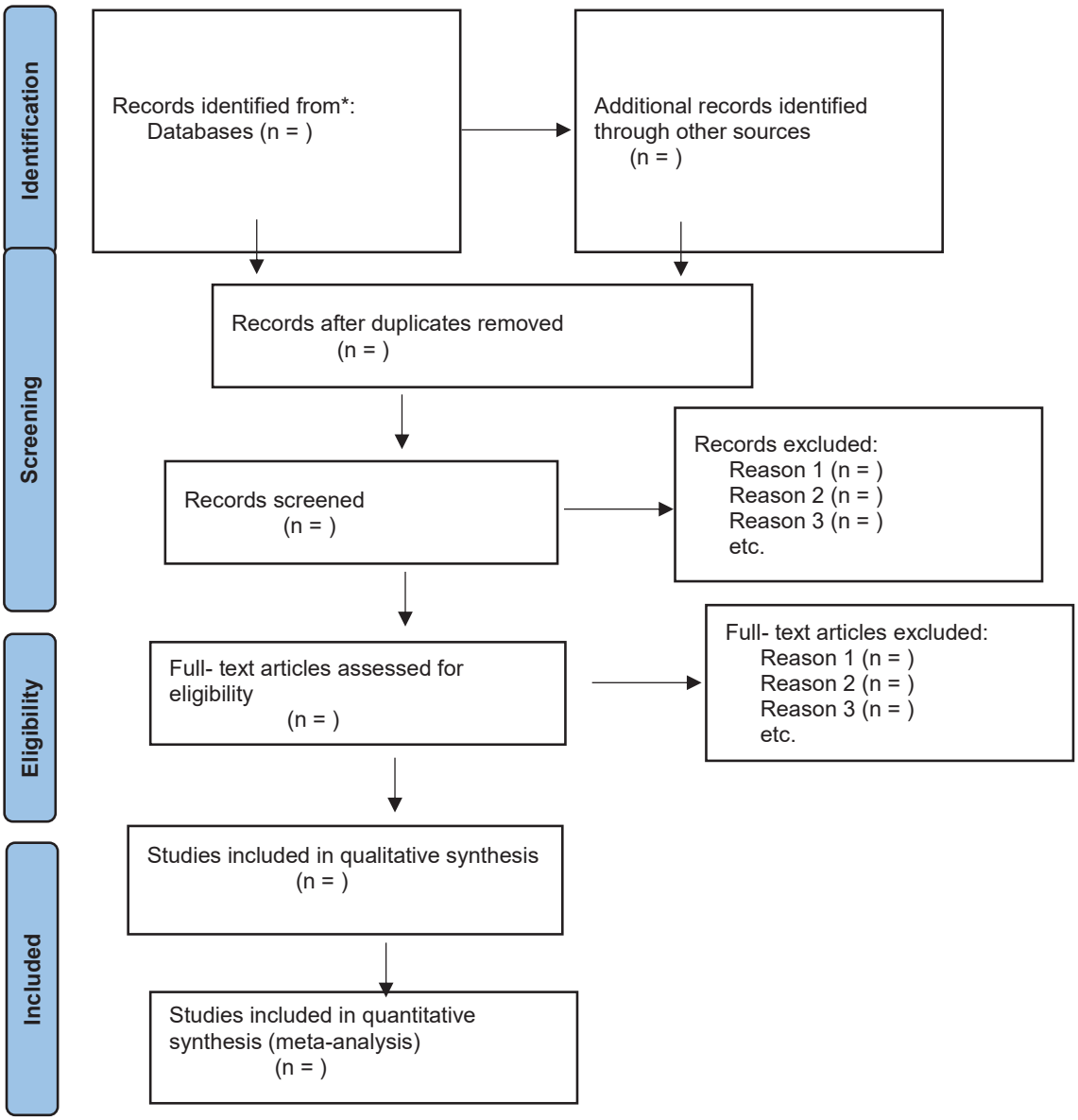

Figure 1. *Flow diagram of the study based on the PRISMA guidelines*

strategy based on Pubmed will be created to determine if this strategy identifies relevant studies in this field, and then, if confirmed, it will be finalized as the ultimate strategy. This search method will then be applied to various databases, and the search strategy used for each database will be reported.

If additional sources or databases will be identified from the entered studies and their reference lists, they will also be searched using an appropriate search strategy. The search strategy used in Pubmed will be shown in Appendix 1.

Publication Date

This systematic review will encompasses all accessible published studies from January 1, 1991, to the fifth month of 2024 for potential inclusion in the analysis.

Publication Language

This systematic review and meta-analysis will not impose any limitations based on language. Based on their title and abstract, studies that pass the initial screening phase and meet the criteria for final inclusion but are written in a language other than English will be translated using

"Google Translate" and reviewed by professional translators. These translated studies will be carefully assessed for final selection.

Search methods for identification of studies

Electronic database search

In order to achieve study objectives, a language-unrestricted search will be conducted across the following electronic databases: PubMed, Scopus, Web of Science, Cochrane Central Register of Controlled Trials in The Cochrane Library (CENTRAL), Medline via PubMed, and Cumulative Index to Nursing and Allied Health Literature (CINAHL).

Gray literature

Additionally, relevant gray literature (e.g., theses or dissertations and conference papers) will be searched in electronic databases such as ProQuest, Scopus, and Google Scholar search engine.

Key journals

Furthermore, a couple of key journals will be studied based on a search in Scopus.

References of Included Research

The reference list of included studies will be reviewed. If any relevant study is found through it, it will be added to the resources.

Others

I. Further search will be conducted in published documents from the following registration systems:

- World Health Organization (WHO) registration systems and relevant data will be included in the study.
- Clinicaltrials.gov
- ISRCTN registration system

II. Contacting experts in the relevant field: Experts will be requested to provide information about any relevant theses or conferences in addition to the database searches when they were contacted for this systematic review.

Study Selection

In this systematic review, randomized controlled trials (RCTs) with at least two intervention groups (oral-motor stimulation) and standard care/sham intervention/non-oral intervention (at least one of these three as the comparison group) will be included using parallel or crossover designs. These clinical trials must be single-blinded in the group of preterm infants undergoing treatment. Obviously, if there was a double- or triple-blind study, they will be included. Qualified clinical trials can be single-center (in one hospital or clinic) or multicenter (in multiple hospitals or clinics). In addition, in crossover trials with two or more phases or periods, only the findings of the initial phase will be utilized. Non-randomized clinical trials or clinical trials with an internal control group (pre-post single-group designs) will be excluded from this systematic review.

The studies will be screened to determine their eligibility based on the review objectives and the PICO criteria for Participants, Interventions, Comparisons, and Outcomes.

A) Participants:

In this systematic review, clinical trials will be included in which the participants are preterm infants (gestational age less than 28 weeks or 28-37 weeks according to the last menstrual period) and belong to at least one of two groups or subgroups of the population, and are of at least one of the two genders (male or female).

Clinical trials involving infants with associated conditions (such as neurologic and structural impairments) will not be excluded, but clinical trials involving infants whose oral feeding is hindered by accompanying issues will be excluded from this systematic review.

In primary studies, participants must have reached

physiological stability before the intervention. Intervention can be provided at any time after birth in primary studies.

Eligible participants will not be limited by race or ethnicity, place of residence, occupation, or socioeconomic status. Moreover, diversity in the above variables in participants of primary studies will not prevent these studies from undergoing systematic review.

B) Intervention and Comparison:

The current study encompasses all clinical trials involving oral stimulation interventions, which have been conducted in any clinical setting by a trained individual or team. The individuals or teams may comprise nurses, occupational therapists, speech and language therapists, other specialized professionals, or parents. The authors will examine and compare various aspects of the present study, including the interventions' frequency, intensity, dosage, duration, and timing. The following comparisons will be made:

- Oral stimulation intervention versus standard care
- Oral stimulation intervention versus sham intervention
- Oral stimulation intervention versus non-oral intervention

C) Outcome:

The availability of data related to secondary outcomes will not be mandatory for clinical trials, and only clinical trials meeting the requirements, based on relevant findings regarding oral feeding, will be included in this systematic review. The potential success measures for this systematic review will include outcome measures that demonstrate improvement in the feeding ability and oral function of preterm infants, reduction in hospitalization in the Neonatal Intensive Care Unit (NICU), and/or reduction in hospitalization duration.

Primary outcomes:

- Time (days) to complete oral feeding will be defined as receiving the total nutrition volume in a 24-hour without supplementation/gavage (MacKin 2001).

Secondary outcomes:

- Length of hospital stay (days)
- Weight gain (g/kg/d)
- feeding efficiency (measured based on milk consumption rate in milliliters per minute)

The process of selection testing (pilot)

To establish reliability among evaluators, the initial phase of the selection process will involve conducting a pilot phase on a subset of articles. The criteria will be revised after discussion among the authors, and experimental screening will be repeated until an agreement of over 80% is reached among all participating reviewers in the screening process.

Screening and Study Selection

At least two reviewers will independently assess each study's title and abstract during the screening phase. They will evaluate the studies using a checklist prepared per the inclusion and exclusion criteria. A study must satisfy all relevant criteria to be eligible for the systematic review. When a study's eligibility is unclear, it will be temporarily included for full-text assessment to determine its eligibility. In the selection phase, at least two independent reviewers will examine the full-text articles obtained from the screening phase and identify the eligible studies for the next stage. Any discrepancies during the screening and evaluation stages will be resolved through reviewers' discussions. A third expert will be engaged if needed to reach a consensus on a study's inclusion or exclusion.

Data Extraction

Two reviewers will independently extract data from the studies included in the review using a designated data extraction form. This form will then be independently reviewed by at least two reviewers, who will assess its effectiveness by applying it to a few samples of the included studies. Any necessary revisions to the data extraction form will be made through discussions and reaching a consensus until it is finalized. If additional information that requires extraction and is not included in the existing form is identified during the data extraction phase and is not included in the existing form, the data form will be updated after discussion and agreement among all reviewers to include these items. Each stage will be adequately documented to ensure the maintenance of the review process. In the pilot phase, when a reviewer is uncertain about specific details of a study during the data extraction process, any discrepancies between reviewers will be addressed through discussions among the reviewers. A third reviewer will be involved in the discussion to facilitate resolution if needed.

Dealing with missing data

In the event of a requirement to obtain missing or extracted data from published articles, our approach will involve reaching out to the author(s) via email to procure the necessary information. The inability to obtain sufficient data, even after sending three emails, will automatically resulted in excluding the study from the data synthesis process.

Risk of Bias Assessment

At least two independent reviewers will evaluate the included studies for the risk of bias using the Cochrane Risk of Bias (ROB2) assessment tool. If there are any disagreements between the reviewers, they will engage in discussions and work towards reaching a consensus. If disagreements persist, a third reviewer will be involved in reaching a consensus. All articles will be included in the study regardless of their risk of bias. A graphical presentation (traffic light plot) of the risk of bias will be created, and the study quality will be added to the characteristics table of the included studies.

Heterogeneity Assessment

All analyses will be performed using Stata V.14 software on a personal laptop. Heterogeneity among primary studies will be evaluated using the I2 statistic and χ^2 test, following the Cochrane Handbook for Systematic Reviews of Interventions guidance. The following sources will be used as a basis for determining the degree of heterogeneity:

- 0-40% will be considered as “no important heterogeneity.”
- 30-60% was considered as “moderate heterogeneity.”
- 50-90% will be considered as “substantial heterogeneity.”
- 75-100% will be considered as “considerable heterogeneity.”

The statistical significance level will be determined as $p<0.05$. Before performing a pooled analysis, the authors will consider the presence of heterogeneity in the studies. If substantial heterogeneity ($I2>50\%$) exists, the results will be described qualitatively in the text and not combined. The reasons for heterogeneity will be investigated by categorizing the studies into subgroups and conducting meta-regression.

Selecting the Computational model will not be based on the results of statistical heterogeneity tests (I2) but rather on the authors’ expectations of whether the studies do not have a common effect size or not, as well as on the study’s analysis objectives. Therefore, when the studies

are not functionally similar (thus assuming no common effect size), a random-effects model will be more justifiable than a fixed-effects model, and the results from the individual studies will be combined using a random-effects model in the meta-analysis.

Publication bias assessment

The first strategy will involve conducting the most comprehensive search in the literature search phase. Additionally, when sufficient studies (≥10) are identified, funnel plots will be used for publication bias assessment. The Begg's and Egger's tests will also be performed, and significant results ($p<0.1$) will indicate considerable publication bias. Finally, the Trim & Fill method will be employed.

Data synthesis

A detailed reading and presentation of all primary studies will be conducted, and their findings will be presented in tables. The tables will provide a summary of the most relevant features, outcomes, and results of the studies (mean scores with their range (SD/95% CI)) for the number of days to achieve full oral feeding, weight gain, length of hospital stay, and average milk consumption per minute (feeding efficacy). This study will aim to conduct a meta-analysis of both primary and secondary outcomes. On the other hand, the decision to conduct a meta-analysis will be based on the number of studies identified in the review, with a minimum requirement of two studies.

The meta-analysis will be conducted using the Stata V .14 software. For dichotomous data, the relative risk ratio and risk difference with a 95% confidence interval will be used, while standardized mean difference or mean difference with a 95% confidence interval will be used for continuous outcomes. The meta-analysis results will be presented in forest plots with a 95% confidence interval.

Additionally, Number Needed to Treat (NNT) and dppc2 indices will be used. If there are sufficient homogeneous studies available for statistical pooling, meta-analysis will be performed for the intervention dosage (≤10 minutes per day, 11 minutes ≤ duration ≤ 20 minutes per day, 21 minutes ≤ duration ≤ 30 minutes per day - 31≤ minutes per day). The model used in the meta-analysis will be a random-effects model, as the identified studies are expected to exhibit a high degree of methodological heterogeneity.

Subgroup Analysis

Subgroup analysis will be performed for the following:

1) Infants born at PMA (post-menstrual age) less than 28 weeks compared to PMA 28 to 30 weeks, PMA 31 to 34 weeks, and PMA 34 weeks and above.

2) Infants exclusively breastfed versus infants exclusively bottle-fed versus infants fed with both breast milk and bottle.

3) Gender of participants: Male versus female.

4) Level of healthcare services (based on region: developing countries versus developed countries).

5) Duration of intervention (≤10 minutes per day, 11 minutes ≤ duration ≤ 20 minutes per day, 21 minutes ≤ duration ≤ 30 minutes per day, and ≥31 minutes per day).

6) Study quality

7) Birth weight (low birth weight: 1500≤weight≤2500 grams, very low birth weight: 1000≤weight<1500 grams, and extremely low birth weight: weight less than 1000 grams).

Sensitivity Analysis

In this section, the authors will examine the factors that influence the conclusion obtained from the meta-analysis. These factors potentially have a significant impact on the outcome, and

based on the nature of this effect, the authors will interpret the observed relationship between this effect and its application within the framework of the main research objective. The results of the sensitivity analysis will be summarized in a brief table. The authors will employ three approaches in sensitivity analysis:

Approach 1: Sensitivity analysis related to publication bias, performed using the Trim and Fill method. In this approach, the authors will investigate whether the combined effect size changed noticeably when the probability of publication bias was high after adding one or more studies.

Approach 2: Sensitivity analysis related to the methodological quality of primary studies using subgroup analysis.

Approach 3: Sensitivity analysis related to the impact of a specific study, which will be conducted using the one-out Remove method.

Certainty (Quality/Strength) of evidence

The authors will use the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to assess the evidence's certainty (quality/strength) at the outcome level. Two independent authors will evaluate the quality of evidence, and a summary table will be prepared. Worth noting that for outcomes with fewer than three studies, the authors will not conduct the GRADE assessment. The authors will considere high-quality evidence from randomized controlled trials. However, they will downgrade the evidence by one level for serious limitations (or by two levels for very serious limitations) based on the following criteria:

1) The limitations of study design details and their precise implementation will be assessed using the Cochrane Risk of Bias (ROB2) assessment tool. The presence of significant limitations in studies led to a decrease in confidence when attempting to estimate the treatment effect (without a problem, the level of evidence does not decrease; a problem in one aspect = one level of decrease; a problem in two or more aspects = two levels of decrease).

2) Inconsistency (or heterogeneity): the authors will assess I2 to evaluate inconsistency in the results. If $I2 < 50\%$, the level of evidence will not decrease. If $50\% \leq I2 < 70\%$, the evidence level decreased by one level. If $I2 > 75\%$, the evidence level will decrease by two levels.

3) Indirectness: By considering the evidence tables for the target population, intervention, and outcome and assessing the generalizability of the population and outcomes of each study to the target population, the authors will determine the level of evidence. If the population and outcome are generalizable, the evidence level will not decrease. If there is a problem in one aspect, the evidence level decreased by one level; if there is a problem in two or more aspects, the evidence level will decrease by two.

4) Imprecision: In cases where the total number of relevant studies related to the outcome or specific subgroup was five or more, the level of evidence will not decrease. In cases where the total number of relevant studies related to the outcome or specific subgroup is less than five studies or the confidence interval of the relevant index is relatively wide, the evidence level will decrease by one level. In cases where the total number of relevant studies related to the outcome or specific subgroup are three or fewer, or the confidence interval of the relevant index is relatively wide, and the distance between the upper limit and the lower limit is large and not close to the previous situation, the evidence level will decrease by two levels.

5) Publication bias: If all methods of publication bias assessment (funnel plot, Beg's and Egger's tests, as well as Trim & Fill method) negate the probability of publication bias, no points will be deducted, and the level of evidence will not decrease. If only one of the publication bias assessment methods supports the presence of publication bias, while the other methods do not support its presence, the level of evidence will decrease by one level. If the majority of publication bias assessment methods indicate the presence of publication bias or the correction performed by the Trim and Fill method has a substantially different result compared to the uncorrected combined estimate, the level of evidence will decrease by two levels.

Overall certainty (quality/strength) of evidence for each outcome will be categorized as high, moderate, low, or very low.

- High-quality evidence will be utilized when the included studies exhibit consistent findings in at least 75% of cases, there are no limitations in the study design, and the data is both consistent and direct, with a high degree of precision and freedom from publication bias. Additionally, it will be unlikely that further research will change the confidence in the estimated effect.
- Moderate-quality evidence will be applied when one of the five domains lacked evidence certainty. The authors will currently possess a moderate confidence level in estimating the effect at this stage, but additional research will probably impact our confidence in the estimated effect.
- Low-quality evidence will be applied when two of the five domains lack the certainty of evidence. At this stage, the authors will have limited confidence in the estimated effect. Subsequent research will be expected to influence our confidence in the effect estimate, and this estimate will likely change.
- Very low-quality evidence will be applied when three out of the five domains lack the certainty of evidence. At this level, our confidence in the effect estimate will be minimal, and a significant amount of uncertainty will be present to estimate it.

When none of the five domains mentioned have certainty of evidence, no certainty of evidence existed.

Discussion

Preterm birth is the primary cause of neonatal death worldwide (21). Additionally, it results in various developmental and medical problems (such as increased frequency of respiratory distress, temperature instability, seizures, and feeding disorders) and, in turn, results in family stress and imposes a significant financial burden on both the family and the community (26, 27). Facilitating oral feeding skills is usually the main focus in the Neonatal Intensive Care Unit (NICU), and achieving oral feeding is often the first criterion for discharge from the NICU for healthy preterm infants (27).

Various therapeutic strategies have been proposed to facilitate oral feeding in preterm infants with varying degrees of success. These treatments often involve environmental/physical modifications, such as reducing external stimuli during feeding, using therapeutic nipples to manage milk flow, and positioning to support the motor system, OMS (9). OMS plays a crucial role in the speech-language pathologists' work in the NICU setting. Different kinds of OMS commonly used by SLPs in the NICU include Nonnutritive sucking (NNS) and Oral Stimulation (9, 27). Published studies have demonstrated that OMS can improve preterm infants' feeding skills. Several systematic

reviews on this topic have been published (1, 9, 11, 18, 21). However, existing systematic reviews have not reached a certain conclusion regarding the effectiveness of OMS treatment for oral feeding in preterm infants. Therefore, conducting a systematic review and meta-analysis to examine the effectiveness of OMS for oral feeding in preterm infants appears necessary.

In Conclusion

Healthcare providers will better understand the effectiveness of OMS through this systematic review with meta-analysis. The authors will attempt to include some high-quality studies that may not have been published yet, as well as grey literature, in this review. In this study, the authors will have no language restrictions for including studies. By adhering to these considerations, the authors will reduce the limitations of previous systematic reviews and improve the conclusions about the results. The present study will be able to help determine whether OMS can benefit oral feeding in preterm infants. If possible, the authors will also determine the appropriate intervention dose and the findings will be able to provide insights for future research.

Acknowledgment

The authors would like to acknowledge the support of Rehabilitation Sciences Research Center of Zahedan university of medical Sciences and the editors for reviewing the article. No ethical concerns are predicted (code of ethics: IR.ZAUMS.REC.1402.237). The systematic review findings will be published in a peer-reviewed journal and presented at academic and clinical conferences.

Author's Contribution

Conceptualization, Investigation, Supervision, Methodology: Faezeh Asadollahpour writting original draft, review & editing: Kowsar Baghban, Farhad Sakhai Methodology, Writing – original draft: Mozhgan Asadi. All authors have read and agreed to the published version of the manuscript.

Conflict of Interest

The authors declare no conflict of interest.

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