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Effect of Premature Infant Oral Motor Intervention on sEMG-Based Muscle Activity and Feeding Outcomes in Preterm Infants: A Randomized Controlled Trial

shamim ghazi
University of Social Welfare and Rehabilitation Sciences
Zahra Sadeghi
zah.sadeghi@uswr.ac.ir

University of Social Welfare and Rehabilitation Sciences
Farin Soleimani
University of Social Welfare and Rehabilitation Sciences
Brenda Lessen Knoll
Illinois Wesleyan University
Iraj Abdollahi
University of Social Welfare and Rehabilitation Sciences
Enayatollah Bakhshi
University of Social Welfare and Rehabilitation Sciences

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Abstract

Purpose

To investigate the effects of Premature Infant Oral Motor Intervention (PIOMI) on surface electromyography (sEMG)-based orofacial muscle activity and feeding-related outcomes in preterm infants with feeding disorders.

Methods

In this randomized controlled trial, 60 preterm infants admitted to neonatal intensive care units in Babol, Iran, were randomly assigned to PIOMI or routine care. PIOMI was administered for 7 days. The primary outcome was sEMG root mean square (RMS) amplitude of the zygomaticus, orbicularis oris, and masseter muscles during non-nutritive sucking. Secondary outcomes included oral feeding readiness, body weight, milk intake, length of hospital stay, and feeding method. Between-group differences were assessed using baseline-adjusted analysis of covariance.

Results

All infants completed the study. Compared with routine care, PIOMI resulted in significantly greater post-intervention sEMG RMS amplitudes for the zygomaticus, orbicularis oris, and masseter muscles)η^2 ranging from 0.77 to 0.85(, as well as higher POFRAS scores and body weight. Milk intake did not differ significantly between groups. Hospital stay was shorter in the PIOMI group (20.60 ± 8.44 vs 30.09 ± 11.70 days; $P < 0.001$), and a greater proportion received breast milk (73.3% vs 36.7%; $P < 0.001$). Changes in POFRAS scores were positively correlated with changes in sEMG activity of all three muscles.

Conclusion

Seven days of PIOMI was associated with greater sEMG-measured orofacial muscle activity and improvements in several feeding-related outcomes in preterm infants with feeding disorders. These findings support further investigation of PIOMI and the clinical validity and reproducibility of sEMG measures in this population.

Trial registration:

IRCT20250205064649N1; registered 1 March 2025.

What is known?

PIOMI has been associated with improved feeding-related outcomes in preterm infants, but evidence remains heterogeneous and objective measures of treatment-related orofacial muscle activity are limited.

What is New?

This randomized controlled trial provides objective sEMG evidence of changes in selected orofacial muscle activity following PIOMI and examines these changes alongside clinical feeding outcomes.

Introduction

Oral feeding is a complex sensorimotor process requiring coordinated activity of the orofacial structures involved in sucking, swallowing, and respiration [1, 2]. In preterm infants, immature oral-motor skills may interfere with the transition from tube feeding to independent oral feeding and contribute to delayed feeding progression [3, 4]. Feeding disorders may manifest as inefficient sucking, difficulty coordinating sucking, swallowing, and respiration, and prolonged dependence on tube feeding [1, 2, 4]. Therefore, early interventions targeting oral-motor and feeding skills may facilitate the development of independent oral feeding and reduce feeding-related delays in preterm infants.

The Premature Infant Oral Motor Intervention (PIOMI) is a structured oral-motor stimulation program developed to support the acquisition of oral feeding skills in preterm infants [4–6]. Previous studies have reported potential benefits of PIOMI and related oral-motor interventions on feeding progression, oral feeding readiness, sucking capacity, and weight gain [4–9]. However, an updated Cochrane review of 28 randomized controlled trials involving 1,831 preterm infants found low- or very-low-certainty evidence for several clinically important outcomes, including transition to oral feeding and length of hospital stay [10]. Differences in intervention protocols, participant characteristics, and outcome measures may contribute to variability across studies [10]. Further well-designed trials are therefore needed to evaluate the effects of PIOMI using both clinically relevant outcomes and complementary objective measures of treatment-related changes.

Clinical measures such as the Preterm Infant Oral Feeding Readiness Assessment Scale (POFRAS) have been widely used to assess feeding readiness and performance [11–13]. Although such measures provide clinically relevant information, they do not directly characterize muscle activation. Surface electromyography (sEMG) is a noninvasive method for recording electrical signals associated with skeletal muscle activation and has been used to characterize orofacial muscle activity during infant feeding [14–16]. Combining sEMG with clinical feeding measures may therefore provide complementary information regarding physiological and functional changes associated with oral-motor intervention.

Interpretation of sEMG findings in infants requires consideration of the motor task and feeding condition. Previous electromyographic studies have demonstrated measurable activity of the masseter and other orofacial muscles during infant feeding and have reported differences according to feeding method and infant population [14–16]. Importantly, non-nutritive sucking (NNS) differs from nutritive feeding. NNS involves sucking without milk transfer, whereas nutritive feeding requires coordinated sucking, swallowing, and respiration during milk transfer [17]. Therefore, sEMG recorded during NNS should not be interpreted as a direct measure of neuromuscular function during nutritive feeding or swallowing. Rather, NNS-based sEMG can provide complementary information about the activation of selected orofacial muscles during a standardized motor task, whereas clinical feeding measures provide information about functional feeding performance [18].

Despite increasing clinical interest in PIOMI, its effects on objectively measured orofacial muscle activity remain insufficiently characterized. Previous PIOMI studies have primarily focused on functional outcomes, including feeding progression, oral feeding, sucking capacity, feeding readiness, and weight gain [4–9]. In

contrast, infant sEMG studies have examined orofacial muscle activity under different feeding conditions and in different populations, including term infants during nutritive feeding and preterm infants during breastfeeding [14–16]. Consequently, to the best of our knowledge, no previous studies have investigated changes in sEMG-derived activity of specific orofacial muscles following PIOMI in preterm infants. Evaluating sEMG-based muscle activity alongside clinically relevant feeding outcomes may provide complementary information about physiological and functional changes associated with PIOMI.

Previous studies of oral motor interventions in preterm infants have reported heterogeneous findings regarding feeding outcomes [10]. Furthermore, the reliance on clinical assessments may limit understanding of the physiological changes underlying treatment effects. Combining sEMG with clinical assessments may provide complementary insights into orofacial muscle activity and feeding performance. However, the effects of PIOMI on sEMG-derived activity of specific orofacial muscles remain unexplored. Therefore, this randomized controlled trial aimed to evaluate the effects of PIOMI on sEMG-derived activity of the zygomaticus, orbicularis oris, and masseter muscles, as well as on clinically relevant feeding outcomes in preterm infants with feeding disorders. We also explored associations between changes in muscle activity and feeding readiness. We hypothesized that PIOMI would result in greater changes in muscle activity and more favorable feeding outcomes than routine care.

Methods

Study Population and Setting

This randomized controlled trial was conducted in three NICUs in three hospitals in Mazandaran Province, Iran, between February and December 2025. The participating NICUs followed the same routine neonatal care and feeding protocols. All units were equipped with standard cardiorespiratory monitoring systems and staffed by multidisciplinary teams, including neonatologists, pediatricians, nurses, speech-language pathologists, and other allied health professionals.

Routine feeding management was standardized across the participating NICUs. Enteral feeding was initiated and advanced according to the infant's clinical condition, gestational maturity, feeding tolerance, and prescribed enteral feeding plan. Oral feeding was considered when the infant was physiologically stable and demonstrated clinical signs of oral feeding readiness, including an appropriate level of alertness, stable cardiorespiratory status, the presence of feeding cues such as rooting, the ability to sustain nonnutritive sucking, and emerging coordination of sucking, swallowing, and breathing. Decisions regarding initiation and progression of oral feeding were made by the neonatal care team as part of routine clinical care. Lactation support and feeding therapy provided by speech-language pathologists were available in all participating NICUs. No additional oral-motor intervention outside the scheduled study intervention was provided during the study period.

The study protocol was approved by the Research Ethics Committee of the University of Social Welfare and Rehabilitation Sciences (IR.USWR.REC.1403.252). The trial was prospectively registered in the Iranian Registry of Clinical Trials (IRCT20250205064649N1). The study was conducted in accordance with the principles of the Declaration of Helsinki and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Participants

Preterm infants were eligible for inclusion if they met the following criteria: (1) gestational age of 29–36 weeks at birth; (2) a diagnosis of feeding disorder, as determined by the attending neonatologist based on clinical assessment. Feeding disorder was identified by the presence of one or more clinically evident feeding difficulties, including impaired suck–swallow–breathing coordination, feeding intolerance during enteral feeding, or delayed transition from tube to oral feeding. These features were assessed as part of routine neonatal clinical care and documented in the infant's medical record. (3) clinical stability at enrollment; (4) Apgar score ≥ 6 at 5 minutes after birth; and (5) absence of major congenital anomalies, chromosomal abnormalities, or severe medical conditions that could interfere with feeding or study procedures, including grade III–IV intraventricular hemorrhage, necrotizing enterocolitis, bronchopulmonary dysplasia, neonatal sepsis, seizures, or birth asphyxia.

Infants were excluded if they were receiving concurrent oral-motor therapy, participating in another interventional study, or had medical conditions that could interfere with study procedures or compromise safety.

Sample Size

The minimum required sample size was calculated a priori based on the results of a previous comparable study [4]. Assuming 80% statistical power and a two-sided alpha level of 0.05, 27 infants per group were required. To account for an anticipated 10% attrition rate, three additional infants were recruited per group, resulting in a final target sample of 30 infants per group (60 infants in total).

Randomization and Allocation

After eligibility was confirmed, the responsible speech-language pathologist (SLP) enrolled the infant into the study. Participants were randomly allocated in a 1:1 ratio to either the PIOMI intervention group or the control group using a computer-generated randomization sequence. The allocation sequence was stratified according to small-for-gestational-age (SGA) status. SGA was defined as birth weight below the 10th percentile for gestational age according to the Fenton preterm growth chart [19]. Infants with birth weight ≥ 10th percentile were classified as appropriate-for-gestational-age (AGA). Six SGA infants were allocated to each study group.

The allocation sequence was generated and concealed by an independent researcher who was not involved in participant recruitment, intervention delivery, or outcome assessment. Group assignments were placed in sequentially numbered, opaque, sealed envelopes. The envelopes were securely maintained and opened only after completion of the participant's baseline assessments. The responsible SLP opened the next envelope to determine the infant's group allocation. Thus, allocation was concealed until the participant had been enrolled and baseline measurements had been obtained.

Intervention: Premature Infant Oral Motor Intervention (PIOMI)

The intervention group received PIOMI, a structured five-minute oral-motor stimulation program adapted from the Bonn Oral Motor Intervention [20]. PIOMI involves systematic tactile stimulation of the lips, cheeks, gums, tongue, and palate using finger-based techniques such as gentle pressure, stroking, and stretching to enhance activation and coordination of orofacial musculature involved in feeding (Fig. 1) [4].

The first author received training in the PIOMI protocol from the developer and subsequently administered the intervention according to the standardized protocol. Intervention fidelity was maintained through adherence to the predefined sequence and duration of the intervention [21]. Infants were positioned in a stable and supported position, typically prone or supported supine within the incubator, according to their clinical condition. The intervention was postponed or discontinued if the infant demonstrated physiological instability or behavioral stress cues, including apnea, bradycardia, oxygen desaturation, or other observable signs of intolerance or stress. No scheduled PIOMI sessions were missed, and all infants in the intervention group completed the planned seven sessions. No adverse events related to the intervention were observed during or immediately after the PIOMI sessions.

Parents, nurses, and other clinicians did not perform additional oral-motor stimulation or other oral-motor intervention outside the scheduled PIOMI sessions during the study period. Infants in the control group received routine NICU care, including standard feeding management, positioning, nesting and swaddling as clinically indicated, and routine environmental care such as minimizing excessive noise and light exposure. No additional oral-motor intervention was provided to control-group infants during the intervention period.

Outcome Measures

Primary outcome: sEMG-Based Orofacial Muscle Activity

sEMG activity was recorded using a MyOnyx 4-Channel Encoder System (Thought Technology Ltd., Montreal, Canada) with BioGraph Infiniti software in PC Control mode. Raw EMG signals were acquired at a sampling rate of 2048 samples/s. sEMG recordings were obtained from the right masseter, zygomaticus, and orbicularis oris muscles, with the mastoid region used as the reference site. Bipolar surface electrodes were placed with an interelectrode distance of approximately 2 cm. The right side was selected to standardize electrode placement and minimize variability in recording conditions across participants and assessment sessions. Before electrode placement, the skin was gently cleaned using sterile water-moistened cotton to improve electrode contact while minimizing skin irritation.

Muscle locations were identified using standard anatomical landmarks and palpation during the relevant oral-motor activity. For the masseter, electrodes were positioned over the muscle belly in the region of greatest palpable activity during jaw contraction. For the zygomaticus, electrodes were placed along the muscle belly extending from the zygomatic region toward the corner of the mouth. For the orbicularis oris, electrodes were positioned around the perioral region over the muscle fibers involved in lip closure. Infants were assessed in a calm and clinically stable state and recordings were obtained under the NNS condition at both baseline and intervention assessments. Signal segments contaminated by artifacts were excluded according to the predefined signal-processing procedure. RMS amplitude was calculated using nonoverlapping 5-second windows from artifact-free signal segments. Rather than representing a single sucking episode, sEMG activity was quantified across multiple artifact-free 5-second windows recorded during the NNS assessment. The mean

RMS amplitude across all artifact-free 5-second windows was calculated for each muscle and used as the participant-level outcome. No maximum voluntary contraction (MVC) normalization or baseline-based normalization was performed because these procedures are not feasible or readily standardized in preterm infants. Therefore, raw RMS amplitudes obtained under standardized recording conditions were used for between-group comparisons.

Assessor Blinding

Outcome assessments were performed by an independent assessor who was blinded to participants' group allocation, was not involved in intervention delivery or sEMG data processing. Following completion of the assessments, the sEMG data were transferred to an independent physiotherapist for signal processing. Because of the nature of the intervention, blinding of the caregivers and intervention provider was not feasible.

Secondary Outcomes

Secondary outcomes included oral feeding readiness, total enteral milk intake, feeding method, body weight, and length of hospital stay. Oral feeding readiness was assessed using the Persian version of the POFRAS, a validated standardized and observer-based scoring instrument for evaluating oral feeding competence in preterm infants, administered according to its published scoring guidelines [13]. The POFRAS has a maximum score of 36, with higher scores indicating greater readiness for oral feeding. The scale evaluates behavioral, physiological, oral-motor, and feeding-related readiness characteristics. The assessor received standardized training from an experienced faculty member before data collection.

Total enteral milk intake was obtained from standardized neonatal feeding records and recorded over a 24-hour period at baseline and after completion of the seven-day intervention period. Feeding method at the post-intervention assessment was categorized as breast-milk feeding or tube feeding. Body weight was measured daily using a calibrated digital neonatal scale under standardized conditions. Measurements were obtained at approximately the same time each day and recorded in grams. Length of hospital stay (LOS) was calculated as the number of days from birth to hospital discharge based on official hospital records.

Data Collection Procedure

Eligible infants were identified through systematic screening of admissions to the participating NICUs. After eligibility was confirmed and written informed consent was obtained from the parent or legal guardian, baseline demographic and clinical characteristics were recorded before randomization. Baseline sEMG recordings and feeding-related assessments were then performed. Following completion of baseline assessments, participants were randomized to either the PIOMI or control group. The intervention group received the intervention once daily for seven consecutive days, approximately 15 minutes before feeding, whereas control-group infants received routine NICU care without additional oral-motor intervention. Post-intervention sEMG and feeding-readiness assessments were performed after completion of the seven-day intervention period using the same procedures and recording conditions as at baseline. The assessor performing outcome assessments was blinded to group allocation. Total enteral milk intake and body weight were obtained from standardized clinical records throughout the study period.

Statistical Analysis

All statistical analyses were performed using SPSS Statistics version 26. Continuous variables were summarized using means and standard deviations, while categorical variables were presented as frequencies and percentages. Baseline demographic characteristics were summarized descriptively for the two groups. For continuous post-intervention outcomes, including sEMG RMS amplitude, POFRAS score, body weight, and total enteral milk intake, analysis of covariance (ANCOVA) was used to compare the groups while adjusting for the corresponding baseline value. Adjusted between-group differences were reported using F statistics, p values, and partial eta squared (η^2p) as a measure of effect size. Partial eta-squared values are considered small if they range between 0.05 and 0.10, moderate if they range between 0.10 and 0.20, and large if they are greater than 0.20 [22]. Length of hospital stay was compared between groups using an independent-samples t test. The distribution of feeding method at the relevant assessment point was compared between groups using the chi-square test, with the phi coefficient reported as an effect-size measure. Exploratory Pearson correlation analyses were conducted to examine associations between changes in POFRAS scores and changes in sEMG RMS amplitude. Change scores were calculated as post-intervention minus baseline values. All statistical tests were two-sided, and a p value < 0.05 was considered statistically significant.

Results

Participant Characteristics

A total of 60 preterm infants were enrolled and randomized to either the intervention group (n = 30) or the control group (n = 30). All participants completed the study protocol and were included in the final analyses (Fig. 2).

Baseline demographic and clinical characteristics are presented in Table 1. The mean gestational age at enrollment was 32.50 ± 2.37 weeks in the intervention group and 32.70 ± 2.48 weeks in the control group. Mean birth weight was 1973.8 ± 522.1 g in the intervention group and 2183.0 ± 570.9 g in the control group. The sex distribution was comparable between groups, with 15 male (50.0%) and 15 female (50.0%) infants in the intervention group, and 13 male (43.3%) and 17 female (56.7%) infants in the control group. No statistically significant differences were observed between groups for any baseline demographic characteristic)P > 0.05).

Table 1
Baseline demographic and clinical characteristics of preterm infants

Characteristics	Intervention group (n = 30)	Control group (n = 30)	P-value
Gestational age (weeks)	32.50 ± 2.37*	32.70 ± 2.48	0.751**
Birth weight (grams)	1973.8 ± 522.1	2183.0 ± 570.9	0.144**
Sex, n (%)			0.605***
Boy	15 (50%)	13 (43.3%)	
Girl	15 (50%)	17 (56.7%)	
* Mean ± SD			
**Independent T Test			
***X^2 Test			

Primary Outcome: sEMG-Based Orofacial Muscle Activity

The primary outcome was sEMG-based electrical activity of the zygomaticus, orbicularis oris, and masseter muscles during non-nutritive sucking. Before and after the intervention descriptive values are presented in Table 2.

Table 2
Descriptive statistics and effects of premature infant oral motor intervention on primary and secondary outcome measures based on an ANCOVA

	Control group M (SD)		Intervention group, PIOMI M (SD)			
	Baseline	**Post-intervention**	**Baseline**	**Post-intervention**	**F**	**η^{2*}**
Primary						
sEMG Zygomatic (μV)	29.26(4.81)	31.03(5.87)	28.56(5.51)	72.53(12.41)	< 0.001	0.85
sEMG Orbicularis oris (μV)	31.19(12.74)	36.54(13.08)	25.59(7.71)	97.23(36.28)	< 0.001	0.56
sEMG Masseter (μV)	29.91(5.93)	31.94(8.92)	28.49(7.52)	68.33(15.53)	< 0.001	0.77
Secondary						
POFRAS	14.10(4.94)	18.43(5.15)	13.97(5.22)	24.77(6.59)	< 0.001	0.47
Weight(g)	2183.03(570.94)	2458.50(599.90)	1973.80(522.05)	2685.00(668.61)	< 0.001	0.28
Milk intake volume (mL)	47.00(13.93)	49.00(14.23)	47.33(13.11)	52.67(18.18)	0.39	0.01

PIOMI, Premature Infant Oral Motor Intervention; POFRAS, Preterm Infant Oral Feeding Readiness Assessment Scale

* η^2 0.05–0.1: small; η^2 0.1–0.2: medium; η^2 > 0.2: large

For the zygomaticus muscle, mean sEMG RMS amplitude increased from 28.56 ± 5.51 μV at baseline to 72.53 ± 12.41 μV after the intervention in the PIOMI group, whereas it increased from 29.26 ± 4.81 μV to 31.03 ± 5.87 μV in the control group. After adjustment for the baseline measurement, ANCOVA demonstrated a statistically significant between-group difference in post-intervention zygomaticus activity ($F_{1,57}$ = 318.90, P < 0.001; partial η^2 =0.85).

For the orbicularis oris muscle, sEMG RMS amplitude increased from 25.59 ± 7.71 μV to 97.23 ± 36.28 μV in the PIOMI group, compared with an increase from 31.19 ± 12.74 μV to 36.54 ± 13.08 μV in the control group. The between-group difference remained statistically significant after adjustment for baseline activity ($F_{1,57}$ = 71.82, P < 0.001; partial η^2 =0.56).

Similarly, masseter sEMG RMS amplitude increased from 28.49 ± 7.52 μV at baseline to 68.33 ± 15.53 μV after the intervention in the PIOMI group, compared with an increase from 29.91 ± 5.93 μV to 31.94 ± 8.92 μV in the

control group. ANCOVA demonstrated a statistically significant between-group difference after adjustment for baseline masseter activity ($F_{1,57}$ = 185.29, P < 0.001; partial η^2 =0.77).

Secondary Outcomes

Oral feeding POFRAS scores increased from 13.97 ± 5.22 at baseline to 24.77 ± 6.59 after the intervention in the PIOMI group, whereas scores increased from 14.10 ± 4.94 to 18.43 ± 5.15 in the control group. After adjustment for baseline, ANCOVA demonstrated a statistically significant between-group difference in post-intervention POFRAS scores ($F_{1,57}$ = 51.20, P < 0.001; partial η^2 =0.47) (Table 2).

Mean body weight increased from 1973.80 ± 522.05 g at baseline to 2685.00 ± 668.61 g after the intervention in the PIOMI group, compared with an increase from 2183.03 ± 570.94 g to 2458.50 ± 599.90 g in the control group. Baseline-adjusted ANCOVA demonstrated a statistically significant between-group difference in post-intervention body weight ($F_{1,57}$ = 22.34, P < 0.001; partial η^2 =0.28) (Table 2).

Mean milk intake volume increased from 47.33 ± 13.11 mL at baseline to 52.67 ± 18.18 mL after the intervention in the PIOMI group, compared with an increase from 47.00 ± 13.93 mL to 49.00 ± 14.23 mL in the control group. After adjustment for baseline milk intake, the between-group difference was not statistically significant ($F_{1,57}$ = 0.74, P = 0.394; partial η^2 =0.01) (Table 2).

The mean length of hospital stay was 20.60 ± 8.44 days in the intervention group and 30.09 ± 11.70 days in the control group. An independent-samples t test demonstrated a statistically significant between-group difference (t = 3.32, P < 0.001; partial η^2 =0.16), with a shorter mean hospital stay observed in the intervention group.

At baseline, all infants were receiving tube feeding. After the 7-day intervention period, 73.3% of infants in the intervention group were receiving breast milk, whereas 26.7% remained on tube feeding. In the control group, 36.7% were receiving breast milk and 63.3% remained on tube feeding. The distribution of feeding method differed significantly between the groups (χ^2 = 8.148, P < 0.001; φ = 0.36).

Associations between changes in muscle activity and feeding readiness

Exploratory Pearson correlation analyses were conducted to examine associations between changes in POFRAS scores and changes in sEMG-based orofacial muscle activity. Change scores were calculated after the intervention minus baseline values, and analyses were performed using the total sample (N = 60).

Changes in POFRAS scores were positively correlated with changes in zygomaticus sEMG RMS amplitude (r = 0.597, P < 0.001), orbicularis oris sEMG RMS amplitude (r = 0.671, P < 0.001), and masseter sEMG RMS amplitude (r = 0.557, P < 0.001).These findings indicate that greater increases in measured orofacial muscle electrical activity were associated with greater improvements in oral feeding readiness (Table 3).

Table 3
Correlations between changes in POFRAS scores and changes in orofacial muscle activity

POFRAS Variables	R	P
Zygomaticus sEMG RMS	0.597	< 0.001
Orbicularis oris sEMG RMS	0.671	< 0.001
Masseter sEMG RMS	0.557	< 0.001

Note. Change scores were calculated as post-intervention minus baseline values. Pearson correlation coefficients were calculated using the total sample (N = 60). POFRAS,Preterm Oral Feeding Readiness Assessment Scale; RMS, root mean square; sEMG, surface electromyography

Discussion

This randomized controlled trial evaluated the effects of a 7-day PIOMI program on sEMG-based orofacial muscle activity and clinically relevant feeding outcomes in preterm infants with feeding disorders. Compared with routine neonatal care, infants receiving PIOMI demonstrated greater increases in sEMG-measured activity of the masseter, orbicularis oris, and zygomaticus muscles, together with higher oral feeding readiness scores and body weight, a shorter hospital stay, and a greater proportion receiving breast milk at the post-intervention assessment. Total enteral milk intake did not differ significantly between groups. Changes in POFRAS scores were also positively associated with changes in sEMG activity of all three assessed muscles. These findings extend previous PIOMI research, which has primarily examined behavioral and clinical feeding outcomes, by providing an objective measure of orofacial muscle activity alongside functional feeding outcomes [4–10].

The significant increase in sEMG RMS amplitude following PIOMI suggests greater electrical activity of the assessed orofacial muscles under the standardized NNS condition. Previous electromyographic studies have demonstrated measurable activity of the masseter and other orofacial muscles during infant sucking and feeding and have reported differences according to feeding method and infant population [14–16, 18]. The increased masseter activity observed in the present study may be compatible with greater activation of the jaw musculature during the assessed motor task, whereas increased orbicularis oris activity may reflect greater activation of the perioral musculature involved in lip closure. Increased zygomaticus activity may similarly reflect altered activation of perioral musculature during sucking-related activity [14–16, 18]. However, these interpretations should remain cautious because the present study measured electrical muscle activity rather than muscle force, intermuscular coordination, or central neural control.

The clinical findings provide complementary information. Infants in the PIOMI group had higher post-intervention POFRAS scores, greater body weight, a higher proportion receiving breast milk, and shorter hospital stays than controls, whereas milk intake did not differ significantly between groups. POFRAS provides information on behavioral, physiological, and oral-motor indicators relevant to oral feeding readiness [11–13], and previous studies have reported improvements in feeding-related outcomes following oral-motor interventions in preterm infants [4–10]. The concurrent improvement in sEMG activity and feeding-related clinical outcomes suggests that these measures may capture related aspects of the response to intervention. Nevertheless, the study was not designed to determine whether changes in muscle activity mediate changes in

feeding performance, and the observed correlations should therefore not be interpreted as evidence of a causal pathway.

The positive correlations between changes in POFRAS scores and changes in sEMG activity of the zygomaticus, orbicularis oris, and masseter muscles provide preliminary evidence of an association between objective muscle activity and clinical feeding readiness. However, these correlations were exploratory and were calculated using change scores in the total sample. They therefore indicate covariation rather than causation. In addition, because sEMG recordings were obtained during NNS, the observed associations should not be interpreted as direct evidence that increased muscle activity during NNS reflects improved neuromuscular coordination during nutritive feeding or swallowing. NNS and nutritive feeding involve overlapping but distinct motor demands, and clinical feeding performance requires coordinated integration of sucking, swallowing, and respiration [17–20].

The improvement observed in the control group should also be considered when interpreting the findings. Preterm infants undergo substantial maturation of sucking, swallowing, and feeding abilities during the neonatal period, and routine NICU care may contribute to progressive improvement in feeding performance over time [17, 21]. Thus, some changes observed during the 7-day study period may reflect developmental maturation or usual clinical care. The greater between-group differences observed after adjustment for baseline values suggest that the PIOMI group experienced changes beyond those observed with routine care alone. However, the relatively short intervention period means that the contribution of spontaneous maturation cannot be completely separated from treatment-related changes.

The present findings are broadly consistent with previous studies reporting beneficial effects of PIOMI and other oral-motor interventions on feeding outcomes in preterm infants [4–10]. Previous research has primarily focused on outcomes such as progression to oral feeding, sucking capacity, feeding readiness, weight gain, and length of hospital stay [4–10].

One possible interpretation is that repeated oral-motor stimulation may influence sensory-motor experience during a period of ongoing feeding maturation. PIOMI involves structured tactile stimulation of the lips, cheeks, gums, tongue, and palate and may increase opportunities for sensory and motor experience related to oral feeding [4, 20, 21, 23].

Several limitations should be considered. First, sEMG reflects electrical muscle activity during NNS but does not directly assess swallowing physiology or suck–swallow–breathing coordination. Future studies should combine sEMG with complementary measures of feeding physiology. Second, the single regional setting and selected study population may limit generalizability; larger multicenter trials with more diverse preterm populations are needed. Third, the 7-day intervention and lack of post-discharge follow-up preclude conclusions about the persistence or long-term relevance of the observed changes. Longitudinal studies should examine whether early sEMG and feeding-readiness measures predict later feeding or neurodevelopmental outcomes. Fourth, the absence of standardized sEMG amplitude normalization limits comparison across infants, highlighting the need for standardized acquisition and processing methods. Finally, although no intervention-related adverse events were observed, safety was not a prespecified outcome; future trials should include systematic safety monitoring.

Conclusion

In this randomized controlled trial, 7 days of PIOMI was associated with greater sEMG-measured activity of the masseter, orbicularis oris, and zygomaticus muscles and with improvements in several clinically relevant feeding outcomes in preterm infants with feeding disorders. The concurrent changes in sEMG activity and feeding readiness, together with their positive associations, provide preliminary evidence that objective muscle measures may complement clinical assessment of feeding-related changes. However, the findings do not establish a causal or mechanistic relationship between increased muscle activity and feeding improvement, nor do they demonstrate coordinated muscle activation or long-term effectiveness. Larger multicenter trials with standardized sEMG methodology, formal safety monitoring, longer follow-up, and evaluation of intervention dose are needed before the findings can be translated into routine clinical protocols.

Declarations

Conflicts of Interest

The authors declare that there are no conflicts of interest.

Ethics Approval

The study protocol was approved by the Research Ethics Committee of the University of Social Welfare and Rehabilitation Sciences (IR.USWR.REC.1403.252) and was conducted in accordance with the Declaration of Helsinki. The trial was registered in the Iranian Registry of Clinical Trials (IRCT20250205064649N1).

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Author Contribution

Author Contributions StatementS.G. conceived and designed the study, coordinated the research, contributed to data collection and interpretation, and drafted the manuscript. Z.S. contributed to the study design, supervised the research, and critically revised the manuscript. F.S. contributed to the study methodology, data interpretation, and critical revision of the manuscript. B.L.K. contributed to the interpretation of the findings and critically revised the manuscript. I.A. contributed to the study design and methodology and critically reviewed the manuscript. E.B. contributed to the statistical analysis, interpretation of the results, and

critical revision of the manuscript. All authors reviewed and approved the final version of the manuscript and agree to be accountable for their respective contributions.

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Data Availability

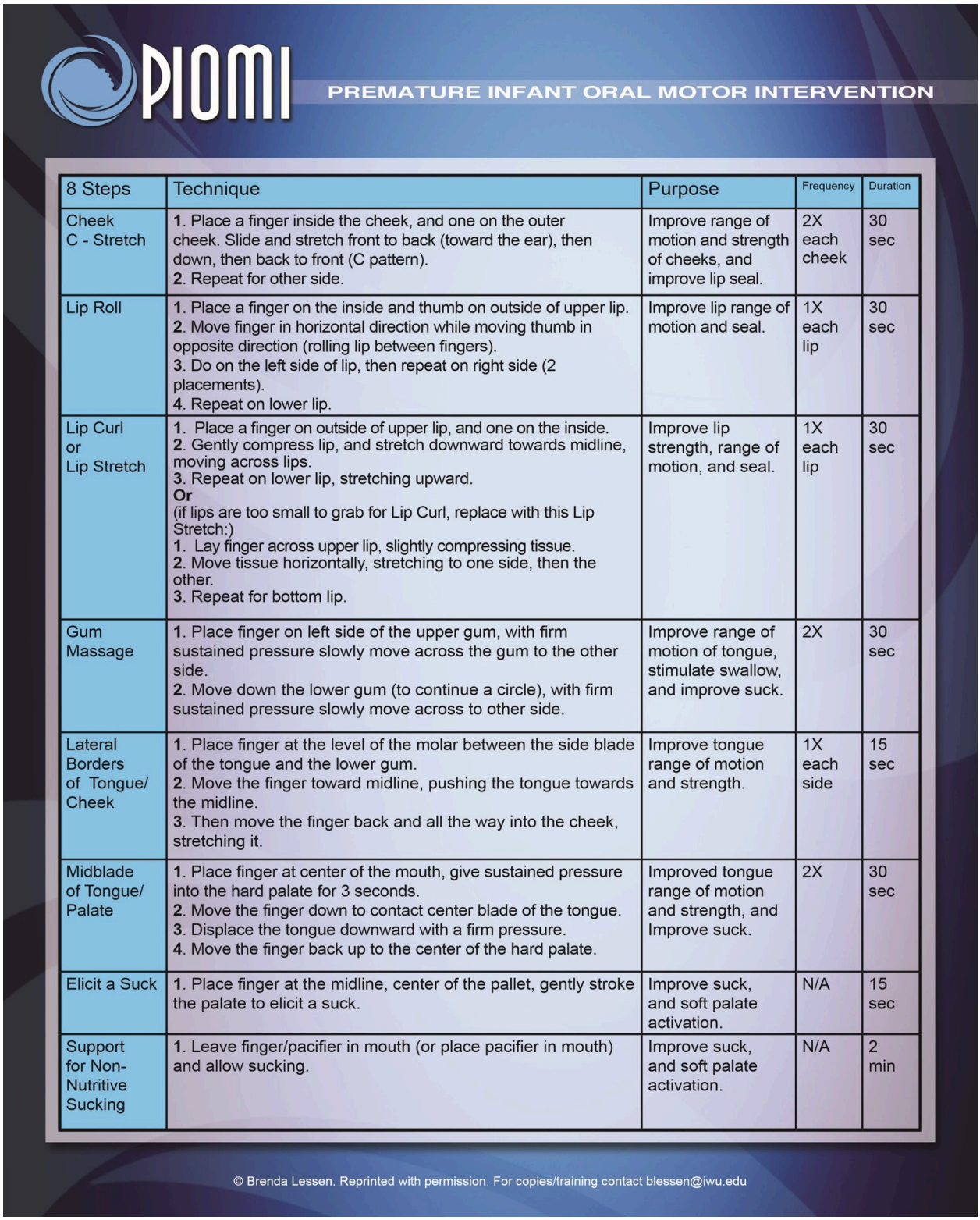
The datasets generated and/or analyzed during the current randomized controlled trial are available from the corresponding author upon reasonable request, in accordance with institutional and ethical regulations.

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Figures



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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Figure 1

The Premature Infant Oral Motor Intervention (PIOMI). From “Establishing Intervention Fidelity of an Oral Motor Intervention for Premature Infants,” by B. Lessen, C. Morello, and L. Williams, 2015, Neonatal Network, 34, pp. 71–82.

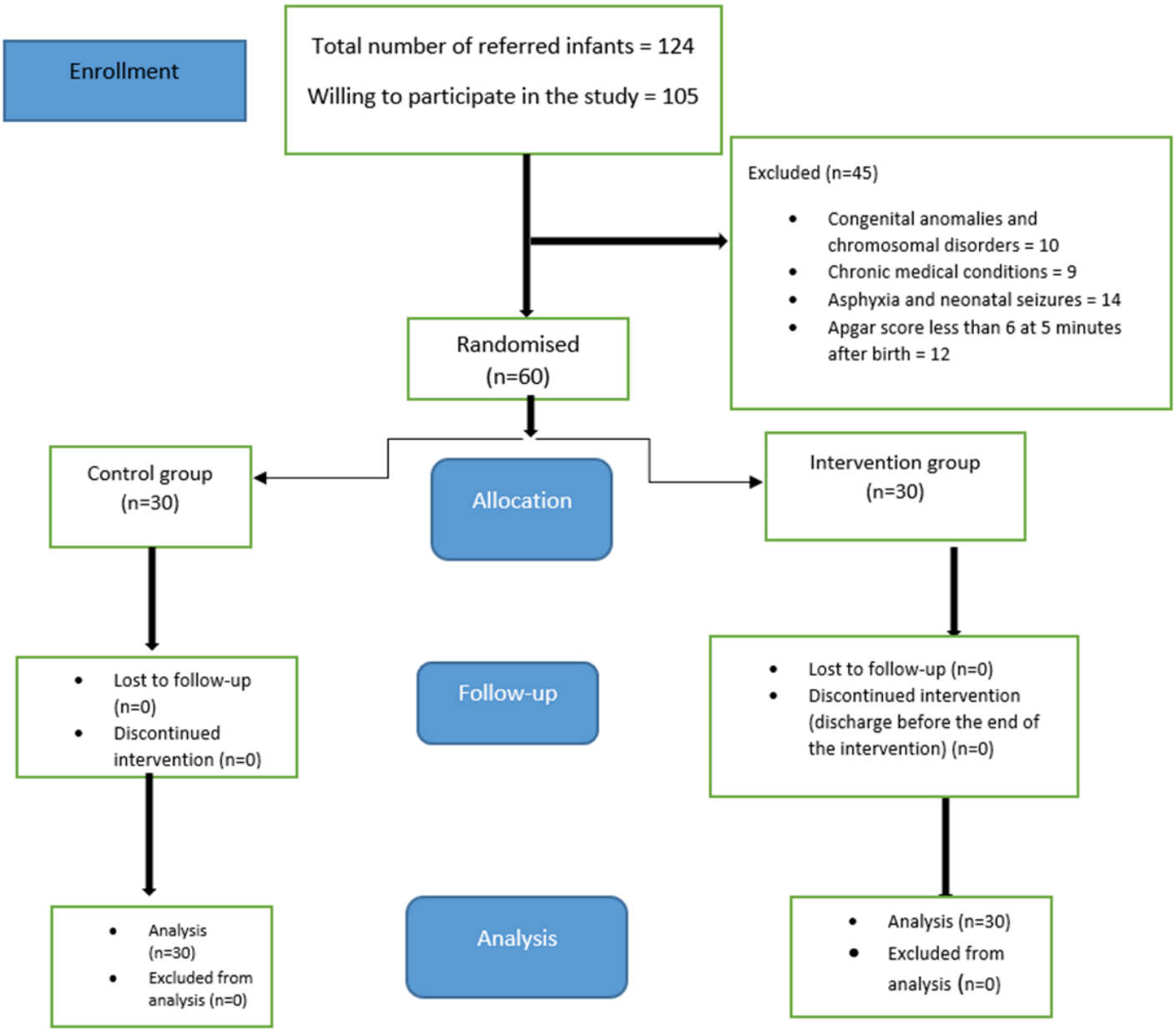


Figure 2

Randomization and Allocation flowchart