Research Paper

Impact of Premature Infant Oral Motor Intervention on Swallowing Muscle Activity and Developmental Outcomes: A Study Protocol

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ABSTRACT

Background: Motor control in infancy begins with feeding and swallowing, which can affect later cognitive, language, social-communication, and motor development. Feeding disorders in preterm infants increase the risk of developmental delays. The premature infant oral motor intervention (PIOMI) is a structured method developed to enhance oral feeding in preterm infants, but its effects on swallowing muscle activity and long-term developmental outcomes remain unclear.

Objectives: This study provides a protocol for a randomized controlled trial (RCT) that will evaluate the impact of PIOMI on swallowing muscle activity and developmental outcomes in preterm infants with feeding disorders.

Methods: This is a protocol for a single-blind RCT with a pre-test/post-test/follow-up design, with the participation of 60 preterm infants with feeding disorders from the neonatal intensive care unit (NICU) of a medical center in Babol, Iran. They will be randomly allocated to the PIOMI and control groups. The PIOMI group will receive daily oral-motor intervention for seven days along with routine care, while the control group will receive only routine care. Swallowing muscle activity will be assessed using surface electromyography (sEMG) pre- and post-intervention. Developmental outcomes, including cognitive, receptive/expressive language, social-communication, and motor skills, will be evaluated at 3 and 6 months post-intervention using the Newsha development scale, the ages and stages questionnaire, third edition (ASQ-3), and the Bayley scales of infant and toddler development, third edition (Bayley-III).

Results: Recruitment began in April 2025, and the intervention and follow-up are expected to conclude in December 2025. The results of data analysis will be ready by summer 2026.

Conclusions: We assume that PIOMI may enhance developmental outcomes, support independent oral feeding, and improve long-term developmental outcomes in preterm infants. Findings of the RCT are expected to inform clinical practice and standards of NICU care.

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Introduction

Global health policies consistently prioritize the promotion, protection, and support of optimal infant feeding as a cornerstone strategy to reduce neonatal mortality and enhance overall health outcomes [1–3]. Adequate nutrition and effective swallowing are essential for development, particularly in preterm infants who frequently experience feeding disorders [4, 5]. Impaired coordination of sucking, swallowing, and breathing may serve as early markers of underlying neurological dysfunction [5, 6]. While associations between early feeding skills and later developmental outcomes exist, the underlying mechanisms remain poorly understood, highlighting a critical knowledge gap [4, 7–10].

The premature infant oral motor intervention (PIOMI) is a structured, evidence-based protocol designed to enhance oral feeding skills in preterm infants [11]. Although prior studies have suggested the impact of PIOMI on oral intake and some developmental outcomes, data on its effects on swallowing muscle activity are limited [12, 13]. Efficient milk extraction depends on coordinated contractions of swallowing muscle activity, including the masseter, temporalis, medial and lateral pterygoids, and suprahyoids, driving mandibular elevation and protrusion [13–15]. Surface electromyography (sEMG) provides a validated, non-invasive method to assess these muscles' activity and offers mechanistic insights into how PIOMI may influence feeding skills and potentially support development [16, 17].

Several theoretical frameworks suggest that early oral-motor skills may influence broader developmental outcomes, including cognitive, language, social-communicative, and motor abilities. These associations are currently hypothetical, and causal links between swallowing muscle activity and later development are not yet established. Recent studies indicate correlations between early oral-motor intervention and developmental outcomes, yet longitudinal evidence from randomized clinical trials (RCTs) with follow-up remains scarce [18–20].

Supporting these theoretical constructs, recent empirical studies have demonstrated associations between feeding skills and developmental outcomes in preterm infants at later stages of development [21–25]. Li et al. [15] showed that early oral motor intervention improved feeding skills and prognosis by supporting neurodevelopment, while Jaywant et al. [16] reported beneficial effects of PIOMI, with or without massage, on social-emotional development. Nevertheless, a significant proportion of preterm infants experience developmental delays from birth until school entry [26, 27], and they remain vulnerable, particularly if diagnosis is delayed or early interventions are not provided [7]. Connell et al. [24] found that even preterm infants who were feeding and developing normally at the time of discharge from the neonatal intensive care units (NICUs) could present with developmental delays during the first year of life. Since the relationship between feeding and development at the end of the first year was not predictable in their study, it underscores the importance of follow-up services for all preterm infants after NICU discharge [28–31].

Despite extensive epidemiological data and decades of research on natural infant development, the relationship between early feeding skills and initial developmental prerequisites in infancy remains unresolved [32–34]. Moreover, while oral motor stimulation has demonstrated long-term benefits in certain domains, such as social-emotional development, self-regulation, and interaction [15, 16], its potential impact on other variables—including cognitive, receptive and expressive language, social-communicative, and motor skills—has been largely overlooked [17]. Given the high prevalence of feeding disorders and developmental delays in preterm infants, this study provides a protocol for a RCT that will evaluate the impact of PIOMI on swallowing muscle activity using sEMG as well as its potential effect on cognitive, language, social-communicative, and motor development. This clinical trial seeks to fill a critical knowledge gap and provide evidence to guide clinical practice in neonatal care.

Materials and Methods

Study design and participants

This is a protocol study for a single-blind RCT (with parallel groups) that will enroll 60 preterm infants diagnosed with feeding disorders from NICUs in Mazandaran Province, Iran (Figure 1). The selected hospitals are equipped with specialized neonatal care facilities and have extensive experience in conducting clinical research, ensuring adequate medical and research support for the study. Eligible preterm infants will be identified through a rigorous review of existing literature and clinical assessment tools [18–26]. Recruitment will follow strict inclusion and exclusion criteria to ensure infant safety and study validity, and written informed consent will be obtained from their parents or legal guardians.

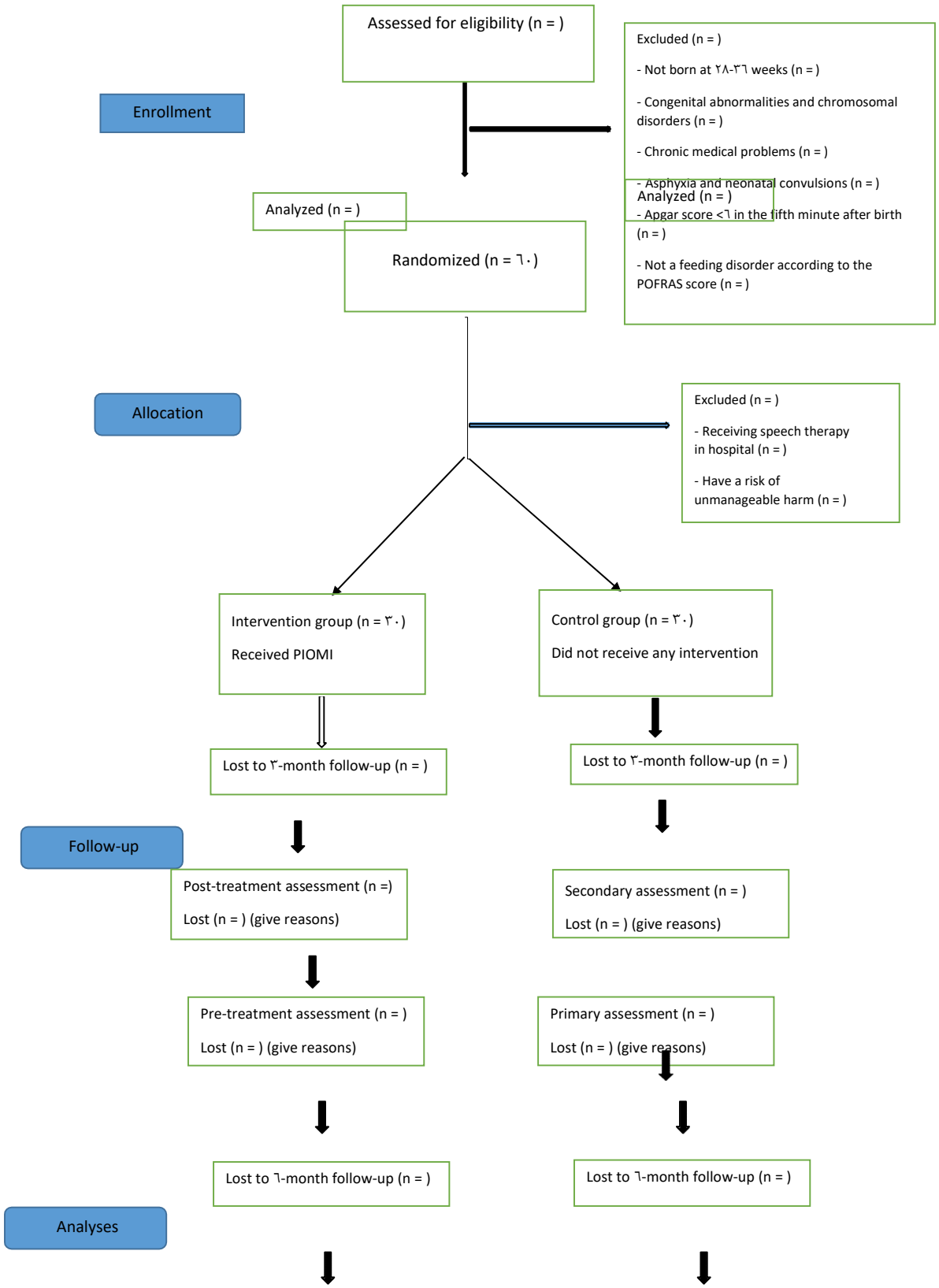


Figure 1. CONSORT diagram of group allocation and sampling process

Infants will be eligible for participation if they meet all of the following criteria: Born at 28-36 weeks of gestational age (GA) with a feeding disorder as determined by pediatrician evaluation, clinically stable at the time of enrollment confirmed by the attending medical staff, no diagnosis of congenital anomalies or chromosomal disorders, no chronic medical conditions such as bronchopulmonary dysplasia, grade 3 or 4 intraventricular hemorrhage, necrotizing enterocolitis, birth asphyxia, neonatal seizures, severe hyperbilirubinemia requiring transfusion, or sepsis; and an Apgar score ≥6 at five minutes after birth. The infants receiving speech or occupational therapy in the hospital (which can confound the effects of the PIOMI, such as structured oral-motor exercises provided by therapists), those participating in another interventional study or a study requiring multiple assessments that can interfere with this trial (e.g. interventions targeting feeding, motor, or developmental outcomes), and those with medical conditions or risks that can result in unmanageable harm during the study (including severe cardiorespiratory instability, major congenital anomalies, or critical neurological impairments as judged by the attending neonatologist) will be excluded from the study.

The sample size was calculated based on prior PIOMI studies to provide adequate power for both primary and secondary outcomes. Assuming a moderate effect size (Cohen's d=0.7) for each outcome, with a standard deviation of 0.8, and a significance level of α=0.05, a total of 27 infants per group are required to achieve 80% power using a two-tailed independent t-test. To account for a possible 10% dropout rate, the sample size will be increased to 30 per group. Participants exceeding this dropout threshold will be replaced, and missing data will be handled using the Markov Chain Monte Carlo (MCMC) method.

Randomization and blinding

Eligible preterm infants will be assigned to intervention or control groups using a covariate-adaptive randomization method (block size=4) in the Sealed Envelope website. This platform supports covariate-adaptive allocation to ensure balanced assignment between study groups. The covariate-adaptive algorithm will include key prognostic variables such as GA and birth weight, to ensure balanced distribution of these characteristics between the groups and control for potential confounding factors. Stratification will be performed by GA and birth weight, distinguishing small for GA (SGA) and appropriate for GA (AGA) infants. Infants will be allocated in a 1:1 ratio, with 30 per group. Randomization sequences will be concealed in opaque envelopes and distributed to the selected medical centers. Sequence generation will be conducted by an independent statistical team, ensuring allocation concealment and minimizing bias.

A single-blind design will be employed: parents and clinical staff will be aware of group assignments, whereas outcome assessors and data analysts will be blinded. Trained raters blinded to group allocation will perform all clinical measurements. sEMG data will be analyzed by a physiotherapist experienced in EMG, and developmental assessments will be conducted by an independent speech-language pathologist (SLP2). Given the tactile nature of the PIOMI, there is a potential risk of unblinding for developmental assessors. To mitigate this risk, standardized assessor protocols and scripts will be used for all participants, parents will receive instructions to avoid discussing intervention details during assessments, and assessors will follow uniform procedures for all infants. To address performance bias from unequal attention between groups, both intervention and control participants will receive equivalent structured engagement time with study staff during routine care and support.

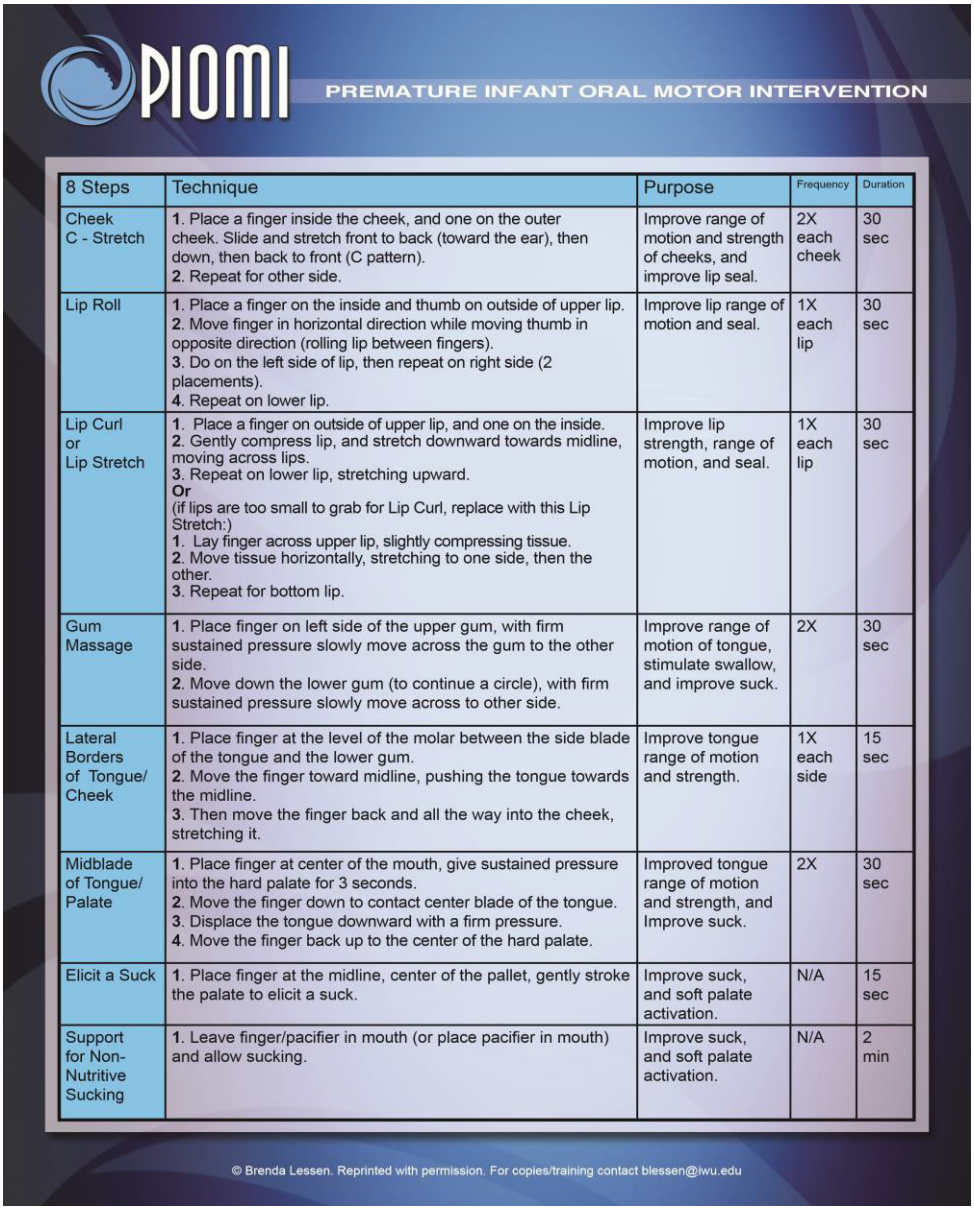
Primary and secondary outcomes

To evaluate the efficacy of the PIOMI on swallowing muscle activity (as primary outcome) using sEMG in preterm infants with feeding disorders. We expect that PIOMI will increase the mean of swallowing muscle activity more than the control group post-intervention (after 7 days). Moreover, we expect that PIOMI will improve developmental outcomes across cognitive, language (receptive and expressive), social-communicative, and motor skills (as secondary outcomes) at 3- and 6-month follow-ups assessed by the Newsha development scale (NDS), the ages and stages questionnaire, third edition (ASQ-3), and the Bayley scales of infant and toddler development, third edition (Bayley-III).

Procedure

Description of the first phase

Preterm infants with feeding disorders based on pediatrician evaluation will be referred to the fellow SLP1. To ensure adherence and minimize attrition, all researchers will undergo thorough training covering clinical research principles, standardized data collection, parent communication, and emergency response protocols. SLP1 will maintain daily in-person contact with parents during the intervention, supplemented by monthly tele-



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

Figure 2. The PIOMI protocol [11]

phone follow-ups to address questions, provide guidance, and reinforce adherence.

Demographic and clinical baseline data—including GA, sex, birth weight, type of feeding (breast, bottle, or gavage), and length of hospital stay—will be recorded by SLP2, who is experienced in NICU procedures. Feeding skills will be assessed using the preterm oral feeding readiness assessment scale (POFRAS), which evaluates general behavior, oral status, oral reflexes, non-nutritive sucking, and stress symptoms using a 0–2 scoring system [35]. Infants will be placed in a supine position within the incubator. To maintain wakefulness during assessment, auditory (calling the infant's name), visual (eye contact), and tactile (gentle limb manipulation) stimuli will be applied.

The sEMG will be used to evaluate activity of the masseter, zygomatic, and orbicularis oris muscles during rest and non-nutritive sucking. Infants must demonstrate physiological stability, with normal heart rate, respiratory rate, and oxygen saturation prior to recording. The skin will be cleaned with water-soaked cotton pads. One electrode will be placed on each target muscle, with a reference electrode attached to the mastoid bone. Non-nutritive sucking will be stimulated using the gloved finger of SLP1. Mean amplitude of muscle activity will be

recorded by SLP1 and analyzed by a physiotherapist to provide quantitative measures of muscle activity.

The intervention group will receive PIOMI daily for 7 consecutive days. Infants will remain supine in the incubator, and stimulation will be administered 15 minutes before scheduled feeding. The procedure involves sequential oral-motor exercises targeting lip, jaw, and tongue muscles, following the structured PIOMI protocol [11] (Figure 2). The control group will receive standard NICU care, including temperature regulation, light control, and skin-to-skin contact.

During all interventions, vital signs will be continuously monitored. Stimulation will be immediately discontinued if infants demonstrate adverse responses, including apnea, bradycardia, oxygen desaturation, or other clinical instability. All adverse events will be documented and reported to the ethics committee within 24 hours. Infants experiencing adverse events will be withdrawn from the trial, and appropriate medical care will be provided.

Description of the second phase

At three- and six-month corrected ages, follow-up assessments will be conducted at the Health and Treatment Center of Babol City. Families will be contacted in advance to schedule appointments at times most convenient for both the infants and their caregivers. Infants will be examined in the presence of a parent or primary caregiver to ensure comfort and security. Assessments will take place in a large, quiet, and distraction-free room, with soft lighting and minimal noise. Infants will be positioned according to their comfort and developmental needs, including: Supine position on a flat or slightly inclined surface, half-sitting with caregiver support, seated in the caregiver's arms, or gentle hugging position for soothing and security. Each evaluation session is expected to last approximately 60 minutes. The examiner will continuously monitor the infant's physiological and behavioral state, including heart rate, oxygen saturation, and signs of distress or fatigue. If an infant becomes tired, inattentive, excessively restless, or uncooperative, the evaluation will be paused for a five-minute break. During breaks, the infant will be soothed by the caregiver or allowed to rest before resuming the assessment.

The developmental outcomes of the infants will be evaluated across multiple domains, including cognitive skills, receptive and expressive language skills, social-communication skills, and motor skills. Assessments will be conducted using three validated instruments: NDS [36], ASQ-3 [37], and Bayley-III [38]. All evaluations will be carried out by a trained examiner at the study center, who is fully familiar with the scoring protocols and administration guidelines of each instrument.

The NDS provides a comprehensive evaluation of developmental outcomes. Cognitive functioning will be assessed through structured problem-solving tasks, attention to visual and auditory stimuli, memory recognition, and object permanence. Receptive language skills will be measured by the infant's responses to verbal instructions, gestures, and environmental cues, while expressive language skills will be evaluated based on spontaneous vocalizations, babbling, early word attempts, and imitation of sounds or gestures. Fine motor performance, including grasping, object manipulation, and hand-eye coordination, and gross motor skills, such as rolling, sitting balance, crawling, and coordinated movements, will be observed and scored. Social development and communication will be assessed through the frequency and quality of eye contact, joint attention, turn-taking, responsiveness to caregiver interactions, and the use of gestures or vocalizations. Quantitative scores will be documented, providing a rich profile of each infant's developmental outcomes.

The ASQ-3 is as a complementary parent-completed screening tool, evaluating five domains: communication, gross motor, fine motor, problem-solving, and personal-social skills. Parents will be guided by the trained examiner to respond to all items based on the infant's typical daily behavior and interactions. Clarifications will be provided for any ambiguous items to ensure accuracy and completeness of responses. Each domain will be scored according to the ASQ-3 scoring method.

The Bayley-III provides a structured, assessment of five domains of cognitive, language, motor, adaptive, and social-emotional development. Cognitive tasks evaluate object recognition, problem-solving skills, and attention to stimuli. Receptive language is measured through the infant's responses to verbal and nonverbal cues, while expressive language is assessed via spontaneous vocalizations, babbling, imitation, and early word production. Fine motor skills, such as grasping, stacking, and transferring objects, and gross motor skills, including rolling, sitting, crawling, and coordinated movements, are systematically evaluated. The trained examiner will record quantitative scores ensuring a comprehensive evaluation of developmental outcomes. For all three instruments, checklists will be completed to capture nu-

merical scores. Data will be anonymized using unique participant identifiers to maintain confidentiality.

Statistical analysis

All statistical analyses will be conducted in SPSS software, version 26, using both descriptive and inferential statistics. Continuous variables will be presented as Mean±SD, along with minimum and maximum values, while categorical variables will be reported as frequency (percentage). Normality of continuous measures will be assessed with the Shapiro-Wilk test, and the homogeneity of variances will be assessed using Levene's test. Baseline group differences will be evaluated using the chi-square test for categorical variables and the Mann-Whitney U test for non-normally distributed continuous variables. Between-group comparisons for normally distributed variables will be performed using independent t-tests, with while non-normal variables will be compared using the Mann-Whitney U test. Within-group comparisons will utilize paired t-tests for normal data and the Wilcoxon signed-rank test for non-normal data. Statistically significant level will be set at 0.05, and 95% confidence intervals (CIs) will be reported for all relevant outcomes.

Fidelity assessment

Therapist fidelity will be ensured following approval from Dr. Brenda Lesson Knoll, the developer of the PIOMI, and completion of her online webinar training, all conducted under the supervision of the study supervisor, who is also the corresponding author of this article. The therapist implementing the intervention (SLP1) has five years of experience applying the PIOMI method and working in the NICUs. During the intervention, sessions will be video-recorded, and approximately 20% of these recordings will be reviewed by the supervisor to confirm adherence to the protocol before continuing. All assessments and interventions will be conducted by a trained speech-language therapist whose qualifications and procedures are verified and approved by the supervisor.

Results

In February 2025, the Research Ethics Committee of the University of Social Welfare and Rehabilitation Sciences approved the study protocol. The recruitment of infants, therapist training, and rater training commenced in April 2025. The therapy and follow-up periods are expected to be completed by December 2025, with pre- and post-intervention evaluations conducted accordingly. Data analysis is currently underway, and the study results are planned to be released by summer 2026.

Discussion

The RCT with a follow-up phase will attempt to explore the potential effects of the PIOMI on swallowing muscle activity and longer-term developmental outcomes in preterm infants with feeding disorders. Although PIOMI has been increasingly implemented in NICUs, important gaps remain regarding its underlying physiological mechanisms, particularly at the level of swallowing muscle activity, and its possible association with later developmental outcomes [15–17, 36–38]. The RCT seeks to address these gaps by integrating sEMG with longitudinal developmental assessments. The sEMG is a validated, non-invasive approach to objectively quantify swallowing muscle activity during feeding [16, 17]. In preterm infants, immature neuromuscular systems may lead to suboptimal coordination of orofacial and suprahyoid muscles, which are critical for safe and efficient swallowing [13–15]. By applying sEMG, the RCT will examine whether PIOMI is associated with measurable changes in swallowing muscle activity, without presuming a direct therapeutic effect. Any observed differences between groups will be interpreted cautiously, recognizing the developmental outcomes inherent in preterm populations.

Beyond short-term feeding skills, the RCT hypothesizes that early oral-motor function may be associated with broader developmental outcomes, including cognitive, receptive/expressive language, social-communication, and motor skills [15–17, 39–43]. Feeding and swallowing represent early manifestations of motor control and share neural substrates with later developmental outcomes [44, 45]. However, the relationship between early muscle activity and subsequent development is complex and influenced by multiple biological and environmental factors. Therefore, any associations identified in the RCT will be considered exploratory rather than causal.

By combining objective physiological measures with standardized developmental follow-up, the findings of the RCT may contribute to a more comprehensive understanding of how PIOMI interacts with developmental processes. Such insights may help refine early intervention strategies in NICUs and support the development of future multicenter studies designed to further investigate mechanistic pathways and long-term outcomes [7, 28–31]. Importantly, this study protocol does not assume superiority of PIOMI but instead aims to generate

evidence that can inform hypothesis-driven research and clinical decision-making.

Feeding disorders and developmental delays seem to have a bidirectional and interrelated course in preterm infants [4, 7–10]. While early oral-motor interventions may facilitate the acquisition of independent oral feeding, it remains unclear whether these early improvements translate into sustained developmental advantages. The RCT will explore these relationships and provide preliminary data that may guide the timing, intensity, and targeting of early interventions in this vulnerable population.

The limitations of the RCT should also be acknowledged. The sample size will be relatively small, which may limit the precision of effect estimates and the detection of small effect sizes, despite appropriate power calculations. The study will be conducted in the NICU of a medical center in one Iranian city, which may restrict the generalizability of the findings to all clinical settings with different care practices. Moreover, the absence of a sham control group limits the ability to fully disentangle the specific effects of PIOMI from non-specific tactile stimulation or increased attention. These limitations will be carefully considered in the study design and will be taken into account when interpreting the results and planning future research.

Conclusions

This study protocol describes an RCT designed to examine whether PIOMI can enhance swallowing muscle activity, support the development of independent oral feeding, and contribute to improved developmental outcomes in preterm infants. By combining sEMG with longitudinal developmental measures, this RCT seeks to generate objective evidence on the potential mechanisms and clinical relevance of PIOMI. The findings can inform clinicians and contribute to the development of evidence-based standards of care in NICUs.

Ethical Considerations

Compliance with ethical guidelines

Throughout the study, stringent safety measures will be implemented to ensure adherence to the highest medical and ethical standards, protecting the infants and maintaining the integrity of the trial. The RCT has received ethical approval from the Research Ethics Committee of the University of Social Welfare and Rehabilitation Sciences, Tehran, Iran (Code: IR.USWR.REC.1403.252), and has been registered by the Iranian Registry of Clinical Trials (IRCT) (Code: IRCT20250205064649N1). Written informed consent will be obtained from the parents or legal guardians prior to enrollment, and each family will receive a copy of the consent form. They will receive comprehensive oral and written information regarding the study objectives, potential benefits, and possible risks. To ensure confidentiality, each infant will be assigned a unique identification code, and all data will be securely stored. Findings will be disseminated through scientific conferences or peer-reviewed journals, with no identifying information disclosed.

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Authors contributions

The authors contributed equally to the preparation of this study protocol.

Conflicts of interest

The authors declared no conflict of interest.

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