Review Article

Effect of Premature Infant Oral Motor Intervention on Oral Feeding and Weight Gain: A Systematic Review and Meta-Analysis

Jyoti[1], Malar Kodi S[2], Rupinder Deol[2]

[1]Nursing Officer, VMMC and Safdarjung Hospital, New Delhi, [2]Department of Paediatrics, College of Nursing, All India Institute of Medical Sciences, Rishikesh, Uttarakhand, India

Abstract

Background: Sucking and swallowing coordination did not achieve until 32–34 weeks of gestation in premature infants. Oral motor stimulations improve oral motor musculature and neurobehavioral synergism which improves the rate of oral feeding readiness and weight gain and ultimately reduces the duration of hospitalization. Premature Infant Oral Motor Interventions (PIOMI) is a specific oral motor therapy effective in improving the clinical outcomes among premature infants. Earlier no review had been conducted specifically to assess the effectiveness of PIOMI on oral feeding progression, weight gain, and Length of hospital Stay (LOS) among premature infants. So, the present review had been planned. **Materials and Methods:** Review was conducted by searching databases like PubMed/Medline, Embase, Ovid, Clinical Key and Academia, Google and Google Scholar (from PIOMI inception to October 2020). Published articles on RCTs and clinical trials were included. **Results:** Six studies, with a total of 301 premature infants, were included in Meta Analysis (MA). PIOMI was found effective in early attainment of feeding progression (Mean Difference (MD) = −4.63 days at 95% Confidence Interval (CI) = −4.97 to − 4.29, $p < 0.001$) and shifting from gavage to independent oral feeding (MD = −2.54 days at 95% CI = −3.13 to − 1.95, $p < 0.001$), shows weight gain at discharge (MD = 51.61 grams at 95% CI = 19.84 to 83.38, $p = 0.001$), and reduces LOS (MD = −2.81 days at 95% CI = −3.51 to − 2.10, $p < 0.001$). **Conclusions:** Review shows shows the effectiveness of PIOMI in improving oral feeding progression and early attainment of gavage to independent oral feedings, and it also showed weight gain at discharge and reduced LOS.

Keywords: *Bottle feeding, breastfeeding, feeding behavior, infant, length of stay, motor skills, mouth, premature, weight gain*

Introduction

Premature birth rates have continued to increase globally for the previous two decades.[1] Every year, approximately 15 million infants are born prematurely, accounting for more than 1 out of every 10 babies, and nearly 1 million children die as a result of complications associated with premature birth. Many premature survivors have to live with disabilities such as learning disabilities and visual and hearing issues.[2,3] Following pneumonia, prematurity is the most common reason for death in children under the age of 5 years and the primary cause of death in the critical first month of life. Breastfeeding milestones generally reach different Postmenstrual Ages (PMAs) for different Gestational Age (GA) groups, but premature infants can start breastfeeding at early times, with some delay in infants less than GA of 2 weeks. Very premature infants had the lowest mean of 35.5 weeks PMA at first complete breastfeed, whereas moderately premature had around 36.4 weeks at the establishment of exclusive breastfeeding.[4] Initiation of oral feeding can occur as early as 29 weeks of PMA in the USA, and around 34 weeks in countries like China, Egypt, Iran, and India. However, GA and PMA are unreliable markers of infant oral feeding ability; other factors like weight, oral motor development, feeding techniques, and feeding experiences are also taken into consideration.[1,5]

Premature babies face many challenges for their survival like difficulty in maintaining temperature due to large body surface area, feeding issues due to improper coordination in sucking and swallowing reflexes as

Address for correspondence:
Dr. Malar Kodi S,
All India Institute of Medical Sciences, Rishikesh, Uttarakhand - 249 203, India.
E-mail: malar.nur@aiimsrishikesh.edu.in

Access this article online

Website: https://journals.lww.com/jnmr

DOI: 10.4103/ijnmr.ijnmr_341_21

Quick Response Code:

How to cite this article: Jyoti, Kodi SM, Deol R. Effect of premature infant oral motor intervention on oral feeding and weight gain: A systematic review and meta-analysis. Iran J Nurs Midwifery Res 2023;28:225-34.

Submitted: 21-Feb-2022. **Revised:** 06-Jun-2022. **Accepted:** 13-Feb-2023. **Published:** 21-Jun-2023.

CNS is not mature, breathing difficulty due to immature lungs, and prone to infection as the immune system is undeveloped.[3] Survival rates differ dramatically around the world. In low-income countries, nearly half of the premature infants born below or around 32 weeks (2 months early) are unable to survive due to a lack of feasibility, cost-effective care, such as warmth, breastfeeding support, and basic care for infections and breathing difficulties. Three-quarters of the deaths from 15 million premature births could be avoided with current low-cost interventions.[2] Few premature infants are adequate oral feeders from birth, and many receive enteral feeds by tube, necessitating a longer hospital stay as they transit from tube (gavage) feeds to oral feeds, hence they may require hospitalization which increases the burden on the family and ultimately on society. According to one recent article from Southeast Asia, median consumables cost per premature infant ranged from Malaysian Ringgit (MYR) 196.0 (161.00) in minimal care to MYR 10,149.8 (4,701.80) in extremely premature intensive (1 MYR = 17.98 Indian Rupee).[5,6] Oral feeding requires the coordination of breathing, sucking, and swallowing in the context of overall motor stability and incoming sensory stimuli. Oral motor therapy improves the oral-motor musculature and neurobehavioral organization; therefore, it improves the rate at which newborns are breastfed exclusively; the onset of therapy varied among studies ranging from 29 to 33 weeks PMA. Available evidence showed that the therapy had a consistently positive effect in switching from gavage to full feedings, that is, 8–13 days versus 13–26 days without therapy which leads to shorter LOS. The progress to successful feeding relies on infants' ability to coordinate the muscles of the jaw, lips, tongue, palate and pharynx, upper trunk, and respiratory systems to allow secure swallowing, and also on normal sensory functioning seen in basic reflexes such as rooting, gag and an intact swallow reflex, and intraoral and pharyngeal sensation. Non-Nutritive Sucking (NNS) and rooting appear to be more accurate predictors of feeding readiness. Some infants may exhibit these behaviors as early as 28 weeks of PMA.[1,5]

The Premature Infant Oral Motor Interventions (PIOMI) is an Oral Motor Intervention (OMI) program that uses assisted movement to activate muscle contraction and resistance movement to strengthen the oral structure developed using the BOMI (Beckman oral motor intervention). BOMI was originally conceived as a 15-min intervention for term infants, children, and adults who had developmental delays that resulted in feeding difficulties; not intended for use with premature infants as they face problems in tolerating the procedures without displaying signs of stress. Furthermore, the small size of the premature infant's oral cavity makes it difficult to spend the full 15-min intervention time on each oral area (palate, tongue, upper gum, lower gum, etc.). Dr. Lessen modified the original BOMI in consultation with Debra Beckman, in which the original 11 steps were reduced to 8, and the 15-min time frame was reduced to 5 min to use specifically in premature infants, as young as 29 weeks PMA. Techniques were slightly modified to accommodate the premature infant's small oral cavity, and proper positioning was included to ensure proper head and neck support. Specific finger stroking was used to stimulate the oral structures (cheeks, lips, gums, and tongue). PIOMI was created using the transactional model, a standardized oral motor therapy for premature infants that had been shown to have high intervention fidelity and tested internationally.[1,7] PIOMI can be effortlessly provided by any professional in health care like nurses, occupational therapists, neonatologists, parents, or other developmental specialists, after accomplishing some level of competency. Even though no adverse effects of PIOMI have been outlined so far, apnea, bradycardia, and oxygen desaturation may be observed as a sign of feeding stress.[1,8]

Several studies have been carried out to know the effectiveness of PIOMI as a specific oral motor therapy.[8–12] Investigators found that use of the PIOMI resulted in weight gain, increased oral intake, reduced transit time to full oral feedings, and decreased Length of hospital Stay (LOS) and also concluded that it increases the mean Neonatal Oro-Motor Assessment Scale (NOMAS), earlier full oral feeding, and improved growth velocity. PIOMI also increases the direct breastfeeding rates at 1 month and 3 months after discharge from the neonatal intensive care unit. Even though there is a strong global interest in the PIOMI due to consistent success, feeding/care models may differ within cultures, which limits external validity. Therefore, continued testing with preterm newborns in different countries is needed.[1] Although, previous studies showed the use of PIOMI resulted in weight gain, increased oral intake, reduced transit time to full oral feedings, and decreased LOS, but they had incorporated a small sample size. Earlier few reviews had been carried out which included PIOMI along with other OMIs,[5,13] and no review had been carried out to date which focuses specifically on the effect of PIOMI. Hence the current systematic review (SR) and MA had been planned to know the effectiveness of PIOMI on oral feeding progression and weight gain in premature infants.

Materials and Methods

We conducted this review including studies from the inception of PIOMI to October 2020 and followed the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) Figure 1[14] guidelines for the present SR and MA. PICO (patient/population, intervention, comparison, and outcomes) framework was used to justify the review question. For data sources and selection criteria, we searched PubMed/Medline, Embase, Ovid, Clinical Key, Academia, Google, and Google Scholar and grey literature for English articles published any time up to October 2020, describing studies assessing the effect of PIOMI on oral

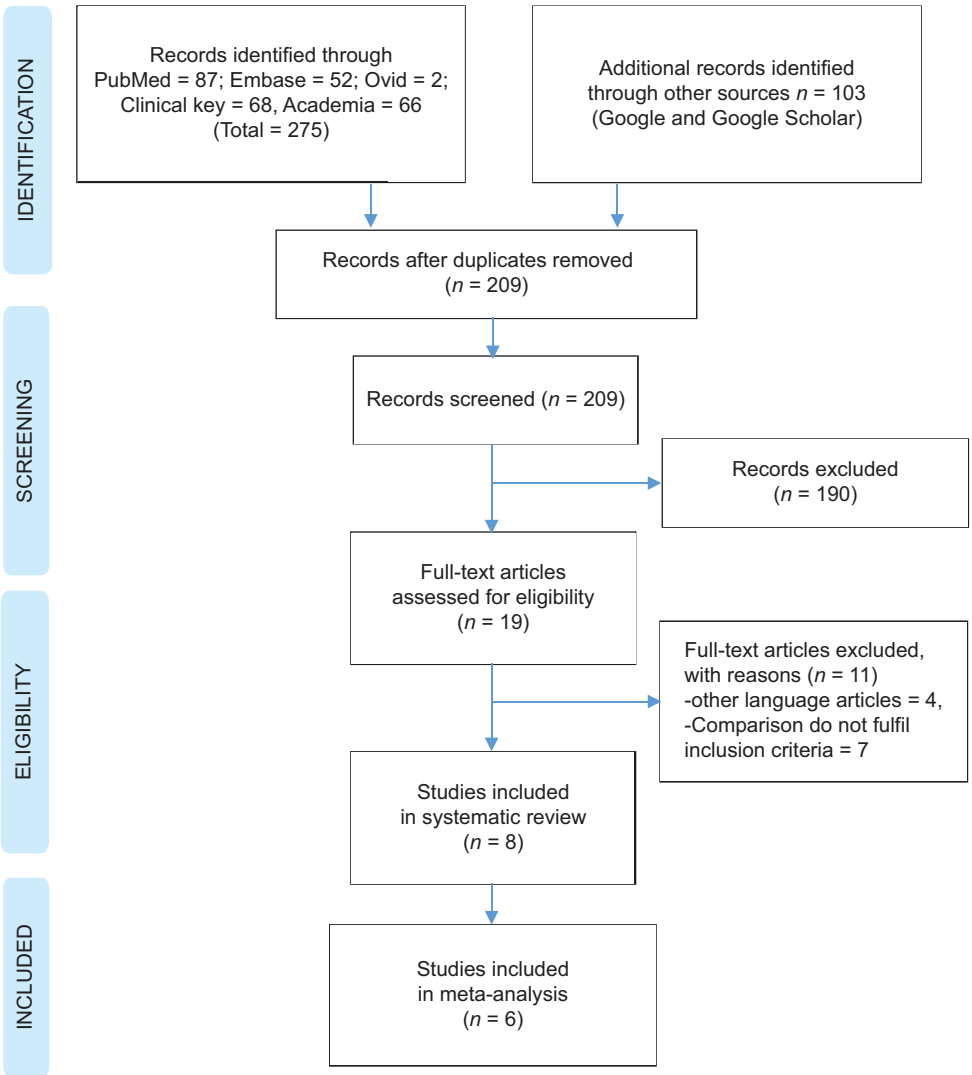

Figure 1: PRISMA flow diagram[14]

feeding progression and weight gain and LOS. The medical subject headings (MeSH) used were ("infant, premature" OR ("infant" AND "premature") OR "premature infant" OR ("premature" AND "infant") AND ("mouth" OR "mouth" OR "oral") AND ("motor" OR "motor's" OR "motoric" OR "motorically" OR "motorics" OR "motoring" OR "motorisation" OR "motorised" OR "motorization" OR "motorized" OR "motors") AND ("intervention s" OR "interventions" OR "interventive" OR "methods" OR "methods" OR "intervention" OR "interventional"). We examined the reference lists of final articles included in the review to identify additional studies and searched the grey literature (Google). Selection of studies was done according to the resource screening process for SRs. Randomized controlled trials and clinical trials were included. Studies were excluded if they did not include PIOMI or if the newborn was born with any co-morbidity such as anomalies of the cardiac, gastrointestinal, and respiratory system and also developed necrotizing enterocolitis. All reviewers who searched examined the eligibility of the studies based on the Cochrane Handbook for Systematic Review of Interventions Joanna Briggs Institute (JBI) Critical appraisal checklist for RCT.

All authors gathered a predefined outcome of the studies, which includes study characteristics. The primary outcomes for this review were oral feeding progression and weight gain. Secondary outcomes were LOS during initial hospitalization. Data extraction was carried out by removing the duplicates related to the selection process; all the authors had worked independently on it. The formal discussions and consensus by the senior reviewer resolved the differences. Data extraction forms were designed to tabulate the characteristics of the included studies [Table 1]. The data were extracted and discussed by the two reviewers and later the third author helped us in resolving discrepancies, if any. Data on the subject of the first author, publication year, country, sample size, population (PMA at birth, birth weight, gender, PMA and weight at start of feeding), intervention (time, frequency,

and duration), outcomes (oral feeding progression, weight gain, LOS, mean volume of oral intake, NOMAS), and results were pulled. Emails were sent to the corresponding authors of the included studies to obtain additional information and also attempted to contact the authors for more detailed information and to know about the missing information. The quality assessment of eight included studies was conducted using the Cochrane checklist and is shown in Figures 2 and 3.[15] In the incident of a disagreement between the authors, the third reviewer was consulted to reach a final decision. The procedure was based on the following seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessor, incomplete outcome data, selective reporting domain and other biases. Two reviewers reviewed all included studies and used the Cochrane Collaboration approach for the assessment of risk bias. Two primary reviewers looked for bias in randomization, allocation concealment, participant and assessor blinding, incomplete outcome data or attrition bias, selective reporting, and other biases. All the included studies were categorized under low, high, or unclear risk. If a study reported low risk in all domains of risk biases, it was considered to be of high quality and vice versa. If a difference in opinion between primary reviewers regarding risk bias was there, the third and fourth reviewers conducted a thorough assessment of the study, and conclusions were reached by mutual consensus.

Random sequence generation was described in four studies,[8–10,16] whereas in another three studies there was a high risk in the process of random selection for study participants.[1,7,12] In two studies allocation concealment lies in low risk[8,10] whereas in the other two studies, it was unclear,[10,12] and in the remaining three studies the allocation concealment lay in high risk.[1,7,16] Participant and personnel blinding were done in two studies[8,9] whereas it was unclear in four studies[1,10,12,16] and in one study by Lessen BS 2011 it falls in high risk.[7] Blinding of outcome assessment was done in four studies[8–10,12] whereas in the other three studies it was unclear. For incomplete outcome data bias, all seven studies were at low risk of bias. The selective reporting bias was at low risk for six studies whereas it was unclear for Arora K *et al*.[10] study as weight gain values were not provided. In other risks of bias, six studies were of low risk, whereas a study by Mahmoodi N *et al*. 2019[16] fall in unclear risk of bias as shown in Figure 2. JBI scoring was used to check the overall quality according to which, four studies got a scoring of 11/13[1,7,11,16] whereas two studies received 12/13[8,9] and one study got 13/13.[10] Scoring between 11 and 13 shows high quality.[17] The quality was high for all included studies. Eight studies met the inclusion criteria and six of them were included for MA. Based on the objectives of the review, a MA was done for the outcomes like weight gain, oral feeding progression, and LOS. Statistical findings were carried out according to the statistical guidance protocol in the latest edition of the Cochrane Handbook for Systematic of RCT. RevMan Manager 5.4 was used for review and data analysis of studies.[18] Outcomes were continuous, so they represented as a mean difference (MD) with 95% confidence interval (CI). Heterogeneity was tested both by visual examination of a forest plot (where non-overlapping CI shows the probability of heterogeneity) and by use of Chi-squared heterogeneity test ($P < 0.05$ shows the presence of heterogeneity). Heterogeneity was also represented as I^2 figures, and 0% shows no heterogeneity. Subgroup analysis and funnel plots were not possible to remove heterogeneity as the studies were small in number (<10). The fixed model effect was used if <50% heterogeneity for statistical analysis.

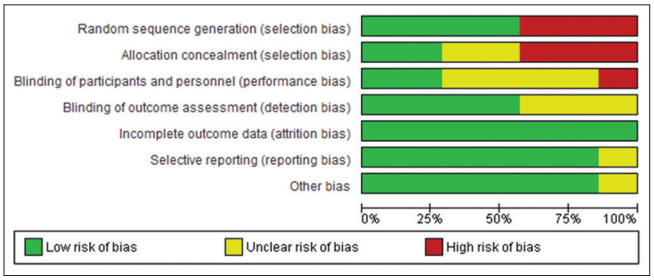

Figure 2: Risk of bias graph: Review authors' judgments about each risk of bias item presented as percentages across all included studies

Ethical consideration

Researchers tried to act in an unbiased way to analyze the retrieved data of articles. Institutional Ethics Committee (IEC) of All India Institute of Medical Sciences (AIIMS) approved this study (Project code: AIIMS/IEC/21/32 on January 09, 2021). We have registered our SR and MA in PROSPERO and our registered ID is CRD42021226135. The authors were committed to avoid the redundant publication and plagiarism. Results that were not statistically significant were expressed and discussed without bias.

Results

Total 275 articles were extracted from databases:

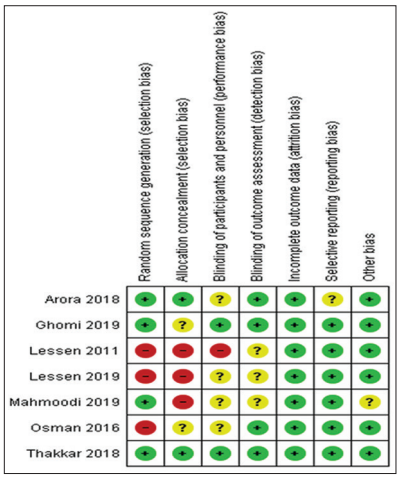

Figure 3: Risk of bias summary: Review authors' judgments about each risk of bias item for each included study

PubMed = 87; EMBASE = 52; Ovid = 2; Clinical Key = 68, Academia = 66. Articles were also identified through other sources than databases (like manual searches through reference lists of articles and Search engines like Google Scholar and Google). A total of 103 articles were retrieved from Google and Google Scholar. No new article was found from manual tracking. No limits based on time and type of study applied.

All articles were imported to Mendeley, checked for duplication and then left with 209 articles. Articles that appear to provide an answer to the research questions were included in the review. A total of 190 articles were excluded based on the screening process. Nineteen articles were found to be eligible after screening the research paper based on title and abstract. After reading full-text articles, 11 articles were excluded, among them 4 articles were in another language, and the remaining 7 articles did not fulfil the inclusion criteria.[19-27] In the end, 8 studies were included in SR, out of them 6 research papers were included for MA, and 2 studies were excluded as the outcomes were measured differently.

Six studies (RCTs and clinical trials) observed the findings of a total of 301 participants; 152 premature infants were in PIOMI group in which intervention occurred in any clinical setting with delivery by a trained person or team of any health professional, considering any duration, frequency, and timing of delivery of the intervention and rest 149 premature infants were in the control group.

Effects of intervention (Outcome)

Feeding progression: Out of 6 studies, 3 studies having 182 premature infants showed that there was a decrease in time to attain full independent oral feeds from first oral feeding. The forest plot shown in Figure 4 reveals that feeding progression is less in the PIOMI intervention group compared to the control group (MD = −4.63; 95%CI: −4.97 to − 4.29 at I^2 = 0% $P < 0.001$), which was statistically significant and the fixed-effect model was used. Further, meta-regression of the included studies could not be performed because we had less than 10 RCTs. Results of the MA of oral feeding had shown consistency, and a review by Tian Xu *et al.* 2015[13] revealed that OMI group showed significant improvement (p = 0.0005) (MD, 0.80; 95%CI: 0.36–1.27) as compared to routine care. An MA by Greene Z *et al.* 2016[3] showed statistically significant results, in which a few days were taken to attain full oral feedings in the intervention group (MD = 4.81, 95%CI: −5.56 to − 4/06, I^2 = 68%). The experimental group was provided with a range of different interventions including Fucile *et al*. protocol and PIOMI protocol.

Gavage to independent oral feeding: Among 6 studies, 3 studies[7,9,10,16] having 89 infants showed that there was a decrease in time for attainment of gavage to independent oral feeds in PIOMI group compared to the control group (MD = −2.54; 95% CI: −3.13 to − 1.95 at 1^2 = 8% p < 0.001) which was statistically significant and fixed-effect model was used as shown in Figure 5.

Weight at discharge: Four studies have talked about an increase in weight of the PIOMI group from baseline, but in the study of Arora K *et al*., the values of weight gain are not provided and in a study conducted by Osman A *et al*.[11] the weight gain values are in different SI units. So, these two studies are not included in the MA for weight gain. Remaining two studies[8,9] are included in the MA with a total of 132 participants. Results favored the PIOMI group, the mean weight gain (MD = 51.61, 95% CI: 19.84 to 83.38 at I^2 = 0% and p = 0.001) is significant and a fixed model effect is used as shown in Figure 6. Unlike the past two reviews, the present review shows significant weight gain values. A review done by Tian Xu *et al.*(2015)[13] showed MD: −17.54, 95%CI: −151.34 to 116.26, I^2 = 88% p = 0.80, whereas a review done in 2016 by Greene Z *et al*.[5] showed MD = 0.74, 95%CI: −1.05 to 2.51, I^2 = 41%, p = 0.42 as non-significant.

LOS: Five studies[7–10,16] including RCTs and clinical trials having 221 infants showed a decrease in LOS during initial hospitalization in PIOMI group compared to the control group (MD = −2.81; 95%CI: −3.51 to − 2.10 at 1^2 = 0% p < 0.001) which was statistically significant and a fixed-effect model was used as shown in Figure 7. The result was in congruence with the previous reviews as a review done in 2016 concluded MD = −5.26; 95% CI: −7.34 to − 3.19, I^2 = 61% $P < 0.001$ and review done in 2015 showed MD = −3.64; 95%CI: −5.57 to − 1.71, I^2 = 21% P = 0.0002, where both revealed significant reduction in LOS.

In two studies[1,8] PIOMI intervention had shown a positive effect on the mean volume of oral intake. In a study by Thakkar P *et al.* (2018),[8] feeding performance was

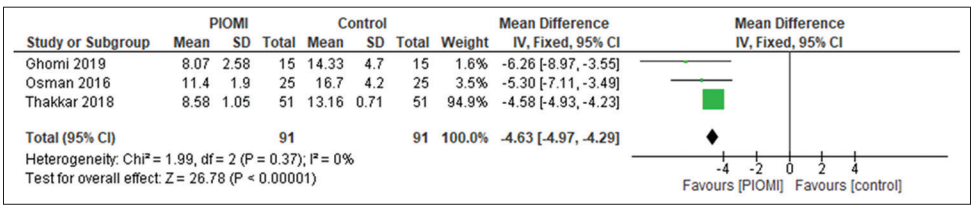

Figure 4: Forest plot of comparison of PIOMI intervention versus standard care/routine care, outcome: Feeding Progression. [NOTE: *P* <0.00001 has been replaced to *p* < 0.001, SD = Standard Deviation, df = Degree of Freedom, CI = Confidence Interval, I^2 = Heterogeneity, Z = Overall Effect Size]

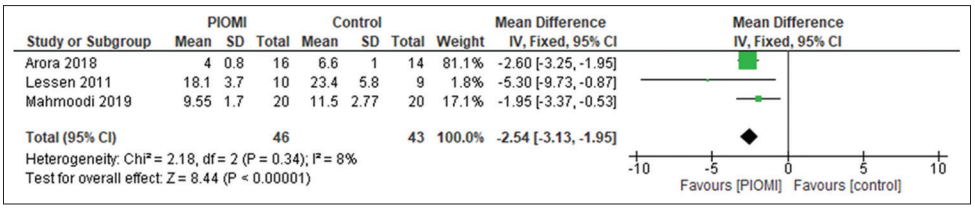

Figure 5: Forest plot of comparison of PIOMI intervention versus standard care/routine care, outcome: Duration of gavage to independent oral feeds. [NOTE: *P* <0.00001 has been replaced to *P* < 0.001, SD = Standard Deviation, df = Degree of Freedom, CI = Confidence Interval, I² = Heterogeneity, Z = Overall Effect Size]

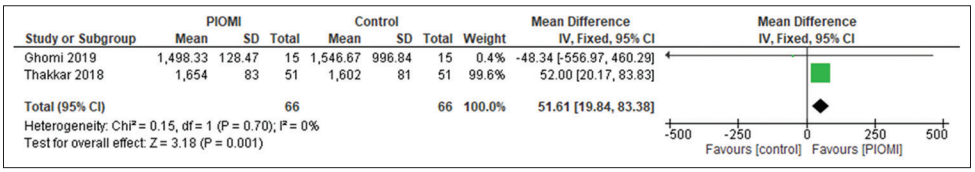

Figure 6: Forest plot of comparison of PIOMI intervention versus standard care/routine care, outcome: weight at discharge. [NOTE: *P* <0.00001 has been replaced to *P* < 0.001, SD = Standard Deviation, df = Degree of Freedom, CI = Confidence Interval, I² = Heterogeneity, Z = Overall Effect Size]

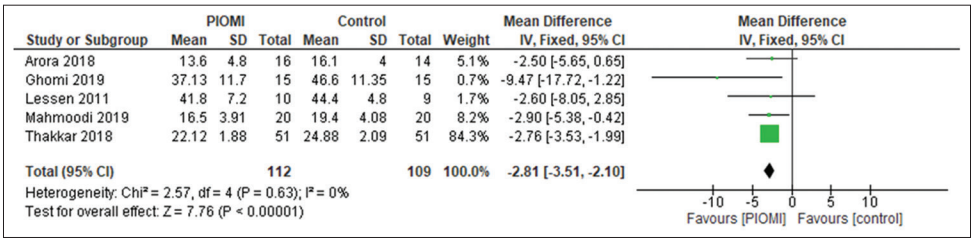

Figure 7: Forest plot of comparison of PIOMI intervention versus standard care/routine care, outcome: length of hospital stay. [NOTE: *P* <0.00001 has been replaced to *P* < 0.001, SD = Standard Deviation, df = Degree of Freedom, CI = Confidence Interval, I² = Heterogeneity, Z = Overall Effect Size]

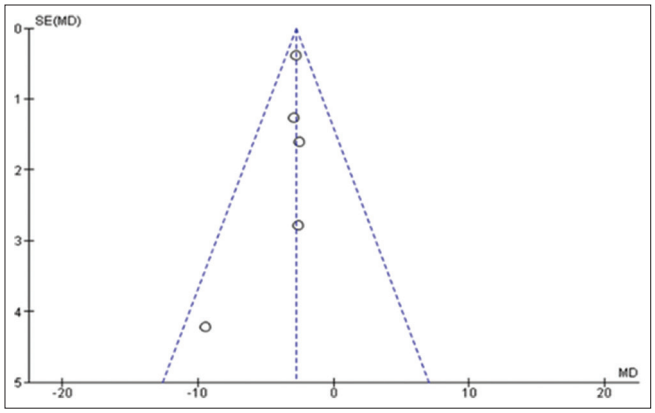

Figure 8: Funnel plot for the length of hospital stay showing symmetrical pattern, indicating no publication bias

assessed based on the overall volume of milk intake (ml/kg/feed) and rate of milk transfer. PIOMI intervention was also effective in improving NOMAS score. A study conducted by Arora K *et al*[10] concluded this along with another study[11] in which the association of infant's characteristics (age at birth, gender, birth weight) with feeding readiness using NOMAS was done.

Publication bias: A funnel plot was used to evaluate the publication bias for the LOS, showing a symmetrical pattern, and all the studies lie within a flannel (inverted triangle) shape, indicating no publication bias as shown in Figure 8.

Discussion

With the advancement in reproductive technologies, there comes a significant improvement in the survival rate of premature infants in the last few years. Underdeveloped neural and weak oral muscles responsible for lack of coordination resulted in delayed attainment of oral feeding, prolonged admission to hospital during initial hospitalization and ultimately increased the emotional and financial burden on the family and eventually on the whole society. As the attainment of independent oral feeding is the main criterion for discharge from the hospital for a healthy premature infant, an effective transition from gavage to oral feeding is therefore the most important goal of health-care professionals.

The previous reviews focusing on OMIs included PIOMI along with other OMIs (like NNS and unstructured oral massage) showing the effectiveness of oral feeding efficiency, weight gain, and total stay in the hospital during initial hospitalization. The present review is the first to focus on studies in which specific OMI, that is, PIOMI, had been used which was designed by Dr. Lessen in 2011 based on the already existing BOMI. In the review, the studies were included till October 2020 and published in the English language and to make suitable and authentic pooled results, we used the Cochrane risk of bias tool and JBI score to critically appraise the methodological quality.

Table 1: Characteristics of included studies

Author, year, country & study design	Total sample, sample size calculated or NOT	Birth wt. Mean (SD)	PMA at birth Mean (SD)	Gender (M: F)	PMA at start of oral feeding Mean (SD)	Weight at start of oral feeding Mean (SD)	Intervention		Outcomes assessed
							PIOMI	Control	
(7) Midwest Clinical trial	Total: 19 PIOMI: 10 Control: 09 Sample size not calculated	PIOMI: 1017.3 (127.1) grams Control: 913.3 (87.8) *P*=0.28	PIOMI: 28.1 (0.6) weeks Control: 28.0 (0.9) weeks *P*=0.842	PIOMI- 4:6 Control- 3:6	-	-	PIOMI for 5 min once daily for 7 days between 29 and 30 weeks	Routine care	a) Transition time from gavage to total oral feedings *p*=0.043, b) LOS: *p*=0.541
(12) Egypt RCT	Total: 50 PIOMI: 25 Control: 25 *P*=0.8716 Sample size calculated	PIOMI: 1.5 (0.2) kg Control: 1.5 (0.3) kg *P*=0.984	PIOMI: 30 weeks=11 (44%) 31 weeks=2 (8%) 32 weeks=12 (48%) Control: 30 weeks=10 (40%) 31 weeks=4 (16%) 32 weeks 11 (44%) *P*=0.8637	PIOMI- 16:9 Control: 16:9	-	-	PIOMI for 5 min once daily until independent oral feeds starting from the day when infants first tube feeding	Routine care	a) Time to achieve full oral feeding, *p*<0.001 b) LOS: *p*<0.001 c) Weight gain
(10) India RCT	Total: 30 PIOMI: 16 Control: 14 Sample size calculated	PIOMI: 1040 (120.6) grams Control: 1063.6 (79.5) grams	PIOMI: 30 (0.9) weeks Control: 30.5 (0.6)	PIOMI 8:8 Control: 8:6	PIOMI: 17.1 (4.5) days Control: 16.1 (4.7) days	PIOMI: 1041.8 (108.6) grams Control: 1067.9 (76.5) grams	PIOMI for 5 min 3 times daily for 7 days	Routine care	a) Time from gavage to full oral feeds *p*<0.001 b) LOS. *p*=0.13 c) Improvement in NOMAS score over 7 days *p*<0.001 d) Weight gain
(8) India RCT	Total: 102 PIOMI: 51 Control: 51 *P*=0.37 Sample size calculated	PIOMI: 1314.04 (105) Control: 1316.13 (80) *P*=0.91	PIOMI: 32.10 (0.8) weeks Control: 32.29 (0.6) *P*=0.19	PIOMI-28:23 Control: 24:27	PIOMI: 33.38 (0.6) weeks Control: 33.5 (0.4) *P*=0.74	PIOMI: 1286.29 (103.1) grams Control: 1309.62 (94.0) grams	PIOMI for 5 min 2 times daily till independent oral feeds	Routine care	a) Feeding performance, b) Transition to independent oral feed, *p*<0.001 c) Weight gain, d) LOS: *p*<0.001
*(11) Egypt, RCT	-	-	-	-	-	-	-	-	a) Association of infant characteristic with feeding readiness using NOMAS b) Feeding readiness and time to reach full oral feeding and LOS (*p*<0.001)

Contd...

Table 1: Contd...

Author, year, country & study design	Total sample, sample size calculated or NOT	Birth wt. M (SD)	PMA at birth Mean (SD)	Gender (M: F)	PMA at start of oral feeding Mean (SD)	Weight at start of oral feeding Mean (SD)	Intervention		Outcomes assessed
							PIOMI	Control	
(1) Thailand RCT	Total: 30 PIOMI: 15 Control: 15 p=0.473 Sample size calculated	PIOMI: 1484 (332.6) grams Control: 1843 (388.5) p=0.01	PIOMI: 30.9 (2.2) Control: 32.4 (2.3) p=0.080	PIOMI: 5:10 Control: 7:8	PIOMI: 34.3 (0.7) weeks Control: 34.5 (0.5) *p*=0.566	-	PIOMI once daily for 5 min for 7 days 15-30 min before tube feeds	Routine care	a) Mean vol. of oral intake on day 1, 3, 5 to know feeding efficiency after the start of oral feeds. b) Percent mean volume of oral intake on day 5: PIOMI: 61.66 (7.44) Control: 34.83 (8.76) p<0.001
(9) Iran Clinical trial	Total: 30 PIOMI: 15 Control: 15 Sample size not calculated	PIOMI: 1275.00 (239.23) grams Control: 1220.0 (159.23) p=0.55	PIOMI: 197.50 (6.02) days Control: 197.60 (7.09) p=0.98	PIOMI: 7:8 Control: 8:7	PIOMI: 218.60 (8.41) days Control: 225.80 (7.96) *p*=0.02	PIOMI: 1267.67 (175.21) grams Control: 1356 (120.94) grams *p*=0.12	PIOMI for 5 min once daily for 10 days starting from 29 weeks.	Routine care	a) Feeding progression, p<0.001 b) LOS: *P*=0.03 c) Weight gain
(16) Iran Clinical trial	Total: 40 PIOMI: 20 Control: 20 p=0.34 Sample size not calculated	-	-	PIOMI: 8:12 Control: 11:9	-	-	5 min PIOMI, 15 min before a feed for 7 days daily	Routine care	a) Initiation of oral feeding using POFRAS scale *P*=0.034 b) LOS: p=0.027

Baseline characteristics of included studies, M: F=Male: Female, M (SD) = Mean (standard deviation), P=Level of significance, LOS=Length of hospital stay, NOMAS=Neonatal oral-motor assessment scale, POFRAS=Preterm oral feeding readiness assessment scale, Osman* = Secondary descriptive analysis of Osman A *et al*. (2016)

The review was conducted to know the effectiveness of PIOMI on oral feeding, weight gain, and as a secondary outcome, LOS; PubMed/Medline, Embase, Ovid, Clinical Key Academia, Google, Google Scholar and other relevant databases and unpublished sources were considered. For the present review, eight studies were included in an SR and out of which six were included in an MA.

MA of included studies showed that the PIOMI intervention helps in the attainment of oral feeding in less duration, weight gain was more in the intervention group compared to the control group, and also helps in reducing LOS. Available pieces of evidence also suggested that PIOMI did not have any adverse effects such as bradycardia, apnea, aspiration, desaturation, and hypothermia. If any adverse event is reported, the intervention can be immediately stopped. This review summarized the evidence to promote clinical use and further research on the effectiveness of PIOMI. The successful shreds of evidence on PIOMI reflect the limitations of traditional care for premature infants. Researchers hope that clinical staff (nurses, doctors, therapists) can improve and update their old care manner and make use of the direction of evidence-based nursery theory.

Even though reviewers had carried out a thorough search with inclusive selection criteria, it is still a possibility that reviewers had not identified all published papers in this area. Due to the limitation of resources, reviewers were not able to separately screen at the abstract level, which may have affected the studies included. Out of eight included studies, three had not performed sample size calculations, which could be an important weakness of trials. For the present review, researchers observed different durations and frequencies while administering PIOMI in premature infants; in some studies, the intervention was provided for 5 min once a day, whereas in others it was provided thrice a day. In some studies, the intervention was provided for seven days, whereas in others, it was extended till the infant had started independent oral feeding. For the present review, the researchers tried to collect additional information which was not included in their articles, but only a few authors responded to our queries. Randomization was done only in half of the studies which might lead to biases, affecting the results.

The MA summarizes the best available evidence for the specific group, that is, healthy premature infants without any co-morbidity. Further, researchers recommend large randomized control trials with rigor methodology to have further evidence to use PIOMI among premature infants. The review included only literature published in the English language, which may result in selection bias and may affect the credibility of the pooled results of our MA. The studies included were using PIOMI for different frequencies and number of days which could question the credibility.

Conclusion

The MA concluded that PIOMI as a specific OMI for premature infants effectively improves weight and helps in the early attainment of oral feeding, reduces time from gavage to independent oral feeds, and reduces LOS during initial hospitalization. It is worthwhile to be used in hospitals to improve the clinical parameters of premature infants. Nurses and midwives play a major role in neonatal ICUs; if they perform these steps effectively then they may help in decreasing the burden on family and society. While RCTs with large participants and high quality are required to further investigate the effectiveness of PIOMI for weight gain, improvement in the amount of milk intake and NOMAS score.

Acknowledgements

First and foremost this review would not have existed without the invention of PIOMI by DR. B Lessen which is helpful for premature infants round the world, and also other researchers and reviewers who have further worked in the same regards.

Financial support and sponsorship

Nil.

Conflicts of interest

Nothing to declare.

References

1. Lessen Knoll BS, Daramas T, Drake V. Randomized controlled trial of a prefeeding oral motor therapy and its effect on feeding improvement in a Thai NICU. JOGNN-J Obstet Gynecol Neonatal Nurs 2019;48:176–88.
2. Preterm birth. Available from: https://www.who.int/news-room/fact-sheets/detail/preterm-birth.
3. Newborn health: Challenges facing preterm babies. Available from: https://www.who.int/news-room/q-a-detail/newborn-health-challenges-facing-preterm-babies.
4. Maastrup R, Hansen BM, Kronborg H, Bojesen SN, Hallum K, Frandsen A, *et al*. Factors associated with exclusive breastfeeding of preterm infants. Results from a Prospective National cohort study. PLoS One 2014;9:e89077. doi: 10.1371/journal.pone.0089077.
5. Greene Z, O'Donnell CP, Walshe M. Oral stimulation for promoting oral feeding in preterm infants. Cochrane Database Syst Rev 2016;9:CD009720. doi: 10.1002/14651858.CD009720.pub2.
6. Zainal H, Dahlui M, Soelar SA, Su TT. Cost of preterm birth during initial hospitalization: A care provider's perspective. Isangula KG, editor. PLoS One 2019;14:e0211997.
7. Lessen BS. Effect of the premature infant oral motor intervention on feeding progression and length of stay in preterm infants. Adv Neonatal Care 2011;11:129–41.
8. Thakkar PA, Rohit HR, Ranjan Das R, Thakkar UP, Singh A. Effect of oral stimulation on feeding performance and weight gain in preterm neonates: A randomised controlled trial. Paediatr Int Child Health 2018;38:181–6.
9. Ghomi H, Yadegari F, Soleimani F, Knoll BL, Noroozi M, Mazouri A. The effects of premature infant oral motor

intervention (PIOMI) on oral feeding of preterm infants: A randomized clinical trial. Int J Pediatr Otorhinolaryngol 2019;120:202–9.

10. Arora K, Goel S, Manerkar S, Konde N, Panchal H, Hegde D, *et al*. Prefeeding oromotor stimulation program for improving oromotor function in preterm infants — A randomized controlled trial. Indian Pediat**r** 2018;55:675–8.
11. Osman A. Oral feeding readiness and premature infant outcomes. J Neonatal Nurs 2019;25:111–5.
12. Osman A, Ahmed E, Mohamed H, Hassanein F, Brandon D. Oral motor intervention accelerates time to full oral feeding and discharge. Int J Adv Nurs Stud 2016;5:228.
13. Tian X, Yi LJ, Zhang L, Zhou JG, Ma L, Ou YX, *et al*. Oral motor intervention improved the oral feeding in preterm infants: Evidence based on a meta-analysis with trial sequential analysis. Medicine (Baltimore) 2015;94:e1310. doi: 10.1097/MD.0000000000001310.
14. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. Br Med J 2009;339:332–6.
15. Higgins JPT, Savović J, Page MJ, Elbers RG, Sterne JAC. Chapter 8: Assessing risk of bias in a randomized trial | Cochrane Training. Available from: https://training.cochrane.org/handbook/current/chapter-08.
16. Mahmoodi N, Knoll BL, Keykha R, Jalalodini A, Ghaljaei F. The effect of oral motor intervention on oral feeding readiness and feeding progression in preterm infants. Iran J Neonatol 2019;10:58–63.
17. Tufanaru C, Munn Z, Aromataris E, Campbell J, Hopp L. Chapter 3: Systematic reviews of effectiveness. In: JBI Manual for Evidence Synthesis. JBI; 2020. Available from: https://doi.org/10.46658/JBIMES-20-04.
18. RevMan | Cochrane Training. Available from: https://training.cochrane.org/online-learning/core-software-cochrane-reviews/revman.
19. Li XL, Liu Y, Liu M, Yang CY, Yang QZ. Early premature infant oral motor intervention improved oral feeding and prognosis by promoting neurodevelopment. Am J Perinatol 2020;37:626–32.
20. Kamitsuka MD, Nervik PA, Nielsen SL, Clark RH. Incidence of nasogastric and gastrostomy tube at discharge is reduced after implementing an oral feeding protocol in premature (<30 weeks) infants. Am J Perinatol 2017;34:606–13.
21. Skaaning D, Kronborg H, Brødsgaard A, Solmer R, Pryds O, Carlsen EM. No long-term effect of oral stimulation on the intra-oral vacuum in healthy premature infants. Acta Paediatr Int J Paediatr 2020;109:2025–32.
22. Skaaning D, Carlsen E, Brødsgaard A, Kyhnæb A, Pedersen M, Ravn S, *et al*. Randomised oral stimulation and exclusive breastfeeding duration in healthy premature infants. Acta Paediatr 2020;109:2017-24.
23. Jaywant SS, Kale JS. Comparative study on the effect of oral motor intervention protocols on oral motor skills of preterm infants from tertiary care hospital in metropolitan city: Pilot study. Int J Contemp Pediatr 2020;7:1506.
24. Jaywant SS, Dandavate PS, Kale JS. Premature infant oral motor intervention (PIOMI) with and without massage therapy on social emotional development in preterm infants. Indian J Occup Ther 2020;52:95-100.
25. Mahmoodi N, Zareii K, Mohagheghi P, Eimani M, Rezaei-Pour M. Evaluation of the effect of the oral motor interventions on reducing hospital stay in preterm infants. Alborz Univ Med J 2013;2:163–6.
26. Linlin L, Jingli C, Guofeng C. Effect of oral motor intervention on breast feeding for preterm infants discharged from hospital. J Nurses Train 2016;31:1266–9.
27. Lessen BS, Morello CA, Williams LJ. Establishing intervention fidelity of an oral motor intervention for preterm infants. Neonatal Netw 2015;34:72–82.