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The effects of premature infant oral motor intervention (PIOMI) on oral feeding of preterm infants: A randomized clinical trial

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ABSTRACT

Objective: Given the increase in the birth and survival rate of the premature infants, a need for supportive health care services becomes more evident. The goal of the present study was to examine the effectiveness of the Premature Infant Oral Motor Intervention (PIOMI) in the feeding progression and early intervention. This study was a double-blind randomized clinical trial.

Methods: This clinical trial included premature infants in the neonatal intensive care units (NICUs) of two hospitals in Tehran, who were randomly assigned into intervention and control group, each containing 15 infants. The PIOMI was administered to the intervention group in the course of 10 days. The infants in the control group received routine nursing services. Repeated measures ANOVA (RMA) were analyzed. The postmenstrual age and weight of the participants were examined at the time points of accomplishing one, four, and eight oral feedings a day and at the time of hospital discharge.

Results: The intervention group reached the first oral feeding (with a mean of 7.2 days) and eight oral feeding (with a mean of 13.47 days) earlier than the control group. The length of hospital stay in intervention group was significantly shorter ($P = 0.03$). RMA wasn't statistically significant between groups for weight (F: 0.76, P: 0.39, ŋ: 0.03); but within-subjects test showed that change of the weight over time and for interaction of time and group was significant (F: 74.437, $P < 0.001$, ŋ: 0.727). The effect size of infants' age in the measurement times was 91%.

Conclusion: the results revealed that PIOMI is a fruitful method for premature infants. We suggest that PIOMI can be integrated in feeding rehabilitation programs of the premature infants born with gestational age of as young as 26–29 weeks, and applied at 29 weeks postmenstrual age (PMA).

The clinical trial registration number: IRCT20180410039260N1.

1. Introduction

Studies conducted in the developed countries show a significant global increase in premature birth during the past 20 years [1]. On the other hand, as a result of advances in medical care, there has been a significant increase in the survival rate of infants with a gestational age of less than 30 weeks. In Iran, the survival rate of low birth weight (LBW) and very low birth weight (VLBW) infants has been reported to be 98.4% and 66.6%, respectively [2]. Infants born at a younger gestational age stay longer in the hospital, as a result, additional costs are imposed on the families and the health care system [3].

The feeding experiences of premature infants in their first year are different from full-term infants. They experience problems in eating foods with new textures, may be sensitive to them, and refuse to eat. In addition, long-term use of endo-tracheal tube or nasogastric tube for feeding can be the main cause of the later sensory problems in premature infants [4].

Because of delay in the development of oral-motor skills and poor suck-swallow-breath coordination, premature babies experience oral-feeding difficulties [5]. This coordination is necessary for safe oral feeding and prevention of apnea, aspiration, bradycardia, and hypo oxygenation [4,6]. Moreover, feeding dysfunctions require the infant to

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use a lot of energy, and may lead to developmental delay [7].

Proper and complete sucking and swallowing in premature infants is a sign of better development. In addition, early oral feeding leads to development of the gastrointestinal tract function [8].

Also, the brain of preterm infant is supposed to constantly make neuronal synaptic connections in response to sensory input and environmental stimuli [9]. Oral motor therapy is an intervention producing neurological growth and maturation during a period of high neuroplasticity while in the NICU. Best practice involves providing therapy within a neuro-protective care environment during the critically sensitive periods of brain development [10].

Most of the times, premature infants experience a period of hospitalization in the NICU. Oral feeding, physiological stability, and weight gain are among the necessary criteria for hospital discharge. The most important cause of delayed hospital discharge for premature infants is the lack of independent feeding. Therefore, oral feeding problems lead to longer hospitalization of premature infants in the NICUs, consequently imposing additional costs on the families and the health care systems of the country [5].

Thus, facilitating oral feeding of premature infants using feeding rehabilitation protocols seems to lead to better development of the infants. This is very important in reducing parental worry, preventing long-term hospitalization of infants in the NICUs, and reducing the costs.

The oral stimulation methods are used frequently in the rehabilitation programs of premature infants. Various studies have shown that providing stimulations before the start of oral feeding can lead to better maturation of the nervous system, performance improvement, and coordination of sucking, swallowing, and respiratory mechanisms [11–14].

To date, different interventions, including the Fucile's protocol, the multi-sensory intervention, the non-nutritive sucking (NNS), and the oral support have been examined and used to facilitate oral feeding in premature infants [7,15–17].

Because their implementation takes a lot of time, the oral stimulation methods used in most previous studies cannot be used for infants with a low gestational age, especially below 30 weeks. In addition, few studies have focused on the impact of oral-motor interventions before the start of oral feeding. Infants with a higher gestational age can tolerate longer stimulations, but younger infants may not benefit from those lengthy interventions due to lack of physiological stability and a small oral cavity. On the other hand, given the medical advances in the NICUs and increase in the birth and survival rate of premature infants with a gestational age of less than 30 weeks, oral-motor interventions are needed that can be tolerated by this group of infants [2].

For these reasons, the Premature Infant Oral Motor Intervention (PIOMI) was designed based on the Beckman's Oral Motor Intervention (BOMI) by Dr. Brenda Lessen. According to a study by Dr. Brenda Lessen, the PIOMI can be tolerated by infants born before 30 weeks [5], if applied at least 29 weeks and older [18]. The PIOMI is also the only preterm oral motor intervention that has established published intervention fidelity based on a formal training program to ensure it is easily taught and can be consistently and reliably performed [5,19,20].

Studies have shown that the PIOMI resulted in increased oral intake [21], reduced transition days to full oral feedings in preterm infants [5,22,23], and decreased length of hospital stay [5,24]. The PIOMI has also been associated with a statistically significant increase in direct breastfeeding rates at one month and three months after discharge from the NICU [25]. Since initial publication of the PIOMI in 2011, thirty nine NICUs in 14 countries have been formally trained to implement the program [20]. All three published meta-analysis on oral motor therapy on preterm infant populations included the PIOMI program [26–28].

The present study was aimed at answering the following questions: 1) can early intervention using the PIOMI improve the oral feeding of premature infants born with a gestational age of 26–29 weeks in the NICU?, and 2) what are the impacts of the PIOMI on the duration of reaching one, four, and eight oral feedings, weight gain and the length of hospitalization in premature infants?

2. Material & method

2.1. Study design and participants

The present randomized clinical trial (RCT) was conducted from July 2017 to January 2018 in the NICUs of the two hospitals in Tehran. A total of 30 premature infants with a gestational age of 26–29 weeks were included in the study according to the inclusion and exclusion criteria. The inclusion criteria were as follows: born with a gestational age of 26–29 weeks, physiological stability at the time of receiving oral stimulations, Apgar score of 6 at 5 min after birth, and parental consent for participation. During the stimulations, the infants could receive oxygen by continues positive airway pressure (CPAP) or nasal prong, if needed.

The exclusion criteria were as follows: congenital disorders and chromosomal abnormalities, chronic medical conditions, such as broncho-pulmonary dysplasia, intraventricular hemorrhage grade III & IV (IVH), necrotizing entero-colitis (NEC), asphyxia and seizures, neonatal jaundice necessitating exchange transfusion, and proven sepsis with positive blood culture; infants with these condition and those who were diagnosed with them during the course of the study were excluded because these factors can delayed of the oral feeding. In addition, those infants who were transferred to other treatment centers, and those who had been prescribed with gavage feeding before week 29 were excluded from the study.

Randomization was simple and used the https://www.randomizer.org site. The random assignment was done by the research assistant, therefore medical staffs were not aware of the assignments and parents because the control group receives the sham intervention were blinded to the groups.

2.2. Intervention

All neonates in study NICUs were monitored for vital signs and SPO2 routinely. We did not use a certain scale to evaluate behavioral states of the infants but in this study when any type of stimulation was presented to the infant, negative physiological cues (such as apnea or hypopnea, bradycardia or tachycardia, and/or decreased PO2) and behavioral cues (signs of stress) were continually monitored. In this program, the intervention was implemented at the beginning of 29 weeks PMA, after the pediatrician allowed for gavage feeding and infant was physiologically stable before, during, and after oral stimulations. During the PIOMI, if any negative cues observed, the stimulation was interrupted. The BOMI's original 11 steps were consolidated into 8 steps, and the 15 min were reduced to 5 min for tolerance and modified specifically for the preterm infant and accommodate the small oral cavity and beyond the excusing a pacifier no other stimulation mentioned.

PIOMI is a 5-min oral-motor protocol that is administered by a therapist. The therapist learned this intervention through a video and interview with Dr Lessen (protocol developer). After training the method, she performed it to 4–5 neonates under supervision of the group's director and filmed it, after improvement, intervention applied to intervention group.

In this protocol, facial and oral structures are stimulated at a given time and frequency according to the manual, including rolling, curling and stretching of lips, c stretch of cheeks, massage of lateral and middle borders of tongue, gums, palate and cheeks elicit sucking and NNS (Appendix 1). Given the suggestions of the previous studies regarding the importance of continuous successive stimulation, the protocol was administered to the intervention group once a day for 10 consecutive days.

Before providing the stimulations, the therapist washed her hands

with soap, water, and hand sanitizer, and put on latex gloves.

After the start of gavage feeding, the time and frequency of oral-feedings per day were decided according to the opinion of the neonatologist as routine in the ward and they were blind about grouping infants. In the present study, oral feeding means breast feeding or bottle feeding, and the criterion for independent feeding is reaching eight oral feedings per day. One oral feeding a day means that the infant can orally receive milk at least one time during a day (through bottle feeding or breastfeeding), while no sign of oxygen deprivation, apnea, or bradycardia is observed during feeding, which is recorded in a chart according to the nurse's opinion. Four and eight oral feedings were also similar to this.

The control group did not receive any stimulation other than the routine nursing services, and during the 10 days, the therapist only stood by their beds for 5 min a day.

In this study, no neurodevelopmental care program or other stimulations was used, and only mother's 24 h bedside presence, breast milk feeding and kangaroo-care was allowed. These conditions were the same for intervention and control groups. Only difference between the two groups was to get a PIOMI massage. Other conditions such as the use of a bottle and pacifier between the newborns of the intervention and control group were the same.

The participants were compared based on their postmenstrual age (PMA) and weight gain at the time of reaching one, four, and eight oral feedings per day, and at the time of hospital discharge.

The weight gain of each infant was measured and recorded using a digital balance. A digital scale sensitive to one g (Seca 334, Mobile digital baby scale, CE 0123) was used daily for weight measurement. This equipment is calibrated every 3 months by the company. The babies were weighed by the same nurse every morning without clothes and diapers and before feeding In addition, the two groups were compared in terms of the time period between the start of gavage feeding and the time of achieving full oral feeding and feeding progression.

Feeding progression means the number of days from the start of oral feeding to the time of achieving independent oral feeding. Obviously, fewer days indicate better progress.

The two groups were also compared in length of hospitalization in order to determine the effectiveness of the intervention in reducing this variable. The present study was approved by the ethics committee at the University of Social Welfare and Rehabilitation Sciences (USWR) (No, IR.USWR.REC.1396.85).

In addition, the clinical trial registration for this study is IRCT20180410039260N1.

2.3. Statistical analysis

The data were analyzed using descriptive statistics and the following statistical tests: chi-square test, independent samples *t*-test, repeated measures ANOVA, and Kolmogorov–Smirnov test. All analyses were performed using SPSS, version 18.

3. Results

A total of 45 infants were included in the study. Two infants were excluded due to sepsis, and three were excluded because they were not prescribed with gavage feeding until week 29. In addition, 4 infants were excluded due to lack of parental consent, and 3 infants died before the start of the intervention (Fig. 1).

A total of 33 infants were included in the study. Seventeen infants were assigned to the intervention and 16 infants to the control group. During the intervention, 2 infants in the intervention group were discharged from the hospital (by their parents' consent) before the end of the intervention, and 1 infant in the control group was excluded from the study due to changing their hospital.

Table 1 shows the comparison of age, gender, birth weight, and time of administering the intervention between the two groups.

Table 2 shows the comparison of PMA and weight at the time achieving one, four, and eight oral feedings and at hospital discharge between the two groups. In addition, the comparison of feeding progression and length of hospitalization is presented in the table.

The Mauchly's test was used to exam of the assumption of sphericity. Result of Mauchly's test showed that sphericity has been violated ($P < 0.001$). Therefore, the Greenhouse-Geisser correction was used to test the factor scores on the multidimensional symptoms of weight in six measurements, regarding within-subject effects (Table 3).

Fig. 2 shows the weight gain trend during hospitalization for both groups in six time measuring the weight.

In regarding age, the assumption of sphericity was not confirmed by the results of this test ($P < 0.001$). Therefore, the Greenhouse-Geisser correction was used to test the factor scores on the multidimensional symptoms of age in six measurements, regarding within-subject effects (Table 4).

Post hoc tests using the Bonferroni correction revealed that PIOMI brought about significant differences for base line (GA) and other times of measurement ($P < 0.05$).

Fig. 3 shows the age of infants in the intervention and control groups in 6 age measurements.

4. Discussion

The RMA for age in the six measurement times for the two groups clearly showed that the intervention group started oral feeding at a lower PMA, and reached independent oral feeding in less time; this indicates a faster oral-motor progression in the intervention group. Therefore, according to the results, the positive impact of the intervention on the development of oral-motor skills of the infants eventually led to their faster development and weight gain and shorter hospitalization. Reduction in the duration of hospitalization can significantly reduce the costs imposed on the families and the health care system. Considering the early birth of newborns and the consequent deprivation of spontaneous sucking and swallowing in the uterus, it seems that performing massage can be effective in the neuronal myelination and oral-motor development of these premature infants.

In addition, examination of weight gain using RMA indicated that there was a similar trend in the two groups in terms of weight gain from birth to the time of hospital discharge, and that no significant group difference was found in this variable. Given the length of hospitalization was 9 days shorter in the intervention group, we can conclude that the intervention group reached the same weight as the control group in less time and at a younger age.

In this study the infants in the intervention group discharged from the hospital 9.47 days earlier ($p = 0.03$). The infants in the present study at the time of the intervention had similar condition of health status, but were younger than the subjects of the previous studies [3,11,13,15,16,29], that led to increased length of hospitalization. However, the significant difference between the two groups in the study indicates the effectiveness of the PIOMI intervention.

In the study by Fucile, the first oral feeding happened at week 34.5 [15]. In the study by Rocha, also the first oral feeding occurred at weeks 35–36 of the PMA [13]. In the study by Lessen, the first oral feeding occurred at week 31.5 [5], and in the present study, the first oral feeding started at week 31.23. This finding may be due to intervention started at lesser PMA to others studies.

Younesian examined the effectiveness of Beckman's protocol on premature infants. It was reported that the duration of transition to independent oral feeding was 13.20 days in the intervention group and 26.90 days in the control group; this is consistent with the results of the present study. The length of hospitalization was 32.70 days in the intervention group and 38.80 days in the control group [30]. In our study duration of hospital stay in intervention and control group was 37.13 and 46.60 days respectively.

Asadollahpour compared the effectiveness of Beckman's protocol

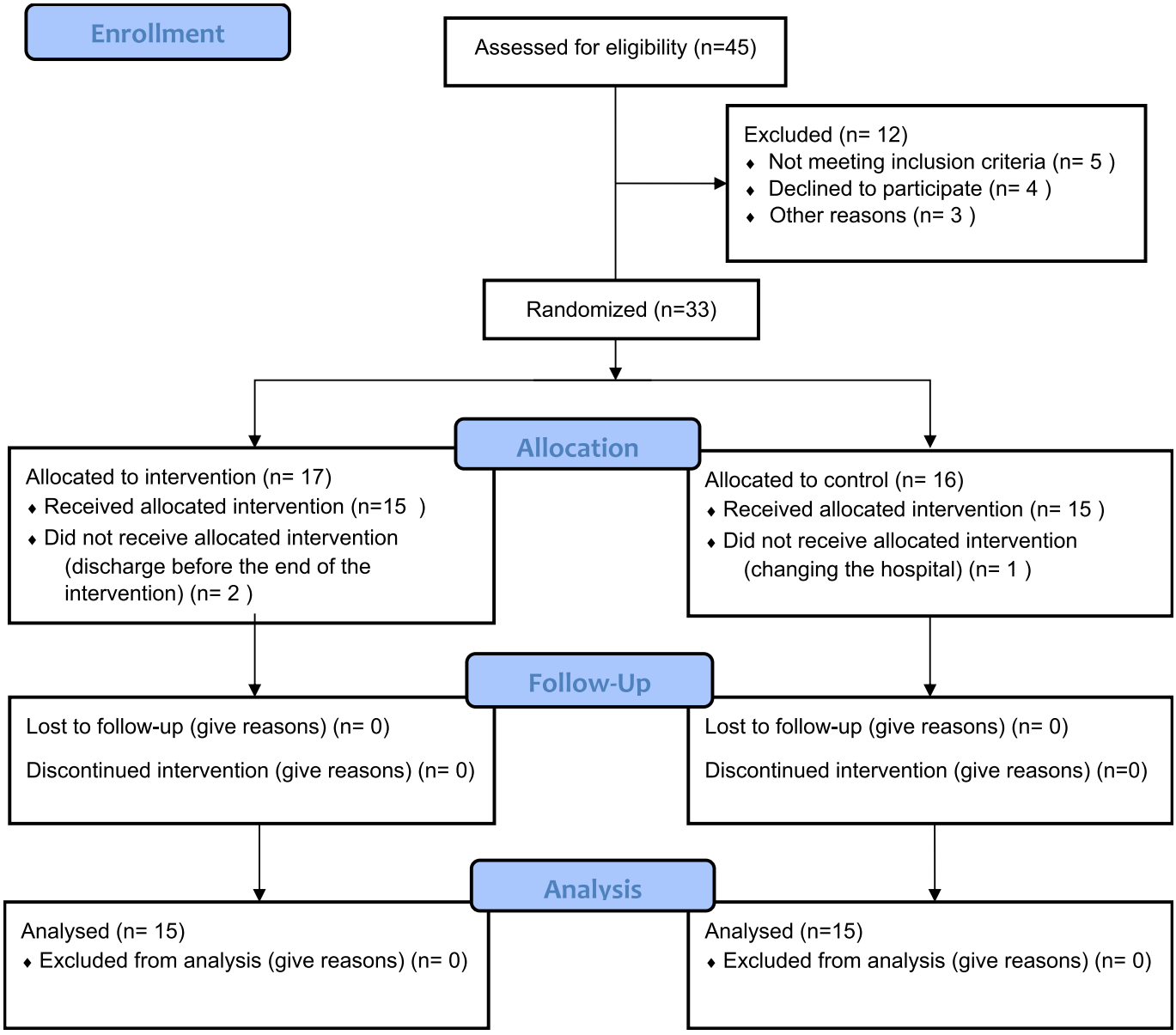

Fig. 1. Participants flowchart.

with that of the NNS among premature. It was found that the NNS group and the Beckman's group reached independent oral feeding 7.55 and 6.07 days earlier than the control group. In addition, length of hospitalization was 27.60 ± 12.57 days in the Beckman's protocol group, 26.54 ± 12.48 days in the NNS group, and 33.45 ± 13.46 days in the control group [31]. In our study, due to working with younger participants, length of hospitalization was longer than the previous studies, but the significant group differences indicated the effectiveness of our protocol.

In the study by Lessen, that used PIOMI, the duration of transition from gavage feeding to independent oral feeding in the intervention group 5 days less than the control group, but in our study this was 14 days [5]. It may be due to intervention duration that in our study was 10 days but in lessen study was 7.

Table 1
Demographic characteristic of the participants.

Characteristic		Intervention group Mean (SD)[a]	Control group Mean (SD)[a]	P-Value	DF
Gestational age at Birth (day)		197.50 (6.02)	197.60 (7.09)	0.98	0.07
Birth Weight (gr)		1275.00 (239.23)	1220.00 (159.23)	0.46	0.55
Gender Distribution (number)	Female	8 (26.7%)	7 (23.3%)	0.70	
	Male	7 (23.3%)	8 (26.7%)		
PMA[b] at the Beginning of gavage (days)		203.13 (4.40)	201.87 (6.80)	0.55	- 1.27
Weight (gr) at the beginning of gavage		1218.67 (214.87)	1167.34 (161.09)	0.46	- 51.33

[a] Standard deviation.
[b] Postmenstrual Age: The sum of fetal and chronological age.

Table 2
Comparison of the characteristics of the two groups.

Variable	Intervention group Mean (SD)[a]	Control group Mean (SD)[a]	P-Value	DF
PMA[b] at the time of the first oral feeding	218.60 (8.41)	225.80 (7.96)	0.02	7.20
weight at the time of the first oral feeding (gr)	1267.67 (175.21)	1356 (120.94)	0.12	88.33
PMA at the time of the fourth oral feedings per day	222.67 (8.96)	232.80 (8.28)	0.03	10.13
weight at the time of the fourth oral feedings per day (gr)	1315.67 (167)	1431.67 (115.29)	0.03	116.00
PMA at the time of eighth oral feedings per day (full oral feeding)	226.67 (9.25)	240.13 (8.60)	P < 0.001	13.47
weight at the time of eighth oral feedings per day (full oral feeding) (gr)	1358.33 (162.01)	1487.00 (111.69)	0.017	128.67
PMA at the discharge	234.67 (10.47)	244.20 (9.33)	0.014	9.53
Weight at the discharge (gr)	1498.33 (128.47)	1546.67 (96.84)	0.25	48.33
Feeding progression (day)	8.07 (2.58)	14.33 (4.70)	P < 0.001	6.27
Duration of gavage to independent oral feeding (day)	23.53 (8.10)	38.27 (9.59)	P < 0.001	14.73
Duration of hospital stay (day)	37.13 (11.70)	46.60 (11.35)	0.03	9.47

[a] Standard deviation.
[b] Post-Menstrual Age: The sum days of fetal and chronological age.

Table 3
Results of within- and between-subject repeated measures ANOVA for weight in six measurements in the intervention and control groups.

Source	Type III Sum of Squares	DF	Mean Square	F	Sig	Partial Eta Squared
between-subjects						
Group	94531.250	1.00	94531.250	0.76	0.39	0.03
Error	3468891.111	28.00	123888.97			
Within-Subjects						
Factor	2162105.694	1.663	1299954.261	74.437	< 0.001	0.727
factor * GROUP	249044.583	1.663	149736.698	8.574	0.001	0.23
Error	813295.556	46.570	174663.911			

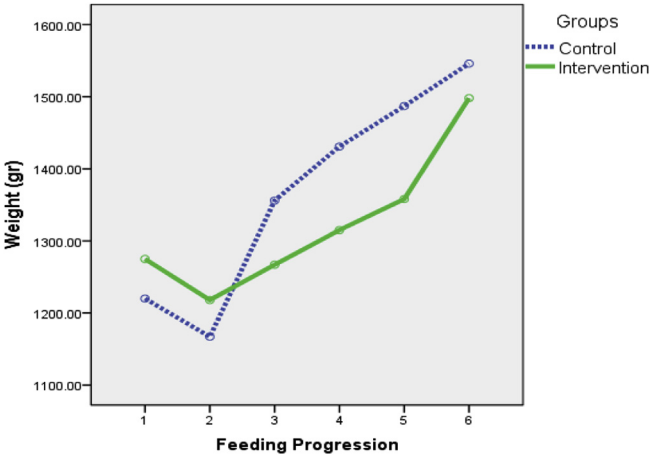

Fig. 2. Weight gain due to the feeding progression. 1: Birth Weight; 2: Weight at the beginning of gavage; 3: weight at the time of the first oral feeding; 4: weight at the time of the fourth oral feedings per day; 5: weight at the time of eighth oral feedings per day; 6: Weight at the discharge.

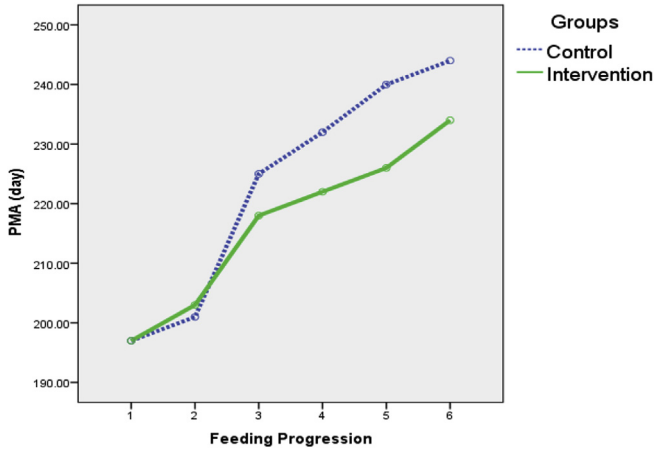

Fig. 3. Comparing the PMA and feeding progression. 1: Gestational age; 2: PMA at the beginning of gavage; 3: PMA at the time of the first oral feeding; 4: PMA at the time of the fourth oral feedings per day; 5: PMA at the time of eighth oral feedings per day; 6: PMA at the discharge.

Lyu et al. used the Fucile's method was used with infants with a gestational age of 29–34 weeks. No difference was found between the intervention and control groups in weight gain and length of hospitalization. In this study, The duration of feeding progression was 4 days in the intervention less than control group [32]. In our study duration of feeding progression in intervention group was 6.27 days

Table 4
Results of within- and between-subject repeated measures ANOVA for age in six measurements in the intervention and control groups.

Source	Type III Sum of Squares	DF	Mean Square	F	Sig	Partial Eta Squared
between-subjects						
Group	1914.272	1.00	1914.272	7.750	0.01	0.217
Error	6916.422	28.00	247.015			
Within-Subjects						
Factor	42900.761	1.438	29837.058	288.692	< 0.001	0.912
factor * GROUP	1298.494	7.438	903.090	8.738	0.002	0.238
Error	4160.911	40.259	103.353			

shorter. Bache also examined the effectiveness of oral stimulations before the start of oral feeding with infants with a gestational age of 26–33 weeks. According to the results of this study, no significant difference was found between the intervention and control groups in duration of transition to oral feeding and length of hospitalization [4]. These findings relate to intervention methods and age of infants.

5. Conclusions

In the present study, appears that the PIOMI is totally appropriate for premature infants at least on 29 PMA weeks, and that 10 days of 5-min intervention using this method can have a positive impact on the development of oral-motor skills, feeding progression, and reduction in the duration of hospitalization in this age group.

5.1. Strong points of our study

Introducing a tolerable protocol for infants with 29 weeks PMA and short intervention time, that reduces hospitalization and reduces costs in developing countries.

5.2. Weak points of our study

Participant loss and the need for precise control of physiological symptoms for this age group were the limitations of this study.

In order to better investigate the effectiveness of the PIOMI, studies with larger sample size are commended.

Declarations of interest

None.

Conflicts of interest

No conflict of interest to declare.

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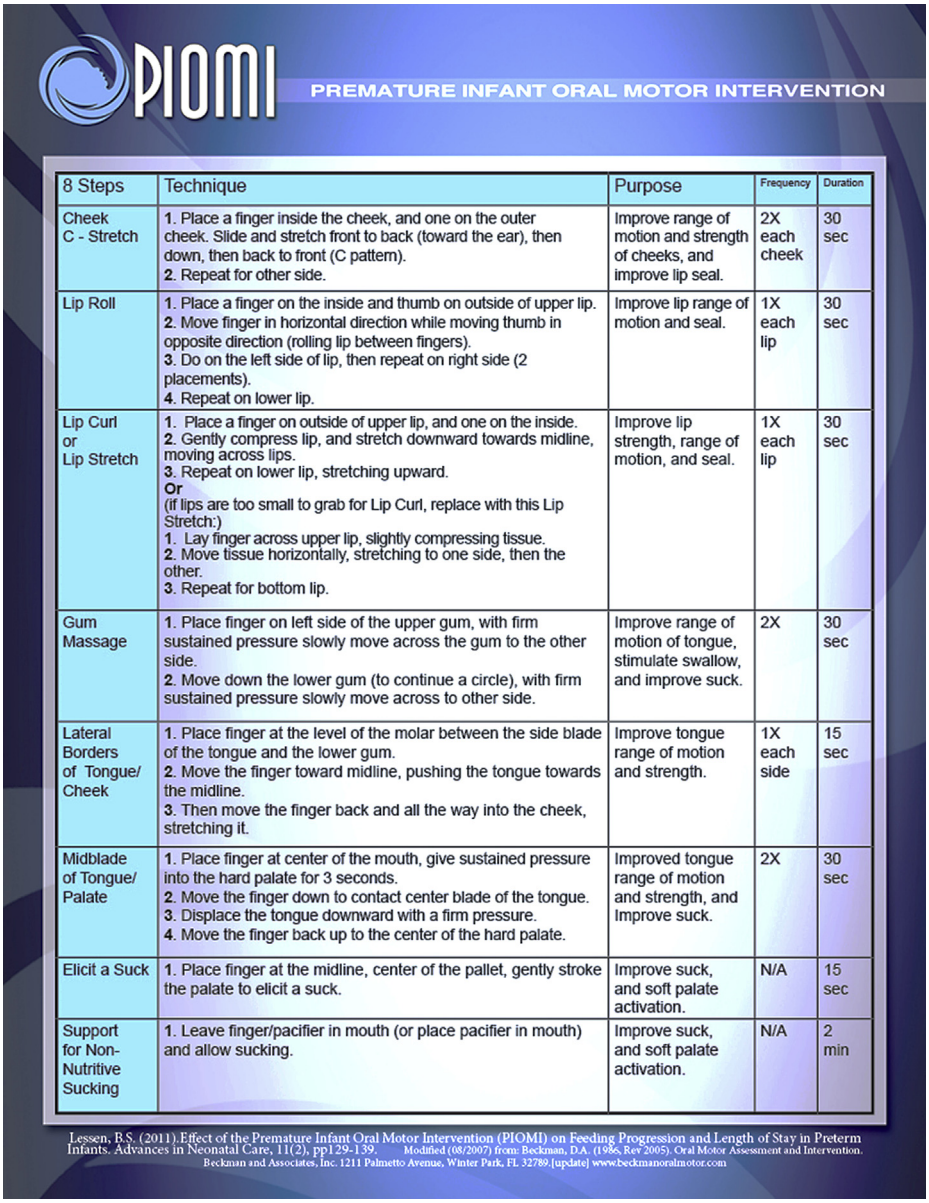
Appendix1



8 Steps	Technique	Purpose	Frequency	Duration
Cheek C - Stretch	1. Place a finger inside the cheek, and one on the outer cheek. Slide and stretch front to back (toward the ear), then down, then back to front (C pattern). 2. Repeat for other side.	Improve range of motion and strength of cheeks, and improve lip seal.	2X each cheek	30 sec
Lip Roll	1. Place a finger on the inside and thumb on outside of upper lip. 2. Move finger in horizontal direction while moving thumb in opposite direction (rolling lip between fingers). 3. Do on the left side of lip, then repeat on right side (2 placements). 4. Repeat on lower lip.	Improve lip range of motion and seal.	1X each lip	30 sec
Lip Curl or Lip Stretch	1. Place a finger on outside of upper lip, and one on the inside. 2. Gently compress lip, and stretch downward towards midline, moving across lips. 3. Repeat on lower lip, stretching upward. **Or** (if lips are too small to grab for Lip Curl, replace with this Lip Stretch:) 1. Lay finger across upper lip, slightly compressing tissue. 2. Move tissue horizontally, stretching to one side, then the other. 3. Repeat for bottom lip.	Improve lip strength, range of motion, and seal.	1X each lip	30 sec
Gum Massage	1. Place finger on left side of the upper gum, with firm sustained pressure slowly move across the gum to the other side. 2. Move down the lower gum (to continue a circle), with firm sustained pressure slowly move across to other side.	Improve range of motion of tongue, stimulate swallow, and improve suck.	2X	30 sec
Lateral Borders of Tongue/ Cheek	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 midline. 3. Then move the finger back and all the way into the cheek, stretching it.	Improve tongue range of motion and strength.	1X each side	15 sec
Midblade of Tongue/ Palate	1. Place finger at center of the mouth, give sustained pressure into the hard palate for 3 seconds. 2. Move the finger down to contact center blade of the tongue. 3. Displace the tongue downward with a firm pressure. 4. Move the finger back up to the center of the hard palate.	Improved tongue range of motion and strength, and Improve suck.	2X	30 sec
Elicit a Suck	1. Place finger at the midline, center of the pallet, gently stroke the palate to elicit a suck.	Improve suck, and soft palate activation.	N/A	15 sec
Support for Non-Nutritive Sucking	1. Leave finger/pacifier in mouth (or place pacifier in mouth) and allow sucking.	Improve suck, and soft palate activation.	N/A	2 min

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