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EFFECT OF STRUCTURED AND UNSTRUCTURED OROMOTOR STIMULATION PROGRAM ON FEEDING OUTCOMES IN PRETERM INFANTS

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Abstract

Background: Oral motor stimulation interventions improve oral feeding readiness and earlier full oral feeding in preterm neonates. However, using a structured method may improve the transition time to full oral feeds and feeding efficiency with respect to weight gain and exclusive breastfeeding when compared to an unstructured intervention. **Aim**: To evaluate the effect of structured and unstructured oromotor stimulation program on feeding outcomes in preterm infants. **Methods:** A single-blind randomized controlled trial design was utilized on a purposive sample of 60 preterm infants in Neonatal Intensive Care Units at El Manial (Kaser Al Aini) that are affiliated to Cairo University from June 2023 to June 2024. The sample was simply randomly assigned to two equal groups, namely PIOMI (structured) group and sham (unstructured) group. **Tools**: Four tools were used for data collection, Preterm infants' characteristics and medical history sheet, Physiologic indicators record, Feeding Outcomes record and Premature Oral Feeding Readiness Assessment Scale (POFRAS). Preterm infants who were randomized to the PIOMI group were administered five minutes oromotor stimulation before the gavage feeding three times daily for seven consecutive days. **Results:** Before intervention, there was no statistical significance difference between both groups baseline characteristics. The length of hospital stay does not significantly differ in both groups. Regarding physiological indicators, a statistically significant difference was detected between the two groups in their mean average of respiratory rate only. The mean weight was increased significantly in PIOMI than sham group at discharge, also, mean milk volume increased significantly at the six and seven days of intervention. Transition time to start suck from bottle and reach full oral feed were significantly earlier in PIOMI group. POFRAS mean score was increased significantly in PIOMI compared to Sham group after intervention. **Conclusion:** Preterm infants' group who received 5-minute structured (PIOMI) three times daily for seven consecutive days showed higher weight gain, milk volume, POFRAS mean score and faster oral feeding transition time than unstructured (sham) group. **Recommendation:** based on the current study findings the researchers recommend PIOMI to be more effective for improved oral feeding in preterm infants. However, multicentric trials with larger sample sizes would be necessary to further strengthen the recommendation.

Keywords: Structured and Unstructured Oromotor Stimulation Program, Feeding Outcomes, Preterm Infants.

1. INTRODUCTION

Annually, approximately 15 million neonates are born prematurely [1], with a high risk for oral feeding difficulties due to uncoordinated suck swallow reflexes and poor oral muscle

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tone [2]. In Egypt, the numbers of preterm births were 13 per 100 live births [3].

Therapies for early attainment of oral feeding are oromotor stimulation (OMS) techniques such as intraoral, perioral stroking and non-nutritive sucking (NNS), Beckman's Oral Motor Intervention (BOMI), and Premature Infant Oral Motor Intervention (PIOMI). PIOMI is a 5-minute 8-step therapy focusing on the lip, jaw, and tongue movements [4]. It simulates the in-utero oral motor experience and has been reported to result in a faster transition to full oral feeds, improved suck strength, and increased breastfeeding rates [5].

The development of effective sucking ability is an important milestone, as it is the major discharge criterion that indicates maturation and the general health status of the preterm infant [6]. Therefore, early intervention strategies are needed to facilitate the development of oral feeding skills in preterm infants [7].

Several studies have been carried out to know the effectiveness of PIOMI as a specific oral motor therapy. Investigators found that use of the PIOMI resulted in weight gain, increased oral intake, reduced transition time to full oral feeding, and decreased Length of hospital Stay (LOS) and concluded that it increases the mean Premature Oral Feeding Readiness Assessment Scale (POFRAS), earlier full oral feeding, and improved growth velocity. PIOMI also increases the direct breastfeeding rates at 1 month and 3 months after discharge from the neonatal intensive care unit [8]. This study was, therefore, to evaluate the effect of structured and unstructured oromotor stimulation program on feeding outcomes in preterm infants.

1.2 Operational definition

For the purpose of the current study the following operational definition will be addressed:

Feeding Outcomes: include physiological indicators (respiratory, heart rate and oxygen saturation), weight gain, volume of daily total milk intake, transition time to start sucking from bottle, reach full oral feeds, hospital stay and premature oral feeding readiness.

2. METHODS

2.1 Aim

To evaluate the effect of structured and unstructured oromotor stimulation program on feeding outcomes in preterm infants.

To achieve the aim of the current study the following research hypotheses were postulated:

H1. Preterm infants' group who will receive 5-minute structured (PIOMI) three times daily for seven consecutive days will have a higher POFRAS mean score than unstructured (sham) group.

H2. Preterm infants' group who will receive 5-minute structured (PIOMI) three times daily for seven consecutive days will have better feeding outcomes than unstructured (sham) group.

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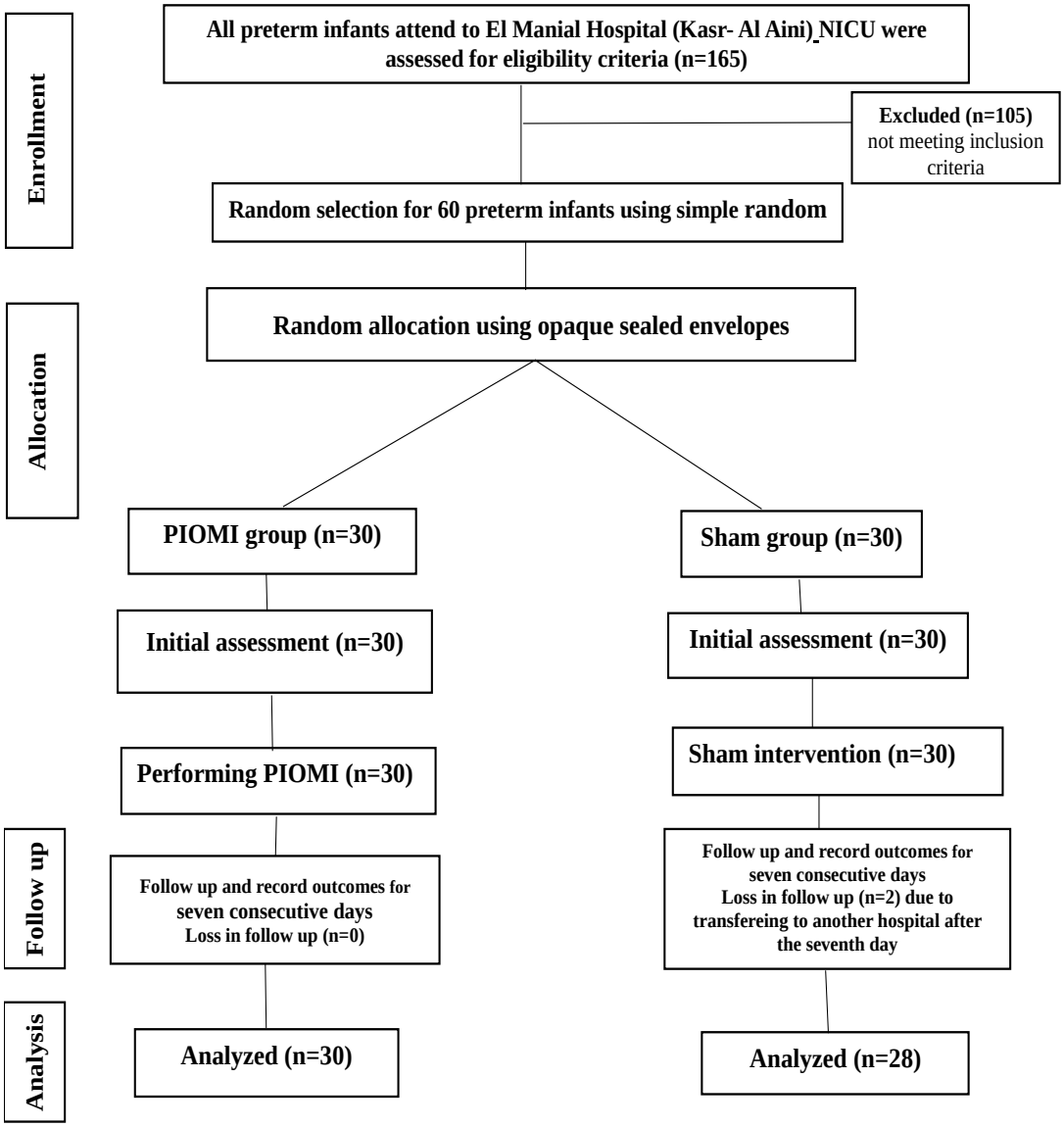
2.2 Design

A single-blinded randomized controlled trial (RCT) design was utilized.



2.3 Setting

The current study was conducted in a tertiary-level neonatal at the Neonatal intensive care unit (NICU) which is allocated at the fourth floor of El Manial University Hospital (Kaser Al Aini). Capacity of this unit is 64 incubators well equipped to provide care for neonates.

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2.4 Participants

Preterm infants that were born between 28 to less than 34 weeks of gestation, once medically stable with no respiratory support for at least 48 hours and on full gavage feeds of 150cc/kg/day, was eligible for enrolment into the study. Preterm infants had respiratory distress syndrome and those with chronic medical complications like Bronchopulmonary Dysplasia (BPD), Intraventricular Hemorrhage (IVH), Periventricular Leukomalacia (PVL), Necrotizing Enterocolitis (NEC), chromosomal anomalies or craniofacial malformation and who was opted out of the study by their parents, died or discharged before the end of the intervention, and develop ill during the intervention were excluded from the study.

Population: a total of 165 preterm infants were eligible. Of those, 105 were not included in the study because they were not eligible based on the previous inclusion criteria. Of the remaining 60 preterm infants, 30 in PIOMI group and 30 in Sham group. Two preterm infants were dropped out from the sham group after the 7^{th} day in follow up the reason for attrition was transferring to another hospital.

2.5 Data Collection Tools

Four tools were used for data collection Tools I, II and III were developed by the researchers, Tool (I): Preterm infants' characteristics and medical history sheet it includes gestational age/week, gender, age/day, date of admission, diagnosis, mode of delivery, age at enrolment and at discharge /day and hospital stay/ day.

Tool II: Physiologic indicators record it includes heart rate/ b/min, respiratory rate/min and oxygen saturation.

Tool (III): Feeding Outcomes record: it includes volume of total milk intake at each feed/ml, time to start sucking from bottle, transition time to reach full bottle feeds, birth, enrolment, and daily weight/gram.

Tool (IV): Premature Oral Feeding Readiness Assessment Scale (POFRAS): is an observational scale developed by [9]. It is comprised of five categories with a total of 18 items to evaluate.

This 18-item scale awards points for factors including gestational age, behavioral state, oral reflex, oral posture, and non-nutritive sucking. Each item is scored 0–2, for a maximum score of 36, in clinical validation studies of the POFRAS, the tool was demonstrated to be both sensitive and specific at a cutoff score of 30 as it is designed to assign a "pass" to score ≥ 30 or "fail" to score < 30 [9].

Validity and reliability

Tools I, II and III: the content validity was reviewed by three experts in pediatric nursing and neonatology to assess the coverage, the relevancy and the clarity of items.

Tool (IV): Is standardized and valid tool. The inter-rater reliability with intra-class correlation coefficient (ICC) = 0.81 (p <value 0.001), 95% CI (0.78- 0.87). Language validation procedure and item-level content validity indices (I-CVIs) for content validity are 1.00, it is available online without permission at www.linKs.lww.com

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2.6 Procedure

The study was carried out on three phases: preparatory, implementation and evaluation phase.

Preparatory phase:

Before conducting the study, an official permission was obtained from the director and the head of the NICUs of the previous mentioned setting after explaining the aim and nature of the study. Written informed consent was obtained from preterm infant's mother after complete description of the purpose and nature of the study.

Random assignment of Sample:

During this step, the researchers started the enrolment process by assessing preterm infants in NICUs for eligibility criteria of the trial. After that, a list of preterm infants who met the criteria was done by the researcher. Thereafter, preterm infants were randomly allocated into PIOMI groups or sham groups by using opaque sealed envelopes reflecting the type of each group and assigned doctor or nurse was asked to choose an envelope to determine to which group the preterm infant was assigned. This technique was utilized to maintain allocation concealment in order to decrease bias and ensure homogeneity between the groups.

Implementation phase:

Once an official permission was granted, the researchers started the actual implementation of study procedure through the following steps: the researchers recorded the preterm infant characteristic data for the two groups with filling tool one from the preterm infant's medical record. Each preterm infant of two groups were connected with a calibrated monitor and pulse oximeter to monitor the physiological indicators (Tool II) as the baseline before any interventions.

Each time before contacting the preterm infant of both groups the researchers performed through hand hygiene and wore a sterile apron, face mask and gloves as septic precautionary measures.

The researchers assessed oromotor skills in both groups by (Tool IV) at enrolment as a baseline and at the seventh day after intervention. The weight was measured at enrolment as a baseline and daily for seven consecutive days at 7:00 am at the same time in day shift.

The structured program (PIOMI) in the study group was done by the researcher and duration was not exceeding 5 minutes for each preterm infant. Every preterm infant was placed in a high fowler position by elevating the head of incubator to 45 degrees, with neck and head support was provided. Each preterm infant was subjected to five minutes of PIOMI intervention; three times (7:00, 10:00 am and 1:00 pm) daily 15-30 minutes before feeding time for 7 consecutive days using all aseptic precautions with gloved fingers. The PIOMI is a 5-minute oral motor intervention whereby the first 3 minutes of

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stimulation consisted of the first 6 steps of facial and oral structures and the last 2 minutes of stimulation consisted of elicit of sucking and nonnutritive sucking.

The first step, the researcher will perform cheek C-stretch two times by placing a finger inside the cheek, and one on the outer cheek, slide and stretch front to back (toward the ear), then down, and then back to front (C pattern) and repeat for the other side.

The second step the researcher will perform lip roll by placing a finger on the side and thumb on outside of upper lip and move finger in horizontal direction while moving thumb on opposite direction (rolling lip between fingers). The researcher will do left side of lip, the repeat on right side and repeat on lower lip.

The third step, the researcher will perform lip curl or lip stretch by placing a finger on outside of upper lip and one on the inside then gently compress lip, and stretch downward toward midline, moving across lips and repeat on lower lip, stretching upward. If lips are too small to grab for lip curl, replace with lip stretch by laying finger across upper lip, slightly compressing tissue and move tissue horizontally, stretching to one side, then the other and repeat for bottom lip.

The fourth step, the researcher will perform gum massage two times by placing finger on left side of upper gum, with firm sustained pressure slowly move across the gum to the other side and move down the lower gum (to continue a circle) with firm sustained pressure slowly move across to other side.

The fifth step, the researcher will perform lateral borders of tongue/ cheek by placing finger at the level of the molar between the side blade of the tongue and the lower gum and move the finger toward midline, pushing the tongue towards the midline. Then move the finger back and all the way into the cheek, stretching it.

The sixth step, the researcher will perform mid-blade of tongue/ palate two times by placing the finger at the centre of the mouth; give sustained pressure into the hard palate for 3 second and move the finger down to contact centre blade of the tongue, displace the tongue downward with a firm pressure and move the finger back up to the centre of the hard palate.

The seventh and eighth steps, the researcher will perform elicit of sucking and nonnutritive sucking by placing finger at the midline, centre of the pallet, gently stroke the palate to elicit a suck then leave finger/ pacifier in mouth (or place pacifier in mouth) and allow sucking for the last 2 minutes of stimulation.

The sham group received a sham intervention program, which the researcher remained beside the incubator for duration that was not exceed 5 minutes for each preterm infant, preterm infant was placed in a high fowler position by elevating the head of incubator 45 degree, with neck and head support was provided and administering gentle perioral touch without performing oral stimulation maneuvers. This sham intervention was performed for seven consecutive days.

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Evaluation phase:

Physiological indicators, weight and feeding outcome were measured by the researcher at enrolment and daily in both groups for seven consecutive days using Tool I, II and III. The POFRAS was measured by the researcher at enrolment and after seven days using Tool IV for both groups.

2.7 Statistical Analysis

A Data was entered in a Microsoft Excel spreadsheet (Microsoft Corp, Redmond, WA, USA) and analysed using IBM SPSS statistical software version 25. Continuous variables were expressed as mean (standard deviation) or median (inter-quartile range), depending on the distribution of the data. Categorical variables were expressed using frequencies and percentages. For qualitative data variables, the Chi-square test was used and for quantitative data variables, two independent sample t and median tests were used. P-value <0.05 was considered significant.

3. RESULTS

3.1 Description of Participants

Figure (1, 2) and table (1) indicate that before intervention, there was no statistical significance differences between preterm infants in the two study groups in relation to their age, gestational age, gender, mode of delivery, APGAR scores at first, fifth and tenth minutes and diagnosis P = (0.07, 0.06, 0.58, 1.00, 0.93, 0.93, 0.93, 0.31) respectively. Length of hospital stay not differed significantly in both group P = (0.38).

3.2 Tests of Hypotheses

Table (2) delineates that a statistically significant difference was detected between the two groups in their mean average of respiratory rate only through the intervention days P = (0.03), while no statistically significant difference in mean average of heart rate and oxygen saturation P = (0.95 & 0.06) respectively.

Table (3) demonstrates that no statistically significant difference was detected between the two groups in their mean weight through the seven intervention days, while it increased significantly in PIOMI compared to Sham group at discharge only P = (<0.001).

Table (4) reveals that mean milk volume increased significantly at the six and seven days of intervention in PIOMI compared to Sham group P = (0.019&0.009) respectively.

Table (5) illustrates that transition time to start suck from bottle and reach full oral feed were significantly earlier in PIOMI compared to Sham group P = (0.015&0.047) respectively.

Table (6) reveals that POFRAS total mean score was increased significantly in PIOMI compared to Sham group after seven days of intervention P = (< 0.001).

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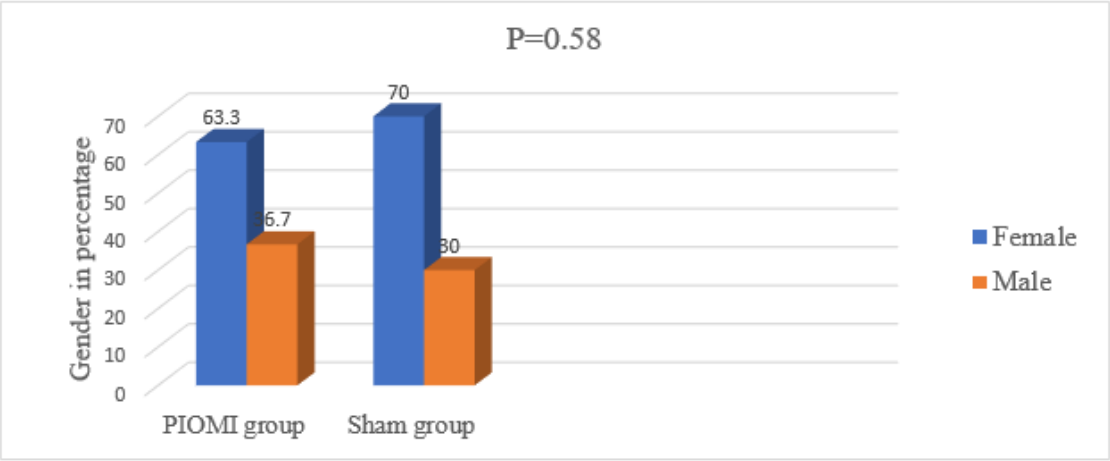

Fig (1): Preterm infants' gender in percentage distribution (n=60)

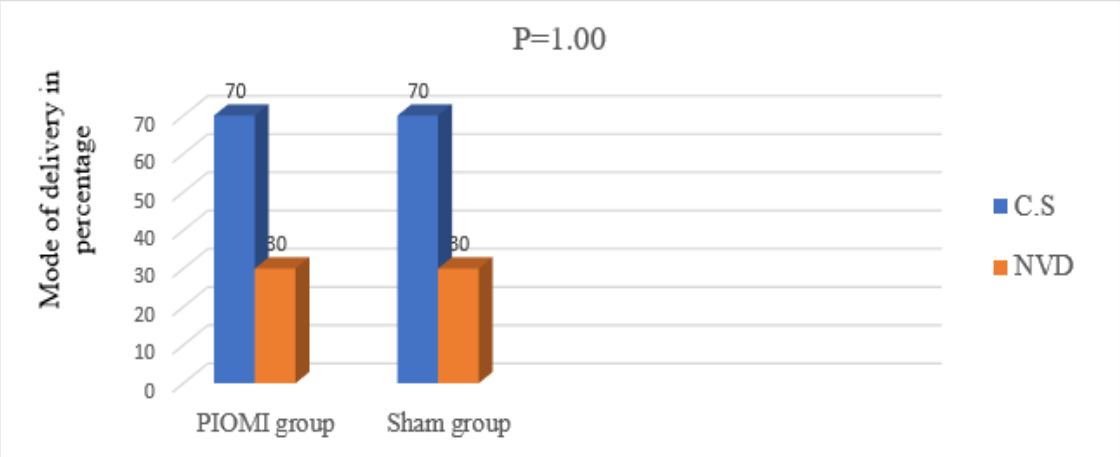

Fig (2): Preterm infants' mode of delivery in percentage distribution (n=60)

Table (1): Distribution of preterm infants' characteristics in study groups (n=60)

Preterm infants' characteristics	Groups				p-value
	PIOMI		Sham		
	No	%	No	%	
Age /days					
<15	15	50.0	20	66.7	0.19
15+	15	50.0	10	33.3	
Mean±SD	18.0±10.0		13.5±8.9		0.07
Gestational /weeks:					
28 - <32	23	76.7	16	53.3	0.06
32 - <34	7	23.3	14	46.7	
APGAR score /min. Mean±SD					
1st	3.5.6±1.7		3.6±1.3		0.93
5th	6.0±1.5		6.0±1.2		0.93
10th	6.0±1.5		6.0±1.2		0.93

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Diagnosis					
LBW, PT, RDS	30	100.0	29	96.7	0.31
NJ	0	0.0	1	3.3	
LOS Mean±SD	16.1±0.4		16.2±0.4		0.38

Table (2): Comparison of physiological indicators ' mean between studied groups through the intervention days

Physiological indicators through the intervention days	Groups		p-value
	PIOMI	Sham	
	Mean±SD	Mean±SD	
HR			
1st	150.1±9.1	147.6±14.9	0.44
2nd	150.7±9.8	148.7±10.6	0.45
3rd	147.9±9.3	148.3±10.3	0.88
4th	147.3±7.7	144.9±12.2	0.36
5th	145.3±6.5	146.7±10.0	0.50
6th	145.0±5.7	149.4±11.6	0.07
7th	144.6±5.8	145.4±12.3	0.75
Average	147.2±4.5	147.3±7.9	0.95
RR			
1st	47.7±23.3	45.9±8.4	0.70
2nd	42.9±5.7	47.5±9.0	0.02
3rd	42.1±7.8	46.4±7.7	0.04*
4th	41.8±7.6	45.7±6.4	0.03*
5th	42.1±7.2	47.1±6.6	0.007*
6th	44.4±9.4	46.5±7.7	0.36
7th	41.8±5.6	44.8±4.6	0.03*
Average	43.4±5.5	46.3±4.7	0.03*
SaO2%			
1st	79.9±2.2	80.7±1.7	0.12
2nd	98.0±1.3	97.9±2.0	0.76
3rd	98.5±1.1	98.3±0.9	0.37
4th	98.0±1.1	97.7±1.7	0.38
5th	98.4±1.1	97.5±2.3	0.053
6th	98.5±0.9	97.8±1.4	0.01*
7th	98.6±0.9	97.8±1.3	0.006*
Average	95.7±0.8	95.4±0.7	0.06

Table (3): Comparison of mean weight between studied groups through the intervention days

Weight /gm. through the intervention days	Groups		p-value
	PIOMI	Sham	
	Mean±SD	Mean±SD	
Birth	1408.2±180.8	1379.8±326.7	0.68
Enrolment	1437.5±111.7	1398.7±219.2	0.39
1st	1436.8±112.2	1402.0±219.0	0.44
2nd	1441.0±102.8	1422.5±217.7	0.68
3rd	1441.5±114.9	1432.7±221.1	0.85
4th	1460.7±11.6.2	1454.9±221.3	0.90

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5th	1485.2±106.8	1470.3±228.9	0.75
6th	1495.3±94.2	1495.2±231.2	1.00
7th	1523.3±90.7	1516.2±244.9	0.88
Discharge	1790.0±277.5	1634.3±89.6	<0.001*

Table (4): Comparison of milk volume mean between studied groups through the intervention days

Milk volume (ml/day) through the intervention days	Groups		p-value
	PIOMI	Sham	
	Mean±SD	Mean±SD	
1st	152.1±3.1	151.6±1.5	0.47
2nd	166.9±16.0	163.5±12.7	0.36
3rd	193.1±33.3	190.4±25.3	0.73
4th	204.5±34.7	205.8±30.3	0.84
5th	223.2±29.7	216.3±30.8	0.38
6th	241.1±27.1	230.3±35.3	0.019*
7th	258.7±25.2	245.1±34.8	0.009*

Table (5): Comparison of transition time to oral feeding mean between studied groups through the intervention days

Transition time to oral feeding	Groups		p-value
	PIOMI	Sham	
	Mean±SD	Mean±SD	
Start sucking from bottle	5.1±4.3	9.8±9.3	0.015*
Reach full bottle feeds	10.7±6.8	14.4±9.1	0.047*

Table (6): Comparison of POFRAS total mean score before and after intervention seven days between both groups

POFRAS score	Groups		p-value
	PIOMI	Sham	
	Mean±SD	Mean±SD	
Before	15.4±4.3	14.3±5.0	0.35
After	30.3±3.3	20.5±1.2	<0.001*

4. DISCUSSION

Regarding preterm infants' baseline characteristics, the current study results demonstrated that there were no statistical significance differences between both groups in relation to their age, gestational age, gender, mode of delivery, APGAR scores at 1st, 5th and 10th minutes and their diagnosis which showed homogeneity among them. These findings are supported by [10], who reported that the intervention and control groups were not significantly different with respect to their baseline characteristics.

Concerning the physiological indicators of preterm infants, the current study delineated that no harms or unintended effects like desaturation, apnea or bradycardia are observed and there were statistically significant differences between PIOMI and Sham group regarding mean average respiratory rate, while no differences between PIOMI and Sham group regarding their mean average of heart rate and oxygen saturation through the

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intervention seven days. These findings are supported by [11] who studied “the effect of non-nutritive sucking combined with oral motor stimulation and oral support on feeding performance in premature infants: A single-blind randomized-clinical trial” and by [12], who studied “Pre-feeding premature infant oral motor intervention (PIOMI) for transition from gavage to oral feeding: A randomised controlled trial” and reported that no adverse events as apnea, bradycardia or desaturation were noted in either group. In contrast, [10], reported that there was statistical significance difference between study and control group regarding heart rate while there are no statistically significant changes between the two groups in terms of respiratory rate and oxygen saturation after 5 days and throughout the study intervention.

In relation to birth and enrolment weight, the current study findings detected that no significance differences between both groups, while PIOMI group had significantly more weight gain at discharge compared to Sham group. These findings go in line with [2], who reported that the preterm infants receiving PIOMI had significantly higher weight gain at discharge only. In contrast, a recent systematic review of clinical trials (eight trials included PIOMI as an intervention) to explore the efficacy of pre-feeding oromotor stimulation in preterm infants demonstrated that its effect on weight gain was not uniform [12]. This discrepancy may be due to the different population characteristics, timing of initiation of the intervention, or type and number of oral stimulations per day, all of which contribute to proper development of oral feeding skills.

The current study results indicated that the mean volume of milk in PIOMI was significantly increased on the 6^{th} and 7^{th} day of intervention compared to Sham group. These findings go in line with [13], who conducted a study on “effect of premature infant oral motor intervention (PIOMI) combined with music therapy on feeding progression of premature infants”, concluded that the mean volume of milk significantly increased on the 5th and 10^{th} day in the intervention than control group.

Respecting the transition time to oral feeding, the current findings revealed that the PIOMI intervention significantly faster transition time to start sucking from bottle feeding and reach full oral feeds in preterm infants. These results are supported by [2] who concluded a significantly faster transition to full oral feeding observed with PIOMI as well [14&15] concluded that oromotor exercises for preterm infants promote the transition to bottle feeding and improve the transition to normal breastfeeding.

Preterm infants in the PIOMI and Sham groups had no statistically significant reduction in the duration of hospital stay. This result is in accordance with [16&11], who concluded that there was no statistically significant difference in length of hospital stay between the intervention and control group. Although, this finding is contradicted with [2&13] who reported that neonates in the PIOMI could be discharged earlier as compared to sham intervention. Regarding achieving oral feeding readiness, the current study results revealed that no statistically significant difference was observed in the total mean POFRAS scores at the first day before intervention between both groups. However, it was significantly higher after administration of 7 days of PIOMI intervention. The previous findings are congruent with [17], who studied “Clinical effects of oral motor intervention

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combined with non-nutritive sucking on oral feeding in preterm infants with dysphagia" showed that the POFRAS scores of the intervention group were higher than those of the control group after intervention. Similarly, [13] where the feeding readiness was evaluated with different measurement tools and reported that post-intervention scores were significantly higher in the PIOMI group. Furthermore, [2&18], evaluated oral feeding readiness by POFRAS score before and after administration of 7 days of oral motor stimulation and observed that the preterm infants receiving PIOMI had a higher increment in post-POFRAS scores, but the result was not statistically significant.

5. CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion: Preterm infants' group who received 5-minute structured (PIOMI) three times daily for seven consecutive days showed higher weight gain, milk volume, POFRAS mean score and faster oral feeding transition time than unstructured (sham) group. **Recommendation:** based on the current study findings the researchers recommend PIOMI to be more effective for improved oral feeding in preterm infants. However, multicentric trials with larger sample sizes would be necessary to further strengthen the recommendation.

6. LIMITATIONS

There were not limitations in the current study.

7. ABBREVIATIONS

Gm	Gram
HR	Heart Rate
LOS	Length of Hospital Stay
LBW	Low Birth Weight
NICU	Neonatal Intensive Care Unit
NJ	Neonatal Jaundice
PIOMI	Premature Infant Oromotor Intervention
POFRAS	Premature Oral Feeding Readiness Assessment Scale
PT	Preterm
RCT	Randomized Control Trial.
RDS	Respiratory Distress Syndrome
RR	Respiratory Rate
SaO2	Oxygen Saturation
SPSS	Statistical Package for Social Science.
WHO	World Health Organization

8. DECLARATIONS

8.1 Ethical Considerations

This study was part of a Doctorate thesis; a primary approval was attained from the research ethical committee in the Faculty of Nursing, Cairo University. All preterm infants' parents who participated in the study were informed about the aim, procedure, benefits,

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and nature of the study and the written consent was obtained by the researchers. The researchers emphasized that participation in the study was voluntary, and parents can refuse to participate in the study without any reason and obtained data was only used for the research purpose. The confidentiality of information was assured, and the parents had the right to withdraw from the study at any time during the study without any effect on the care provided to their neonates.

8.2 Availability of data and materials

The data that support the findings of this trial are available from the corresponding author upon reasonable request.

8.3 Competing Interests

The authors declare that they have no competing interests.

8.4 Funding

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